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French agency for food, environmental
and occupational health & safety



Investigate, evaluate, protect

Updating of the PNNS guidelines: revision of the food-based dietary guidelines

ANSES opinion
Collective expert report

Décember 2016

Scientific Edition



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The Director General

Maisons-Alfort, 12 December 2016

OPINION
of the French Agency for Food, Environmental
and Occupational Health & Safety

on the "updating of the PNNS guidelines: revision of the food-based dietary guidelines"

ANSES undertakes independent and pluralistic scientific expert assessments.

ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are published on its website.

This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 12 December 2016 shall prevail.

This opinion is organised as follows:

| | | |
|----------|---|----|
| 1. | Background and purpose of the request | 5 |
| 2. | Procedures for addressing and organising the expert appraisal | 6 |
| 2.1. | Questions addressed and organisation of the expert appraisal | 6 |
| 2.1.1. | Questions addressed and thematic breakdown | 6 |
| 2.1.2. | Scope of the work | 8 |
| 2.1.3. | Hearings with qualified individuals and stakeholders | 9 |
| 2.2. | Prevention of risks of conflicts of interest | 9 |
| 3. | Analysis and conclusions of the CES | 10 |
| 3.1. | Approaches for establishing food consumption benchmarks - background information .. | 10 |
| 3.2. | Method implemented: food optimisation to meet three challenges | 11 |
| 3.2.1. | Prevention of nutritional risk | 11 |
| 3.2.1.1. | Coverage of nutrient requirements | 11 |
| 3.2.1.2. | Preventing the risk of chronic non-communicable diseases | 26 |
| 3.2.2. | Taking dietary habits into account | 32 |

| | |
|---|----|
| 3.2.2.1. Principle | 32 |
| 3.2.2.2. Data used | 32 |
| 3.2.3. Limiting exposure to contaminants | 33 |
| 3.2.3.1. Principle | 33 |
| 3.2.3.2. Case of substances whose use is regulated | 33 |
| 3.2.3.3. Environmental contaminants | 34 |
| 3.2.3.4. Data used | 35 |
| 3.3. A decision-support tool (integrating these three challenges) | 36 |
| 3.3.1. Optimisation at the population level | 36 |
| 3.3.2. Optimisation of the food groups | 36 |
| 3.3.3. Description of the optimisation tool | 40 |
| 3.3.4. Limitations and uncertainties of the optimisation tool | 41 |
| 3.3.5. A step-by-step optimisation approach | 42 |
| 3.3.5.1. Approach followed for adult men (Figure 3) | 42 |
| 3.3.5.2. Approach followed for adult women | 43 |
| 3.4. Results - Discussion | 47 |
| 3.5. Conclusion of the CES | 51 |
| 3.5.1. In terms of nutritional intakes | 51 |
| 3.5.2. In terms of exposure to contaminants | 51 |
| 3.5.3. In terms of consumption of food groups | 52 |
| 3.6. Outlook | 54 |
| 4. Agency conclusions and recommendations | 55 |
| Keywords | 58 |
| References | 59 |
| Annex 1: Presentation of participants | 61 |
| Annex 2: Dissenting positions | 71 |
| Annex 3: Table of constraints integrated in the optimisation tool | 72 |
| Annex 4: Summary of the ADIs for additives and pesticide residues | 78 |
| Annex 5: Definition of the size of servings | 81 |
| Annex 6: Distribution of intakes (g/d) in each food sub-group and group for adult women and men | 83 |

The following abbreviations are used in the opinion:

TEI: total energy intake

AFDN: French Association of Dieticians-Nutritionists

MUFA: monounsaturated fatty acid

PUFA: polyunsaturated fatty acid

SFA: saturated fatty acid

ALA: alpha-linolenic acid

ANC: *apport nutritionnel conseillé* (French term encompassing, depending on the situation, PRI, AI and RI)

ANIA: French National Association of Food Industries

ANSES: French Agency for Food, Occupational and Environmental Health & Safety¹

AI: adequate intake

BMDL: benchmark dose limit

AR: average requirement

BPA: bisphenol A

CES: ANSES Expert Committee

CIQUAL: nutritional composition of foods

IARC: International Agency for Research on Cancer

CUP: WCRF continuous update project

D-A-CH: German-speaking countries (Germany, Austria, Switzerland)

DHA: docosahexaenoic acid

ADI: acceptable daily intake

TDI: tolerable daily intake

PTWI: provisional tolerable weekly intake

PTMI: provisional tolerable monthly intake

TDS: total diet study

EFSA: European Food Safety Authority

EPA: eicosapentaenoic acid

OR: oestrogen receptor

ERCA: assessment of the physical and chemical risks in food

FBDG: food-based dietary guidelines

PAH4: polycyclic aromatic hydrocarbon

HBCDD: hexabromocyclododecane

gamma-HCH: gamma-hexachlorocyclohexane, lindane

BMI: body mass index

INCa: French National Cancer Institute

INCA: French Individual Survey on Food Consumption

IOM: Institute of Medicine²

RI: reference intake range

¹ On 1 July 2010, AFSSA and AFSSET merged to become ANSES

² On 15 March 2016, the IOM changed its name and is now called the HMD (Health & Medicine Division)

JECFA: FAO/WHO expert committee on food additives

JMPR: Joint FAO/WHO Meetings on Pesticide Residues

MRL: maximum residue limit

UL: tolerable upper intake level

CVD: cardiovascular disease

LPA: level of physical activity

NCM: Nordic Council of Ministers

NHMRC-MoH: Australian National Health and Medical Research Council - New Zealand Ministry of Health

WHO: World Health Organisation

Oqali: French Observatory of Food Quality

PBB: polybrominated biphenyl

PCB: polychlorinated biphenyl

PNNS: French National Health and Nutrition Programme

POP: persistent organic pollutant

PRI: population reference intake

SACN: Scientific Advisory Committee on Nutrition

SFN: French Nutrition Society

HBGV: Health-based guidance value

WCRF: World Cancer Research Fund



1. BACKGROUND AND PURPOSE OF THE REQUEST

On 3 April 2012, the Director General for Health (DGS) made a formal request to ANSES to update the food-based dietary guidelines of the National Health and Nutrition Programme (PNNS).

In the framework of the 2001-2005 PNNS, AFSSA had been asked to develop the scientific principles for formulating food-based dietary guidelines (Request 2001-SA-0126). Several PNNS food guidelines had been published based on the scientific evidence provided by AFSSA.

The current PNNS guidelines focus on different food groups (fruits and vegetables, starches, etc.) and on physical activity, broken down for specific populations (the elderly, children, adolescents, pregnant and breastfeeding women).

The developments in scientific data over the last ten years have made it necessary to revise these food-based dietary guidelines and, more generally, the scientific foundation on which the public health nutrition objectives are established.

Accordingly, the 2011-2015 PNNS provides for the updating of the guidelines concerning both food and physical activity (Action 11.1). This action is part of Measure 4 aimed at developing nutritional information and education actions. In addition, the updating of the nutrition recommendations (known in French as *apports nutritionnels conseillés* - ANC) and the assessments relating to the benefits and risks associated with the consumption of certain food groups had led ANSES, in 2011, to include the revision of the food-based dietary guidelines in its work programme.

The request made by the DGS particularly concerns the following points:

- 1) Propose a new formulation for the PNNS guidelines, including those concerning physical activity, on the basis of new ANCs, data on consumption from the INCA studies (French Individual Survey on Food Consumption), food composition (with the data from the CIQUAL table and from OQALI) and the international references available.
- 2) Clarify the position of certain foods within the categories currently used in the food-based dietary guidelines, taking into account their nutritional quality and also how they are perceived by consumers. In particular, clarification was sought regarding the groups to which the following belong: dried fruits and oilseeds, sweetcorn (which can, depending on the criteria considered, be classified among vegetables or cereals) and processed products.
- 3) Quantify the servings, if this concept is useful in the new formulation of the food-based dietary guidelines.

In view of the request made by the DGS, the aim of the work was to propose the scientific principles necessary for formulating the food-based dietary guidelines.

The approach implemented takes account of the need to 1) limit the nutritional risk – i.e. cover the nutritional requirements and limit the risk of chronic non-communicable diseases associated with the consumption of certain food groups, 2) limit the risk with regard to foodborne chemical contaminants³, 3) while taking dietary habits into account, in order to facilitate acceptance and implementation of the food-based dietary guidelines.

³ In the remainder of this document, chemical contaminants will be referred to as contaminants.

2. PROCEDURES FOR ADDRESSING AND ORGANISING THE EXPERT APPRAISAL

ANSES entrusted examination of this request to the Working Group on "Updating of the PNNS guidelines: revision of the food-based dietary guidelines", reporting to the Expert Committees on "Human Nutrition" and "Assessment of the physical and chemical risks in food" (ERCA).

The methodological and scientific aspects of this group's work were regularly submitted to the Expert Committees (CESs). The work conducted by the Working Group takes account of the observations and additional information provided by the CES members.

This work was therefore conducted by a group of experts with complementary skills. Final validation of the opinion took place at the meeting of the CES on "Human Nutrition" of 13 October 2016.

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

The request was addressed within ANSES's Risk Assessment Department (DER). The Nutritional Risk Assessment Unit (UERN) was responsible for the scientific coordination of the Working Group. Due to the cross-cutting nature of the expert appraisal, other DER units made a contribution:

- Food Risk Assessment Unit
- Methodology and Studies Unit
- Food Observatory Unit
- Phytopharmacovigilance and Observatory of Pesticide Residues Unit

The people who contributed to this work are listed in Annex 1.

2.1. Questions addressed and organisation of the expert appraisal

2.1.1. Questions addressed and thematic breakdown

An organisation into parallel working sub-groups was adopted in order to take a triple constraint into account: applying ethics rules (see 2.2 Prevention of risks of conflicts of interest), applying a broad diversity of specific skills essential to the assessment, and optimising the implementation of the expert appraisal. A monitoring group, made up of experts with cross-cutting skills, ensured the synthesis, consistency and scientific validity of the expert appraisal and acted as guarantor of the work to the CES on "Human Nutrition".

For establishing food-based dietary guidelines, EFSA (2012) advocates conducting the expert appraisal in several parts that should be adapted to the specificities of the population of the country considered (particularly in terms of prevalence of diseases and nutritional situation) and aim to:

- characterise the relationship between the consumption of certain foods and the risks of chronic non-communicable diseases;
- identify the nutrients of interest to public health (i.e. nutrients for which there is a risk of inadequate or excessive intakes);
- identify the foods and food groups that are vectors of the nutrients of interest and contribute to meeting requirements;
- characterise the dietary habits of the population.

To do this, thematic working groups were formed, adopting complementary approaches according to several points of entry: by nutrient, by food and by eating behaviour. The following five thematic working groups were therefore set up:

- updating of dietary reference values (Theme 1);
- study of the bioavailability of vitamins and minerals depending on the food matrix in order to, where appropriate, weight the nutrient levels of foods in the event of increased or limited bioavailability (Theme 2);

- identification of priority nutrients in terms of public health (Theme 3);
- study of the relationships between the consumption of food groups and the risk of chronic non-communicable diseases (Theme 4);
- determination of a new categorisation for foods and definition of serving sizes representing those of French consumers as closely as possible (Theme 5).

In addition, a computer tool for optimising food consumption was developed. It proposes combinations of food groups that meet the objectives set, i.e. coverage of nutritional requirements as a whole, prevention of chronic non-communicable diseases, minimisation of exposure to food contaminants, while remaining within a range of intakes that are relatively close to current consumption.

Moreover, other elements need to be taken into account for formulating food-based dietary guidelines. In particular, to ensure that they are adequately understood, it is important to identify the clearest possible way of expressing the recommended quantities of food (such as for example the share of the plate, the contents of a handful, the weight) as well as the most appropriate temporal references (i.e. define whether it is more meaningful to express the guidelines per meal, per day or per week). In addition, the dietary rhythms, the structuring of meals and the consumption contexts may also influence health. The analysis of these elements could provide an interesting complement to the scientific principles presented in this opinion.

Figure 1 below shows how the Agency coordinated all the work carried out or planned (for the study of the formats of expression and eating behaviours) for formulating the food-based dietary guidelines.

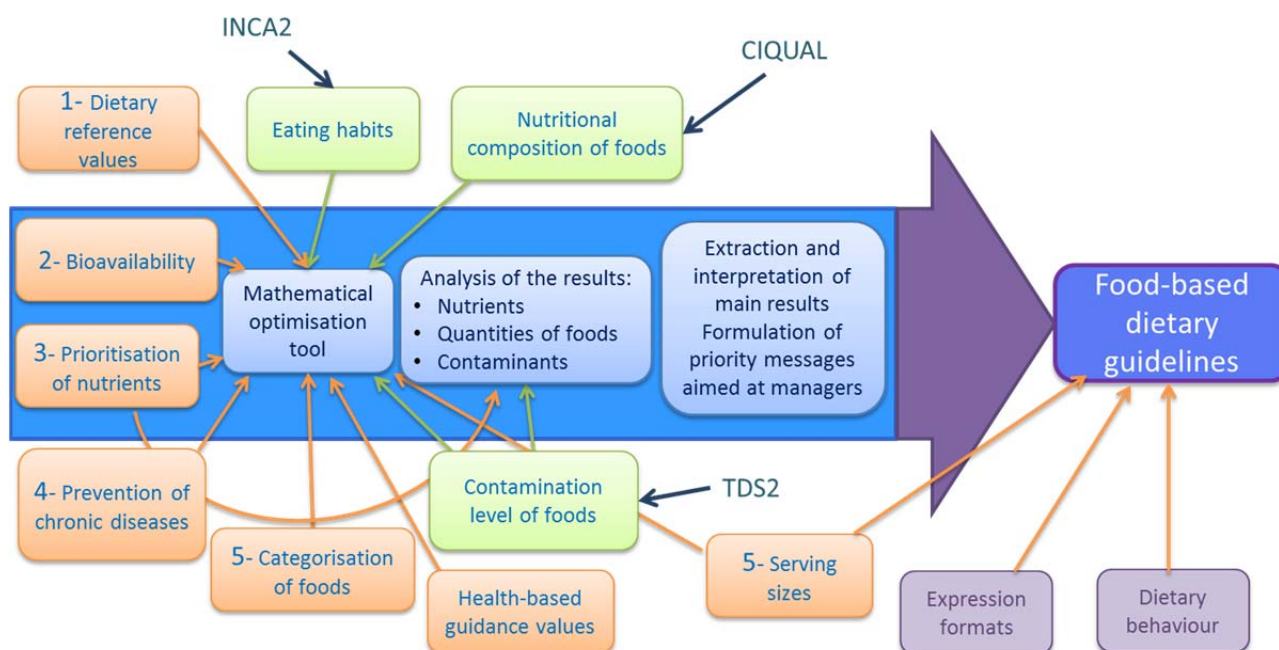


Figure 1. Coordination of the work

The green boxes represent the data from studies (INCA2, TDS2) and databases (CIQUAL); the orange boxes represent the areas to be examined by the Working Group, the blue boxes represent the stages of the mathematical optimisation process and its interpretation, the purple boxes represent the descriptive and contextual elements of food intake to be taken into account for formulating the food-based dietary guidelines.

This opinion brings together, for adult men and women, some initial scientific elements of use for formulating guidelines for the population. It thus presents the summaries of the thematic working groups that directly participated in the development of the approach and the main results of the optimisation. It concerns the work of the thematic working groups 1, 4 and 5.

Only the summaries of the working methods and discussions are presented here. An annex report entitled "ANSES report on the updating of the PNNS guidelines: revision of the food-based dietary guidelines" details the elements described in this opinion, in particular the optimisation results (ANSES 2017d). It is supplemented by specific and thematic documents, published in parallel:

- Opinion on the updating of the PNNS guidelines: revision of the dietary reference values for vitamins and minerals for the general adult population (Theme 1);
- Report "Updating of the PNNS guidelines: study of the relationships between the consumption of food groups and the risk of chronic non-communicable diseases" (Theme 4);
- Report "Balance between macronutrients: contribution of macronutrients to energy intake";
- Opinion on the establishment of recommendations on sugar intake;
- Report "Balance between macronutrients: recommendations on sugar intake";
- Report "Balance between macronutrients: recommendations on fibre intake".

With regard to the work of Thematic Group 2 (*Bioavailability of micronutrients*), in the absence of sufficient bioavailability data on the human species, only absorption data were considered. The inadequacy and disparity of the data concerning the influence of the chemical forms of nutrients, the matrix containing them or the diet mean that it was not possible to define absorption coefficients that could be used in the optimisation. They are therefore not presented in this summary opinion.

Similarly, the work of Thematic Group 3 is not presented here. This work focused on estimating the risks of inadequate or excessive nutrient intakes for the French population, with the aim of considering the advisability of prioritising the coverage of certain nutrients. These estimates are available in ANSES's opinions on vitamins and minerals (ANSES 2015b), and on fatty acids (ANSES 2015a). After analysing the validity of the biomarkers of nutritional status and their measurement methods, the prevalence of inadequate nutritional status was assessed. Taking both types of data into account (data on nutrient intakes and biomarkers of nutritional status) made it possible to identify more precisely the nutrients for which there are manifest risks of deficiency or excess. This work therefore helped provide a picture of the nutritional situation of different populations, and can serve as a basis for formulating specific public health measures. Nevertheless, it was not used directly in the optimisation work because the decision was made to consider all the nutrients as equal. Indeed, it was decided that the proposed food-based dietary guidelines should be able to cover the requirements for all nutrients, regardless of the current nutritional status of the population for each one.

2.1.2. Scope of the work

This work aims to determine optimal consumption levels for the healthy, non-allergic adult population. Men are thus regarded as being from 18 to 64 years of age, and women from 18 to 54 years. From 55 years of age, the specific needs of women change, and should be studied separately. In addition, only normal food (i.e. excluding food supplements) has been considered. Alcoholic beverages were not taken into account in this work. Indeed, defining guidelines for alcoholic beverages would require a detailed benefit/risk assessment of all their effects. Accordingly, in this opinion, total energy intake (TEI) corresponds to energy intake without alcohol.

In addition, this work did not incorporate economic or environmental considerations (ecological impact such as the carbon footprint), but only considerations related to the nutritional and toxicological risks. Nor did it take into account the variability of nutritional compositions and contaminant levels according to crop varieties, production systems (for example, conventional or alternative practices), storage and processing conditions, geographical origin, modes of preparation (for example cooking type), or any other agri-food consideration.

2.1.3. Hearings with qualified individuals and stakeholders

In addition to the scientific contributions identified at the beginning of the expert appraisal, specific skills were called on whenever necessary in order to stimulate the discussion and take advantage of experiences in other countries. These contributions were obtained through hearings.

More specifically, the questioning focused on data collection in the population groups (such as the vegetarian population⁴), the research conducted by manufacturers on their products, the studies relating to consumers' perception of the guidelines, the methodology adopted to assess the quality of the study and the strength of the evidence in different European countries, and work to optimise food rations using linear programming.

The following parties were interviewed regarding these objectives: eminent scientists (who participated in the Eurreca project or in optimisation work at INRA), the National Food Institute at the Technical University of Denmark (which recently worked on the issue of food-based dietary guidelines), the French Association of Dieticians-Nutritionists (AFDN), learned societies (the French Nutrition Society – SFN), as well as manufacturers (in partnership with the ANIA) and consumer associations (Société Végane, UFC-Que Choisir, etc.).

The aim of these hearings was to consult the stakeholders as broadly as possible in order to gain information from the field and formulate specific questions likely to be examined by the expert group.

These hearings helped advance the reflections of the Working Group on the implementation of the optimisation tool, eating behaviours, diet types, the nutritional composition of certain foods and the ways of expressing the quantities of food consumed.

2.2. Prevention of risks of conflicts of interest

ANSES analyses the links of interest declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.

The experts' declarations of interests are made public *via* the ANSES website (www.anses.fr).

The adoption of this opinion was not confronted with any dissenting views, with the exception of the dietary reference values for vitamin C in women and for magnesium (see Annex 2).

⁴ Food-based dietary guidelines for this specific population may be proposed at a later stage

3. ANALYSIS AND CONCLUSIONS OF THE CES

3.1. Approaches for establishing food-based dietary guidelines – background information

The food-based dietary guidelines proposed to the general public are derived from a summary of the available data on food and its links with health. Their purpose is to maintain or improve the state of health of a population. While the oldest guidelines were constructed empirically, more recent ones are based on a large corpus of more detailed data and rely on systematic methods.

Thus, the previous French food-based dietary guidelines were based on an analysis of the types of food consumption identified in the French population. Nutrient intakes were estimated for each of these types and compared with dietary reference values, which helped identify the type of diet enabling optimal coverage of nutrient requirements, as well as the limiting nutrients for each of the diet types. With this method, the adequacy of nutrient intakes is estimated *a posteriori* from a limited number of diet types observed in the population at the time the consumption surveys are carried out. Taking one of the observed diet types as a basis can be regarded as an advantage because of its acceptability by the whole population, but has the disadvantage of not ensuring adequate intakes with regard to all the dietary reference values.

In 2007, Canada put in place a comprehensive two-step approach, based on the use of "food models". The first step involved creating food groups. Each of these was assigned a nutrient and energy content on the basis of the nutritional composition and consumption frequency of the foods making up the group. Then the number of servings was defined for each of these groups, in order to build a food model with a satisfactory nutrient content with regard to the dietary reference values, for each population considered. The development of this model integrated data on the prevention of chronic non-communicable diseases and was also based on general considerations of dietary practices. The goodness of fit of the model was assessed by simulating a large number of typical diets including one food from each group selected at random from among the most widely consumed foods. The distribution of nutrient intakes from the typical diets was compared with the dietary reference values. If the distribution of one or more nutrients was not acceptable, the food model was modified, until a satisfactory model was obtained. Thus, the final food model obtained was the result of a process of successive iterations, assessing *a posteriori* whether nutritional requirements are satisfied.

In Europe, despite a convergence of diets and lifestyles, there are still significant differences between countries, in particular in terms of dietary habits and the associated health issues. Thus, EFSA has proposed that each country develop its own "nutritional recommendations depending on the diet" expressed in terms of foods (food-based dietary guidelines, FBDG) (EFSA 2010a). As a preamble, EFSA reiterates that the foods taken together constitute diets, they are not only combinations of nutrients, and these nutrients interact with each other according to the food matrix in which they are found. Processing and preparation methods can modify the nutritional value of the foods. In addition, it has been clearly established that certain eating habits are associated with a reduction in the risk of some chronic non-communicable diseases, whether this association is linked to one or more nutrients or to a food type. Lastly certain food constituents may have beneficial biological functions, even though the mechanisms of action or the exact nature of these compounds have not been fully identified. Besides these general considerations, EFSA recommends several steps for establishing food-based dietary guidelines, which ANSES referred to when establishing its method.

3.2. Method implemented: food optimisation to address three challenges

Formulating food consumption recommendations usually involves expressing the dietary reference values in the form of food combinations. This must take account of the need to cover the nutritional requirements of different groups with the aim of promoting health and reducing the risk of disease, in accordance with EFSA's recommendations (2010). The current context of exposure to contaminants means that it is also necessary to try and limit the risk with regard to foodborne contaminants, in the process of drafting the recommendations. This more comprehensive approach is therefore similar to a benefit-risk type assessment. It involves taking into account all the available data concerning the risks, whether they are related to nutrient intakes (intakes above the tolerable upper intake level, UL) or exposure to contaminants (level of exposure higher than the health-based guidance values, HBGV) and comparing them with the expected nutritional benefits (meeting requirements and preventing diseases).

Prevention of nutritional risk is the first challenge of the food consumption optimisation approach developed in this work. The nutritional risk is conceived at two levels: that of the nutrient, whose consumption must cover the requirements in the population considered, and that of the food groups, whose consumption should reduce the risk of chronic diseases.

Another important element to take into account is dietary habits, since this may facilitate the acceptance and implementation of the food-based dietary guidelines. Thus, the approach involved incorporating the optimised levels of food consumption in the range of intakes observed in the French population. However, when a requirement cannot be met under the observed intake conditions, variations may be considered to the extent that they help maintain a certain acceptability *a priori*: for example, substituting foods with the same purpose can be considered, such as replacing refined bread by wholemeal bread to promote coverage of requirements in fibre.

Lastly, current levels of food contamination should be taken into account in the process of optimising food consumption to limit exposure to contaminants, whether or not the substances are subject to regulations on use⁵.

In order to be able to integrate all this information in a systematic approach, a computer tool for optimising food consumption was developed. The optimisation solutions represent combinations of food groups that meet the objectives set, i.e. coverage of nutritional requirements as a whole, reduction of the risk of chronic non-communicable diseases, minimisation of exposure to food contaminants, while remaining within a range of intakes that are relatively close to current consumption. This innovative approach firstly took into account *a priori* the nutritional constraints related to the coverage of requirements and the prevention of diseases, and also integrated the risks associated with chemical contaminants.

3.2.1. Prevention of nutritional risk

3.2.1.1. Coverage of nutrient requirements

To respond to the first point of the request from the DGS, work to update the dietary reference values was conducted by a dedicated group of experts. Its objectives were to:

- identify the types of dietary reference values available: average requirement, population reference intakes, adequate intakes, etc.;
- define the dietary reference values to be used in establishing food-based dietary guidelines for the French population. These values relate to vitamins and minerals, energy macronutrients (fats and fatty acids, proteins and amino acids, carbohydrates and saccharides) and water.

⁵ Substances naturally present in food or resulting from contamination of environmental origin (such as inorganic and mineral contaminants) are distinguished from substances used for technological (such as additives) or agronomic (such as pesticides) reasons, whose use is regulated.

Definition of the different dietary reference values

The definitions of the terms used in nutrition have varied according to the authors and over time. A review of the terms used (ANSES 2017a) revealed a need to harmonise those used to describe the same concept. This harmonisation should be based on a better characterisation of the scientific foundation (type and quality of data) on which the selected value and, therefore its use, is based. Thus, the terms relating to dietary reference values, i.e. the average requirement (AR), the population reference intake (PRI), the adequate intake (AI), the reference intake range (RI) and the tolerable upper intake level (UL), have essentially been defined by the approaches implemented to establish them, and are as follows:

- **Average Requirement (AR):** average daily need within the population, as estimated from individual intake data in relation to a criterion of nutritional adequacy in experimental studies.
- **Population Reference Intake (PRI):** daily intake that covers the requirement of almost the entire population considered, as estimated from experimental data. The PRI is calculated from an estimate of the parameters of distribution of the requirement. Most often the PRI is estimated from the AR, to which are added two standard deviations, in order to determine the intake that covers the requirement of 97.5% of the population. As the standard deviation is most often estimated at 15% of the AR, the PRI is therefore 1.3 times the AR. There is a consensus on this definition around the world. It corresponds to that of the previously used French term "*apport nutritionnel conseillé*" (ANC), which was also used by extension for different types of dietary reference values. In the interests of clarity, the term ANC has been abandoned in favour of PRI and two new types of dietary reference values: the adequate intake and the reference intake range.
- **Adequate Intake (AI):** average daily intake of a population or sub-group whose nutritional status is considered adequate.

The French AI is the dietary reference value selected:

- when the AR and therefore the PRI cannot be estimated due to the lack of sufficient data, and corresponds to the EFSA definition of "Adequate Intake (AI)";
- or when the value of the PRI can be estimated but is not considered satisfactory in view of long-term observations of the population establishing that this PRI cannot meet health criteria that would be more appropriate than the criteria used to estimate the AR. Thus, unlike the EFSA AI, the French AI is not solely intended as a substitute for the PRI in the case where the latter cannot be calculated. This definition also takes into account the fact that there are more and more data concerning the relationships between intake and modulation of the risk of disease in the long term.
- **Reference Intake Range (RI):** range of intakes considered adequate for maintaining the population in good health. It is a dietary reference value specific to energy macronutrients, expressed as a percentage of total energy intake.
- **Tolerable Upper Intake Level (UL):** chronic maximum daily intake of a vitamin or a mineral considered unlikely to present a risk of adverse health effects for the entire population.

Identification of a dietary reference value for water

In 2010, EFSA defined an adequate intake of water for adult men and women with a moderately active lifestyle (level of physical activity, LPA⁶ = 1.6) and living in a temperate environment. This adequate intake concerns all sources of water, i.e. drinking water, the water present in other beverages and the water contained in food.

⁶ The LPA is calculated as the ratio between energy expenditure over 24 h and the basal metabolism. It corresponds to the average MET (Metabolic Equivalent of a Task) over 24 h.

EFSA defined an adequate intake of 2 L/d for women and 2.5 L/d for men, based on both observed intakes and data on intakes able to achieve adequate urinary osmolality of 500 mOsm/L (EFSA 2010b).

Identification of a dietary reference value for the energy requirement

Besides the dietary reference values for vitamins, minerals and macronutrients, it was proposed to determine the level of energy intake used to express the dietary reference values depending directly on energy intake, such as for example vitamin B1.

Estimating the energy requirement assumes knowledge of the basal energy requirement of the individuals in a population, which itself is estimated from the age, sex, height and weight, as well as the LPA.

In order to assess the median energy requirement of the general adult population, an estimate of the basal metabolism was necessary. Based on the conclusions of EFSA's report, it was considered that none of the five predictive equations that can be used in adults were preferable to the others (EFSA 2013). Thus, for each age group and each sex, the basal metabolism was estimated according to these five equations (Schofield *et al.* 1985, Harris and Benedict 1919, Henry 2005, Mifflin *et al.* 1990, Muller *et al.* 2004). Similarly, for each age group and each sex, the reference weight was calculated from the median size of the population reported in the INCA2 study and on the basis of a body mass index (BMI) of 22 kg/m². Indeed, more than 40% of the individuals in the population of the INCA2 study were overweight or obese. In order to estimate the requirement of a population of normal weight, it was decided to consider not the actual weight but a weight corresponding to a normal BMI. A presumed healthy BMI of 22 kg/m² was selected because it falls in the centre of the range (20-25 kg/m²) regarded as healthy and already used by EFSA in its calculations of energy requirement (EFSA 2013). These calculations are described in the report (ANSES 2017d).

Concerning the LPA, the Scientific Advisory Committee on Nutrition (SACN 2011) estimated the 24h energy expenditure of 929 individuals with the reference technique, i.e. the doubly labelled water method. The study reported a median LPA of 1.63 and values at the 25th and 75th percentiles of 1.49 and 1.78, respectively, for a healthy adult population. Applied to the basal metabolism values estimated according to the five equations, this median LPA of 1.63 was used to estimate the median energy requirements of French men and women according to their age between 18 and 79 years and for a BMI of 22 kg/m². These estimates are described in the annex report (ANSES 2017d). Thus, an energy requirement of 2600 kcal/d and 2100 kcal/d (averages performed on all values, all age groups obtained from the five equations) for men aged 18 to 69 years and women aged 18 to 59 years, respectively, was selected.

Identification of dietary reference values for vitamins and minerals

It was decided to systematically compare the reference values for vitamins and minerals proposed in international reports and opinions from the following organisations:

- WHO (World Health Organisation, 2004 and 2014);
- EFSA (European Food Safety Authority, since 2013 and still ongoing);
- IOM (Institute of Medicine, series of opinions between 1997 and 2011);
- NCM (the Nordic Council of Ministers, Nordic Nutrition Recommendations, (NCM 2012));
- D-A-CH (Germany – Austria – Switzerland, 2013 and 2015) (D-A-CH 2015);
- NHMRC-MoH (Australian National Health and Medical Research Council – New Zealand Ministry of Health, 2006).

These reports were chosen because they come from international (WHO, EFSA, NCM, D-A-CH, NHMRC-MoH) or national (IOM) agencies whose populations follow a Western-type diet and because they were recent.

However, in 2010 EFSA began a complete reassessment of the dietary reference values. Accordingly, ANSES decided to give priority consideration to the reference values proposed by EFSA, adapting them if necessary and on the basis of explicit considerations to specific conditions concerning the French population. Only the EFSA opinions published or otherwise submitted for public consultation before 1 July 2015 have been considered here. To establish the dietary reference values, the decision tree shown below was followed:

- ✓ Existence of an assessment by EFSA:
 - **The EFSA Panel proposes an AR and a PRI:** the value, after analysis of the approach followed by EFSA and comparison with the French situation, may be endorsed unless strong objections are raised, in which case a new argument is developed to support the proposal to revise the value proposed by EFSA;
 - **The EFSA Panel proposes an AI:**
 - ✓ on the basis of data on markers or epidemiological studies: the value, after analysis of the approach followed by EFSA and compared with the French situation, may be selected;
 - ✓ on the basis of an average consumption observed at European level. In this case, the principle and the approach followed are taken into account but a value derived from the French average consumption⁷ (excluding consumption of food supplements) for each population, including possible under-reporters, is selected;
- ✓ Absence of any assessment by EFSA: the choice of dietary reference value is made from the dietary reference values in the various reports and opinions cited above, on a case-by-case basis, substantiated, where necessary, by new bibliographic data.

With regard to the reference values relating to excessive intakes, the ULs laid down at European level by the Scientific Committee on Food (SCF) and then by EFSA were the only ones considered.

Identification of dietary reference values for energy macronutrients

The dietary reference values for energy macronutrients were defined by a dedicated working group, whose deliberations focused firstly, on the balance between fats, carbohydrates and proteins and secondly, on the formulation of dietary reference values for carbohydrates including sugars and fibre (ANSES 2017e).

This expert appraisal therefore sought to update the recommendations on macronutrient intakes by considering the joint balance between the three macronutrients, on the basis of the existing dietary reference values for proteins (AFSSA 2007) and fats (ANSES 2011b).

Moreover, given the age of the most recent recommendations in France concerning carbohydrates, which were issued in 2001 (AFSSA 2001), a revision of the dietary reference values for carbohydrates proved necessary (ANSES 2017b, f). The aim of this work was to specify the recommended sugar intakes and update those on fibre, in light of the latest literature data on the health effects of various types of carbohydrates, while taking into account developments concerning the scientific approach with which the carbohydrates are studied (terminology, definitions, classification).

⁷ Data from the INCA2 study for the population of men aged 18 to 64 years and women aged 18 to 54 years (AFSSA 2009)

Distribution of macronutrients in total energy intake (TEI)

The objective was to propose recommendations in the form of consumption ranges for each macronutrient expressed as a percentage of TEI. This approach is based on the simultaneous consideration of several macronutrients, as was done by the IOM in its report published in 2005 on *Dietary Reference Intakes* (DRIs).

Table 1 summarises the approach adopted. A complete description of the method followed and an analysis of the data that led to the recommendations mentioned below are available in the ANSES report (ANSES 2017e).

The balance between the different macronutrients in energy intake must enable the requirements to be met for essential nutrients (essential amino acids and fatty acids). In addition, it must correspond to the minimum risk of overweight, metabolic disorders and chronic non-communicable diseases (cardiovascular diseases – CVDs, diabetes, some cancers). The literature on these two types of data was summarised. For each of the three macronutrients, an adequate intake range for TEI was therefore obtained, defined by a lower and upper limit. These recommendations imply an energy budget that is balanced between expenditure and intake.

Table 1: Approach adopted for establishing the upper and lower limits in macronutrients

| | Minimum % | Maximum % |
|---------------|--|--|
| Fats | 2011 recommendations | 2011 recommendations |
| Proteins | Expression of the minimum intake established in g/kg bw/d (AFSSA recommendations, 2007) | Literature search on the increased risk of metabolic disorders and/or chronic diseases according to the % of proteins |
| Carbohydrates | Literature search on the increased risk of metabolic disorders and/or chronic diseases according to the % of carbohydrates | Literature search on the increased risk of metabolic disorders and/or chronic diseases according to the % of carbohydrates |

With regard to the lower limits

Protein intake must be a minimum of 10% of TEI for the majority of the general population with, however, this minimum intake increased to 12% of TEI for women over the age of 50 and men over the age of 60 with a very low LPA.

Fat intake must be a minimum of 35% of TEI firstly, to ensure the intake of essential fatty acids and secondly, in view of primary prevention of chronic non-communicable diseases.

Carbohydrate intake must be a minimum of 40% of TEI, the threshold below which the risk of metabolic disorders may be increased.

With regard to the upper limits

The upper values are determined on the basis of possible or proven risks of metabolic disorders. Each upper value must also be compatible with the lower values of the other two macronutrients.

The maximum protein intake is difficult to determine due to a strong apparent tolerance to high protein intakes and the absence of any compelling evidence concerning a metabolic risk. However, as a precautionary measure, we have chosen a limit at 20% of TEI. The maximum fat intake is 40% of TEI, the value above which the risk of an energy imbalance and its possible consequences is increased.

The maximum carbohydrate intake is 55% of TEI, the value above which the risks of insulin resistance, diabetes, cardiovascular disease and certain cancers are increased.

Besides establishing RIs for the energy macronutrients, this work to update the recommendations on macronutrient intakes highlighted the fact that the nature of the diets associated with the macronutrient intake levels is an important, even critical, variable for explaining the relationships with health. In particular, besides the quantitative aspects of macronutrient intakes, it was necessary to take the qualitative aspects into account.

For fats and carbohydrates, it is important to ensure that the quality of their food vectors is sufficient to cover the requirements for essential fatty acids, vitamins and minerals, on the one hand, and to guarantee the recommended intakes in monounsaturated fatty acids (MUFAs), polyunsaturated fatty acids (PUFAs) and fibre, on the other, while limiting sugar intakes and favouring complex carbohydrates with low glycaemic indexes.

In contrast, for proteins, the levels of consumption and the diversity of sources already cover the essential amino acid requirements in the general population. The question of quality only arises in cases where intakes are close to the lower values. In this situation, the protein sources will need to be chosen to obtain a balanced intake of amino acids in the diet.

Recommendations for fatty acid intakes

Regarding the recommendations for fatty acid intakes, the ones proposed in 2011 remain unchanged (ANSES 2011b):

- The recommendation for alpha-linolenic acid (ALA) was set at 1% of TEI for adult men and women, with the aim of preventing CVDs. It is an AI value.
- The recommendation for linoleic acid set at 4% of TEI for adults arises from a concern to reach a total for PUFAs favourable to cardiovascular prevention and to limit intakes to ensure a linoleic acid/ALA ratio below 5.
- The recommendation for docosahexaenoic acid (DHA) was set at 250 mg/d due to its very low rate of conversion from ALA. It is an AI value.
- The recommendation for eicosapentaenoic acid (EPA) was set at 250 mg/d, on the basis of data on prevention, in particular of CVDs. It is an AI value.
- Saturated fatty acids (SFAs) are not considered as a homogeneous whole because they differ in their structure, metabolism, cellular functions and even their harmful effects in the event of excess. Only the sub-group of "lauric, myristic and palmitic acids" is regarded as atherogenic in the event of excess. On the basis of observational studies and not formal intervention studies, a maximum intake of 8% of TEI was set for the sub-group "lauric, myristic and palmitic acids".
- The recommendation for oleic acid was set in the form of a range from 15 to 20% of TEI. The lower intake limit was underpinned by the risk associated with the substitution of oleic acid by SFAs that are "atherogenic in excess". With regard to the upper intake limit, it was suggested by epidemiological and clinical data on the cardiovascular risk factors. It is an RI value.

Recommendations on sugar intakes (ANSES 2017b)

The analysis of the different nomenclatures used to characterise carbohydrates (simple or complex, slow or rapid, sugars, added sugars) shows that there is no single categorisation, and that these differences have an impact on the interpretation of data concerning the relationships between added sugar intakes and health. In this opinion, to differentiate the different types of carbohydrates found in food, it was decided to adopt the following definitions:

- total sugars: mono- and disaccharides and by analogy glucose or fructose syrups digested and/or absorbed and metabolised;
- starches and digestible derivatives of starch: carbohydrates digested and predominantly absorbed in the intestine in the form of glucose.

Furthermore, within the total sugars, the sugars naturally present in food (such as fructose and sucrose from fruits and vegetables or lactose from dairy products) were distinguished from sugars added during the manufacture of food products, whether in the form of sugars or sweeteners (including honey, agave or maple syrup, fruit-based concentrates including jams, etc.). The term "added sugar" applies here to any compound increasing the sugar content of a food or a food preparation.

There are currently many recommendations concerning added sugars or free sugars, including those of the WHO (WHO 2015) (less than 10% of TEI, intakes below 5% would have additional benefits on health). In light of the available data, a recommendation focusing only on intakes of "added" sugars is not justified. Indeed, the available data cannot be used to distinguish the health effects of sugars naturally present in food from those of added sugars.

The literature analysis conducted in the framework of this expert appraisal shows that there is a range of evidence converging towards the harmful effects of high sugar intakes which makes it necessary to issue recommendations limiting sugar intakes in the population. The data currently available cannot be used to precisely establish the threshold of total sugars from which these effects appear. It was however considered necessary to set a maximum limit to this intake.

In order to establish this limit, it was decided to transpose the most reliable literature data to all of the sugars. In general, these data have been obtained with fructose.

By assuming that the specific effects of sugars are related to their fructose content, the choice was made to set a maximum limit based on the intake of sugars containing fructose (sucrose, glucose-fructose syrups, honey or other syrups and natural concentrates containing fructose, and pure fructose). The lowest intake identified in the literature above which a change in risk markers is observed was considered. The minimum consumption for which a significant increase in blood concentrations of triglycerides was observed is 50 g of fructose per day.

Concerning lactose and galactose, which are the other two sugars consumed by the general population, the available data are not sufficient to be able to establish a relationship with a risk. The proposed maximum consumption limit for sugars does not therefore relate to the sugars naturally present in milk and dairy products.

An intake of 50 g of fructose corresponds to an intake of 100 g of sucrose. Thus, an upper limit of 100 g/d was set for total consumption of sugars, excluding lactose and galactose. This limit applies to the general healthy adult population, and concerns total sugars, whether they are naturally present in food or added during food manufacture or preparation. This value represents an upper intake limit not to be exceeded, and not an intake recommendation.

Recommendations on fibre intakes (ANSES 2016)

The definition of the *Codex Alimentarius*, proposed in 2009 (Codex, ALINORM 09/32/26), was used: "Dietary fibre means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- edible carbohydrate polymers naturally occurring in the food as consumed;
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities;

- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities."

The results presented below are derived from the analysis of the available literature, carried out until April 2013. They take into account studies and meta-analyses on the physiological effects of fibre and on the relationships between fibre consumption and primary prevention of chronic diseases, published after 2006, the date of the most recent WHO expert appraisal on fibre (Mann *et al.* 2007). For the specific theme of cancer, they considered the latest work of the WCRF/AIRC (WCRF 2007) and its updates carried out in the framework of the Continuous Update Project (CUP).

Consumption of dietary fibre is associated with a reduction in the risk for CVDs, type 2 diabetes, and colorectal and breast cancers. This reduction is sometimes observed from 25 g/d and more consistently for an intake of 30 g/d.

Thus, an AI at 30 g of total dietary fibre per day was selected.

All the references for vitamins and minerals are summarised in

Table 2 and **Table 3** for men and women respectively. The references for energy macronutrients for men and women are summarised in **Table 4**.



Table 2: Summary of dietary reference values for vitamins and minerals for adult men

| Vitamins/ Minerals | AR | PRI | AI | Observations | Source | UL ⁸ |
|------------------------|------------------------------|------------------------------|---------------------------|--|---|---|
| Vitamin A (µg RE/d) | 570 | 750 | | | EFSA, 2015 | 3000 |
| Vitamin B1 (mg) | | | 0.14 mg/MJ or 1.5 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B2 (mg) | | | 0.17 mg/MJ or 1.8 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B3 (mg) | 1.3 mg NE/MJ or 14.4 mg/d | 1.6 mg NE/MJ or 17.4 mg/d | | | EFSA, 2014 | 10 (nicotinic acid) 900 (nicotinamide) |
| Vitamin B5 (mg) | | | 5.8 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2014 Adapted to the French population | ND |
| Vitamin B6 (mg) | | | 1.8 | Adequate intake From intake data associated with a metabolic marker | AFSSA, 2001 | 25 |
| Vitamin B9 (µg DFE) | 250 | 330 | | | EFSA, 2014 | 1000 (folic acid) |
| Vitamin B12 (µg) | | | 4 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2015 | ND |
| Vitamin C (mg) | 90 | 110 | | | EFSA, 2013 | ND |
| Vitamin D (µg) | 10 | 15 | | | IOM, 2011 | 50 |
| Vitamin E (mg) | | | 10.5 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2015 Adapted to the French population | 300 |
| Calcium (mg) | 860 750 | 1000 950 | | Before 25 years old After 25 years old | EFSA, 2015 | 2500 |
| Copper (mg) | 1 | 1.3 | | | AFSSA, 2001 Adapted, based on recent studies | 5 |
| Iron (mg) | 6 | 11 | | | EFSA, 2015 | ND |
| Iodine (µg) | | | 150 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 600 |
| Magnesium (mg) | ND | 420 | | Adequate intake From intake data associated with epidemiological data | AFSSA, 2001 Adapted, based on recent studies | ND |
| Manganese (mg) | | | 2.8 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2013 Adapted to the French population | ND |

⁸ The ULs are from EFSA's opinions of 2006 and 2012 (for vitamin D and calcium) and have been updated in the European agency's opinions on each vitamin and mineral since 2013.

| Vitamins/ Minerals | AR | PRI | AI | Observations | Source | UL ⁸ |
|-----------------------|------------------|-------------------|-----|---|------------|-----------------|
| Phosphorus (mg) | | | 700 | Adequate intake Based on a Ca/P equimolar ratio | EFSA, 2014 | ND |
| Potassium (mg) | | | | To be determined based on a Na/K equimolar ratio | WHO, 2012 | ND |
| Selenium (µg) | | | 70 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 300 |
| Sodium (mg) | - | - | | Available data non-consensual | - | ND |
| Zinc (mg) | 7.5 9.3 11 | 9.4 11.7 14 | | If 300 mg/d of phytates If 600 mg/d of phytates If 900 mg/d of phytates | EFSA, 2014 | 25 |

RE: retinol equivalent; DFE: dietary folate equivalent; NE: niacin equivalent; ND: not defined, it was not possible to use the available data to set a NOAEL⁹ or a threshold above which toxicity had been identified.

⁹ No Observed Adverse Effect Level

Table 3: Summary of dietary reference values for vitamins and minerals for adult women

| Vitamins/ Minerals | AR | PRI | AI | Observations | Source | UL ¹⁰ |
|------------------------|------------------------------|-------------------------------|---------------------------|---|---|---|
| Vitamin A (µg RE) | 490 | 650 | | | EFSA, 2015 | 3000 |
| Vitamin B1 (mg) | | | 0.14 mg/MJ or 1.2 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B2 (mg) | | | 0.17 mg/MJ or 1.5 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B3 (mg) | 1.3 mg NE/MJ or 11.4 mg/d | 1.6 mg NE/MJ or 14 mg/d | | | EFSA, 2014 | 10 (nicotinic acid) 900 (nicotinamide) |
| Vitamin B5 (mg) | | | 4.7 | Adequate intakes Equal to the mean consumption of the French population, INCA2 | EFSA, 2014 Adapted to the French population | ND |
| Vitamin B6 (mg) | | | 1.5 | Adequate intake From intake data associated with a metabolic marker | AFSSA, 2001 | 25 |
| Vitamin B9 (µg DFE) | 250 | 330 | | | EFSA, 2014 | 1000 (folic acid) |
| Vitamin B12 (µg) | | | 4 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2015 | ND |
| Vitamin C (mg) | 90 | 110 | | | EFSA, 2013 Adapted to the French population | ND |
| Vitamin D (µg) | 10 | 15 | | | IOM, 2011 | 50 |
| Vitamin E (mg) | | | 9.9 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2015 Adapted to the French population | 300 |
| Calcium (mg) | 860 750 | 1000 950 | | Before 25 years old After 25 years old | EFSA, 2015 | 2500 |
| Copper (mg) | 0.8 | 1 | | | AFSSA, 2001 Adapted, based on recent studies | 5 |
| Iron (mg) | 6 | 11 or 16 | | Depending on use of a hormonal contraceptive | EFSA, 2015 | ND |
| Iodine (µg) | | | 150 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 600 |
| Magnesium (mg) | | | 360 | Adequate intake From intake data associated with epidemiological data | AFSSA, 2001 Adapted, based on recent studies | ND |
| Manganese (mg) | | | 2.5 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2013 Adapted to the French population | ND |

¹⁰ The ULs are from EFSA's opinions of 2006 and 2012 (for vitamin D and calcium) and have been updated in the European agency's opinions on each vitamin and mineral since 2013.

| Vitamins/ Minerals | AR | PRI | AI | Observations | Source | UL ¹⁰ |
|-----------------------|-------------------|------------------|-----|---|------------|------------------|
| Phosphorus (mg) | | | 700 | Adequate intake Based on a Ca/P equimolar ratio | EFSA, 2014 | ND |
| Potassium (mg) | | | | To be determined based on a Na/K equimolar ratio | WHO, 2012 | ND |
| Selenium (µg) | | | 70 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 300 |
| Sodium (mg) | - | - | | Available data non-consensual | - | ND |
| Zinc (mg) | 6.2 7.6 8.9 | 7.5 9.3 11 | | if 300 mg/d of phytates if 600 mg/d of phytates if 900 mg/d of phytates | EFSA, 2014 | 25 |

RE: retinol equivalent; DFE: dietary folate equivalent; NE: niacin equivalent; ND: not defined, it was not possible to use the available data to set a NOAEL¹¹ or a threshold above which toxicity had been identified.

¹¹ No Observed Adverse Effect Level

Table 4: Summary of dietary reference values for energy macronutrients for adult men and women

| Energy macronutrients | RI | | AI | Maximum intake level |
|--|-------------|-------------|-----|----------------------|
| | Lower bound | Upper bound | | |
| Proteins (% TEI) | 10 | 20 | | |
| Fats (% TEI) | 35 | 40 | | |
| Total saturated fatty acids (% TEI) | | | | 12 |
| Lauric + myristic + palmitic acids (% TEI) | | | | 8 |
| Linoleic acid (% TEI) | | | 4 | |
| α -linolenic acid (% TEI) | | | 1 | |
| EPA + DHA (mg) | | | 500 | |
| Carbohydrates (% TEI) | 40 | 55 | | |
| Total sugars excluding lactose (g) | | | | 100 |
| Fibre (g) | | | 30 | |

TEI, total energy intake; AI, adequate intake; RI, reference intake range

Inclusion of dietary reference values in the optimisation tool

In the framework of this food optimisation work, it should be noted that the use of dietary reference values for certain minerals and vitamins requires work to interpret the selected values and place them in context.

With regard to the AIs for example, some were established on the basis of observed intakes, with a level of evidence deemed too low to be able to integrate them in the optimisation tool. Thus, for vitamins B5 and E, as well as manganese, no dietary reference value was included in the optimisation tool. However, a check was made to ensure that the quantities of nutrients proposed by the optimisation solutions were of the same order of magnitude as the intakes currently observed in France (in the INCA2 study).

In some cases, the use of the values required information from food intake or composition data which is not always available. Thus, with regard to zinc, EFSA has proposed four PRI values depending on the phytate content of the diet (300, 600, 900 and 1200 mg/d) (EFSA 2014d). The phytate content increases in line with higher intakes of wholegrain foods and pulses. An estimate of phytate intakes in the French general population is needed to determine which of the four values should be used for the target population. In the case of the French population, for the purposes of this work, the phytate intakes were assumed to be similar to those observed in the United Kingdom and estimated at between 600 and 900 mg/d, according to the age groups and sex. Thus, the PRI set at 14 mg/d for men and 11 mg/d for women was selected as the lower nutritional constraint, corresponding to phytate intakes of 900 mg/d. This is consistent with the objective of maximising intakes in wholegrain cereal products (see Section 3.1.1.2).

With regard to the upper intake level for vitamin B3, which is presented in the form of either nicotinic acid or nicotinamide, an upper intake level had been set at 10 mg and 900 mg, respectively. These two forms of intake have not been differentiated in the nutritional composition tables. It has been estimated that vitamin B3 occurs in food largely in the form of nicotinamide, which argues in favour of the introduction of an upper intake level of 900 mg/d in the optimisation tool.

With regard to vitamin B9, there is no upper intake level (UL) for folate (natural form of vitamin B9), but there is one for folic acid, which has been set at 1000 µg. As folates are the form found most predominantly in food, it did not seem relevant to use the UL of 1000 µg relating to folic acid in the optimisation tool.

In other cases, the use of the values depended on the metabolism and physiology of the individual. This was the case, for example, with vitamin D, for which the PRI was established assuming endogenous synthesis via exposure to the sun to be zero. This extreme hypothesis was selected because it is not possible to estimate the level of endogenous synthesis in the population, as this varies greatly according to the individuals (in particular due to the colour of the skin), the time spent outdoors, and the latitude where the individual lives. Nevertheless, this PRI is difficult to achieve by current dietary intake alone (AFSSA 2009). Thus, the lower nutritional constraint for vitamin D cannot be regarded as a blocking constraint in the optimisation process and could be made flexible if necessary.

In the case of iron for the female population, the value of the dietary reference value is dependent on menstrual losses that are sometimes difficult to estimate and qualify. Nevertheless, two different dietary reference values were established according to the menstrual losses of women: 11 mg/d for no losses or low to normal losses, and 16 mg/d for high losses. Thus, for the female population, two food optimisation series were proposed to comply with the non-Gaussian distribution of requirements for iron, according to the level of menstrual losses and, as a consequence, the mode of contraception in most of the cases.

The following approaches were therefore proposed:

- a "low iron" optimisation approach for women with low menstrual losses, in particular women using hormonal contraception;
- and a "high iron" optimisation approach for women whose menstrual losses are high.

Lastly, it was not always possible to propose dietary reference values for all the vitamins and minerals, such as sodium, for example, as there is not currently sufficient knowledge for establishing them (ANSES 2017a). However, given the intakes observed today with regard to the public health objectives, the risk of excessive sodium intakes is regarded as greater than the risk of insufficient intake. In this situation, no increase in sodium intakes in the population should be set as a public health objective. Therefore, for the work to update the food-based dietary guidelines (ANSES 2017d), median consumption was selected as the maximum value not to be exceeded, which amounts to reducing intakes in the half of the population with higher intake levels, in agreement with the public health policies (PNNS). The median intakes from the INCA2 data on sodium are as follows (excluding sodium from salt added at the table): 2273 mg for women and 2994 mg for men. Establishing a "maximum" value for sodium then makes it possible to propose a value for potassium, in accordance with the recommendations of the WHO, which advocates an equimolar sodium/potassium ratio.

All of the nutritional constraints integrated in the optimisation tool are shown in **Table 7** in Annex 3.

3.2.1.2. *Preventing the risk of chronic non-communicable diseases*

The consumption of certain food groups can reduce or, on the contrary, increase the risk of different chronic non-communicable diseases.

Because prevention of these diseases is one of the challenges addressed by the food-based dietary guidelines, the Working Group sought to characterise, from an epidemiological point of view, the relationships between the food groups and the risk of major non-communicable diseases: CVDs, type 2 diabetes, overweight/obesity, breast, prostate and colorectal cancers, bone health and mental health.

This work is covered in a specific report entitled "Study of the relationships between the consumption of food groups and the risk of chronic non-communicable diseases" (ANSES 2017c). This section summarises this work.

Many organisations have previously conducted this type of expert appraisal and the most recent work served as the starting point for the literature search. Thus, after a review of the existing consensus documents at international level (EFSA, WHO, etc.), the report by the NHMRC on the literature available until the end of 2009 (NHMRC 2011) was chosen as the starting point for all diseases except cancers. For cancers, the report by the World Cancer Research Fund (WCRF) published in 2007 and its updates (*Continuous Update Project, CUP*) were selected (WCRF 2007, 2011). The literature search thus focused on the years subsequent to these expert appraisals. The work of the WHO/IARC (IARC 2015) and that of the INCA (INCA 2014) was also examined.

Most of the work identified came from prospective observational studies that cannot in themselves be used to define a causal link, only the existence of a statistical association between the food group considered and the disease studied. In addition, the meta-analyses taken into account in this expert appraisal helped increase the precision and explain any apparent contradictions resulting from the heterogeneity of the studies that can be resolved by analysing them in sub-groups.

The WCRF defined four levels of evidence to qualify the relationships, which have been adopted for this work:

- "convincing" relationships: there are several good quality studies including at least two independent prospective cohort studies, with no substantial unexplained heterogeneity, with biological plausibility supported by experimental studies either in humans or in relevant animal models. There is a dose/response effect in the association, which need not be linear if this non-linearity is biologically plausible.
- "probable" relationships: there are two independent prospective studies or at least five good-quality case-control studies, with no substantial unexplained heterogeneity, and biological plausibility of the relationship.
- "limited - suggestive" relationships: the data suggest an increase or decrease in the risk but are insufficient to conclude as to a causal relationship.
- "limited - no conclusion" relationships: there are not enough data to reach a conclusion.

The only relationships presented here are those in which the level of evidence is classified as "convincing", "probable" and "limited - suggestive". In the food optimisation work, only the relationships characterised by a "convincing" and "probable" level of evidence were considered.

Moreover, because the diseases studied in this expert appraisal are primarily manifested as age advances, the available studies generally focus on adult populations, which limits these conclusions to these populations only.

The analysis of all the studies highlighted:

- food groups whose consumption is associated only with an increase in the risk of diseases;
- food groups whose consumption is associated only with a decrease in the risk of diseases;
- food groups whose consumption is associated with both a decrease in the risk of certain diseases and an increase in the risk of other diseases.

The studies considered in this review focus primarily on populations consuming a Western-type diet. However, the food supply, modes of consumption and prevalence of genetic polymorphisms vary greatly from one country to another, even within the so-called Western countries. Thus the confounding factors may vary according to the context, which limits the extrapolation of the findings in the foreign studies.

The studies considered in this expert appraisal are observational epidemiological studies on food groups, and not on nutrients or micro-constituents. Therefore, the observed variations in the risk incorporate simultaneously the effects of nutrients, micro-constituents, potential contaminants and the food matrix of a given food group. In addition, most prospective studies monitored their cohorts over many years, making it possible to estimate the long-term relationships between food consumption and the incidence of slowly-evolving diseases. Nevertheless, dietary habits and nutrient and contaminant compositions evolve over time, which limits the understanding of these relationships.

In this analysis, close attention was paid to the quantities of foods associated with reductions or increases in risk. However, the extraction of quantified recommendations has proved to be questionable. Indeed, the quantities associated with a variation in the risk are specific to the study (characteristics of the population and the food, dietary survey method used, discontinuous assessment by groups of percentiles or continuous assessment by increment, etc.) and the risks are always estimated relative to a reference group, which may vary from one study to another. In addition, some meta-analyses, although they have the advantage of "smoothing" the inter-studies variability, express the variations in risk in consumption increments (dose-effect relationship) and not by reference to a threshold value. Furthermore, the relationships between food groups

consumed and risk levels are valid for the range of intakes observed in the population studied. Extrapolation outside these limits is risky.

Groups of foods whose consumption increases the risk of chronic diseases

Red meat and delicatessen meats

The limitations associated with the term "delicatessen meats" (*charcuterie*) should be clarified. Epidemiological studies conducted in English-speaking countries do not make reference only to delicatessen meats but more generally to all processed meats. This description "processed meat" corresponds to meat that has undergone transformation processes with the aim of improving storage and/or developing the aromas, such as salting, drying, fermentation or smoking. Examples include ham, sausages, bacon, corned beef, dried beef and canned meats. In the French context, processed meats correspond essentially to delicatessen meats – *charcuterie* (cooked or raw ham, sausages, dried sausage, pâté, etc.). Thus, the conclusions relating to delicatessen meats are extrapolated to studies of a wider food group, that of processed meat.

The consumption of red meat and processed meats (including delicatessen meats) increases the risk of colorectal cancer, with a convincing level of evidence, and the risk of CVD and type 2 diabetes, with a "probable" level of evidence. In addition, consumption of meat in general or red meat in particular may increase the risk of breast cancer according to the expression of oestrogen receptors (ORs), and the risk of prostate cancer, as well as the risk of weight gain with, however, a "limited but suggestive" level of evidence¹².

For the diseases for which the levels of evidence are found to be convincing or probable, the meta-analyses indicate that for each 100 g increase in daily intake of red meat, the risk of these diseases increases by 10% to 20%. For processed meats including delicatessen meats, each 50 g/d increase leads to increases in risk of up to 50%.

These data indicate that the consumption of red meat and delicatessen meats should be limited, without being able to precisely propose a maximum intake quantity. Nevertheless, in view of the increased risk caused by the consumption of red meat, it was deemed necessary to establish a maximum intake limit. To do this, the epidemiological studies on colorectal cancer were considered individually: most of them reported a statistically significant increase in risk, compared to the reference group, from 70 to 80 g/d of consumption. This value fits with the maximum individual consumption limit of 500 g per week of red meat proposed by the WCRF (WCRF 2011). With regard to processed meats, the analysis of the individual studies reported statistically significant increases in risk from 25 g/d. Because these increases are high, and in the absence of data on the increased risk for lower levels of consumption, it was deemed necessary to limit the consumption of delicatessen meats.

It is also recommended to limit the consumption of meat cooked at a high temperature (barbecued, fried, etc.) and to vary the cooking methods (boiling, roasting, etc.).

This analysis of the risk associated with the consumption of red meat is in agreement with that of INCa (National Cancer Institute), which concluded that there is an increased risk of colorectal cancer associated with the consumption of red meat, with a "convincing" level of evidence (INCA 2014). It is also similar to that of the IARC (International Agency for Research on Cancer), whose purpose is to classify carcinogenic compounds. The IARC considers that red meat is classified as probably carcinogenic to humans (Group 2A). This ranking is based on limited evidence (in particular due to the relative heterogeneity of the results) from epidemiological studies showing positive associations between the consumption of red meat and the development of colorectal cancer. These elements are supported by mechanistic data (IARC 2015). It means that a positive association was observed between exposure to the consumption of red meat and the risk of

¹² The WCRF's update on stomach cancer also finds an increased risk of this cancer associated with the consumption of processed meat, with a probable level of evidence (WCRF 2016)

colorectal cancer, but that other explanations for these observations (technically designated by terms such as *random*, *bias* or *confounding factors*) cannot be excluded. With regard to processed meat, the INCa also qualified the relationship with the risk of colorectal cancer as convincing. Similarly, the IARC has classified processed meat as carcinogenic to humans (Group 1). This classification is based on convincing evidence of the causal link between the consumption of processed meat and colorectal cancer in humans. This assessment is generally based on epidemiological studies showing the development of cancer in exposed people. The increased risk of colorectal cancer is estimated to be 18% for each consumption increment of 50 g/d of processed meat.

Sugar-sweetened beverages

The group of sugar-sweetened beverages includes drinks ranging from non-artificially-sweetened sodas to fruit juices made with 100% pure juice, containing vitamins and fibre, and including nectars, which are intermediate in terms of nutritional quality. The beverages included in this group vary according to the studies. Thus, the meta-analyses cannot be used in particular to distinguish sodas from fruit juices.

The consumption of sugar-sweetened beverages increases the risk of weight gain, with a convincing level of evidence: each additional glass of sugar-sweetened beverage per day is associated with a weight gain of around 200 g/year.

The risks of type 2 diabetes and CVD are also increased, with a probable level of evidence. Daily consumption of one glass is associated with an increased risk of these diseases of around 20% compared to zero or exceptional consumption (around once a month).

Significant increases in the risk of weight gain, CVD and type 2 diabetes are observed with the consumption of one glass of sugar-sweetened beverage per day, without any more detailed information below this threshold. Thus, the analysis of the available data concludes that there is a need to limit the consumption of sugar-sweetened beverages considered as a whole.

Inclusion in the optimisation tool

These associations between the consumption of red meat, delicatessen meats and sugar-sweetened beverages, and the risk of diseases were taken into account in the optimisation tool in two ways. First of all, the tool was designed to offer solutions that minimise the quantities of these food groups to be consumed. However, as this minimisation is relative, it was decided to also impose a maximum quantity not to be exceeded, in order to adopt an approach that is sufficiently protective. This has the advantage of constraining the optimisation tool to propose quantities below those associated with the increased risks. Thus, in the case of red meat, a weekly maximum quantity of 500 g, or 71 g/d was selected. It corresponds to the quantity from which an increased risk of colorectal cancer is generally observed (ANSES 2017c). For delicatessen meats, the value of 25 g/d, associated with increased risks, was adopted¹³. With regard to sugar-sweetened drinks, considerable increases in risk are observed with the consumption of one glass of sugar-sweetened beverage per day, without any more detailed information below this threshold. An upper consumption limit was set for all sugar-sweetened beverages (juices, nectars and sodas), corresponding to the median volume of the glass consumed in the INCA2 study, i.e. 263 g for men and 216 g for women.

¹³There are no data available to date regarding the increased risk for lower levels of consumption (see the report, ANSES 2016c)

Food groups whose consumption reduces the risk of chronic diseases

Fruits and vegetables

The consumption of fruits and vegetables reduces the risk of CVD, with a convincing level of evidence. Their consumption is also associated with a decrease in the risk of colorectal cancer and ER-negative (ER-) breast cancer, as well as type 2 diabetes and weight gain, with a "limited but suggestive" level of evidence.

The international guidelines, adopted at national levels, advocate daily consumption of at least five 80 g servings of fruits and vegetables. For CVDs, benefits are observed from the consumption of one daily serving. Any additional serving reduces the risk of CVD by around 4%. The consumption of a wider variety of fruits and vegetables from different families may contribute to the consumption of a wide variety of constituents of interest in the prevention of CVDs.

Wholegrain cereal products

The consumption of wholegrain cereal products reduces the risk of type 2 diabetes, CVD and colorectal cancer, with a probable level of evidence.

The risk of type 2 diabetes is decreased by up to 25% for the highest consumption levels. The risk of colorectal cancer decreases by 20% for each additional consumption of 90 g/d.

On the basis of this evidence, the consumption of wholegrain cereal products should be encouraged, without a minimum quantity being identified.

Inclusion in the optimisation tool

These associations between the consumption of wholegrain cereal products and fruits and vegetables on the one hand, and the risk of diseases on the other, were taken into account in the optimisation tool. The tool was designed to offer solutions that maximise the quantities of fresh fruit, vegetables, wholemeal bread and other wholegrain starches to be consumed. This means that with two equivalent solutions, the optimisation tool will present the one that offers the largest quantities of these food groups.

Food groups whose consumption reduces the risk of certain diseases and increases the risk of others

Milk and dairy products

Milk

Consumption of milk reduces the risk of colorectal cancer, with a probable level of evidence. The analysis of the dose-effect relationship showed a non-linear relationship, with a more pronounced risk reduction, of around 10%, for consumption of milk in excess of 200 g/d.

In contrast, with regard to prostate cancers, the data suggest an increased risk for low fat milk; an increased risk of 6% is reported for each additional consumption of 200 g/d¹⁴, with a "limited but suggestive" level of evidence, in the absence of any association in the advanced stages.

Dairy products

The association between the consumption of dairy products, overall or by type, and the risk of disease is less substantiated, and more difficult to study given, in particular, the diversity of this food group. In addition, the types of products included in this group, as well as their nutritional composition, differ according to the countries (and therefore, according to the studies).

Despite these limitations, it appears that total consumption of dairy products (including milk) probably reduces the risk of type 2 diabetes, with a reduced risk of around 5 to 10% for each

¹⁴ On the basis of six studies included in the CUP's dose response meta-analysis – high heterogeneity of 67%

400 g/d increase in dairy products. With regard to the types of dairy products, the relationship seems better demonstrated for yoghurts, cheese and reduced-fat dairy products.

Total consumption of dairy products could also decrease the risk of CVD (risk reduction of around 10-20% for the highest consumers of various dairy products), with a "limited - suggestive" level of evidence.

On the other hand, total consumption of dairy products is associated with an increased risk of prostate cancers (any stage) (increased risk of 7% for each 400 g/d increase in dairy products and 9% for each 50 g/d increase in cheese) with a "limited - suggestive" level of evidence. The data are limited in particular because no association is identified when the results are analysed according to the stage of the cancer.

With regard to the risk of bone fracture, the Working Group was unable to reach a conclusion with respect to the potential relationships between total consumption of dairy products and the risk of fracture, on the basis of the small number of available studies published between 2009 and 2013. Since this analysis of the literature, one study (Michaelsson *et al.* 2014) has reported an increase in the fracture risk associated with the consumption of milk, in women only. Given this unusual result, the CES on "Human Nutrition" updated this analysis of the literature in June 2016 in order to consider all the available data. Since the end of 2013, four prospective studies (including that by Michaelsson) and one case-control study have been published on the subject, for the adult population. Considered together, these studies were not designed specifically to respond to the question about the effect of consumption of dairy products on the risk of bone fractures. They lack statistical power and are heterogeneous in terms of protocol, assessment criterion and result. No study has found the same increased risk reported in the study by Michaelsson. In conclusion, the data are insufficient to draw any conclusions concerning the link between the consumption of dairy products (whether this relates to all milk products or just certain types) and the risk of bone fractures.

Fish

The consumption of fish reduces the risk of CVD, with a probable level of evidence. For each additional weekly consumption, a 6% decrease in mortality by coronary heart disease has been reported. For two additional weekly consumptions, a 4% reduction in the risk of ischemic and haemorrhagic stroke has been reported.

With regard to dementia, in the absence of any more recent publications, the conclusions of the report by the Australian NHMRC (NHMRC 2011), according to which the consumption of fish is associated with a reduction in the risk of dementia, with a probable level of evidence, are adopted.

Consumption of fish is associated with a higher risk of type 2 diabetes, concordantly in North American populations and inadequately documented in European populations. On the other hand, it is associated with a decrease in the risk in Asian populations consuming fish raw or cooked at a low temperature. It is suggested that the mode of preparation and consumption influences these relationships. Thus, additional epidemiological studies are needed to better describe the relationships between fish consumption and the risk of type 2 diabetes, taking into account the mode of storage and cooking.

In addition, consumption of fish cooked at a high temperature, salted or smoked may be associated with an increased risk of prostate cancer, with a "limited - suggestive" level of evidence.

Inclusion in the optimisation tool

For these food groups, whose consumption reduces the risk of certain diseases and increases the risk of others, it seems necessary to obtain more information to qualify the risk on the one hand, and the benefit on the other, in order to conduct an in-depth benefit/risk analysis.

The consumptions of the food sub-groups associated with both an increase in the risk of certain diseases and a decrease in the risk of others were not assigned any maximisation or minimisation objectives.

Table 5: Summary of the epidemiological relationships integrated in the mathematical optimisation tool

| Foods | Maximum limit introduced | Objective |
|---|--------------------------------------|--------------|
| Fresh fruits | - | maximisation |
| Vegetables | - | maximisation |
| Bread and other wholegrain starches | - | maximisation |
| Delicatessen meats | 25 g/day | minimisation |
| Red meat | 71 g/day | minimisation |
| Sugar-sweetened beverages such as soda or fruit juice | 263 g/d for men 216 g/d for women | minimisation |

3.2.2. Taking dietary habits into account

3.2.2.1. Principle

In order to facilitate the acceptance and implementation of the food-based dietary guidelines, it is important to take the dietary habits of the population into account and to try and stay as close to them as possible. For this reason, in the food optimisation tool designed for this work, the consumption habits were taken into account at several levels. In particular, the tool was configured so that, in general, the quantities of food groups proposed were:

- between the 5th and 95th percentile of consumption;
- and as close as possible to the consumption averages.

This last parameter was not applied to food groups whose consumption is associated with an increase or a decrease in the risk of chronic non-communicable diseases. For red meat, delicatessen meats and sugar-sweetened beverages, the maximum limits defined from epidemiological studies replaced the 95th percentile of consumption. In addition, for these groups, the objective was not to minimise the differences in consumption observed, but to minimise consumption. Similarly, for wholegrain starches, fresh fruits and vegetables, the objective was not to minimise the differences in consumption observed, but to maximise consumption.

Furthermore, in order to facilitate the coverage of requirements for fibre and ALA, the substitution of refined starches by wholegrain starches and of vegetable oils that are poor in ALA (for example sunflower oil) by oils rich in this fatty acid (for example rapeseed or walnut oils) was made possible.

3.2.2.2. Data used

The consumption data used came from the INCA2 study conducted in 2006-07 in three phases, on 4079 individuals aged from 3 to 79 years old (1455 children from 3-17 years old and 2624 adults from 18-79 years old) (AFSSA 2009). Only the data for the men aged 18-64 years and women aged 18-54 years were used in this opinion.

Participants were selected according to a three-stage design, stratified by the size of the urban area and the region, from the 1999 population census and the sampling frame of new housing built between 1999 and 2004.

Data on consumption by the individuals in this sample were collected using a 7-day food consumption diary in which they noted the type of foods and quantities consumed, estimated using a photograph manual, standard units or household measures. Each line in the diary corresponded to a food (or beverage) consumed. Each collected line of food was codified using a nomenclature specifically developed for the INCA2 study and containing 1342 items.

A weighting was applied to each individual to ensure the representativeness of the sample at national level (metropolitan France excluding Corsica). It focused on the following parameters: the region, the size of the urban area, the size of the household, the sex of the surveyed individual, his/her age and profession and social category.

In the results presented in this opinion, the individuals identified as under-reporting their energy intake according to the method developed by Goldberg and collaborators (Goldberg *et al.* 1991) were retained in the sample. Indeed, according to EFSA, Goldberg's method could lead to subjects being excluded whose intakes are actually low during the survey period and ruling out certain obese individuals, while retaining subjects who really are under-reporters but have a high level of physical activity (EFSA 2014a). The under-reporters thus considered account for around 31% of the male population aged 18-64 years and 28% of the female population aged 18-54 years.

In addition, all individuals and not just the consumers of the food sub-group were considered for estimating the levels of consumption of each of the food sub-groups previously defined.

3.2.3. Limiting exposure to contaminants

3.2.3.1. Principle

Because the contaminants found in food have an impact on health, it was considered appropriate to take them into account in this preliminary work for the formulation of food-based dietary guidelines.

The substances (contaminants and additives) considered in this work are those analysed in the second French Total Diet Study (TDS2), as well as bisphenol A (BPA) (ANSES 2011a). These substances were regarded as a public health priority when the TDS2 was set up. The method of selection, still valid, is described in the TDS2 report.

The assessment of the health risks incurred by the population is based on the comparison of estimates of dietary exposure with the reference values: acceptable (ADI) or tolerable daily intake (TDI), provisional tolerable weekly intake (PTWI), provisional tolerable monthly intake (PTMI), benchmark dose limit (BMDL¹⁵), etc. They are covered by the more generic term "health-based guidance values" in this opinion and were used in the framework of the optimisation work.

Selection of the health-based guidance values (HBGV) drew on an analysis of the values established by the main French, European or international scientific bodies: ANSES, EFSA, WHO, US-EPA, ATSDR, JECFA, etc. The literature watch was carried out until the first half of 2015. The reference value regarded as the most relevant was identified by the experts in the framework of specific work published recently (ANSES, 2016). These substances were not all considered in the same way in the food optimisation work.

3.2.3.2. Case of substances whose use is regulated

Because food additives and pesticides (excluding those identified as persistent organic pollutants, or POPs) are products subject to authorisation at European level, they were not included in the optimisation tool. Indeed, the European process of assessment and authorisation of additives and pesticides, as well as the establishment of maximum residue limits (MRLs) for pesticides and

¹⁵ The "benchmark dose limit" corresponds to the lower limit of the confidence interval of the "benchmark dose". The benchmark dose is a dose producing a non-zero effect corresponding to a given level compared to a control group. This approach is based on modelling of the experimental data taking into account the entire dose-response curve.

authorised uses, take dietary habits into account, as well as agricultural practices for pesticides. For this study, it was considered that the reduction of contaminations, exposures and risks should take place through a change to the authorised uses (e.g. reduction in doses or frequency of doses applied for pesticide residues) and should not affect the definition of food-based dietary guidelines. As soon as contamination problems are identified, the population should be informed in order to enlighten them as to their modes of consumption. Nevertheless, in the medium term, it is important for regulatory provisions to be implemented in order to protect consumers regardless of their dietary habits. Therefore, it is worthwhile verifying *a posteriori* that the food-based dietary guidelines are compatible with the ADIs for additives and pesticide residues, in order to reconsider, if applicable, the maximum limits authorised in foods. The substances considered *a posteriori* in the framework of this study are presented, together with their ADIs, in **Table 10** in **Annex 4**.

3.2.3.3. *Environmental contaminants*

The situation is very different in the case of environmental contaminants (which here include BPA) for which there may be more limited room for manoeuvre to restrict the contamination of foods. In some cases, consumption recommendations are necessary; this is already the case, for example, for some fish.

For each of these contaminants, a reference value not to be reached and not to be exceeded was integrated in the tool. The integrated values differ according to three cases:

- For contaminants with a threshold dose, the reference value considered to be most relevant was identified by the experts, on the basis of HBGV established by the main French, European or international scientific bodies. The exposure resulting from the optimisation can be compared directly to a HBGV.
- For contaminants without a threshold dose (the case with genotoxic compounds) or for which a BMDL has been chosen as the toxicological reference, the median exposure of the population estimated in the TDS2 (described in the paragraph below) was selected by default as the maximum value. Indeed, since a threshold cannot be selected for these contaminants, the decision was taken to prevent the exposure resulting from the optimisation being higher than the current exposure of the population. In this case, characterisation of the risk involved calculating a margin of exposure (MOE) for genotoxic carcinogenic substances, or a margin of safety (MOS) for non-genotoxic substances whose effects appear from a certain threshold. These margins of exposure or safety correspond to the ratio between a critical exposure (BMDL for example) and the exposure resulting from the optimisation. These margins were then compared to a critical margin defined when the BMDL was established by national and international bodies, in order to conclude as to the risk to the population.
- Lastly, for other contaminants, no maximum value was chosen as a constraint in the optimisation tool: these are contaminants for which no organisation has proposed a toxicity reference value, or for which the existing reference value(s) were not considered sufficiently robust. In this case, a comparison was made with the median exposure from the TDS2.

The toxicological constraints are summarised in **Table 8** in **Annex 3**. Out of the 98 substances or groups of substances selected, 40 were assigned a maximum exposure limit (reference value or median exposure from the TDS2). For the other 58, no maximum exposure limit was available. It was nevertheless necessary to seek to minimise their exposure and to introduce this minimisation in the "objective" function for all 98 substances or groups of substances.

In addition, all the exposures from the optimisation work will be compared with the average exposure from the TDS2, which reflects the current situation in France. Any possible differences in exposure may therefore be due to differences both in terms of food intakes but also body weight (average weight for the TDS2 against "ideal" weight calculated from a BMI of 22 kg/m²).

3.2.3.4. *Data used*

The concentrations in foods of contaminants, additives and pesticide residues came from the second French total diet study (TDS2). Conducted between 2006 and 2011, this study presents a review of the contamination of the foods consumed in France, the exposure of the population and the health risk associated with this exposure, for 445 substances of interest (ANSES 2011a).

The TDS2 focused on 212 food types, representing around 90% of the diet of the population, according to the INCA2 study. A sampling plan was developed between 2007 and 2009, so as to be representative of consumption habits in France, including the origin of the products, the places of purchase, the modes of storage, and also the domestic food preparation practices. The foods were collected in several regions over more than a year, in order to take account of any possible regional or seasonal variability in the concentrations. In all, 20,000 food products were purchased, prepared as consumed by the population, packaged in 1319 composite samples, and analysed for the substances of interest. Thus, each sample analysed was a composite sample of 15 sub-samples of the same food, reflecting the consumption of the population.

In the present study, the left-censored concentration data (results below the analytical limits) were processed according to an average assumption ("middle bound"). Thus, the values below the limit of detection were assumed to be equal to half this limit, and the values below the limit of quantification but above the limit of detection were assumed to be equal to half the limit of quantification or, where applicable, half of the sum of the two limits.

In addition, because trace elements were analysed for their total form only, for three of them (mercury, arsenic and chromium), speciation assumptions were applied to the concentrations in order to obtain an estimate of the concentrations of their different chemical forms.

- Concerning mercury, it was assumed, according to the "maximum" assumptions (which can lead to totals higher than 100%), that in fish, 100% of the mercury was in the form of methylmercury and 20% in the form of inorganic mercury (EFSA 2012). For molluscs and crustaceans, it was assumed that 80% of the mercury was in the form of methylmercury and 50% in the form of inorganic mercury. For the other foods, it was assumed that the mercury was present only in the form of inorganic mercury.
- Concerning arsenic, it was assumed that 100% of the arsenic was in inorganic form in water (EFSA 2014b). In the other foods, it was assumed that 70% of the arsenic was in inorganic form and 30% in organic form.
- Concerning chromium (EFSA 2014c), a maximalist approach was adopted that assumed that firstly, 100% of the chromium in food was in the form of Cr(III) and secondly, 10% of the chromium was in the form of Cr(VI). For water, it was assumed that 100% of the chromium was in the form of Cr(VI). As for methylmercury, the use of the maximum assumption leads to a total higher than 100%.

3.3. A decision-support tool (integrating these three challenges)

A mathematical optimisation tool was developed with the aim of identifying combinations of foods that are able to meet the objectives set, i.e. the reduction of nutritional risk (by ensuring adequate nutrient intakes and appropriate consumption of the food groups associated with the risk of chronic non-communicable diseases) and the taking into account of exposure to food contaminants, straying as little as possible from current food habits and preferences, in order to facilitate their acceptance and implementation.

The optimisation solutions are daily quantities of food groups, dependent on the choice of parameters set.

3.3.1. Optimisation at the population level

The tool was designed to identify combinations of food adapted to the population considered (in this case adult men or women). For this reason, it integrated not individual, but aggregated data.

Thus, to ensure coverage of the nutritional requirement, the population reference intakes (PRIs) were chosen because they cover the requirements for around 98% of the population. Failing this, the adequate intakes (AIs) were used.

This approach is therefore protective, to the extent that it is able to cover the greatest needs and thus avoid inadequate intake for the majority of the population. Accordingly, the nutrient intakes proposed by the optimisation tool were higher than the individual requirements for the majority of French people.

With regard to energy, the way the tool was configured ensured that the food combinations provide energy corresponding to the average energy requirements of the population. As the identified food optimisation solutions are supposed to cover the nutritional requirements of virtually all the population, the method tended to promote the consumption of nutritionally dense foods in view of the allocated energy envelope.

The optimisation solutions are not in any way standard menus to be followed on an individual basis. However, they do make it possible to verify the compatibility of all the constraints and identify major trends in the consumption levels of certain groups. The optimisation tool thus constitutes a decision-support tool for the implementation of public health measures.

3.3.2. Optimisation of the food groups

As the ultimate objective was to develop easily communicated and therefore concise food-based dietary guidelines, it seemed essential to establish guidelines for a limited number of food categories, giving consumers the freedom to vary the foods of their choice within a given category.

A test of the optimisation of food item combinations (and not food groups) showed, in addition to the lack of consumer freedom to choose the foods within a category, that only a small number of foods were proposed for each category, which is incompatible with a varied diet, and that the proposed amounts (for example, for vegetables, proposing 3 g of salsify, 2 g of Jerusalem artichoke, 2 g of leek, etc.) were not easy to interpret in terms of actual use.

Accordingly, the optimisation was carried out based on food categories, for which the average composition was calculated by taking consumption habits into account, i.e., by weighting the nutritional composition of each food making up the category by the share represented by its consumption within the category as observed in the INCA2 study, for each population studied. This method ensured that the foods contained in the category were more representative and thus that the messages would be applied more effectively. For example, the food-based dietary guideline for fruits would be established on the basis of the composition of the fruits most frequently consumed by the population in the INCA2 study: apples and bananas. Conversely, if the work had been carried out on the foods taken individually, the groupings made subsequently would probably not have led to food categories that reflect consumption habits.

To do this, the foods were categorised on the basis of considerations of use and nutritional composition. The categorisation method is described in the report (ANSES 2017d).



Table 6 presents this categorisation of foods into 32 sub-groups divided between 10 food groups. The classification work highlighted the need to create two additional groups with respect to the groups defined for the previous guidelines: the group of pulses (which had previously been classified with the starches) and the group of waters, which had previously been classified with beverages. The food optimisation work was carried out using these 32 sub-groups.

Moreover, this categorisation responds to the DGS's request concerning the positioning of certain foods within the groups currently used in the PNNS's food-based dietary guidelines, such as for example, the positioning of sweetcorn, dried fruits, oilseeds and processed products in the sense of mixed dishes.

With regard to mixed dishes such as ready meals (paella, lasagne, savoury tarts, etc.), sandwiches (baguette sandwiches, hamburgers, etc.), or certain desserts (rice pudding, etc.), they were not considered as a group as such, but as a sum of foods belonging to different groups. Indeed, as their name indicates, these products are made from ingredients belonging to different food groups. In addition, they are characterised by very high variability in their intra- and inter-food nutritional composition.



Table 6: Updating of the food categorisation

| Food groups (PNNS 2001) | Sub-groups established | Examples of foods | Updated groups |
|--|--|---|---|
| Fruits and vegetables | Fresh fruits | Apples, bananas, oranges | Fruits and vegetables |
| | Dried fruits | Dried apricots, prunes | |
| | Processed fruits | Fruit purees, fruits in syrup | |
| | Vegetables | Courgettes, carrots, tomatoes, green beans, sweetcorn, green peas | |
| | Oilseeds | Walnuts, almonds | |
| Starches: Breads, cereals, potatoes and dried vegetables | Wholegrain bread and bread products | Wholegrain bread and rusks | Starches |
| | Refined bread and bread products | White bread and rusks | |
| | Starch-based, sweet/fatty processed products | Breakfast cereals | |
| | Starch-based, savoury/fatty processed products | French fries, snack biscuits | |
| | Other wholegrain starches | Brown rice, whole wheat | |
| | Other refined starches | Rice, pasta, boiled potatoes | |
| | Pulses | Lentils, chickpeas, broad beans | Pulses |
| Meat and poultry, fishery products, eggs | Delicatessen meats | Sausage, ham, pâté | Meat and delicatessen meats, fishery products, eggs |
| | Eggs | Eggs | |
| | Oily fish | Salmon, mackerel, sardine, herring | |
| | Other fish, molluscs and crustaceans | Cod, bass, bream, mussels, shrimp | |
| | Red meat | Beef, veal, pork, mutton, lamb, horse, offal, game | |
| | Poultry | Chicken, duck | |
| Milk and dairy products | Sweetened dairy desserts | Cream desserts, ice-creams | Milk and dairy products |
| | Cheeses | Soft, pressed cheeses | |
| | Milk | Semi-skimmed milk, whole milk | |
| | Plain fresh dairy products | Plain yoghurts, white cheese (<i>fromage blanc</i>) | |
| | Sweetened fresh dairy products | Sweetened yoghurts | |
| Added fats | Butter and reduced-fat butter | Butter | Added fats |
| | Vegetable oils rich in ALA | Rapeseed oil, walnut oil | |
| | Vegetable oils poor in ALA and margarines | Sunflower oil, olive oil | |
| | Sauces, fresh creams and condiments | Mayonnaise, ketchup, fresh cream | |
| Sweetened products | Sweet or sweet and fat products | Jam, croissant-like pastries, biscuits, cakes | Sweet or sweet and fat products |
| Beverages | Drinking water | Water | Water |
| | Sugar-sweetened beverages such as soda | Sodas, lemonade | Sugar-sweetened beverages |
| | Fruit juice | Orange juice | |
| Salt | Salt | Salt | Salt |

3.3.3. Description of the optimisation tool

The aim of the optimisation work was to calculate the daily consumption X_g of each sub-group of foods g for each of the populations considered, to ensure that the nutritional requirements are covered, without exceeding the maximum nutritional or toxicological limits, and while remaining within a range of intakes observed in the population.

Linear programming of combined models was used to calculate the optimal consumption of each food sub-group. It involved searching for solutions to a combinatorial decision problem subject to constraints, with the aim of maximising or minimising an evaluation function known as the objective function.

The analysis program was developed in C++ language and uses the IBM® CPLEX solver. The algorithm uses the method known as "simplex" (Dantzig 1963), which was previously used for the development of food rations. The algorithm helps determine a target value by successive iterations on one or more variables, taking into account the constraints imposed. The algorithm searches for the only optimal solution in the domain of possible ones corresponding to a polyhedron with N dimensions defined by the constraints. As the solution is optimal, it is necessarily located on a vertex (Dantzig 1963) (see **Figure 2**).

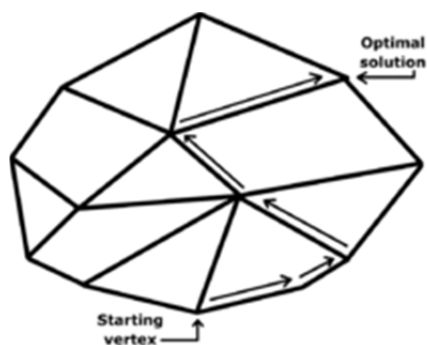


Figure 2. Illustration of the simplex algorithm

The nutritional constraints, those related to consumption habits and those related to contaminants can be integrated in the optimisation tool by means of inequalities. These inequalities define the limits of the polyhedron.

- Nutritional constraints:
 - Nutrient intake resulting from the optimisation must be higher than the PRI, the AI or the lower bound of the reference intake range and lower than the UL or the upper bound of the reference intake range (see

- Table 2 and **Table 3**).
- Consumption of red meat, delicatessen meats and sugar-sweetened beverages must be lower than the maximum consumption level determined by the epidemiological data (see **Table 5**).

- Constraints related to consumption habits:

Consumption of the sub-group resulting from the optimisation must be higher than the 5th percentile of the INCA2 consumption level and lower than the 95th percentile of the INCA2 consumption level.

In addition, substitutions were authorised between refined and wholegrain cereal products, and vegetable oils that are poor and rich in ALA (see Section 3.2.2.1 and **Table 9** in Annex 3).

- Constraints related to contaminants:

Exposure to the contaminant resulting from the optimisation must be lower than the HBGV or, if applicable, the median exposure from the TDS2 (see **Table 8** in Annex 3).

In cases where, for scientific reasons, certain constraints are considered to be too restrictive, they can be made flexible, i.e., by allowing the optimisation tool not to achieve certain nutritional target values or to exceed certain toxicological benchmarks.

While the constraints make it possible to define a set of solutions, the criteria make it possible to define an optimised solution in view of these criteria. They are combined in an "objective" function that reflects the objectives of this work.

- Nutritional criteria:

- minimise the breach of the nutritional constraints made flexible, i.e. get as close as possible to the dietary reference value;
- minimise the consumption of red meat, delicatessen meats and sugar-sweetened beverages;
- maximise the consumption of fresh fruits, vegetables, wholegrain bread and bread products and other wholegrain starches.

- Criteria related to consumption habits:

- minimise the gap with the average INCA2 consumption.

- Criteria related to contaminants:

- minimise the breach of the contaminant-related constraints made flexible, i.e. get as close as possible to the HBGV or the median exposure from the TDS2 depending on the case;
- minimise the total exposure to contaminants.

The objective function thus corresponds to a composite variable that efforts are made to minimise: it is the sum of the terms to be minimised and the terms to be maximised (by minimising the opposite of the sum).

3.3.4. Limitations and uncertainties of the optimisation tool

In addition to the limitations related to the population-based approach and the optimisation by food sub-groups, one of the main limitations lies in the construction of the "objective" function. This is in fact a sum of terms to be minimised: it is the total sum that is minimised, and not each term independently. The data were standardised (see the full report (ANSES 2017d)) in order to overcome differences of scale between the different sets of input data. However, it may be mathematically more interesting to focus the minimisation effort on one or more terms of the sum, and not on all the terms of the function. This means that the optimisation solution will overall be the

most interesting (i.e. it will better meet the demands shaped by the tool parameters), but that some terms may not have been minimised. Indeed, the "cost" (or the "loss") associated with the non-minimisation of these terms allows a significant "gain" in other criteria, and thus other expectations configured in the optimisation tool.

Sources of uncertainty can be identified in all the tool's input data, in particular, the data on nutritional composition and food contamination, and the data on current consumption (INCA2) and exposure (TDS2), but also in the nutritional or toxicological reference values.

Besides these uncertainties, it should be emphasised that the optimisation results obtained also depend on the parameters used and are therefore based on choices and compromises, such as the choice of the consumption bounds of the food groups at the 5th and 95th percentile, the choice of the constraints that were made flexible, the choice of food sub-groups for which substitution is possible, or the choice to weight the nutritional composition and contamination of each food sub-group by the consumption levels.

3.3.5. A step-by-step optimisation approach

In order to assess the effect of each of the constraints and test their compatibility with each other, a step-by-step approach was followed. First, the mutual compatibility of the nutritional constraints was tested by integrating in the tool only the nutritional constraints and criteria (Scenario A). Then, the consumption habits were also taken into account by including the constraint of the consumption bounds as well as the goal to minimise deviations from the average consumption (Scenario B). Lastly, the constraints and criteria related to contaminants were added to test the compatibility of all the constraints and measure the impact on the proposed solution of taking the contaminants into account (Scenario C).

Scenario B did not integrate the contaminants since they are extrinsic components of the food whose impact needs to be reduced, whereas the nutrients are intrinsic components of the food and are sought to cover the body's needs. This scenario represents a long-term view, in which effective management measures may have resulted in a reduction in contamination levels such that they no longer interfere in the determination of the food-based dietary guidelines.

Taking the contaminants into account (excluding additives and pesticides but including POPs, see Section 3.2.3) as an optimisation constraint (Scenario C) aimed to propose a solution that takes account of the reality of current contamination levels, and to study the influence of taking the contaminants into account on the food consumption resulting from the optimisation. This short- and medium-term approach does not rule out the establishment of possible management measures aiming to reduce contamination levels – on the contrary.

Food additives and pesticide residues (excluding POPs) are substances subject to authorisation at European level and it is therefore the responsibility of the authorities to determine conditions of use that are compatible with the food-based dietary guidelines. They were therefore not integrated in the constraints in the scenarios studied.

This approach was applied to the populations studied with adaptations specific to each one.

3.3.5.1. Approach followed for adult men (Figure 3)

An initial optimisation was carried out taking only the nutritional risk into account (Scenario A0). The solution obtained was very remote from the consumption habits and varied little in terms of food sub-groups.

Integration of the consumption bounds in the optimisation tool (Scenario B0) did not enable a solution to be reached. Thus, the constraint for vitamin D was made flexible (reaching the PRI for vitamin D is no longer an obligation but the optimisation seeks to get as close as possible to it). Indeed, the PRI for vitamin D was established without considering the endogenous synthesis of

vitamin D and is very difficult to reach given the supply and consumption habits observed. This scenario (B1) yielded a solution.

Lastly, integrating the contaminants in the optimisation tool (Scenario C0 and C1 with flexibility on the PRI for vitamin D) did not yield a solution. Thus, the constraints on three contaminants were made flexible: hexabromocyclododecane (HBCDD), polycyclic aromatic hydrocarbons (PAH4s) and polybrominated biphenyls (PBBs) (Scenario C2). Indeed for these contaminants, the CES ERCA determined that the margins of exposure or safety were high enough for them to be unlikely to cause a health risk. Therefore, it was assumed that a small increase in the level of exposure above that of the TDS2 was unlikely to lead to a risk. This scenario (C2) yielded a solution.

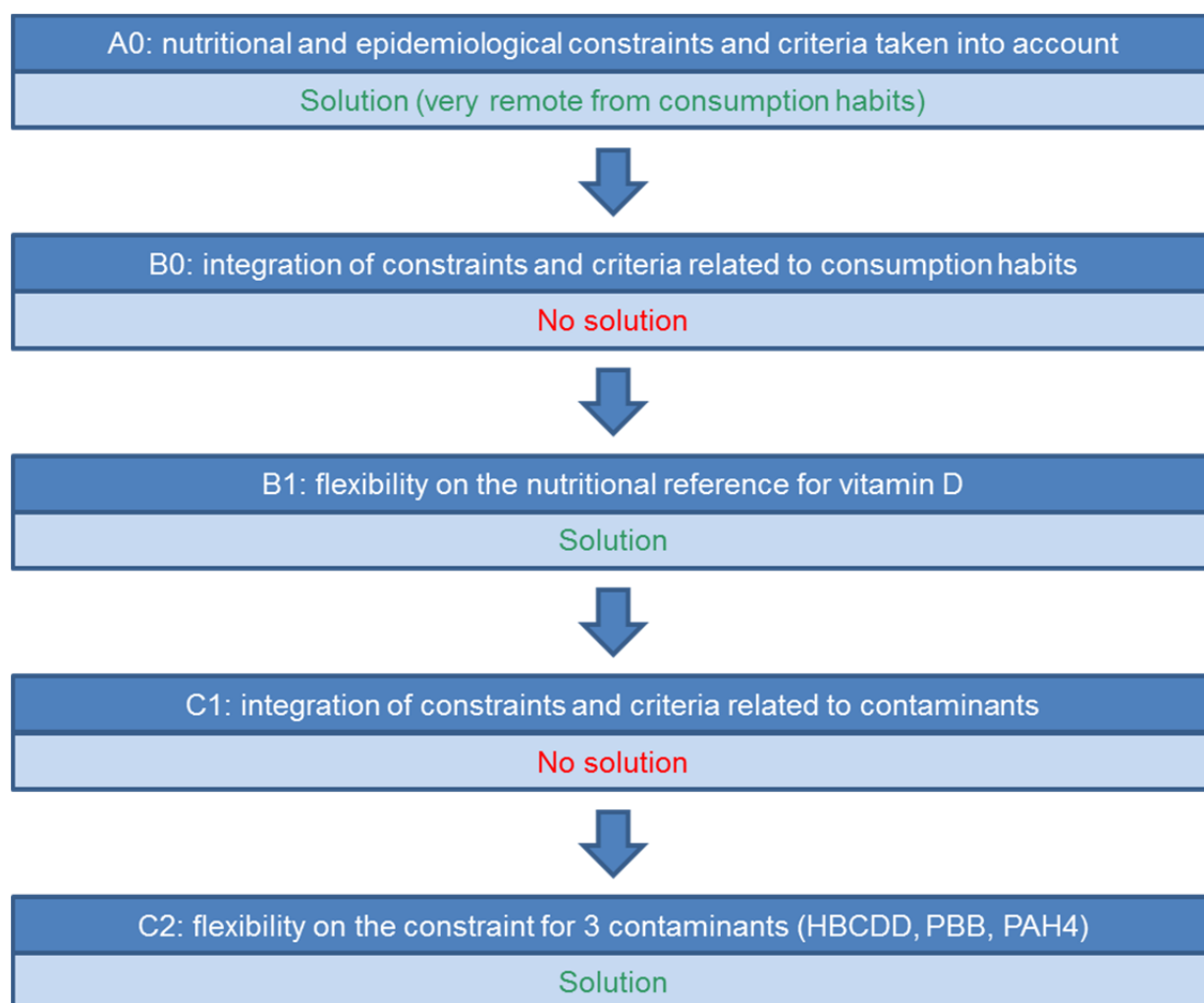


Figure 3. Approach followed for men

3.3.5.2. Approach followed for adult women

Two separate approaches were followed, for women whose iron requirements are low and for those whose iron requirements are high (see Section 3.2.1.1).

It was decided to begin with the optimisation for women with low iron requirements. Indeed, because the PRI for iron is less constraining in this population, the solutions are easier to identify. The approach followed for this population is shown in **Figure 4**.

An initial optimisation was carried out taking only the nutritional risk into account (Scenario A0). As with the men, the solution obtained was very remote from the consumption habits and varied little in terms of food sub-groups.

Integration of the consumption habits in the tool (Scenario B0) did not yield a solution. Therefore, the constraint for vitamin D was made flexible. Unlike the approach in men, this scenario (B1) did not yield a solution.

The nutrients for which the proposed intakes in Scenario B1 in men were at the level of the PRI and therefore regarded as limiting were then sought: these were vitamin B1, zinc, fats, ALA, EPA+DHA and fibre. As the dietary reference values for vitamin B1, fats and ALA are dependent on energy requirements, the intake to be reached (in absolute value) is lower for women, so it seems unlikely that it was these values that prevented a solution from being found. The PRI for zinc was established by making the assumption that phytate intakes were high (900 mg/d). Because this assumption could not be verified, the application of flexibility on the nutritional constraint for zinc (in addition to that on the nutritional constraint for vitamin D) was tested. The dietary reference value for fibre (30 g/d) is based on epidemiological data showing a beneficial effect from 25 g/d of fibre. It was therefore decided to apply a tolerance of 15% on the constraint for fibre, which corresponded to intakes above 25 g/d being imposed. With regard to EPA and DHA, the PRI was fixed at 500 mg/d on the basis of epidemiological studies highlighting a decrease in the risk of CVD, and possibly of metabolic syndrome, breast and colon cancer (AFSSA 2010). Therefore, no relaxing of the PRI was tested. While the relaxing of the constraint for zinc did not lead to any solution, the application of a tolerance for fibre that required fibre intakes to be higher than 25 g/d, and as close as possible to 30 g/d, enabled a result to be obtained (Scenario "B2 low iron").

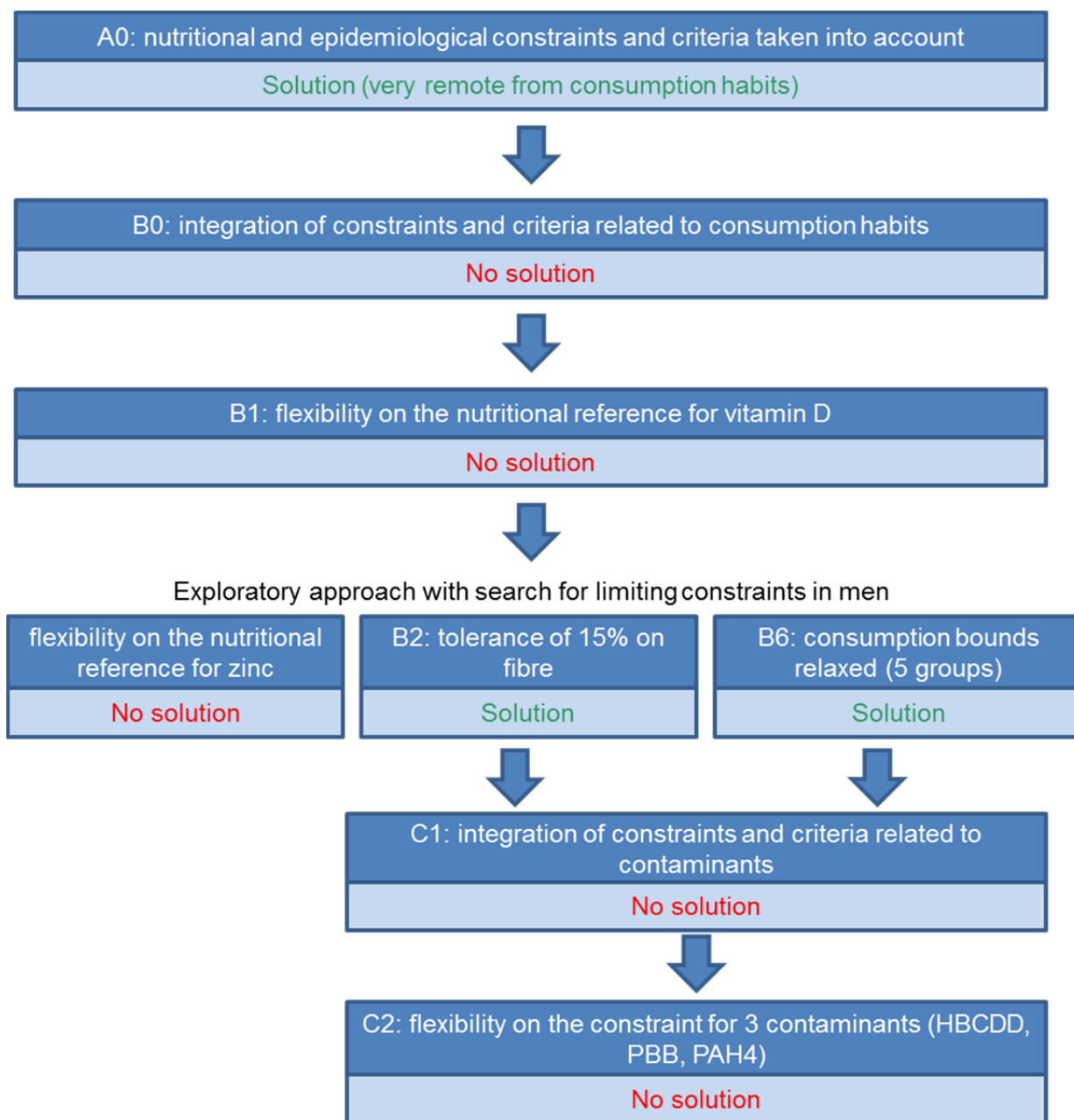


Figure 4. Approach followed for women with low iron requirements

For women whose iron requirements are high, a similar approach was followed with an initial optimisation that took into account only the nutritional risk (Scenario "A0 high iron") (see **Figure 5**). As with the men, the solution obtained was very remote from the consumption habits and varied little in terms of food sub-groups.

As expected, in view of the results for women whose iron requirements are low, the integration of consumption habits in the optimisation tool (Scenario B0) did not yield a solution, any more than the application of flexibility on the nutritional constraint for vitamin D (Scenario B1).

As with the women whose requirements for iron are low, a tolerance of 15% for fibre was applied (Scenario B2) but was unable to yield a solution. By testing the introduction of an increasing tolerance level for iron, a solution was obtained with at most an iron intake of 13.52 mg (corresponding to a tolerance of 15.5%).

An exploratory approach was then put in place by additionally applying a tolerance of 5% on all lower nutritional constraints except for those relating to water and energy, and 10% on all the upper consumption bounds except for those resulting from epidemiological relationships. This approach was unable to find a solution proposing 16 mg/d of iron; 15.2 mg of iron at most was reached but to the detriment of certain PRIs (calcium, ALA, EPA+DHA, vitamins C and D, and fibre) (Scenario B3 high iron).

It therefore seems impossible to find a solution taking the consumption habits into account with an iron intake of 16 mg/d. An intake of around 15 mg/d could help obtain solutions. This value corresponds in particular to the D-A-CH recommendation that was defined to cover the requirements of 90% of the female population.

An approach involving an increase in the consumption bound for sub-groups of iron-rich foods or those contributing predominantly to iron intake was followed. Among these food sub-groups, those for which consumption above the 95th percentile is acceptable and would help significantly increase iron intakes were identified. They are wholegrain bread, the sub-group "other fish", pulses, nuts and dried fruit. For these five groups, the upper bound was increased to the level of the highest serving (the definition of servings is described in **Annex 5**). This approach only yielded a solution by applying a tolerance of 15% on fibre (corresponding to a minimum intake of 25.5 g/d) and 6% on iron (which corresponds to an intake of 15 mg/d) (Scenario B4 high iron). As this approach to relax five specific bounds helped obtain solutions, it was also used for women whose iron requirements are low (Scenario B6 low iron) and yielded a solution.

Lastly, if the contaminant-related constraints were added to the selected scenarios, no solution was obtained, whether for women whose iron requirements are low or those whose iron requirements are high, despite the application of flexibility for the constraints related to the three contaminants HBCDD, PAH4 and PBBS, as was done for the men.

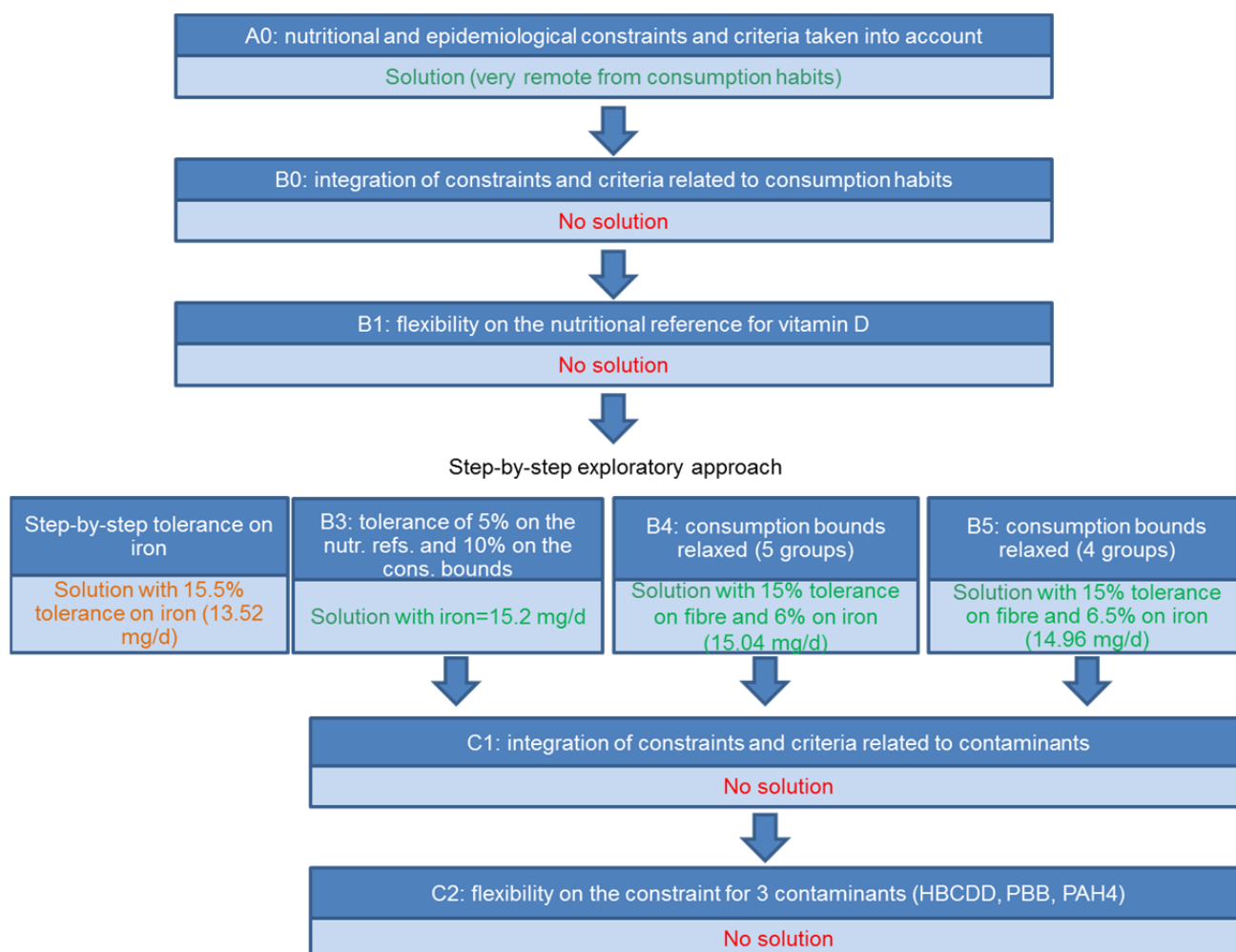


Figure 5. Approach followed for women with high iron requirements

3.4. Results – Discussion

The optimisation work for identifying food consumptions meeting a series of constraints revealed, firstly, through Scenario A, the compatibility between the constraints relating to nutrients ("nutritional constraints") and the epidemiological objectives and constraints relating to the families of foods. The solutions obtained can be regarded in this work as consumptions that are "optimised" for health and reducing the risk of certain chronic diseases. However, the small number of food sub-groups represented (12 out of 32 sub-groups) and the consumptions that are very remote from the dietary habits observed in France (as described in the INCA2 study) mean that it is not possible to imagine real compliance by the population with any food-based dietary guidelines that may be based on this type of scenario. It was deemed necessary to propose a scenario taking dietary habits into account (type B scenario) in order to arrive at food-based dietary guidelines that could be adopted.

The type B scenarios show that there are solutions that respect the vast majority of nutritional and epidemiological constraints while taking consumption habits into account. These solutions are mainly characterised by:

- High consumption of fruits and vegetables; these values are at the maximum levels authorised in the optimisation tool, i.e. the 95th percentile of consumption from the INCA2 study.

- Very high consumption of wholegrain cereal products at the expense of refined cereal products.
- High consumption of pulses compared to the average consumption from INCA2.
- Consumption of red meat that is difficult to reduce because of the nutritional constraints to be met in men and in women whose iron requirements are high, despite the epidemiological objective to minimise consumption.
- Significantly lower consumption of delicatessen meats than the average consumption from INCA2, except for women whose iron requirements are high, for whom consumption levels are at the maximum authorised in the optimisation tool (maximum defined on the basis of epidemiological studies).
- High consumption of oily fish compared to the average consumption from INCA2, close to the 95th percentile of consumption.
- Consumption of milk almost systematically at the maximum level authorised in the optimisation tool, i.e. the 95th percentile of consumption from the INCA2 study. Consumption of other dairy products close to the average consumption from INCA2.
- Among the added fats, oils rich in ALA are widely preferred.
- Consumption of sweet or sweet and fatty products close to the average consumption from INCA2.
- Low consumption of sugar-sweetened beverages compared to the average consumption from INCA2, mainly explained by a lack of consumption of soda type beverages.

However, these type B scenarios were unable to reach the PRI in vitamin D for men and women, and, to a lesser extent, the AI in fibre for women. The intakes of these nutrients in the proposed solutions are nevertheless higher than the average intakes reported in the INCA2 study.

In addition, for women whose menstrual losses are high, there was also the inability to achieve the PRI in iron: the tested scenarios were unable to provide more than 15 mg/d (rather than the 16 mg/d of the PRI). However, given that the physiological adaptation that increases iron absorption when reserves are low was not taken into account when establishing the requirement, the requirements of women whose losses are high are likely to be lower than estimated (see the summary report (ANSES 2017d)). This likely overestimation of the requirement, combined with the difficulty of identifying women with high requirements, led to the conclusions formulated for women whose menstrual iron losses are normal to low being retained for all women. With regard to the women likely to have high iron requirements (in particular women whose menstrual losses are high), monitoring of the iron status is recommended.

With regard to the energy macronutrients, protein intake is systematically close or equal to the upper limit of the RI (20% of TEI) for men and for women whose iron requirements are high, and to a lesser extent for women whose iron requirements are low.

For the type B scenarios, the *a posteriori* analysis of levels of exposure to contaminants (excluding pesticides but including POPs) identified some contaminants for which a health risk cannot be ruled out due to the exposure levels corresponding to the type B scenarios:

- Inorganic arsenic, for which exposure was close to (for men) or even exceeded (for women) the estimated exposure in the TDS2, which was already considered to be of concern;
- Lead, for which exposure in women was slightly higher than that estimated in the TDS2; the situation has therefore not improved compared to the results of the TDS2 in which the risk associated with exposure to lead could not be ruled out;
- BPA, for which the exposure of women whose iron requirements are high reached ANSES's toxicological benchmark in two scenarios out of three. However, these scenarios are not required to be taken into consideration in the formulation of food-based dietary

guidelines, for the reasons mentioned in the previous section. Moreover, the exposure values used for BPA result from data produced in the framework of the TDS2 (2007-2009) and they therefore pre-date the management measures imposed regarding BPA concentrations in food containers (2013);

- Nickel, for which exposure in women was slightly higher than the HBGV recently updated by EFSA; the situation is therefore considered to be of concern.

Concerning chromium VI, exposure for both men and women was close to or even higher than that estimated in the TDS2. However, there is great uncertainty about the relative share of Cr(III) compared to Cr(VI) in food, and EFSA's very conservative assumptions (see Section 3.2.3.4) were followed. Thus, it is impossible to conclude as to the risk associated with exposure.

Concerning the four food additives considered in this study, regardless of the population or the scenario considered, exposure was of the same order of magnitude as that calculated in the framework of the TDS2, and was in every case lower than the corresponding HBGV. Consequently, the exposure to these four food additives determined by the optimisation tool is not considered to be of concern.

Concerning the 232 pesticide residues analysed in the TDS2, the estimated exposures according to the type B scenarios were lower than the HBGV, with the exception of lindane (HCH-gamma), an older pesticide prohibited in the framework of the International Stockholm Convention. An environmental contaminant, this POP can be found in the food chain and in particular in certain foodstuffs of animal origin. This exceeding of the HBGV for lindane according to the type B scenarios should be put in perspective in view of several points:

- the estimated dietary exposure for lindane in these scenarios was between 12% and 18% of the estimated exposure in the TDS2, and is therefore lower than the current exposure;
- in the TDS2, lindane was only detected in three samples of foods of animal origin, contrary to other substances that were much more frequently detected;
- the HBGV was observed to have been exceeded when considering the HBGV of 0.01 $\mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ used in the recent expert appraisals (ANSES, 2014). However, when considering the HBGV of 5 $\mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ of the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) (FAO/WHO 2003) used in the framework of the annual European *a posteriori* assessments (EFSA, 2015), exposure to lindane remains lower than the HBGV.

The vast majority (over 75%) of pesticides had exposure levels higher than that of the TDS2. This difference in exposure levels can be explained mainly, for the majority of pesticides, by higher consumption levels of fruits and vegetables and, for a more limited number of substances, by higher consumption levels of cereals at the end of the optimisation according to the type B scenarios.

The levels of exposure to pesticides in women whose requirements for iron are high were broadly similar to those in women whose iron requirements are low. More specifically, the exposure values were very slightly higher according to the "low iron" scenarios for 76% of the pesticides assessed. Conversely, for POPs and other lipophilic substances that are rather detected in foods of animal origin (meat, fish and eggs in particular), exposure was higher according to the "high iron" scenarios. For example for lindane, exposure was close to 150% of the HBGV according to the "high iron" scenarios compared with 105% according to the "low iron" scenarios. However, these "high iron" scenarios are not required to be taken into consideration in the formulation of food-based dietary guidelines, for the reasons mentioned previously.

With regard to the type C scenario, which incorporated the constraints related to contaminants excluding additives and pesticides but incorporating POPs¹⁶, no solution was identified according

¹⁶ As additives and non-POP (persistent organic pollutant) pesticides are subject to regulations on use, their level of exposure was not subject to a constraint in the optimisation tool; this exposure was calculated for each combination of foods proposed as a solution for the different scenarios (see Section 3.2.3.2).

to the original parameters, for men or for women. For men, by introducing a flexibility (refer to the method in section 3.3.5) on the constraints related to contaminants (HBCDD, PBB and PAH4), a solution was identified. In contrast, for women, an exploratory review was conducted but did not lead to any optimised solution. It was decided not to prolong this review to the point where it would have led to an excessive number of constraints being relaxed, given the initial requirements: to cover the nutritional requirements of virtually all the population without increasing the risk associated with exposure to contaminants and while remaining within a range of observed food intakes.

The absence of a type C scenario for women is not surprising in view of the *a posteriori* analysis of the exposure levels in the type B scenarios for women. In fact, in these scenarios, exposure to multiple contaminants (nickel, lead, inorganic arsenic) exceeded the HBGV or the median from the TDS2 in women only. Several factors may explain this situation. In the first place, certain dietary reference values are identical for men and women, whereas the energy requirement is lower for women, which leads the optimisation tool to search for foods that are even more nutritionally dense than for men, thus limiting the possible solutions. In addition, as the body weight of women is lower than that of men, for an equivalent intake of contaminated food, the level of exposure will accordingly be higher in women, since it is related to the kg of body weight.

The solution for men can be distinguished from those from the type B scenarios in particular by:

- higher consumption of pulses;
- zero consumption of delicatessen meats and higher consumption of eggs at the maximum levels authorised in the optimisation tool;
- zero consumption of milk and higher consumption of cheese and dairy products close to the maximum authorised in the optimisation tool;
- higher consumption of fruit juices at the maximum level authorised in the optimisation tool (defined by the epidemiological constraint).

Many parameters influence the optimisation results and it is difficult to put forward simple assumptions, involving few parameters, to explain the consequences of taking contaminants into account on the major changes identified here that concern dairy products and fruit juices. However, some assumptions may be made:

With regard to the contaminants for which exposure in scenario B in men was higher than the maximum limit specified in the tool, milk is a main contributor to exposure to inorganic arsenic and chromium VI (8 and 13% respectively). Milk is the second largest contributor to exposure to inorganic arsenic, after fish, for which the amount proposed by the tool was probably mainly driven by the nutritional constraint relating to EPA and DHA (since fish are almost the sole source). Similarly, milk is the second main contributor to exposure to chromium VI, after water, for which the quantity proposed by the tool was driven by the constraint on water intakes. Thus, the decrease in the quantities of milk proposed seems to be a mathematically effective lever for reducing exposure to these two contaminants below the maximum limit established in the tool.

The water intake associated with milk in scenario B was compensated in scenario C by a high intake of fruit juice. With regard to calcium intake, it was almost entirely compensated by higher intakes of other dairy products, mainly cheese. Thus the "dairy products" group contributed to 55% (646 mg) of calcium intakes in scenario C compared with 60% (727 mg) in scenario B1.

It is important to emphasise that the concentrations of 211 contaminants are available for milk, and only around a hundred for other dairy products, which may partly explain, with the objective of minimising the sum of the exposures to contaminants, the drastic decrease in the quantities of milk proposed. However, the difference in levels of contamination of these two types of products may not reflect reality, due to disparities in the quantity of the data available on the contaminants for dairy products and for milk.

With regard to contaminants excluding additives and pesticides but including POPs, all the toxicological constraints were respected, except for HBCDD, for which exposure was higher than

that estimated in the TDS2. However, the margin of safety was much higher than the critical margin of safety adopted. The exposure therefore seems unlikely to lead to a health risk.

3.5. Conclusion of the CES

The optimisation tool developed made it possible to integrate all the nutritional data (relating to nutrients and food groups) and data relating to contaminants and dietary habits. It is a decision-support tool, useful in the formulation of food-based dietary guidelines, which requires both choices to be made in advance (concerning the parameters and the type of scenarios selected) and subsequent interpretation in view of the priority messages.

The results from the tested scenarios helped demonstrate intake levels of nutrients and contaminants of concern in public health terms, but also identify trends for certain food groups, in terms of quantities proposed, common to all the scenarios.

3.5.1. In terms of nutritional intakes

The solutions proposed by the optimisation tool can cover the nutritional requirements of virtually all the population, with the exception of a few nutrients. Thus, the situations of inadequate intakes reported in the opinion of 13 March 2015 (ANSES 2015b) can be avoided by adequate consumption of common foods, at levels already consumed by a part of the population, without needing to turn to food supplements. This is particularly the case with magnesium, in which the prevalence of inadequacy reached 67% in men and 77% in women, and vitamin C, in which the prevalence of inadequacy reached 53% in men and 41% in women. Conversely, as stressed in the opinion cited previously, it is not possible to meet the requirement for vitamin D given the supply and consumption habits observed, which was confirmed by the absence of an optimisation solution if achievement of the PRI in vitamin D was imposed, as currently defined. The results of the European ODIN consortium, whose aim is to propose dietary solutions to achieve optimal coverage of vitamin D requirements, may provide information for establishing the management measures that now seem necessary. With regard to iron, the optimisation results show that satisfactory solutions are obtained for 80% of women at least, whereas this is not the case for women whose requirements may be higher, although this need is likely to be overestimated. This likely overestimation of the requirement, combined with the difficulty of identifying women with high requirements, led to the conclusions formulated for women whose menstrual iron losses are normal to low being retained for all women. With regard to the women likely to have a high requirement for iron, monitoring of the iron status is recommended.

3.5.2. In terms of exposure to contaminants

In this study, two types of values were selected for the constraints related to exposures to contaminants. The health-based guidance values were selected when they were available (this was the case in particular with compounds with "threshold" effects). Otherwise (for example, in the case of substances whose effects are "without a threshold dose"), the medians of exposure calculated in the TDS2 were selected to avoid aggravating the current situation. In this last case, the values selected by default are not necessarily protective (this was the case with acrylamide, inorganic arsenic and lead, for which the situations were already considered to be of concern in the framework of the TDS2).

The optimisation work emphasised the difficulty of identifying solutions that can cover the nutritional requirements of virtually all the population without increasing the risk associated with exposure to contaminants, and while remaining within a range of observed food intakes. It was

necessary to relax the constraints related to some contaminants in order to identify a solution for men. In contrast, for women, an exploratory review was conducted but did not reach any optimised solution. It was decided not to prolong this review because it would have led to an excessive number of constraints being relaxed, bearing in mind the initial requirements.

This work also helped identify substances whose levels of contamination are likely to increase the health risk. Indeed, for certain substances, the exposure resulting from the optimisations was higher than that of the TDS2: it was not possible to estimate the health impact. In this case, with regard to inorganic arsenic, the situation remains a concern.

It should be stressed that for some contaminants, in the current state of estimates of contamination, although the dietary intakes proposed by the optimisation tool resulted in exposure below that of the TDS2, the health concern remains real. This is particularly the case with acrylamide and lead. Efforts to reduce the level of food contamination should therefore be continued.

Food additives and pesticides (non-POP plant protection substances) are systematically assessed before they can be placed on the market in Europe. The authorities lay down the conditions of use and maximum residue limits compatible with the food-based dietary guidelines established in advance. The same is true, to the extent possible, with the strategy of setting maximum levels for other contaminants (heat-induced, or of industrial or environmental origin). For pesticides, taking the consumptions proposed by the optimisation tool into account *a posteriori* revealed an overall increase in exposure compared to the TDS2, with the exception of lindane. This increase can be explained mainly by the increase in consumption of fresh fruits, vegetables and cereal products. However, the corresponding HBGVs were not observed to have been exceeded, except for lindane. For this last substance, earlier work, in particular the TDS2, had already highlighted the need to reduce exposure related to this POP, which has been prohibited in France since 1998.

3.5.3. In terms of consumption of food groups

The work helped identify optimisation solutions according to several scenarios that identify common trends on the levels of consumption of certain food groups. The food-based dietary guidelines can be established on the basis of these common trends, and not on one particular solution.

The optimisation results according to the type B scenarios (including the prevention of nutritional risk and the consumption habits), in men and in women whose iron requirements are low, were compared with each other and with the average consumption in the INCA2 study. The average and the extreme consumptions (5th and 95th percentiles) of the food sub-groups and groups are listed in **Annex 6**. The CES stresses that the results of this work can only be interpreted with regard to average food consumption in the population. It reiterates the large inter-individual variability of consumption in the population and warns against an individual-level interpretation of the recommendations for changes that concern the consumption averages in the population.

The CES's analysis is based on results that are both consistent¹⁷ between the scenarios and differing regarding the consumption habits¹⁸. When the results indicate a quantity that differs greatly from the usual consumption, the corresponding consumption frequency (calculated using the serving sizes defined in Annex 5, **Table 11**) is reported. The CES's recommendations are also based on the maximum intake limits resulting from the analysis of epidemiological data.

¹⁷ The results are regarded as consistent when, for all scenarios, the same trend (increase or decrease) compared to the average consumption estimated in INCA2 is observed.

¹⁸ The results are regarded as differing when they are 15% higher or lower than the average consumption estimated in INCA2.

Thus, in view of this analysis, the CES has formulated the following findings and recommendations:

- Current average consumption of the "fruits and vegetables" group is insufficient and should be increased considerably¹⁹, giving preference to the "fresh fruits" and "vegetables" sub-groups.
- Current average consumption of refined starches is too high and should be reduced. Conversely, consumption of wholegrain starches should be increased considerably, to become daily, which would result in an increase in total starch consumption.
- Current average consumption of pulses is insufficient and should be increased considerably. They should be consumed several times a week.
- Current average consumption of vegetable oils and margarines poor in ALA is too high. It should be reduced. Conversely, consumption of vegetable oils rich in ALA should be increased considerably, which would result in an increase in the total consumption of vegetable oils. Consumption of vegetable oils rich in ALA (such as walnut or rapeseed oils²⁰) should be daily.
- Consumption of red meat must remain below 500 g/week, as established on the basis of the epidemiological data.
- Current average consumption of delicatessen meats is too high and should be reduced considerably. It must remain below 25 g/d, as established on the basis of the epidemiological data.
- Current average consumption of oily fish is insufficient and should be increased. The CES considers that the recommendations defined in 2010 should be followed, i.e. "two servings of fish per week, including one with a high EPA-DHA content, and varying the species and sources of supply" (ANSES 2010).
- Current average consumption of the "sugar-sweetened beverages such as soda" sub-group is too high. It should be considerably reduced. In addition, the CES reiterates that consumption of the "sugar-sweetened beverages" group must remain below one glass a day, as established by the epidemiological data.

The observed trends correspond to substantial changes in consumption of food sub-groups compared to the current situation, for example, with increases ranging from a factor of 2 for vegetables to 70 for wholegrain starches. The highest increases correspond in reality to sub-groups that are consumed little or not at all (this is particularly the case with oils rich in ALA). In these cases, these sub-groups should be introduced into the dietary habits of all consumers. Conversely, it was noted that substantial decreases are desirable in other sub-groups: this is especially the case with delicatessen meats.

In certain cases, the CES was not able to identify recommendations because taking contaminants into account substantially modified the solutions.

- The quantities of milk proposed in the type B scenarios are considerably higher than the current average consumption. However, when the constraints related to contaminants are added (type C2 scenario in men), the quantity of milk proposed by the optimisation is null. For the other dairy products, the proposed consumption is close to current average consumption for the type B scenarios whereas it is greater for the type C scenario.

¹⁹ The qualifier "considerably" is used when the difference between the optimisation results and the average consumption estimated in INCA2 is greater than a factor of 2.

²⁰ To be consumed according to the conditions of use defined in the opinion of 22 June 2005 (AFSSA 2005)

- The quantity of fruit juice proposed by the optimisation is greatly reduced in the type B scenarios compared to the average consumption from INCA2. However, when the constraints related to contaminants are added (scenario C2), the quantity of fruit juice proposed by the optimisation is increased considerably and equates to one glass a day.

3.6. Outlook

This work provides the scientific evidence necessary for the formulation of food-based dietary guidelines. The formulation of these guidelines and their communication to the consumer will in particular require a thorough knowledge of the means of expression that are most understandable to the consumer. It will require identifying the most suitable formats of expression (by reference for example to the share of the plate or the weight) and temporal references (on the scale of the meal, the day or the week) to be used to formulate practical guidelines.

This work could usefully be supplemented by an assessment of the health effects of the frequencies of food intakes in the day, the internal structuring of food intakes, and the different consumption contexts (such as consumption outside the home or at home, the factors modulating attention during food intake, etc.), which would enable recommendations to be made with regard to the modes of food consumption.

The approach used for this work may be applied for other population groups on the basis of physiological criteria (such as children and adolescents or the elderly) or from specific eating behaviours (for example, food preferences or avoidance of certain foods).

Lastly, this report highlights the need to conduct research aiming to reduce the uncertainties relating to the nutritional or toxicological references. The optimisation work should be refined taking into account the effects of the food matrix on the bioavailability of certain vitamins and minerals, and the effects of the mode of production on the nutritional quality and levels of contaminants in foods. This work has enabled significant progress in a scientific approach developed to formulate food-based dietary guidelines aimed at the public by making the best possible use of the scientific information currently available, and has helped identify the needs for additional scientific knowledge.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

ANSES adopts the conclusions and recommendations of the Working Group and the CES on "Human Nutrition".

The work carried out is the scientific foundation needed for formulating food-based dietary guidelines for adult men and women excluding specific populations. In particular, it consisted in updating the dietary reference values and studying the relationships between the consumption of foods and the risk of chronic non-communicable diseases. An optimisation tool was also designed to identify combinations of foods able to simultaneously cover the nutritional requirements, prevent the risk of chronic non-communicable diseases and limit the risk associated with exposure to contaminants, while limiting deviations from the consumption practices observed. This taking account of dietary habits aims to facilitate the acceptance of any future guidelines. Accordingly, there were other solutions, more remote from common consumption habits. These were able to meet the nutritional objectives but were not considered, given the request by the public authorities. The optimisation was carried out to meet public health objectives, therefore, the solutions obtained are not directly applicable at individual level.

In addition, the Agency examined the issue of categorisation of foods. A debate was conducted on this topic incorporating nutritional composition data, consumption uses and epidemiological data. Thus, a new categorisation was proposed: there are now nine food groups instead of the seven groups from the categorisation used since the first PNNS. This new categorisation will ultimately make it possible to formulate more targeted food-based dietary guidelines. Pulses have been separated from the group of starches due to their high levels of protein and fibre, and constitute a new group. Drinking water (tap water, spring water and mineral water), the only indispensable beverage, is distinguished from the group of beverages and constitutes a group of its own. The sub-group of fruit juices is removed from the group of fruits and vegetables and added to the beverages such as soda within the sugar-sweetened beverages group, in view of the results of epidemiological studies relating to overweight, obesity, type 2 diabetes or cardiovascular diseases and focusing on sugar-sweetened beverages²¹.

The Agency's work led to important changes with regard to the previous recommendations. It relied on an energy intake calculated for a BMI of 22, taking into account moderate physical activity. This energy intake is in fact below real energy intakes for more than 40% of the population, which is overweight. These changes mainly relate to reinforced and regular consumption of pulses (in particular lentils, broad beans or chickpeas), the nutritional requirement to give preference to wholegrain cereal products (wholemeal bread and pasta, and brown rice) as well as the benefits of favouring the consumption of vegetable oils rich in alpha-linolenic acid (rapeseed and walnut oils). As a counterpoint, the Agency insists on the need for a considerable reduction in the consumption of delicatessen meats (ham, dried sausage, sausage, pâté, etc.) that should remain below 25 g per day, and the need for controlled consumption of red meat (beef, pork, lamb, etc.), not to exceed 500 g per week. ANSES also stresses that consumption of sugar-sweetened beverages must be less than one drink per day. Consumption of fruits and vegetables remains crucial and must be reinforced by giving preference to vegetables. Lastly, the benefits of bi-weekly consumption of fish including an oily fish (for example sardines, mackerel) is reaffirmed.

It should be noted that this work did not take into account coffee, tea, or alcoholic beverages. Indeed, coffee and tea contain highly variable amounts of caffeine, which has many adverse effects (including anxiety, tachycardia, sleep disorders, migraines). Thus, because of the great variability in sensitivity of individuals to caffeine (ANSES, 2013), the Agency is not able to propose a consumption recommendation for coffee and tea. Alcoholic beverages were not considered for this work, in particular because of the addictive potential and the behavioural disorders (risks of accidents and violence) associated with them.

²¹ These sugar-sweetened beverages include sodas, nectars, fruit juices made from concentrate, fresh fruit juices, smoothies, etc.

With the exception of a few nutrients, the proposed solutions are able to cover the nutritional requirements of virtually all the population. Thus, it is not possible to meet the requirement for vitamin D given the supply and consumption habits observed. The estimated dietary requirement for vitamin D is still the subject of numerous scientific debates. The Agency believes that a study assessing the vitamin D status of the French population, using a reference method and focusing in particular on at-risk populations, is necessary prior to the implementation of adequate management measures. Various non-exclusive management measures could be considered:

- personalised supplementation through the healthcare system directed at the adult population,
- specific recommendations for exposure to the sun, compatible with the prevention of skin cancers, could be proposed,
- fortification of foodstuffs in vitamin D overseen by the public authorities, assuming a detailed analysis of the health issues and the expected benefits and risks.

With regard to iron, around 20% of women have high requirements for iron that are difficult to meet with the current diet. Thus, ANSES advocates monitoring of the iron status for women likely to have a high requirement for iron.

With regard to sodium, the evolving state of knowledge did not enable the experts to confirm the dietary reference values previously produced by other bodies or to propose a new one. However, given the intakes observed today for a significant fraction of the population, with regard to the public health objectives, the risk of excessive sodium intakes is regarded as greater than the risk of insufficient intake. Thus, the experts' work sought to reduce the intakes of high consumers. In collaboration with ANSES, the French National Consumer Institute (INC) showed that the decline in salt levels in certain food products remains insufficient for achieving the objectives set by successive PNNSs. These results show that besides voluntary charters, it seems necessary to undertake additional actions, regulatory if necessary, in order to take action within a managed timetable, on the number of products concerned and the degree of reduction in salt levels in processed foods, in view of the pressing public health issues associated with sodium.

With regard to sugars²², the available data could not be used to distinguish the health effects of sugars naturally present in food from those of added sugars, irrespective of the effect of the matrix. Evidence is converging towards the harmful effects of high sugar intakes making it necessary to establish a maximum intake limit. This limit has been set at 100 g/d in adults. In order to reduce total intakes for the most exposed population, controlling the consumption of foods that are vectors of added sugars, in particular in the form of beverages, seems to be an important tool. Thus, efforts should be made in this respect by all the players (consumers, manufacturers, public authorities). However the effectiveness of the charters put in place to reduce the content of added sugars is debatable²³. A regulatory approach has already been initiated in the overseas territories by the decree of 9 May 2016 limiting the level of added sugars in products distributed in the overseas territories to the highest content found in metropolitan France. A regulatory approach, targeting the main vectors of added sugars, could also be considered in metropolitan France.

In addition, the optimisation work emphasised the difficulty of identifying solutions that can cover the nutritional requirements of virtually all the population while controlling exposure to contaminants. For a limited number of contaminants, the exposure levels remain a concern; this is the case in particular with inorganic arsenic, acrylamide and lead. Efforts to reduce the level of food contamination should therefore be continued. In this regard, ANSES recalls its recent opinions

²² Sugars are understood to mean mono- and disaccharides and by analogy glucose or fructose syrups digested and/or absorbed and metabolised

²³ Combris, P.; Enderli, G.; Gauvreau, J.; Ménard, C.; Soler, L.-G.; Spiteri, M.; Volatier, J.-L., 2014. Interventions publiques et démarches d'entreprises pour l'amélioration de la qualité nutritionnelle de l'offre alimentaire : apports et limites. Cahier de nutrition et de diététique. 49(1), 22-31.

(TDS2, iTDS) on these strategic issues and its recommendations to the public authorities. These reduction efforts concerning contaminants of concern are crucial since they ultimately enable the population's food choices to be governed by nutritional constraints and not by the levels of contamination in the food supply. Furthermore, ANSES reiterates its recommendation to consumers to diversify their diet and sources of supply.

This work provides the scientific evidence necessary for the formulation of food-based dietary guidelines. The formulation of these guidelines and their communication to the consumer will require identifying the most suitable formats of expression, whether for the quantities consumed, or the rhythms or frequencies of consumption. ANSES also plans to supplement this work with an assessment of the health effects of the frequencies of food intakes in the day, the internal structuring of food intakes, and the different consumption contexts (such as consumption outside the home or at home, the factors modulating attention during food intake, etc.).

In addition, the approach used for this work will subsequently be applied for other population groups defined on the basis of physiological criteria (such as age or sex, etc.) or from specific eating behaviours (for example, food preferences or avoidance of certain foods).

In the longer term, other issues deserve to be taken into account in establishing food-based dietary guidelines, in order to include them as part of a comprehensive and sustainable approach. In particular, the Agency will need to grasp issues of an environmental or socio-economic nature that will ultimately have to form the basis of such consumption guidelines.

Dr Roger Genet

KEYWORDS

Plan national nutrition santé, risque santé, nutrition, consommation alimentaire, nutriment, références nutritionnelles, optimisation, programmation linéaire, maladies chroniques non transmissibles, classification des aliments, contaminant

French National Health & Nutrition Programme, health risks, nutrition, food intake, nutrient, dietary reference values, optimisation, linear programming, chronic non-communicable diseases, food classification, contaminant

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ANNEX 1: PRESENTATION OF PARTICIPANTS

PREAMBLE: Outside experts, Expert Committee and WG members, or designated *rapporteurs* are all appointed in their personal capacity, *intuitu personae*, and do not represent their parent organisation.

WORKING GROUP

Chairman

Mr Jean-Louis BRESSON – University Professor – Hospital Practitioner – AP-HP Necker Hospital – Sick Children, Centre for Clinical Investigation, CIC 0901 – Paediatrics, public health

Members

Ms Marie-Joséphine AMIOT-CARLIN – Research Director – INRA "Nutrition, obesity and thrombotic risk" – Plant trace elements, metabolism of cholesterol

Ms Janine BULLIARD – Dietician, REPOPOP_FC – Dietetics, specific diets

Mr Marc BONNEFOY – University Professor – Hospital Practitioner – Claude-Bernard Lyon 1 University, Lyon Sud Medicine UFR, Hospices Civils de Lyon, Inserm 1060 – Elderly people

Ms Marie-Christine BOUTRON-RUAULT – Research Director – CESP Inserm U1018 team 9 "Nutrition, hormones and women's health" – Epidemiology of cancers and nutrition

Ms Katia CASTETBON – Unit Manager, French Institute of Public Health Surveillance (InVS) – Epidemiology, dietary recommendations

Ms Martine Field – Research Director, INRA – Carbohydrates

Mr Jean-Michel CHARDIGNY – UMR Director, INRA – Fats

Ms Véronique COXAM – Research Director, INRA – Nutritional prevention, osteoporosis

Ms Héléne ESCALON – Research Manager, INPES – Prevention for health

Mr Anthony FARDET²⁴ – Research Manager – INRA Clermont-Ferrand/Theix, Human Nutrition Unit, UMR 1019 INRA/University of Auvergne – Research and bibliographical analysis, preventive nutrition

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Ms Anne GALINIER – Manager of the Biology micronutrition UF, Ranguel University Hospital – Water-soluble vitamins

Ms Mariette GERBER – INSERM Retiree – Epidemiology

Mr Jean-Philippe GIRARDET – Professor, AP-HP – Paediatrics, infant nutrition

Mr Jean-François HUNEAU – Professor – AgroParisTech, Biology and Human Nutrition UFR – General nutrition, proteins, modelling, dietary reference values

Mr Lionel LAFAY – Project Leader in Epidemiology, National Cancer Institute – Epidemiology

Mr François MARIOTTI – Professor – AgroParisTech, Biology and Human Nutrition UFR – General nutrition, proteins, modelling

Mr Ambroise MARTIN – former University Professor – Hospital Practitioner, Claude Bernard Lyon I University – Nutrition & public health

²⁴Mr Fardet took part in the working group until the change in his public declaration of interests (PDI) in February 2015

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Mr Fabrice NESSLANY – Manager of the Toxicology Laboratory – Institut Pasteur de Lille – Toxicology

Ms Monique ROMON – University Professor – Hospital Practitioner, University of Lille 2 – Epidemiology, public health

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Mr Dominique TURCK – University Professor – Hospital Practitioner, Lille University Hospital – Paediatrics, public health

Mr Stéphane WALRAND – Research Director – INRA Clermont-Ferrand/Theix, Human Nutrition Unit, UMR 1019 INRA/University of Auvergne – General nutrition, proteins, sarcopenia

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These experts were directed towards the following thematic groups:

- **Thematic group 1: Identification of dietary reference values**

Ms CHAMP, Mr CHARDIGNY, Ms GERBER, Mr GIRARDET, Mr HUNEAU and Mr MARTIN

- **Thematic group 2: Bioavailability of micronutrients**

Mr FARDET²⁵, Mr HUNEAU, Ms ROUSSEAU

- **Thematic group 3: Nutrients of interest for the different groups of the population**

Ms CHAMP, Ms FERRY, Ms GALINIER, Ms GERBER, Mr GIRARDET

- **Thematic group 4: Relationships between the food groups and the risk of chronic diseases**

Ms AMIOT-CARLIN, Ms CASTETBON, Mr FARDET, Ms FERRY, Ms GERBER, Mr LAFAY, Ms ROMON

- **Thematic group 5: Categorisation of foods and definition of serving sizes**

Ms BULLIARD, Ms CASTETBON, Ms COXAM, Ms ESCALON, Ms MARTINEAU, Ms WERLE

- **Tool monitoring group: Monitoring of the computer tool for optimising food consumption and analysis of results**

Mr HUNEAU, Mr MARIOTTI, Mr MARTIN, Mr NESSLANY, Mr ROUDOT, Mr WALRAND

These thematic groups were coordinated by a **monitoring group** that ensured the consistency of the work on the sub-themes. Its members were:

Mr BRESSON (Chair), Mr BONNEFOY, Ms BOUTRON-RUAULT, Mr MARTIN and Mr TURCK

²⁵ Mr Fardet took part in the working group until the change in his PDI in February 2015

EXPERT COMMITTEE

The work that is the subject of this report was monitored and adopted by the following CESs:

- Human Nutrition – mandate 2012-2015

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Mr Jacques BELEGAUD – Honorary University Professor – Picardie-Amiens University – Specialities: toxicology

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- Human Nutrition – mandate 2015-2018

Chairman

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Members

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Ms Sabrina HAVARD – Methodology and Studies Unit

Ms Esther KALONJI – Deputy Head of the Nutritional Risk Assessment Unit (until January 2016)

Ms Anne MORISE – Nutritional Risk Assessment Unit

Ms Perrine NADAUD – Nutritional Risk Assessment Unit (until June 2014)

Ms Véronique SIROT – Methodology and Studies Unit

Ms Sandrine WETZLER – Nutritional Risk Assessment Unit

Other scientific contributions

Ms Claire BLADIER – Nutritional Risk Assessment Unit – scientific contribution

Ms Carine DUBUISSON – Methodology and Studies Unit – scientific contribution on categorisation and the estimation of serving sizes. Production of consumption data and food composition tables

Ms Laure DU CHAFFAUT – Food Observatory Unit – production and updating of the CIQUAL table

Ms Ariane DUFOUR – Methodology and Studies Unit – scientific contribution to the calculation of prevalence of inadequate intakes

Ms Aurélie MAHE – Foodborne Risk Assessment Unit – production of tables of levels of and exposure to contaminants, and the table of reference values for contaminants.

Ms Céline MENARD – Food Observatory Unit – production and updating of the CIQUAL table

Ms Mathilde MERLO – Phytopharmacovigilance and Observatory of Pesticide Residues Unit – scientific contribution on the subject of pesticides

Mr Alexandre NOUGADERE – Phytopharmacovigilance and Observatory of Pesticide Residues Unit – production of tables of levels, exposures and reference values for pesticides, and analysis of results on pesticides

Ms Marine OSEREDCZUK – Food Observatory Unit – production and updating of the CIQUAL table

Mr Gilles RIVIERE – Foodborne Risk Assessment Unit – scientific contribution on the subject of contaminants: choice of reference values, analysis of results

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French Association of Dieticians-Nutritionists (AFDN)

Ms Isabelle PARMENTIER – President of the AFDN – Senior Manager & Dietician, Lille University Hospital

Société Végane

Mr Constantin IMBS – President of the Société Végane

Ms Vanessa CLARKE – Administrator of the Société Végane

International Vegetarian Union

Mr Stephen WALSH – Scientific Coordinator of the International Vegetarian Union

APSARes (Association of Health Professionals for Responsible Food)

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➤ **Fruit juices and nectars sector**

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Ms Nazila SENEHIPOUR – Regulatory Affairs Manager, Pepsico

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➤ **Oils & fats sector**

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Ms CAMILLE SIMONNEAU – Nutrition and Regulatory Affairs Manager, St Hubert

Ms Valérie BUSSON – Director of Communication and Public Relations, Lesieur

Ms Amélie DHAUSSY – Regulatory Affairs and Nutrition Manager, Lesieur

➤ **Sugar sector**

Mr Philippe REISER – Director of Scientific Affairs, Sugar Study and Documentation Centre (CEDUS)

Ms Anne-Claire DURAND – Scientific Information Manager, CEDUS

➤ **Meat sector**

Ms Christelle DUCHENNE – Nutrition Project Leader, French Meat Information Centre (CIV)

Ms Claire CHAMBRIER – Project Officer, National Interprofessional Association for Livestock and Meat (Interbev)

➤ **Fresh dairy products sector**

Ms Isabelle GILLES – Delegate General, Syndifrais

Ms Valérie BENOIT – Scientific Affairs and Health Manager, Yoplait

Ms Tiphaine GIMBERT – Scientific Relations Manager, Danone Fresh Dairy Products

➤ **Cereals sector**

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CONTRIBUTIONS OUTSIDE THE GROUP(S)

Eurodecision

Ms Raja REBAI – Optimisation Consultant – Participation in development of the optimisation tool

ANNEX 2: DISSENTING POSITIONS

Mr François Mariotti, as a member of the CES, and Mr Jean-François Huneau, member of the CES and the Working Group for Theme 1, stated their dissenting position on the subject of dietary reference values for vitamin C for women. Indeed, they considered that the CES's decision departed from the rule governing the group's work, i.e. the principle of endorsing EFSA's approach except in the case of compelling evidence to the contrary. For this very specific case, they felt that the evidence against EFSA's proposed rationale, although interesting, was too weak. In brief, they felt they were not in a position to determine whether ultimately the requirements of women were the same as or different to those of men, but with this uncertainty, they wished to register their opinion in the Working Group's decision rationale according to the mandate it had been given.

In addition, Mr Ambroise Martin, a member of the group for sub-theme 1, expressed the same dissenting position concerning the dietary reference values for vitamin C for women, as well as the dietary reference value for magnesium for men and women. It should be noted that Mr Martin is the Chairman of the NDA Panel (dietetic products, nutrition and allergies), which developed the dietary reference values endorsed by EFSA.

ANNEX 3: TABLE OF CONSTRAINTS INTEGRATED IN THE OPTIMISATION TOOL

Table 7: Summary of nutritional constraints used for the optimisation tool

| Nutrient | Lower nutritional constraints | | Upper nutritional constraints | |
|-------------------------------------|--|--|-------------------------------|--------|
| | Men | Women | Men | Women |
| Energy (kcal) | ≥ 2470 | ≥ 1995 | < 2730 | < 2205 |
| Vitamin A (µg/d) | ≥ 750 | ≥ 650 | < 3000 | < 3000 |
| Vitamin B1 (mg/kcal) | ≥ 0.00058 | ≥ 0.00058 | - | - |
| Vitamin B2 (mg/kcal) | ≥ 0.00071 | ≥ 0.00071 | - | - |
| Vitamin B3 (mg NE/kcal) | ≥ 0.0067 | ≥ 0.0067 | < 900 | < 900 |
| Vitamin B5 (mg) | - | - | - | - |
| Vitamin B6 (mg) | ≥ 1.8 | ≥ 1.5 | < 25 | < 25 |
| Vitamin B9 (µg DFE) | ≥ 330 | ≥ 330 | - | - |
| Vitamin B12 (µg) | ≥ 4 | ≥ 4 | - | - |
| Vitamin C (mg) | ≥ 110 | ≥ 110 | - | - |
| Vitamin D (µg) | ≥ 15 | ≥ 15 | < 50 | < 50 |
| Vitamin E (mg) | - | - | < 300 | < 300 |
| Calcium (mg) | ≥ 1000 | ≥ 1000 | < 2500 | < 2500 |
| Copper (mg) | ≥ 1.25 | ≥ 1 | < 5 | < 5 |
| Iron (mg) | ≥ 11 | ≥11 ("low iron") or ≥16 ("high iron") | - | - |
| Iodine (µg) | ≥ 150 | ≥ 150 | < 600 | < 600 |
| Magnesium (mg) | ≥ 420 | ≥ 360 | - | - |
| Manganese (mg) | - | - | - | - |
| Phosphorus (mg) | ≥ 700 | ≥ 700 | - | - |
| Potassium (mg) | Calculated so that the Na/K molar ratio is less than or equal to 1 | | - | - |
| Selenium (µg) | ≥ 70 | ≥ 70 | < 300 | < 300 |
| Sodium (mg) | - | - | < 2994 | < 2273 |
| Zinc (mg) | ≥ 14 | ≥ 11 | < 25 | < 25 |
| Water (g) | ≥ 2375 | ≥ 1900 | < 2625 | < 2100 |
| Proteins (% TEI) | ≥ 10 | ≥ 10 | < 20 | < 20 |
| Fats (% TEI) | ≥ 35 | ≥ 35 | < 40 | < 40 |
| Total saturated fatty acids (% TEI) | - | - | < 12 | < 12 |
| Lauric + myristic + palmitic acids | - | - | < 8 | < 8 |
| Linoleic acid (% TEI) | ≥ 4 | ≥ 4 | - | - |
| α-linolenic acid (% TEI) | ≥ 1 | ≥ 1 | - | - |
| Linoleic acid / α-linolenic acid | - | - | < 5 | < 5 |
| EPA + DHA (mg) | ≥ 500 | ≥ 500 | - | - |
| Carbohydrates (% TEI) | ≥ 40 | ≥ 40 | < 55 | < 55 |
| Total sugars excluding lactose (g) | - | - | < 100 | < 100 |
| Fibres (g) | ≥ 30 | ≥ 30 | - | - |

TEI, total energy intake; DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; NE, niacin equivalent; DFE, dietary folate equivalent.

Table 8: Summary of toxicological constraints used for the optimisation tool

| Classes | Substances | Toxicological constraints | Substances | Toxicological constraints |
|--------------------------------------|--|--|---------------------------------|---|
| Trace elements | Aluminium | TWI = 1 mg/kg bw/wk (EFSA, 2013) | Cadmium | TWI = 2.5 µg/kg bw/d (EFSA, 2009) |
| | Germanium | No value | Tin | No value |
| | Antimony | No value | Gallium | No value |
| | Nickel | TDI = 2.8 µg/kg bw/d (EFSA, 2015) | Mercury | Organic Hg: PTWI = 1.3 µg/kg bw/wk (EFSA, 2012) Inorganic Hg: TWI = 4 µg/kg bw/wk (EFSA, 2012) |
| | Chromium | Cr(VI): TDS2 exposure Cr(III): TDI = 300 µg/kg bw/d (EFSA, 2014) | Lead | TDS2 exposure |
| | Cobalt | HBGV = 1.6 µg/kg bw/d (AFSSA, 2010) | Strontium | TDI = 0.6 mg/kg bw/d (US-EPA, 1996) |
| | Silver | No value | Tellurium | No value |
| | Inorganic arsenic | TDS2 exposure | Vanadium | No value |
| | Barium | RfD = 0.2 mg/kg bw/d (US-EPA, 2005) | | |
| Persistent organic pollutants | Dioxins and furans | HBGV = 0.7 pg TEQ _{WHO} /kg bw/d (US-EPA, 2012) | Hexabromocyclo-dodecane (HBCDD) | Sum of the 3 isomers: TDS2 exposure |
| | Non dioxin-like polychlorinated biphenyls (NDL-PCBs) | TDI = 10 ng/kg bw/d (AFSSA, 2007) | Polybrominated biphenyls (PBB) | TDS2 exposure |
| | Polybrominated diphenyl ethers (PBDEs) | Sum of the 7 PBDEs: HBGV = 10 ng/kg bw/d (AFSSA, 2007) BDE-209: TDS2 exposure | Perfluorinated compounds | PFOS: RfD = 0.08 µg/kg bw/d (US-EPA, 2009) PFOA: RfD = 0.2 µg/kg bw/d (US-EPA, 2009) Other compounds: - |
| Mycotoxins | Aflatoxins | TDS2 exposure | Ochratoxin A | PTWI = 0.12 µg/kg bw/wk (EFSA, 2006) |
| | Trichothecenes | T-2 and HT-2 toxins: PMTDI = 0.06 µg/kg bw/d (EFSA, 2011) Deoxynivalenol: TDI = 1 µg/kg bw/d (EFSA, 2007) Nivalenol: TDI = 1.2 µg/kg bw/d (EFSA, 2013) | Zearalenone and derivatives | TDI = 0.25 µg/kg bw/d (EFSA, 2014) |

| Classes | Substances | Toxicological constraints | Substances | Toxicological constraints |
|---|---|--------------------------------------|---------------------------------|--|
| | Patulin | PMTDI = 0.4 µg/kg bw/d (JECFA, 1995) | Fumonisin | FB1 + FB2: PMTDI = 2 µg/kg bw/d (EFSA, 2014) |
| Heat-induced substances | Polycyclic aromatic hydrocarbons (PAHs) | PAH4: TDS2 exposure | Acrylamide | TDS2 exposure |
| Pesticide residues (Persistent organic pollutants) | Lindane (HCH-gamma) | ADI = 0.01 µg/kg bw/d | Dieldrin (sum) | PTDI = 0.1 µg/kg bw/d |
| | Campechlor (toxaphene) | ADI = 0.033 µg/kg bw/d | HCH (sum, except for gamma-HCH) | ADI = 0.6 µg/kg bw/d |
| | Chlordane (sum) | ADI = 0.5 µg/kg bw/d | Heptachlor (sum) | ADI = 0.1 µg/kg bw/d |
| | DDT (sum) | ADI = 10 µg/kg bw/d | Hexachlorobenzene | ADI = 0.8 µg/kg bw/d |
| Endocrine disruptors | Bisphenol A (BPA) | ADI = 0.2 µg/kg bw/d | | |

TWI: Tolerable weekly intake, ADI: acceptable daily intake, TDI: tolerable daily intake, PTWI: provisional tolerable weekly intake, PMTDI: provisional maximum tolerable daily intake, PTDI: provisional tolerable daily intake, TDS2: 2nd total diet study, HBGV: health-based guidance value, RfD: reference dose, PFOS: perfluorooctanesulfonic acid, PFOA perfluorooctanoic acid, PCB: polychlorinated biphenyl, PBB: polybrominated biphenyl, HBCDD: hexabromocyclododecane, PBDE: polybrominated diphenyl ether.

Table 9: Summary of consumption bounds for each food sub-group entered in the optimisation tool

| Food sub-groups | Men | | | | Women | | | |
|--|-------------------------------|---------------------------|-------------------------------|----------------------------|-------------------------------|---------------------------|-------------------------------|----------------------------|
| | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) |
| Vegetables | 16 | 123 | 285 | - | 21 | 124 | 282 | - |
| Fresh fruits | 0 | 115 | 376 | - | 0 | 111 | 332 | - |
| Dried fruits | 0 | 1 | 3 | - | 0 | 1 | 4 | - |
| Processed fruits: purees and cooked fruit | 0 | 8 | 53 | - | 0 | 12 | 57 | - |
| Oilseeds | 0 | 2 | 9 | - | 0 | 1 | 5 | - |
| Refined bread and bread products | 0 | 102 | 260 | 284 | 0 | 60 | 161 | 177 |
| Wholegrain bread and bread products | 0 | 16 | No upper limit | | 0 | 12 | No upper limit | |
| Other refined starches | 14 | 113 | 255 | 257 | 14 | 83 | 193 | 193 |
| Other wholegrain starches | 0 | 3 | No upper limit | | 0 | 2 | No upper limit | |
| Starch-based, sweet/fatty processed products | 0 | 14 | 71 | - | 0 | 15 | 61 | - |
| Starch-based, savoury/fatty processed products | 0 | 27 | 79 | - | 0 | 20 | 57 | - |
| Pulses | 0 | 14 | 64 | - | 0 | 11 | 50 | - |
| Poultry | 0 | 38 | 122 | - | 0 | 25 | 75 | - |
| Red meat | 0 | 64 | 71 | - | 0 | 41 | 71 | - |
| Delicatessen meats | 0 | 39 | 25 | - | 0 | 26 | 25 | - |

ANSES Opinion
Request No 2012-SA-0103

| Food sub-groups | Men | | | | Women | | | |
|---|-------------------------------|---------------------------|-------------------------------|----------------------------|-------------------------------|---------------------------|-------------------------------|----------------------------|
| | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) |
| Oily fish | 0 | 5 | 27 | - | 0 | 4 | 25 | - |
| Other fish | 0 | 23 | 70 | - | 0 | 22 | 67 | - |
| Eggs | 0 | 13 | 46 | - | 0 | 12 | 43 | - |
| Milk | 0 | 98 | 386 | - | 0 | 87 | 350 | - |
| Plain fresh dairy products | 0 | 28 | 129 | - | 0 | 36 | 157 | - |
| Sweetened fresh dairy products | 0 | 42 | 154 | - | 0 | 47 | 161 | - |
| Sweetened dairy desserts | 0 | 18 | 86 | - | 0 | 16 | 57 | - |
| Cheeses | 0 | 36 | 94 | - | 0 | 24 | 65 | - |
| Butter and reduced-fat butter | 0 | 6 | 26 | - | 0 | 4 | 17 | - |
| Vegetable oils rich in ALA | 0 | 0 | No upper limit | 21 | 0 | 0 | No upper limit | 16 |
| Vegetable oils poor in ALA and margarines | 0 | 5 | 20 | | 0 | 4 | 16 | |
| Sauces, fresh creams and condiments | 0 | 13 | 43 | - | 0 | 14 | 39 | - |
| Sweet or sweet and fatty products | 0 | 68 | 174 | - | 1 | 59 | 141 | - |
| Drinking water | 0 | 775 | 2000 | - | 51 | 806 | 1886 | - |
| Sugar-sweetened beverages such as soda | 0 | 93 | No upper limit | 263 | 0 | 58 | No upper limit | 216 |
| Fruit juice | 0 | 59 | No upper limit | | 0 | 61 | No upper limit | |
| Salt | 0 | 0 | 1 | - | 0 | 0 | 1 | - |

The boxes in yellow represent the consumption limits from the INCA2 consumption data (P5 for the lower limit and P95 for the upper limit). The boxes in red represent the consumption limits introduced following epidemiological justifications. The food sub-groups in green are coupled sub-groups, i.e. sub-groups for which the limit relates to consumption of the sum of the two sub-groups



ANNEX 4: SUMMARY OF THE ADIS FOR ADDITIVES AND PESTICIDE RESIDUES

Table 10: Summary of the acceptable daily intakes (ADIs) for additives and pesticide residues excluding POPs, which were not integrated in the optimisation tool (and for which an *a posteriori* check was made that the ADIs have not been exceeded)

| Classes | Substances | Target values | Substances | Target values |
|--------------------|---------------------|----------------------|--------------------|----------------------|
| Additives | Annatto | ADI = 65 µg/kg bw/d | Sulphites | ADI = 0.7 mg/kg bw/d |
| | Nitrites | ADI = 60 µg/kg bw/d | Tartaric acid | ADI = 30 mg/kg bw/d |
| Pesticide residues | 2,4-D | ADI = 50 µg/kg bw/d | Diflubenzuron | ADI = 100 µg/kg bw/d |
| | Alphamethrin | ADI = 15 µg/kg bw/d | Epoxiconazole | ADI = 8 µg/kg bw/d |
| | Benalaxyl | ADI = 40 µg/kg bw/d | Fenpropidin | ADI = 20 µg/kg bw/d |
| | Carbendazim (sum) | ADI = 20 µg/kg bw/d | Fenpropimorph | ADI = 3 µg/kg bw/d |
| | Chlorothalonil | ADI = 15 µg/kg bw/d | Fenpyroximate | ADI = 10 µg/kg bw/d |
| | Chlorpropham (sum) | ADI = 50 µg/kg bw/d | Fludioxonil | ADI = 370 µg/kg bw/d |
| | Chlorpyrifos-ethyl | ADI = 1 µg/kg bw/d | Flutolanil | ADI = 90 µg/kg bw/d |
| | Chlorpyrifos-methyl | ADI = 10 µg/kg bw/d | Mepiquat | ADI = 200 µg/kg bw/d |
| | Cyfluthrin | ADI = 3 µg/kg bw/d | Pyriproxyfen | ADI = 100 µg/kg bw/d |
| | Cypermethrin | ADI = 50 µg/kg bw/d | Bifenthrin | ADI = 15 µg/kg bw/d |
| | Deltamethrin | ADI = 10 µg/kg bw/d | Chlorthal-dimethyl | ADI = 10 µg/kg bw/d |
| | Dinocap | ADI = 4 µg/kg bw/d | Etofenprox | ADI = 30 µg/kg bw/d |
| | Diquat | ADI = 2 µg/kg bw/d | Imidacloprid | ADI = 60 µg/kg bw/d |
| | Esfenvalerate | ADI = 20 µg/kg bw/d | Teflubenzuron | ADI = 10 µg/kg bw/d |
| | Flusilazole | ADI = 2 µg/kg bw/d | Tetraconazole | ADI = 4 µg/kg bw/d |
| | Imazalil | ADI = 25 µg/kg bw/d | Triadimenol (sum) | ADI = 50 µg/kg bw/d |
| | Iprodione (sum) | ADI = 60 µg/kg bw/d | Triflumuron | ADI = 14 µg/kg bw/d |
| | Lambda-cyhalothrin | ADI = 2.5 µg/kg bw/d | Cymoxanil | ADI = 13 µg/kg bw/d |
| | Linuron | ADI = 3 µg/kg bw/d | Cyromazine | ADI = 60 µg/kg bw/d |
| | Pendimethalin | ADI = 125 µg/kg bw/d | Diphenylamine | ADI = 75 µg/kg bw/d |
| | Propiconazole | ADI = 40 µg/kg bw/d | Tebuconazole | ADI = 30 µg/kg bw/d |
| | Propyzamide | ADI = 20 µg/kg bw/d | Tebufenpyrad | ADI = 10 µg/kg bw/d |
| | Pyridate | ADI = 36 µg/kg bw/d | Triallate | ADI = 25 µg/kg bw/d |
| | Thiabendazole | ADI = 100 µg/kg bw/d | Acrinathrin | ADI = 10 µg/kg bw/d |
| | Acephate | ADI = 30 µg/kg bw/d | Bitertanol | ADI = 3 µg/kg bw/d |
| | Aldicarb (sum) | ADI = 3 µg/kg bw/d | Bioresmethrin | ADI = 30 µg/kg bw/d |
| | Amitraz (sum) | ADI = 3 µg/kg bw/d | Bromopropylate | ADI = 30 µg/kg bw/d |
| | Atrazine (sum) | ADI = 20 µg/kg bw/d | Bromuconazole | ADI = 10 µg/kg bw/d |
| | Azinphos-ethyl | ADI = 2 µg/kg bw/d | Bupirimate | ADI = 50 µg/kg bw/d |
| | Azinphos-methyl | ADI = 5 µg/kg bw/d | Buprofezin | ADI = 10 µg/kg bw/d |
| | Chlozolinate | ADI = 100 µg/kg bw/d | Carbetamide | ADI = 60 µg/kg bw/d |
| | Endosulfan (sum) | ADI = 6 µg/kg bw/d | Carboxin | ADI = 8 µg/kg bw/d |
| | Fenarimol | ADI = 10 µg/kg bw/d | Chinomethionat | ADI = 6 µg/kg bw/d |
| | Fenthion (sum) | ADI = 7 µg/kg bw/d | Chlorfenson | ADI = 10 µg/kg bw/d |
| | Fentin acetate | ADI = 0.4 µg/kg bw/d | Chlorfluazuron | ADI = 5 µg/kg bw/d |
| | Fentinhydroxide | ADI = 0.4 µg/kg bw/d | Cyhexatin | ADI = 3 µg/kg bw/d |
| | | | Cyproconazole | ADI = 20 µg/kg bw/d |
| | Methamidophos | ADI = 1 µg/kg bw/d | Dichlobenil | ADI = 10 µg/kg bw/d |
| | Paraquat | ADI = 4 µg/kg bw/d | Dichlofluanid | ADI = 300 µg/kg bw/d |

ANSES Opinion
Request No 2012-SA-0103

| Classes | Substances | Target values | Substances | Target values |
|--------------------|------------------------|-----------------------|-------------------------|-----------------------|
| Pesticide residues | Parathion | ADI = 0.6 µg/kg bw/d | Diclobutrazol | ADI = 30 µg/kg bw/d |
| | Parathion-methyl (sum) | ADI = 3 µg/kg bw/d | Dicofol (sum) | ADI = 2.2 µg/kg bw/d |
| | Permethrin (sum) | ADI = 50 µg/kg bw/d | Dicloran | ADI = 5 µg/kg bw/d |
| | Procymidone | ADI = 2.8 µg/kg bw/d | Diethofencarb | ADI = 430 µg/kg bw/d |
| | Pyrazophos | ADI = 4 µg/kg bw/d | Diniconazole | ADI = 20 µg/kg bw/d |
| | Quintozene (sum) | ADI = 10 µg/kg bw/d | Ethirimol | ADI = 7.5 µg/kg bw/d |
| | Simazine | ADI = 5 µg/kg bw/d | Etridiazole | ADI = 15 µg/kg bw/d |
| | Tecnazene | ADI = 20 µg/kg bw/d | Fenazaquin | ADI = 5 µg/kg bw/d |
| | Vinclozolin (sum) | ADI = 5 µg/kg bw/d | Fenbuconazole | ADI = 6 µg/kg bw/d |
| | Captan | ADI = 100 µg/kg bw/d | Fenbutatin oxide | ADI = 50 µg/kg bw/d |
| | Cyprodinil | ADI = 30 µg/kg bw/d | Fenoxycarb | ADI = 53 µg/kg bw/d |
| | Dichlorprop-P | ADI = 60 µg/kg bw/d | Fenpropathrin | ADI = 30 µg/kg bw/d |
| | Dimethoate (sum) | ADI = 1 µg/kg bw/d | Fluazifop-p-butyl (sum) | ADI = 10 µg/kg bw/d |
| | Dimethomorph | ADI = 50 µg/kg bw/d | Flubenzimine | ADI = 25 µg/kg bw/d |
| | Diuron (sum) | ADI = 7 µg/kg bw/d | Flufenoxuron | ADI = 10 µg/kg bw/d |
| | Ethoprophos | ADI = 0.4 µg/kg bw/d | Fluquinconazole | ADI = 2 µg/kg bw/d |
| | Fenamiphos (sum) | ADI = 0.8 µg/kg bw/d | Flutriafol | ADI = 10 µg/kg bw/d |
| | Fipronil [parent] | ADI = 0.2 µg/kg bw/d | Hexaconazole | ADI = 5 µg/kg bw/d |
| | Folpet | ADI = 100 µg/kg bw/d | Hexaflumuron | ADI = 20 µg/kg bw/d |
| | Metconazole | ADI = 10 µg/kg bw/d | Hexythiazox | ADI = 30 µg/kg bw/d |
| | Methiocarb (sum) | ADI = 13 µg/kg bw/d | Mepronil | ADI = 50 µg/kg bw/d |
| | Metribuzin | ADI = 13 µg/kg bw/d | Methacrifos | ADI = 6 µg/kg bw/d |
| | Oxamyl | ADI = 1 µg/kg bw/d | Metoxuron | ADI = 5 µg/kg bw/d |
| | Phosmet (sum) | ADI = 10 µg/kg bw/d | Myclobutanil | ADI = 25 µg/kg bw/d |
| | Pirimicarb (sum) | ADI = 35 µg/kg bw/d | Nitrothal-isopropyl | ADI = 50 µg/kg bw/d |
| | Pirimiphos-methyl | ADI = 4 µg/kg bw/d | Nuarimol | ADI = 21 µg/kg bw/d |
| | Propamocarb | ADI = 290 µg/kg bw/d | Ofurace | ADI = 30 µg/kg bw/d |
| | Pyrimethanil | ADI = 170 µg/kg bw/d | Oxadixyl | ADI = 10 µg/kg bw/d |
| | Tolclofos methyl | ADI = 64 µg/kg bw/d | Pencycuron | ADI = 200 µg/kg bw/d |
| | Tolyfluanid | ADI = 100 µg/kg bw/d | Penconazole | ADI = 30 µg/kg bw/d |
| | Triticonazole | ADI = 25 µg/kg bw/d | Prochloraz | ADI = 10 µg/kg bw/d |
| | Azamethiphos | ADI = 3 µg/kg bw/d | Propachlor | ADI = 16 µg/kg bw/d |
| | Bendiocarb | ADI = 4 µg/kg bw/d | Pyridaben | ADI = 10 µg/kg bw/d |
| | Benfuracarb | ADI = 10 µg/kg bw/d | Tau-fluvalinate | ADI = 5 µg/kg bw/d |
| | Bromophos | ADI = 40 µg/kg bw/d | Tebufenozide | ADI = 20 µg/kg bw/d |
| | Bromophos-ethyl | ADI = 3 µg/kg bw/d | Tefluthrin | ADI = 5 µg/kg bw/d |
| | Cadusafos | ADI = 0.4 µg/kg bw/d | Tetradifon | ADI = 15 µg/kg bw/d |
| | Carbaryl | ADI = 7.5 µg/kg bw/d | Tetramethrin | ADI = 20 µg/kg bw/d |
| | Carbofuran (sum) | ADI = 0.15 µg/kg bw/d | Tralomethrin | ADI = 1 µg/kg bw/d |
| | Carbosulfan | ADI = 5 µg/kg bw/d | Triforine | ADI = 20 µg/kg bw/d |
| | Chlorfenvinphos | ADI = 0.5 µg/kg bw/d | OPP | ADI = 400 µg/kg bw/d |
| | Chlorobenzilate | ADI = 20 µg/kg bw/d | Ethoxyquin | ADI = 5 µg/kg bw/d |
| | Diazinon | ADI = 0.2 µg/kg bw/d | Pyrethrins | ADI = 40 µg/kg bw/d |
| | Dichlorvos | ADI = 4 µg/kg bw/d | Sulphur | ADI = 1500 µg/kg bw/d |
| | Ethiofencarb | ADI = 100 µg/kg bw/d | Biphenyl | ADI = 500 µg/kg bw/d |
| | Ethion | ADI = 2 µg/kg bw/d | Phoxim | ADI = 4 µg/kg bw/d |

| Classes | Substances | Target values | Substances | Target values |
|--------------------|--------------------------------|-----------------------|-----------------------------|----------------------|
| Pesticide residues | Fenitrothion | ADI = 5 µg/kg bw/d | Rotenone | ADI = 1 µg/kg bw/d |
| | Haloxypop | ADI = 0.65 µg/kg bw/d | Piperonylbutoxide | ADI = 200 µg/kg bw/d |
| | Heptenophos | ADI = 2 µg/kg bw/d | Fenchlorphos | ADI = 10 µg/kg bw/d |
| | Malathion (sum) | ADI = 30 µg/kg bw/d | Acetamiprid | ADI = 25 µg/kg bw/d |
| | Mecarbam | ADI = 2 µg/kg bw/d | Acibenzolar-S-methyl | ADI = 100 µg/kg bw/d |
| | Methidathion | ADI = 1 µg/kg bw/d | Azoxystrobin | ADI = 200 µg/kg bw/d |
| | Methomyl (sum) | ADI = 2.5 µg/kg bw/d | Boscalid | ADI = 40 µg/kg bw/d |
| | Methoxychlor | ADI = 5 µg/kg bw/d | Fenamidone | ADI = 30 µg/kg bw/d |
| | Metolachlor (sum) | ADI = 100 µg/kg bw/d | Fenhexamid | ADI = 200 µg/kg bw/d |
| | Monocrotophos | ADI = 0.6 µg/kg bw/d | Indoxacarb | ADI = 6 µg/kg bw/d |
| | Oxydemeton-methyl (sum) | ADI = 0.3 µg/kg bw/d | Iprovalicarb | ADI = 15 µg/kg bw/d |
| | Pentachlorophenol | ADI = 1500 µg/kg bw/d | Kresoxim-methyl | ADI = 400 µg/kg bw/d |
| | Phorate (sum) | ADI = 0.7 µg/kg bw/d | Mepanipyrim | ADI = 20 µg/kg bw/d |
| | Phosalone | ADI = 10 µg/kg bw/d | Metalaxyl-M | ADI = 80 µg/kg bw/d |
| | Profenofos | ADI = 30 µg/kg bw/d | Metrafenone | ADI = 250 µg/kg bw/d |
| | Promecarb | ADI = 50 µg/kg bw/d | Picoxystrobin | ADI = 43 µg/kg bw/d |
| | Prometryn | ADI = 40 µg/kg bw/d | Pymetrozine | ADI = 30 µg/kg bw/d |
| | Propoxur | ADI = 20 µg/kg bw/d | Pyraclostrobin | ADI = 30 µg/kg bw/d |
| | Quinalphos | ADI = 0.5 µg/kg bw/d | Quinoxifen | ADI = 200 µg/kg bw/d |
| | Temephos | ADI = 100 µg/kg bw/d | Spiroxamine | ADI = 25 µg/kg bw/d |
| | Terbufos | ADI = 0.6 µg/kg bw/d | Trifloxystrobin | ADI = 100 µg/kg bw/d |
| | Tetrachlorvinphos | ADI = 50 µg/kg bw/d | Coumaphos | ADI = 0.5 µg/kg bw/d |
| | Thiometon | ADI = 3 µg/kg bw/d | Dithiocarbamates | ADI = 6 µg/kg bw/d |
| | Triazophos | ADI = 1 µg/kg bw/d | Abamectin | ADI = 2.5 µg/kg bw/d |
| | Trichlorfon | ADI = 2 µg/kg bw/d | Clofentezine | ADI = 20 µg/kg bw/d |
| | Trifluralin | ADI = 15 µg/kg bw/d | Dicamba | ADI = 300 µg/kg bw/d |
| | Vamidothion | ADI = 8 µg/kg bw/d | Difenoconazole | ADI = 10 µg/kg bw/d |

ADI: acceptable daily intake

ANNEX 5: DEFINITION OF THE SIZE OF SERVINGS

In the framework of the revision of the food-based dietary guidelines, new quantities of food are proposed as consumption guidelines for different food sub-groups. To be expressed simply and clearly, these quantities must be translated into a given number of servings. The objective of this section is to determine the size of a usual serving of the different food sub-groups.

The consumption data used come from the INCA2 study described in Section 3.2.2.2.

Method

The serving sizes were estimated for each of the 32 food sub-groups resulting from the food categorisation work described in Section 3.3.2. These sub-groups are also grouped into 10 food groups.

A food serving has been defined as the total amount consumed (in g) during an act of consumption, i.e. one line from the INCA2 consumption diary. Thus, for example, 3 biscuits consumed in the course of 3 different meals correspond to 3 servings of biscuits (3 different lines in the diary) while 3 biscuits consumed during a single act of consumption (1 line in the diary) correspond to a single serving.

As with the other sections, two populations were considered: women aged 18 to 54 years and men aged 18 to 64 years. The estimates were therefore carried out for each of these populations but also by considering the entire adult sample (women aged 18-54 years and men aged 18-64 years).

Results

After verifying that the average serving sizes were statistically different between the male and female populations, an analysis of the distributions of the serving sizes was conducted separately for men and women. Given the distribution curves observed, a case-by-case approach was followed to determine a serving size that reflected the sizes actually consumed. Depending on the shape of the distributions, the mode or the median were considered more relevant and representative of practices than the average. For sugar-sweetened beverages such as soda, the size of the commercial container was chosen (33 cl).

In some cases, the distribution was bimodal, related to the fact that the sub-group could be consumed as a starter or main course, in different proportions. It thus proved necessary to distinguish the serving sizes according to the consumption occasions (starter or main course). This was the case with vegetables, starch-based, savoury/fatty processed products (such as potato chips or French fries) and fish (such as smoked salmon or salmon steaks).

In other cases, the bimodal or multimodal distribution could be explained by the fact that some individuals consume one serving while others consume two or more. In this case, the modes are multiples and the serving selected is the smallest. This explains why the serving sizes selected are often identical for men and women (82%) whereas the average quantities are mostly higher in men. For some sub-groups, the servings are larger in men. This is particularly the case with bread, cheese and starch-based, savoury/fatty processed products consumed as a main meal (**Table 11**).

Table 11: Serving size of the sub-groups for men and women and according to the consumption occasions if applicable

| Sub-groups | Consumption occasion | Serving size for men (g) | Serving size for women (g) |
|--|----------------------|--------------------------|----------------------------|
| Vegetables | As a starter | 50 | 50 |
| | As a main dish | 100 | 100 |
| Fresh fruits | - | 150 | 150 |
| Dried fruits | - | 20 | 20 |
| Processed fruits: purees and cooked fruit | - | 100 | 100 |
| Oilseeds | - | 15 | 15 |
| Refined bread and bread products | - | 60 | 50 |
| Wholegrain bread and bread products | - | 60 | 50 |
| Other refined starches | - | 100 | 100 |
| Other wholegrain starches | - | 100 | 100 |
| Starch-based, sweet/fatty processed products | - | 50 | 50 |
| Starch-based, savoury/fatty processed products | As a main dish | 100 | 50 |
| | As a snack | 20 | 20 |
| Pulses | - | 100 | 100 |
| Poultry | - | 130 | 130 |
| Red meat | - | 130 | 130 |
| Delicatessen meats | - | 50 | 50 |
| Oily fish | As a starter | 40 | 20 |
| | As a main dish | 110 | 110 |
| Other fish | As a starter | 40 | 40 |
| | As a main dish | 100 | 100 |
| Eggs | - | 50 | 50 |
| Milk | - | 250 | 250 |
| Plain fresh dairy products | - | 125 | 125 |
| Sweetened fresh dairy products | - | 125 | 125 |
| Sweetened dairy desserts | - | 125 | 100 |
| Cheeses | - | 45 | 30 |
| Butter and reduced-fat butter | - | 10 | 10 |
| Vegetable oils rich in ALA | - | 10 | 10 |
| Vegetable oils poor in ALA and margarines | - | 10 | 10 |
| Sauces, fresh creams and condiments | - | 15 | 15 |
| Sweetened products | - | 15 | 15 |
| Sugar-sweetened beverages such as soda | - | 330 | 330 |
| Fruit juice | - | 150 | 150 |

ANNEX 6: DISTRIBUTION OF INTAKES (G/D) IN EACH FOOD SUB-GROUP AND GROUP FOR ADULT WOMEN AND MEN

| Food sub-group | Women | | | | | | | | Men | | | | | | | |
|--|-------|-------|-------|---------------|------|-------|-------|---------------|------|-------|-------|---------------|-------|-------|-------|---------------|
| | P5 | P50 | P95 | Mean ± SD | P5 | P50 | P95 | Mean ± SD | P5 | P50 | P95 | Mean ± SD | P5 | P50 | P95 | Mean ± SD |
| Vegetables | 21.4 | 111.9 | 281.5 | 124.5 ± 76.0 | 39.3 | 219.9 | 564.8 | 249.2 ± 161.0 | 15.7 | 107.3 | 284.5 | 123.1 ± 92.6 | 23.9 | 198.3 | 572.6 | 248.4 ± 204.8 |
| Fresh fruits | 0 | 85.5 | 332.3 | 111.1 ± 107.3 | | | | | 0 | 71.4 | 376.2 | 114.5 ± 146.2 | | | | |
| Dried fruits | 0 | 0 | 3.7 | 0.6 ± 2.6 | | | | | 0 | 0 | 2.9 | 0.8 ± 4.9 | | | | |
| Processed fruits: purees and cooked fruit | 0 | 0 | 57.1 | 12.3 ± 22.6 | | | | | 0 | 0 | 52.9 | 8.5 ± 22.5 | | | | |
| Oilseeds | 0 | 0 | 4.6 | 0.8 ± 2.6 | | | | | 0 | 0 | 8.6 | 1.5 ± 4.5 | | | | |
| Refined bread and bread products | 0 | 47.9 | 161.4 | 59.8 ± 47.9 | 68.7 | 185.4 | 380.7 | 193.2 ± 84.0 | 0 | 90.0 | 260 | 101.6 ± 89.7 | 112.9 | 255.0 | 500.0 | 274.0 ± 132.4 |
| Wholegrain bread and bread products | 0 | 0 | 64.3 | 12.4 ± 25.2 | | | | | 0 | 0 | 94.3 | 15.8 ± 44.4 | | | | |
| Other refined starches | 14.3 | 71.4 | 192.9 | 83.2 ± 53.5 | | | | | 14.3 | 100.0 | 255.3 | 113.0 ± 82.5 | | | | |
| Other wholegrain starches | 0 | 0 | 16.4 | 2.5 ± 10.2 | | | | | 0 | 0 | 21.4 | 2.5 ± 10.9 | | | | |
| Starch-based, sweet/fatty processed products | 0 | 5.1 | 60.6 | 15.4 ± 21.7 | | | | | 0 | 0 | 71.1 | 13.9 ± 29.6 | | | | |
| Starch-based, savoury/fatty processed products | 0 | 14.3 | 57.1 | 19.8 ± 19.1 | | | | | 0 | 21.4 | 78.6 | 27.2 ± 28.5 | | | | |
| Pulses | 0 | 0 | 50.0 | 11.0 ± 17.1 | 0 | 0 | 50.0 | 11.0 ± 17.1 | 0 | 0 | 64.3 | 14.5 ± 25.8 | 0 | 0 | 64.3 | 14.5 ± 25.8 |
| Poultry | 0 | 18 | 75.0 | 25.0 ± 24.9 | 50.9 | 126.4 | 226.6 | 130.9 ± | 0 | 27.1 | 122.1 | 38.3 ± 45.1 | 72.8 | 172.6 | 312.3 | 181.3 ± 80.6 |

ANSES Opinion
Request No 2012-SA-0103

| | | | | | | | | | | | | | | | | |
|---|-----|------|-------|--------------|------|-------|-------|---------------|---|------|-------|--------------|------|-------|-------|---------------|
| Red meat | 0 | 37.1 | 95.8 | 41.1 ± 27.7 | | | | 51.3 | 0 | 55.7 | 148.3 | 63.5 ± 46.6 | | | | |
| Delicatessen meats | 0 | 21.2 | 66.6 | 26.1 ± 20.3 | | | | | 0 | 32.6 | 99.4 | 39.4 ± 34.7 | | | | |
| Oily fish | 0 | 0 | 25.1 | 4.4 ± 8.4 | | | | | 0 | 0 | 27.1 | 4.7 ± 11.2 | | | | |
| Other fish | 0 | 17.1 | 67.4 | 22.0 ± 20.6 | | | | | 0 | 17.1 | 70 | 22.7 ± 26.8 | | | | |
| Eggs | 0 | 7.5 | 42.9 | 12.3 ± 15.0 | | | | | 0 | 7.5 | 45.7 | 12.7 ± 17.7 | | | | |
| Milk | 0 | 17.1 | 350 | 86.9 ± 116.8 | | | | | 0 | 6.9 | 385.7 | 98.0 ± 177.8 | | | | |
| Plain fresh dairy products | 0 | 14.3 | 157.1 | 35.7 ± 50.6 | | | | | 0 | 0 | 128.6 | 27.9 ± 59.0 | | | | |
| Sweetened fresh dairy products | 0 | 32.1 | 160.7 | 47.2 ± 55.7 | 24.1 | 174.6 | 505.7 | 209.2 ± 138.6 | 0 | 17.9 | 153.6 | 42.0 ± 64.4 | 17.9 | 172.0 | 556.4 | 221.7 ± 209.0 |
| Sweetened dairy desserts | 0 | 6.4 | 57.1 | 15.5 ± 21.6 | | | | | 0 | 0 | 85.7 | 18.3 ± 36.0 | | | | |
| Cheeses | 0 | 19.6 | 64.8 | 23.9 ± 20.7 | | | | | 0 | 29.2 | 94.1 | 35.5 ± 33.6 | | | | |
| Butter and reduced-fat butter | 0 | 1.4 | 17.1 | 4.2 ± 6.0 | | | | | 0 | 1.4 | 25.7 | 5.6 ± 10.6 | | | | |
| Vegetable oils rich in ALA | 0 | 0 | 1.9 | 0.3 ± 1.2 | | | | | 0 | 0 | 1.4 | 0.3 ± 1.9 | | | | |
| Vegetable oils poor in ALA and margarines | 0 | 2.3 | 15.7 | 4.3 ± 5.4 | 1.4 | 19.4 | 55.3 | 22.5 ± 15.7 | 0 | 1.4 | 20.3 | 4.5 ± 7.7 | 0.7 | 19.3 | 62.3 | 23.4 ± 20.8 |
| Sauces, fresh creams and condiments | 0 | 10.3 | 39.3 | 13.8 ± 12.5 | | | | | 0 | 8.4 | 42.7 | 13.0 ± 16.5 | | | | |
| Sweetened products | 0.5 | 50.0 | 141.2 | 58.7 ± 41.6 | 0.5 | 50.0 | 141.2 | 58.7 ± 41.6 | 0 | 57.9 | 174.3 | 68.1 ± 58.0 | 0 | 57.9 | 174.3 | 68.1 ± 58.0 |
| Sugar-sweetened beverages such as soda | 0 | 0 | 292.9 | 57.9 ± 159.2 | | | | | 0 | 0 | 500 | 93.1 ± 189.9 | | | | |
| Fruit juice | 0 | 17.7 | 228.6 | 60.5 ± 80.9 | 0 | 57.1 | 428.6 | 118.4 ± 179.4 | 0 | 0 | 250 | 58.7 ± 100.6 | 0 | 71.4 | 582.9 | 151.8 ± 223.2 |

SD: standard deviation



**Updating of the PNNS guidelines:
revision of the food-based dietary guidelines**

Request No. 2012-SA-0103

Collective Expert Appraisal REPORT

Expert Committee on "Human Nutrition"

Expert Committee on "Assessment of physical and chemical risks in food"

Working Group: "Updating of the PNNS guidelines: revision of the food-based dietary guidelines"

November 2016

Keywords:

Plan national nutrition santé, risque santé, nutrition, consommation alimentaire, nutriment, références nutritionnelles, optimisation, programmation linéaire, maladies chroniques non transmissibles, classification des aliments, contaminant

French National Health & Nutrition Programme, health risks, nutrition, food intake, nutrient, dietary reference values, optimisation, linear programming, chronic non-communicable diseases, food classification, contaminant

Presentation of participants

PREAMBLE: Outside experts, Expert Committee and WG members, or designated rapporteurs are all appointed in their personal capacity, *intuitu personae*, and do not represent their parent organisation.

WORKING GROUP

Chairman

Mr Jean-Louis BRESSON – University Professor – Hospital Practitioner – AP-HP Necker Hospital – Sick Children, Centre for Clinical Investigation, CIC 0901 – Paediatrics, public health

Members

Ms Marie-Joséphine AMIOT-CARLIN – Research Director – INRA "Nutrition, obesity and thrombotic risk" – Plant trace elements, metabolism of cholesterol

Ms Janine BULLIARD – Dietician, REPOPOP– FC – Dietetics, specific diets

Mr Marc BONNEFOY – University Professor – Hospital Practitioner – Claude-Bernard Lyon 1 University, Lyon Sud Medicine UFR, Hospices Civils de Lyon, Inserm 1060 – Elderly people

Ms Marie-Christine BOUTRON-ROUQUET – Research Director – CESP Inserm U1018 team 9 "Nutrition, hormones and women's health" – Epidemiology of cancers and nutrition

Ms Katia CASTETBON – Unit Manager, French Institute of Public Health Surveillance (InVS) – Epidemiology, dietary recommendations

Ms Martine CHAMP – Research Director, INRA – Carbohydrates

Mr Jean-Michel CHARDIGNY – UMR Director, INRA – Fats

Ms Véronique COXAM – Research Director, INRA – Nutritional prevention, osteoporosis

Ms Hélène ESCALON – Research Manager, INPES – Prevention for health

Mr Anthony FARDET¹ – Research Manager – INRA Clermont-Ferrand/Theix, Human Nutrition Unit, UMR 1019 INRA/University of Auvergne – Research and bibliographical analysis, preventive nutrition

Ms Monique FERRY-GRAND – Doctor-Nutritionist, INSERM U557-University – Elderly people

Ms Anne GALINIER – Manager of the Biology Micronutrition UF, Ranguel University Hospital – Water-soluble vitamins

Ms Mariette GERBER – INSERM Retiree – Epidemiology

Mr Jean-Philippe GIRARDET – Professor, AP-HP – Paediatrics, infant nutrition

Mr Jean-François HUNEAU – Professor – AgroParisTech, Biology and Human Nutrition UFR – General nutrition, proteins, modelling, dietary reference values

Mr Lionel LAFAY – Project Leader in Epidemiology, National Cancer Institute – Epidemiology

Mr François MARIOTTI – Professor – AgroParisTech, Biology and Human Nutrition UFR – General nutrition, proteins, modelling

Mr Ambroise MARTIN – former University Professor and Hospital Practitioner – Claude Bernard Lyon I University – Nutrition & public health

¹ Mr Fardet took part in the Working Group until the change in his public declaration of interests (PDI) in February 2015

Ms Caroline MARTINEAU – Dietetics department manager, Toulouse University Hospital – Mass Catering Dietician

Mr Fabrice NESSLANY – Manager of the Toxicology Laboratory – Institut Pasteur de Lille – Toxicology

Ms Monique ROMON – University Professor – Hospital Practitioner – University of Lille 2 – Epidemiology, public health

Ms Anne-Sophie ROUSSEAU – Teacher-Researcher, University of Nice Sophia Antipolis – Micronutrient bioavailability, physical activity

Mr Alain-Claude ROUDOT – University Professor, University of Western Brittany – Contaminants, toxicology, statistics

Mr Dominique TURCK – University Professor – Hospital Practitioner, Lille University Hospital – Paediatrics, public health

Mr Stéphane WALRAND – Research Director – INRA Clermont-Ferrand/Theix, Human Nutrition Unit, UMR 1019 INRA/University of Auvergne – General nutrition, proteins, sarcopenia

Ms Carolina WERLE – Associate Professor in the Marketing Department at the Grenoble School of Management – Preventive health campaigns

These experts were directed towards various working groups with the following themes:

• **Thematic group 1: Identification of dietary reference values**

Ms CHAMP, Mr CHARDIGNY, Ms GERBER, Mr GIRARDET, Mr HUNEAU and Mr MARTIN

• **Thematic group 2: Bioavailability of micronutrients**

Mr FARDET², Mr HUNEAU, Ms ROUSSEAU

• **Thematic group 3: Nutrients of interest for the different groups of the population**

Ms CHAMP, Ms FERRY, Ms GALINIER, Ms GERBER, Mr GIRARDET

• **Thematic group 4: Relationships between the food groups and the risk of chronic diseases**

Ms AMIOT-CARLIN, Ms CASTETBON, Mr FARDET, Ms FERRY, Ms GERBER, Mr LAFAY, Ms ROMON

• **Thematic group 5: Categorisation of foods and definition of serving sizes**

Ms BULLIARD, Ms CASTETBON, Ms COXAM, Ms ESCALON, Ms MARTINEAU, Ms WERLE

• **Tool monitoring group: Monitoring of the computer tool for optimising food consumption and analysis of results**

Mr HUNEAU, Mr MARIOTTI, Mr MARTIN, Mr NESSLANY, Mr ROUDOT, Mr WALRAND

These thematic groups were coordinated by a **steering group** that ensured the consistency of the work on the sub-themes. Its members were:

² Mr Fardet took part in the Working Group until the change in his public declaration of interests (PDI) in February 2015

Mr BRESSON (Chair), Mr BONNEFOY, Ms BOUTRON-RUAULT, Mr MARTIN and Mr TURCK

EXPERT COMMITTEE

The work that is the subject of this report was monitored and adopted by the following CESs:

- Human Nutrition – mandate 2012-2015

Chair

Mr François MARIOTTI – Professor (AgroParisTech) – Specialities: metabolism of proteins, amino acids, intakes, nutritional requirements and recommendations, postprandial metabolism, metabolic syndrome

Members

Ms Latifa ABDENNEBI-NAJAR – Research Director (LaSalle Beauvais Polytechnic Institute) – Specialities: human nutrition, obesity

Mr Jacques BELEGAUD – Honorary University Professor – Picardie-Amiens University – Specialities: toxicology

Ms Catherine BENNETAU-PELISSERO – Professor (Bordeaux Sciences Agro) – Specialities: phyto-oestrogens, isoflavones, endocrine disruptors, bone health

Ms Marie BODINIER – Research Manager (INRA Nantes) – Specialities: food allergies, intestinal and immune system physiology

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CONTENTS

| | |
|--|-----------|
| Presentation of participants | 3 |
| Acronyms and abbreviations | 16 |
| List of tables | 18 |
| List of figures | 19 |
| 1 Background, purpose and procedure for handling the request..... | 20 |
| 1.1 Background..... | 20 |
| 1.2 Requests made by the Directorate General for Health..... | 20 |
| 1.3 Procedures for addressing and organising the expert appraisal..... | 21 |
| 1.3.1 Objectives of the Working Group..... | 21 |
| 1.3.2 Approach and organisation of the expert appraisal..... | 21 |
| Approach adopted..... | 21 |
| Questions addressed and thematic breakdown | 22 |
| Hearings with qualified individuals and stakeholders | 23 |
| Development of a tool for optimisation of food consumption..... | 24 |
| Coordination of this work for the formulation of guidelines..... | 24 |
| 1.3.3 Presentation of the work | 25 |
| 1.4 Prevention of risks of conflicts of interest..... | 26 |
| 2 Defining dietary reference values | 27 |
| 2.1 Distinguishing between the various types of dietary reference values | 27 |
| 2.2 Identification of dietary reference values for vitamins and minerals..... | 28 |
| 2.2.1 Background..... | 28 |
| 2.2.2 Objectives | 29 |
| 2.2.3 General approach | 29 |
| 2.2.4 Limitations of the work | 30 |
| 2.2.5 Dietary reference values selected | 30 |
| Vitamin A | 30 |
| Vitamin B1 | 32 |
| Vitamin B233 | |
| Vitamin B3 | 34 |
| Vitamin B5 | 35 |
| Vitamin B6 | 36 |
| Vitamin B9 | 37 |
| Vitamin B12 | 39 |
| Vitamin C | 40 |
| Vitamin D | 41 |
| Vitamin E | 43 |
| Calcium | 45 |
| Copper | 46 |
| Iodine | 4848 |
| Iron | 499 |
| Magnesium | 522 |
| Manganese | 53 |
| Phosphorus..... | 54 |

| | |
|--|-----------------------------|
| Potassium | 56 |
| Selenium | 56 |
| Sodium | 57 |
| Zinc | 59 |
| 2.2.6 Identification of dietary reference values for energy macronutrients..... | 64 |
| 2.2.7 Identification of a dietary reference value for water..... | 64 |
| 3 Preventing chronic non-communicable diseases..... | 65 |
| 3.1 Objective and approach | 65 |
| 3.2 Summary of the epidemiological relationships..... | 67 |
| 3.2.1 Relationships between the consumption of food groups and the risk of chronic non-communicable diseases | 67 |
| Red meat and delicatessen meats | 67 |
| Sugar-sweetened beverages..... | 68 |
| Fruits and vegetables | 68 |
| Wholegrain cereal products..... | 69 |
| Milk and dairy products..... | 69 |
| Fish | 70 |
| 3.2.2 Food typologies..... | Erreur ! Signet non défini. |
| 4 Limiting exposure to contaminants | 722 |
| 5 Determining food consumptions addressing the nutritional and toxicological challenges and taking consumption habits into account..... | 733 |
| 5.1 Objective of the approach..... | 733 |
| 5.2 Work on foods or on food groups? | 744 |
| 5.2.1 Foods or food groups?..... | 744 |
| 5.2.2 Process of defining the groups | 75 |
| First approach: principal component analysis and ascending hierarchical classification applied to foods from the INCA2 nomenclature..... | 75 |
| Second approach: joint approach combining ascending hierarchical classification and consumption practices | 76 |
| 5.2.3 List of groups | 80 |
| 5.3 Optimisation method..... | 84 |
| 5.3.1 Principle of the tool used | 84 |
| 5.3.2 Mathematical definition of the constraints and criteria..... | 85 |
| 5.4 Choice of constraints | 88 |
| 5.4.1 What level of energy requirement should be considered for the optimisation?..... | 88 |
| 5.4.2 How should the dietary reference values be used? | 91 |
| What type of reference should be used? | 91 |
| Specific case of sodium..... | 91 |
| Summary of nutritional constraints selected | 91 |
| 5.4.3 How should the epidemiological relationships be expressed? | 94 |
| 5.4.4 How should consumption habits be taken into account? | 94 |
| 5.4.5 How should contaminants be taken into account? | 98 |
| Case of substances whose use is regulated..... | 98 |
| Other contaminants | 98 |
| What type of reference should be taken into account?..... | 98 |
| 5.5 Databases used as input in the optimisation..... | 101 |
| 5.5.1 Consumption data..... | 101 |

| | | |
|---------------------|--|------------|
| 5.5.2 | Table of nutritional composition of foods | 101 |
| 5.5.3 | Table of contaminant levels in foods | 102 |
| 5.5.4 | Exposure data..... | 103 |
| 5.6 | General optimisation approach | 103 |
| 5.7 | Results of the optimisation | 104 |
| 5.7.1 | Results of the optimisation for adult men | 104 |
| | Approach followed for men (Figure 4) | 104 |
| | Scenario A1: only the nutritional and epidemiological constraints were taken into account | 105 |
| | Scenario B1: the nutritional and epidemiological constraints and also the consumption habits were taken into account..... | 108 |
| | Scenario C2: the nutritional and epidemiological constraints, the consumption habits and the constraints related to contaminants were taken into account | 113 |
| 5.7.2 | Results of the optimisation for women..... | 117 |
| | Approach followed in women..... | 117 |
| | Scenario A1: only the nutritional and epidemiological constraints were taken into account | 120 |
| | B scenarios – low iron | 123 |
| | B scenarios – high iron | 127 |
| | Scenario C: the nutritional and epidemiological constraints, the consumption habits and the constraints related to contaminants were taken into account | 132 |
| 5.7.3 | Summary of the results of the optimisation | 132 |
| 6 | Scope of the work and uncertainties | 136 |
| 7 | Discussion and conclusion | 138 |
| 8 | References..... | 145 |
| ANNEXES..... | | 150 |

Acronyms and abbreviations

ADI: acceptable daily intake

AFDN: French Association of Dietitians-Nutritionists

AHC: ascending hierarchical classification

AI: adequate intake

ALA: alpha-linolenic acid

ANC: *apport nutritionnel conseillé* (French term encompassing, depending on the situation, PRI, AI and RI)

ANIA: French National Association of Food Industries

AR: average requirement

ATSDR: Agency for Toxic Substances and Disease Registry

BMDL: benchmark dose limit

BMI: body mass index

BPA: bisphenol A

CES: ANSES Expert Committee

CIQUAL: nutritional composition of foods

CUP: WCRF continuous update project

CVD: cardiovascular disease

D-A-CH: German-speaking countries (Germany, Austria, Switzerland)

DFE: dietary folate equivalent

DHA: docosahexaenoic acid

DL-PCB: dioxin-like polychlorinated biphenyl

DON: deoxynivalenol

EFSA: European Food Safety Authority

EPA: eicosapentaenoic acid

Gamma-HCH: gamma-hexachlorocyclohexane, lindane

HBCDD: hexabromocyclododecane

HBGV: Health-based guidance value

INCa: French National Cancer Institute

INCA: French Individual Survey on Food Consumption

IARC: International Agency for Research on Cancer

IOM: Institute of Medicine³

JECFA: FAO/WHO expert committee on food additives

JMPR: Joint FAO/WHO Meetings on Pesticide Residues

LPA: level of physical activity

MMA: methylmalonic acid

MOE: margin of exposure

MOS: margin of safety

MRL: maximum residue limit

³ On 15 March 2016, the IOM changed its name and is now called the HMD (Health & Medicine Division)

MUFA: monounsaturated fatty acid

NCM: Nordic Council of Ministers

NE: niacin equivalent

NHMRC-MoH: Australian National Health and Medical Research Council – New Zealand Ministry of Health

NOAEL: no observed adverse effect level

PAH4: polycyclic aromatic hydrocarbon

PBB: polybrominated biphenyl

PCA: principal component analysis

PCB: polychlorinated biphenyl

PFOA: perfluorooctanoic acid

PFOS: perfluorooctanesulfonic acid

PNNS: French National Health and Nutrition Programme

POP: persistent organic pollutant

PRI: population reference intake

PUFA: polyunsaturated fatty acid

PTMI: provisional tolerable monthly intake

PTWI: provisional tolerable weekly intake

OR: oestrogen receptor

RBCGR: red blood cell glutathione reductase

RI: reference intake range

SACN: Scientific Advisory Committee on Nutrition

SFA: saturated fatty acid

SFN: French Nutrition Society

SOD: superoxide dismutase

TEI: total energy intake

TDI: tolerable daily intake

TDS: total diet study

UL: tolerable upper intake level

US EPA: US Environmental Protection Agency

VPO: group of meat, fish and eggs (*Viandes, Poissons, Œufs*)

WCRF: World Cancer Research Fund

WHO: World Health Organisation

List of tables

| | |
|---|-----|
| Table 1. Review of dietary reference values for vitamin A ($\mu\text{g RE/d}$) | 31 |
| Table 2: Review of dietary reference values for vitamin B1 (mg/d unless otherwise indicated) | 32 |
| Table 3: Review of dietary reference values for vitamin B2 (mg/d unless otherwise indicated) | 33 |
| Table 4: Review of dietary reference values for vitamin B3 (mg NE/MJ)..... | 35 |
| Table 5: Review of dietary reference values for vitamin B5 (mg/d)..... | 36 |
| Table 6: Review of dietary reference values for vitamin B6 (mg/d)..... | 37 |
| Table 7: Review of dietary reference values for vitamin B9 ($\mu\text{g DFE/d}$) | 38 |
| Table 8: Review of dietary reference values for vitamin B12 ($\mu\text{g/d}$) | 39 |
| Table 9: Review of dietary reference values for vitamin C (mg/d) | 41 |
| Table 10: Review of dietary reference values for vitamin D ($\mu\text{g/d}$) | 43 |
| Table 11: Review of dietary reference values for vitamin E (mg/d)..... | 44 |
| Table 12: Review of dietary reference values for calcium (mg/d) | 46 |
| Table 13: Review of dietary reference values for copper (mg/d) | 47 |
| Table 14: Review of dietary reference values for iron (mg/d) | 50 |
| Table 15: Review of dietary reference values for iodine ($\mu\text{g/d}$)..... | 49 |
| Table 16: Review of dietary reference values for magnesium (mg/d)..... | 53 |
| Table 17: Review of dietary reference values for manganese (mg/d)..... | 54 |
| Table 18: Review of dietary reference values for phosphorus (mg/d)..... | 55 |
| Table 19: Review of dietary reference values for potassium (mg/d) | 56 |
| Table 20: Review of dietary reference values for selenium ($\mu\text{g/d}$ unless otherwise indicated) | 57 |
| Table 21: Review of dietary reference values for sodium (mg/d)..... | 58 |
| Table 22: Review of dietary reference values for zinc (mg/d) | 60 |
| Table 23. Summary of dietary reference values for adult men | 61 |
| Table 24. Summary of dietary reference values for adult women | 63 |
| Table 25: Summary of the groups and sub-groups created for categorising the foods | 82 |
| Table 26. Estimate of the basal metabolism (kcal/d) according to the median height of the population reported by INCA2 and the five predictive equations selected by EFSA | 89 |
| Table 27: Estimate of the energy requirement (kcal/d) according to the median height of the population reported by INCA2 and the five predictive equations selected by EFSA from a median LPA of 1.63.. | 90 |
| Table 28: Nutritional constraints introduced in the optimisation tool | 93 |
| Table 29. Summary of consumption bounds for each food sub-group entered in the optimisation tool | 96 |
| Table 30: Summary of toxicological constraints used for the optimisation tool..... | 99 |
| Table 31: Consumption levels proposed by Scenario A1 for adult men | 106 |
| Table 32: Consumption levels proposed by Scenario B1 for adult men | 109 |
| Table 33. Consumption levels proposed by Scenario C2 for adult men | 114 |
| Table 34: Consumption levels proposed by Scenario A1 for women with high iron requirements | 121 |
| Table 35: Consumption levels proposed by Scenarios B2 and B6 for women with low iron requirements..... | 124 |
| Table 36: Consumption levels proposed by Scenarios B3, B4 and B5 for women with high iron requirements..... | 128 |
| Table 37: Sources of uncertainty identified in the work to determine optimal consumption | 137 |
| Table 38: Serving size of the sub-groups for men and women and according to the consumption occasions if applicable..... | 171 |

List of figures

| | |
|---|-----|
| Figure 1. Coordination of the work considered..... | 25 |
| Figure 2. Illustration of the simplex algorithm..... | 84 |
| Figure 3. Energy requirement (kcal/d) of men and women estimated according to age and the predictive equation of the basal metabolism | 90 |
| Figure 4. Approach followed for men | 104 |
| Figure 5. Approach followed for women with low iron requirements..... | 118 |
| Figure 6. Approach followed for women with high iron requirements | 120 |

1 Background, purpose and procedure for handling the request

1.1 Background

On 3 April 2012, the Director General for Health (DGS) made a formal request to ANSES to update the food-based dietary guidelines of the National Health and Nutrition Programme (PNNS) (**Annex 1**).

In the framework of the 2001-2005 PNNS, AFSSA had been asked (Request 2001-SA-0126) to develop the scientific principles for formulating food-based dietary guidelines. Several PNNS food guidelines had been published based on the scientific evidence provided by AFSSA.

The current PNNS guidelines focus on different food groups (fruits and vegetables, starches, etc.) and on physical activity, broken down for specific populations (the elderly, children, adolescents, pregnant and breastfeeding women).

The developments in scientific data over the last ten years have made it necessary to revise these food-based dietary guidelines and, more generally, the scientific foundation on which the public health nutrition objectives are established.

Accordingly, the 2011-2015 PNNS provides for the updating of the guidelines concerning both food and physical activity (Action 11.1). This action is part of Measure 4, aimed at developing nutritional information and education actions. In addition, the updating of the nutrition recommendations (known in French as *apports nutritionnels conseillés*: ANC) and the assessments relating to the benefits and risks associated with the consumption of certain food groups had led ANSES, in 2011, to include the revision of the food-based dietary guidelines in its work programme.

1.2 Requests made by the Directorate General for Health

The request made by the DGS particularly concerns the following points:

- 1) Propose a new formulation for the PNNS guidelines, including those concerning physical activity, on the basis of new ANCs, data on consumption from the INCA studies (French Individual Survey on Food Consumption), food composition (with the data from the CIQUAL table and from OQALI) and the international references available.
- 2) Clarify the position of certain foods within the categories currently used in the food-based dietary guidelines, taking into account their nutritional quality and also how they are perceived by consumers. In particular, clarification was sought regarding the groups to which the following belong: dried fruits and oilseeds, sweetcorn (which can, depending on the criteria considered, be classified among vegetables or cereals) and processed products.
- 3) Quantify the servings, if this concept is useful in the new formulation of the food-based dietary guidelines.

1.3 Procedures for addressing and organising the expert appraisal

ANSES entrusted examination of this request to the Working Group on "Updating of the PNNS guidelines: revision of the food-based dietary guidelines", reporting to the Expert Committees on "Human Nutrition" and "Assessment of physical and chemical risks in food" (ERCA).

The methodological and scientific aspects of this group's work were regularly submitted to the Expert Committees (CESs). The work conducted by the Working Group takes account of the observations and additional information provided by the CES members.

This work was therefore conducted by a group of experts with complementary skills.

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

The request was addressed within ANSES's Risk Assessment Department (DER). The Nutritional Risk Assessment Unit (UERN) was responsible for the scientific coordination of the Working Group. Due to the cross-cutting nature of the expert appraisal, other DER units also contributed:

- Food Risk Assessment Unit
- Methodology and Studies Unit
- Food Observatory Unit
- Phytovacovigilance and Observatory of Pesticide Residues Unit

1.3.1 Objectives of the Working Group

In view of the request made by the DGS, the Working Group's objective was to propose the scientific principles necessary for formulating food-based dietary guidelines for the adult population.

The approach implemented took account of the need to limit the nutritional risk – i.e. cover the nutritional requirements and limit the risk of chronic non-communicable diseases – and the risk with regard to foodborne chemical contaminants⁴, while taking dietary habits into account, in order to make it easier for the population to follow the guidelines.

Food choices are influenced by a multitude of factors (such as state of health, food quality, variety of the food supply, environment, taste, convenience, culture, beliefs, financial accessibility) and the respective weight of each of these varies from one individual to another, in both space and time. Besides the scientific foundation, it is therefore essential that the food-based dietary guidelines ultimately proposed to consumers take into account all the objective data associated with these factors. The current eating habits and preferences of French consumers were therefore integrated whenever possible.

1.3.2 Approach and organisation of the expert appraisal

Approach adopted

The previous food-based dietary guidelines were based on an analysis of the existing dietary patterns in the French population. Nutrient intakes were estimated for each of the observed dietary patterns and compared with dietary reference values, which helped identify those enabling optimal coverage of nutrient requirements, as well as the limiting nutrients for each of the dietary patterns. With this method, the adequacy of nutrient intakes is estimated a

⁴ In the remainder of this document, chemical contaminants will be referred to as contaminants.

posteriori from a limited number of diet types: those observed in the population at the time the consumption surveys are carried out. While the prior existence of the selected dietary pattern can be regarded as an advantage for its generalisation to the entire population, this approach is unable to guarantee adequate nutrient intakes with regard to all the dietary reference values. In addition, changes in dietary behaviour mean that regular updates of the dietary patterns are necessary.

The Working Group therefore turned to an approach considering the *a priori* nutritional requirements for the French population, and thus sought to define a dietary pattern that possibly differed from those observed.

Questions addressed and thematic breakdown

Parallel working sub-groups were set up in order to take three separate constraints into account: applying ethics rules (see 1.4), applying a broad diversity of specific skills essential to the assessment, and optimising the implementation of the expert appraisal. A monitoring group, made up of experts with cross-cutting skills, ensured the synthesis, consistency and scientific validity of the expert appraisal and acted as guarantor of the work to the CES on "Human Nutrition".

For establishing food-based dietary guidelines, EFSA advocates conducting the expert appraisal in several parts that should be adapted to the specificities of the population of the country considered (particularly in terms of prevalence of diseases and nutritional situation) (EFSA 2010a) and aim to:

- characterise the relationship between the consumption of certain foods and the risks of chronic non-communicable diseases;
- identify the nutrients of interest to public health (i.e. nutrients for which there is a risk of inadequate or excessive intakes);
- identify the foods and food groups that are vectors of the nutrients of interest and contribute to meeting requirements;
- characterise the dietary habits of the population.

To do this, thematic working groups were formed, adopting complementary approaches according to several points of entry: nutrients, foods and eating behaviour.

i. Thematic work on nutrients

- ***Thematic group 1: Identification of dietary reference values***

The objectives of this thematic group were therefore to:

- identify the types of dietary reference values available: average requirement, population reference intakes (formerly referred to in French as *apports nutritionnels conseillés*), adequate intakes, etc.;
- define the dietary reference values to be used in establishing food-based dietary guidelines for the French population. These values relate to vitamins, minerals and water. The energy macronutrients (fats and fatty acids, proteins and amino acids, carbohydrates and saccharides, fibre) were dealt with by a separate working group, entitled "Balance between macronutrients".

- ***Thematic group 2: Bioavailability of vitamins and minerals***

The objectives of this thematic group were therefore to:

- study the bioavailability of nutrients according to the food matrix in which they are found, their chemical form and the overall diet of the individuals;

- where appropriate, weight the nutrient content of foods in the event of increased or limited bioavailability.
- **Thematic group 3: Nutrients of interest for the different groups of the population**

The objectives of this thematic group were therefore to:

- characterise the nutritional situation of the population, i.e. identify the nutrients for which there are inadequate or excessive intakes in relation to the dietary reference values;
- characterise the nutritional status of the population using direct biomarker measurements when the data are available.

ii. Thematic work on the foods

- **Thematic group 4: Relationships between the food groups and the risk of chronic diseases**

The objective of this thematic group was to confirm or refute the links between dietary intakes (at the scale of the food groups) and the risk of chronic non-communicable diseases, on the basis of the new data available.

- **Thematic group 5: Categorisation of foods, definition of serving sizes**

The objectives of this thematic group were to:

- propose a food categorisation method to be used for expressing the food-based dietary guidelines.
- define serving sizes representing those of French consumers as closely as possible.

iii. Overall consistency of the expert appraisal

- *Monitoring Group:*

The objective of the monitoring group was to ensure the coordination and consistency of the expert appraisals carried out by the different thematic groups. It regularly monitored and commented on the work carried out, leading to the necessary adjustments being made within the themes.

This consistency was also confirmed by the CES on "Human Nutrition", during regular presentations of the working methods and progress of the work.

Hearings with qualified individuals and stakeholders

In addition to the scientific contributions identified at the beginning of the expert appraisal, the Working Group occasionally called on specific skills when necessary to stimulate the discussion and take advantage of experiences in other countries. These contributions were obtained through hearings.

More specifically, the questioning focused on data collection in the population groups (such as the vegetarian population⁵), the research conducted by manufacturers on their products, the studies relating to the consumers' perception of the guidelines, the methodology adopted to assess the quality of the study and the strength of the evidence in different European countries, and work to optimise food rations using linear programming.

⁵ Food-based dietary guidelines for this population will be proposed at a later stage

The following parties were interviewed regarding these objectives: eminent scientists (who participated in the EURRECA project or in optimisation work at INRA), the National Food Institute at the Technical University of Denmark (which recently worked on the issue of food-based dietary guidelines), the French Association of Dieticians-Nutritionists (AFDN), learned societies (the French Nutrition Society – SFN), as well as manufacturers (in partnership with the ANIA) and consumer associations (Société Végane, UFC-Que Choisir, etc.).

The aim of these hearings was to consult the stakeholders as broadly as possible in order to gain information from the field and formulate specific questions likely to be examined by the expert group.

These hearings helped advance the reflections of the Working Group on the implementation of the optimisation tool (see section below), eating behaviours, dietary patterns, the nutritional composition of certain foods and the ways of expressing the quantities of food consumed.

Development of a tool for optimisation of food consumption

A computer tool for optimising food consumption was developed. It proposes combinations of foods that meet the objectives set, i.e. coverage of nutritional requirements as a whole, prevention of chronic non-communicable diseases, and minimisation of exposure to food contaminants, while remaining within a range of intakes that are relatively close to current consumption.

Development of this tool was entrusted to an external service provider⁶ specialised in the mathematical modelling of such optimisation problems, on the basis of an initial preliminary model developed in-house.

A thematic group "Monitoring of the optimisation tool" was set up to supervise and monitor this work. It was called on to discuss the approaches, validate the set of constraints and optimisation criteria used in the tool, monitor the steps of the optimisation work and interpret the solutions.

Coordination of this work for the formulation of guidelines

Other elements need to be taken into account for formulating food-based dietary guidelines. In particular, to ensure adequate understanding of the guidelines, it is important to identify the clearest possible way of expressing the recommended quantities of food (such as for example the share of the plate, a handful, the weight) as well as the most appropriate temporal references (i.e. define whether it is more meaningful to express the guidelines per meal, per day or per week). In addition, the dietary rhythms, the structuring of meals and the consumption contexts may also influence health. The analysis of these elements could provide an interesting complement to the scientific principles presented in this opinion.

Figure 1 below shows how the Agency coordinated all the work carried out or planned (for the study of the formats of expression and eating behaviours) for formulating the food-based dietary guidelines.

⁶ Eurodécision (Versailles)

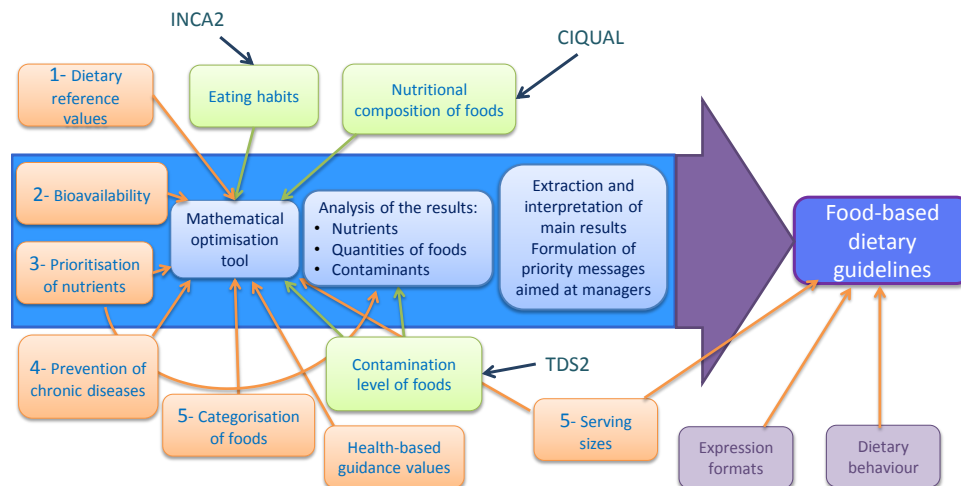


Figure 1. Coordination of the work considered

The green boxes represent the data from studies (INCA2, TDS2) and databases (CIQUAL); the orange boxes represent the areas to be examined by the Working Group, the blue boxes represent the stages of the mathematical optimisation process and its interpretation, the purple boxes represent the descriptive and contextual elements of food intake to be taken into account for formulating the food-based dietary guidelines.

1.3.3 Presentation of the work

The objective of this report was to present the approach and the optimisation results that will be used to formulate the food-based dietary guidelines to be proposed for the population of adult men and women. More specifically, these results concern firstly, adult men aged 18 to 64 years and secondly, non-menopausal adult women (18 to 54 years), to take account of their different physiological needs. This optimisation work could in due course be broken down for different population groups (children and adolescents, the elderly, etc.). Other populations could also be studied, defined not on the basis of physiological criteria (age, sex, etc.) but from eating behaviour (for example, preferences or avoidance of certain foods, etc.).

This report thus brings together, for adult men and women, the necessary scientific elements for formulating guidelines for the population. Only summaries of the working methods and discussions are presented here.

Given the scale of the work carried out, this report presents the conclusions of the thematic groups that participated directly in the development of the approach and the production of the preliminary results. This concerns the work of Thematic Groups 1 and 4, the work of Thematic Group 5 on the categorisation of foods and the definition of serving sizes, and the work of the thematic group on "Monitoring of the optimisation tool" (see corresponding sections).

With regard to the work of Thematic Group 2 (*Bioavailability of micronutrients*), based on the data analysis carried out, it was not possible to introduce nutrient bioavailability coefficients according to their chemical form, the matrix containing them or the diet, for use in the optimisation. The data were often considered too fragmentary to modify the bioavailability coefficients (for example, the bioavailability of calcium has been documented in only a few studies focusing on a small number of foods, not always consumed in France, and no general rule could be identified from the few data collected). In other cases, the differences in bioavailability identified could not be translated into the optimisation work due to a lack of composition data (for example, although phytates decrease the bioavailability of zinc, it was not possible to introduce a bioavailability coefficient for zinc because of the absence of data on phytate content). Therefore, the definition of the nutritional requirement was estimated by

considering its overall bioavailability in the diets commonly consumed by Western populations.

The work of Thematic Group 3 focused on estimating the risks of inadequate or excessive nutrient intakes for the French population, with the aim of considering the advisability of prioritising the coverage of certain nutrients. These estimates are available in ANSES's opinions on vitamins and minerals (ANSES 2015b), and on fatty acids (ANSES 2015a), based on data from the INCA2 study (AFSSA 2009). After an analysis of the validity of the biomarkers of nutritional status and their measurement methods, the prevalence of inadequate nutritional status was assessed using several studies, including the National Nutrition and Health Study (ENNS) (InVS 2006). Taking both types of data into account (data on nutrient intakes and biomarkers of nutritional status) made it possible to identify more precisely the nutrients for which there are manifest risks of deficiency or excess. This work therefore helped provide a picture of the nutritional situation of different populations, and can serve as a basis for formulating specific public health measures. Nevertheless, it was not used directly in the optimisation work because the decision was made to consider all the nutrients as equal. Indeed, it was suggested that the proposed food-based dietary guidelines should be able to cover the requirements for all nutrients, regardless of the current nutritional status of the population for each one.

The work conducted gave rise to this summary report and the corresponding opinion (ANSES 2017b). This report is supplemented by specific and thematic documents:

- Opinion on the revision of the dietary reference values for vitamins and minerals for the general adult population (Theme 1) (ANSES 2017a);
- Report on the study of the relationships between the consumption of food groups and the risk of chronic non-communicable diseases (Theme 4) (ANSES 2017d);
- Report on the contribution of macronutrients to energy intake (ANSES 2017e);
- Opinion (ANSES 2017c) and report on the establishment of recommendations on sugar intake;
- Report on the recommendations on fibre intakes (ANSES 2017f).

1.4 Prevention of risks of conflicts of interest

ANSES analyses the links of interest declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.

The experts' declarations of interests are made public *via* the ANSES website (www.anses.fr).

The adoption of this report was not confronted with any dissenting views, with the exception of the dietary reference values for vitamin C in women and for magnesium (see **Annex 2**).

2 Defining dietary reference values

2.1 Distinguishing between the various types of dietary reference values

The definitions of the terms used in nutrition have varied according to the authors and over time. Concerning the "nutritional requirement", the definition is, in principle, very broad: **The nutritional requirement is the minimum quantity of a nutrient to be consumed by an individual for his or her good health.** This definition is in the spirit of that of the FAO (WHO/FAO 2004) or AFSSA (AFSSA 2001), but its simple formulation and the reference to the broad term "health" enable all of the roles to be incorporated with a view to optimal nutrition: this covers the classical roles attributed to nutrients, relating to their essential nature and metabolic use, but also their physiological consequences, or their possible implication in long-term pathophysiological phenomena. This definition is consistent with other broad definitions that may have been proposed, including by the WHO (WHO/FAO 2003), which defined the nutritional requirement (for a micronutrient) as "the level of intake that satisfies a criterion of adequacy, thus reducing the risk of inadequate or excessive intake".

Practical assessment also depends on the method used, with two rather inconsistent approaches: the experimental approach, which involves assigning intake levels to individuals in order to study the impact on the criteria of adequacy, and the observational (or "epidemiological") approach, which consists in observing in a real situation the relationships between intake and satisfaction of the criterion.

Thus, the terms relating to dietary reference values, i.e. the average requirement (AR), the population reference intake (PRI) and the adequate intake (AI) have essentially been defined by the approaches implemented. The reference intake range (RI) and the tolerable upper intake level (UL) have also been used. For these terms, the following definitions and approaches are proposed:

Average Requirement (AR): this is the average need within the population, as estimated from individual intake data in relation to a criterion of nutritional adequacy in experimental studies.

These data are often obtained on a small number of individuals. Experimental studies are conducted at several intake levels. The criteria used are often criteria of nutrient balance, metabolic renewal, change in the state of reserves, or markers of functions associated with the nutrient in depletion-repletion studies. In certain physiological situations (growth, pregnancy), the requirement can be calculated by the factor method on the basis of the criteria previously described and taking into account additional components related to these situations.

Population Reference Intake (PRI): this is the intake that covers the requirement of almost the entire population considered, as estimated from experimental data.

The PRI is calculated from an estimate of the parameters of distribution of the requirement. Most often the PRI is estimated from the AR, to which are added two standard deviations, in order to determine the intake that covers the requirement of 97.5% of the population. For example, for a standard deviation of 15%, the PRI is 1.3 times the AR.

There is a consensus on this definition around the world. It corresponds to that of the previously used French term "*apport nutritionnel conseillé*" (ANC), which was also used by extension for different types of dietary reference values. In the interests of clarity, the term

ANC has been abandoned in favour of PRI and two new types of dietary reference values: the adequate intake and the reference intake range.

Adequate Intake (AI) is defined as the average intake of a population or sub-group whose nutritional status is considered adequate.

The French AI is the dietary reference value selected:

- when the AR and therefore the PRI cannot be estimated due to the lack of sufficient data, and corresponds to the EFSA definition of "Adequate Intake (AI)";
- or when the value of the PRI can be estimated but is not considered satisfactory in view of long-term observations of the population establishing that this PRI cannot meet health criteria that would be more appropriate than the criteria used to estimate the AR. Thus, unlike the EFSA AI, the French AI is not solely intended as a substitute for the PRI in the case where the latter cannot be calculated. This definition also takes into account the fact that there are more and more data concerning the relationships between intake and modulation of the risk of disease in the long term.

The data used to estimate the nutritional status are often obtained by observational studies but sometimes come from experimental studies. The criteria may relate to clinical (e.g. the rate of growth), metabolic (e.g. normal or desirable concentration of nutrients or indicator metabolites), or physiological criteria (e.g. visual evoked potentials) and can take the long-term risk of disease into account directly or indirectly.

Reference intake range (RI) is defined as a range of intakes considered adequate for maintaining the population in good health.

It is a dietary reference value specific to energy macronutrients, expressed as a percentage of total energy intake.

Tolerable Upper Intake Level (UL) is defined as the chronic maximum daily intake of a vitamin or a mineral considered unlikely to present a risk of adverse health effects for the entire population.

This limit is estimated by a risk assessment, i.e. an identification and then characterisation of the risk (WHO/FAO 1995, IOM 1998b, 2000b, EFSA 2000).

2.2 Identification of dietary reference values for vitamins and minerals

2.2.1 Background

In the past, the concepts of dietary reference values and food consumption benchmark values have been confused in nutrition. At present, most of the agencies and organisations responsible for defining dietary reference values separate these two concepts and thus distinguish two steps, formalised by EFSA (EFSA 2010a):

- the establishment of dietary reference values, considering only the relationship between consumption of a nutrient and health;
- the establishment of nutritional goals and food-based dietary guidelines resulting from these dietary reference values, for a given population in a given context. These food-based dietary guidelines need to explicitly take account of other criteria such as feasibility, dietary habits, and socio-economic or environmental considerations.

In France, the dietary reference values currently used for vitamins and minerals are those available in the work of 2001 on ANCs (AFSSA 2001). However, many data have been published since then and an update had become absolutely necessary.

2.2.2 Objectives

The objectives of this work are to:

- identify the dietary reference values available from the various agencies and organisations responsible for defining and characterising them;
- define the dietary reference values to be used in establishing food-based dietary guidelines for the French population, in particular in the optimisation step.

2.2.3 General approach

It was decided to systematically compare the reference values for vitamins and minerals proposed in international reports and opinions from the following organisations:

- World Health Organisation (WHO/FAO 2004, WHO 2012a, b);
- European Food Safety Authority (opinions published since 2013);
- Institute of Medicine⁷ (IOM 2001, 2000b, 1998b);
- Nordic Council of Ministers (NCM 2014);
- Germany, Austria, Switzerland cooperation (D-A-CH 2015);
- Australian National Health and Medical Research Council - New Zealand Ministry of Health (NHMRC-MoH 2006).

These reports were chosen because they come from international (WHO, EFSA, NCM, D-A-CH, NHMRC-MoH) or national (IOM) agencies and concern populations following a Western-type diet, and because they were published recently.

However, in 2010, EFSA began a complete reassessment of the dietary reference values. Accordingly, ANSES decided to give priority consideration to the reference values proposed by EFSA, adapting them if necessary and on the basis of explicit considerations to specific conditions concerning the French population. Only the EFSA opinions published or otherwise submitted for public consultation before 1 July 2015 have been considered here. To establish the dietary reference values, the decision tree shown below was followed:

- ✓ Existence of an assessment by EFSA:
 - **The EFSA Panel proposes an AR and a PRI:** the value, after analysis of the approach followed by EFSA and comparison with the French situation, may be endorsed unless strong objections are raised, in which case a new argument is developed to support the proposal to revise the value proposed by EFSA;
 - **The EFSA Panel proposes an AI:**
 - ✓ on the basis of data on markers or epidemiological studies: the value, after analysis of the approach followed by EFSA and compared with the French situation, may be selected;
 - ✓ on the basis of an average consumption observed at European level. In this case, the principle and the approach followed are taken into account but only a value derived from the French average consumption⁸

⁷ On 15 March 2016, the IOM changed its name and is now called the HMD (Health and Medicine Division).

⁸ Data from the INCA2 study for the population of men aged 18 to 64 years and women aged 18 to 54 years (ref. INCA2)

(excluding consumption of food supplements) for each population, including possible under-reporters, is selected;

- ✓ Absence of any assessment by EFSA: the choice of dietary reference value is made from the dietary reference values in the various reports and opinions cited above, on a case-by-case basis, substantiated, where necessary, by new bibliographic data.

With regard to the reference values relating to excessive intakes, the ULs laid down at European level by the Scientific Committee on Food (SCF), endorsed by EFSA in 2006 and updated in EFSA's opinions on each vitamin and mineral published since 2013 were the only ones considered.

2.2.4 Limitations of the work

The Working Group initially focused its thinking on the adult population, from the age of 18. Specific populations (the elderly, children, pregnant and breastfeeding women, as well as individuals with low intakes of products of animal origin, and vegetarians) will be considered at a later time.

In addition, the work presented here concerns only those vitamins and minerals whose dietary reference values were integrated as constraints in the tool for optimisation of food consumption. This therefore excludes minerals and vitamins for which we had no data on composition, i.e. vitamin B8, chromium, molybdenum and vitamin K. Beta-carotene was not introduced as such in the optimisation tool but was counted as retinol equivalent and included in total vitamin A intakes. The dietary reference values for these will be updated later.

Lastly, while the revision of the dietary reference values was commissioned because of the need to use them to establish the dietary guidelines, this work to define the dietary reference values was carried out independently. Thus, the use of these dietary reference values in the food consumption optimisation tool will be detailed in Section 5.4.2.

2.2.5 Dietary reference values selected

Vitamin A

The term vitamin A includes free and esterified retinol found in food, its metabolites produced in the body and responsible for its biological activity (retinol and retinoic acids), and provitamin carotenoids (β -carotene, α -carotene and β -cryptoxanthin). To take account of the incomplete conversion of provitamin carotenoids into retinol, the vitamin activity of these compounds has been expressed in retinol equivalent (RE) according to the following formulas:

$$1 \mu\text{g retinol} = 1 \mu\text{g RE}$$

$$1 \mu\text{g } \beta\text{-carotene} = 1/12 \mu\text{g RE}$$

This coefficient of 1/12 corresponds to an average value proposed by the IOM for a Western-type diet and a population with satisfactory reserves in vitamin A (IOM 2001).

Review of dietary reference values laid down by the selected international and national organisations (Table 1)

AFSSA (2001) estimated the AR on the basis of the results of a depletion-repletion study (Hume and Krebs 1949) and on the results from monitoring a tracer dose of vitamin A (Sauberlich *et al.* 1974). A PRI of 800 $\mu\text{g RE/d}$ was proposed, taking into account an inter-individual coefficient of variation of 15% and rounding up to the nearest hundred.

The D-A-CH proposed an AR of 600 µg RE/d, considering the results of experimental studies and the application of a coefficient of variation of 30%, leading to a PRI of 1000 µg RE/d (D-A-CH 2015).

The IOM estimated the AR as the intake able to maintain adequate minimum liver reserves of retinol (20 µg/g of liver) (Olson 1987), calculated on the basis of studies estimating the total quantities of retinol by isotope dilution in healthy subjects. From this average requirement estimated at 625 µg RE/d for a man of 76 kg and 500 µg/d for a woman of 61 kg, the PRIs were proposed on the basis of a coefficient of variation of the requirement of 20% (IOM 2001). This same approach was adopted by Australia and New Zealand (NHMRC-MoH 2006) as well as by the Nordic countries during the update of the NNRs in 2012 (NCM 2014).

The WHO set an average requirement, i.e. a daily intake necessary to prevent xerophthalmia, of 4-5 µg/kg of body weight, 300 µg RE/d for men and 270 µg RE/d for women, on the basis of the study by (Saubertlich *et al.* 1974). A recommended intake of 500 µg RE/d for women and 600 µg RE/d for men was proposed on the basis of the approach of Olson (Olson 1987), and considering a coefficient of variation of 20% (WHO/FAO 2004).

EFSA used the same approach as the IOM to estimate the AR for vitamin A, but by applying the median European weights calculated for men and women with a body mass index (BMI) of 22 kg.m⁻² (EFSA 2015d). By applying a coefficient of variation of the requirement of 15%, the dietary reference values for the population proposed by EFSA were 750 µg/d in men and 650 µg/d in women.

Table 1. Review of dietary reference values for vitamin A (µg RE/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2015) | IOM ^a (2001) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|------------------|----------------|----------------------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | 600 | 600 | 570 | 625 | 625 | 600 | ND |
| <i>Population reference intake</i> | 800 | 1000 | 750 | 900 | 900 | 900 | 600* |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-50 | > 18 | 19-50 | 19-50 | > 18 | 19-50 |
| <i>AR</i> | 600 | 600 | 490 | 500 | 500 | 500 | ND |
| <i>Population reference intake</i> | 800 | 800 | 650 | 700 | 700 | 700 | 500* |

^a Expressed in µg of retinol activity equivalent (RAE)

* Adequate intake

ND: not defined

Conclusion

EFSA's approach was adopted. Thus, the selected dietary reference values are summarised below:

- Men > 18 years old:
AR: 570 µg RE/d
PRI: 750 µg RE/d
- Women > 18 years old:
AR: 490 µg RE/d
PRI: 650 µg RE/d

With regard to the risks of excessive intakes, EFSA confirms the tolerable upper intake level of 3 mg/d set by the SCF (EFSA 2006), mainly for considerations relating to hepatotoxic and teratogenic effects (EFSA 2015d).

Vitamin B1

Review of dietary reference values laid down by the selected international and national organisations (Table 2)

In 2001, AFSSA considered a range of clinical, epidemiological and biological arguments before proposing a recommended vitamin B1 intake of 0.14 mg/MJ in men and women.

The recommendations of the Nordic countries (NCM 2014) are the same as those from 2004. They felt that there were no studies justifying a review of the recommendations. They refer to studies indicating that urinary excretion of thiamine and erythrocyte transketolase activity coefficients were normalised at intake levels of 0.07-0.08 mg/MJ (0.30-0.33 mg/1000 kcal).

The IOM based its estimate of the AR on a depletion/repletion study showing that an intake of 1 mg/d (0.07 mg/MJ) is sufficient to cover the requirement on the basis of the urinary excretion of thiamine and the maintenance of normal erythrocyte transketolase activity in humans (Sauberlich *et al.* 1979, IOM 1998a). As for the WHO (WHO/FAO 2004), it based its recommendations on another depletion/repletion study where only erythrocyte transketolase activity was considered (Anderson and Nicol 1986).

The German-speaking countries (D-A-CH 2015) relied on balance studies to establish their dietary reference values. They divided the male population into two sub-groups: adults under 25 years of age and those over 25 years.

Table 2: Review of dietary reference values for vitamin B1 (mg/d unless otherwise indicated)

| | AFSSA (2001) | D-A-CH (2015) | EFSA | IOM (1998) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-------------------------------------|------------------|------|---------------|-----------------|-------------------------------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | 19-25 25-65 | > 18 | 19-70 | 19-65 | 18-74 | 19-65 |
| <i>AR</i> | ND | ND | - | 1.0 | 1.0 | 0.10 mg/MJ i.e. 1.2 [#] | ND |
| <i>Population reference intake</i> | 0.14 mg/MJ i.e. 1.5 ⁺ | 1.3* 1.2* | - | 1.2 | 1.2 | 0.12 mg/MJ i.e. 1.4 [#] | 1.2* |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | > 19 | > 18 | 19-50 | 19-50 | 18-74 | 19-50 |
| <i>AR</i> | ND | ND | - | 0.9 | 0.9 | 0.10 mg/MJ i.e. 0.9 [#] | ND |
| <i>Population reference intake</i> | 0.14 mg/MJ i.e. 1.2 ⁺ | 1.0* | - | 1.1 | 1.1 | 0.12 mg/MJ i.e. 1.1 [#] | 1.1* |

* Adequate intake

[#] Estimate on the basis of an energy requirement between 11 and 11.7 MJ for men and between 8.8 and 9.4 MJ for women, according to age (18-30 years and 31-60 years) and for an LPA = 1.6.

⁺ Estimate for information purposes on the basis of an energy intake of 2600 kcal (10.9 MJ) for men and 2100 kcal (8.8 MJ) for women, according to the estimated energy requirements in the INCA2 population.

ND: not defined

Conclusion

In the absence of any reference values proposed by EFSA and given the similar nature of the values proposed by the various bodies considered, the reference values relating to energy intake as proposed by AFSSA in 2001 were selected and are summarised below:

- Men > 18 years old:
AI: 0.14 mg/MJ/d i.e. 1.5 mg/d
- Women > 18 years old:
AI: 0.14 mg/MJ/d i.e. 1.2 mg/d

Given the available data and the low toxicity observed at a high dose, no upper intake level for vitamin B1 could be established by EFSA (2006).

Vitamin B2

Review of dietary reference values laid down by the selected international and national organisations (Table 3)

The recommended requirements and intakes for vitamin B2 (riboflavin) are often related to the energy ingested, due to the role of this vitamin in energy metabolism.

In 2001, AFSSA considered that the data available could not be used to propose an AR for vitamin B2. The proposed ANC restated the earlier recommendation and adjusted it to the energy intake recommended in 2001.

In the recommendations of the Nordic countries (NCM 2014), the AR had been estimated at 0.12 mg/MJ on the basis of studies assessing riboflavin status by measuring its urinary excretion and by measuring erythrocyte glutathione reductase (EGR) activation by riboflavin. The AR was set at 0.12 mg/MJ and the PRI at 0.14 mg/MJ.

The IOM has also used studies examining these two criteria to propose an average requirement of 1.1 mg/d in men and 0.9 mg/d in women, with the resulting reference values for the population (IOM 1998a). These estimates were adopted in full by Australia and New Zealand (NHMRC-MoH 2006).

Table 3: Review of dietary reference values for vitamin B2 (mg/d unless otherwise indicated)

| | AFSSA (2001) | D-A-CH (2015) | EFSA | IOM (1998) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|-----------------------------|--------------------------------------|---|------|------------|--------------|-------------------------------------|------------|
| Men | | | | | | | |
| Age | 20-65 | 19-51 > 51 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| AR | ND | ND | - | 1.1 | 1.1 | 0.12 mg/MJ i.e. 1.4 | ND |
| Population reference intake | 0.17 mg/MJ i.e. 1.8* ⁺ | 0.14 mg/MJ* i.e. between 1.4 and 1.3 | - | 1.3 | 1.3 | 0.14 mg/MJ i.e. 1.7 [#] | 1.3* |
| Women | | | | | | | |
| age | 20-54 | 19-51 > 51 | > 18 | 19-50 | 19-50 | + 18 | 19-50 |
| AR | ND | ND | - | 0.9 | 0.9 | 0.12 mg/MJ | ND |
| Population reference intake | 0.17 mg/MJ i.e. 1.5* ⁺ | 0.14 mg/MJ* i.e. between 1.1 and 1.0 | - | 1.1 | 1.1 | 0.14 mg/MJ i.e. 1.3 [#] | 1.1* |

* Adequate intake

Or for an LPA observed in the population equal to 1.6, between 1.5 and 1.6 mg/d for men whose energy requirement is between 11 and 11.7 MJ and between 1.2 and 1.4 mg/d for women whose energy requirement is between 8.8 and 9.4 MJ, according to age (18-30 years and 31-60 years).

+ Estimate for information purposes on the basis of an energy intake of 2600 kcal (10.9 MJ) for men and 2100 kcal (8.8 MJ) for women, according to the estimated energy requirements in the INCA2 population.

ND: not defined

The German-speaking countries (D-A-CH, 2015) based their recommendations only on the measurement of EGR activation. They proposed values on the basis of a level of physical activity (LPA) of 1.4, and an energy intake ranging from 1700 to 1900 kcal according to age for women, and between 2200 and 2400 kcal according to age for men. A similar approach based on the measurement of EGR activation was used by the WHO (WHO/FAO 2004).

Conclusion

In the absence of any reference values proposed by EFSA and given the very similar nature of the values proposed by the various bodies considered, the estimate relating to energy intake proposed by AFSSA in 2001 was selected and is summarised below:

- Men > 18 years old:
AI: 0.17 mg/MJ/d i.e. 1.8 mg/d
- Women > 18 years old:
AI: 0.17 mg/MJ/d i.e. 1.5 mg/d

Given the available data and the low toxicity observed at a high dose, no upper intake level for vitamin B2 could be proposed by EFSA (2006).

Vitamin B3

Review of dietary reference values laid down by the selected international and national organisations (Table 4)

Vitamin B3 encompasses nicotinic acid and nicotinamide (preformed niacin from food). It can be synthesised by the liver from tryptophan. Vitamin B3 intake is expressed in niacin equivalent (NE) based on the levels of preformed niacin (1 mg niacin = 1 mg NE) and tryptophan (1 mg NE = 60 mg tryptophan) in foods. Because of the role of vitamin B3 in energy and protein metabolism, the requirements and recommendations are frequently expressed in mg/MJ.

In 2001, AFSSA's estimate of vitamin B3 requirements drew on the results of depletion-repletion studies in healthy men that assessed the minimum intakes in preformed niacin or tryptophan needed to prevent the appearance of a deficiency (pellagra) or restore normal urinary excretion of two methylated metabolites of nicotinamide. The AR was set at 1.08 mg/MJ and the recommended intake at 1.2 mg/MJ.

The IOM considered that urinary excretion of N-methylnicotinamide (NMN) was the best marker for defining the AR. The results of four experimental studies suggest that urinary NMN excretion of 1 mg/d reflects a higher level of NE intake than that causing the appearance of a deficiency. This estimated intake of 1.3 mg NE/MJ (or 11.6 mg/d in humans) corresponds to the AR from which a PRI was derived (IOM 1998a). A similar reasoning was applied by the WHO (2004), the D-A-CH (2015) and the NCM (2014).

According to EFSA, there is no sign of niacin deficiency in individuals whose diet contains at least approximately 1 mg EN/MJ and does not provide less than 8.4 MJ/d (2000 kcal/d) (EFSA 2014f). Diets providing at least 1.3 mg EN/MJ/d have proved to be sufficient to prevent depletion and maintain body reserves of niacin, as indicated by the sharp increase in the excretion of niacin metabolites above this level of ingestion. This value of 1.3 mg/MJ/d was chosen as the AR and the dietary reference value for the population, established on the basis of a coefficient of variation of the requirement of 10%.

Table 4: Review of dietary reference values for vitamin B3 (mg NE/MJ)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2014) | IOM (2002) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | 19-65 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | 1.08 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | ND |
| <i>Population reference intake</i> | 1.2 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | 1.3** |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-65 | > 18 | 19-50 | 19-50 | + 18 | 19-50 |
| <i>AR</i> | 1.08 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 | ND |
| <i>Population reference intake</i> | 1.2 | 1.6 | 1.6 | 1.6 | 1.6 | 1.6 | 1.3** |

** Lower safety intake level

ND: not defined

NE: Niacin Equivalent (1 mg niacin = 1 mg NE = 60 mg tryptophan)

Conclusion

The WG decided to select the dietary reference values related to energy set by EFSA, which are of the same order of magnitude as those proposed by the other organisations. For information purposes, an estimate in absolute value was calculated on the basis of a total energy intake of 2600 kcal (10.9 MJ) for men and 2100 kcal (8.8 MJ) for women, according to the estimated energy requirements in the INCA2 population, and is presented below:

➤ Men > 18 years old:

AR: 1.3 mg NE/MJ, i.e. 14.4 mg/d

PRI: 1.6 mg NE/MJ, i.e. 17.4 mg/d

➤ Women > 18 years old:

AR: 1.3 mg NE/MJ, i.e. 11.4 mg/d

PRI: 1.6 mg NE/MJ, i.e. 14 mg/d

For EFSA, the tolerable upper intake level for free nicotinic acid is 10 mg/d and the UL for nicotinamide is 900 mg/d for adults (EFSA 2014f). These were the values adopted by EFSA in 2006. Note that these two forms of intake have not been differentiated in the nutritional composition tables. This raises the question of whether or not to propose a distinction in the composition tables.

Vitamin B5

Review of dietary reference values laid down by the selected international and national organisations (Table 5)

To date, all the national and international agencies have concluded that there were insufficient data to establish an AR for vitamin B5. In 2001, AFSSA had set the ANC, determining it as an AI, at 5 mg/d in adults, on the basis of the average intake of the North American population deemed to be in good health (Tarr *et al.* 1981).

The adequate intake proposed by the IOM (IOM 1998a) and adopted by the WHO was established according to the same observations (WHO/FAO 2004).

The D-A-CH (2015) and the NHMRC (2006) also relied on observed consumption to propose an adequate intake.

The NCM considered that the evidence was insufficient to select a value (NCM 2014).

In its Opinion of 2014, EFSA considers that there are no appropriate biomarkers to define an AR and proposes an AI for all the population groups, based on the average consumption observed in different national consumption surveys carried out in the EU, in the absence of data suggesting that this intake may be insufficient. This average consumption varies according to country from 3.2 to 5.3 mg/d and from 4.0 to 6.8 mg/d in women and men under 65 years of age, respectively (EFSA 2014g).

Table 5: Review of dietary reference values for vitamin B5 (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2014) | IOM (2002) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|---|-----------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | ND | ND | ND | ND | ND | ND | ND |
| <i>Population reference intake*</i> | 5 | 6 | 5 | 5 | 6 | ND | 5 |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-50 | > 18 | 19-50 | 19-50 | + 18 | 19-50 |
| <i>AR</i> | ND | ND | ND | ND | ND | ND | ND |
| <i>Population reference intake*</i> | 5 | 6 | 5 | 5 | 4 | ND | 5 |

* Adequate intake
ND: not defined

Conclusion

EFSA's approach was adopted and an adequate intake was defined from the average consumption value for the French population (INCA2 study) excluding food supplements, namely:

- Men > 18 years old:
AI: 5.8 mg/day
- Women > 18 years old:
AI: 4.7 mg/day

Given the available data, EFSA has not proposed a tolerable upper intake level for vitamin B5 (EFSA 2014g). Intakes that significantly exceed the generally observed consumption levels do not appear to pose a safety problem for the population (EFSA 2006).

Vitamin B6

Review of dietary reference values laid down by the selected international and national organisations (Table 6)

To establish its ANCs, AFSSA drew on the plasma concentration of pyridoxal phosphate (PLP), which seems to be the best indicator of vitamin B6 status. AFSSA selected a plasma concentration threshold of 30 nmol/L proposed by Leklem (Leklem 1990), corresponding to an extremely low risk of presenting a deficiency. Using data from the SU.VI.MAX study, a dietary reference value was calculated on the basis of intakes able to achieve this threshold of 30 nmol/L and taking account of the variability of the requirement.

In 1998, the IOM set the AR based on the intake able to maintain a plasma PLP concentration at least equal to 20 nmol/L in depletion-repletion studies, considering that the studies did not report any deleterious clinical effect for concentrations lower than 15 nmol/L. This explains why the requirements and recommendations are slightly lower than those proposed by AFSSA.

The values proposed by the WHO (2004) and the NCM (2014) also relied on these results.

Table 6: Review of dietary reference values for vitamin B6 (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA | IOM (1998) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|---|-----------------|------------------|------|----------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | 19-65 | | 19-50 50-70 | 19-50 51-70 | 18-60 | 19-50 > 50 |
| <i>AR</i> | ND | - | - | 1.1 1.4 | 1.1 1.4 | 1.3 | - |
| <i>Population reference intake*</i> | 1.8* | 1.5 | - | 1.3 1.7 | 1.3 1.7 | 1.5 | 1.3* 1.7* |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-65 | | 19-50 50-70 | 19-50 51-70 | 18-60 | 19-50 > 50 |
| <i>AR</i> | ND | - | - | 1.1 1.3 | 1.1 1.3 | 1.1 | - |
| <i>Population reference intake*</i> | 1.5* | 1.2 | - | 1.3 1.5 | 1.3 1.5 | 1.2 | 1.3* 1.5* |

* Adequate intake

ND: not defined

Conclusion

The value defined by AFSSA in 2001 was selected, which is close to the values proposed by the IOM and the other agencies. The fact that the value is slightly higher could be because it meets other criteria that have not been directly taken into account, such as a limitation of its contribution to increasing plasma homocysteine levels and the possible associated risk.

The adequate intake is summarised below:

- Men > 18 years old:
AI: 1.8 mg/day
- Women > 18 years old:
AI: 1.5 mg/day

Given the available data, EFSA proposed an UL for adults of 25 mg/d (EFSA 2006).

Vitamin B9

Review of dietary reference values laid down by the selected international and national organisations (Table 7)

Folic acid is more stable than folate and has better bioavailability, which can reach 85%, while that of natural folate is around 50%.

To account for this difference in bioavailability, the concept of dietary folate equivalent (DFE) is used. Thus, 1 µg DFE is equivalent to 1 µg of dietary folate and 0.6 µg of folic acid.

The D-A-CH (2015) considered that a daily intake of 200 µg DFE was sufficient to achieve plasma and erythrocyte folate concentrations of at least 10 and 340 nmol/L, respectively, which were found to be satisfactory. Considering that the assay methods underestimate the levels of dietary folate, the AR was set at 220 µg/d, and the PRI at 300 µg/d on the basis of a coefficient of variation of the requirement of 15%.

The IOM drew on the concentrations of two biological markers, plasma folates and plasma homocysteine levels, to set an AR on the basis of intervention studies that characterised the relationship between folate intake and these markers (IOM 1998a). This AR was set at 320

µg/d and the population reference intake at 400 µg/d, taking into account a coefficient of variation of the requirement estimated at 10%.

This approach and the resulting reference values were adopted in full by the WHO (2004) and the NHMRC (2006).

The NCM estimated an AR of 200 µg/d on the basis of studies showing that such a level of intake could maintain the plasma folate concentration above 6.8 nmol/L and plasma homocysteine levels below 12 µmol/L. The population reference intake was set at 300 µg/d (NCM 2014).

In 2001, AFSSA did not set an AR for folate but proposed a population reference intake (adequate intake) on the basis of the data from the SU.VI.MAX cohort showing that folate intakes greater than or equal to 330 µg/d in men and 276 µg/d in women were associated with plasma homocysteine levels below 10 µmol/L. For the population of women of childbearing age, the recommendation was set at 300 µg/d, to partly take into account the need for early prevention of neural tube closure defects.

In 2014, EFSA proposed an AR for folate on the basis of a depletion-repletion study showing that an intake of 250 µg/d DFE is sufficient to maintain an adequate status determined by a plasma folate concentration greater than or equal to 10 nmol/L in 50% of individuals (EFSA 2014d). A coefficient of variation of the requirement of 15% was used to propose a population reference intake of 330 µg/d DFE.

Table 7: Review of dietary reference values for vitamin B9 (µg DFE/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2014) | IOM (1998) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|--------------------|------------------|----------------|---------------|-----------------|-------------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | ND | 220 | 250 | 320 | 320 | 200 µg folates | 320 |
| <i>Population reference intake</i> | 330 µg folates* | 300 | 330 | 400 | 400 | 300 µg folates | 400 |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-50 | > 18 | 19-50 | 19-50 | + 18 | 19-50 |
| <i>AR</i> | ND | 220 | 250 | 320 | 320 | 200 µg folates | 320 |
| <i>Population reference intake</i> | 300 µg folates* | 300 | 330 | 400 | 400 | 300 µg folates | 400 |

* Adequate intake
ND: not defined

Conclusion

The values proposed by EFSA (2014) were adopted:

- Men and women > 18 years old:
AR: 250 µg/d DFE
PRI: 330 µg/d DFE

For women in the periconceptional period (eight weeks before and after conception), the need for an additional intake, able to achieve 400 µg/d DFE to reduce the risk of neural tube closure defects, was selected.

EFSA (2014) confirmed the UL proposed by the SCF (EFSA 2006), namely 1 mg/d in adults, which relates only to folic acid, the synthetic form of vitamin B9 used in fortification and in

food supplements. The EFSA Panel considered that there was no risk associated with high consumption of folate, the natural form of vitamin B9. With regard to the data on the nutritional composition of foods, the source of vitamin B9 should therefore be ascertained.

Vitamin B12

Review of dietary reference values laid down by the selected international and national organisations (Table 8)

In 2001, AFSSA proposed an AR of 2 µg/d and a PRI of 2.4 µg/d, on the basis of losses estimated at 0.8 µg/d, a bioavailability of 40% and a coefficient of variation of the requirement of 10%.

The NNR based the estimate of the AR on studies showing that daily intramuscular injections of 0.5 to 1.0 µg of cobalamin are sufficient to normalise the haematological parameters of most subjects with pernicious anaemia – a disease induced by a vitamin B12 deficiency – and considering oral bioavailability of 50%.

Most of the other national and international agencies based their recommendations on the links between intakes and biological markers and on the prevention of haematological changes induced by a vitamin B12 deficiency. The AR proposed by the IOM (2 µg/d) thus corresponds to the minimum intake required for maintaining plasma cobalamin and methylmalonic acid (MMA) respectively above and below the thresholds considered satisfactory. This AR also corresponds to the theoretical intake needed to prevent the recurrence of haematological abnormalities in subjects suffering from Biermer's anaemia. The WHO (2004) and the NHMRC (2006) adopted the reasoning and the reference values proposed by the IOM (1998).

EFSA considered that the approach based on a combination of four biomarkers of vitamin B12 status, i.e., plasma concentrations of cobalamin, holotranscobalamin (holoTC), MMA and homocysteine, was the most appropriate one for defining nutritional recommendations for vitamin B12 (EFSA 2015b). It believes that there is sufficient evidence to conclude that intakes greater than or equal to 4 µg/d are associated firstly with holoTC and cobalamin concentrations within the reference intake ranges defined for healthy subjects, and secondly with MMA and homocysteine concentrations lower than the maximum values proposed in adults, which indicates an adequate cobalamin status.

Table 8: Review of dietary reference values for vitamin B12 (µg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2015) | IOM (1998) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | 2 | 2 | ND | 2 | 2 | 1.4 | 2 |
| <i>Population reference intake</i> | 2.4 | 3 | 4* | 2.4 | 2.4 | 2 | 2.4 |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-50 | > 18 | 19-50 | 19-50 | > 18 | 19-50 |
| <i>AR</i> | 2 | 2 | ND | 2 | 2 | 1.4 | 2 |
| <i>Population reference intake</i> | 2.4 | 3 | 4* | 2.4 | 2.4 | 2 | 2.4 |

* Adequate intake

ND: not defined

Conclusion

The experts believed here that none of the markers of the metabolic activity of cobalamin were sufficient by themselves to reflect all the metabolic functions of cobalamin, and therefore accepted the approach followed by EFSA, based on taking four biomarkers into account, and adopted the adequate intake proposed by EFSA in men and women, namely:

➤ Men and women > 18 years old:

AI: 4 µg/d

EFSA considers that there is no tolerable upper intake level, because of the lack of toxicity, and in particular carcinogenicity, at the doses considered (EFSA 2015b).

Vitamin C

Review of dietary reference values laid down by the selected international and national organisations (Table 9)

For a long time, recommendations for vitamin C were based on the observed intakes regarded as adequate in healthy Western populations. In depletion-repletion studies conducted at the end of the last century, it was observed that the plasma concentration of vitamin C reached a plateau for relatively moderate intakes of vitamin C. This led AFSSA to use this parameter as a marker of requirements being met. To establish the ANC in 2001, AFSSA used observational data from the SU.VI.MAX survey providing the link between intakes and plasma vitamin C concentrations in around 6000 adult subjects (women aged 35 to 60 years and men aged 40 to 60 years), healthy at the time of inclusion. This led to an ANC of 110 mg/d for adults of both sexes being selected.

The IOM (IOM 2000a) and the D-A-CH (2015) used the data from depletion-repletion studies and proposed recommendations between 75 and 100 mg/d.

The Nordic countries considered that to reach the threshold of 32 µg/L of plasma vitamin C, from which the risk of cardiovascular and cancer morbidity and mortality was reduced, an intake of 60 mg/d for men and 50 mg/d for women was necessary (NCM 2014).

The WHO (2004) made its recommendations on the basis of a body content of 900 mg of vitamin C, halfway between tissue saturation and the store associated with the appearance of a risk of scurvy, absorption of 85% and losses of 2.9% per day. They are 45 mg in both men and women. The average requirement was set as the intermediate intake between the recommendation and the minimum intake sufficient to prevent the risk of scurvy (10 mg/d).

EFSA recently reassessed the dietary reference values for vitamin C (EFSA 2013b). The requirement was established taking into account observations showing a decrease in absorption with an increase in the ingested dose, a sharp increase in urinary excretion above an intake of 50 mg/d and a plateau obtained for plasma concentrations of vitamin C and for its catabolism with increased intakes. On the basis of this metabolic evidence, the requirement in men was set at 90 mg/d and the PRI at 110 mg/d, which fits with the figures proposed by AFSSA (2001). In women, EFSA proposed a lower requirement and PRI (95 mg/d), considering that the plasma concentration plateau was obtained for a slightly lower intake than in men (EFSA 2013b).

Table 9: Review of dietary reference values for vitamin C (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2013a) | IOM (2000) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|------------------|-----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 18-75 | > 19 | > 18 | > 19 | > 19 | > 18 | > 19 |
| <i>AR</i> | 85 | 82 | 90 | 75 | 30 | 60 | 25-30 |
| <i>Population reference intake</i> | 110 | 100 | 110 | 90 | 45 | 75 | 45 |
| Women | | | | | | | |
| <i>Age</i> | 18-75 | > 19 | > 18 | > 19 | > 19 | > 18 | > 19 |
| <i>AR</i> | 85 | 82 | 80 | 60 | 30 | 50 | 25-30 |
| <i>Population reference intake</i> | 110 | 100 | 95 | 75 | 45 | 75 | 45 |

Conclusion

The approach adopted by EFSA to simply derive the PRI for the female population from that proposed for men is not satisfactory. The data from the SU.VI.MAX study focusing on a large number of subjects indeed show a higher plasma concentration plateau in women than in men (respectively $64 \pm 1 \mu\text{mol/L}$ and $56 \mu\text{mol/L} \pm 3 \mu\text{mol/L}$). In these conditions, it was considered that the requirements and recommendations for the female French population should take into account the need to reach this higher value, and not the one chosen for the male population. For these reasons, it was decided to keep the same AR and PRI values in men and women. Within ANSES's Expert Committee on "Human Nutrition", this decision gave rise to two minority opinions, defending the dietary reference values proposed by EFSA (**Annex 2**). The dietary reference values selected are as follows:

- Men and women > 18 years old:
AR: 90 mg/day
PRI: 110 mg/day

EFSA confirms its position published in 2006 and considers that the data are insufficient to propose a UL for vitamin C (EFSA 2013b).

Vitamin D

Review of dietary reference values laid down by the selected international and national organisations (Table 10)

Vitamin D occupies a special place among the vitamins because its intake is provided by both food and endogenous production resulting from exposure to UVB (solar radiation).

In France, vitamin D requirements were estimated from the minimum daily intakes of vitamin D needed to prevent or correct a clinic and/or biological vitamin D deficiency in children and adults, i.e. 10 to 15 μg (400-600 IU) per day. The biological marker of vitamin D status used was the concentration of 25-hydroxycholecalciferol (25-OH-D3), which is the reserve form. However, although the biological threshold corresponding to a deficiency was set at 30 nmol/L, there is no threshold corresponding to an adequate, or even optimal status. In 2001, the discussion on the establishment of the ANC indeed focused on determining the amount of vitamin D that should be provided by food, since satisfactory exposure to the sun would theoretically be enough to meet requirements. It was considered that the previous position (Dupin *et al.* 1992) proposing the value of 10 $\mu\text{g/d}$ (in order to cover the requirements of individuals who did not expose themselves to the sun) could be excessive for subjects with "sufficient" or even high solar exposure; the value of 5 $\mu\text{g/d}$ was therefore finally put forward.

The IOM believed that the serum 25-OH-D3 measurements were a good reflection of food intake and dermal synthesis in the sense that they enable the relationship between consumption or solar exposure and pathologies to be studied (IOM 2011). The Institute therefore determined the threshold concentration of 25-OH-D3 from which the biological functions of vitamin D are adequately performed and then estimated the food intake able to achieve this threshold value. The IOM considered that the main function of vitamin D in adults was to maintain bone mineral density and that the intestinal absorption of calcium was greatest for 25-OH-D3 concentrations of between 30 and 50 nmol/L. The IOM selected a median 25-OH-D3 concentration of 40 nmol/L as the target value for setting the AR and observed that this concentration could be reached with an intake of 10 µg/d, on the basis of observational studies making the link between vitamin D intake and the plasma concentration of 25-OH-D3 in populations with minimal solar exposure (Scandinavia, Antarctica). The reference for a population with little exposure to the sun has been set as the intake required to reach the upper bound of the interval of the target concentration of 25-OH-D3, or 50 nmol/L. This population reference intake is 15 µg/d.

The Nordic recommendations (NCM 2014) set the plasma 25-OH-D3 concentration to be achieved on the basis of data making the link between this concentration and the bone mineral status, the risk of rickets and that of osteomalacia. They considered 50 nmol/L to be the optimal value. It is suggested that an intake of 7.2 µg/d may maintain the average serum level in winter around 50 nmol/L. However, there is great interindividual variability partly dependent on the basal serum level. It was shown that the intakes needed to reach a sufficient serum 25-OH-D3 concentration during the winter period in 95% of subjects are between 9 and 12 µg/d. All of these results led the NCM to propose an AR of 7.5 µg/d and a PRI of 10 µg/d. This value takes into account a certain contribution to serum concentration from endogenous synthesis arising from activities performed outdoors during the summer period (from the end of the spring to early autumn), while considering that some groups, especially those with darker skin, may require higher doses.

The German-speaking countries (D-A-CH, 2015) believed that to achieve a serum 25-OH-D3 concentration of at least 50 nmol/L, vitamin D intake through normal food is not sufficient, and that the difference must be compensated by endogenous synthesis. They recommend regular exposure to the sun to ensure an adequate intake of vitamin D without it being necessary to resort to the consumption of a vitamin supplement.

The WHO (2004) estimated the food intake required to maintain a plasma 25-OH-D3 concentration greater than 27 nmol/L, able to maintain good bone health according to different age groups (before and after 50 years of age).

The NHMRC (2006) also adopted the threshold of 27 nmol/L to estimate the adequate intake needed to achieve this plasma threshold.

Table 10: Review of dietary reference values for vitamin D ($\mu\text{g}/\text{d}$)

| | AFSSA (2001) | D-A-CH (2015) | EFSA ⁹ | IOM (2011) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|--|--|-------------------|---------------|-----------------|---------------|----------------|
| Men | | | | | | | |
| <i>Age</i> | 19-74 | > 19 | | > 19 | 19-50 51-70 | 18-75 | 19-50 51-65 |
| <i>AR</i> | ND | ND | - | 10 | ND | 7.5 | ND |
| <i>Population reference intake</i> | 5* 10* in the event of non- exposure | 20* in the event of non- exposure | 15 ^{ab} | 15 | 5* 10* | 10 | 5* 10* |
| Women | | | | | | | |
| <i>Age</i> | 19-74 | > 19 | | > 19 | 19-50 51-70 | 18-75 | 19-50 |
| <i>AR</i> | ND | ND | - | 10 | ND | 7.5 | ND |
| <i>Population reference intake</i> | 5* 10* in the event of non- exposure | 20* in the event of non- exposure | 15 ^{ab} | 15 | 5* 10* | 10 | 5* 10* |

* Adequate intake

Conclusion

EFSA's assessment of the dietary reference values for vitamin D has not yet been published. The WG considered that the IOM's approach was relevant and proposes adopting the IOM's value for the PRI set for unexposed subjects, which is extrapolated to the general population because these values are well below the UL. This value is able to meet the requirements of the vast majority of the population. Thus, the following dietary reference values were selected:

➤ Men and women > 18 years old:

AR: 10 $\mu\text{g}/\text{d}$

PRI: 15 $\mu\text{g}/\text{d}$

A change to the tolerable upper intake level was published in 2012, from 50 to 100 $\mu\text{g}/\text{d}$ (EFSA 2012b).

Vitamin E

Review of dietary reference values laid down by the selected international and national organisations (Table 11)

The ANC proposed by AFSSA in 2001 endorsed the recommendation issued in 1992 by Dupin *et al.* based on the average consumption observed in the population (12 mg/d), in the absence of data for estimating an AR.

The Nordic countries (NCM 2014) proposed a vitamin E requirement on the basis of a vitamin E/polyunsaturated fatty acid (PUFA) ratio in food equal to 0.4, deemed sufficient to prevent lipid peroxidation, considering an average PUFA intake in the Scandinavian population corresponding to 5% of total energy intake. Under these conditions, the AR and

⁹ EFSA submitted its opinion on the dietary reference values for vitamin D for consultation in February 2016. The European Agency is proposing an adequate intake of 15 μg (EFSA 2016).

the recommended intake were 6 and 10 mg for men, and 5 and 8 mg for women, respectively.

The IOM drew on the results of *in vitro* studies showing that a plasma α -tocopherol concentration below 12 $\mu\text{mol/L}$ was associated with hydrogen peroxide-induced haemolysis above 12%, the value regarded as normal (IOM 2000a). On the basis of intervention studies, the IOM considered that an intake of at least 12 mg/d was necessary to achieve this plasma concentration. The requirement was therefore set at 12 mg/d without any gender distinction, and the population reference intake was set at 15 mg/d taking into account a coefficient of variation of the requirement of 10%.

EFSA considered that firstly, the quantity of α -tocopherol necessary for preventing the peroxidability of PUFAs varied according to their degree of unsaturation and secondly, the PUFA intake varied significantly among European countries (EFSA 2015e). For these reasons, PUFA consumption could not be used as a basis for establishing an adequate intake in vitamin E. Similarly, EFSA considered that it was not possible to set an adequate intake on the basis of intakes of nutrients acting synergistically with vitamin E to combat oxidative stress, such as vitamin C, selenium, niacin and vitamin K. The relationships between vitamin E intake and biological markers (i.e. plasma concentration of vitamin E, urinary excretion of vitamin E metabolites or markers of lipid peroxidation such as the F2-isoprostanes, haemolysis related to membrane peroxidation) were deemed insufficiently characterised for the establishment of an AR. Accordingly, EFSA proposed an adequate intake of 13 mg/d for men and 11 mg/d for women on the basis of the average intake observed in a series of national consumption surveys, considering that there was no evidence to suggest that vitamin E intake was inadequate in the European population.

Table 11: Review of dietary reference values for vitamin E (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2015) | IOM (2000) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|--------------------|----------------|---------------|-----------------|---------------|------------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | -25 yrs +25 yrs | > 18 | 19-+70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | ND | ND | ND | 12 | ND | 6 | 10 ^a |
| <i>Population reference intake</i> | 12* | 15* 14* | 13* | 15 | 10* | 10 | ND |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | 19-65 | > 18 | 19-50 | 19-50 | + 18 | 19-50 |
| <i>AR</i> | ND | ND | ND | 12 | ND | 5 | 7.5 ^a |
| <i>Population reference intake</i> | 12* | 12* | 11* | 15 | 7* | 8 | ND |

* Adequate intake

^a The data are insufficient for determining a PRI, this is the best estimate of the requirements.

ND: not defined

Conclusion

EFSA's approach was followed and an adequate intake was adopted on the basis of the average consumption value for the French population, excluding fortified products and food supplements (as estimated in the INCA2 study), and the finding that there was no evidence likely to indicate a vitamin E deficiency in this population. This average intake is slightly lower than that reported by EFSA. Thus, the following dietary reference values were selected:

- Men > 18 years old:
AI: 10.5 mg/day
- Women > 18 years old:
AI: 9.9 mg/day

Based on coagulation studies in humans that have shown no effect on bleeding time up to supplementation of 537 mg/d, by applying a safety factor of 2 to this dose and rounding up to the nearest hundred, EFSA reiterated its 2006 conclusions and proposed a UL of 300 mg/d (of α -tocopherol equivalent) (EFSA 2015e).

Calcium

Review of dietary reference values laid down by the selected international and national organisations (Table 12)

In AFSSA's work establishing the ANCs in 2001, the nutritional requirement for calcium was estimated using a factor-based approach. The net maintenance requirement, corresponding to losses through urine, faeces and perspiration in a situation of very low intake, is equal to 260 mg/d for an adult man. Fractional absorption of 38% was chosen, for a reasonably low calcium intake (around 500 mg/d, with few dairy products), leading to an average requirement of 690 mg/d and a population reference intake of 900 mg/d. In women the requirement is greater after the menopause.

In 2011, the IOM estimated an average requirement for calcium based on a series of calcium balance studies. Between 19 and 50 years, a neutral calcium balance is obtained for an intake of 740 mg/d, rounded up to 800 mg/d for the average requirement. The population reference intake was set at 1000 mg/d according to the 97.5th percentile in the balance studies. The IOM considered that after the age of 50, the average requirement did not change in men, but proposed increasing the recommendation of 200 mg/d for the female population, to limit the decline in bone mineral density (IOM 2011).

The recommendations proposed by the NHMRC (2006), NCM (2014) and D-A-CH (2015) are similar to those proposed by the IOM (2011) and AFSSA (2001). They also rely on the results of balance studies.

The WHO proposed two sets of requirements and recommendations on calcium intake to take account of the variability in nutritional contexts (WHO/FAO 2004). The highest values correspond to the recommendations for Western populations, while the low values are intended for populations with low intakes of animal protein (less than 40 g/d) and therefore of proteins generally, and whose urinary losses of calcium are correspondingly lower.

In 2015, EFSA based its estimate of the requirement in individuals aged 25 years and over, whose bone growth is complete, on the same balance studies as those considered by the IOM. EFSA took into account dermal losses estimated at 40 mg/d, which had been neglected in these studies, to propose an average requirement of 750 mg/d. The recommended intake was estimated according to the 97.5th percentile of intakes able to obtain a neutral balance, or 950 mg/d. In young adults (18-25 years) whose growth is not complete, the average requirement was estimated as the average of the requirements for adults 25 years and over, and adolescents aged 15 to 17 years, i.e. 860 mg/d. No specific recommendation was made for women after the menopause (EFSA 2015f).

Table 12: Review of dietary reference values for calcium (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2015) | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|------------------|----------------|----------------|-----------------|---------------|--|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | 18-19 > 19 | 18-24 > 24 | 19-50 51-70 | 19-70 | 18-20 > 21 | 19-65 |
| <i>AR</i> | 690 | 1000 741 | 860 750 | 800 800 | 840 | - 500 | 600-840 [£] |
| <i>Population reference intake</i> | 900 | 1200 1000 | 1000 950 | 1000 1000 | 1000 | 900 800 | 750-1000 [£] |
| Women | | | | | | | |
| <i>Age</i> | 20-55 | 18-19 > 19 | 18-24 > 24 | 19-50 51-70 | 19-50 > 51 | 18-20 > 21 | 19-50 > 50 |
| <i>AR</i> | 690 | 1000 741 | 860 750 | 800 1000 | 840 1100 | - 500 | 600-840 [£] 750-1100 [£] |
| <i>Population reference intake</i> | 900 | 1200 1000 | 1000 950 | 1000 1200 | 1000 1300 | 900 800 | 670-1000 [£] 800-1300 [£] |

[£] The first value corresponds to the requirements or recommendations for animal protein intakes < 40 g/d. The second value corresponds to the recommendations for a Western diet

Conclusion

The Working Group endorsed the most recent recommendations proposed by EFSA for the adult population, namely:

- Adult men and women < 24 years old:
AR: 860 mg/day
PRI: 1000 mg/day
- Adult men and women > 24 years old:
AR: 750 mg/day
PRI: 950 mg/day

A tolerable upper intake level of 2500 mg/d was proposed by EFSA in 2006 on the basis of many long-duration intervention studies (food and food supplements) in which no deleterious effect was reported for intakes of 2500 mg/d. EFSA's opinion does not challenge this value (EFSA 2015f).

Copper

Review of dietary reference values laid down by the selected international and national organisations (Table 13)

There is no consensus between the different agencies with regard to the estimated requirements for copper and the setting of the recommendations. In 2001, AFSSA estimated the nutritional requirement for copper in adult subjects using the factor method, taking into account mandatory losses estimated at 400-500 µg/d and fractional absorption of 30%. A coefficient of variation of 15% of the requirement was selected in order to propose, after approximation, a PRI of 2.0 mg/d in men. A PRI of 1.5 mg/d was deduced in women on the basis of the body weight ratio between men and women.

In adults, the IOM established a nutritional requirement for copper of 0.7 mg/d in men and women by relying on the variation in the marker of copper status (serum copper levels, caeruloplasmin, erythrocyte superoxide dismutase (SOD)) during depletion/repletion studies

(IOM 2001). The recommendation derived from this requirement was 0.9 mg/d. These values were adopted without change by the NCM (2014).

In 2006, the NHMRC considered that the available data were insufficient to establish a nutritional requirement for copper and proposed a recommendation based on an observed intake of 1.2 mg/d in women and 1.7 mg/d in men.

Recently, the D-A-CH proposed an average requirement of 1.0 mg/d in men and women and a recommended intake of 1.5 mg/d (D-A-CH 2015).

Table 13: Review of dietary reference values for copper (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA ¹⁰ | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|-----------------|------------------|--------------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-50 51-65 | > 19 | | 19-+70 | 19-65 | > 18 | |
| <i>AR</i> | - ^a | - | - | 0.7 | ND | 0.7 | - |
| <i>Population reference intake</i> | 2.0 1.5 | 1.0-1.5* | 1.6* | 0.9 | 1.7* | 0.9 | - |
| Women | | | | | | | |
| <i>Age</i> | > 20 | > 19 | | 19-50 | 19-50 | > 18 | |
| <i>AR</i> | - ^a | - | - | 0.7 | ND | 0.7 | - |
| <i>Population reference intake</i> | 1.5 | 1.0-1.5* | 1.3* | 0.9 | 1.2* | 0.9 | - |

* Adequate intake

^a the AR estimated in 2001 is between 1.35 and 1.65 mg/d.

Conclusion

At this stage, there is no consensus concerning the establishment of an average requirement and the formulation of a recommendation for copper. The values originally proposed by AFSSA rely on a total loss of 400 to 500 µg/d and a fractional absorption coefficient of 30%. The latter seems to be low in view of more recent and more reliable estimates suggesting fractional absorption of close to 50% (Harvey, Dainty, *et al.* 2005, Harvey *et al.* 2003, Harvey *et al.* 2002). The application of such a coefficient seems more relevant. It leads to the definition of recommendations that are closer to those proposed by the other agencies. As of 1 July 2015, EFSA had not submitted its opinion on the dietary reference values for copper for consultation; the following reference values were therefore selected:

➤ Adult men > 18 years old:

AR: 1.0 mg/day

PRI: 1.3 mg/day

➤ Adult women > 18 years old:

AR: 0.8 mg/day

PRI: 1.0 mg/day

¹⁰ At the time of validation of this report by the CES, the EFSA opinion was out for consultation. This opinion was published on 21 October 2015 (EFSA 2014e). EFSA proposed an adequate intake of 1.6 mg for men and 1.3 mg for women.

Chronic consumption of copper at a high dose can cause severe liver damage. EFSA proposed a tolerable upper intake level of 5 mg/d (EFSA 2006), established from a NOAEL of 10 mg/d from a long-term supplementation study in humans and adopting an uncertainty factor of 2 to take into account the small number of subjects in this study.

Iodine

Review of dietary reference values laid down by the selected international and national organisations (Table 14)

In 2004, the WHO set an adequate intake of 150 µg/d for adult men and women, corresponding to a median urine iodine level higher than or equal to 100 µg/L and a plasma concentration higher than or equal to 1 µg/L, thresholds below which there is an increased risk of goitre and possible impairment of thyroid hormone synthesis.

Because of insufficient iodine intakes in certain regions and certain categories of the population in Germany and Austria, and considering other parameters such as the iodine content of food and water, the D-A-CH decided to retain the value of 200 µg/d for the German and Austrian populations but to select the WHO value of 150 µg/d for the Swiss population, due to a better iodine status and the existence of a salt enrichment programme set up several decades ago (D-A-CH 2015).

In 2004, the Nordic countries set an AR of 100 µg/d in men and women, corresponding to a plateau of iodine concentration in the thyroid gland and the iodine turnover in subjects with no thyroid gland. A population reference intake of 150 µg/d was deduced, including a margin of safety for goitrogens in food. This value was maintained by the NCM in its revision of 2014.

In 2001, the IOM drew on data on balance measurements, thyroid iodine renewal in subjects with normal thyroid function, and the measurement of urinary excretion of iodine, to estimate the average requirement. This was set at 95 µg/d for adults, without any gender distinction. A coefficient of variation of 20% was chosen to estimate the population reference intake of 150 µg/d.

In 2001, AFSSA retained this recommendation of 150 µg/d for men and women, proposed by Delange (Delange 1993) for the European population.

In 2006, the NHMRC defined an AR on the same bases as the IOM, also taking into account a New Zealand study combining the urinary excretion of iodine and the thyroid volume. All the results led to the average requirement being met with intakes between 85 and 100 µg/d. The population reference intake was set at 150 µg/d on the basis of a coefficient of variation of the requirement estimated at 20% and after rounding up to the nearest ten to take into account the influence of natural goitrogens found in the environment.

More recently, EFSA considered that the balance studies could not be used to establish recommendations for iodine (EFSA 2014e). It was felt that the size of the thyroid was an integrative long-term biomarker of the coverage of the iodine requirement. An adequate intake was defined from a broad European epidemiological study on children, indicating that the prevalence of goitre was lowest for urinary iodine concentrations above 100 µg/L. In the absence of similar data in other populations, EFSA applied this limit to adults. Taking into account the average diuresis and a coefficient of absorption of 92%, an adequate intake of 150 µg/d was set in adults.

Table 14: Review of dietary reference values for iodine ($\mu\text{g}/\text{d}$)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2014) | IOM (2001) | NHMRC (2006) | NCM (2004) | WHO (2004) |
|--|-----------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | > 18 | 19-50 > 51 | > 18 | > 19 | > 19 | > 18 | > 13 |
| <i>AR</i> | ND | ND | ND | 95 | 100 | 100 | ND |
| <i>Population reference intake</i> | 150* | 200* 180* | 150* | 150 | 150 | 150 | 150* |
| Women | | | | | | | |
| <i>Age</i> | > 18 | 19-50 > 51 | > 18 | > 19 | > 19 | > 18 | > 13 |
| <i>AR</i> | ND | ND | ND | 95 | 100 | 100 | ND |
| <i>Population reference intake</i> | 150* | 200* 180* | 150* | 150 | 150 | 150 | 150* |

* Adequate intake

Conclusion

The Working Group proposed adopting EFSA's values, which are identical to those defined by AFSSA in 2001, namely:

- Men and women > 18 years old:
AI: 150 $\mu\text{g}/\text{d}$

The upper intake levels established by the SCF were endorsed by EFSA in 2006. The value of 500 $\mu\text{g}/\text{d}$ in adults adopted by AFSSA was considered appropriate to avoid the development of hyperthyroidism in the countries that have a long history of inadequate iodine intake. In its Opinion of 2014, EFSA confirmed the UL of 600 $\mu\text{g}/\text{d}$ (EFSA 2014e).

Iron

Review of dietary reference values laid down by the selected international and national organisations (Table 15)

The nutritional requirement for iron is generally defined as the minimum intake needed to balance overall losses in subjects without iron reserves (i.e. with serum ferritin > 15 $\mu\text{g}/\text{L}$) (IOM 2001, AFSSA 2001). It has been assessed by all national or international bodies by dividing mandatory losses by fractional absorption. This approach is justified by the fact that iron losses are not regulated; homeostasis is ensured by adjusting the level of fractional absorption according to the state of the reserves.

The dietary reference values proposed by the IOM in 2001 were based on iron bioavailability of 18%, estimated by taking into account a 10% proportion of haem iron in food and fractional absorption in subjects without reserves estimated at 16.8% and 25% for metallic iron and haem iron, respectively. The distribution of mandatory losses was estimated by Monte Carlo simulation, on the basis of losses excluding menstrual bleeding estimated at 14 $\mu\text{g}/\text{kg}/\text{d}$, menstrual losses equal to 0.51 and 2.32 mg/d at the 50th and 97.5th percentile, respectively, and the distribution of body weights observed in the population of the United States. The proposed recommendations for women after the menopause are the same as those intended for the male population.

This reasoning and the resulting values were adopted in full by the NHMRC in 2006.

AFSSA (2001) and the Nordic countries (2014) used a slightly lower fractional absorption coefficient (15%) to propose their reference values. For women of childbearing age, the nutritional recommendation proposed in the NCM corresponds to the estimated requirement at the 90th percentile, and not the 97.5th percentile.

In its estimates, the WHO (2004) took into account the diversity of food contexts and proposed a range of recommendations, with the high values corresponding to diets very low in meat and fish, rich in components interfering with iron absorption (phytates and tannins) and for which the fractional absorption of iron is close to 6%, while the low values correspond to the Western context with high bioavailability of dietary iron. The low values of the range of recommendations proposed by the WHO are very close to the values proposed by the other health authorities.

Recently, EFSA proposed reference values based on the modelling of mandatory losses in iron calculated for 28 men and 20 menstruating women extracted from a study conducted by Hunt (Hunt 2003). The mandatory losses at the 50th, 95th and 97.5th percentiles were estimated respectively at 0.95, 1.61 and 1.72 mg/d in men and 1.34, 2.80 and 3.13 mg/d in menstruating women. Intestinal absorption coefficients of 16% for men and 18% for women – corresponding to estimates for subjects with serum ferritin of 30 µg/L (Dainty *et al.* 2014) – were applied to calculate the median nutritional requirement (for a subject whose losses are at the 50th percentile of the distribution) and the population reference intake (for a subject whose losses are at the 97.5th percentile of the distribution for men and the 95th percentile for women). Because the number of post-menopausal women included in the Hunt study was insufficient to allow the modelling of losses, EFSA proposed adopting the male PRIs for this sub-population (EFSA 2015g).

Table 15: Review of dietary reference values for iron (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2015) | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|------------------------------------|-----------------|------------------|----------------|---------------|-----------------|---------------|---|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | 19-65 | > 18 | 19-65 |
| <i>AR</i> | 7 | ND | 6 | 6 | 6 | 7 | 7 to 21 depending on the bioavailability of dietary iron |
| <i>Population reference intake</i> | 9 | 10 | 11 | 8 | 8 | 9 | 9.1 to 27.4 depending on the bioavailability of dietary iron |
| Women | | | | | | | |
| <i>Age</i> | 20-54 / | 19-50 > 50 | > 18 | 19-50 | 19-50 | + 18 | 19-50 |
| <i>AR</i> | 9 | ND | 7 | 8 | 8 | 10 | 9.7 to 29 depending on the bioavailability of dietary iron |
| <i>Population reference intake</i> | 16 | 15 10 | 16 | 18 | 18 | 15 | 19.6 to 58.8 depending on the bioavailability of dietary iron |

ND: not defined

Conclusion

The dietary reference values proposed by EFSA (2015) were obtained by a different approach from those used by the national authorities and the other international authorities to date, and relied on the complex modelling of mandatory losses estimated from a restricted sample (28 men and 20 menstruating women) rather than on a simulation at the population scale. Although the characteristics of this sample, in terms of their build and lifestyle, are not representative of the French population, the dietary reference values proposed by EFSA are very close to those proposed by AFSSA or the IOM in 2001.

However, the strongly biased nature of the distribution of iron requirements in menstruating women led to a population reference intake (requirement at the 95th percentile) equal to more than double the average requirement. This distribution is the direct consequence of that of the menstrual bleeding, whose volume varies enormously within the population aged 18 to 55 years, due to genetic factors related to haemostasis, age and contraceptive method. For instance, the use of a hormonal contraceptive leads to a significant reduction in menstrual losses, while conversely the use of an intrauterine device more often leads to an increase in bleeding. For these reasons, the Working Group considered that the single population recommendation proposed by EFSA, and previously by the IOM and AFSSA, was difficult to apply as is, and chose to propose two levels of recommendations respectively for women with low or moderate menstrual losses – in particular women using hormonal contraception – and women with high menstrual losses.

To do this, the Working Group considered the distribution of menstrual losses of iron reported in a study conducted in 90 British women aged 20 to 45 years and whose contraceptive practices were representative of those observed in the French population (35% used a hormonal contraceptive and 5% an intrauterine device). This study shows a distribution of menstrual losses of iron according to an exponential law, with a median of 0.28 mg/d, an 80th percentile at 0.70 mg/d and a 95th percentile at 1.50 mg/d (Harvey, Armah, *et al.* 2005). Combined with the basal losses and considering the fractional absorption coefficient of 18% used by EFSA, this distribution of menstrual losses leads to an estimated median nutritional requirement equal to 7 mg/d, a nutritional requirement at the 95th percentile of 16 mg/d, corresponding to the population recommendation proposed by EFSA, and a nutritional requirement at the 80th percentile of 11 mg/d. This last value moreover corresponds to the estimated nutritional requirement at the 80th percentile for the population of menstruating women estimated by the IOM in 2001. Accordingly, the following values were selected:

- Men
AR: 6 mg/day
PRI: 11 mg

- Menstruating women
AR: 7 mg/day
PRI for women with low or normal menstrual losses (80% of the population): 11 mg/day
PRI for women with high menstrual losses: 16 mg/d corresponding to the population reference intake proposed by EFSA

In 2006, EFSA had considered that the gastrointestinal adverse effects – nausea, constipation, epigastric discomfort – reported after acute consumption outside mealtimes of 50 to 60 mg of iron meant that it was not possible to propose a tolerable upper intake level for the iron present in food. In 2015, EFSA did not call into question its assessment of the UL (EFSA 2015g).

Magnesium

Review of dietary reference values laid down by the selected international and national organisations (Table 16)

There is no validated biological marker of magnesium status that can be used to estimate the nutritional requirement. An AR was determined by the IOM (1997), AFSSA (2001) and the NHMRC (2006) based on the results of balance studies. In subjects aged 19 to 30 years, the IOM established an AR of 330 and 225 mg/d in men and women, leading to recommended intakes of 400 and 310 mg/d respectively. The observation of magnesium balances that are more frequently negative in subjects over 30 years of age, which could be due to higher non-fermentable fibre intakes, led the IOM to propose slightly higher reference values for the 31-70 years age group. The IOM proposals were adopted in full by the NHMRC.

As for AFSSA, it only proposes a single set of reference values for each sex, and the estimated average requirement in women is higher than that proposed by the IOM.

In 2001, the WHO considered that the available data were too limited to estimate the nutritional requirement in magnesium, and proposed a provisional recommendation for magnesium intake that relies on balance studies and observed consumptions: the recommended intake is 0.10 mg/kcal/d, i.e. 220 mg for women and 260 mg for men. The recent NCM recommendations were not based on a precise estimate of the requirement.

In its opinion recently submitted for consultation (EFSA 2015h)¹¹, EFSA cites a study containing 27 balance studies involving 664 individual observations in men aged 28 ± 8 years and women aged 51 ± 17 years, for magnesium intakes between 84 and 598 mg/d (Hunt and Johnson 2006). This study reported a stable magnesium balance in 50% of subjects for an intake of 165 mg/d, with a 97.5th percentile at 237 mg/d. Furthermore, a growing number of large-scale prospective studies have reported a positive association between magnesium intake and a reduced risk of diabetes, hypertension and stroke. Thus, according to a recent meta-analysis encompassing 13 longitudinal studies involving 536,000 subjects, a 14% reduction (RI = 0.86 [0.84-0.89]) in the risk of diabetes may be associated with each 100 mg/d increase in magnesium intake (Dong *et al.* 2011). The high intakes in these studies were on average close to 390 mg/d, but EFSA considered that they could not be used as a basis for setting a threshold below which the risk of diabetes no longer decreased. Based on all these studies, EFSA considered that it was impossible to set an AR and proposed an AI based on average intakes observed in several European countries.

¹¹ Opinion published on 28 July 2015, i.e. after the publication of this report by the CES on "Human Nutrition".

Table 16: Review of dietary reference values for magnesium (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2015) | IOM (1997) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|--|------------------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | < 24 > 24 | 18-24 > 24 | 19-30 > 31 | 19-30 > 31 | 12-20 >21 | 19-65 > 65 |
| <i>AR</i> | 350 i.e. 5 mg/kg bw | ND | ND | 330 350 | 330 350 | ND | ND |
| <i>Population reference intake</i> | 420 | 400* 350* | 350* | 400 420 | 400 420 | 350* | 260* |
| Women | | | | | | | |
| <i>Age</i> | 20-55 | < 24 > 24 | 18-24 > 24 | 19-30 > 31 | 19-30 > 31 | 18-20 >21 | 19-50 > 50 |
| <i>AR</i> | 300 i.e. 5 mg/kg bw | ND | ND | 225 265 | 255 265 | ND | ND |
| <i>Population reference intake</i> | 360 | 350* 300* | 300* | 310 320 | 310 320 | 280* | 220* |

* Adequate intake

ND: not defined

On the basis of the results of the meta-analysis by Dong *et al.* (2011), it was considered that the recommendations proposed by AFSSA in 2001 were more protective than those of EFSA, because they were able to take account of a lower risk of type 2 diabetes, even though uncertainties persist regarding the characterisation of the relationship between magnesium intake and the risk.

Thus, no AR was established but the decision was made to maintain these recommendations in the form of adequate intakes:

- Men:
AI: 420 mg/day
- Women:
AI: 360 mg/day

EFSA confirmed the UL of 250 mg/d proposed in 2006, which applies to dissociable magnesium (sulphate, chloride, lactate, etc.) and to the magnesium oxide consumed in the form of food supplements or added to beverages and foods, on the basis of studies showing the absence of any gastrointestinal side effect (diarrhoea) at this level of supplementary intake (EFSA 2015h).

Manganese

Review of dietary reference values laid down by the selected international and national organisations (Table 17)

Most of the agencies, the D-A-CH (2015), the IOM (2001) and the NHMRC (2006), have established dietary reference values on the basis of the median intakes observed in a population regarded as healthy.

In 2001, AFSSA considered that the requirement was between 1 and 2.5 mg/d but was not able to propose a reference value.

In 2013, EFSA considered that in the usual intake ranges, the potential biomarkers currently used to define manganese status (serum or cellular concentration, enzyme activities) were not sensitive enough to be used as criteria for establishing reference values for manganese. There are too few epidemiological studies on the link between intake or markers of

manganese status and the health consequences for them to be used to set the reference values (EFSA 2013a).

Many manganese balance studies have been published: it appears that stable or positive manganese balances are constantly found above an intake of 2.5 mg/d, showing that this balance can stabilise within a wide range of intakes.

EFSA therefore considered that the average intake was around 3 mg/d in most food surveys conducted at European level and concluded that this value was an adequate intake for the European population.

Table 17: Review of dietary reference values for manganese (mg/d)

| | AFSSA (2001) | D-A-CH (2013) | EFSA (2013) | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|------------------------------------|-----------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | > 18 | > 15 | > 18 | > 19 | > 19 | | |
| <i>AR</i> | 1-2.5 | ND | ND | ND | ND | - | - |
| <i>Population reference intake</i> | ND | 2-5* | 3* | 2.3* | 5.5* | - | - |
| Women | | | | | | | |
| <i>Age</i> | > 18 | > 15 | > 18 | > 19 | > 19 | | |
| <i>AR</i> | 1-2.5 | ND | ND | ND | ND | - | - |
| <i>Population reference intake</i> | ND | 2-5* | 3* | 1.8* | 5* | - | - |

*Adequate intake, ND: not defined

Conclusion

EFSA's approach was followed and it was decided to adopt as the adequate intake the average consumption value for the French population (INCA2 study) considering that there is no indication of manganese deficiency in this population. This average intake is slightly lower than that reported by EFSA. Thus, the following dietary reference values were selected:

- Men > 18 years old:
AI: 2.8 mg/day
- Women > 18 years old:
AI: 2.5 mg/day

EFSA confirmed that the animal studies conducted could not be used to identify a NOAEL, and given the limited data in humans, it is not possible to propose a tolerable upper intake level for manganese (EFSA 2013a).

Phosphorus

Review of dietary reference values laid down by the selected international and national organisations (

Table 18)

In adults, the average requirement for phosphorus was determined by the factor method, from the amount of absorbed phosphorus needed to maintain serum phosphorus levels at the lower limit of normal values, and assuming fractional absorption of 65%. On this basis, the nutritional requirement was set by most of the agencies in a consensual manner at 580 mg/d in men and women. The population reference intakes differed according to the choice

of coefficient of variation applied: this was set at 10% by the IOM, 15% by AFSSA and 35% by the NHMRC. The value of 35% was derived from the quantities of phosphorus to be ingested to raise serum phosphorus levels from the lower bound of values regarded as normal (0.87 mmol/L) to the median (1.00 mmol/L), while the values of 10 and 15% correspond to the coefficients of variation generally accepted for nutritional requirements.

The NCM recommendations were established on the basis of an ideal molar ratio of P/Ca = 1 which, because of atomic mass differences, led to reference values for phosphorus equal to 2/3 of those proposed for calcium.

Considering that calcium and phosphorus are in equimolar proportion in the body, EFSA also based its reference values on those proposed for calcium (EFSA 2015c). This agency proposed an adequate intake of 700 mg/d calculated from the population reference intake for calcium of 950 mg/d and the ratio of the atomic masses of phosphorus and calcium (P/Ca = 0.775), rounding the final result (738 mg/d) down to the nearest hundred to take account of the higher bioavailability of phosphorus compared to calcium.

Table 18: Review of dietary reference values for phosphorus (mg/d)

| | AFSSA (2001) | D-A-CH (2013) | EFSA (2014) | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO |
|--|-----------------|------------------|----------------|---------------|-----------------|---------------|-----|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | > 19 | 18-20 >21 | |
| <i>AR</i> | 580 | ND | ND | 580 | 580 | - | - |
| <i>Population reference intake</i> | 750 | 700* | 700* | 700 | 1000 | 700 600 | - |
| Women | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | 19-70 | > 19 | 18-20 >21 | |
| <i>AR</i> | 580 | ND | ND | 580 | 580 | - | - |
| <i>Population reference intake</i> | 750 | 700* | 700* | 700 | 1000 | 700 600 | - |

*Adequate intake, ND: not defined

Conclusion

It was proposed to adopt the reference value put forward by EFSA, close to the population reference intake set in 2001 and equal to the population reference intake proposed by the IOM.

Accordingly, the reference values selected here for the adult population are as follows:

- Men and women from 20 to 65 years old:
AI: 700 mg/day

In 2006, EFSA considered that the gastrointestinal disorders observed in a few individuals consuming phosphorus-based supplements (>750 mg/d) meant that it was not possible to propose an upper intake level for all the forms of phosphorus. In 2015, EFSA confirmed that no UL could be proposed for this element (EFSA 2015c).

Potassium

Review of dietary reference values laid down by the selected international and national organisations (

Table 19)

In 2001, AFSSA did not propose a recommendation for potassium and considered that the usual intakes observed in Western countries (between 60 and 150 mmol, or 2340 to 5850 mg per 24 h) could constitute an adequate intake.

The IOM (2001) proposed an adequate potassium intake of 4700 mg/d, which is able to limit the blood pressure increases associated with high sodium intakes, and reduce the risk of kidney stones and bone mineral loss.

The NHMRC (2006) also proposed an adequate intake, set at 3800 mg/d, corresponding to the median intake of potassium from the national consumption survey.

The NCM population reference intakes (2014) were based primarily on considerations relating to blood pressure.

The WHO set the reference value for potassium in relation to the maximum value proposed for sodium set at 2000 mg, in order to respect a Na/K molar ratio equal to 1 (WHO 2012a).

Table 19: Review of dietary reference values for potassium (mg/d)

| | AFSSA (2001) | D-A-CH (2013) | EFSA | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO (2012) |
|------------------------------------|-----------------|------------------|------|---------------|-----------------|---------------|-------------------|
| Men | | | | | | | |
| <i>Age</i> | > 18 | > 15 | > 18 | > 19 | > 19 | > 18 | > 18 |
| <i>AR</i> | ND | ND | - | ND | ND | ND | ND |
| <i>Population reference intake</i> | ND | 2000 | - | 4700* | 3800* | 3500 | 3510 [§] |
| Women | | | | | | | |
| <i>Age</i> | > 18 | > 15 | > 18 | > 19 | > 19 | > 18 | > 18 |
| <i>AR</i> | ND | ND | - | ND | ND | ND | ND |
| <i>Population reference intake</i> | ND | 2000 | - | 4700* | 2800* | 3100 | 3510 [§] |

* Adequate intake

[§] On the basis of a sodium intake of 2000 mg, to maintain a Na/K molar ratio = 1

ND: not defined

Conclusion

The approach used by the WHO in 2012 was adopted. It was proposed that an equimolar ratio of sodium and potassium be retained. The choice of a dietary reference value for K is therefore determined by sodium intake.

EFSA (2006) considered that the data were insufficient to propose a tolerable upper intake level for potassium provided naturally by food.

Selenium

Review of dietary reference values laid down by the selected international and national organisations (**Table 20**)

Like most of the other expert bodies, such as the IOM, the WHO and the NHMRC, in 2001 AFSSA had used saturation of plasma glutathione peroxidase activity to establish an ANC at

1 µg/kg of body weight, i.e. 70 µg/d. It was suggested that selenoprotein P, which helps regulate selenium homeostasis and is essential to its cell transfer, may be a more appropriate marker, whose maximisation could be used to conclude that all the functions of selenium are then performed.

The NCM (2014) and EFSA (2014) therefore used this biomarker to establish their dietary reference value. However, EFSA considered that the studies on the relationship between dietary intakes of selenium and plasma concentrations of selenoprotein P were insufficient to establish an AR on this basis, but could be used to define an adequate intake, set at 70 µg/d for men and women (EFSA 2014h). EFSA mainly drew on data on intakes of 50-60 µg/d regarded as sufficient for the selenoprotein P concentration to reach a plateau, and on data on Finnish, American and British populations reporting that intakes of more than 100 µg/d enabled this plateau to be reached.

EFSA also conducted a review of observational studies and randomised controlled clinical studies on the relationships between selenium intakes and certain health parameters. This review showed no extra benefit associated with selenium intakes greater than those needed to reach the selenoprotein P concentration plateau.

Table 20: Review of dietary reference values for selenium (µg/d unless otherwise indicated)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2014) | IOM (2000) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|------------------------------------|-----------------|------------------|----------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | > 19 | > 19 | > 18 | 19-65 |
| <i>AR</i> | ND | ND | ND | 45 | 60 | ND | ND |
| <i>Population reference intake</i> | 1 µg/kg/d | 70* | 70* | 55 | 70 | 60* | 34* |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | > 19 | > 18 | > 19 | > 19 | > 18 | 19-65 |
| <i>AR</i> | ND | ND | ND | 45 | 50 | ND | ND |
| <i>Population reference intake</i> | 1 µg/kg/d* | 60* | 70* | 55 | 60 | 50* | 26* |

* Adequate intake
ND: not defined

Conclusion

The Working Group endorsed EFSA's conclusions and thus adopted an adequate intake very close to the value determined by AFSSA in 2001:

- Men and women from 20 to 65 years old:
AI: 70 µg/d

In 2006, EFSA established a tolerable upper intake level of 300 µg/d based on a cohort study of patients with selenosis used to derive a NOAEL of 850 µg/d and applying an uncertainty factor of 3. In 2014, EFSA confirmed this UL (EFSA 2014h).

Sodium

Review of dietary reference values laid down by the selected international and national organisations (Table 21)

The homeostasis of sodium is closely controlled through the activity of various transport systems regulated by different hormonal systems, in particular the renin-angiotensin-aldosterone system. The sodium balance can thus be stabilised at highly variable intake levels, to the extent that daily urinary sodium excretion (24 h natriuresis) is, in medical or epidemiological practice and for normal intake levels, regarded as an excellent reflection of dietary intakes.

Some agencies (AFSSA, NCM, WHO, D-A-CH) have set a minimum requirement at around 500 mg/d, on the basis of sodium balance data. However, none have deemed the data sufficient for establishing an average requirement or a population reference intake. These organisations have proposed an adequate intake (NHMRC), maximum intake limits (WHO, NCM, IOM) or management measures (AFSSA 2002) for sodium, based most often on the prevention of a risk of high blood pressure for part of the population.

Only the NHMRC (2006) estimated an adequate intake based on this minimum requirement, and established it so as to ensure an adequate intake of other nutrients. It specified that this adequate intake was not suited to highly active people such as athletes practising endurance sports or labourers exposed to high temperatures, who therefore have higher perspiration losses.

To date, EFSA has not submitted its revision of dietary reference values for sodium for consultation.

Table 21: Review of dietary reference values for sodium (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA | IOM (2005) | IOM (2013) | NHMRC (2006) | NCM (2014) | WHO (2012) |
|------------------------------------|-----------------|------------------|------|---------------|---------------|-----------------|---------------|---------------|
| Men | | | | | | | | |
| <i>Age</i> | 18-75 | > 19 | > 18 | > 19 | > 19 | > 19 | > 18 | > 19 |
| <i>Minimal requirement</i> | From 575 to 787 | 550 | - | ND | ND | ND | 575 | 200-500 |
| <i>AR</i> | ND | ND | - | ND | ND | ND | ND | ND |
| <i>Population reference intake</i> | ND | ND | - | 1500 | ND | 460-920* | ND | ND |
| <i>Tolerable intake level</i> | ND | ND | - | 2300 | ND | ND | 2400* | 2000* |
| Women | | | | | | | | |
| <i>Age</i> | 18-75 | > 19 | > 18 | > 19 | > 19 | > 19 | > 18 | > 19 |
| <i>Minimal requirement</i> | From 575 to 787 | 550 | - | ND | ND | ND | 575 | 200-500 |
| <i>AR</i> | ND | ND | - | ND | ND | ND | ND | ND |
| <i>Population reference intake</i> | ND | ND | - | 1500* | ND | 460-920* | ND | ND |
| <i>Tolerable intake level</i> | ND | ND | - | 2300 | ND | ND | 2400* | 2000* |

* Adequate intake
ND: not defined

Conclusion

The WHO in 2012, the NCM in 2014 and the IOM in 2005 set maximum intake levels on the basis of the risk of hypertension. This intermediate criterion is regarded as a criterion of substitution for data on cardiovascular morbidity, without the direct link between sodium

intakes and risk of stroke and coronary events being clearly demonstrated. However, the WHO considered that the close relationship between blood pressure and the risk of cardiovascular diseases demonstrated indirectly but sufficiently that a reduction in sodium intakes could reduce the risk of cardiovascular disease (CVD) through a decrease in arterial blood pressure.

In 2013, the IOM questioned its tolerable intake level of 2300 mg/d, considering that the results of epidemiological studies on the cardiovascular risk (and not on an intermediate factor such as hypertension) were neither consistent nor sufficient to determine whether an intake below this threshold increases or decreases the risk of CVD or mortality from any cause.

In addition, the relationship between sodium intakes and blood pressure is the subject of a long-standing debate, and had already been mentioned by AFSSA in 2001. Indeed, in normotensive and *a priori* healthy subjects, the level of blood pressure depends little or not at all on the amount of salt consumed, which is not the case for subjects who are hypertensive and/or sensitive to salt (AFSSA 2001). Recent data also reinforce this view (Mente *et al.* 2014).

In addition, a recent meta-analysis (Graudal *et al.* 2014) and two prospective studies reported a U-shaped or J-shaped relationship between sodium intakes and cardiovascular risk (Pfister *et al.* 2014, O'Donnell *et al.* 2014). However the reality of the increased risk at low intake levels is the subject of debate. Indeed, in the study by Pfister *et al.* (2014), the adjustment for the presence of pre-existing cardiac or inflammatory disorders results in the increased risk of heart attack for low sodium intakes no longer being significant.

Given the limitations of these observational studies, in particular the reverse causality, the Cochrane review of 2014 only refers to intervention trials. It corroborates the IOM report in concluding that there are insufficient data for confirming a clinically relevant effect of the reduction of sodium intakes on cardiovascular mortality in normotensive or hypertensive subjects (Adler *et al.* 2014).

The experts agreed with the position of the IOM (2013) and believe that the data are insufficient for establishing an upper reference value such as a UL, or a lower reference value such as a PRI or AI. They emphasise, however, particularly in relation to the link between salt intake and the risk of hypertension, and the positive association between hypertension and the risk of cardiovascular disease, the need to conduct a systematic in-depth analysis of all the available studies in order to determine a UL.

Zinc

Review of dietary reference values laid down by the selected international and national organisations (Table 22)

In the absence of a marker for zinc status, the nutritional requirement for zinc was established by most national and international agencies using a factor-based approach, and adopting variable fractional absorption coefficients according to the dietary contexts. A coefficient of 40% was thus retained by the Nordic countries (NCM 2014), leading to slightly lower recommended intakes and values than those proposed by the IOM or AFSSA in 2001.

The recommendations on zinc intake were recently reviewed by EFSA. The amount of zinc needing to be absorbed to compensate for all total losses (physiological need) was estimated by regression, taking into account the collinearity between absorption and faecal losses. This need is related to body weight by the following equation:

$$\text{Physiological requirement (mg/d)} = 0.642 + 0.038 \times \text{weight}$$

The fractional absorption of zinc was estimated using a recently-developed model and taking into account zinc and phytate intakes. From these estimates, EFSA proposed estimated average requirements and population reference intakes for men and women, taking into

account the weights at the 50th (58.1 and 68.1 kg, respectively) and 97.5th percentiles (68.1 and 79.4 kg, respectively), for individuals with BMIs of 22, and phytate intakes of 300, 600, 900 and 1200 mg/d. The values presented in Table 22 correspond to the requirements and recommendations for minimum and maximum phytate intakes (EFSA 2014i).

Table 22: Review of dietary reference values for zinc (mg/d)

| | AFSSA (2001) | D-A-CH (2015) | EFSA (2014) | IOM (2001) | NHMRC (2006) | NCM (2014) | WHO (2004) |
|------------------------------------|--|------------------|---|---------------|-----------------|---------------|---|
| Men | | | | | | | |
| <i>Age</i> | 20-65 | > 19 | > 18 | > 19 | > 19 | > 18 | > 19 |
| <i>AR</i> | - | 7.5 | 7.5-12.7 | 9.4 | 12.0 | 6.4 | - |
| <i>Population reference intake</i> | 9-14 For diets with high and low bio-availability | 10 | 9.4-16.3 depending on the phytate intakes (300-1200 mg/d) | 11 | 14.0 | 8 | 4.2-7.0-14.0 For diets with high, medium and low bioavailability |
| Women | | | | | | | |
| <i>Age</i> | 20-54 | > 19 | > 18 | > 19 | > 19 | > 18 | 19-50 |
| <i>AR</i> | - | 5.5 | 6.2-10.2 | - | 6.5 | 5.7 | - |
| <i>Population reference intake</i> | 7 – 12 For diets with high and low bio-availability | 7 | 7.5-12.7 depending on the phytate intakes (300-1200 mg/d) | 8 | 8.0 | 7 | 3.0-4.9-9.8 For diets with high, medium and low bioavailability |

* Adequate intake

Conclusion

EFSA's conclusions regarding the ARs and PRIs for zinc intake were adopted. The levels of phytate consumption in the French population are not known. Given the moderate levels of consumption of wholegrain cereal products and pulses in the French population, and the few data available for other European countries (United Kingdom, Italy, Sweden, Italy), it does not seem reasonable to adopt for the general population the highest value in the range proposed by EFSA corresponding to consumption of 1200 mg/d of phytates. These high values may be suited to sub-populations consuming no or very few animal products. The median and maximum weights used for these estimates were lower than the median weights used for the recommendations for the French population. However, given the low coefficient associated with the weight in the equation used to calculate the requirements, it was not necessary to revise the estimates made by EFSA.

In these conditions, the reference values are therefore as follows (for phytate intakes of 300 and 900 mg/d):

- Men:
AR: 7.5 - 11 mg/d
PRI: 9.4 - 14 mg/d
- Women:
AR: 6.2 - 8.9 mg/d
PRI: 7.5 - 11.0 mg/d

In 2006, drawing on a series of studies carried out under highly controlled intake conditions and showing a change in markers of copper status in subjects consuming 50 mg of zinc, EFSA proposed an upper intake level of 25 mg/d, selecting an uncertainty factor of 2 to

account for the small number of individuals included in the studies used as a basis for establishing the tolerable upper intake level. In 2014, EFSA confirmed this UL (EFSA 2014i).

All these references are summarised in **Table 23** for men and **Table 24** for women.

Table 23. Summary of dietary reference values for adult men

| Nutrient | AR | PRI | AI | Observations | Source | UL ¹² |
|------------------------|---------------------------------|------------------------------|---------------------------|--|---|---|
| Vitamin A (µg RE/d) | 570 | 750 | | | EFSA, 2015 | 3000 |
| Vitamin B1 (mg) | | | 0.14 mg/MJ or 1.5 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B2 (mg) | | | 0.17 mg/MJ or 1.8 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B3 (mg) | 1.3 mg NE/MJ or 14.4 mg/d | 1.6 mg NE/MJ or 17.4 mg/d | | | EFSA, 2014 | 10 (nicotinic acid) 900 (nicotinamide) |
| Vitamin B5 (mg) | | | 5.8 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2014 Adapted to the French population | ND |
| Vitamin B6 (mg) | | | 1.8 | Adequate intake From intake data associated with a metabolic marker | AFSSA, 2001 | 25 |
| Vitamin B9 (µg DFE) | 250 | 330 | | | EFSA, 2014 | 1000 (folic acid) |
| Vitamin B12 (µg) | | | 4 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2015 | ND |
| Vitamin C (mg) | 90 | 110 | | | EFSA, 2013 | ND |
| Vitamin D (µg) | 10 | 15 | | | IOM, 2011 | 50 |
| Vitamin E (mg) | | | 10.5 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2015 Adapted to the French population | 300 |
| Calcium (mg) | 860 750 | 1000 950 | | Before 25 years old After 25 years old | EFSA, 2015 | 2500 |

¹² The ULs are from EFSA's opinions of 2006 and have been updated in EFSA's opinions on each vitamin and mineral published since 2013

| Nutrient | AR | PRI | AI | Observations | Source | UL ¹² |
|-----------------|------------------|-------------------|-----|--|--|------------------|
| Copper (mg) | 1 | 1.3 | | | AFSSA, 2001 Adapted based on recent studies | 5 |
| Iodine (µg) | | | 150 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 600 |
| Iron (mg) | 6 | 11 | | | EFSA, 2015 | ND |
| Magnesium (mg) | | | 420 | Adequate intake From intake data associated with epidemiological data | AFSSA, 2001 Adapted based on recent studies | ND |
| Manganese (mg) | | | 2.8 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2013 Adapted to the French population | ND |
| Phosphorus (mg) | | | 700 | Adequate intake Based on a Ca/P equimolar ratio | EFSA, 2014 | ND |
| Potassium (mg) | | | | To be determined based on a Na/K equimolar ratio | WHO, 2012 | ND |
| Selenium (µg) | | | 70 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 300 |
| Sodium (mg) | - | - | | Available data non-consensual | - | ND |
| Zinc (mg) | 7.5 9.3 11 | 9.4 11.7 14 | | Phytate intakes: 300 mg Phytate intakes: 600 mg Phytate intakes: 900 mg | EFSA, 2014 | 25 |

ND: not defined, it was not possible to use the available data to set a NOAEL¹³ or a threshold above which toxicity had been identified.

DFE: dietary folate equivalent

NE: niacin equivalent

¹³ No Observed Adverse Effect Level

Table 24. Summary of dietary reference values for adult women

| Nutrient | AR | PRI | AI | Observations | Source | UL |
|---------------------|---------------------------|-------------------------|------------------------|---|--|---|
| Vitamin A (µg RE) | 490 | 650 | | | EFSA, 2015 | 3000 |
| Vitamin B1 (mg) | | | 0.14 mg/MJ or 1.2 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B2 (mg) | | | 0.17 mg/MJ or 1.5 mg/d | Adequate intake From intake data associated with metabolic markers | AFSSA, 2001 | ND |
| Vitamin B3 (mg) | 1.3 mg NE/MJ or 11.4 mg/d | 1.6 mg NE/MJ or 14 mg/d | | | EFSA, 2014 | 10 (nicotinic acid) 900 (nicotinamide) |
| Vitamin B5 (mg) | | | 4.7 | Adequate intakes Equal to the mean consumption of the French population, INCA2 | EFSA, 2014 Adapted to the French population | ND |
| Vitamin B6 (mg) | | | 1.5 | Adequate intake From intake data associated with a metabolic marker | AFSSA, 2001 | 25 |
| Vitamin B9 (µg DFE) | 250 | 330 | | | EFSA, 2014 | 1000 (folic acid) |
| Vitamin B12 (µg) | | | 4 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2015 | ND |
| Vitamin C (mg) | 90 | 110 | | | EFSA, 2013 | ND |
| Vitamin D (µg) | 10 | 15 | | | IOM, 2011 | 50 |
| Vitamin E (mg) | | | 9.9 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2015 Adapted to the French population | 300 |
| Calcium (mg) | 860 750 | 1000 950 | | Before 25 years old After 25 years old | EFSA, 2015 | 2500 |
| Copper (mg) | 0.8 | 1 | | | AFSSA, 2001 Adapted based on recent studies | 5 |
| Iodine (µg) | | | 150 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 600 |
| Iron (mg) | 6 | 11 or 16 | | Depending on use of a hormonal contraceptive | EFSA, 2015 | ND |
| Magnesium (mg) | | | 360 | Adequate intake From intake data associated with epidemiological data | AFSSA, 2001 Adapted based on recent studies | ND |
| Manganese (mg) | | | 2.5 | Adequate intake Equal to the mean consumption of the French population, INCA2 | EFSA, 2013 Adapted to the French population | ND |

| Nutrient | AR | PRI | AI | Observations | Source | UL |
|-----------------|-------------------|------------------|-----|--|------------|-----|
| Phosphorus (mg) | | | 700 | Adequate intake Based on a Ca/P equimolar ratio | EFSA, 2014 | ND |
| Potassium (mg) | | | | To be determined based on a Na/K equimolar ratio | WHO, 2012 | ND |
| Selenium (µg) | | | 70 | Adequate intake From intake data associated with a metabolic marker | EFSA, 2014 | 300 |
| Sodium (mg) | - | - | | Available data non-consensual | - | ND |
| Zinc (mg) | 6.2 7.6 8.9 | 7.5 9.3 11 | | Phytate intake: 300 mg Phytate intake: 600 mg Phytate intake: 900 mg | EFSA, 2014 | 25 |

ND: not defined, it was not possible to use the available data to set a NOAEL¹⁴ or a threshold above which toxicity had been identified.

DFE: dietary folate equivalent

NE: niacin equivalent

RE: Retinol Equivalent

2.2.6 Identification of dietary reference values for energy macronutrients

The dietary reference values for energy macronutrients were defined by a dedicated WG, whose deliberations focused firstly, on the balance between fats, carbohydrates and proteins and secondly, on the formulation of dietary reference values for carbohydrates including sugars and fibre. This work was covered in specific reports entitled "Contribution of macronutrients to energy intake" (ANSES 2017e), "Establishment of recommendations on sugar intake" (ANSES 2017c) and "Recommendations on fibre intake" (ANSES 2017f).

2.2.7 Identification of a dietary reference value for water

In 2010, EFSA defined an adequate intake of water for adult men and women with a moderate level of physical activity (LPA = 1.6) and living in a temperate environment. This adequate intake concerns all sources of water, i.e. drinking water, the water present in other beverages and the water contained in food.

EFSA believes that the data available for adults can be used to define an adequate intake, based on both observed intakes and data on intakes able to achieve adequate urinary osmolarity of 500 mOsm/L. The adequate intake is thus defined as 2 L/d for women and 2.5 L/d for men (EFSA 2010b).

Section 5.4.2 will detail how the nutrients were included in the optimisation tool.

¹⁴ No Observed Adverse Effect Level

3 Preventing chronic non-communicable diseases

3.1 Objective and approach

The aim of this work was to characterise, from an epidemiological point of view, the relationships between the food groups and the risk of major non-communicable diseases (cardiovascular diseases, type 2 diabetes, overweight/obesity, breast, prostate and colorectal cancers, bone health and mental health), in order to provide a scientific basis to the updating of the PNNS food-based dietary guidelines.

This work is covered in a specific report entitled "Study of the relationships between the consumption of food groups and the risk of chronic non-communicable diseases" (ANSES 2017d). This section summarises this work.

Many organisations have previously conducted this type of expert appraisal and the most recent work served as the starting point for the literature search. Thus, after a review of the existing consensus documents at international level (EFSA, WHO, etc.), the report by the NHMRC on the literature available until the end of 2009 (NHMRC 2011) was chosen as the starting point for all diseases except cancers. For cancers, the report by the World Cancer Research Fund (WCRF) published in 2007 and its updates (*Continuous Update Project, CUP*) were selected (WCRF 2007, 2011). The literature search thus focused on the years subsequent to these expert appraisals. The work of the WHO/IARC and that of the French National Cancer Institute, INCa (INCA 2014) were also examined.

Most of the work identified came from prospective observational studies that cannot in themselves be used to define a causal link, only the existence of a statistical association between the food group considered and the disease studied. In addition, the meta-analyses taken into account in this expert appraisal helped increase the precision and explain any apparent contradictions resulting from the heterogeneity of the studies that can be resolved by analysing them in sub-groups.

The WCRF defined four levels of evidence to qualify the relationships, which were adopted by the Working Group:

- "*convincing*" relationships: there are several good quality studies including at least two independent prospective cohort studies, with no substantial unexplained heterogeneity, with biological plausibility supported by experimental studies either in humans or in relevant animal models. There is a dose/response effect in the association, which need not be linear if this non-linearity is biologically plausible.
- "probable" relationships: there are two independent prospective studies or at least five good-quality case-control studies, with no substantial unexplained heterogeneity, and biological plausibility of the relationship.
- "limited but suggestive" relationships: the data suggest an increase or decrease in the risk but are insufficient to conclude as to a causal relationship.
- "limited – no conclusion" relationships: there are not enough data to reach a conclusion.

The only relationships presented here are those in which the level of evidence is classified as "convincing", "probable" and "limited - suggestive".

Moreover, because the diseases studied in this expert appraisal primarily appear with advancing age, the available studies generally focus on adult populations, which limits our conclusions to these populations only.

The analysis of all the studies highlighted:

- food groups associated only with an increase in the risk of diseases;
- food groups associated only with a decrease in the risk of diseases;
- food groups whose consumption is associated with both a decrease in the risk of certain diseases and an increase in the risk of other diseases.

The studies considered in this review focus primarily on populations consuming Western-type diets. However, the food supply, modes of consumption and prevalence of genetic polymorphisms vary greatly from one country to another, even within the so-called Western countries. Thus the confounding factors may vary according to the context, which limits the extrapolation of the findings in the foreign studies.

The studies considered in this expert appraisal are observational epidemiological studies on food groups, and not on nutrients or micro-constituents. Therefore, the observed variations in the risk incorporate simultaneously the effects of nutrients, micro-constituents, potential contaminants and the food matrix of a given food group. In addition, most prospective studies monitored their cohorts over many years, making it possible to estimate the long-term relationships between food consumption and the incidence of slowly-evolving diseases. Nevertheless, dietary habits and nutrient and contaminant compositions evolve over time, which limits the understanding of these relationships.

In its analysis, the Working Group paid close attention to the quantities of foods associated with reductions or increases in risk. However, the extraction of quantified recommendations has proved to be questionable. Indeed, the quantities associated with a variation in the risk are specific to the study (characteristics of the population and the food, dietary survey method used, discontinuous assessment by groups of percentiles or continuous assessment by increment, etc.) and the risks are always estimated relative to a reference group, which may vary from one study to another. In addition, some meta-analyses, although they have the advantage of "smoothing" the inter-studies variability, express the variations in risk in consumption increments (dose-effect relationship) and not by reference to a threshold value. Furthermore, the relationships between food groups consumed and risk levels are valid for the range of intakes observed in the population studied. Extrapolation outside these limits is risky.

3.2 Summary of the epidemiological relationships

3.2.1 Relationships between the consumption of food groups and the risk of chronic non-communicable diseases

Consumption of certain food groups **increases** the risk of certain chronic diseases. This is the case with red meat, delicatessen meats and sugar-sweetened beverages.

Red meat and delicatessen meats

The limitations associated with the term "delicatessen meats" (*charcuterie*) should be clarified. Epidemiological studies conducted in English-speaking countries do not make reference only to delicatessen meats but more generally to all processed meats. This description "processed meat" corresponds to meat that has undergone transformation processes with the aim of improving storage and/or developing the aromas, such as salting, drying, fermentation or smoking. Examples include ham, sausages, bacon, corned beef, dried beef and canned meats. In the French context, processed meats correspond essentially to delicatessen meats – *charcuterie* (cooked or raw ham, sausages, dried sausage, pâté, etc.). Thus, the conclusions relating to delicatessen meats are extrapolated to studies of a wider food group, that of processed meat.

The consumption of red meat and processed meats (including delicatessen meats) increases the risk of colorectal cancer, with a convincing level of evidence, and the risk of CVD and type 2 diabetes, with a probable level of evidence. In addition, consumption of meat in general or red meat in particular may increase the risk of breast cancer according to the expression of oestrogen receptors (ORs), and the risk of prostate cancer, as well as the risk of weight gain with, however, a "limited but suggestive" level of evidence¹⁵.

For the diseases for which the levels of evidence are found to be convincing or probable, the meta-analyses indicate that for each 100 g increase in daily intake of red meat, the risk of these diseases increases by 10% to 20%. For processed meats including delicatessen meats, each 50 g/d increase leads to increases in risk of up to 50%.

These data indicate that the consumption of red meat and delicatessen meats should be limited, without being able to precisely propose a maximum intake quantity. Nevertheless, in view of the increased risk caused by the consumption of red meat, it was deemed necessary to establish a maximum intake limit. To do this, the epidemiological studies on colorectal cancer were considered individually: most of them reported a statistically significant increase in risk, compared to the reference group, from 70 to 80 g/d of consumption. This value fits with the maximum individual consumption limit of 500 g per week of red meat proposed by the WCRF (WCRF 2011). With regard to processed meats, the analysis of the individual studies reported statistically significant increases in risk from 25 g/d. Because these increases are high, and in the absence of data on the increased risk for lower levels of consumption, it was deemed necessary to limit the consumption of delicatessen meats.

It is also recommended to limit the consumption of meat cooked at a high temperature (barbecued, fried, etc.) and to vary the cooking methods (boiling, roasting, etc.).

This analysis of the risk associated with the consumption of red meat is in agreement with that of INCa, which concluded that there is an increased risk of colorectal cancer associated with the consumption of red meat, with a "convincing" level of evidence (INCA 2014). It is also similar to that of the IARC (International Agency for Research on Cancer), whose

¹⁵ The WCRF's update on stomach cancer also finds an increased risk of this cancer associated with the consumption of processed meat, with a probable level of evidence (WCRF 2016)

purpose is to classify carcinogenic compounds. The IARC considers that red meat is classified as probably carcinogenic to humans (Group 2A). This ranking is based on limited evidence (in particular due to the relative heterogeneity of the results) from epidemiological studies showing positive associations between the consumption of red meat and the development of colorectal cancer. These elements are supported by mechanistic data (IARC 2015). It means that a positive association was observed between exposure to the consumption of red meat and the risk of colorectal cancer, but that other explanations for these observations (technically designated by terms such as *random*, *bias* or *confounding factors*) cannot be excluded. With regard to processed meat, the INCa also qualified the relationship with the risk of colorectal cancer as convincing. Similarly, the IARC has classified processed meat as carcinogenic to humans (Group 1). This classification is based on convincing evidence of the causal link between the consumption of processed meat and colorectal cancer in humans. This assessment is generally based on epidemiological studies showing the development of cancer in exposed people. The increased risk of colorectal cancer is estimated to be 18% for each consumption increment of 50 g/d of processed meat.

Sugar-sweetened beverages

The group of sugar-sweetened beverages comprises drinks ranging from sodas sweetened only with sugar to fruit juices made with 100% pure juice, containing vitamins and fibre, and includes nectars, which are intermediate in terms of nutritional quality. The beverages included in this group vary according to the studies. Thus, the meta-analyses cannot be used in particular to distinguish sodas from fruit juices.

The consumption of sugar-sweetened beverages increases the risk of weight gain, with a convincing level of evidence: each additional glass of sugar-sweetened beverage per day is associated with a weight gain of around 200 g/year.

The risks of type 2 diabetes and CVD are also increased, with a probable level of evidence. Daily consumption of one glass is associated with an increased risk of these diseases of around 20% compared to zero or exceptional consumption (around once a month).

Significant increases in the risk of weight gain, CVD and type 2 diabetes are observed with the consumption of one glass of sugar-sweetened beverage per day, without any more detailed information below this threshold. Thus, the available data indicate that it is necessary to limit the consumption of sugar-sweetened beverages considered as a whole.

Consumption of certain food groups **reduces** the risk of certain chronic diseases. This is the case with fruits and vegetables and wholegrain cereal products.

Fruits and vegetables

The consumption of fruits and vegetables reduces the risk of CVD, with a convincing level of evidence. Their consumption is also associated with a decrease in the risk of colorectal cancer and ER-negative (ER-) breast cancer, as well as type 2 diabetes and weight gain, with a "limited but suggestive" level of evidence.

The international guidelines, adopted at national levels, advocate daily consumption of at least five 80 g servings of fruits and vegetables. For CVDs, benefits are observed from the consumption of one daily serving. Any additional serving reduces the risk of CVD by around 4%. The consumption of a wider variety of fruits and vegetables from different families may contribute to the consumption of a wide variety of constituents of interest in the prevention of CVDs.

Wholegrain cereal products

The consumption of wholegrain cereal products reduces the risk of type 2 diabetes, CVD and colorectal cancer, with a probable level of evidence.

The risk of type 2 diabetes is decreased by up to 25% for the highest consumption levels. The risk of colorectal cancer decreases by 20% for each additional consumption of 90 g/d.

On the basis of this evidence, the consumption of wholegrain cereal products should be encouraged, without a minimum quantity being identified.

Lastly, the consumption of certain food groups is associated with risk concerning several diseases, in **reducing or increasing** the risk according to the disease considered. This is the case with dairy products and fish. These relationships may also differ depending on the modes of preparation.

For these food groups, it seems necessary to obtain more information to qualify the risk on the one hand, and the benefit on the other, to enable an in-depth benefit/risk analysis to be conducted.

Milk and dairy products

Milk

Consumption of milk reduces the risk of colorectal cancer, with a probable level of evidence. The analysis of the dose-effect relationship showed a non-linear relationship, with a more pronounced risk reduction, of around 10%, for consumption of milk in excess of 200 g/d.

In contrast, with regard to prostate cancers, the data suggest an increased risk for milk with low fat content (around 1%); an increased risk of 6% is reported for each additional consumption of 200 g/d¹⁶, with a "limited but suggestive" level of evidence, in the absence of any association in the advanced stages.

Dairy products

The association between the consumption of dairy products, overall or by type, and the risk of disease is less substantiated, and more difficult to study given, in particular, the diversity of this food group. In addition, the types of products included in this group, as well as their nutritional composition, differ according to the countries (and therefore, according to the studies).

Despite these limitations, it appears that total consumption of dairy products (including milk) probably reduces the risk of type 2 diabetes, with a reduced risk of around 5 to 10% for each 400 g/d increase in dairy products. With regard to the types of dairy products, the relationship seems better demonstrated for yoghurts, cheese and reduced-fat dairy products.

Total consumption of dairy products could also decrease the risk of CVD (risk reduction of around 10-20% for the highest consumers of various dairy products), with a "limited but suggestive" level of evidence.

On the other hand, total consumption of dairy products is associated with an increased risk of prostate cancers (any stage) (increased risk of 7% for each 400 g/d increase in dairy products and 9% for each 50 g/d increase in cheese) with a "limited but suggestive" level of evidence. The data are limited in particular because no association is identified when the results are analysed according to the stage of the cancer.

¹⁶ On the basis of six studies included in the CUP's 2014 dose response meta-analysis - high heterogeneity of 67% (WCRF 2014)

With regard to the risk of bone fracture, the Working Group was unable to reach a conclusion with respect to the potential relationships between total consumption of dairy products and the risk of fracture, on the basis of the small number of available studies published between 2009 and 2013. Since this analysis of the literature, one study (Michaelsson *et al.* 2014) has reported an increase in the fracture risk associated with the consumption of milk, in women only. Given this unusual result, the CES on "Human Nutrition" updated this analysis of the literature in June 2016 in order to compare all the available data. Since the end of 2013, four prospective studies (including that by Michaelsson *et al.*) and one case-control study have been published on the subject, for the adult population. Considered together, these studies were not designed specifically to respond to the question about the effect of consumption of dairy products on the risk of bone fractures. They lack statistical power and are heterogeneous in terms of protocol, assessment criterion and result. No study has found the same increased risk reported in the study by Michaelsson. In conclusion, the data are insufficient to draw any conclusions concerning the link between the consumption of dairy products (whether this relates to all milk products or just certain types) and the risk of bone fractures.

Fish

The consumption of fish reduces the risk of CVD, with a probable level of evidence. For each additional weekly consumption, a 6% decrease in mortality by coronary heart disease has been reported. For two additional weekly consumptions, a 4% reduction in the risk of ischemic and haemorrhagic stroke has been reported.

For dementia, in the absence of any more recent publications, the conclusions of the report by the Australian NHMRC (2011), according to which the consumption of fish is associated with a reduction in the risk of dementia, with a probable level of evidence, are adopted.

Consumption of fish is associated with a higher risk of type 2 diabetes in Western populations, concordantly in North American populations and inadequately documented in European populations. On the other hand, it is associated with a decrease in the risk in Asian populations consuming fish raw or cooked at a low temperature. It is suggested that the mode of preparation and consumption influences these relationships. Thus, additional epidemiological studies are needed to better describe the relationships between fish consumption and the risk of type 2 diabetes, taking into account the mode of storage and cooking.

In addition, consumption of fish cooked at a high temperature, salted or smoked may be associated with an increased risk of prostate cancer, with a "limited but suggestive" level of evidence.

3.2.2 Dietary patterns

Given the complex interactions between foods, in particular the substitutions between food groups, an analysis of the links between diet and chronic non-communicable diseases cannot be restricted to that of a limited number of food groups. The diet as a whole must be studied using dietary patterns.

Thus, in addition to the previous results on the food groups considered individually, it appears that Western-type diets, characterised mainly by high intakes of red meat and processed meat (for example delicatessen meats), potato and refined cereal products, full-fat dairy products and butter, and poor in fruits and vegetables, pulses, wholegrain cereal products and fish, increase the risk of type 2 diabetes with a probable level of evidence. In addition, Western-type diets are associated with an increased risk of breast and colon cancer with a "limited but suggestive" level of evidence.

Mediterranean-type diets or other "healthy" and "prudent" diets, characterised mainly by high consumption of vegetables, fruits and nuts, pulses, fish and wholegrain cereal products, moderate consumption of alcohol and low consumption of red meat, processed meats (for example delicatessen meats) and dairy products, reduce the risk of cardiovascular diseases with a convincing level of evidence, and are also associated with a decrease in the risk of type 2 diabetes, breast cancer and colorectal cancer, with a "limited but suggestive" level of evidence.

The results from these studies dietary patterns are consistent with the results observed on the individual food groups.

Section 5.4.3 will detail how the epidemiological relationships between food groups and the risk of diseases were taken into account in the optimisation tool.

4 Limiting exposure to contaminants

The substances (contaminants and food additives) considered in this work are those analysed in the second French Total Diet Study (TDS2), as well as bisphenol A (BPA), i.e. 445 substances, some of which were grouped together, corresponding to 325 substances or substance groups (ANSES 2011). These substances were regarded as a public health priority when the TDS2 was set up. The method of selection, still valid, is described in the TDS2 report.

The assessment of the health risks incurred by the population is based on the comparison of estimates of dietary exposure with the reference values: acceptable (ADI) or tolerable daily intake (TDI), provisional tolerable weekly intake (PTWI), provisional tolerable monthly intake (PTMI), etc. These reference values are maximum values not to be exceeded. They are covered by the more generic term health-based guidance values (HBGV) in this report.

Selection of the HBGV drew on an analysis of the reference values established by the main French, European or international scientific bodies: ANSES, EFSA, WHO, US-EPA, ATSDR, JECFA, etc. The literature watch was carried out until the first half of 2015. The reference value regarded as the most relevant was identified by the experts in the framework of specific work recently published (ANSES, 2016)(see the list in **Table 30**, Section 5.4.5 and **Annex 3**).

Section 5.4.5 will detail how the contaminants were taken into account in the optimisation tool.

5 Determining food consumptions addressing the nutritional and toxicological challenges and taking consumption habits into account

5.1 Objective of the approach

Food-based dietary guidelines usually aim to express the dietary reference values in the form of food combinations. This must take account of the need to cover the nutritional requirements of different population groups with the aim of promoting health and reducing the risk of disease, in accordance with EFSA's recommendations (EFSA 2010a). The current context of exposure to contaminants means that it is also necessary to try and limit the risk with regard to food contaminants, in the process of drafting the recommendations. This more comprehensive approach is therefore similar to a benefit-risk type assessment. It involves taking into account all the available data concerning the risks, whether they are related to nutrient intakes (intakes above the tolerable upper intake level, UL) or exposure to contaminants (level of exposure higher than the health-based guidance value, HBGV) and comparing them with the expected nutritional benefits (meeting requirements and preventing diseases).

Prevention of nutritional risk is the first challenge of the food consumption optimisation approach developed in this work. The nutritional risk is conceived at two levels: that of the nutrient, whose consumption should meet the requirements in the population considered, and that of the food groups, whose consumption should reduce the risk of chronic non-communicable diseases.

Another important element to take into account is dietary habits, since this may facilitate the acceptance and implementation of the food-based dietary guidelines. This second challenge involved incorporating the optimised levels of food consumption in the range of intakes observed in the French population. However, when a requirement cannot be met under the observed intake conditions, variations may be considered to the extent that they help maintain a certain acceptability *a priori*: for example, substituting foods with the same purpose can be considered, such as replacing refined bread by wholemeal bread to promote coverage of requirements in fibre.

Lastly, the third challenge involved taking into account current levels of food contamination in the process of optimising food consumption to limit exposure to contaminants, whether or not the substances are subject to regulations on use¹⁷.

In order to be able to integrate all this information in a systematic approach, a computer tool for optimising food consumption was developed. The optimisation solutions represent combinations of food groups that meet the objectives set, i.e. coverage of nutritional requirements as a whole, reduction of the risk of chronic non-communicable diseases, minimisation of exposure to food contaminants, while remaining within a range of intakes that are relatively close to current consumption. This innovative approach firstly took into account *a priori* the nutritional constraints related to the coverage of requirements and the prevention of diseases, and also integrated the risks associated with chemical contaminants.

¹⁷ Substances naturally present in food or resulting from contamination of environmental origin (such as inorganic and mineral contaminants) are distinguished from substances used for technological (such as additives) or agronomic (such as pesticides) reasons, whose use is regulated.

Moreover, because the food-based dietary guidelines are intended for populations and not individuals, a population-level approach was followed. Thus, the optimisation tool was configured so that the nutrient intakes were greater than or equal to the PRI, or failing this, the AI. This is a protective approach to the extent that these intakes are able to meet the nutritional requirements of virtually the entire population.

5.2 Work on foods or on food groups?

5.2.1 Foods or food groups?

As the ultimate objective was to develop easily communicated and therefore concise food-based dietary guidelines, it seemed essential to establish guidelines for a limited number of food categories, giving consumers the freedom to vary the foods of their choice within a given category.

A test of the optimisation of food combinations showed, in addition to the lack of consumer freedom to choose the foods within a category, that only a small number of foods were proposed for each category, which is incompatible with a varied diet, and that the proposed amounts (such as for example, for vegetables, proposing 3 g of salsify, 2 g of Jerusalem artichoke, 2 g of leek, etc.) were not easy to interpret in terms of actual use. This is why the tool was designed to offer combinations of food groups and not combinations of foods.

To do this, the foods were grouped together using the approach presented below. Within each group, actual consumption of each food was taken into account, which ensured that the foods contained in the sub-group were more representative and that the messages would be applied more effectively. For example, the dietary guidelines for fruits would be established on the basis of the composition of the fruits mostly frequently consumed by the population in the INCA2 study: apples and bananas. Conversely, if the work had been carried out on the foods taken individually, the groupings made subsequently would probably not have led to food groups that reflect consumption habits.

In addition, ANSES had been asked to clarify the position of certain foods within the groups currently used in the PNNS's dietary guidelines, such as for example, whether to classify sweetcorn among the vegetables or the starches. This position had to take account of the nutritional quality of the foods but also their image as generally accepted by the consumer. Work to categorise the foods was therefore undertaken in this context.

In this approach, some foods were not considered. This was mainly the case with mixed dishes such as ready meals (paella, lasagne, savoury tarts, etc.), sandwiches (baguette sandwiches, hamburgers, etc.), and certain desserts (rice pudding, etc.). Indeed, as their name indicates, these products are made from ingredients belonging to different food groups. In addition, they are characterised by very high variability in their intra- and inter-food nutritional composition.

Hot beverages such as tea and coffee were not considered because their composition is similar to that of water for the majority of nutrients, and the specific composition of these beverages in other substances such as caffeine or polyphenols was not taken into account because composition data were not always available for every food for all of these substances. In addition, coffee and tea contain highly variable amounts of caffeine, which has many adverse effects (including anxiety, tachycardia, sleep disorders, migraines). Thus, because of the great variability in individual sensitivity to caffeine (ANSES 2013), it was not considered appropriate to include these foods in the optimisation.

Beverages containing artificial sweeteners and flavoured waters were excluded from this work because they accounted for few foods (6 foods), with a variable sugar content. Soy-based desserts and beverages were not considered because they accounted for very few foods (3 foods) in the INCA2 nomenclature (the market for these products was still relatively undeveloped at the time of data collection for the INCA2 study).

Lastly, it was considered that to establish recommendations relating to alcoholic beverages, it would be necessary to conduct a thorough assessment of all their effects, in terms of chronic non-communicable diseases, which were not all studied here, behaviour (risks of accidents and violence) and addiction. Thus, alcoholic beverages were not considered in this work.

5.2.2 Process of defining the groups

There are many systems for categorising foods: botanical categorisation (roots, tubers, seeds, fruits), animal/plant products, terrestrial/aquatic products, for example, which meet diverse objectives and criteria (such as the degree of contamination or the composition of certain nutrients). The aim of the categorisation carried out here was to constitute families of foods with a homogeneous nutritional composition, while taking into account the food consumption practices in the population. Identifying such food families, characterised by a specific nutritional profile, then makes it possible to propose dietary guidelines for consumers and also fulfils a goal of nutritional education.

To update the food categorisation, the existing groups from the dietary guidelines developed in 2001 were used as a starting point. They were as follows:

- fruits and vegetables;
- breads, cereals, potatoes and legumes or pulses;
- milk and dairy products (yoghurts, cheeses);
- meat and poultry, fishery products, eggs;
- added fats;
- sweetened products;
- beverages.

The Working Group also based its work on a list of 1280 foods specifically developed for the INCA2 study (2006-2007) (AFSSA 2009). Each food from this nomenclature was associated with a specific nutritional composition, covering 35 nutrients. Certain foods now found on the market were at the time consumed very little or not at all, and were therefore not included in the list of foods used. These foods were not therefore categorised here (this is the case, for example, with soy products).

Only foods consumed as such were retained in the list of INCA2 foods. Ingredients (gelatine, paraffin oil, sweeteners, nutritional yeast, stock cubes, fish oil) were not taken into account. Concentrated foods sold in powder form but consumed in a reconstituted form (for example, dehydrated soup or powdered milk) were not taken into account for the constitution of the food sub-groups and were subsequently integrated in the sub-group containing the equivalent reconstituted food (for example, soups). Meal replacements and baby foods were not considered due to the specific populations for which these foods are intended. Food supplements were not taken into account in this process.

The classification process consisted of several approaches.

First approach: principal component analysis and ascending hierarchical classification applied to foods from the INCA2 nomenclature

In an initial exploratory approach, statistical classification methods were applied to foods from the INCA2 nomenclature to group them according to their nutritional composition (ascending hierarchical classification, AHC, whether or not coupled with a principal component analysis, PCA).

The hierarchical classification was carried out on the basis of the following 14 nutrients: sodium, calcium, iron, iodine, protein, starch, sugars and fibre, MUFAs, PUFAs, SFAs, beta-

carotene and vitamin C. These nutrients were selected on the basis of health considerations (for example, sugar or sodium) or because they characterised a food group commonly used in dietetics (for example, iodine for seafood products or starch for grains and starchy vegetables).

It was difficult to obtain homogeneous groups, as the food groupings obtained lacked stability, probably because too many nutrients were considered or due to the ubiquity of the nutrients.

To resolve this problem, a principal component analysis on the 14 nutrients was carried out. It served to create factorial axes summarising the information contained in the 14 variables in a reduced number of synthetic variables. Five factorial axes were selected: they explained 56% of the total variability. The ascending hierarchical classification was then repeated using these five factors. It helped identify slightly more robust food groupings around 24 or 25 classes.

These results were not retained, however, because they sometimes lacked clarity and consistency in terms of the consumption practices. For example, one class grouped together butters, various sauces and nuts; another encompassed mixed dishes (pizzas, sandwiches, etc.), pulses (chickpeas, kidney beans, etc.) and starches (rice, pasta, etc.); yet another grouped together fresh dairy products and meat dishes in sauce. It therefore became necessary to add criteria on consumption practices to this approach based solely on nutritional criteria.

Second approach: joint approach combining ascending hierarchical classification and consumption practices

The first step in this approach was to clarify the boundaries of the existing groups in the current guidelines and create food sub-groups within the established groups (Step A). The foods from the INCA2 nomenclature were then distributed among the sub-groups created (Step B).

A. Creation of food sub-groups and clarification of the boundaries of certain groups in the current guidelines

The first step consisted in identifying nutritionally consistent food sub-groups from the food groups in the current PNNS guidelines. The positioning of certain food sub-groups in the current guidelines was also clarified or revised, potentially giving rise to new groups. The nutrients for which risks of inadequate intakes (insufficient or excessive intakes) were identified (ANSES 2015b) were regarded as discriminating for the identification of the sub-groups. This mainly concerned fibre, sugar, salt, total fats and certain fatty acids.

The foods classified in each of the sub-groups are specified in Part B and in the final summary table.

Fruits and vegetables

When identifying the sub-groups belonging to this group, fruits were distinguished from vegetables, due to their different sugar content. Moreover, some epidemiological results distinguish between fruits and vegetables when studying the relationships between their consumption and the risk of chronic non-communicable diseases (in particular cardiovascular diseases and certain cancers) (Anses, 2017d).

Similarly, a distinction was made between dried fruits and fresh fruits, due to their different sugar content.

An ascending hierarchical classification was performed on the processed fruits, i.e. on fruit juices, nectars, fruits in syrup and purees, on the basis of their sugar and fibre content. This

statistical method suggested creating two classes, the first one encompassing all the fruit juices and some nectars (fruit cocktail and orange nectars), and the second class grouping together cooked fruits (fruits in syrup and purees), and pear and apricot nectars. The second class is characterised by a significantly higher sugar and fibre content than in the first class. The first class gave rise to the sub-group "Processed Fruits – Juice" and the second to the sub-group "Processed Fruits – Fruits in syrup and purees".

In addition, epidemiological studies on sugar-sweetened beverages and the risk of overweight or obesity do not usually distinguish between fruit juices, nectars or beverages such as soda (see 3.2.1 Relationships between the consumption of food groups and the risk of chronic non-communicable diseases). Therefore, the sub-group "Processed fruits – Juice" was incorporated into the group of beverages rather than the group of fruits and vegetables, the classification used previously in the framework of the PNNS.

It should be noted that some processed fruits with reduced sugar content (for example, purees without added sugars or fruits in light syrup), despite being part of the offer available on the market, are not concerned by this classification because they were not distinguished from processed fruits with added sugar in the INCA2 nomenclature used here as a basis for the work.

Lastly, the "oilseeds" (which include nuts) were formed into a specific sub-group because their nutritional composition differs greatly from other fruits, in particular their high energy density and high polyunsaturated fatty acid content (including alpha-linolenic acid, ALA).

Starches

It was considered necessary to separate bread and bread products (rusks mainly) from the other starches because the ways in which they are consumed differ from those of the other foods in the group. These products also contain more sodium than other starches.

Given their different fibre content, wholegrain starches were separated from refined starches.

Sub-groups entitled "Starch-based, savoury/fatty processed products" and "Starch-based, sweet/fatty processed products" were identified to take account of the addition of fat, salt or sugar during the manufacture or preparation of some of the foods in this group (such as French fries, breakfast cereals, or certain dry biscuits).

The "Pulses" were removed from the "Starches" group to form their own group, due to their high protein and fibre content compared to the other foods in this group.

Meat, poultry, fish, eggs VPO

The differences in nutritional composition found in red meat (i.e. beef, veal, pork, sheep, mutton, horse and offal), poultry and delicatessen meats, especially in terms of salt and fat, justified the differentiation of these three sub-groups. This distinction is corroborated by the epidemiological data, which consider these products separately when studying the relationships between their consumption and the incidence of chronic non-communicable diseases (especially colorectal cancer, CVDs and type 2 diabetes) (see Section 3.2.1 Relationships between the consumption of food groups and the risk of chronic non-communicable diseases).

A sub-group for eggs was also identified.

On the basis of the Agency's earlier work (AFSSA 2010b), it seemed relevant and necessary to distinguish oily fish from other fish and seafood products, because of their higher omega 3 PUFA content and also their higher but heterogeneous contamination (mainly by polychlorinated biphenyls - PCBs, and dioxins). An ascending hierarchical classification of the fish and fishery products according to the sum of their EPA + DHA content revealed a threshold at 1 g/100 g, making it possible to separate them into two classes: higher ("oily fish") or lower ("other fish") EPA + DHA content.

Milk and dairy products

Milk and cheese were identified as two sub-groups, due to their different modes of consumption and different nutritional composition in terms of fats and salt.

In addition, an ascending hierarchical classification was carried out on dairy-based foods (products sold in the fresh produce section such as dairy-based and cream desserts, yoghurts, white cheese (*fromage blanc*) or ice creams), on the basis of their sugar, fat and calcium content. This AHC suggested the creation of two classes. The first class was characterised by a lower sugar and, to a lesser extent, fat content compared to the levels in the second class. Conversely, it was characterised by a higher calcium content. This class corresponded almost exclusively to "Plain fresh dairy products" without added sugars, such as *fromage blanc* or plain yoghurt, and gave rise to the creation of a sub-group. Taking into account the heterogeneity of the products found in the second class (fruit yoghurts, fermented milk beverages, cream desserts, etc.), in particular in terms of sugar content, it was decided to split it into two sub-groups: "Sweetened fresh dairy products" and "Sweetened dairy desserts" (the thresholds are defined and presented in the next section).

Added fats

An ascending hierarchical classification was performed on the added fats on the basis of the content in total fats, ALA, oleic acid, and the sum of the content in lauric, myristic and palmitic acids (atherogenic SFAs in the event of excess). This suggested the creation of four classes. The first three classes were characterised by a high average fat content:

- the first comprises mainly butters and fats that are relatively high in the sum of lauric, myristic and palmitic acids (such as lard or goose and duck fat);
- the second class groups together vegetable oils and margarines with a lower SFA content;
- the third class encompasses oils rich in ALA;
- and the last class is essentially made up of sauces and fresh creams.

These four classes thus gave rise to four sub-groups entitled "Butter and reduced-fat butter", "Vegetable oils and margarines", "Vegetable oils rich in ALA", "Sauces, fresh creams and condiments".

Sweet or sweet and fatty products

This group encompasses foods such as biscuits, cakes, confectionery, pastries, jam and honey, and foods whose sugar and/or fat content are too high to belong to another sub-group (on the basis of the thresholds defined and presented in the next section).

Salt

A sub-group "Salt", added to foods at the time of their preparation or consumption, was also considered.

Beverages

"Water" was distinguished from "Sugar-sweetened beverages". With regard to drinking water, water with an average composition was considered (corresponding to the average composition of spring waters, mineral waters and tap water, weighted by their consumption levels).

The sugar-sweetened beverages essentially bring together sodas, but also fruit beverages such as fruit juices.

Overview

Thirty-two food sub-groups were thus created. They are presented in the final summary table with a reminder of the considerations that led to their identification.

B. Distribution of INCA2 foods among the sub-groups identified

The foods from the INCA2 nomenclature were distributed among the 32 sub-groups identified.

Some products were placed directly into one of these sub-groups on the basis of the consideration of the ANSES scientists. For example, the food "Wholegrain or fibre-rich rusk" was placed directly into the "Wholegrain bread and bread products" sub-group.

For other foods, the results of the ascending hierarchical classifications described above were transposed directly. This was the case for the classification of processed fruits (see Part A above).

For other foods, it proved more difficult to identify the sub-groups into which they should be placed. For example, the issue arose of the classification of certain cream desserts in the "Sweetened dairy desserts" or "Sweet or sweet and fatty products" sub-groups. Similarly, the placing of certain biscuits in the group of "Starch-based sweet products" or with the "Sweet or sweet and fatty products" raised questions. In order to better determine their classification into one or other sub-group on the basis of nutritional criteria, ascending hierarchical classifications were carried out on the following foods and nutrients:

- classification of sweetened foods (in particular biscuits, cakes, pastries, breakfast cereals, chocolate, confectionery) on the basis of their sugar, starch, fat and fibre content; and
- classification of dairy-based foods (products sold in the fresh produce section such as dairy-based and cream desserts, yoghurts, white cheese (*fromage blanc*) or ice creams), on the basis of their sugar, fat and calcium content.

The results of these ascending hierarchical classifications were taken into account as explained below in the distribution of the foods among the 32 groups. The number of classes suggested by the AHCs was not adopted because the sub-groups had been predefined according to the procedure presented in the previous section. Nevertheless, these AHCs helped highlight the most discriminating nutritional criteria for classifying the products, as well as the thresholds to be considered when deciding to which sub-group a product should belong. Other nutritional criteria, such as the criteria of the GEMRCN¹⁸ for mass catering (GEMRCN 2015), were also applied (in particular to determine the minimum calcium content to consider for characterising sweetened dairy desserts) in order to place the foods in one or other sub-group.

Distribution of dairy-based foods among the sub-groups of the "Dairy products" group

This involved distributing the dairy-based foods (products sold in the fresh produce section such as dairy-based and cream desserts, yoghurts, white cheese (*fromage blanc*) or ice creams, etc.) among the sub-groups identified in the previous part, i.e. plain fresh dairy products, sweetened fresh dairy products and sweetened dairy desserts.

¹⁸ Study group of the mass catering and nutrition market, practical guide on the nutritional quality of meals served in mass social catering.

Liquid creams and fresh creams were excluded and directly classified on the basis of their associated consumption practices into the "Sauces, fresh creams and condiments" group. Similarly, sweetened whipped cream (*chantilly*) was placed directly in the "Sweet or sweet and fatty products" group because of its high fat content.

The remaining products were then distinguished on the basis of their calcium content. To do this, the threshold used in the GEMRCN criteria for mass catering was applied: all products containing less than 80 mg of calcium per 100 g of food were ruled out and placed in the "Sweet or sweet and fatty products" group.

All products considered subsequently therefore contained more than 80 mg of calcium/100 g. They were distributed among the identified sub-groups according to their sugar content (this criterion emerged as a priority compared to the fat content in the initial results of the ascending hierarchical classification):

The "Plain fresh dairy products" encompassed the unsweetened products (without added sugar or fruit). They were characterised by a sugar content below 5 g/100 g and mainly included yoghurts, white cheese (*fromage blanc*) and plain *petit suisse*.

The "Sweetened fresh dairy products" grouped together products containing added sugars but whose sugar content was below 15 g/100 g (this threshold corresponds to the maximum sugar content observed for a sweetened fruit yoghurt): it mainly concerned sweetened and/or fruit yoghurts and *petit suisse* with fruit. Artificially sweetened products were also included in this group because some of them contain fruits or sometimes added sugars.

The "Sweetened dairy desserts" encompassed products containing more than 15 g of sugars per 100 g: they mainly include cream desserts, jelly desserts and ice creams.

Distribution of sweetened foods among the "Starch-based, sweet/fatty processed products" sub-group and the "Sweet or sweet and fatty products" group

This involved distributing sweetened cereal-based foods (biscuits, breakfast cereals, cakes, etc.) among these two sub-groups based on their sugar, starch and fat content. The thresholds used to classify these products were defined from a broader ascending hierarchical classification carried out on sweetened products as a whole (biscuits, cakes, confectionery, breakfast cereals, pastries, croissant-like pastries, chocolate bars, jams, etc.). This was used to characterise a class of sweetened starch-based foods with a minimum starch content of 30 g/100 g, a sugar content below 45 g/100 g and a fat content below 18 g/100 g.

Thus, to distribute the sweetened cereal-based foods between the "Starch-based, sweet/fatty processed products" and the "Sweet or sweet and fatty products", the following criteria were applied:

- Foods containing less than 30 g of starch per 100 g were placed directly in the "Sweet or sweet and fatty products" group. This was the case for example with croissant-like pastries, certain cakes, biscuits and pastries.
- Among the foods containing more than 30 g of starch per 100 g, the foods with a high sugar or fat content (respectively above 45 g/100 g and 18 g/100 g) were placed in the "Sweet or sweet and fatty products" group. This was the case with certain biscuits (shortbread biscuits, for example).

Thus, the "Starch-based, sweet/fatty processed products" sub-group ultimately brought together products such as breakfast cereals, cereal bars and certain dry biscuits, containing more than 30 g of starch, less than 45 g of sugars and less of 18 g of fats for 100 g.

5.2.3 List of groups

The categorisation methods used as described then enabled 32 sub-groups to be defined. These sub-groups encompass foods that are relatively homogeneous in terms of nutritional composition, particularly regarding the nutrients of interest to public health (i.e. whose intakes are remote from the population reference intakes, being either too high or too low). In addition, these sub-groups are consistent with consumption practices. However, due to the rapid development of the food supply, some products now found on the market, for example soy-based products, could not be taken into account when establishing the sub-groups (see 5.2.2).

The food consumption optimisation was thus performed on these 32 sub-groups described in **Table 25**.

Table 25: Summary of the groups and sub-groups created for categorising the foods

| Groups from the 2001 PNNS dietary guidelines | Summary of arguments for the identification of a sub-group or the creation of a group | Sub-groups established | Examples of foods | Updated groups |
|---|---|--|---|--|
| Fruits and vegetables | Distinction between fruits/vegetables because of the different sugar content Distinction between fresh fruits/dried fruits because of the different sugar content Processed fruits: separation into two sub-groups suggested by the AHC Oilseeds considered separately given their energy density and alpha-linolenic acid content | Fresh fruits | Apples, bananas, oranges | Fruits and vegetables |
| | | Dried fruits | Dried apricots, prunes | |
| | | Processed fruits: purees and cooked fruit | Fruit purees, fruits in syrup | |
| | | Vegetables | Courgettes, carrots, tomatoes, green beans, sweetcorn, green peas | |
| | | Oilseeds | Walnuts, almonds | |
| Starches: Breads, cereals, potatoes and dried vegetables | Useful to distinguish bread from other starches given that the ways in which it is consumed differ from those of other starches Useful to separate wholegrain starches from refined starches given the fibre content Identification of the "Starch-based, savoury/fatty processed products" and "Starch-based, sweet/fatty processed products" subgroups to take account of the fat, salt and sugar added during the manufacture/preparation of certain foods | Wholegrain bread and bread products | Wholegrain bread and rusks | Starches |
| | | Refined bread and bread products | White bread and rusks | |
| | | Starch-based, sweet/fatty processed products | Breakfast cereals | |
| | | Starch-based, savoury/fatty processed products | French fries, snack biscuits | |
| | | Other wholegrain starches | Brown rice, whole wheat | |
| | | Other refined starches | Rice, pasta, boiled potatoes | |
| | Pulses: Group identified as requiring a separate classification in view of the high protein and fibre content | Pulses | Kidney beans, chickpeas, lentils, broad beans | Pulses |
| Meat and poultry, fishery products, eggs | Distinction between meat, poultry and delicatessen meats, on the basis of epidemiological data and differences in nutritional composition Oily fish distinguished from other fishery products (including molluscs and | Delicatessen meats | Sausage, ham, pâté | Meat and delicatessen meats, fishery products, eggs (VPO) |
| | | Eggs | Eggs | |
| | | Oily fish | Salmon, mackerel, sardine, herring | |
| | | Other fish, molluscs and crustaceans | Cod, bass, bream, mussels, shrimp | |

| Groups from the 2001 PNNS dietary guidelines | Summary of arguments for the identification of a sub-group or the creation of a group | Sub-groups established | Examples of foods | Updated groups |
|--|---|---|---|--|
| | crustaceans) given the levels of n-3 fatty acids and contaminants | Red meat | Beef, veal, pork, mutton, lamb, horse, offal, game | |
| | | Poultry | Chicken, duck | |
| Milk and dairy products | Distinction between milk, cheese and all dairy-based desserts sold in the fresh produce section due to different nutritional compositions and modes of consumption Among the dairy-based desserts sold in the fresh produce section: creation of three sub-groups on the basis of their sugar, calcium and fat content | Sweetened dairy desserts | Cream desserts, ice-creams | Milk and dairy products |
| | | Cheeses | Soft, pressed cheeses | |
| | | Milk | Semi-skimmed milk, whole milk | |
| | | Plain fresh dairy products | Plain yoghurts, white cheese (<i>fromage blanc</i>) | |
| | | Sweetened fresh dairy products | Sweetened yoghurts | |
| Added fats | Distinction between different sub-groups for added fats according to the results of an AHC based on the content in total fats, alpha-linolenic acid, oleic acid and the sum of the content in lauric, myristic and palmitic acids | Butter and reduced-fat butter | Butter | Added fats |
| | | Vegetable oils rich in ALA | Rapeseed oil, walnut oil | |
| | | Vegetable oils poor in ALA and margarines | Sunflower oil, olive oil | |
| | | Sauces, fresh creams and condiments | Mayonnaise, fresh cream | |
| Sweetened products | All foods that exceed 45 g of sugars/100 g and 18 g of fats/100 g were included in this group | Sweet or sweet and fatty products | Jam, croissant-like pastries, biscuits, cakes | Sweet or sweet and fatty products |
| Beverages | Distinction between water and sugar-sweetened beverages on the basis of the sugar content | Drinking water | Water | Water |
| | | Sugar-sweetened beverages such as soda | Sodas, lemonade | Sugar-sweetened beverages |
| | | Fruit juice | Orange juice | |
| Salt | | Salt | Salt | Salt |

5.3 Optimisation method

As described above, the aim was to propose food combinations able to cover the nutritional requirements as a whole, taking into account exposure to food contaminants, while preventing chronic non-communicable diseases, and straying as little as possible from current food habits and preferences.

5.3.1 Principle of the tool used

The aim was to calculate the daily consumption X_g of each sub-group of foods g for each of the populations considered, to ensure that the nutritional requirements were covered, without exceeding the maximum nutritional or toxicological limits, and while remaining within a range of intakes observed in the population.

Linear programming of combined models was used to calculate the optimal consumption of each food sub-group. This involved searching for solutions to a combinatorial decision problem subject to constraints, with the aim of maximising or minimising an evaluation function known as the objective function.

The analysis program was developed in C++ language and uses the IBM® CPLEX solver. The algorithm uses the method known as "simplex" (Dantzig 1963), which was previously used for the development of food rations. The algorithm helps determine a target value by successive iterations on one or more variables, taking into account the constraints imposed. The algorithm searches for the only optimal solution in the domain of possible ones corresponding to a polyhedron with N dimensions defined by the constraints. As the solution is optimal, it is necessarily located on a vertex (Dantzig 1963) (see **Figure 2**).

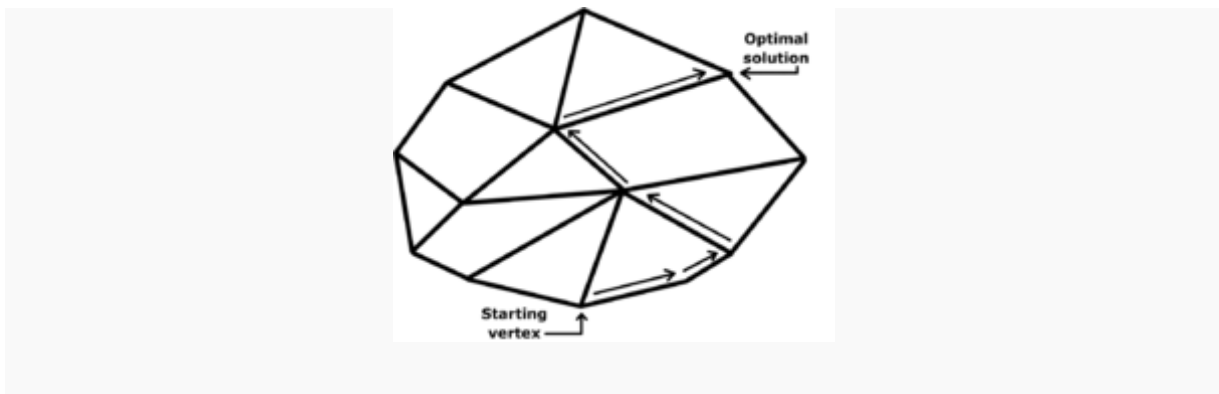


Figure 2. Illustration of the simplex algorithm

The nutritional constraints, those related to consumption habits and those related to contaminants can be integrated in the optimisation tool by means of inequalities.

The objective function corresponds to a combination of several criteria, reflecting the objectives of this work: to minimise deviations from current consumption, minimise (or maximise) the consumption of certain food sub-groups in order to prevent non-communicable diseases (see Section 3) and possibly minimise the exposure to contaminants.

Two additional criteria can later be included in the optimisation tool: minimisation of the breach of the nutritional constraints and of the toxicological constraints. These criteria enable some constraints to be made flexible, i.e. by allowing the optimisation tool not to achieve certain nutritional target values or to exceed certain toxicological references, but they introduce the objective of staying as close to them as possible.

5.3.2 Mathematical definition of the constraints and criteria

As indicated above, constraints on nutrient intakes, contaminant exposure and consumption can be defined by means of inequalities. This involves identifying, for a given population, the daily consumption X_g of each food sub-group g , able to cover the nutritional requirements without exceeding the maximum limits. As X_g is a quantity consumed, the variable X_g is positive or zero.

The nutrient intakes are calculated according to the formula:

$$I_i = \sum_{g=1}^{32} X_g \cdot C_{g,i}$$

where:

- I_i is the average daily intake of nutrient i ;
- X_g is the theoretical optimal consumption of the food sub-group g ;
- $C_{g,i}$ is the concentration of nutrient i in the food sub-group g (see Section 5.5.2);
- 32 is the total number of food sub-groups included in the optimisation tool.

Similarly, exposure to contaminants is calculated according to the formula:

$$E_i = \frac{1}{BW} \sum_{g=1}^{32} X_g \cdot C_{g,i}$$

where:

- E_i is the average daily exposure to contaminant i ;
- BW is the body weight of the population considered (see Section 5.4.1);
- X_g is the theoretical optimal consumption of the food sub-group g ;
- $C_{g,i}$ is the concentration of contaminant i in the food sub-group g (see Section 5.5.3);
- 32 is the total number of food sub-groups included in the optimisation tool.

The constraints on the nutrient intakes and that relating to energy can be included in the optimisation tool for each population according to the formula:

$$I_i \geq \text{PRI, AI or lower bound of the reference intake range (referred to hereafter as the lower nutritional constraint)}$$

$$\text{or } I_i \leq \text{UL or upper bound of the reference intake range (referred to hereafter as the upper nutritional constraint)}$$

Similarly, constraints on contaminant exposure can be included for each population according to the formula:

$$E_i \leq \text{HBGV or exposure not to be exceeded}$$

In addition, constraints on the consumptions X_g can be added for each population, for example to take account of existing consumption levels, according to the formulae (see Sections 5.4.3 and 5.4.4):

$$X_g \geq \text{lower consumption limit and } X_g \leq \text{upper consumption limit}$$

Concerning the constraints on intakes of total fats, the sum of lauric, myristic and palmitic acids, total SFAs, total carbohydrates and proteins, the intake limits to be reached or not exceeded were formulated as a percentage of total energy intake¹⁹. These limits were

¹⁹ As alcohol is not included in the recommendations in this document, the consumption of alcoholic beverages was not taken into account in this optimisation work. Therefore, in this report, TEI corresponds to energy intake without alcohol.

therefore converted into kilocalories, on the basis of the total energy intake resulting from the optimisation (5.4.1).

The objective function corresponds to a combination of terms to be minimised (the deviations from average consumption, the consumption of certain food sub-groups, and possibly exposure to contaminants) or maximised (the consumption of other food sub-groups).

In order to minimise the consumption deviations, two additional variables were created for each food sub-group g , measuring the deviation from average consumption: "PositiveDeviation(g)" and "NegativeDeviation(g)". These variables are positive or zero. In order to overcome the differences of scale between the consumptions in the various sub-groups, the deviations from average consumption were related to the standard deviation of the average consumption (standardisation). Thus, the term to be minimised can be expressed according to the following formula for all the food sub-groups g :

$$\sum_g \left[\frac{\text{PositiveDeviation}(g) + \text{NegativeDeviation}(g)}{\text{StandardDeviationCons}(g)} \right]$$

The consumption of certain sub-groups can be minimised directly in the objective function. In order to overcome the differences of scale between the consumptions in the various sub-groups, the consumptions resulting from the optimisation were related to the upper consumption limit established. Thus, the minimised term can be expressed according to the following formula for all the food sub-groups g :

$$\sum_g \left[\frac{\text{OptimalCons}(g)}{\text{Upper consumption limit}(g)} \right]$$

The consumption of certain sub-groups can be maximised by minimising the opposite of "OptimalCons". In order to overcome the differences of scale between the consumptions in the various sub-groups, the consumptions resulting from the optimisation were also related to the upper consumption limit established. Thus, the minimised term can be expressed according to the following formula for all the food sub-groups g :

$$\sum_g \left[\frac{-\text{OptimalCons}(g)}{\text{Upper consumption limit}(g)} \right]$$

Exposure to contaminants can be minimised directly in the objective function. In order to overcome the differences of scale between exposures to different substances, the exposures resulting from the optimisation (see above) were related to the maximum exposure (MaxExpo), which corresponds either to the HBGV (or toxicological constraint) or, in the case where there is no toxicological constraint, to the median exposure estimated in the TDS2. Thus the minimised term can be expressed according to the following formula for each substance i :

$$\sum_g \left[\frac{\text{Exposure}(i)}{\text{MaxExpo}(i)} \right]$$

As indicated above, criteria for minimising the breach of the constraints can be integrated in order to make the nutritional or toxicological constraints flexible. To do this, flexibility parameters are added and further variables are created, called goal variables. The flexibility parameter is equal to 1 if the constraint has been made flexible, otherwise it is equal to 0. The goal variable measures the difference between a target value and the result of the optimisation. For example, if the constraint relating to achieving the dietary reference value for vitamin D is made flexible, the "Flexibility_PRI(VitD)" parameter will be equal to 1 and the goal variable "Goal_PRI(vitD)" will measure the difference between the vitamin D intake resulting from the optimisation and the PRI that has not been reached. In order to overcome the differences of scale between the different dietary intakes and between the exposures to different substances, the deviations from the target value were related to the target value (PRI, UL or maximum exposure). Thus the minimised terms can be expressed according to the following formulas, respectively to minimise the breach of the nutritional and toxicological constraints:

$$\sum_i \left[\frac{\text{Flexibility_PRI}(i) \times \text{Goal_PRI}(i)}{\text{PRI}(i)} + \frac{\text{Flexibility_UL}(i) \times \text{Goal_UL}(i)}{\text{UL}(i)} \right]$$

$$\text{and } \sum_i \left[\frac{\text{Flexibility_MaxExpo}(i) \times \text{Goal_MaxExpo}(i)}{\text{MaxExpo}(i)} \right]$$

5.4 Choice of constraints

5.4.1 What level of energy requirement should be considered for the optimisation?

Besides the dietary reference values for vitamins, minerals and macronutrients, it was necessary to set the level of energy intake used as the target in the optimisation.

Initially, the intention was to perform optimisations for several levels of energy requirement (low, median and high requirements). However, the nutritional requirement for nutrients is more or less dependent on the energy requirement and is determined in a sample of the population regarded as representative of the general population. Thus, the AR is only valid for the general population to the extent that the energy requirements of the general population are similar to those of the sample. Accordingly, to consider a population with low energy requirements, the dietary reference values for this population must be available. It was therefore decided to assume that this was a population with an energy requirement corresponding to the median requirement of the French population.

Estimating the energy requirement assumes knowledge of the energy expenditure related to the basal metabolism of the individuals in a population, which itself is estimated from the age, sex, height and weight, as well as the physical activity level (PAL). Thus, the energy requirement is calculated by multiplying the basal metabolism by the PAL²⁰.

To estimate the median energy requirement of the general adult population, the conclusions of EFSA's report were adopted for estimating the basal metabolism (EFSA 2013c). These conclusions reveal that none of the five predictive equations that can be used in adults were preferable to the others (Harris and Benedict 1919, Henry 2005, Mifflin *et al.* 1990, Muller *et al.* 2004, Schofield *et al.* 1985). Thus, for each age group and each sex, the WG estimated the basal metabolism according to these five equations. Similarly, for each age group and each sex, the reference weight was calculated to obtain a BMI of 22 kg/m² from the median height of the population reported in the INCA2 study. Indeed, more than 40% of the individuals in the population of the INCA2 study were overweight or obese. In order to estimate the requirement of a population of normal weight, it was decided to consider not the actual weight but a weight corresponding to a normal BMI. A presumed healthy BMI of 22 was selected because it falls in the centre of the range (20-25) regarded as healthy and already used by EFSA in its calculations of energy requirement (EFSA 2013c).

This simulation is summarised in **Table 26** below.

²⁰ The PAL is calculated as the ratio between energy expenditure over 24 h and the basal metabolism. It corresponds to the average MET (Metabolic Equivalent of a Task) over 24 h.

Table 26. Estimate of the basal metabolism (kcal/d) according to the median height of the population reported by INCA2 and the five predictive equations selected by EFSA

| Men | | | Basal metabolism (kcal/d) | | | | |
|-------------|--------------------------|---|---------------------------|--------------|------------------------|-------------|------------|
| Age group | INCA2 median height (cm) | Weight (kg) for BMI of 22 kg/m ² | Schofield 1985 | Mifflin 1990 | Harris & Benedict 1919 | Müller 2004 | Henry 2005 |
| 18-29 years | 178 | 69.7 | 1742 | 1696 | 1753 | 1708 | 1659 |
| 30-39 years | 178 | 69.7 | 1673 | 1642 | 1679 | 1670 | 1579 |
| 40-49 years | 176 | 68.1 | 1655 | 1564 | 1580 | 1617 | 1557 |
| 50-59 years | 174 | 66.6 | 1637 | 1487 | 1481 | 1565 | 1535 |
| 60-69 years | 172 | 65.1 | 1350 | 1410 | 1383 | 1514 | 1411 |
| Women | | | Basal metabolism (kcal/d) | | | | |
| Age group | INCA2 median height (cm) | Weight (kg) for BMI of 22 kg/m ² | Schofield 1985 | Mifflin 1990 | Harris & Benedict 1919 | Müller 2004 | Henry 2005 |
| 18-29 years | 163 | 58.5 | 1353 | 1324 | 1403 | 1340 | 1319 |
| 30-39 years | 163 | 58.5 | 1321 | 1270 | 1352 | 1302 | 1261 |
| 40-49 years | 163 | 58.5 | 1321 | 1220 | 1305 | 1267 | 1261 |
| 50-59 years | 161 | 57 | 1309 | 1144 | 1241 | 1217 | 1248 |

Concerning the PAL, the Working Group used the data of the Scientific Advisory Committee on Nutrition (SACN 2011), which estimated the PAL from 929 measurements of 24-hour energy expenditure, carried out with the doubly labelled water method, the reference technique. The conclusions concerning a healthy adult population gave a median PAL of 1.63, corresponding to a low level of activity, and values at the 25th and 75th percentiles of 1.49 and 1.78, respectively. Applied to the basal metabolism values estimated according to the five equations, this median PAL of 1.63 was used to estimate the median energy requirements of French men and women according to their age between 18 and 79 years and for a BMI of 22 kg/m². The calculations are summarised in **Table 27** below.

Table 27: Estimate of the energy requirement (kcal/d) according to the median height of the population reported by INCA2 and the five predictive equations selected by EFSA from a median PAL of 1.63

| Men | | Energy requirement (kcal/d) for a median PAL of 1.63 | | | | |
|-------------|----------------|--|------------------------|-------------|------------|--|
| Age group | Schofield 1985 | Mifflin 1990 | Harris & Benedict 1919 | Müller 2004 | Henry 2005 | |
| 18-29 years | 2839 | 2764 | 2857 | 2784 | 2704 | |
| 30-39 years | 2727 | 2676 | 2737 | 2722 | 2574 | |
| 40-49 years | 2698 | 2533 | 2575 | 2636 | 2538 | |
| 50-59 years | 2668 | 2424 | 2414 | 2551 | 2502 | |
| 60-69 years | 2201 | 2298 | 2254 | 2468 | 2300 | |
| Women | | Energy requirement (kcal/d) for a median PAL of 1.63 | | | | |
| Age group | Schofield 1985 | Mifflin 1990 | Harris & Benedict 1919 | Müller 2004 | Henry 2005 | |
| 18-29 years | 2205 | 2157 | 2288 | 2184 | 2150 | |
| 30-39 years | 2153 | 2069 | 2204 | 2122 | 2055 | |
| 40-49 years | 2153 | 1989 | 2127 | 2065 | 2055 | |
| 50-59 years | 2134 | 1865 | 2023 | 1984 | 2034 | |

This simulation was used to define a mean energy requirement of 2600 kcal/d and 2100 kcal/d (averages performed on all values, all age groups obtained from the five equations) for men aged 18 to 69 years and women aged 18 to 59 years, respectively (**Figure 3** below).

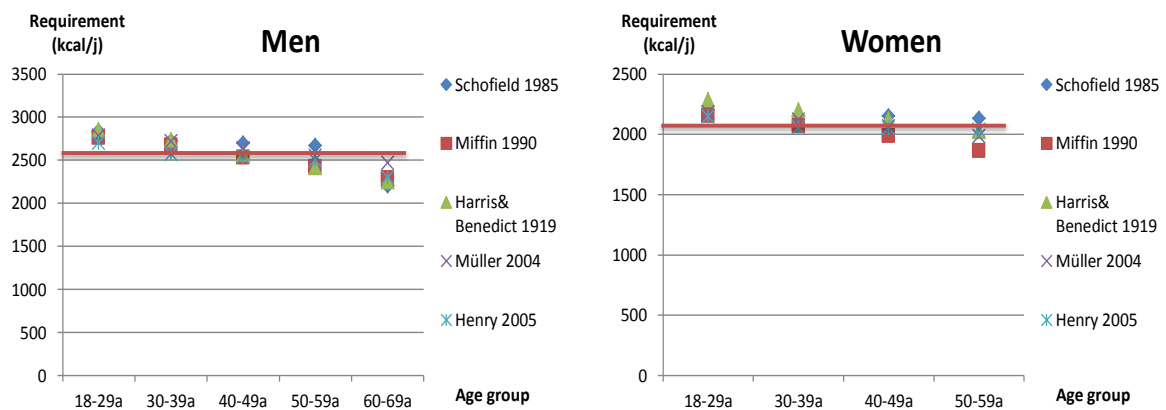


Figure 3. Energy requirement (kcal/d) of men and women estimated according to age and the predictive equation of the basal metabolism

In the optimisation tool, a 5% variation around these values was authorised, so that the lower dietary reference value was 2470 kcal for men and 1995 kcal for women, and the upper dietary reference value was 2730 kcal for men and 2205 kcal for women.

5.4.2 How should the dietary reference values be used?

What type of reference should be used?

As described in Section 2.1, the types of dietary reference values defined differ depending on the nutrients, which raises the question of the choice of the type of dietary reference value to be taken into account in the optimisation.

In the interests of covering the nutritional requirements of the majority of the population, the population reference intakes were chosen because they cover the requirements for 98% of the population. Failing this, the adequate intakes were used. However, some of the adequate intakes were established on the basis of observed intakes, with a level of evidence deemed too low to be able to integrate them in the optimisation tool. Thus, for these nutrients (vitamins B5 and E, manganese), no dietary reference value was included in the optimisation tool. However, a check was made to ensure that the quantities of nutrients proposed by the optimisation solutions were of the same order of magnitude as the intakes currently observed in France (in the INCA2 study).

This approach is therefore protective, to the extent that it is able to cover the greatest needs and thus avoid inadequate intake for 98% of the population. Accordingly, the nutrient intakes proposed by the optimisation tool will be higher than the individual requirements for the majority of French people.

Specific case of sodium

In the absence of dietary reference values (a "lower" value, such as a PRI or AI, or an "upper" value, such as a UL) for sodium that have been validated thus far by the WG and the CES on "Human Nutrition", the question arose as to whether to introduce a constraint value in the optimisation tool. Given the intakes observed today with regard to the public health objectives, the risk of excessive sodium intakes was regarded as greater than the risk of insufficient intake. The need to introduce a maximum bound for sodium intake in the optimisation tool was thus agreed. In this situation, the most protective and robust option is an objective not to increase sodium intakes in the population. This equates to using the sodium intakes observed today as the upper bound. The median consumption was selected as the indicator of observed intakes: the aim of this choice was to reduce the intakes of the half of the population with higher intakes, in agreement with the public health policies (PNNS). The median intakes from the INCA2 data on sodium are as follows (excluding sodium from salt added at the table): 2273 mg for women (i.e. around 5.8 g of salt) and 2994 mg for men (around 7.6 g of salt). These values were therefore chosen as the upper nutritional constraints, i.e. the values not to be exceeded.

Because the WHO advocates an equimolar sodium/potassium ratio, this constraint was introduced in the optimisation tool to ensure that the molar intake in potassium was above or equal to that in sodium.

Summary of nutritional constraints selected

With regard to zinc, EFSA has proposed four PRI values depending on the phytate content of the diet (300, 600, 900 and 1200 mg/d) (EFSA 2014i). This content increases in line with higher intakes of fruits and vegetables. The WG estimated the phytate intakes in the general French population to be between 300 and 900 mg/d (on the basis of intake data from several countries, synthesised and summarised in EFSA's opinion). Accordingly, for phytate intakes between 300 and 900 mg/d, the PRI selected for zinc vary between 9.4 and 14 mg/d for men and between 7.5 and 11.0 mg/d for women. EFSA states that the median phytate intakes for the adult population in the United Kingdom are between 600 and 900 mg/d, according to age and sex. Taking the estimated median intakes of the British population as a reference, the WG proposed selecting as the nutritional constraint for zinc in the optimisation tool the value

corresponding to phytate intakes of 900 mg/d for the general adult population, i.e. a PRI for zinc of 14 mg/d for men and 11 mg/d for women. This is consistent with the objective of maximising intakes in wholegrain cereal products. In the absence of data on phytate composition, it was not possible to adapt the reference value for zinc to the phytate intakes likely to be obtained in the optimisation solutions.

With regard to the upper intake level for vitamin B3, which is presented in the form of either nicotinic acid or nicotinamide, it should be noted that an upper intake level has been set at 10 mg for nicotinic acid and 900 mg for nicotinamide. These two forms of intake have not been differentiated in the nutritional composition tables. It has been estimated that vitamin B3 occurs in food largely in the form of nicotinamide, which argued in favour of the introduction of an upper intake level of 900 mg/d as an upper nutritional constraint in the optimisation tool.

Moreover, in general, for the vitamins involved in energy metabolism, such as vitamins B1, B2 and B3, the lower nutritional constraint was related to the kilocalorie, by converting the dietary reference value initially expressed in megajoules, in order to be able to express it in proportion to the energy intake from the optimisation solutions.

With regard to vitamin B9, there is no upper intake level (UL) for folate (natural form of vitamin B9), but there is one for folic acid, which has been set at 1000 µg. Because folates are by far the predominant form found in food, the UL of 1000 µg relative to folic acid was not introduced as a constraint in the optimisation tool.

With regard to calcium, one PRI has been defined for subjects aged 18 to 25 years (1000 mg) and another for those over 25 years of age (950 mg). As the optimisation was performed for the population over 18 years of age, it was necessary to choose one single lower nutritional constraint. The value of 1000 mg was chosen because it is able to cover the requirements of the entire adult population, regardless of age.

With regard to water, in the same way as for energy, lower and upper nutritional constraints were defined within a range of 5% around the value recommended by EFSA (2000 g for women and 2500 g for men) (EFSA 2010b). Thus, the lower nutritional constraint was set at 2375 g for men and 1900 g for women, and the upper nutritional constraint was set at 2625 g for men and 2100 g for women.

With regard to vitamin D, the PRI was established assuming endogenous synthesis via exposure to the sun to be zero. This extreme hypothesis was selected because it is not possible to estimate the level of endogenous synthesis, as this varies greatly according to the individuals (in particular due to the colour of the skin), the time spent outdoors, and the latitude where the individual lives.

Nevertheless, this PRI is difficult to achieve by current food consumption alone (AFSSA 2009). Thus, the lower nutritional constraint for vitamin D cannot be regarded as a blocking constraint in the exploitation of the optimisation solutions and could be made flexible if necessary.

With regard to iron, for the female population it was decided to carry out two different optimisation scenarios to comply with the non-Gaussian distribution of requirements for iron, according to the level of menstrual losses and as a result of the mode of contraception. The following approaches were therefore proposed:

- a "low iron" approach for women with normal to low menstrual losses, in particular women using hormonal contraception;
- and a "high iron" approach for women whose menstrual losses are high.

All of the nutritional constraints integrated in the optimisation tool are shown in **Table 28** below.

Table 28: Nutritional constraints introduced in the optimisation tool

| Nutrient | Lower nutritional constraints | | Upper nutritional constraints | |
|-------------------------------------|--|--------------------------------------|-------------------------------|------------------------|
| | Men (18-64 years) | Women (18-54 years) | Men (18-64 years) | Women (18-54 years) |
| Energy (kcal) | ≥ 2470 | ≥ 1995 | < 2730 | < 2205 |
| Vitamin A (µg/d) | ≥ 750 | ≥ 650 | < 3000 | < 3000 |
| Vitamin B1 (mg/kcal) | ≥ 0.00058 | ≥ 0.00058 | - | - |
| Vitamin B2 (mg/kcal) | ≥ 0.00071 | ≥ 0.00071 | - | - |
| Vitamin B3 (mg NE/kcal) | ≥ 0.0067 | ≥ 0.0067 | < 900 | < 900 |
| Vitamin B5 (mg) | - | - | - | - |
| Vitamin B6 (mg) | ≥ 1.8 | ≥ 1.5 | < 25 | < 25 |
| Vitamin B9 (µg DFE) | ≥ 330 | ≥ 330 | - | - |
| Vitamin B12 (µg) | ≥ 4 | ≥ 4 | - | - |
| Vitamin C (mg) | ≥ 110 | ≥ 110 | - | - |
| Vitamin D (µg) | ≥ 15 | ≥ 15 | < 50 | < 50 |
| Vitamin E (mg) | - | - | < 300 | < 300 |
| Calcium (mg) | ≥ 1000 | ≥ 1000 | < 2500 | < 2500 |
| Copper (mg) | ≥ 1.25 | ≥ 1 | < 5 | < 5 |
| Iodine (µg) | ≥ 150 | ≥ 150 | < 600 | < 600 |
| Iron (mg) | ≥ 11 | ≥11 "low iron" or ≥16 "high iron" | - | - |
| Magnesium (mg) | ≥ 420 | ≥ 360 | - | - |
| Manganese (mg) | - | - | - | - |
| Phosphorus (mg) | ≥ 700 | ≥ 700 | - | - |
| Potassium (mg) | Calculated so that the Na/K molar ratio is less than or equal to 1 | | - | - |
| Selenium (µg) | ≥ 70 | ≥ 70 | < 300 | < 300 |
| Sodium (mg) | - | - | < 2994 | < 2273 |
| Zinc (mg) | ≥ 14 | ≥ 11 | < 25 | < 25 |
| Water (g) | ≥ 2375 | ≥ 1900 | < 2625 | < 2100 |
| Proteins (% TEI) | ≥ 10 | ≥ 10 | < 20 | < 20 |
| Fats (% TEI) | ≥ 35 | ≥ 35 | < 40 | < 40 |
| Total saturated fatty acids (% TEI) | - | - | < 12 | < 12 |
| Lauric + myristic + palmitic acids | - | - | < 8 | < 8 |
| Linoleic acid (% TEI) | ≥ 4 | ≥ 4 | - | - |
| α-linolenic acid (% TEI) | ≥ 1 | ≥ 1 | - | - |
| Linoleic acid / α-linolenic acid | - | - | < 5 | < 5 |
| EPA + DHA (mg) | ≥ 500 | ≥ 500 | - | - |
| Carbohydrates (% TEI) | ≥ 40 | ≥ 40 | < 55 | < 55 |
| Total sugars excluding lactose (g) | - | - | < 100 | < 100 |
| Fibres (g) | ≥ 30 | ≥ 30 | - | - |

DFE, dietary folate equivalent; DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; NE, niacin equivalent; TEI, total energy intake.

5.4.3 How should the epidemiological relationships be expressed?

The analysis of epidemiological studies on the relationships between the food sub-groups and the risk of chronic diseases (see Section 3.2) highlighted an increased risk associated with the consumption of:

- red meat;
- processed meats, which in France mainly correspond to delicatessen meats (*charcuterie*);
- sugar-sweetened beverages, without being able to make a distinction between fruit juices, nectars and sodas.

This analysis also highlighted a reduced risk of diseases associated with the consumption of fruits and vegetables and wholegrain cereal products (bread and starches).

The objective to minimise the level of consumption of red meat, delicatessen meats and sugar-sweetened beverages, and maximise that of fresh fruits, vegetables and wholegrain breads and other starches, was introduced into the optimisation tool.

Consumptions of the food sub-groups associated with both an increase in the risk of certain diseases and a decrease in the risk of others (such as the fish sub-groups) were not assigned any maximisation or minimisation objectives.

In addition, although the data cannot be used to precisely determine a maximum intake quantity, it was deemed necessary to establish one for the sub-groups to be minimised, in order to adopt an approach that was sufficiently protective. This has the advantage of constraining the optimisation tool to propose quantities below those associated with the increased risks. Thus, in the case of red meat, a maximum weekly quantity of 500 g, or 71 g/d, corresponding to the quantity from which an increase in the risk of colorectal cancer is generally observed, was selected (see Section 3.2). For delicatessen meats, the value of 25 g/d, associated with increased risks, was adopted²¹. With regard to sugar-sweetened drinks, considerable increases in risk are observed with the consumption of one glass of sugar-sweetened beverage per day, without any more detailed information below this threshold. Thus, an upper consumption limit was set for all sugar-sweetened beverages (juices, nectars and sodas), corresponding to the median volume of the glass consumed in the INCA2 study, i.e. 263 g for men and 216 g for women (see **Table 29**).

5.4.4 How should consumption habits be taken into account?

Three levers were used to take account of the dietary habits of the population:

- taking consumption habits into account in the constitution of the 32 food sub-groups;
- introducing constraints relating to the consumption bounds (see below);
- introducing the objective not to stray too far from current average consumption.

The average content in each nutrient, estimated for each of the 32 food sub-groups, was calculated by weighting the nutritional composition of each food constituting the sub-group by the share represented by its consumption within the sub-group, as observed in the INCA2 study, for each population studied. Thus, a food that was actually more frequently consumed within a sub-group (e.g. apples among the fresh fruits) had a greater weight in the average composition of the sub-group than a food that was less frequently consumed. The same approach was followed for calculating average levels of contaminants.

In addition, to ensure that the consumption levels proposed by the optimisation tool remained within a range of realistic intakes, consumption limits were set for each food sub-group. As

²¹ There are no data available to date regarding the increased risk for lower levels of consumption (see Section 0)

well as ensuring the applicability of the solutions derived from the optimisation, this approach made it possible to propose quantities of foods actually consumed by certain individuals, about which we had a certain history of consumption, thereby limiting any possible risks associated with high consumption of food constituents for which no dietary reference values have been defined (such as phytosterols or polyphenols).

In most cases, these limits were based on the consumption levels estimated in the INCA2 study. The lower consumption limit selected was the level of intake of the food sub-group at the 5th percentile in the INCA2 study, while the upper limit was the level of intake of the food sub-group at the 95th percentile.

In the case of the sub-groups to be minimised (red meat, delicatessen meats and sugar-sweetened beverages), the maximum limits derived from epidemiological studies replaced those of the 95th percentile of consumption because they were lower (**Table 29**). For these same sub-groups, for which the aim was to minimise consumption, the lower consumption limit was set to zero.

Moreover, it was considered that the consumption of certain sub-groups could replace that of another sub-group, without compromising their applicability for the consumer. This was the case with the following sub-groups:

- "Wholegrain bread and bread products" could replace the "Refined bread and bread products" sub-group;
- "Other wholegrain starches" could replace the "Other refined starches" sub-group;
- "Vegetable oils rich in ALA" could replace the "Vegetable Oils poor in ALA and margarines" sub-group²².

To allow this substitution in the optimisation tool, no upper consumption limit was set for any of the sub-groups "Wholegrain bread and bread products", "Other wholegrain starches" and "Vegetable oils rich in ALA", but an upper limit combining the two replaceable sub-groups was set. This corresponds to the 95th percentile of consumption of the sum of the two replaceable sub-groups (**Table 29**). For example, a maximum consumption limit was assigned to the two "Bread" sub-groups together (wholegrain + refined), corresponding to the 95th percentile of consumption of all bread combined (wholegrain + refined).

Lastly, as described in Section 5.3, the objective function of the optimisation tool included the minimisation of the deviation from average consumption, in order not to stray too far from current consumption, for each of the sub-groups except those for which evidence from epidemiological studies was used (fresh fruits; vegetables; wholegrain bread and bread products; other wholegrain starches; red meat; delicatessen meats; sugar-sweetened beverages).

²² To be consumed according to the conditions of use defined in the AFSSA Opinion of 22 June 2005 on the change in the criterion of distinction between vegetable oils for "seasoning" and for "frying and seasoning" based on the alpha-linolenic acid content (AFSSA 2005).

Table 29. Summary of consumption bounds for each food sub-group entered in the optimisation tool

| Food sub-groups | Men | | | | Women | | | |
|--|-------------------------------|---------------------------|-------------------------------|----------------------------|-------------------------------|---------------------------|-------------------------------|----------------------------|
| | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) |
| Vegetables | 16 | 123 | 285 | - | 21 | 124 | 282 | - |
| Fresh fruits | 0 | 115 | 376 | - | 0 | 111 | 332 | - |
| Dried fruits | 0 | 1 | 3 | - | 0 | 1 | 4 | - |
| Processed fruits: purees and cooked fruit | 0 | 8 | 53 | - | 0 | 12 | 57 | - |
| Oilseeds | 0 | 2 | 9 | - | 0 | 1 | 5 | - |
| Refined bread and bread products | 0 | 102 | 260 | 284 | 0 | 60 | 161 | 177 |
| Wholegrain bread and bread products | 0 | 16 | No upper limit | | 0 | 12 | No upper limit | |
| Other refined starches | 14 | 113 | 255 | 257 | 14 | 83 | 193 | 193 |
| Other wholegrain starches | 0 | 3 | No upper limit | | 0 | 2 | No upper limit | |
| Starch-based, sweet/fatty processed products | 0 | 14 | 71 | - | 0 | 15 | 61 | - |
| Starch-based, savoury/fatty processed products | 0 | 27 | 79 | - | 0 | 20 | 57 | - |
| Pulses | 0 | 14 | 64 | - | 0 | 11 | 50 | - |
| Poultry | 0 | 38 | 122 | - | 0 | 25 | 75 | - |
| Red meat | 0 | 64 | 71 | - | 0 | 41 | 71 | - |
| Delicatessen meats | 0 | 39 | 25 | - | 0 | 26 | 25 | - |
| Oily fish | 0 | 5 | 27 | - | 0 | 4 | 25 | - |
| Other fish | 0 | 23 | 70 | - | 0 | 22 | 67 | - |
| Eggs | 0 | 13 | 46 | - | 0 | 12 | 43 | - |
| Milk | 0 | 98 | 386 | - | 0 | 87 | 350 | - |

| Food sub-groups | Men | | | | Women | | | |
|---|-------------------------------|---------------------------|-------------------------------|----------------------------|-------------------------------|---------------------------|-------------------------------|----------------------------|
| | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) | Lower consumption limit (g/d) | Average consumption (g/d) | Upper consumption limit (g/d) | Upper coupling limit (g/d) |
| Plain fresh dairy products | 0 | 28 | 129 | - | 0 | 36 | 157 | - |
| Sweetened fresh dairy products | 0 | 42 | 154 | - | 0 | 47 | 161 | - |
| Sweetened dairy desserts | 0 | 18 | 86 | - | 0 | 16 | 57 | - |
| Cheeses | 0 | 36 | 94 | - | 0 | 24 | 65 | - |
| Butter and reduced-fat butter | 0 | 6 | 26 | - | 0 | 4 | 17 | - |
| Vegetable oils rich in ALA | 0 | 0 | No upper limit | 21 | 0 | 0 | No upper limit | 16 |
| Vegetable oils poor in ALA and margarines | 0 | 5 | 20 | | 0 | 4 | 16 | |
| Sauces, fresh creams and condiments | 0 | 13 | 43 | - | 0 | 14 | 39 | - |
| Sweet or sweet and fatty products | 0 | 68 | 174 | - | 1 | 59 | 141 | - |
| Drinking water | 0 | 775 | 2000 | - | 51 | 806 | 1886 | - |
| Sugar-sweetened beverages such as soda | 0 | 93 | No upper limit | 263 | 0 | 58 | No upper limit | 216 |
| Fruit juice | 0 | 59 | No upper limit | | 0 | 61 | No upper limit | |
| Salt | 0 | 0 | 1 | - | 0 | 0 | 1 | - |

The boxes in yellow represent the consumption limits from the INCA2 consumption data (P5 for the lower limit and P95 for the upper limit). The boxes in red represent the consumption limits introduced following epidemiological justifications. The food sub-groups in green are coupled sub-groups, i.e. sub-groups for which the limit relates to consumption of the sum of the two sub-groups.

5.4.5 How should chemical compounds be taken into account?

Case of substances whose use is regulated

Because food additives and pesticides (excluding those identified as persistent organic pollutants, or POPs) are products subject to authorisation at European level, they were not considered for the definition of the constraints integrated in the optimisation tool. Indeed, the European process of assessment and authorisation of additives and pesticides, as well as the establishment of maximum residue limits (MRLs) and authorised uses, take dietary habits into account, as well as agricultural practices for pesticides. For this study, it was considered that the reduction of contaminations, exposures and risks should take place through a change to the authorised uses (e.g. reduction in doses or frequency of doses applied for pesticide residues) and should not affect the definition of dietary guidelines. As soon as health problems related to contamination levels are identified, the population should be informed in order to enlighten them as to their modes of consumption. Nevertheless, in the medium term, it is important for regulatory provisions to be implemented in order to protect consumers regardless of their dietary habits.

On the other hand, it is worthwhile testing *a posteriori* the food-based dietary guidelines in order to determine whether they are compatible with the ADIs for additives and pesticide residues, with a view to reconsidering, if applicable, the maximum limits authorised in foods. The substances considered *a posteriori* in the framework of this study are presented, together with their TDIs, in **Annex 3**.

Other contaminants

The situation is very different in the case of environmental contaminants for which there may be more limited room for manoeuvre to restrict the contamination of foods. Bisphenol A (BPA) is considered among these contaminants. In some cases, consumption recommendations are necessary; this is already the case, for example, for some fish.

Therefore, to define the constraints to be integrated in the optimisation tool, 98 substances or groups of substances were considered out of the 325 analysed in the TDS2 (see list shown in **Table 30**).

What type of reference should be taken into account?

Three cases can be distinguished:

- For contaminants with a threshold dose, the reference value considered to be most relevant was identified by the experts, as indicated in Section 4, on the basis of health-based guidance values (HBGVs) established by the main French, European or international scientific bodies. The exposure resulting from the optimisation can be compared directly to a HBGV.
- For contaminants without a threshold dose (the case with genotoxic compounds) or for which a benchmark dose limit²³, BMDL, has been chosen as the toxicological reference, the median exposure of the population estimated in the TDS2 (described in Section 5.5.3) was selected by default as the maximum value. Since a threshold

²³ The "benchmark dose limit" corresponds to the lower limit of the confidence interval of the benchmark dose. The benchmark dose is a dose producing a non-zero effect corresponding to a given level of response compared to a control group. This approach is based on modelling of the experimental data taking into account the entire dose-response curve.

cannot be selected for these contaminants, the decision was taken to prevent the exposure resulting from the optimisation being higher than the current exposure of the population. In this case, characterisation of the risk involved calculating a margin of exposure (MOE) for genotoxic carcinogenic substances, or a margin of safety (MOS) for non-genotoxic substances whose effects appear from a certain threshold. These margins of exposure or safety correspond to the ratio between a critical exposure (BMDL for example) and the exposure resulting from the optimisation. These margins were then compared to a critical margin defined when the BMDL was established by national and international bodies, in order to conclude as to the risk to the population.

- Lastly, for other chemical compounds, no maximum value was chosen as a constraint in the optimisation tool: these are chemical compounds for which no organisation has proposed a reference value, or for which the existing reference value(s) were not considered sufficiently robust. This is particularly the case with phyto-oestrogens.

The toxicological constraints are summarised in **Table 30**. Out of the 98 substances or groups of substances selected, 40 were assigned a maximum exposure limit (HBGV or median exposure from the TDS2). For the other 58, no maximum exposure limit was available. It was nevertheless necessary to seek to minimise their exposure and to introduce this minimisation in the "objective" function for all 98 substances or groups of substances.

In addition, all the exposures from the optimisation work will be compared with the results from the TDS2, which reflect the current situation in France. Any possible differences in exposure may therefore be due to differences both in terms of food intakes but also body weight (average weight for the TDS2 against "ideal" weight calculated from a BMI of 22).

Table 30: Summary of toxicological constraints used for the optimisation tool

| Classes | Substances | Toxicological constraints | Substances | Toxicological constraints |
|----------------|--------------------|---|---------------------------------|---|
| Trace elements | Aluminium | TWI = 1 mg/kg bw/wk (EFSA, 2013) | Cadmium | TWI = 2.5 µg/kg bw/d (EFSA, 2009) |
| | Germanium | No value | Tin | No value |
| | Antimony | No value | Gallium | No value |
| | Nickel | TDI = 2.8 µg/kg bw/d (EFSA, 2015) | Mercury | Organic Hg: PTWI = 1.3 µg/kg bw/wk (EFSA, 2012) Inorganic Hg: TWI = 4 µg/kg bw/wk (EFSA, 2012) |
| | Chromium | Cr(VI): TDS2 exposure Cr(III): TDI = 300 µg/kg bw/d (EFSA, 2014) | Lead | TDS2 exposure |
| | Cobalt | HBGV = 1.6 µg/kg bw/d (AFSSA, 2010) | Strontium | TDI = 0.6 mg/kg bw/d (US-EPA, 1996) |
| | Silver | No value | Tellurium | No value |
| | Inorganic arsenic | TDS2 exposure | Vanadium | No value |
| | Barium | RfD = 0.2 mg/kg bw/d (US-EPA, 2005) | | |
| Persistent | Dioxins and furans | HBGV = 0.7 pg TEQ _{WHO} /kg bw/d (US-EPA, 2012) | Hexabromocyclodo decane (HBCDD) | Sum of the 3 isomers: TDS2 exposure |

| Classes | Substances | Toxicological constraints | Substances | Toxicological constraints |
|---|--|--|---------------------------------|---|
| organic pollutants | Non dioxin-like polychlorinated biphenyls (NDL-PCBs) | TDI = 10 ng/kg bw/d (AFSSA, 2007) | Polybrominated biphenyls (PBBs) | TDS2 exposure |
| | Polybrominated diphenyl ethers (PBDEs) | Sum of the 7 PBDEs: HBGV = 10 ng/kg bw/d (AFSSA, 2007) BDE-209: TDS2 exposure | Perfluorinated compounds | PFOS: RfD = 0.08 µg/kg bw/d (US-EPA, 2009) PFOA: RfD = 0.2 µg/kg bw/d (US-EPA, 2009) Other compounds: - |
| Mycotoxins | Aflatoxins | TDS2 exposure | Ochratoxin A | PTWI = 0.12 µg/kg bw/wk (EFSA, 2006) |
| | Trichothecenes | T-2 and HT-2 toxins: PMTDI = 0.06 µg/kg bw/d (EFSA, 2011) Deoxynivalenol: TDI = 1 µg/kg bw/d (EFSA, 2007) Nivalenol: TDI = 1.2 µg/kg bw/d (EFSA, 2013) | Zearalenone and derivatives | TDI = 0.25 µg/kg bw/d (EFSA, 2014) |
| | Patulin | PMTDI = 0.4 µg/kg bw/d (JECFA, 1995) | Fumonisin | FB1 + FB2: PMTDI = 2 µg/kg bw/d (EFSA, 2014) |
| Heat-induced substances | Polycyclic aromatic hydrocarbons (PAHs) | PAH4: TDS2 exposure | Acrylamide | TDS2 exposure |
| Substances migrating from food contact materials | Bisphenol A (BPA) | Toxicological value = 0.083 µg/kg bw/d | | |
| Pesticide residues (Persistent organic pollutants) | Lindane (HCH-gamma) | ADI = 0.01 µg/kg bw/d | Endrin | ADI = 0.2 µg/kg bw/d |
| | Campechlor (toxaphene) | ADI = 0.033 µg/kg bw/d | HCH (sum, except for gamma-HCH) | ADI = 0.6 µg/kg bw/d |
| | Chlordane (sum) | ADI = 0.5 µg/kg bw/d | Heptachlor (sum) | ADI = 0.1 µg/kg bw/d |
| | DDT (sum) | ADI = 10 µg/kg bw/d | Hexachlorobenzene | ADI = 0.8 µg/kg bw/d |
| | Dieldrin (sum) | PTDI = 0.1 µg/kg bw/d | | |

TWI: Tolerable weekly intake, PTDI: provisional tolerable daily intake, ADI: acceptable daily intake, TDI: tolerable daily intake, PMTDI: provisional maximum tolerable daily intake, TDS2: 2nd total diet study, HBCDD: hexabromocyclododecane, HBGV: health-based guidance value, PBB: polybrominated biphenyl, PBDE: polybrominated diphenyl ether, PCB: polychlorinated biphenyl, PFOA perfluorooctanoic acid, PFOS: perfluorooctanesulfonic acid, RfD: reference dose,

5.5 Databases used as input in the optimisation

5.5.1 Consumption data

The consumption data used came from the INCA2 study conducted in 2006-07 in three phases, on 4079 individuals aged from 3 to 79 years old (1455 children from 3-17 years old and 2624 adults from 18-79 years old) (AFSSA 2009). Only the data for the men aged 18-64 years and women aged 18-54 years were used in this report.

Participants were selected according to a three-stage design, stratified by the size of the urban area and the region, from the 1999 population census and the sampling frame of new housing built between 1999 and 2004.

Data on consumption by the individuals in this sample were collected using a 7-day food consumption diary in which they noted the type of foods and quantities consumed, estimated using a photograph manual, standard units or household measures. Each line in the diary corresponded to a food (or beverage) consumed. Each collected line of food was codified using a nomenclature specifically developed for the INCA2 study and containing 1342 items. A weighting was applied to each individual to ensure their representativeness at national level (metropolitan France excluding Corsica). It focused on the following parameters: the region, the size of the urban area, the size of the household, the sex of the surveyed individual, his/her age and profession and social category of the head of the family.

In the results presented in this opinion, the individuals identified as under-reporting their energy intake according to the method developed by Goldberg and collaborators (Goldberg *et al.* 1991) were retained in the sample. Indeed, according to EFSA, Goldberg's method could lead to subjects being excluded whose intakes are actually low during the survey period and ruling out certain obese individuals, while retaining subjects who really are under-reporters but have a high level of physical activity (EFSA 2014a). The under-reporters thus considered account for around 31% of the male population aged 18-64 years and 28% of the female population aged 18-54 years.

In addition, all individuals and not just the consumers of the food sub-group were considered for estimating the levels of consumption of each of the food sub-groups previously defined.

Thus, from these individual consumption data, the daily average consumption of each food sub-group (in g/d), as well as that estimated at the 5th and 95th percentiles, were estimated for each of the populations of interest.

5.5.2 Table of nutritional composition of foods

The data on the nutritional composition of the INCA2 foods used in the optimisation tool are based on those from the table produced by ANSES's French Information Centre on Food Quality (CIQUAL)²⁴. This composition table relates to the generic foods consumed in France and is produced by aggregating data collected by CIQUAL (data from the literature, *ad hoc* analyses, research projects, obtained from professionals or by calculations). However, the data used have been significantly improved compared to this last table:

- Data on lactose have been added. Lactose does not appear among the constituents currently published in the online CIQUAL table. The data were produced by aggregating data collected by CIQUAL.

²⁴ ANSES 2013 CIQUAL Table [online database]. <https://pro.anses.fr/TableCIQUAL/index.htm>

- Data on the individual fatty acids were updated based on the table produced by the CIQUAL in 2015 in the framework of internal request No. 2014-SA-0117 on estimating detailed fatty acid intakes in the French population and defining the prevalence of inadequate intakes in view of the ANCs established in 2010.
- Lastly, the data for vitamins and minerals were updated. In particular, the work in progress on production and validation of the forthcoming CIQUAL table to appear online was used to rule out a number of extreme levels deemed incompatible with the rest of the dataset.

The method of producing data to fill in the missing values is specified in **Annex 4**.

5.5.3 Table of contaminant levels in foods

The concentrations in the foods of contaminants, food additives and pesticide residues came from the second French total diet study (TDS2). Conducted between 2006 and 2011, this study presents a review of the contamination of the foods consumed in France, the exposure of the population and the health risk associated with this exposure, for 445 substances of interest (ANSES 2011).

The TDS2 focused on 212 food types, representing around 90% of the diet of the population, according to the INCA2 study. A sampling plan was developed between 2007 and 2009, so as to be representative of consumption habits in France, including the origin of the products, the places of purchase, the modes of storage, and also the domestic food preparation practices. The foods were collected in several regions over more than a year, in order to take account of any possible regional or seasonal variability in the concentrations. In all, 20,000 food products were purchased, prepared as consumed by the population, packaged in 1319 composite samples, and analysed for the substances of interest. Thus, each sample analysed was a composite sample of 15 sub-samples of the same food, reflecting the consumption of the population.

In the present study, the left-censored concentration data (i.e. the results below the analytical limits) were processed according to an average assumption ("middle bound"). Thus, the values below the limit of detection were assumed to be equal to half this limit, and the values below the limit of quantification but above the limit of detection were assumed to be equal to half the limit of quantification or, where applicable, half of the sum of the two limits.

In addition, because trace elements were analysed for their total form only, for three of them (mercury, arsenic and chromium), speciation assumptions were applied to the concentrations in order to obtain an estimate of the concentrations of their different chemical forms.

- Concerning mercury, it was assumed, according to the "maximum" assumptions, that in fish, 100% of the mercury was in the form of methylmercury and 20% in the form of inorganic mercury (EFSA 2012a). For molluscs and crustaceans, it was assumed that 80% of the mercury was in the form of methylmercury and 50% in the form of inorganic mercury. For the other foods, it was assumed that the mercury was present only in the form of inorganic mercury. The use of the maximum assumption leads to a total higher than 100%.
- Concerning arsenic, it was assumed that 100% of the arsenic was in inorganic form in water (EFSA 2014b). In the other foods, it was assumed that 70% of the arsenic was in inorganic form and 30% in organic form.
- Concerning chromium (EFSA 2014c), a maximalist approach was adopted that assumed that, firstly, 100% of the chromium in food was in the form of Cr(III) and secondly, 10% of the chromium was in the form of Cr(VI). For water, it was assumed

that 100% of the chromium was in the form of Cr(VI). As for methylmercury, the use of the maximum assumption leads to a total higher than 100%.

5.5.4 Exposure data

The data on exposure to contaminants and pesticide residues, as well as the data on intakes in food additives, came from the TDS2. These were median and average values for exposure and intakes estimated in the French population on the basis of the estimated consumptions in the INCA2 study, the concentrations in food measured in the TDS2 and the average weight of individuals from the INCA2 study. To enable a comparison to be made between the TDS2 exposure values and the solutions from the optimisation tool, the same average assumption ("middle bound") was used.

5.6 General optimisation approach

In order to assess the effect of each of the constraints and test their compatibility with each other, a step-by-step approach was followed. First, the mutual compatibility of the nutritional constraints (i.e. the dietary reference values and the data from epidemiology) was tested by integrating in the tool only the nutritional constraints and criteria (Scenario A). Then, the consumption habits were also taken into account by including the constraints relating to the consumption bounds as well as the criterion to minimise deviations from the average consumption (Scenario B). Lastly, the constraints and criteria related to contaminants were added to test the compatibility of all the constraints and estimate the impact on the proposed solution of taking the contaminants into account (Scenario C).

Scenario B did not integrate the contaminants since they are extrinsic components of the food whose impact needs to be reduced, whereas the nutrients are intrinsic components of the food and are sought to cover the body's needs. This scenario represents a long-term view, in which effective management measures may have resulted in a reduction in contamination levels such that they no longer interfere in the determination of the food-based dietary guidelines.

Taking the contaminants into account (excluding additives and pesticides apart from POPs, see Section 5.4.5) as an optimisation constraint (Scenario C) aimed to propose a solution that takes account of the reality of current contamination levels, and to study the influence of taking the contaminants into account on food consumption. This short- and medium-term approach does not rule out the establishment of possible management measures aiming to reduce contamination levels, on the contrary.

Food additives and pesticide residues (excluding POPs) are substances subject to authorisation at European level and it is therefore the responsibility of the authorities to determine conditions of use that are compatible with the food-based dietary guidelines.

This approach was applied to the studied populations with adaptations specific to each one, which are presented below.

5.7 Results of the optimisation

5.7.1 Results of the optimisation for adult men

Approach followed for men (Figure 4)

An initial optimisation was carried out taking only the nutritional and epidemiological constraints into account (Scenario A0). The solution obtained was very remote from the consumption habits and varied little in terms of food sub-groups.

Integration of the consumption bounds in the optimisation tool (Scenario B0) did not enable a solution to be reached. Thus, the constraint for vitamin D was made flexible (reaching the PRI for vitamin D is no longer an obligation but the optimisation seeks to get as close as possible to it). Indeed, the PRI for vitamin D was established without considering the endogenous synthesis of vitamin D and is very difficult to reach in the current food context. This scenario yielded the solution presented below. In order to measure the impact of integrating consumption habits in the optimisation tool, a Scenario A1 (with flexibility on the vitamin D constraint) was generated and will be presented here.

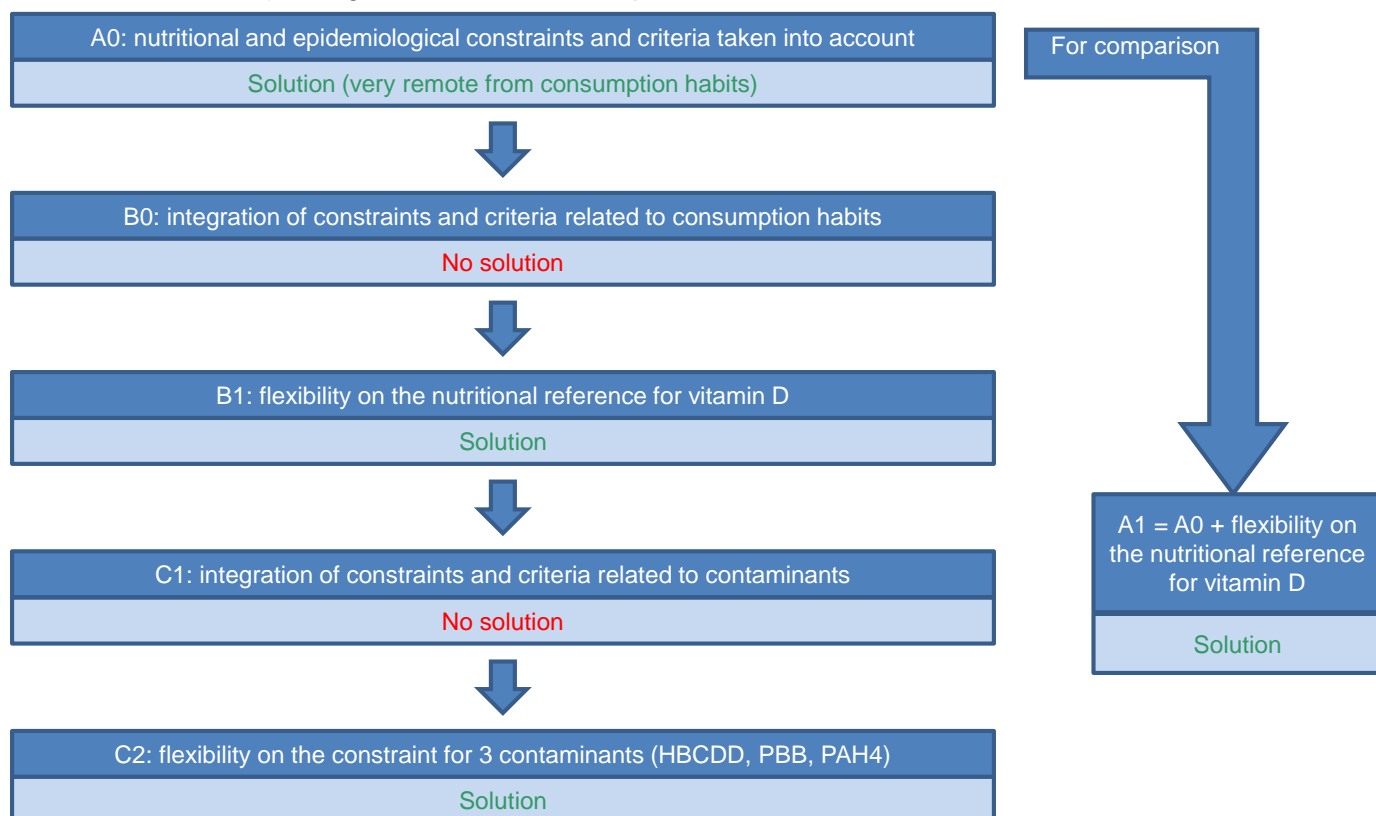


Figure 4. Approach followed for men

Lastly, integrating the contaminants in the optimisation tool (Scenario C0 and C1 with flexibility on the PRI for vitamin D) did not yield a solution. Thus, the constraints on three contaminants were made flexible: HBCDD, PAH4 and PBB (Scenario C2). Indeed for these contaminants, the CES ERCA determined that the margins of exposure or safety were high enough for them to be unlikely to cause a health risk. Therefore, it was assumed that a small increase in the level of exposure above that of the TDS2 was unlikely to lead to a risk. This scenario yielded the solution presented below.

Scenario A1: only the nutritional and epidemiological constraints were taken into account

In this scenario, only the nutritional and epidemiological constraints were taken into account, while providing flexibility to the constraint for vitamin D.

- Food intakes

The optimisation carried out according to Scenario A1 proposed a small number of food sub-groups (**Table 31**), with large quantities of vegetables (1.3 kg/d) and plain wholegrain cereal products (800 g/d). With regard to the group "Meat, delicatessen meats, fishery products and eggs" (VPO), the optimisation solution gave preference to eggs (around 3 eggs/d) and red meat (63 g/d) rather than poultry (0 g/d). The quantity of delicatessen meats proposed was at the maximum limit imposed by the epidemiological data. Among the dairy products, only cheese (29 g/d) was proposed. The proposed sources of added fat were more varied (butter, oils rich in ALA and other oils). No sweetened products (in either solid or liquid form) were proposed.

Table 31: Consumption levels proposed by Scenario A1 for adult men

| Food sub-group | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food group (g/d) |
|--|---|---------------------------------|--|-------------------------------|-------------------------------|---|
| Vegetables | 1352 | 123 | 998 | no limit ²⁵ | no limit | Fruits and vegetables excluding oilseeds 1352 |
| Fresh fruits | 0 | 115 | -100 | no limit | no limit | |
| Dried fruits | 0 | 0.8 | -100 | no limit | no limit | |
| Processed fruits: purees and cooked fruit | 0 | 8.5 | -100 | no limit | no limit | |
| Oilseeds | 0 | 1.5 | -100 | no limit | no limit | |
| Refined bread and bread products | 0 | 102 | -100 | no limit | no limit | Starches 798 |
| Plain Wholegrain bread and bread products | 0 | 16 | -100 | no limit | no limit | |
| Starch-based, sweet/fatty processed products | 0 | 14 | -100 | no limit | no limit | |
| Starch-based, savoury/fatty processed products | 0 | 27 | -100 | no limit | no limit | |
| Other refined starches | 0 | 113 | -100 | no limit | no limit | |
| Other plain wholegrain starches | 798 | 2.5 | 31427 | no limit | no limit | |
| Pulses | 0 | 14 | -100 | no limit | no limit | Pulses 0 |
| Poultry | 0 | 38 | -100 | no limit | no limit | Meat and delicatessen meats, fishery products, eggs 272 |
| Red meat | 63 | 64 | -0.61 | no limit | 71 | |
| Delicatessen meats | 25 | 39 | -37 | no limit | 25 | |

²⁵ The absence of a limit was expressed in the tool by 0 for the lower limit and 1000000 for the upper limit

| Food sub-group | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food group (g/d) |
|---|---|---------------------------------|--|-------------------------------|-------------------------------|--|
| Oily fish | 26 | 5 | 459 | no limit | no limit | |
| Other fish | 0 | 23 | -100 | no limit | no limit | |
| Eggs | 158 | 13 | 1145 | no limit | no limit | |
| Milk | 0 | 98 | -100 | no limit | no limit | Milk and dairy products 29 |
| Plain fresh dairy products | 0 | 28 | -100 | no limit | no limit | |
| Sweetened fresh dairy products | 0 | 42 | -100 | no limit | no limit | |
| Sweetened dairy desserts | 0 | 18 | -100 | no limit | no limit | |
| Cheeses | 29 | 36 | -18 | no limit | no limit | |
| Butter and reduced-fat butter | 12 | 6 | 112 | no limit | no limit | Added fats 46 |
| Vegetable oils rich in ALA | 23 | 0.3 | 8493 | no limit | no limit | |
| Vegetable oils and margarines poor in ALA | 11 | 4.5 | 138 | no limit | no limit | |
| Sauces, fresh creams and condiments | 0 | 13 | -100 | no limit | no limit | |
| Sweet or sweet and fatty products | 0 | 68 | -100 | no limit | no limit | Sweet or sweet and fatty products 0 |
| Drinking water | 722 | 775 | -7 | no limit | no limit | Water 722 |
| Sugar-sweetened beverages such as soda | 0 | 93 | -100 | no limit | 263 | Sugar-sweetened beverages 0 |
| Fruit juice | 0 | 59 | -100 | no limit | | |
| Salt | 0.7 | 0.2 | 288 | no limit | no limit | Salt 0.7 |

The red boxes represent the consumption limits introduced following epidemiological justifications.

- Nutrient intakes

The nutrient intakes are presented in **Annex 5**. All the lower and upper nutritional constraints were respected, with the exception of the lower nutritional constraint for Vitamin D, for which intake was 5.4 µg/d.

- Exposure to contaminants

This scenario was not intended to serve as a basis for the food-based dietary guidelines since it did not incorporate dietary habits. By comparison with Scenario B, it was used to assess the impact on the optimisation of taking dietary habits into account; moreover, no analysis of exposure to contaminants was carried out at this stage.

Scenario B1: the nutritional and epidemiological constraints and also the consumption habits were taken into account

In this scenario, the nutritional and epidemiological constraints and also the consumption habits were taken into account, while introducing flexibility to the constraint for vitamin D.

- Food intakes

In this optimisation taking dietary habits into account, all the sub-groups were represented, except for the refined bread and bread products and sugar-sweetened beverages such as soda (**Table 32**). Proposed consumption of fresh fruits was trebled and that of vegetables was doubled compared to the average consumption of the French population, reaching the 95th percentile. Total intake of the fruits and vegetables group thus reached 679 g/d. Fruits were proposed almost exclusively in the form of fresh fruit. Starches were overwhelmingly proposed in wholegrain form, with their intake reaching 377 g/d. Optimised consumption of the VPO group was 235 g/d, and consisted overwhelmingly of red meat (71 g/d, i.e. the maximum limit based on the epidemiological data) and poultry (97 g/d). The proposed consumption of delicatessen meats remained well below the maximum limit based on the epidemiological data (10 vs 25 g/d). With regard to the "Milk and dairy products" group, only the consumption of milk was increased considerably (quadrupled) compared to the average consumption. Among the added fats, the consumption of vegetable oils rich in ALA was largely given preference²⁶, reaching 20 g/d.

²⁶ To be consumed according to the conditions of use defined in the AFSSA Opinion of 22 June 2005 on the change in the criterion of distinction between vegetable oils for "seasoning" and for "frying and seasoning" based on the alpha-linolenic acid content (AFSSA 2005).

Table 32: Consumption levels proposed by Scenario B1 for adult men

| Food sub-groups | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food groups (g/d) | |
|--|---|---------------------------------|--|-------------------------------|-------------------------------|--|-----|
| Vegetables | 285 | 123 | 131 | 16 | 285 | Fruits and vegetables excluding oilseeds 670 | |
| Fresh fruits | 376 | 115 | 228 | 0 | 376 | | |
| Dried fruits | 0.8 | 0.8 | 0 | 0 | 2.9 | | |
| Processed fruits: purees and cooked fruit | 8.5 | 8.5 | 0 | 0 | 53 | | |
| Oilseeds | 8.6 | 1.5 | 471 | 0 | 8.6 | | |
| Refined bread and bread products | 0 | 102 | -100 | 0 | 260 | Starches 377 | |
| Plain wholegrain bread and bread products | 79 | 16 | 398 | 0 | No limit | | 284 |
| Starch-based, sweet/fatty processed products | 14 | 14 | 0 | 0 | 71 | | |
| Starch-based, savoury/fatty processed products | 27 | 27 | 0 | 0 | 79 | | |
| Other refined starches | 14 | 113 | -87 | 14 | 257 | | 257 |
| Other plain wholegrain starches | 243 | 3 | 9489 | 0 | No limit | | |
| Pulses | 36 | 15 | 152 | 0 | 64 | Pulses 36 | |
| Poultry | 97 | 38 | 154 | 0 | 122 | VPO 235 | |
| Red meat | 71 | 64 | 12 | 0 | 71 | | |
| Delicatessen meats | 9.7 | 39 | -76 | 0 | 25 | | |
| Oily fish | 21 | 5 | 339 | 0 | 27 | | |
| Other fish | 23 | 23 | 0 | 0 | 70 | | |
| Eggs | 13 | 13 | 0 | 0 | 46 | | |

| Food sub-groups | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food groups (g/d) | |
|---|---|---------------------------------|--|-------------------------------|-------------------------------|--|----|
| Milk | 386 | 98 | 293 | 0 | 386 | Milk and dairy products 510 | |
| Plain fresh dairy products | 28 | 28 | 0 | 0 | 129 | | |
| Sweetened fresh dairy products | 42 | 42 | 0 | 0 | 154 | | |
| Sweetened dairy desserts | 18 | 18 | 0 | 0 | 86 | | |
| Cheeses | 36 | 36 | 0 | 0 | 94 | | |
| Butter and reduced-fat butter | 6 | 6 | 0 | 0 | 26 | Added fats 39 | |
| Vegetable oils rich in ALA | 20 | 0.3 | 7680 | 0 | No limit | | 21 |
| Vegetable oils and margarines poor in ALA | 0.4 | 4.5 | -91 | 0 | 20 | | |
| Sauces, fresh creams and condiments | 13 | 13 | 0 | 0 | 43 | | |
| Sweet or sweet and fatty products | 68 | 68 | 0 | 0 | 174 | Sweet or sweet and fatty products 68 | |
| Drinking water | 965 | 776 | 24 | 0 | 2000 | Water 965 | |
| Sugar-sweetened beverages such as soda | 0 | 93 | -100 | 0 | 263 | Sugar-sweetened beverages 5 | |
| Fruit juice | 5 | 59 | -92 | 0 | | | |
| Salt | 0.0 | 0.2 | -100 | 0 | 1.1 | Salt 0 | |

The yellow boxes represent the consumption limits from the INCA2 consumption data (P5 for the lower limit and P95 for the upper limit). The red boxes represent the consumption limits introduced following epidemiological justifications. The food sub-groups in green are coupled sub-groups, i.e. sub-groups for which the limit relates to consumption of the sum of the two sub-groups.

- Nutrient intakes

The nutrient intakes are presented in **Annex 6**. All the lower and upper nutritional constraints were respected, with the exception of the lower nutritional constraint for Vitamin D, for which intake reached 3.8 µg/d. Intakes of vitamins B5 and E, and of manganese were higher than the adequate intake, defined on the basis of the average intakes observed in INCA2, and were not integrated as a constraint in the optimisation tool.

Intakes of vitamin B1, zinc, fibre, total fats, ALA and EPA+DHA were limited to the lower nutritional constraint, which suggests that they were limiting factors in this optimisation.

- Exposure to the studied contaminants and food additives

Concerning the four food additives studied (Annex 7), for three out of the four, the exposure levels calculated according to Scenario B1 were lower than the exposure from the TDS2 and their respective ADI_{ss}. Only exposure to tartaric acid was above the exposure from the TDS2, but it was still below its ADI (0.2% of its ADI).

Concerning the substances excluding food additives and pesticides (Annex 8) for 39 out of the 93, exposure was above the average exposure estimated in the TDS2. The greatest difference was noted for hexabromocyclododecane (HBCDD, 7 times higher). This observation can be explained by the higher consumption of oily fish proposed by Scenario B1 compared to the average consumption from the INCA2 study. In addition, for certain substances, for which the health risk could not be ruled out in view of the results of the TDS2, exposure was lower. This was particularly the case with acrylamide, aluminium, deoxynivalenol, methylmercury, lead and cadmium.

However, while exposure to certain substances was higher than that estimated in the TDS2, it is important to emphasise that the values were mostly below the selected reference values (health-based guidance values or, when these were unavailable, the median exposure values from the TDS2). This was particularly the case with dioxins, furans and DL-PCBs (exposure was 4% higher than the exposure from the TDS2, and was 60% of the health-based guidance value) as well as the perfluoroalkyl acids PFOA and PFOS, for which exposure remained below 1% of their respective health-based guidance values. Lastly, for certain substances or groups of substance, exposure was higher than for the TDS2. However, these substances have no HBGV, making interpretation impossible in terms of the risks: this was particularly the case with the phyto-oestrogens, certain mycotoxins (ochratoxin B), perfluoroalkyl compounds (excluding PFOA and PFOS), organic arsenic, molybdenum and tin.

Only three substances presented exposure above the selected maximum values (namely the median exposure values from the TDS2). They were HBCDD (+800%), chromium(VI) (+5%) and inorganic arsenic (+27%).

- HBCDD: exposure was higher than in the TDS2, however the margin of safety was higher than 2000, bearing in mind that the critical margin of safety adopted by EFSA was 8 and the one selected by the CES ERCA was 25 (in the framework of the Infant TDS (Anses, 2016)). Given these critical margins, this exposure seems unlikely to lead to a health risk.
- Cr(VI): exposure was almost equivalent to that from the TDS2 (105%), but there nevertheless remains great uncertainty about the share of Cr(VI) in the total chromium measured (as a reminder, EFSA's very conservative assumptions were used here, see Section 5.5.3).

- Inorganic arsenic: exposure reached 127% of the median exposure estimated in the TDS2 and 103% of the average exposure, levels that were already considered to be of concern.

Concerning pesticide residues (Annex 9), among the 232 pesticides that had been analysed in the TDS2, the vast majority (78%) of substances (n = 182) presented exposure that was higher than in the TDS2. This difference in exposure levels can mainly be explained, for the majority of pesticides, by higher consumption levels of fruits and vegetables and, for a more limited number of substances, by higher consumption levels of cereals resulting from the optimisation according to Scenario B2.

Only exposure to lindane (HCH-gamma) exceeded the HBGV (109% of the ADI), which should be put in perspective in view of several points:

- the dietary exposure estimated according to Scenario B1 for lindane accounted for only 12% of the estimated exposure in the TDS2, i.e. the exposure resulting from Scenario B1 was lower;
- in the TDS2, lindane was only detected in three samples of foods of animal origin, despite the high coverage level of foods, contrary to other substances that were much more frequently detected;
- the HBGV was observed to have been exceeded when considering the HBGV of 0.01 $\mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ used in the recent expert appraisals (ANSES, 2014). However, when considering the ADI of 5 $\mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ of the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) (FAO/WHO 2002) used in the framework of the annual European *a posteriori* assessments (EFSA 2015a), exposure to lindane in this Scenario B1 remains lower than the HBGV.

A small proportion of substances (8%, n = 18) presented exposure levels between 10% and 100% of the ADI (**Annex 9**). More specifically, 3% (n = 7) were active plant protection substances authorised (A) according to Regulation No 1107/2009/EC, or were older pesticides now prohibited and listed in the Stockholm Convention on Persistent Organic Pollutants (POPs). These results should be considered alongside the exposure levels observed in more recent surveillance plans (**Annex 9**). Indeed, the method for managing censored data (substituting non-detected results by the LOD/2) could lead to exposure being overestimated (see Section 5.5.3).

Among these authorised active substances or POPs, three were frequently detected in the 2010 to 2013 national surveillance plans, and had already been identified in ANSES's most recent opinion on the updating of food risk indicators (ANSES, 2014). They are two organophosphate insecticides (chlorpyrifos-ethyl and dimethoate) detected in fruits and vegetables, and dithiocarbamate fungicides detected in leafy vegetables, in particular lettuces (**Annex 9**). For these three substances, the exposure levels estimated in Scenario B1 were higher than those estimated in the TDS2. These levels reached 152% of the TDS2 exposure for chlorpyrifos-ethyl (11% of the HBGV), 109% for dimethoate (66% of the HBGV) and 123% for the dithiocarbamates (17% of the HBGV). For these three substances, it will be necessary to maintain reinforced monitoring of levels of dietary exposure, as recommended in ANSES's most recent opinion (ANSES, 2014).

For the other 15 substances whose exposure was between 10 and 100% of the ADI, a chronic risk can be ruled out:

- 11 substances are not authorised in Europe, and have never or only rarely been detected²⁷ (in italics in the table in **Annex 9**);

²⁷ Due to the "middle bound" assumption, a substance that is never detected may nevertheless lead to exposure being calculated as non-zero.

- two authorised substances (ethoprophos and fipronil), never or only exceptionally detected;
- two POPs for which the levels estimated in Scenario B1 were 6 to 8 times lower than those from the TDS2 (including lindane).

Among the substances whose exposure was higher than that estimated in the TDS2, while not exceeding the ADI, some were classified as a priority in terms of monitoring of chronic dietary exposure in the Agency's most recent opinion (ANSES, 2014), and their exposure will be the subject of enhanced monitoring:

- abamectin
- bifenthrin
- boscalid: this substance was also particularly detected in fruits and vegetables
- beta-cyfluthrin
- cyromazine
- dimethoate
- etofenprox
- fipronil
- fluazifop-p
- fluquinconazole
- imazalil
- pyrethrins
- tau-fluvalinate
- tetraconazole
- thiabendazole

Scenario C2: the nutritional and epidemiological constraints, the consumption habits and the constraints related to contaminants were taken into account

This scenario took into account the nutritional and epidemiological constraints, the consumption habits and the constraints related to contaminants excluding pesticides and additives, but including POPs, while introducing flexibility on the constraints related to vitamin D, HBCDD, PAH4 and PBB.

- Food intakes

Taking the contaminants into account in the optimisation resulted in a decrease in the number of sub-groups consumed, compared to Scenario B1: consumption of milk, sweetened dairy products, delicatessen meats, butter, and vegetable oils and margarines poor in ALA was no longer proposed (**Table 33**). Consumption of fruits and vegetables, starches and, to a lesser extent, VPO was similar to that proposed in Scenario B1. The proposed consumption of pulses reached the maximum limit (95th percentile of consumption). The optimisation no longer proposed milk. The nutrients, mainly calcium, provided by milk in Scenario B1 appeared to be provided here by cheese, whose consumption more than doubled. With regard to the volume of water associated with the consumption of milk in Scenario B1, it was partly compensated by an increase in the consumption of fruit juices, which reached the maximum limit based on the epidemiological data. Among the added fats, the consumption of vegetable oils rich in ALA was given considerable preference²⁸ and reached the maximum limit, at the expense of butter and other vegetable oils.

²⁸ To be consumed according to the conditions of use defined in the AFSSA Opinion of 22 June 2005 on the change in the criterion of distinction between vegetable oils for "seasoning" and for "frying and seasoning" based on the alpha-linolenic acid content (AFSSA 2005).

Table 33. Consumption levels proposed by Scenario C2 for adult men

| Food sub-groups | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food groups (g/d) | |
|--|---|---------------------------------|--|-------------------------------|-------------------------------|---|-----|
| Vegetables | 285 | 123 | 131 | 16 | 285 | Fruits and vegetables excluding oilseeds 669 | |
| Fresh fruits | 376 | 115 | 228 | 0 | 376 | | |
| Dried fruits | 2.9 | 0.8 | 280 | 0 | 2.9 | | |
| Processed fruits: purees and cooked fruit | 5.5 | 8.5 | -34 | 0 | 53 | | |
| Oilseeds | 8.6 | 1.5 | 471 | 0 | 8.6 | | |
| Refined bread and bread products | 0 | 102 | -100 | 0 | 260 | Starches 375 | |
| Plain wholegrain bread and bread products | 70 | 16 | 345 | 0 | No limit | | 284 |
| Starch-based, sweet/fatty processed products | 31 | 14 | 126 | 0 | 71 | | |
| Starch-based, savoury/fatty processed products | 16 | 27 | -42 | 0 | 79 | | |
| Other refined starches | 14 | 113 | -87 | 14 | 257 | | 257 |
| Other plain wholegrain starches | 243 | 3 | 9489 | 0 | No limit | | |
| Pulses | 50 | 15 | 243 | 0 | 64 | Pulses 50 | |
| Poultry | 122 | 38 | 219 | 0 | 122 | Meat and delicatessen meats, fishery products, eggs 268 | |
| Red meat | 71 | 64 | 12 | 0 | 71 | | |
| Delicatessen meats | 0 | 39 | -100 | 0 | 25 | | |
| Oily fish | 22 | 5 | 371 | 0 | 27 | | |
| Other fish | 7 | 23 | -68 | 0 | 70 | | |
| Eggs | 46 | 13 | 260 | 0 | 46 | | |
| Milk | 0 | 98 | -100 | 0 | 386 | Milk and dairy products 218 | |
| Plain fresh dairy products | 122 | 28 | 338 | 0 | 129 | | |
| Sweetened fresh dairy products | 0 | 42 | -100 | 0 | 154 | | |
| Sweetened dairy desserts | 15 | 18 | -19 | 0 | 86 | | |

| Food sub-groups | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food groups (g/d) |
|---|---|---------------------------------|--|-------------------------------|-------------------------------|---|
| Cheeses | 81 | 36 | 127 | 0 | 94 | |
| Butter and reduced-fat butter | 0 | 6 | -100 | 0 | 26 | Added fats 25 |
| Vegetable oils rich in ALA | 21 | 0.3 | 7842 | 0 | No limit | |
| Vegetable oils poor in ALA and margarines | 0.4 | 4.5 | -100 | 0 | 20 | |
| Sauces, fresh creams and condiments | 4.4 | 13 | -66 | 0 | 43 | |
| Sweet or sweet and fatty products | 28 | 68 | -59 | 0 | 174 | Sweet or sweet and fatty products 28 |
| Drinking water | 1002 | 776 | 29 | 0 | 2000 | Water 1002 |
| Sugar-sweetened beverages such as soda | 0 | 93 | -100 | 0 | 263 | Sugar-sweetened beverages 263 |
| Fruit juice | 263 | 59 | 348 | 0 | | |
| Salt | 0.0 | 0.2 | -100 | 0 | 1.1 | Salt 0 |

The yellow boxes represent the consumption limits from the INCA2 consumption data (P5 for the lower limit and P95 for the upper limit). The boxes in red represent the consumption limits introduced following epidemiological justifications. The food sub-groups in green are coupled sub-groups, i.e. sub-groups for which the limit relates to consumption of the sum of the two sub-groups.

- Nutrient intakes

The nutrient intakes are presented in **Annex 10**. All the lower and upper nutritional constraints were respected, with the exception of the lower nutritional constraint for Vitamin D, which was 4.3 µg.

Intakes of vitamins B5 and E, and of manganese were higher than the adequate intake, defined on the basis of the average intakes observed in INCA2, and were not integrated as a constraint in the optimisation tool.

As in Scenario B1, intakes of vitamin B1, zinc, fibre, total fats, alpha-linolenic acid and EPA+DHA were limited to the lower nutritional constraint, which suggests that they were limiting factors in this optimisation. This was also the case here with iodine.

- Exposure to the studied contaminants and food additives

Concerning the four additives studied (Annex 11), the exposure levels according to Scenario C2 were lower than the exposure from the TDS2 and their respective ADIs.

Concerning the substances excluding food additives and pesticides (Annex 12):

For 20 out of the 93 substances, exposure was strictly above the average exposure estimated in the TDS2. The greatest differences were noted for HBCDD (around twice as high). These observations resulted from the higher consumption levels of oily fish selected in Scenario C2 compared to those from the INCA2 study. In addition, for certain substances, for which the risk could not be ruled out in view of the results of the TDS2, exposure was lower. This was particularly the case with acrylamide, aluminium, deoxynivalenol (DON), lead and cadmium.

Lastly, for certain substances or groups of substances, exposure was higher than for the TDS2. However, because no HBGVs have been selected, interpretation is impossible in terms of the health risks: this was particularly the case with certain phyto-oestrogens (such as coumestrol), one mycotoxin (ochratoxin B), molybdenum and tin.

Only HBCDD presented exposure above the maximum value selected, namely, the median exposure value from the TDS2 (+300%). Nevertheless, the margin of safety amounted to 660, bearing in mind that the critical margin of safety adopted by EFSA was 8 and the one selected by the CES ERCA was 25 (in the framework of the Infant TDS, (Anses, 2016)). The exposure therefore seems unlikely to lead to a health risk.

Concerning the pesticide residues:

Among the 232 pesticides that had been analysed in the TDS2, 79% of the substances (n = 184) presented exposure that was higher than that from the TDS2. This difference in exposure levels can mainly be explained, for the majority of pesticides, by higher consumption levels of fruits and vegetables and, for a more limited number of substances, by higher consumption levels of cereals resulting from the optimisation according to Scenario C2.

In this scenario, no pesticide presented exposure above the TDI. The highest dietary exposure concerned lindane (95% of the HBGV of 0.01 µg.kg bw⁻¹.i⁻¹ used by ANSES, see Scenario B1), which remained well below the exposure level estimated in the TDS2 (11%).

A small proportion of substances (8%, n = 19) presented exposure levels above 10% of the ADI (**Annex 13**). More specifically, 3% (n = 8) were active plant protection substances authorised (A) according to Regulation No 1107/2009/EC, or were older pesticides listed in the Stockholm Convention on Persistent Organic Pollutants (POPs). These results should be

considered alongside the exposure levels observed in more recent surveillance plans (**Annex 13**). Indeed, the method for managing censored data (substituting non-detected results by the LOD/2) could lead to exposure being overestimated (see 5.5.3).

Among these authorised active substances or POPs, three were frequently detected in the 2010 to 2013 national surveillance plans, and had already been identified in ANSES's most recent opinion on the updating of food risk indicators (ANSES, 2014). They are two organophosphate insecticides (chlorpyrifos-ethyl and dimethoate) detected in fruits and vegetables, and dithiocarbamate fungicides detected in leafy vegetables, in particular lettuces (**Annex 13**). For these three substances, the exposure levels estimated according to Scenario C2 were higher than those estimated in the TDS2. These levels reached 158% of the TDS2 exposure for chlorpyrifos-ethyl (11% of the ADI), 119% for dimethoate (73% of the ADI) and 152% for the dithiocarbamates (21% of the ADI). For these three substances, it is necessary to maintain reinforced monitoring of levels of dietary exposure, as recommended in ANSES's most recent opinion (ANSES, 2014).

For the other 16 active substances whose exposure was between 10 and 100% of the ADI, a chronic risk can be ruled out:

- 11 substances are not authorised in Europe, and have never or only rarely been detected²⁹ (in italics in the table in **Annex 13**);
- two authorised active substances (ethoprophos and fipronil), never or only exceptionally detected;
- three POPs for which the levels estimated in Scenario C2 were 6 to 8 times lower than those from the TDS2 (including lindane).

Among the substances whose exposure was higher than that in the TDS2, while not exceeding the ADI, some were classified as a priority in terms of monitoring of chronic dietary exposure in the Agency's most recent opinion (ANSES 2014), and their exposure will be the subject of enhanced monitoring. These were the same substances as for Scenario B1, with similar or lower exposure levels (**Annex 13**).

5.7.2 Results of the optimisation for women

Approach followed in women

Two separate approaches were followed, for women whose iron requirements are low and for those whose iron requirements are high (Section 2.2.5).

It was decided to begin with the optimisation for women with low iron requirements. Indeed, because the PRI for iron is less constraining in this population, the solutions are easier to identify. The approach followed for this population is shown in **Figure 5**.

An initial optimisation was carried out taking only the nutritional and epidemiological constraints into account (Scenario A0). As with the men, the solution obtained was very remote from the consumption habits and varied little in terms of food sub-groups.

Integration of the consumption habits in the optimisation tool (Scenario B0) did not yield a solution. Thus, the constraint for vitamin D was made flexible (reaching the PRI for vitamin D is no longer an obligation but the optimisation seeks to get as close as possible to it). Unlike the approach in men, this Scenario (B1) did not yield a solution either.

²⁹ Due to the "middle bound" assumption, a substance that is never detected may nevertheless lead to exposure being calculated as non-zero.

The nutrients for which the proposed intakes in Scenario B1 in men were at the level of the PRI and therefore regarded as limiting were then sought: these were vitamin B1, zinc, fats, alpha-linolenic acid, EPA+DHA and fibre. As the dietary reference values for vitamin B1, fats and alpha-linolenic acid are dependent on energy requirements, the intake to be reached (in absolute value) is lower for women, so it seems unlikely that it was these values that prevented a solution from being found. The PRI for zinc was established by making the assumption that phytate intakes were high (900 mg/d). Because this assumption could not be verified, the application of flexibility on the nutritional constraint for zinc (in addition to that on the nutritional constraint for vitamin D) was tested. The dietary reference value for fibre (30 g/d) is based on epidemiological data showing a beneficial effect from 25 g/d of fibre. It was therefore decided to apply a tolerance of 15% on the constraint for fibre, which corresponded to intakes above 25 g/d being imposed. With regard to EPA and DHA, the PRI was fixed at 500 mg/d on the basis of epidemiological studies highlighting a decrease in the risk of cardiovascular diseases, and possibly of metabolic syndrome, breast and colon cancer (AFSSA 2010a). Therefore, no relaxing of the PRI was tested. While the relaxing of the constraint for zinc did not lead to any solution, the application of a tolerance for fibre that required fibre intakes to be higher than 25 g/d, and as close as possible to 30 g/d, enabled a result to be obtained (Scenario "B2 low iron").

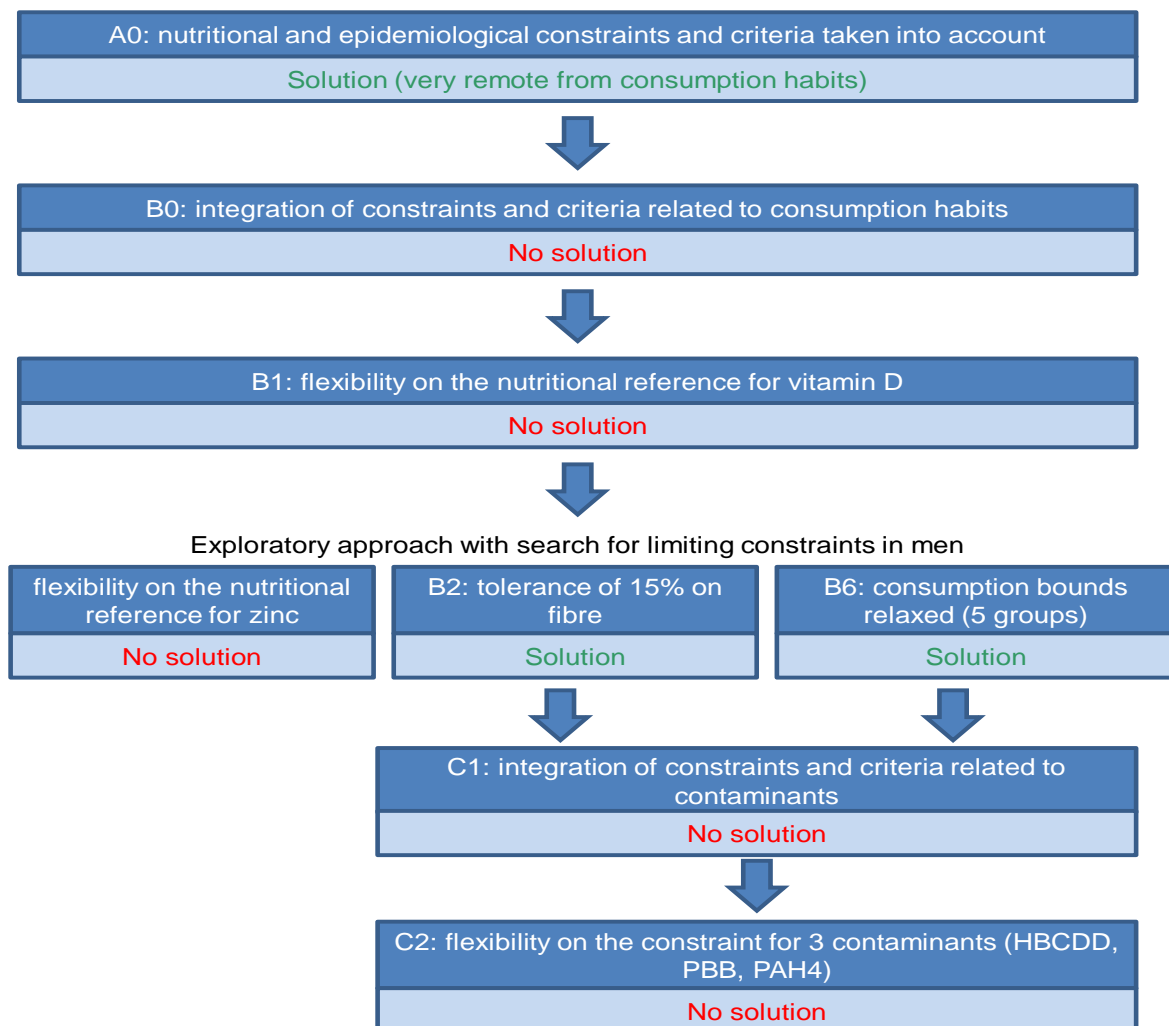


Figure 5. Approach followed for women with low iron requirements

For women whose iron requirements are high, a similar approach was followed with an initial optimisation that took into account only the nutritional and epidemiological constraints (Scenario "A0 high iron") (see **Figure 6**). As with the men, the solution obtained was very remote from the consumption habits and varied little in terms of food sub-groups.

As expected, in view of the results for women whose iron requirements are low, the integration of consumption habits in the optimisation tool (Scenario B0) did not yield a solution, any more than the application of flexibility on the nutritional constraint for vitamin D (Scenario B1).

As with the women whose requirements for iron are low, a tolerance of 15% for fibre was applied (Scenario B2) but was unable to yield a solution. By testing the introduction of an increasing tolerance level for iron, a solution was obtained with at most an iron intake of 13.52 mg (corresponding to a tolerance of 15.5%).

An exploratory approach was put in place by additionally applying a tolerance of 5% on all lower nutritional constraints except for those relating to water and energy, and 10% on all the upper consumption bounds except for those resulting from epidemiological relationships. This approach was unable to find a solution proposing 16 mg/d of iron, 15.2 mg of iron at most was reached but to the detriment of certain PRIs (calcium, ALA, EPA+DHA, vitamins C and D, and fibre) (Scenario B3 high iron).

It therefore seems impossible to find a solution taking the consumption habits into account with an iron intake of 16 mg/d. An intake of around 15 mg/d could help obtain solutions. This value corresponds in particular to the D-A-CH recommendation that was defined to cover the requirements of 90% of the female population.

An approach involving an increase in the consumption bound for sub-groups of iron-rich foods or those contributing predominantly to iron intake was followed. Among these food sub-groups, those for which consumption above the 95th percentile is acceptable and would help significantly increase iron intakes were identified. They are wholemeal bread, the sub-group "other fish", pulses, nuts and dried fruits. For these five groups, the upper bound was increased to the level of the highest serving (the definition of servings is described in **Annex 14**). This approach only yielded a solution by applying a tolerance of 15% on fibre (corresponding to a minimum intake of 25.5 g/d) and 6% on iron (which corresponds to an intake of 15 mg/d) (Scenario B4 high iron). Another optimisation was carried out by opening the consumption bounds for wholemeal bread, pulses, nuts and dried fruits without opening that of the sub-group "other fish", in order to limit exposure to certain contaminants and the consumption of VPO. It also yielded a solution (Scenario B5 high iron).

As this approach to relax five specific bounds helped obtain solutions, it was also used for women whose iron requirements are low (Scenario B6 low iron) and yielded a solution.

Lastly, if the contaminant-related constraints were added to the selected scenarios, no solution was obtained, whether for women whose iron requirements are low or those whose iron requirements are high, despite the application of flexibility for the constraints related to the three contaminants HBCDD, PAH4 and PBBS, as was done for the men (Section 5.7.1).

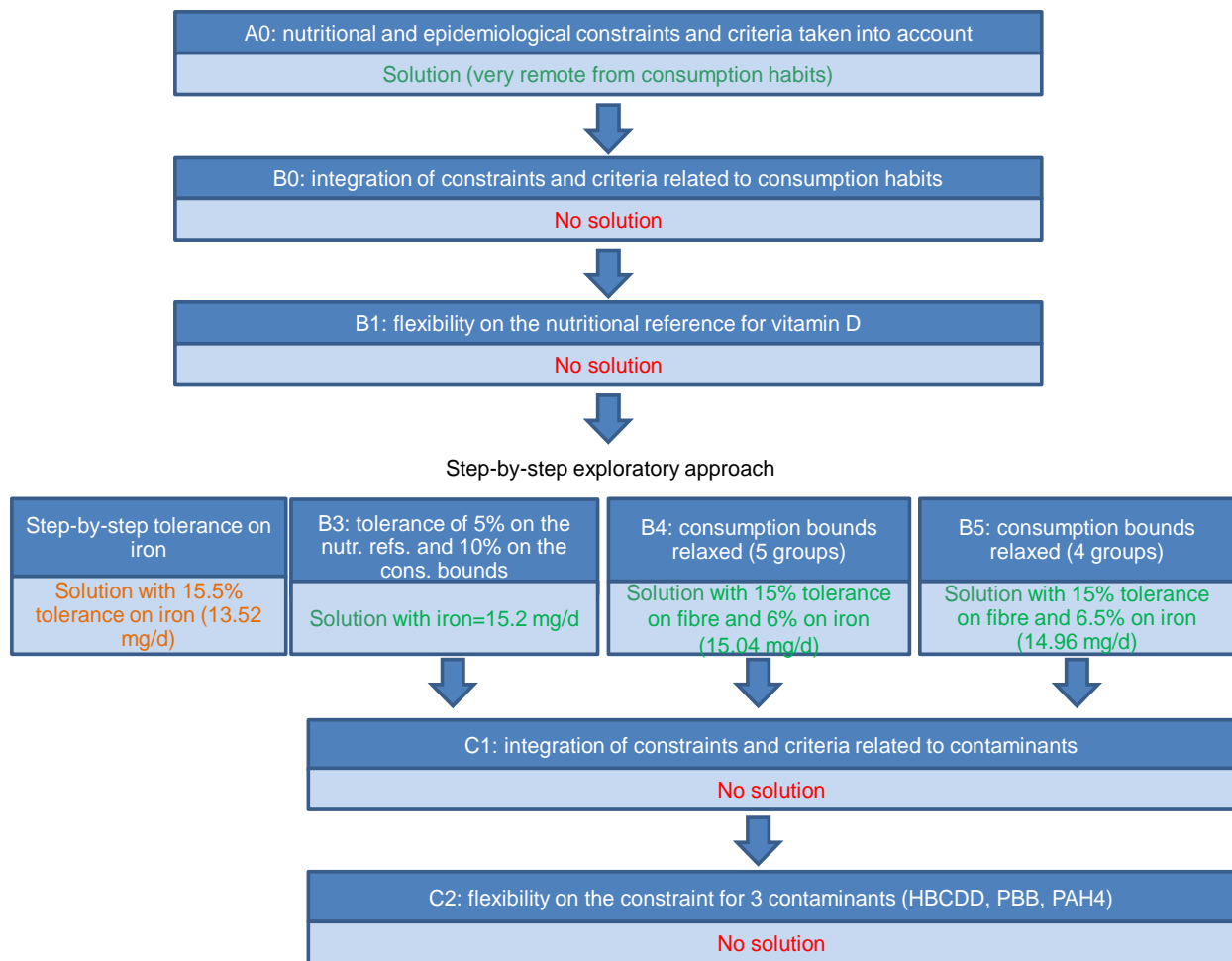


Figure 6. Approach followed for women with high iron requirements

Scenario A1: only the nutritional and epidemiological constraints were taken into account

In this scenario, only the nutritional and epidemiological constraints were taken into account, while providing flexibility to the constraint for vitamin D.

Only the results for women with high iron requirements are presented here.

- Food intakes (Table 34)

As with the men, the optimisation carried out according to Scenario A1 proposed a small number of food sub-groups (Section 5.7.1), with large quantities of vegetables (1 kg/d) and plain wholegrain starches (more than 600 g/d). With regard to the group "Meat, delicatessen meats, fishery products and eggs" (VPO), the optimisation solution gave preference to eggs (around 3 eggs per day) and oily fish. The quantity of delicatessen meats proposed was almost at the maximum limit imposed by the epidemiological data (24 vs 25 g/d), which was not the case with the red meat, for which the proposed intake remained well below the maximum limit based on epidemiological considerations (17 vs 71 g/d). Among the dairy products, only milk (68 g/d) and cheese (46 g/d) were proposed. No sweetened products (in either solid or liquid form) were proposed.

Table 34: Consumption levels proposed by Scenario A1 for women with high iron requirements

| Food sub-groups | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food groups (g/d) |
|--|---|---------------------------------|--|-------------------------------|-------------------------------|---|
| Vegetables | 1022 | 124 | 721 | no limit | no limit | Fruits and vegetables excluding oilseeds 1022 |
| Fresh fruits | 0 | 111 | -100 | no limit | no limit | |
| Dried fruits | 0 | 1 | -100 | no limit | no limit | |
| Processed fruits: purees and cooked fruit | 0 | 12 | -100 | no limit | no limit | |
| Oilseeds | 0 | 0.8 | -100 | no limit | no limit | |
| Refined bread and bread products | 0 | 60 | -100 | no limit | no limit | Starches 624 |
| Plain wholegrain bread and bread products | 0 | 12 | -100 | no limit | no limit | |
| Starch-based, sweet/fatty processed products | 0 | 15 | -100 | no limit | no limit | |
| Starch-based, savoury/fatty processed products | 0 | 20 | -100 | no limit | no limit | |
| Other refined starches | 0 | 83 | -100 | no limit | no limit | |
| Other plain wholegrain starches | 624 | 2 | 25062 | no limit | no limit | |
| Pulses | 0 | 11 | -100 | no limit | no limit | Pulses 0 |
| Poultry | 0 | 25 | -100 | no limit | no limit | Meat and delicatessen meats, fishery products, eggs 237 |
| Red meat | 17 | 41 | -58 | no limit | 71 | |
| Delicatessen meats | 24 | 26 | -6 | no limit | 25 | |
| Oily fish | 47 | 4 | 978 | no limit | no limit | |
| Other fish | 0 | 22 | -100 | no limit | no limit | |
| Eggs | 149 | 12 | 1106 | no limit | no limit | |

| Food sub-groups | Quantity proposed by the optimisation (g/d) | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | Lower consumption limit (g/d) | Upper consumption limit (g/d) | Food groups (g/d) |
|---|---|---------------------------------|--|-------------------------------|-------------------------------|---|
| Milk | 68 | 87 | -22 | no limit | no limit | Milk and dairy products 114 |
| Plain fresh dairy products | 0 | 36 | -100 | no limit | no limit | |
| Sweetened fresh dairy products | 0 | 47 | -100 | no limit | no limit | |
| Sweetened dairy desserts | 0 | 16 | -100 | no limit | no limit | |
| Cheeses | 46 | 24 | 91 | no limit | no limit | |
| Butter and reduced-fat butter | 0 | 4 | -100 | no limit | no limit | Added fats 25 |
| Vegetable oils rich in ALA | 18 | 0 | 6673 | no limit | no limit | |
| Vegetable oils poor in ALA and margarines | 7 | 4 | 59 | no limit | no limit | |
| Sauces, fresh creams and condiments | 0 | 14 | -100 | no limit | no limit | |
| Sweet or sweet and fatty products | 0 | 59 | -100 | no limit | no limit | Sweet or sweet and fatty products 0 |
| Drinking water | 558 | 806 | -31 | no limit | no limit | Water: 558 |
| Sugar-sweetened beverages such as soda | 0 | 58 | -100 | no limit | 216 | Sugar-sweetened beverages 0 |
| Fruit juice | 0 | 61 | -100 | no limit | | |
| Salt | 0.0 | 0.2 | -100 | no limit | no limit | Salt 0 |

The red boxes represent the consumption limits introduced following epidemiological justifications.

- Nutrient intakes

The nutrient intakes are presented in **Annex 15**. All the lower and upper nutritional constraints were respected, with the exception of the lower nutritional constraint for Vitamin D, for which intake reached 6.8 µg/d.

- Exposure to contaminants

This Scenario A1 was not intended to serve as a basis for the food-based dietary guidelines since it does not integrate the dietary habits. By comparison with Scenario B, it was used to assess the impact on the optimisation of taking dietary habits into account; in addition, the analysis of exposure to contaminants was not carried out at this stage.

B scenarios – low iron

- Food intakes

In these two optimisation scenarios (B2 and B6) taking dietary habits into account, all the sub-groups were represented, except for the refined bread and bread products, sugar-sweetened beverages such as soda and delicatessen meats (**Table 35**). The solutions of the two scenarios were relatively similar in terms of food consumption: the main difference related to the pulses and oilseeds, whose consumption was higher in Scenario B6 in which the consumption bounds for these two sub-groups were higher. Conversely, the proposed consumption of VPO was slightly lower in Scenario B6 (146 vs 165 g/d in Scenario B2). Just like in men, both scenarios proposed trebling the consumption of fresh fruits and doubling that of vegetables compared to the average consumption of the French population. Total intake of the fruits and vegetables group thus reached around 630 g/d. Starches were overwhelmingly proposed in wholegrain form, with their intake reaching 290 g/d. The proposed intake of red meat was well below the maximum consumption limit based on the epidemiological data, while that of delicatessen meats was zero. With regard to the "Milk and dairy products" group, only the consumption of milk was greatly increased (quadrupled) compared to the average consumption. Among the added fats, the consumption of vegetable oils rich in ALA, such as rapeseed and walnut oils, was given considerable preference³⁰, reaching 20 g/d.

³⁰ To be consumed according to the conditions of use defined in the AFSSA Opinion of 22 June 2005 on the change in the criterion of distinction between vegetable oils for "seasoning" and for "frying and seasoning" based on the alpha-linolenic acid content (AFSSA 2005).

Table 35: Consumption levels proposed by Scenarios B2 and B6 for women with low iron requirements

| Food sub-groups | Quantity proposed by the optimisation (g/d) | | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | | Lower consumption limit (g/d) | Upper consumption limit (g/d) | | Food groups (g/d) | | | |
|--|---|-------------|---------------------------------|--|-------------|-------------------------------|-------------------------------|---------------------|--|--|------------------------|------------------------|
| | Scenario B2 | Scenario B6 | | Scenarios B2 and B6 | Scenario B2 | | Scenario B6 | Scenarios B2 and B6 | Scenario B2 | Scenario B6 | Scenario B2 | Scenario B6 |
| Vegetables | 282 | 282 | 124 | 126 | 126 | 21 | 282 | | Fruits and vegetables excluding oilseeds 627 | Fruits and vegetables excluding oilseeds 627 | | |
| Fresh fruits | 332 | 332 | 111 | 199 | 199 | 0 | 332 | | | | | |
| Dried fruits | 0.6 | 0.6 | 0.6 | 0 | 0 | 0 | 3.7 | 20 | | | | |
| Processed fruits: purees and cooked fruit | 12 | 12 | 12 | 0 | 0 | 0 | 57 | | | | | |
| Oilseeds | 4.6 | 12 | 0.8 | 481 | 1434 | 0 | 4.6 | 15 | | | | |
| Refined bread and bread products | 0 | 0 | 60 | -100 | -100 | 0 | 161 | 177 | 161 | 200 | Starches 288 | Starches 287 |
| Plain wholegrain bread and bread products | 60 | 59 | 12 | 382 | 374 | 0 | no limit | | no limit | | | |
| Starch-based, sweet/fatty processed products | 15 | 15 | 15 | 0 | 0 | 0 | 61 | | | | | |
| Starch-based, savoury/fatty processed products | 20 | 20 | 20 | 0 | 0 | 0 | 57 | | | | | |
| Other refined starches | 14 | 14 | 83 | -83 | -83 | 14 | 193 | 193 | 193 | 193 | | |
| Other plain wholegrain starches | 179 | 179 | 3 | 7096 | 7096 | 0 | no limit | | no limit | | | |
| Pulses | 32 | 100 | 11 | 189 | 812 | 0 | 50 | 100 | Pulses 32 | Pulses 100 | | |
| Poultry | 25 | 25 | 25 | 0 | 0 | 0 | 75 | | VPO 165 | VPO 146 | | |
| Red meat | 57 | 43 | 41 | 39 | 4 | 0 | 71 | | | | | |
| Delicatessen meats | 0 | 0 | 26 | -100 | -100 | 0 | 25 | | | | | |
| Oily fish | 16 | 20 | 4 | 255 | 353 | 0 | 25 | | | | | |
| Other fish | 55 | 31 | 22 | 150 | 41 | 0 | 67 | 100 | | | | |
| Eggs | 12 | 28 | 12 | 0 | 126 | 0 | 43 | | | | | |

| Food sub-groups | Quantity proposed by the optimisation (g/d) | | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | | Lower consumption limit (g/d) | Upper consumption limit (g/d) | | | | Food groups (g/d) | |
|---|---|-------------|---------------------------------|--|-------------|-------------------------------|-------------------------------|---------------------|-------------|----|--|--|
| | Scenario B2 | Scenario B6 | | Scenarios B2 and B6 | Scenario B2 | | Scenario B6 | Scenarios B2 and B6 | Scenario B2 | | Scenario B6 | |
| Milk | 341 | 350 | 87 | 292 | 303 | 0 | 350 | | | | Milk and dairy products 463 | Milk and dairy products 472 |
| Plain fresh dairy products | 36 | 36 | 36 | 0 | 0 | 0 | 157 | | | | | |
| Sweetened fresh dairy products | 47 | 47 | 47 | 0 | 0 | 0 | 161 | | | | | |
| Sweetened dairy desserts | 16 | 16 | 16 | 0 | 0 | 0 | 57 | | | | | |
| Cheeses | 24 | 24 | 24 | 0 | 0 | 0 | 65 | | | | | |
| Butter and reduced-fat butter | 4.2 | 4.2 | 4.2 | 0 | 0 | 0 | 17 | | | | Added fats 50 | Added fats 45 |
| Vegetable oils rich in ALA | 16 | 16 | 0.3 | 5928 | 5928 | 0 | no limit | 16 | no limit | 16 | | |
| Vegetable oils poor in ALA and margarines | 0 | 0 | 4.3 | -100 | -100 | 0 | 16 | | 16 | | | |
| Sauces, fresh creams and condiments | 30 | 25 | 14 | 117 | 79 | 0 | 39 | | | | | |
| Sweet or sweet and fatty products | 55 | 59 | 59 | -6 | 0 | 1 | 141 | | | | Sweet or sweet and fatty products: 55 | Sweet or sweet and fatty products: 59 |
| Drinking water | 806 | 789 | 806 | 0 | -2 | 51 | 1886 | | | | Water: 806 | Water: 789 |
| Sugar-sweetened beverages such as soda | 0 | 0 | 58 | -100 | -100 | 0 | 216 | | | | Sugar-sweetened beverages 28 | Sugar-sweetened beverages 21 |
| Fruit juice | 28 | 21 | 61 | -53 | -65 | 0 | | | | | | |
| Salt | 0.0 | 0.0 | 0.2 | -100 | -100 | 0 | 1.1 | | | | Salt 0 | |

The yellow boxes represent the consumption limits from the INCA2 consumption data (P5 for the lower limit and P95 for the upper limit). The red boxes represent the consumption limits introduced following epidemiological justifications. The food sub-groups in green are coupled sub-groups, i.e. sub-groups for which the limit relates to consumption of the sum of the two sub-groups. The maximum limits in bold highlight the changes in maximum consumption bounds between scenarios B2 and B6.

- Nutrient intakes

The nutrient intakes are presented in **Annex 16**. All the upper and lower nutritional constraints were respected, with the exception of the lower nutritional constraints for vitamin D, for which intake reached 3.4 µg/d, and fibre, for which intake reached 26 g/d for Scenario B2, and with the exception of the lower nutritional constraint for vitamin D only (for which intake reached 3.5 µg/d) for Scenario B6. However, these vitamin D and fibre intakes were higher than the average intakes observed in the INCA2 study.

- Exposure to the studied contaminants and food additives

Concerning food additives (Annex 17), the situation was identical to that of Scenario B1 in men. Indeed, for three out of the four additives, the exposure levels were lower than those from the TDS2 and their respective ADIs. Only exposure to tartaric acid was above the exposure from the TDS2, but it was still below its ADI (0.2-0.3% of the ADI depending on the scenario).

Concerning the substances excluding food additives and pesticides, as with the scenarios for "adult men", for the majority of the substances (53 or 56 out of 93, depending on the scenario), exposure was above the average exposure estimated in the TDS2 (**Annex 18**). The greatest differences were noted for hexabromocyclododecane (HBCDD, 9 times higher), which were probably related to a high consumption of fish in this scenario. In addition, for certain substances, for which the risk could not be ruled out in view of the results of the TDS2, exposure was lower. This was particularly the case with acrylamide and deoxynivalenol (DON).

For some of these substances, exposure remained below the critical values selected (health-based guidance values or, when these were unavailable, the median exposure values from the TDS2). This was particularly the case with methylmercury (exposure accounted for up to 21% of the tolerable weekly intake), and dioxins, furans and DL-PCBs (exposure was 28% higher than the exposure from the TDS2 and was 73% of the health-based guidance value). Lastly, for certain substances or groups of substances such as the phyto-oestrogens, as with the scenarios for adult men, exposure was higher than for the TDS2. However, because there are no HBGVs for these substances, interpretation is impossible in terms of the risks. The high exposure to phyto-oestrogens in this scenario can be explained by the high proposed intakes of vegetables, pulses and milk.

Depending on the scenario considered, four or five substances presented exposure above the maximum values selected. They were HBCDD (+1100%), inorganic arsenic (+50 to 80%), lead (+20%), nickel (114% of the HBGV in just one scenario) and chromium(VI) (+9%).

- HBCDD: exposure was higher than in the TDS2, nevertheless the margin of safety amounted to 1800, bearing in mind that the critical margin of safety adopted by EFSA was 8 and the one selected by the CES ERCA was 25 (in the framework of the Infant TDS, (Anses, 2016). This exposure therefore seems unlikely to lead to a health risk;
- inorganic arsenic: exposure reached up to 180% of the median exposure and 152% of the average exposure estimated in the TDS2, which were already considered to be of concern;
- lead: exposure reached 120% of the median exposure estimated in the TDS2, which was already considered to be of concern;
- nickel: exposure exceeded the HBGV set by EFSA in 2015. A health risk cannot therefore be ruled out;
- chromium(VI): exposure was equivalent to that from the TDS2 (109% of the median and 99% of the average), but there nevertheless remains great uncertainty about the relative share of Cr(III) compared to Cr(VI) (as a reminder, EFSA's very conservative assumptions were used here, see Section 5.5.3).

Concerning pesticide residues, 85% to 86% of the substances, depending on the scenario considered, presented exposure higher than that from the TDS2. This difference in exposure levels can mainly be explained, for the majority of pesticides, by higher consumption levels of fruits and vegetables and, for a more limited number of substances, by higher consumption levels of cereals resulting from the optimisation according to these B scenarios.

As with the men, the HBGV was only exceeded for lindane (HCH-gamma). The low levels involved (respectively 104% and 108% of the HBGV) should be put in perspective in view of several points:

- the dietary exposure estimated under this scenario for lindane was lower than that in the TDS2 (12%);
- in the TDS2, lindane was only detected in three samples, despite the high coverage level of foods, contrary to other substances that were much more frequently detected;
- the HBGV was observed to have been exceeded when considering the HBGV of 0.01 $\mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ used in the recent expert appraisals (ANSES 2014). However, when considering the HBGV of 5 $\mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ of the JMPR (FAO/WHO 2002) used in the framework of the annual European *a posteriori* assessments (EFSA 2015a), exposure to lindane in this Scenario B remains lower than the HBGV.

In addition, a small proportion of substances (8%, n = 18) presented exposure levels between 10% and 100% of the ADI (**Annex 19**). These substances are identical to those mentioned in Section 5.7.1 (scenarios B1 and C2 for men). It mainly concerns organophosphate insecticides (chlorpyrifos-ethyl and dimethoate) detected in fruits and vegetables, and dithiocarbamate fungicides detected in leafy vegetables (**Annex 19**).

B scenarios – high iron

- Food intakes

Compared to the intakes proposed by the scenarios for women whose iron requirements are low, these three scenarios for women with high iron requirements proposed intakes of VPO that were almost doubled (300 g/d vs 150-160 g/d) (**Table 36**). In particular, the intakes of red meat and delicatessen meats reached the maximum limit based on the epidemiological studies. Intakes of fruits and vegetables were slightly lower.

Scenarios B4 and B5, characterised by a relaxing of the targeted consumption bounds, differed little from each other; the difference related to the consumption of "other fish", which was lower in Scenario B5 where the consumption bound for this sub-group had not been relaxed. This was offset by higher consumption of poultry.

These two scenarios differed from Scenario B3, which was characterised by a slight overall relaxing of the consumption bounds and the constraints related to the dietary reference values. The major differences between the results of scenarios B4 and B5 on the one hand and B3 on the other, related to intakes of the sub-groups whose bounds were relaxed, i.e., pulses, dried fruits and oilseeds, which were higher in scenarios B4 and B5. To compensate, intakes in plain wholegrain starches, vegetables and poultry were higher in Scenario B3. Fruit juice intakes were also higher in scenarios B4 and B5.

Table 36: Consumption levels proposed by Scenarios B3, B4 and B5 for women with high iron requirements

| Food sub-groups | Quantity proposed by the optimisation (g/d) | | | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | | | Lower consumption limit (g/d) | Upper consumption limit (g/d) | | | Food groups (g/d) | | |
|--|---|-------------|-------------|---------------------------------|--|-------------|-------------|-------------------------------|-------------------------------|-------------|---------------------------------|--|--|--|
| | Scenario B3 | Scenario B4 | Scenario B5 | | Scenario B3 | Scenario B4 | Scenario B5 | | Scenario B3 ³¹ | Scenario B4 | Scenario B5 | Scenario B3 | Scenario B4 | Scenario B5 |
| Vegetables | 310 | 282 | 282 | 124 | 149 | 126 | 126 | 21 | 282 | | | Fruits and vegetables excluding oilseeds 595 | Fruits and vegetables excluding oilseeds 574 | Fruits and vegetables excluding oilseeds 571 |
| Fresh fruits | 272 | 272 | 269 | 111 | 145 | 145 | 142 | 0 | 332 | | | | | |
| Dried fruits | 0.6 | 20 | 20 | 0.6 | 0 | 3377 | 3377 | 0 | 3.7 | 20 | 20 | | | |
| Processed fruits: purees and cooked fruit | 12 | 0 | 0 | 12 | 0 | -100 | -100 | 0 | 57 | | | | | |
| Oilseeds | 0.8 | 14 | 15 | 0.8 | 0 | 1722 | 1806 | 0 | 4.6 | 15 | 15 | | | |
| Refined bread and bread products | 1 | 0 | 0 | 60 | -99 | -100 | -100 | 0 | 161 for B3, B4 and B5 | | 177 for B3 200 for B4 and B5 | Starches 299 | Starches 140 | Starches 137 |
| Plain wholegrain bread and bread products | 0 | 0 | 0 | 12 | -100 | -100 | -100 | 0 | no limit | | | | | |
| Starch-based, sweet/fatty processed products | 67 | 61 | 61 | 15 | 333 | 294 | 294 | 0 | 61 | | | | | |
| Starch-based, savoury/fatty processed products | 20 | 0 | 0 | 20 | 0 | -100 | -100 | 0 | 57 | | | | | |
| Other refined starches | 14 | 14 | 14 | 83 | -83 | -83 | -83 | 14 | 193 for B3, B4 and B5 | | 193 for B3, B4 and B5 | | | |
| Other plain wholegrain starches | 198 | 65 | 62 | 2.5 | 7874 | 2532 | 2397 | 0 | no limit | | | | | |
| Pulses | 55 | 100 | 100 | 11 | 402 | 812 | 812 | 0 | 50 | 100 | 100 | | | |
| Poultry | 83 | 25 | 44 | 25 | 230 | 0 | 75 | 0 | 75 | | | VPO 307 | VPO 288 | VPO 275 |
| Red meat | 71 | 71 | 71 | 41 | 73 | 73 | 73 | 0 | 71 | | | | | |
| Delicatessen | 25 | 25 | 25 | 26 | -4 | -4 | -4 | 0 | 25 | | | | | |

³¹ In Scenario B3, a tolerance of 10% was applied to the consumption bounds, allowing the tool to propose solutions that exceed the upper consumption limit by 10%.

| Food sub-groups | Quantity proposed by the optimisation (g/d) | | | INCA2 average consumption (g/d) | Deviation from the average consumption (%) | | | Lower consumption limit (g/d) | Upper consumption limit (g/d) | | | Food groups (g/d) | | |
|---|---|-------------|-------------|---------------------------------|--|-------------|-------------|-------------------------------|-------------------------------|----------------------|-------------|---------------------------------------|--|--|
| | Scenario B3 | Scenario B4 | Scenario B5 | | Scenario B3 | Scenario B4 | Scenario B5 | | Scenario B3 ³¹ | Scenario B4 | Scenario B5 | Scenario B3 | Scenario B4 | Scenario B5 |
| meats | | | | | | | | | | | | | | |
| Oily fish | 8 | 25 | 25 | 4.4 | 72 | 475 | 475 | 0 | 25 | | | | | |
| Other fish | 74 | 100 | 67 | 22 | 237 | 355 | 207 | 0 | 67 | 100 | 67 | | | |
| Eggs | 47 | 41 | 43 | 12 | 282 | 236 | 247 | 0 | 43 | | | | | |
| Milk | 326 | 350 | 350 | 87 | 275 | 303 | 303 | 0 | 350 | | | | | |
| Plain fresh dairy products | 36 | 0 | 17 | 36 | 0 | -100 | -51 | 0 | 157 | | | Milk and dairy products 423 | Milk and dairy products 416 | Milk and dairy products 432 |
| Sweetened fresh dairy products | 0 | 0 | 0 | 47 | -100 | -100 | -100 | 0 | 161 | | | | | |
| Sweetened dairy desserts | 61 | 57 | 57 | 16 | 292 | 268 | 268 | 0 | 57 | | | | | |
| Cheeses | 0 | 9 | 7 | 24 | -100 | -62 | -70 | 0 | 65 | | | | | |
| Butter and reduced-fat butter | 0 | 0 | 0 | 4.2 | -100 | -100 | -100 | 0 | 17 | | | | | |
| Vegetable oils rich in ALA | 18 | 16 | 16 | 0.3 | 6531 | 5928 | 5928 | 0 | no limit | 16 for B3, B4 and B5 | | Added fats 32 | Added fats 22 | Added fats 18 |
| Vegetable oils poor in ALA and margarines | 0 | 0 | 0 | 4.3 | -100 | -100 | -100 | 0 | 16 for B3, B4 and B5 | | | | | |
| Sauces, fresh creams and condiments | 14 | 6.3 | 2.3 | 14 | 0 | -55 | -83 | 0 | 39 | | | | | |
| Sweet or sweet and fatty products | 49 | 70 | 70 | 59 | -17 | 19 | 19 | 1 | 141 | | | | | |
| Drinking water | 813 | 877 | 880 | 806 | 1 | 9 | 9 | 51 | 1886 | | | Water 813 | Water 877 | Water 880 |
| Sugar-sweetened beverages such as soda | 0 | 0 | 0 | 58 | -100 | -100 | -100 | 0 | 216 | | | Sugar-sweetened beverages 0 | Sugar-sweetened beverages 46 | Sugar-sweetened beverages 47 |
| Fruit juice | 0 | 46 | 47 | 61 | -100 | -25 | -23 | 0 | | | | | | |
| Salt | 0.2 | 0.2 | 0.2 | 0.2 | 0 | 0 | 0 | 0 | 1.1 | | | Salt 0 | Salt 0 | Salt 0 |

The yellow boxes represent the consumption limits from the INCA2 consumption data (P5 for the lower limit and P95 for the upper limit). The red boxes represent the consumption limits introduced following epidemiological justifications. The green food sub-groups are coupled sub-groups, i.e. sub-groups for which the limit relates to consumption of the sum of the two sub-groups. The orange boxes represent the consumption limits for which targeted relaxations were applied.

- Nutrient intakes

The nutrient intakes are presented in **Annex 20**. For scenarios B4 and B5, all the upper and lower nutritional constraints were respected, with the exception of the lower nutritional constraints for vitamin D, for which intake reached 5.7 and 5.2 µg/d respectively, iron (15 instead of 16 mg/d) and fibre, for which intake reached 26 g/d in both scenarios. Scenario B3 allowed a tolerance of 5% for all the dietary reference values. The tolerance was applied for vitamin C, iron, EPA + DHA and vitamin B3, for which intakes were 10% below the lower nutritional constraint.

- Exposure to the studied contaminants and food additives

Concerning additives, exposure levels were lower than the ADI for the four additives and in the three scenarios (exposures accounted for 0.3 to 9% of the ADIs depending on the case) (**Annex 21**). For nitrites and sulphites, exposure was respectively lower than or close to that from the TDS2, in the three scenarios. With regard to tartaric acid and annatto, exposure levels were higher than those from the TDS2, except in the case of Scenario B3 for annatto.

Concerning the substances excluding food additives and pesticides, for the majority of them (53 to 56 out of 93, depending on the scenario), exposure was above the average exposure estimated in the TDS2 (**Annex 22**). The greatest differences were noted for hexabromocyclododecane (HBCDD, around 8.5 times higher) and methylmercury (between 2.5 and 3.5 times), which were probably related to a high consumption of fish in this scenario compared to the INCA2 study. In addition, for certain substances, for which the risk could not be ruled out in view of the results of the TDS2, exposure was lower. This was particularly the case with acrylamide and deoxynivalenol (DON).

For some substances, exposure remained below the critical values selected (health-based guidance values or, when these were unavailable, the median exposure values from the TDS2). This was particularly the case with methylmercury (exposure accounted for up to 38% of the tolerable weekly intake), and dioxins, furans and DL-PCBs (exposure was 90% of the health-based guidance value). Lastly, for other substances or groups of substance, exposure was higher than that calculated in the TDS2. When no HBGV was available for these substances, interpretation in terms of the risks was not possible. This was the case with the phyto-oestrogens, for which exposure was very high, particularly in relation with a high consumption of vegetables, pulses, and milk.

Depending on the scenario considered, seven or eight substances presented exposure above the maximum values selected. They were HBCDD (+1000%), inorganic arsenic (+130 to 180%), lead (+20%), the sum of PAH4 (+20% in just one scenario), nickel (116% of the HBGV), BDE-209 (+11 to 18%), chromium(VI) (+10%), and BPA (101 to 103% of the toxicological benchmark).

- HBCDD: exposure was above that of the TDS2, nevertheless the margin of safety amounted to 1900, bearing in mind that the critical margin adopted by EFSA was 8 and the one selected by the CES ERCA was 25 (in the framework of the Infant TDS, (Anses, 2016). Given these critical margins, this exposure seems unlikely to lead to a health risk.
- inorganic arsenic: exposure reached up to 180% of the median exposure and 136% of the average exposure estimated in the TDS2, which were already considered to be of concern.
- lead: exposure reached 120% of the median exposure and 111% of the average exposure estimated in the TDS2, which were already considered to be of concern.
- sum of four regulated PAHs: exposure was close to the exposure in the TDS2 (between 87 and 105% of the average exposure), but the margin of exposure was still much higher than the critical margin of exposure of 10,000 defined by EFSA for genotoxic compounds.

- nickel: exposure exceeded the HBGV set by EFSA in 2015. A health risk cannot therefore be ruled out.
- BDE-209: exposure was close to the estimated exposure in the TDS2 (between 76 and 105% of the average exposure), however the margin of exposure was still much higher than the critical margin of exposure of 2.5 defined by EFSA.
- chromium(VI): exposure was close to that from the TDS2 (110% of the median exposure and 100% of the average exposure), but there nevertheless remains great uncertainty about the relative share of Cr(III) compared to Cr(VI) (as a reminder, EFSA's conservative assumptions were used here, see Section 5.5.3).
- BPA: exposure exceeded the toxicological value set by ANSES in 2013. A health risk cannot therefore be ruled out.

With regard to pesticide residues, among the 232 pesticides that had been analysed in the TDS2, 84% to 85% presented exposure that was higher than that from the TDS2. This difference can be explained, for the majority of pesticides, mainly by higher consumption levels of fruits and vegetables and, for a more limited number of substances, by higher consumption levels of cereals at the end of the optimisation according to the type B scenarios.

As with the men and the women with low iron requirements, the HBGV was only exceeded for lindane (HCH-gamma). The fact that the HBGV was exceeded by around 150% in the three scenarios should be put in perspective in view of several points:

- the dietary exposure estimated under this scenario for lindane was lower than the current exposure: it accounts for around 17% of the estimated exposure in the TDS2;
- in the TDS2, lindane was only detected in three samples, despite the high coverage level of foods, contrary to other substances that were much more frequently detected;
- the HBGV was observed to have been exceeded when considering the HBGV of $0.01 \mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ used in the recent expert appraisals (ANSES, 2014). However, when considering the ADI of $5 \mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ of the JMPR (FAO/WHO, 2003) used in the framework of the annual European *a posteriori* assessments (EFSA, 2015a), exposure to lindane in this Scenario B remains lower than the HBGV.

A small proportion of substances (8%, $n = 18$) presented exposure levels between 10% and 100% of the ADI (**Annex 23**). These substances are identical to those mentioned in Section 5.7.1 (scenarios B1 and C2 for men). It mainly concerns organophosphate insecticides (chlorpyrifos-ethyl and dimethoate) detected in fruits and vegetables, and dithiocarbamate fungicides detected in leafy vegetables.

Thus, the levels of exposure to pesticides in women whose requirements for iron are high were broadly similar to those in women whose iron requirements are low. More specifically, the exposure values were very slightly higher according to the "low iron" scenarios for 76% of the pesticides assessed. Conversely, for POPs and other lipophilic substances that are rather detected in foods of animal origin (meat, fish and eggs in particular), exposure was higher according to the "high iron" scenarios. For example for lindane, exposure was close to 150% of the ADI according to the "high iron" scenarios compared with 105% according to the "low iron" scenarios.

Scenario C: the nutritional and epidemiological constraints, the consumption habits and the constraints related to contaminants were taken into account

Integration in the optimisation tool of toxicological constraints to the various solutions generated previously did not yield a solution, despite the application of flexibility on the same substances as for men (HBCDD, PBB, sum of PAH4).

5.7.3 Summary of the results of the optimisation

This optimisation work for identifying food consumptions meeting a series of constraints revealed, firstly, through Scenario A, the compatibility between the constraints relating to nutrients ("nutritional constraints") and the epidemiological objectives and constraints relating to the families of foods. The solutions obtained can be regarded in this work as consumptions that are "optimised" for health and reducing the risk of certain chronic diseases. However, the small number of food sub-groups represented (12 out of 32 sub-groups) and the consumptions that are very remote from the dietary habits observed in France (as described in the INCA2 study) mean that it is not possible to imagine real compliance by the population with any food-based dietary guidelines that may be based on this type of scenario. It was deemed necessary to propose a scenario taking dietary habits into account in order to arrive at food-based dietary guidelines that could actually be adopted. The type B scenarios show that there are solutions that respect the vast majority of nutritional and epidemiological constraints while taking consumption habits into account. These solutions are mainly characterised by:

- High consumption of fruits and vegetables; they are situated at the maximum authorised in the optimisation tool, i.e. the 95th percentile of consumption from the INCA2 study.
- Very high consumption of wholegrain cereal products at the expense of refined cereal products.
- High consumption of pulses compared to the average consumption from INCA2.
- Consumption of red meat that is difficult to reduce because of the nutritional constraints to be met in men and in women whose iron requirements are high, despite the epidemiological objective to minimise consumption.
- Significantly lower consumption of delicatessen meats than the average consumption from INCA2, except for women whose iron requirements are high, for whom consumption levels are at the maximum authorised in the optimisation tool (maximum defined on the basis of epidemiological studies).
- High consumption of oily fish compared to the average consumption from INCA2, close to the 95th percentile of consumption.
- Consumption of milk situated almost systematically at the maximum authorised in the optimisation tool, i.e. the 95th percentile of consumption from the INCA2 study. Consumption of other dairy products close to the average consumption from INCA2.
- Among the added fats, oils rich in ALA are widely preferred.
- Consumption of sweet or sweet and fatty products close to the average consumption from INCA2.
- Low consumption of sugar-sweetened beverages compared to the average consumption from INCA2, mainly explained by a lack of consumption of soda type beverages.

However, these type B scenarios were unable to reach the PRI in vitamin D for men and women, and, to a lesser extent, the AI in fibre for women. The intakes of these nutrients in the proposed solutions are nevertheless higher than the average intakes reported in the INCA2 study.

In addition, for women whose menstrual losses are high, there was also the inability to achieve the PRI in iron: the tested scenarios were unable to provide more than 15 mg/d (rather than the 16

mg/d of the PRI). However, given that the physiological adaptation that increases iron absorption when reserves are low was not taken into account when establishing the requirement, the requirements of women whose losses are high are likely to be lower than estimated (see Section 0). This likely overestimation of the requirement, combined with the difficulty of identifying women with high requirements, led to the conclusions formulated for women whose losses in iron are low being retained for all women. With regard to the women likely to have high iron requirements (in particular women whose menstrual losses are high), monitoring of the iron status is recommended. The type B scenarios were also characterised by a high protein intake; close or equal to the upper limit of the reference intake range (20% of TEI) for men and for women whose iron requirements are high, and to a lesser extent for women whose iron requirements are low.

For the type B scenarios, the *a posteriori* analysis of the exposure levels for contaminants and food additives identified a few substances for which a health risk cannot be ruled out:

- Inorganic arsenic, for which exposure was close to (for men) or even exceeded (for women) the estimated exposure in the TDS2, which was already considered to be of concern;
- Lead, for which exposure in women was slightly higher than that estimated in the TDS2; the situation has therefore not improved compared to the results of the TDS2 in which the possibility of a risk associated with exposure to lead could not be ruled out;
- BPA, for which the exposure of women whose iron requirements are high reached ANSES's toxicological value in two scenarios out of three. However, these scenarios are not required to be taken into consideration in the formulation of food-based dietary guidelines, for the reasons mentioned in the previous section. Moreover, the exposure values used for BPA result from data produced in the framework of the TDS2 (2007-2009) and they therefore pre-date the management measures imposed regarding BPA concentrations in food containers (2013);
- Nickel, for which exposure in women was slightly higher than the HBGV recently updated by EFSA; the situation is therefore considered to be of concern.

Concerning chromium(VI), exposure for both men and women was close to or even higher than that estimated in the TDS2, however there remains great uncertainty about the relative share of Cr(III) compared to Cr(VI) and EFSA's very conservative assumptions (see Section 5.5.3) were followed. Thus, it is impossible to conclude as to the risk associated with exposure.

With regard to the four food additives considered in this study, regardless of the population or the scenario considered, exposure was of the same order of magnitude as that calculated in the framework of the TDS2, and was in every case lower than the corresponding ADI. Consequently, the exposure to these four food additives determined by the optimisation tool is not considered to be of concern.

Concerning the 232 pesticide residues analysed in the TDS2, the estimated exposures according to the type B scenarios were lower than the HBGV, with the exception of lindane (HCH-gamma), an older pesticide prohibited in the framework of the International Stockholm Convention. An environmental contaminant, this POP can be found in the food chain and in particular in certain foodstuffs of animal origin. This exceeding of the HBGV for lindane according to the type B scenarios should be put in perspective in view of several points:

- the estimated dietary exposure for lindane was between 12% and 18% of the estimated exposure in the TDS2, and was therefore lower than the exposure from the TDS2;
- in the TDS2, lindane was only detected in three samples of foods of animal origin, contrary to other substances that were much more frequently detected;
- the HBGV was observed to have been exceeded when considering the HBGV of $0.01 \mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ used in the recent expert appraisals (ANSES, 2014). However, when considering the HBGV of $5 \mu\text{g.kg bw}^{-1}.\text{d}^{-1}$ of the Joint FAO/WHO Meetings on Pesticide Residues

(JMPR) (FAO/WHO 2002) used in the framework of the annual European *a posteriori* assessments (EFSA 2015a), exposure to lindane remains lower than the HBGV.

The vast majority (over 75%) of pesticides had exposure levels higher than those from the TDS2. This increase in exposure levels is due for most substances to the increase in the proposed consumption of fruits and vegetables and, for a more limited number of substances, to that of cereals.

The levels of exposure to pesticides in women whose requirements for iron are high were broadly similar to those in women whose iron requirements are low. More specifically, the exposure values were very slightly higher according to the "low iron" scenarios for 76% of the pesticides assessed. Conversely, for POPs and other lipophilic substances that are rather detected in foods of animal origin (meat, fish and eggs in particular), exposure was higher according to the "high iron" scenarios. For example for lindane, exposure was close to 150% of the HBGV according to the "high iron" scenarios compared with 105% according to the "low iron" scenarios.

With regard to the type C Scenario, which incorporated the constraints related to contaminants excluding food additives and pesticides (but incorporating POPs), no solution was identified according to the original parameters, for men or for women. For men, by introducing a flexibility (see section 5.7.1) on the constraints related to contaminants (HBCDD, PBB and PAH4), a solution was identified. In contrast, for women, an exploratory review was conducted but did not lead to any optimised solution. It was decided not to prolong this review to the point where it would have led to an excessive number of constraints being relaxed, given the initial requirements: to cover the nutritional requirements of virtually all the population without increasing the risk associated with exposure to contaminants and while remaining within a range of observed food intakes.

The absence of a type C scenario for women is not surprising in view of the *a posteriori* analysis of the exposure levels in the type B scenarios for women. In these scenarios, exposure to multiple contaminants (nickel, lead, inorganic arsenic) exceeded the HBGV or the TDS2 median in women only. Several factors may explain this situation. In the first place, certain dietary reference values are identical for men and women, whereas the energy requirement is lower for women, which leads the optimisation tool to search for foods that are even more nutritionally dense than for men, thus limiting the possible solutions. In addition, as the body weight of women is lower than that of men, for an equivalent intake of contaminated food, the level of exposure will accordingly be higher in women, since it is related to the kg of body weight.

The solution of Scenario C for men can be distinguished from those from the type B scenarios in particular by:

- higher consumption of pulses;
- zero consumption of delicatessen meats and higher consumption of eggs situated at the maximum authorised in the optimisation tool;
- zero consumption of milk and higher consumption of cheese and dairy products close to the maximum authorised in the optimisation tool;
- higher consumption of fruit juices situated at the maximum authorised in the optimisation tool (defined by the epidemiological constraint).

Many parameters influence the optimisation results and it is difficult to put forward simple assumptions, involving few parameters, to explain the consequences of taking contaminants into account on the major changes identified here that concern dairy products and fruit juices. However, some assumptions may be made:

With regard to the contaminants for which exposure in Scenario B in men was higher than the maximum limit specified in the tool, milk is a major contributor to exposure to inorganic arsenic and chromium VI (8 and 13% respectively). Milk is the second largest contributor to exposure to

inorganic arsenic, after fish, for which the amount proposed by the tool was probably mainly determined by the nutritional constraint relating to EPA and DHA (since fish are almost the sole source). Similarly, milk is the second largest contributor to exposure to chromium VI, after water, for which the quantity proposed by the tool was determined by the constraint on water intakes. Thus, the decrease in the quantities of milk proposed seems to be a mathematically effective lever for reducing exposure to these two contaminants below the maximum limit established in the tool.

The water intake associated with milk in Scenario B was compensated in Scenario C by a high intake of fruit juice. With regard to calcium intake, it was almost entirely compensated by higher intakes of other dairy products, mainly cheese. Thus the "dairy products" group contributed to 55% (646 mg) of calcium intakes in Scenario C compared with 60% (727 mg) in Scenario B1.

It is important to emphasise that the concentrations of 211 contaminants are available for milk, and only around a hundred for other dairy products, which may partly explain, with the objective of minimising the sum of the exposures to contaminants, the drastic decrease in the quantities of milk proposed. However, the difference in levels of contamination of these two types of products may not reflect reality, due to disparities in the quantity of the data available on the contaminants for dairy products and for milk.

With regard to contaminants excluding food additives and pesticides but including POPs, all the toxicological constraints were respected, except for HBCDD, for which exposure was higher than that estimated in the TDS2. However, the margin of safety was much higher than the critical margin of safety adopted. The exposure therefore seems unlikely to lead to a health risk.

In this scenario, no pesticide presented exposure above the TDI.

6 Scope of the work and uncertainties

In order to be able to judge the conclusions of this work, it is essential to analyse the uncertainties and limitations associated with the approach that was followed. It is now generally recognised that health risk assessments should examine the sources and types of uncertainty (EFSA 2009, WHO/ICPS 2008). Analysing the strengths and weaknesses of this work is all the more important given that it will lead to the PNNS food consumption guidelines.

Limitations related to the scope of the work can be distinguished from uncertainties related to the lack of data. Concerning the limitations related to the scope, it should be emphasised that this work aimed to determine optimal consumption levels for the healthy, non-allergic adult population (men aged 18 to 64 years and women aged 18 to 54 years). Only common foods were considered, excluding alcoholic beverages. Indeed, defining dietary guidelines for alcoholic beverages would require a detailed benefit/risk assessment of all their effects to be conducted. Therefore, in this report, TEI corresponds to energy intake without alcohol.

In addition, this work did not incorporate economic or environmental considerations (ecological impact such as the carbon footprint), but only considerations related to the nutritional and toxicological risks. Nor did it take into account the variability of nutritional compositions and contaminant levels according to crop varieties, production systems (for example, conventional or alternative practices), storage and processing conditions, geographical origin, modes of preparation (for example cooking type), etc.

It is also important to emphasise one of the limits of the optimisation tool used. The "objective" function of the optimisation tool, which consists of a sum of terms to be minimised, has already been described. It should therefore be stressed that it is the total sum that is minimised, and not each term independently. The data were standardised (see Section 5.3.2) in order to overcome differences of scale between the different sets of input data. However, it may be mathematically more interesting to focus the minimisation effort on one or more terms of the sum, and not on all the terms of the function. This means that the solution resulting from the optimisation will overall be the most interesting (i.e. it will better meet the demands shaped by the tool parameters), but that some terms may not have been minimised. Indeed, the "cost" (or the "loss") associated with the non-minimisation of these terms allows a significant "gain" in other criteria, and thus other expectations configured in the optimisation tool.

Regarding the uncertainty, this can be found in the different steps of the process of establishing the food-based dietary guidelines (**Table 37**). The sources of uncertainty can be classified into two categories:

- uncertainties associated with the data from the literature. These can relate to the health-based guidance values, for which the mixture effects in particular have not been taken into account, the dietary reference values, the bioavailability of nutrients depending on the food matrix, which was not taken into account, and the relationships between food groups and diseases;
- uncertainties associated with the optimisation tool's input data, namely the data on nutritional composition and food contamination, and the data on current consumption (INCA2) and exposure (TDS2).

Table 37: Sources of uncertainty identified in the work to determine optimal consumption

| Sources of uncertainty |
|--|
| Reference values entered in the optimisation tool |
| Validity of dietary reference values (to be reached or not exceeded) |
| Validity of health-based guidance values |
| Validity of the relationships between food groups and diseases, and determination of the corresponding consumption thresholds |
| Data entered in the optimisation tool |
| Representativeness of the data on consumption and exposure, nutritional composition and contamination |
| Failure to take into account fortified foods available on the market since the consumption study (2006-07) and since the collection of data on nutritional composition and contamination |
| Failure to take into account foods newly available on the market, since the consumption study (2006-07) |
| Categorisation of foods based on methodological choices |

Besides these uncertainties, it should be emphasised that the optimisation results obtained also depend on the parameters used and are therefore based on choices and compromises, such as the choice of the consumption bounds of the food groups at the 5th and 95th percentiles, the choice of the constraints that were made flexible and the choice of tolerance levels, the choice of weights allocated to each criterion of the objective function (equally weighted), or the choice to weight the nutritional composition and contamination of each food sub-group by the consumption levels.

7 Discussion and conclusion

The 2011-2015 National Health and Nutrition Programme (PNNS) provides for the updating of the food-based dietary guidelines. In this regard, the DGS made a formal request to ANSES to develop the scientific principles to underpin these guidelines. The Agency was also asked to clarify the position of certain foods within the categories currently used in the guidelines, and to quantify the concept of serving.

In this context, this expert appraisal work sought to provide the scientific foundation on which to establish the food-based dietary guidelines. This approach was based on translating the dietary reference values into food combinations, while integrating the relationships between the consumption of families of foods and the risk of chronic non-communicable diseases, the dietary habits, and the risk associated with exposure to contaminants.

To do this, work in the field of nutrition was carried out according to five themes:

- updating of the dietary reference values;
- review of the data on the bioavailability of vitamins and minerals depending on the food matrices, their chemical form and the overall diet of individuals, in order, where appropriate, to weight the nutrient levels of foods in the event of increased or limited bioavailability;
- identification of the nutrients of interest with regard to the nutritional status of different population groups (based on estimates of inadequate intakes and biomarker measurements);
- analysis of the relationships between the food groups and the risk of chronic non-communicable diseases;
- definition of a categorisation for foods and identification of the most commonly used serving sizes.

With regard to the contaminants, the work consisted in identifying the substances to be taken into account and the health-based guidance values to be considered.

Lastly, a study was conducted on how to integrate all of these elements in order to obtain quantified intakes of food sub-groups that take account of these nutritional objectives and constraints. The Working Group thus opted for a method using a mathematical optimisation tool, based on the use of the simplex algorithm. The tool incorporated parameters relating to:

- nutrient intakes: with the aim of reaching the population reference intake, without exceeding the tolerable upper intake level;
- the epidemiological relationships between food groups and the prevention of chronic non-communicable diseases: with the aim of maximising or minimising the consumption of certain food groups;
- exposure to contaminants: with the aim of minimising exposure and without exceeding the health-based guidance values (HBGVs) or, when the HBGVs are not available, the median exposure from the TDS2;
- while remaining within the range of intakes observed in the entire population.

The analysis of the data on the bioavailability of vitamins and minerals showed that these data were insufficient to enable nutrient bioavailability coefficients to be introduced in the analysis according to their chemical form, the matrix containing them, or the diet.

It was decided to consider in the optimisation tool all the nutrients for which references have been defined and composition data are available. The Working Group considered that the food optimisation process should be able to meet the requirements for each nutrient, regardless of the current nutritional status of the population.

The optimisation tool did not take into account data on dietary rhythms and consumption contexts, which could nevertheless be useful to managers when communicating the food-based dietary guidelines. These data will be available at a later date.

Justification of the methodological choices

In 2001, the previous dietary guidelines were based on an analysis of the existing food typologies in the French population. Nutrient intakes were estimated for each of the observed typologies and compared with dietary reference values, which helped identify the type of diet enabling optimal coverage of nutrient requirements, as well as the limiting nutrients in each of the dietary patterns. With this method, the adequacy of nutrient intakes is estimated *a posteriori* for a limited number of dietary typologies observed in the population. While the prior existence of the selected typology can be regarded as an advantage for its generalisation to the entire population, this approach is unable to guarantee adequate intakes with regard to all the guidelines.

The Working Group therefore turned to a method considering the *a priori* nutritional requirements for the French population, and thus sought to identify a consumption typology that possibly differed from those observed, even if the consumption of each food sub-group remained within the range of what was observed. The optimisation tool was developed in such a way that the nutrient intakes were above or at least equal to the PRI or, failing this, the AI. This is a protective approach to the extent that these intakes are able to meet the nutritional requirements of virtually the entire population.

In addition, given the purpose of the approach, i.e. the development of easily communicated and therefore concise dietary guidelines, it seemed essential to examine a limited number of food sub-groups. Taking into account both the consumption practices and the nutritional composition, the Working Group created new food groups or moved some foods or sub-groups compared to the categorisation used for the previous PNNS:

- creation of the "Pulses" group, which was previously a sub-group integrated in the "Starches" group;
- creation of the "Drinking water" group, which was previously a sub-group integrated in the "Beverages" group;
- reclassification of the "Fruit juices" sub-group, which was previously a sub-group integrated in the "Fruits and vegetables" group, into the "Sugar-sweetened beverages" group.

In this approach, mixed dishes such as ready meals (paella, lasagne, savoury tarts, etc.), sandwiches (baguette sandwiches, hamburgers, etc.), and certain desserts (rice pudding, etc.) were not grouped together. This is because they can vary considerably in their nutritional composition. The constituent ingredients of these products were therefore considered separately, i.e. within the sub-groups to which they belong.

For each food sub-group, the nutrient (data from the CIQUAL) and contaminant (data from the TDS2) composition was weighted by the consumption levels of the foods in the INCA2 study, in order to take the dietary habits of consumers into account. Thus, a food that was actually more frequently consumed within a sub-group had a greater weight in the average composition of the sub-group than a food that was only rarely consumed. While these composition and consumption data are relatively old, they are still representative of the current data to the extent that the compositions of the sub-groups are largely determined by the composition of the most frequently consumed foods for which the data are the most reliable. Thus, any subsequent update of the composition and consumption data (from the INCA3 survey) is not expected to significantly alter the results.

During development of this tool, many configuration choices were made. For example, taking the dietary habits into account was mainly based on the definition of a range of realistic intakes within which the identified optimisation solutions are found. The Working Group chose as the minimum consumption limit the intake level of the food sub-group at the 5th percentile in the INCA2 study, while the maximum limit was the intake level of the food sub-group at the 95th percentile. Besides

guaranteeing the feasibility of the solutions from the optimisation, which promotes their acceptability, this approach avoids proposing high consumption of food sub-groups containing other food compounds (i.e. food substances other than nutrients), for which conversely there is no history of consumption at these levels.

However, in the preliminary work, the upper consumption bound for certain food sub-groups was unable to meet the requirements for alpha-linolenic acid and fibre. In order to overcome this difficulty, while remaining close to the consumption practices, the Working Group chose to allow the substitution of intakes between certain food sub-groups with similar uses, for example, between wholemeal breads and refined breads.

In addition, the solutions proposed by the optimisation tool depended on the constraint set on energy intake. In this context, the Working Group sought to limit excessive energy intakes as far as possible with regard to prevention of the risk of overweight and obesity. It was decided to optimise the food intakes for an individual with a height corresponding to the median of the INCA2 population, an ideal body mass index of 22 kg/m² and a low level of physical activity³². Given that the identified food optimisation solutions should be able to cover the nutritional requirements of virtually all the population, the method tended to promote the consumption of nutritionally dense foods in view of the allocated energy envelope. This was even truer for women. Indeed, for certain nutrients, the dietary reference values are identical for men and women whereas the allocated energy envelope is lower for the latter.

Step-by-step optimisation approach

In order to assess the impact of each of the constraints (nutritional and epidemiological, related to consumption habits, and related to contamination levels in foods) and test their mutual compatibility, the Working Group adopted a step-by-step method. Initially, the joint compatibility of just the nutritional and epidemiological constraints was tested (Scenario A). Then, the consumption habits were also taken into account by adding the consumption bounds as constraints as well as the criterion to minimise deviations from the average consumption as an objective (Scenario B). Lastly, the constraints related to contaminants and the objective to minimise exposure were added to test the compatibility of all the constraints and estimate the impact on the proposed solution of taking the contaminants into account (Scenario C).

Scenario A thus aimed to demonstrate the possibility of achieving the nutritional (including epidemiological) and energy goals independently of the food practices commonly observed.

Scenario B sought to achieve the nutritional goals as far as possible by adding the consumption bounds as constraints to better reflect the commonly observed consumption habits, potentially making it easier to implement the guidelines produced on the basis of this scenario.

Taking contaminants into account (excluding food additives and pesticides but including POPs) in the optimisation tool (Scenario C) made it possible to propose a solution that took account of the reality of current levels of contamination. This approach should ultimately guide decision-makers in implementing measures to control the contamination observed in the foods in question. Where necessary, it will help influence the food-based dietary guidelines with regard to the contamination issues. This is consistent with the implementation of management measures aimed at reducing contamination levels over the long term.

The Working Group opted for a rational and *a priori* well-defined approach rather than a multi-assay approach, which would have needed it to rule *a posteriori* on the benefits of the solutions found. Accordingly, a limited number of scenarios were explored and therefore a limited number of solutions were established.

³² Corresponding to the median level observed in the English population

The step-by-step method followed showed that it was necessary to compromise on certain constraints in order to find a combination of foods able to satisfy the constraints regarding nutrients, while taking into account the epidemiological relationships and the consumption habits of the population (Scenario B). Thus, in the first place, for the optimisation carried out for men, the decision was taken not to impose achievement of the PRI for vitamin D. This PRI was established to provide a high level of protection for the population because it assumes zero endogenous synthesis via exposure to the sun. This extreme hypothesis was selected because it is not possible to estimate the level of endogenous synthesis, which varies greatly according to the individuals, the time spent outdoors, and the latitude where the individual lives. It was also necessary, in Scenario C, to compromise on the constraints relating to contaminants. The Working Group decided to increase the upper exposure constraint (median exposure from the TDS2) for hexabromocyclododecane (HBCDD), regulated polycyclic aromatic hydrocarbons (PAH4) and polybrominated biphenyls (PBBs). Indeed, the margins of exposure or safety estimated for these contaminants in the TDS2 were higher than the respective critical margins, to the extent that exposure slightly above the level of the TDS2 is seen as unlikely to lead to a health risk. Although relaxing these constraints made it possible to generate a solution for men, this was not the case for women. It was decided not to prolong the search for solutions for the latter: this would have led to an excessive number of constraints being relaxed, given the initial requirements: to cover the nutritional requirements of virtually all the population without increasing the risk associated with exposure to contaminants and while remaining within a range of observed food intakes.

For both women and men, it was decided not to impose achievement of the PRI for vitamin D. It was also necessary to lower the PRI for fibre from 30 g/d to 25 g/d in the type B scenarios. This was considered acceptable in view of the epidemiological data, which show a beneficial effect from 25 g/d of fibre. In addition, for the female population with high iron requirements (16 mg/d), the PRI for this nutrient could not be achieved when all the nutritional and epidemiological constraints, and those related to consumption habits, were considered jointly. An exploratory approach showed that an iron intake of 15 mg could be reached by relaxing the constraints relating to consumption habits. An exploratory review was subsequently conducted in order to identify solutions for Scenario C by introducing flexibility on the constraints defined above, and on those relating to HBCDD, PAH4 and PBB. No solution was found.

It was decided not to prolong this review to the point where it would have led to an excessive number of constraints being relaxed, given the initial requirements: to cover the nutritional requirements of virtually all the population without increasing the risk associated with exposure to contaminants and while remaining within a range of observed food intakes.

Discussion of the results of the optimisation

The direct translation of the quantitative results from the optimisation scenarios into servings (on the basis of the newly established serving sizes) was not carried out in this work.

Even if they could plausibly be constructed, the scenarios are not typical diets. Some major trends do emerge, however, regardless of the scenarios studied, concerning the levels of consumption of certain groups.

Compared to the average consumptions reported by the INCA2 study, consumption of the following groups or sub-groups should be increased: fresh fruits (multiplied by 3), vegetables (multiplied by 2), pulses (multiplied by more than 2), oily fish (multiplied by more than 4), wholegrain cereal

products (multiplied by more than 70) and vegetable oils rich in alpha-linolenic acid such as rapeseed or walnut oil³³ (multiplied by more than 600).

Conversely, the consumption of other groups or sub-groups should be reduced. This is the case with sugar-sweetened beverages such as soda, for which consumption proposed by the optimisation tool was zero, refined starches (divided by 7 to 10) and delicatessen meats (consumption of almost zero).

This innovative method led to optimisation results that are generally consistent with the consumption guidelines currently proposed to the population, which had been established in a more pragmatic way. A few significant differences can already be identified: this is the case with fruit juices, which are no longer in the group of fruits and vegetables but are instead in the group of sugar-sweetened beverages, and pulses that now constitute a group of their own.

The solutions proposed by the optimisation tool can cover the nutritional requirements of virtually all the population, with the exception of a few nutrients. Thus, the situations of inadequate intakes reported in the opinion of 13 March 2015 (ANSES 2015b) can be avoided by adequate consumption of common foods, at levels already consumed by a part of the population, without needing to turn to food supplements. This is particularly the case with magnesium, in which the prevalence of inadequacy reached 67% in men and 77% in women, and vitamin C, in which the prevalence of inadequacy reached 53% in men and 41% in women. Conversely, as stressed in the opinion, it is not possible to meet the requirement for vitamin D given the supply and consumption habits observed, which was confirmed by the absence of an optimisation solution if achievement of the PRI in vitamin D was imposed, as currently defined. The results of the European ODIN consortium, whose aim is to propose dietary solutions to achieve optimal coverage of vitamin D requirements, may provide information for establishing the management measures that now seem necessary. With regard to iron, the optimisation results show that satisfactory solutions are obtained for 80% of women at least, whereas this is not the case for women whose requirements may be higher, although this requirement is likely to be overestimated. This likely overestimation of the requirement, combined with the difficulty of identifying women with high requirements, led to the conclusions formulated for women whose losses in iron are low being retained for all women. With regard to the women likely to have a high requirement for iron, monitoring of the iron status is recommended.

In this study, two types of values were selected for the constraints related to exposures to contaminants. The health-based guidance values were selected when they were available (this was the case in particular with compounds with "threshold" effects). Otherwise (for example, in the case of substances whose effects are "without a threshold dose"), the average exposures calculated in the TDS2 were selected to avoid aggravating the current situation. In this last case, the values selected by default are not necessarily protective (this was the case with acrylamide, arsenic and lead, for which the situations were already considered to be of concern in the framework of the TDS2).

Whatever the scenario, for certain substances, the optimisation results led to exposure higher than that of the TDS2, for which the health impact cannot be estimated. In this case, with regard to inorganic arsenic, the situation remains a concern.

It should be stressed that for some contaminants, in the current state of estimates of contamination, although the dietary intakes proposed by the optimisation tool resulted in exposure below that of the TDS2, the health concern remains real. This is particularly the case with acrylamide and lead. Efforts to reduce the level of food contamination should therefore be continued.

³³ To be consumed according to the conditions of use defined in the AFSSA Opinion of 22 June 2005 on the change in the criterion of distinction between vegetable oils for "seasoning" and for "frying and seasoning" based on the alpha-linolenic acid content (AFSSA 2005).

Food additives and pesticides (except for persistent organic pollutants, or POPs³⁴) are systematically assessed before they can be placed on the market in Europe. The authorities lay down the conditions of use and maximum residue limits compatible with the observed food consumption levels. For pesticides (except for POPs), taking the consumptions proposed by the optimisation tool into account *a posteriori* revealed an overall increase in exposure compared to the TDS2. This increase can be explained mainly by the increase in consumption of fresh fruits, vegetables and cereal products. However, the corresponding health-based guidance values were not observed to have been exceeded.

For lindane (which is a persistent pesticide) exposure levels lower than those of the TDS2, but higher than the health-based guidance value, were observed in the type B scenarios. Earlier work, in particular the TDS2, had already highlighted the need to reduce exposure related to this persistent organic pollutant, which has been prohibited in France since 1998.

With regard to the type C scenario, which incorporated the constraints related to contaminants excluding food additives and pesticides, but incorporating POPs, no solution was identified according to the original parameters, for men or for women. For men, by introducing flexibility (see Section 5.3) on the constraints related to some contaminants (HBCDD, PBB and PAH4), a solution was found. In contrast, for women, an exploratory review was conducted but did not lead to any optimised solution. It was decided not to prolong this review to the point where it would have led to an excessive number of constraints being relaxed, given the initial requirements: to cover the nutritional requirements of virtually all the population without increasing the risk associated with exposure to contaminants and while remaining within a range of observed food intakes.

The absence of a type C scenario for women is not surprising in view of the *a posteriori* analysis of the exposure levels in the type B scenarios for women. In fact, in these scenarios, exposure to multiple contaminants (nickel, lead, inorganic arsenic) exceeded the HBGV or the TDS2 median in women only. Several factors may explain this situation. In the first place, certain dietary reference values are identical for men and women, whereas the energy requirement is lower for women, which leads the optimisation tool to search for foods that are even more nutritionally dense than for men, thus limiting the possible solutions. In addition, as the body weight of women is lower than that of men, for an equivalent intake of contaminated food, the level of exposure will accordingly be higher in women, since it is related to the kg of body weight.

Thus, the optimisation tool developed is able to integrate all the nutritional data, as well as those on contaminants and dietary habits. It is a decision-support tool, useful in the formulation of food-based dietary guidelines, which requires both choices to be made in advance (concerning the parameters and the type of scenario selected) and subsequent interpretation in view of the priority messages.

Lastly, this report highlights the need to conduct research aiming to reduce the uncertainties relating to the nutritional or toxicological references. The optimisation work should be refined taking into account the effects of the food matrix on the bioavailability of certain vitamins and minerals, and the effects of the mode of production on the nutritional quality and levels of contaminants in foods. This work has enabled significant progress in a scientific approach developed to formulate dietary guidelines aimed at the public by making the best possible use of the scientific information currently available, and has helped identify the needs for additional scientific knowledge.

³⁴ As additives and non-POP (persistent organic pollutant) pesticides are subject to regulations on use, their level of exposure was not subject to a constraint in the optimisation tool; this exposure was calculated for each combination of foods proposed as a solution, for the different scenarios (see Section 5.4.5).

The collective expert appraisal report was validated by the Working Group in several stages:

- On 10 July 2015 by the members of the WG dealing with Theme 1 on the revision of the dietary reference values for vitamins and minerals for the general adult population, for this specific part;
- On 5 November 2014 by the members of the WG dealing with Theme 4 on the study of the relationships between the consumption of foods and the risk of chronic non-communicable diseases, for this specific part;
- On 8 February 2016 by the members of the thematic group on monitoring of the optimisation tool, for the parts describing the tool and the results of the optimisation;
- On 8 February 2016 by the members of the monitoring group for the entire document and in particular the conclusion.

The collective expert appraisal report was validated by the Expert Committee on "Human Nutrition" on 7 April 2016.

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ANNEXES

Annex 1: Formal request letter

Classe 6 NUT JP

2012-SA-0103

COURRIER ARRIVE

- 5 AVR. 2012

DIRECTION GENERALE



Paris, le 03 AVR. 2012

DIRECTION GENERALE DE LA SANTE
Sous-direction Prévention des risques liés à
l'environnement et à l'alimentation
Bureau de l'alimentation et de la nutrition
DGS/EA3 – N° 123

Mission PNNS PO – Secrétariat général

Personne chargée du dossier :
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Le directeur général de la santé

A

Monsieur le Directeur général de l'Anses
27-31 avenue du Général Leclerc
94701 Maisons-Alfort

Objet : *Actualisation des repères du PNNS***Eléments de contexte**

Dans le cadre du Programme national nutrition santé 2001 – 2005 (PNNS), suite à trois saisines, l'Agence française de sécurité sanitaire des aliments (AFSSA) a élaboré les bases scientifiques pour la formulation des repères nutritionnels du PNNS pour la population générale ainsi que pour les enfants et adolescents, pour les personnes de plus de 55 ans, pour les personnes âgées et pour les femmes pendant et après la grossesse. A partir des éléments fournis par l'AFSSA ont été édités les divers guides du PNNS : le guide pour tous, le guide pour les parents d'enfants, le guide pour les plus de 55 ans, le guide pour les aidants de personnes âgées ainsi que le guide pour les femmes avant et pendant la grossesse. Ces repères ont servi de base aux différents messages du PNNS émis par les pouvoirs publics.

Cadre général de la saisine

Le Programme national nutrition santé 2011-2015 formule divers principes. Ils mentionnent notamment « les repères nutritionnels du PNNS visent à promouvoir une alimentation et une activité physique favorables à un état nutritionnel et un état de santé optimaux. Aucun des messages du PNNS ne proscrit la consommation d'un quelconque aliment ou boisson mis sur le marché. Les repères nutritionnels conduisent, dans un objectif de santé, à promouvoir certaines catégories d'aliments et boissons, ainsi qu'à recommander la limitation d'autres catégories ».

L'ANSES travaille actuellement sur les bases scientifiques de la répartition énergétique entre les trois macronutriments (les Apports Nutritionnels Conseillés – ANC). Après les protéines en 2007 et les lipides en 2010, une expertise sur les glucides, en lien avec les recommandations sur les deux autres macronutriments, est prévue au programme de travail de l'Unité d'évaluation des risques liés à la nutrition pour 2012. Ces ANC sont des repères pour les professionnels de la santé et de la nutrition et ont donc besoin d'être traduits en recommandations alimentaires pratiques pour la population.

C'est pour cette raison que l'action 11.1 du PNNS 2011-2015 prévoit « l'actualisation des repères nutritionnels » qui doivent correspondre à un objectif communication et d'appropriation par le grand public. Il est entendu que les repères sont destinés à la population générale ne souffrant pas de pathologies spécifiques.

Questions posées :

Il est demandé à l'ANSES

1) de proposer une nouvelle formulation des repères nutritionnels du PNNS, y compris ceux concernant l'activité physique sur la base :

- des nouveaux ANC
- des données de consommations INCA
- de la composition des aliments (Oqali, CIQUAL)
- des références internationales

2) de clarifier le positionnement de certains aliments au sein des catégories actuellement utilisées dans les repères nutritionnels en tenant compte de leur qualité nutritionnelle mais également de leur image communément admise par le consommateur :

- (1) les fruits frais, secs et oléagineux ;
- (2) les produits pouvant appartenir à deux catégories différentes : les légumes et les céréales y compris le cas du maïs doux.
- (3) les produits transformés.

3) de quantifier la notion de portion s'il est utile de la préciser dans la nouvelle formulation des repères nutritionnels.

Délai de réponse :

L'avis de l'ANSES est attendu pour la fin du premier semestre 2013. La Direction générale de la santé l'adressera pour commentaires aux acteurs économiques de l'alimentation. Puis le document sera transmis au Haut conseil de la santé publique pour une prise en compte du contexte global de santé publique. L'INPES s'attachera ensuite à la formulation des repères en vue de leur communication vers le grand public notamment dans le cadre de l'actualisation des guides nutrition et des messages sanitaires apposés sur les publicités alimentaires.

Copie : DGAL

DGCCRF

Le Directeur Général de la Santé,

Dr Jean-Yves GRALL

Annex 2: Presentation of dissenting positions

Mr François Mariotti, as a member of the CES, and Mr Jean-François Huneau, member of the CES and the Working Group for Theme 1, stated their dissenting position on the subject of dietary reference values for vitamin C for women. Indeed, they considered that the CES's decision departed from the rule governing the group's work, i.e. the principle of endorsing EFSA's approach except in the case of compelling evidence to the contrary. For this very specific case, they felt that the evidence against EFSA's proposed rationale, although interesting, was too weak. In brief, they felt they were not in a position to determine whether ultimately the requirements of women were the same as or different to those of men, but with this uncertainty, they wished to register their opinion in the Working Group's decision rationale according to the mandate it had been given.

In addition, Mr Ambroise Martin, a member of the thematic WG 1, expressed the same dissenting position concerning the dietary reference values for vitamin C for women, as well as the dietary reference value for magnesium for men and women. It should be noted that Mr Martin is the Chairman of the NDA Panel (dietetic products, nutrition and allergies), which developed the dietary reference values endorsed by EFSA.

Annex 3. Summary of the acceptable daily intakes (ADIs) for food additives and pesticide residues excluding POPs, which were not selected for the optimisation tool (and for which an *a posteriori* check was made that the ADIs have not been exceeded)

| Classes | Substances | Target values | Substances | Target values |
|--------------------|------------------------|----------------------|--------------------|----------------------|
| Additives | Annatto | ADI = 65 µg/kg bw/d | Sulphites | ADI = 0.7 mg/kg bw/d |
| | Nitrites | ADI = 60 µg/kg bw/d | Tartaric acid | ADI = 30 mg/kg bw/d |
| Pesticide residues | 2,4-D | ADI = 50 µg/kg bw/d | Diflubenzuron | ADI = 100 µg/kg bw/d |
| | Alphamethrin | ADI = 15 µg/kg bw/d | Epoxiconazole | ADI = 8 µg/kg bw/d |
| | Benalaxyl | ADI = 40 µg/kg bw/d | Fenpropidin | ADI = 20 µg/kg bw/d |
| | Carbendazim (sum) | ADI = 20 µg/kg bw/d | Fenpropimorph | ADI = 3 µg/kg bw/d |
| | Chlorothalonil | ADI = 15 µg/kg bw/d | Fenpyroximate | ADI = 10 µg/kg bw/d |
| | Chlorpropham (sum) | ADI = 50 µg/kg bw/d | Fludioxonil | ADI = 370 µg/kg bw/d |
| | Chlorpyrifos-ethyl | ADI = 1 µg/kg bw/d | Flutolanil | ADI = 90 µg/kg bw/d |
| | Chlorpyrifos-methyl | ADI = 10 µg/kg bw/d | Mepiquat | ADI = 200 µg/kg bw/d |
| | Cyfluthrin | ADI = 3 µg/kg bw/d | Pyriproxyfen | ADI = 100 µg/kg bw/d |
| | Cypermethrin | ADI = 50 µg/kg bw/d | Bifenthrin | ADI = 15 µg/kg bw/d |
| | Deltamethrin | ADI = 10 µg/kg bw/d | Chlorthal-dimethyl | ADI = 10 µg/kg bw/d |
| | Dinocap | ADI = 4 µg/kg bw/d | Etofenprox | ADI = 30 µg/kg bw/d |
| | Diquat | ADI = 2 µg/kg bw/d | Imidacloprid | ADI = 60 µg/kg bw/d |
| | Esfenvalerate | ADI = 20 µg/kg bw/d | Teflubenzuron | ADI = 10 µg/kg bw/d |
| | Flusilazole | ADI = 2 µg/kg bw/d | Tetraconazole | ADI = 4 µg/kg bw/d |
| | Imazalil | ADI = 25 µg/kg bw/d | Triadimenol (sum) | ADI = 50 µg/kg bw/d |
| | Iprodione (sum) | ADI = 60 µg/kg bw/d | Triflumuron | ADI = 14 µg/kg bw/d |
| | Lambda-cyhalothrin | ADI = 2.5 µg/kg bw/d | Cymoxanil | ADI = 13 µg/kg bw/d |
| | Linuron | ADI = 3 µg/kg bw/d | Cyromazine | ADI = 60 µg/kg bw/d |
| | Pendimethalin | ADI = 125 µg/kg bw/d | Diphenylamine | ADI = 75 µg/kg bw/d |
| | Propiconazole | ADI = 40 µg/kg bw/d | Tebuconazole | ADI = 30 µg/kg bw/d |
| | Propyzamide | ADI = 20 µg/kg bw/d | Tebufenpyrad | ADI = 10 µg/kg bw/d |
| | Pyridate | ADI = 36 µg/kg bw/d | Triallate | ADI = 25 µg/kg bw/d |
| | Thiabendazole | ADI = 100 µg/kg bw/d | Acrinathrin | ADI = 10 µg/kg bw/d |
| | Acephate | ADI = 30 µg/kg bw/d | Bitertanol | ADI = 3 µg/kg bw/d |
| | Aldicarb (sum) | ADI = 3 µg/kg bw/d | Bioresmethrin | ADI = 30 µg/kg bw/d |
| | Amitraz (sum) | ADI = 3 µg/kg bw/d | Bromopropylate | ADI = 30 µg/kg bw/d |
| | Atrazine (sum) | ADI = 20 µg/kg bw/d | Bromuconazole | ADI = 10 µg/kg bw/d |
| | Azinphos-ethyl | ADI = 2 µg/kg bw/d | Bupirimate | ADI = 50 µg/kg bw/d |
| | Azinphos-methyl | ADI = 5 µg/kg bw/d | Buprofezin | ADI = 10 µg/kg bw/d |
| | Chlozolinate | ADI = 100 µg/kg bw/d | Carbetamide | ADI = 60 µg/kg bw/d |
| | Endosulfan (sum) | ADI = 6 µg/kg bw/d | Carboxin | ADI = 8 µg/kg bw/d |
| | Fenarimol | ADI = 10 µg/kg bw/d | Chinomethionat | ADI = 6 µg/kg bw/d |
| | Fenthion (sum) | ADI = 7 µg/kg bw/d | Chlorfenson | ADI = 10 µg/kg bw/d |
| | Fentin acetate | ADI = 0.4 µg/kg bw/d | Chlorfluaazuron | ADI = 5 µg/kg bw/d |
| | Fentin hydroxide | ADI = 0.4 µg/kg bw/d | Cyhexatin | ADI = 3 µg/kg bw/d |
| | | | Cyproconazole | ADI = 20 µg/kg bw/d |
| | Methamidophos | ADI = 1 µg/kg bw/d | Dichlobenil | ADI = 10 µg/kg bw/d |
| | Paraquat | ADI = 4 µg/kg bw/d | Dichlofluanid | ADI = 300 µg/kg bw/d |
| | Parathion | ADI = 0.6 µg/kg bw/d | Diclobutrazol | ADI = 30 µg/kg bw/d |
| | Parathion-methyl (sum) | ADI = 3 µg/kg bw/d | Dicofol (sum) | ADI = 2.2 µg/kg bw/d |
| | Permethrin (sum) | ADI = 50 µg/kg bw/d | Dicloran | ADI = 5 µg/kg bw/d |

| Classes | Substances | Target values | Substances | Target values |
|--------------------|-----------------------|-----------------------|-------------------------|-----------------------|
| Pesticide residues | Procymidone | ADI = 2.8 µg/kg bw/d | Diethofencarb | ADI = 430 µg/kg bw/d |
| | Pyrazophos | ADI = 4 µg/kg bw/d | Diniconazole | ADI = 20 µg/kg bw/d |
| | Quintozene (sum) | ADI = 10 µg/kg bw/d | Ethirimol | ADI = 7.5 µg/kg bw/d |
| | Simazine | ADI = 5 µg/kg bw/d | Etridiazole | ADI = 15 µg/kg bw/d |
| | Tecnazene | ADI = 20 µg/kg bw/d | Fenazaquin | ADI = 5 µg/kg bw/d |
| | Vinclozolin (sum) | ADI = 5 µg/kg bw/d | Fenbuconazole | ADI = 6 µg/kg bw/d |
| | Captan | ADI = 100 µg/kg bw/d | Fenbutatin oxide | ADI = 50 µg/kg bw/d |
| | Cyprodinil | ADI = 30 µg/kg bw/d | Fenoxycarb | ADI = 53 µg/kg bw/d |
| | Dichlorprop-P | ADI = 60 µg/kg bw/d | Fenpropathrin | ADI = 30 µg/kg bw/d |
| | Dimethoate (sum) | ADI = 1 µg/kg bw/d | Fluazifop-p-butyl (sum) | ADI = 10 µg/kg bw/d |
| | Dimethomorph | ADI = 50 µg/kg bw/d | Flubenzimine | ADI = 25 µg/kg bw/d |
| | Diuron (sum) | ADI = 7 µg/kg bw/d | Flufenoxuron | ADI = 10 µg/kg bw/d |
| | Ethoprophos | ADI = 0.4 µg/kg bw/d | Fluquinconazole | ADI = 2 µg/kg bw/d |
| | Fenamiphos (sum) | ADI = 0.8 µg/kg bw/d | Flutriafol | ADI = 10 µg/kg bw/d |
| | Fipronil [parent] | ADI = 0.2 µg/kg bw/d | Hexaconazole | ADI = 5 µg/kg bw/d |
| | Folpet | ADI = 100 µg/kg bw/d | Hexaflumuron | ADI = 20 µg/kg bw/d |
| | Metconazole | ADI = 10 µg/kg bw/d | Hexythiazox | ADI = 30 µg/kg bw/d |
| | Methiocarb (sum) | ADI = 13 µg/kg bw/d | Mepronil | ADI = 50 µg/kg bw/d |
| | Metribuzin | ADI = 13 µg/kg bw/d | Methacrifos | ADI = 6 µg/kg bw/d |
| | Oxamyl | ADI = 1 µg/kg bw/d | Metoxuron | ADI = 5 µg/kg bw/d |
| | Phosmet (sum) | ADI = 10 µg/kg bw/d | Myclobutanil | ADI = 25 µg/kg bw/d |
| | Pirimicarb (sum) | ADI = 35 µg/kg bw/d | Nitrothal-isopropyl | ADI = 50 µg/kg bw/d |
| | Pirimiphos-methyl | ADI = 4 µg/kg bw/d | Nuarimol | ADI = 21 µg/kg bw/d |
| | Propamocarb | ADI = 290 µg/kg bw/d | Ofurace | ADI = 30 µg/kg bw/d |
| | Pyrimethanil | ADI = 170 µg/kg bw/d | Oxadixyl | ADI = 10 µg/kg bw/d |
| | Tolclofos methyl | ADI = 64 µg/kg bw/d | Pencycuron | ADI = 200 µg/kg bw/d |
| | Tolyfluanid | ADI = 100 µg/kg bw/d | Penconazole | ADI = 30 µg/kg bw/d |
| | Triticonazole | ADI = 25 µg/kg bw/d | Prochloraz | ADI = 10 µg/kg bw/d |
| | Azamethiphos | ADI = 3 µg/kg bw/d | Propachlor | ADI = 16 µg/kg bw/d |
| | Bendiocarb | ADI = 4 µg/kg bw/d | Pyridaben | ADI = 10 µg/kg bw/d |
| | Benfuracarb | ADI = 10 µg/kg bw/d | Tau-fluvalinate | ADI = 5 µg/kg bw/d |
| | Bromophos | ADI = 40 µg/kg bw/d | Tebufenozide | ADI = 20 µg/kg bw/d |
| | Bromophos-ethyl | ADI = 3 µg/kg bw/d | Tefluthrin | ADI = 5 µg/kg bw/d |
| | Cadusafos | ADI = 0.4 µg/kg bw/d | Tetradifon | ADI = 15 µg/kg bw/d |
| | Carbaryl | ADI = 7.5 µg/kg bw/d | Tetramethrin | ADI = 20 µg/kg bw/d |
| | Carbofuran (sum) | ADI = 0.15 µg/kg bw/d | Tralomethrin | ADI = 1 µg/kg bw/d |
| | Carbosulfan | ADI = 5 µg/kg bw/d | Triforine | ADI = 20 µg/kg bw/d |
| | Chlorfenvinphos | ADI = 0.5 µg/kg bw/d | OPP | ADI = 400 µg/kg bw/d |
| | Chlorobenzilate | ADI = 20 µg/kg bw/d | Ethoxyquin | ADI = 5 µg/kg bw/d |
| | Diazinon | ADI = 0.2 µg/kg bw/d | Pyrethrins | ADI = 40 µg/kg bw/d |
| | Dichlorvos | ADI = 4 µg/kg bw/d | Sulphur | ADI = 1500 µg/kg bw/d |
| | Ethiofencarb | ADI = 100 µg/kg bw/d | Biphenyl | ADI = 500 µg/kg bw/d |
| Ethion | ADI = 2 µg/kg bw/d | Phoxim | ADI = 4 µg/kg bw/d | |
| Fenitrothion | ADI = 5 µg/kg bw/d | Rotenone | ADI = 1 µg/kg bw/d | |
| Haloxypop | ADI = 0.65 µg/kg bw/d | Piperonyl butoxide | ADI = 200 µg/kg bw/d | |
| Heptenophos | ADI = 2 µg/kg bw/d | Fenchlorphos | ADI = 10 µg/kg bw/d | |
| Malathion (sum) | ADI = 30 µg/kg bw/d | Acetamiprid | ADI = 25 µg/kg bw/d | |
| Mecarbam | ADI = 2 µg/kg bw/d | Acibenzolar-S-methyl | ADI = 100 µg/kg bw/d | |
| Methidathion | ADI = 1 µg/kg bw/d | Azoxystrobin | ADI = 200 µg/kg bw/d | |

| Classes | Substances | Target values | Substances | Target values |
|--------------------|--------------------------------|-----------------------|-------------------------|----------------------|
| Pesticide residues | Methomyl (sum) | ADI = 2.5 µg/kg bw/d | Boscalid | ADI = 40 µg/kg bw/d |
| | Methoxychlor | ADI = 5 µg/kg bw/d | Fenamidone | ADI = 30 µg/kg bw/d |
| | Metolachlor (sum) | ADI = 100 µg/kg bw/d | Fenhexamid | ADI = 200 µg/kg bw/d |
| | Monocrotophos | ADI = 0.6 µg/kg bw/d | Indoxacarb | ADI = 6 µg/kg bw/d |
| | Oxydemeton-methyl (sum) | ADI = 0.3 µg/kg bw/d | Iprovalicarb | ADI = 15 µg/kg bw/d |
| | Pentachlorophenol | ADI = 1500 µg/kg bw/d | Kresoxim-methyl | ADI = 400 µg/kg bw/d |
| | Phorate (sum) | ADI = 0.7 µg/kg bw/d | Mepanipyrim | ADI = 20 µg/kg bw/d |
| | Phosalone | ADI = 10 µg/kg bw/d | Metalaxyl-M | ADI = 80 µg/kg bw/d |
| | Profenofos | ADI = 30 µg/kg bw/d | Metrafenone | ADI = 250 µg/kg bw/d |
| | Promecarb | ADI = 50 µg/kg bw/d | Picoxystrobin | ADI = 43 µg/kg bw/d |
| | Prometryn | ADI = 40 µg/kg bw/d | Pymetrozine | ADI = 30 µg/kg bw/d |
| | Propoxur | ADI = 20 µg/kg bw/d | Pyraclostrobin | ADI = 30 µg/kg bw/d |
| | Quinalphos | ADI = 0.5 µg/kg bw/d | Quinoxifen | ADI = 200 µg/kg bw/d |
| | Temephos | ADI = 100 µg/kg bw/d | Spiroxamine | ADI = 25 µg/kg bw/d |
| | Terbufos | ADI = 0.6 µg/kg bw/d | Trifloxystrobin | ADI = 100 µg/kg bw/d |
| | Tetrachlorvinphos | ADI = 50 µg/kg bw/d | Coumaphos | ADI = 0.5 µg/kg bw/d |
| | Thiometon | ADI = 3 µg/kg bw/d | Dithiocarbamates | ADI = 6 µg/kg bw/d |
| | Triazophos | ADI = 1 µg/kg bw/d | Abamectin | ADI = 2.5 µg/kg bw/d |
| | Trichlorfon | ADI = 2 µg/kg bw/d | Clofentezine | ADI = 20 µg/kg bw/d |
| | Trifluralin | ADI = 15 µg/kg bw/d | Dicamba | ADI = 300 µg/kg bw/d |
| Vamidotion | ADI = 8 µg/kg bw/d | Difenoconazole | ADI = 10 µg/kg bw/d | |

ADI: acceptable daily intake

Annex 4: Procedure for filling in missing values from the CIQUAL database

The foods used for the optimisation tool were based on the foods consumed in the INCA2 survey. For a food consumed during this survey, if the CIQUAL had not collected any data from *ad hoc* analyses, research projects, professionals or the scientific literature, the value was said to be "missing": no value is available to the general public in the tables published by the CIQUAL. However, the nutrient intakes can only be estimated from complete composition data for each food consumed in the framework of the INCA2 survey and each constituent exploited by the optimisation tool.

For the constituents excluding vitamins and minerals, the method used to fill in the missing values was as follows:

- retrieval of data from a similar food;
- calculations by recipe;
- use of the average data for the food group or sub-group to which the food with a missing value belongs;
- logical deduction (for example, if the food does not contain carbohydrates, then it does not contain total sugars or lactose).

For the vitamins and minerals, a different method was used to fill in the missing values:

- The experts began by discarding any source data for the 2013 CIQUAL table identified as outliers following a systematic verification conducted to prepare for the next CIQUAL table to be published.
- Then, the aggregated and verified values for the vitamins and minerals, already prepared for the future 2016 CIQUAL table, were used to fill in these missing values (updating the vitamin and mineral contents had no impact on the other constituents).
- If a value was still missing after the previous steps, the data were borrowed from a similar food.
- Failing this, the average of the INCA2 food sub-group for the constituent in question was used.
- In a few cases, the missing value was estimated at zero when this seemed plausible.

Annex 5. Nutrient intakes obtained after optimisation according to Scenario A1 in men

| Nutrient | Intake as absolute value | Lower nutritional constraint | Upper nutritional constraint | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) |
|--|--------------------------|------------------------------|------------------------------|---|---|
| Total energy intake (TEI) (kcal) | 2730 | 2470 | 2730 | 111 | 100 |
| Vitamin A (µg) | 2175 | 750 | 3000 | 290 | 73 |
| Vitamin B1 (mg/kcal) | 0.00058 | 0.00058 | - | 100 | - |
| Vitamin B2 (mg/kcal) | 0.00077 | 0.00071 | - | 108 | - |
| Vitamin B3 (mg/kcal) | 0.0067 | 0.0067 | - | 100 | - |
| Vitamin B5 (mg) | 8.8 | - | - | - | - |
| Vitamin B6 (mg) | 2.3 | 1.8 | 25 | 127 | 9 |
| Vitamin B9 (µg) | 846 | 330 | - | 256 | - |
| Vitamin B12 (µg) | 5.8 | 4 | - | 144 | - |
| Vitamin C (mg) | 149 | 110 | - | 135 | - |
| Vitamin D (µg) | 5.4 | 15 | 50 | 36 | 11 |
| Vitamin E (mg) | 24 | - | 300 | - | 8 |
| Calcium (mg) | 1000 | 1000 | 2500 | 100 | 40 |
| Copper (mg) | 3.98 | 1.25 | 5 | 319 | 80 |
| Iron (mg) | 21 | 11 | - | 188 | - |
| Iodine (µg) | 150 | 150 | 600 | 100 | 25 |
| Magnesium (mg) | 573 | 420 | - | 136 | - |
| Manganese (mg) | 7 | - | - | - | - |
| Phosphorus (mg) | 1986 | 700 | - | 284 | - |
| Potassium (mg) | 4796 | - | - | - | - |
| Selenium (µg) | 131 | 70 | 300 | 188 | 44 |
| Sodium (mg) | 2828 | - | 2992 | - | 95 |
| Zinc (mg) | 14 | 14 | 25 | 100 | 56 |
| Water (g) | 2625 | 2375 | 2625 | 111 | 100 |
| Proteins (% TEI) | 16 | 10 | 20 | 163 | 81 |
| Fats (% TEI) | 35 | 35 | 40 | 100 | 88 |
| SFA (% TEI) | 9.6 | - | 12 | - | 80 |
| Lauric + myristic + palmitic acids (% TEI) | 6.6 | - | 8 | - | 82 |
| Linoleic acid (% TEI) | 5 | 4 | - | 125 | - |
| Alpha-linolenic acid (% TEI) | 1 | 1 | - | 100 | - |
| EPA + DHA (mg) | 581 | 500 | - | 116 | - |
| Carbohydrates (% TEI) | 44 | 40 | 55 | 111 | 80 |
| Total sugars excluding lactose (g) | 41 | - | 100 | - | 41 |
| Fibres (g) | 52 | 30 | - | 174 | - |

Bold indicates the nutrients whose intake is limited to the lower nutritional constraint

Annex 6. Nutrient intakes obtained after optimisation according to Scenario B in men

| Nutrient | Intake as absolute value | Lower nutritional constraint | Upper nutritional constraint | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) |
|--|--------------------------|------------------------------|------------------------------|---|---|
| Total energy intake (TEI) (kcal) | 2502 | 2470 | 2730 | 101 | 92 |
| Vitamin A (µg) | 968 | 750 | 3000 | 129 | 32 |
| Vitamin B1 (mg/kcal) | 0.00058 | 0.00058 | - | 100 | - |
| Vitamin B2 (mg/kcal) | 0.00093 | 0.00071 | - | 131 | - |
| Vitamin B3 (mg/kcal) | 0.0106 | 0.0067 | - | 158 | - |
| Vitamin B5 (mg) | 7.4 | - | - | - | - |
| Vitamin B6 (mg) | 2.6 | 1.8 | 25 | 146 | 11 |
| Vitamin B9 (µg) | 430 | 330 | - | 130 | - |
| Vitamin B12 (µg) | 6.9 | 4 | - | 173 | - |
| Vitamin C (mg) | 112 | 110 | - | 102 | - |
| Vitamin D (µg) | 3.8 | 15 | 50 | 25 | 8 |
| Vitamin E (mg) | 16 | - | 300 | - | 5 |
| Calcium (mg) | 1214 | 1000 | 2500 | 121 | 49 |
| Copper (mg) | 2.32 | 1.25 | 5 | 186 | 46 |
| Iron (mg) | 14 | 11 | | 123 | |
| Iodine (µg) | 158 | 150 | 600 | 105 | 26 |
| Magnesium (mg) | 463 | 420 | - | 110 | - |
| Manganese (mg) | 6 | - | - | - | - |
| Phosphorus (mg) | 1914 | 700 | - | 273 | - |
| Potassium (mg) | 4022 | - | - | - | - |
| Selenium (µg) | 90 | 70 | 300 | 128 | 30 |
| Sodium (mg) | 2372 | - | 2992 | - | 79 |
| Zinc (mg) | 14 | 14 | 25 | 100 | 56 |
| Water (g) | 2375 | 2375 | 2625 | 100 | 90 |
| Proteins (% TEI) | 19 | 10 | 20 | 185 | 93 |
| Fats (% TEI) | 35 | 35 | 40 | 100 | 88 |
| SFA (% TEI) | 12 | - | 12 | - | 97 |
| Lauric + myristic + palmitic acids (% TEI) | 7.6 | - | 8 | - | 96 |
| Linoleic acid (% TEI) | 4.6 | 4 | - | 115 | - |
| Alpha-linolenic acid (% TEI) | 1 | 1 | - | 100 | - |
| EPA + DHA (mg) | 500 | 500 | - | 100 | - |
| Carbohydrates (% TEI) | 44 | 40 | 55 | 109 | 79 |
| Total sugars excluding lactose (g) | 92 | - | 100 | - | 92 |
| Fibres (g) | 30 | 30 | - | 100 | - |

Bold indicates the nutrients whose intake is limited to the lower nutritional constraint

Annex 7. Levels of exposure to food additives obtained after optimisation according to Scenario B1 in men

| Substance (unit) | ADI | TDS2 median exposure | TDS2 average exposure | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure |
|-------------------------|-----|----------------------|-----------------------|----------------------------------|-------|------------------------|-------------------------|
| Tartaric acid (mg/kg/d) | 30 | 0.03 | 0.05 | 0.06 | 0.2 | 215 | 114 |
| Nitrites (µg/kg/d) | 60 | 1.33 | 1.65 | 0.34 | 1 | 25 | 21 |
| Annatto (µg/kg/d) | 65 | 0.82 | 1.17 | 0.68 | 1 | 83 | 59 |
| Sulphites (mg/kg/d) | 0.7 | 0.15 | 0.22 | 0.03 | 5 | 22 | 15 |

The values in red are higher than 100%.

Annex 8. Levels of exposure to contaminants excluding pesticides obtained after optimisation according to Scenario B1 in men

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
|---|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| Acrylamide (ng/kg/d) | 406.537 | 406.54 | 474.17 | 340.50 | 84 | 84 | 72 |
| Aflatoxins (ng/kg/d) | 0.454219 | 0.45 | 0.49 | 0.13 | 28 | 28 | 26 |
| Ag (µg/kg/d) | | 1.35 | 1.68 | 1.54 | | 114 | 92 |
| Al (µg/kg/d) | 142.857 | 36.12 | 38.29 | 37.38 | 26 | 103 | 98 |
| AN (ng/kg/d) | | 1.04 | 1.15 | 0.99 | | 95 | 86 |
| Inorganic As (µg/kg/d) | 0.43161 | 0.43 | 0.53 | 0.55 | 127 | 127 | 104 |
| Organic As (µg/kg/d) | | 0.16 | 0.2 | 0.22 | | 136 | 110 |
| Ba (µg/kg/d) | 200 | 6.16 | 6.54 | 8.30 | 4 | 135 | 127 |
| BcFL (ng/kg/d) | | 0.26 | 0.28 | 0.16 | | 61 | 57 |
| BDE-209 = (ng/kg/d) | 0.316157 | 0.32 | 0.37 | 0.28 | 89 | 89 | 76 |
| BghiP (ng/kg/d) | | 0.39 | 0.43 | 0.36 | | 93 | 84 |
| Biochanin A (ng/kg/d) | | 0.00 | 2.04 | 3.98 | | | 195 |
| BjF (ng/kg/d) | | 0.14 | 0.16 | 0.11 | | 81 | 70 |
| BkF (ng/kg/d) | | 0.11 | 0.13 | 0.08 | | 73 | 64 |
| BPA (µg/kg/d) | 0.083 | 0.04 | 0.05 | 0.05 | 64 | 128 | 107 |
| Cd (µg/kg/d) | 0.357143 | 0.15 | 0.16 | 0.15 | 42 | 98 | 93 |
| Co (µg/kg/d) | 1.6 | 0.18 | 0.19 | 0.17 | 11 | 95 | 91 |
| Coumestrol (ng/kg/d) | | 7.46 | 18.37 | 40.46 | | 542 | 220 |
| CPP (ng/kg/d) | | 0.41 | 0.44 | 0.28 | | 67 | 63 |
| CrIII (µg/kg/d) | 300 | 3.95 | 4.08 | 3.92 | 1 | 99 | 96 |
| CrVI (µg/kg/d) | 0.496725 | 0.50 | 0.53 | 0.52 | 105 | 105 | 98 |
| Daidzein (ng/kg/d) | | 68.98 | 2252.04 | 253.80 | | 368 | 11 |
| DAS (ng/kg/d) | | 8.58 | 9.15 | 9.08 | | 106 | 99 |
| DbaeP (ng/kg/d) | | 0.12 | 0.13 | 0.07 | | 58 | 54 |
| DBahA (ng/kg/d) | | 0.07 | 0.07 | 0.04 | | 56 | 58 |
| DbahP (ng/kg/d) | | 0.11 | 0.12 | 0.08 | | 74 | 66 |
| DbaiP (ng/kg/d) | | 0.11 | 0.12 | 0.08 | | 75 | 67 |
| DbalP (ng/kg/d) | | 0.13 | 0.14 | 0.08 | | 61 | 56 |
| Dioxins and furans (pg TEQ05/kg/d) | | 0.15 | 0.16 | 0.15 | | 104 | 94 |
| Dioxins, furans and DL-PCBs (pg TEQ05/kg/d) | 0.7 | 0.36 | 0.41 | 0.43 | 61 | 120 | 105 |
| DOM1 (ng/kg/d) | | 8.24 | 8.8 | 7.89 | | 96 | 90 |
| DON (ng/kg/d) | 1000 | 415.98 | 441.66 | 317.06 | 32 | 76 | 72 |
| Enterolactone (ng/kg/d) | | 10.35 | 57 | 187.22 | | 1808 | 328 |
| Equol (ng/kg/d) | | 7.98 | 47.6 | 152.02 | | 1905 | 319 |
| FA (ng/kg/d) | | 2.99 | 3.17 | 2.19 | | 73 | 69 |
| FB1+FB2 (ng/kg/d) | 2000 | 23.12 | 28.57 | 8.40 | 0.4 | 36 | 29 |
| Formononetin (ng/kg/d) | | 0.00 | 14.42 | 13.88 | | | 96 |
| FusX (ng/kg/d) | | 8.58 | 9.15 | 9.08 | | 106 | 99 |
| Ga (µg/kg/d) | | 0.02 | 0.02 | 0.02 | | 94 | 82 |
| Ge (µg/kg/d) | | 0.05 | 0.06 | 0.04 | | 79 | 68 |
| Genistein (ng/kg/d) | | 52.96 | 3092.04 | 297.27 | | 561 | 10 |
| Glycitein (ng/kg/d) | | 11.23 | 498.17 | 78.57 | | 699 | 16 |
| PAH4 (ng/kg/d) | 1.34052 | 1.34 | 1.5 | 0.98 | 73 | 73 | 66 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
|---------------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| HBCD (ng/kg/d) | 0.155667 | 0.16 | 0.21 | 1.42 | 913 | 913 | 677 |
| Inorganic Ag (µg/kg/d) | 0.571429 | 0.09 | 0.09 | 0.09 | 15 | 96 | 95 |
| IP (ng/kg/d) | | 0.17 | 0.19 | 0.13 | | 76 | 70 |
| Li (µg/kg/d) | | 0.49 | 0.66 | 0.40 | | 82 | 61 |
| MAS (ng/kg/d) | | 8.58 | 9.15 | 7.89 | | 92 | 86 |
| Matairesinol (ng/kg/d) | | 0.00 | 19.95 | 4.70 | | | 24 |
| MCH (ng/kg/d) | | 0.12 | 0.12 | 0.06 | | 48 | 49 |
| MeHg (µg/kg/d) | 0.185714 | 0.00 | 0.02 | 0.02 | 9 | 681 | 83 |
| Mo (µg/kg/d) | | 1.34 | 1.43 | 1.88 | | 140 | 131 |
| Ni (µg/kg/d) | 2.8 | 2.28 | 2.38 | 2.72 | 97 | 119 | 114 |
| Niv (ng/kg/d) | 1200 | 28.02 | 31.61 | 35.78 | 3 | 128 | 113 |
| OTA (ng/kg/d) | 17.1429 | 1.02 | 1.08 | 1.13 | 7 | 111 | 105 |
| OTB (ng/kg/d) | | 0.81 | 0.85 | 1.09 | | 135 | 128 |
| Pat (ng/kg/d) | 400 | 8.85 | 10.14 | 13.64 | 3 | 154 | 135 |
| Pb (µg/kg/d) | 0.194746 | 0.19 | 0.21 | 0.18 | 93 | 93 | 86 |
| PBB (ng/kg/d) | 0.0086457 | 0.01 | 0.01 | 0.00 | 57 | 57 | 50 |
| PBDE (7) (ng/kg/d) | 10 | 0.15 | 0.21 | 0.29 | 3 | 189 | 140 |
| PCB indicators (6) (pg/kg/d) | 10000 | 1337.46 | 1821.97 | 2416.94 | 24 | 181 | 133 |
| DL-PCBs (pg TEQ05/kg/d) | | 0.22 | 0.25 | 0.28 | | 129 | 112 |
| PFBA (ng/kg/d) | | 1.29 | 1.35 | 1.64 | | 128 | 122 |
| PFBS (ng/kg/d) | | 0.56 | 0.61 | 0.75 | | 133 | 123 |
| PFDA (ng/kg/d) | | 0.16 | 0.17 | 0.25 | | 160 | 148 |
| PFDaA (ng/kg/d) | | 0.32 | 0.4 | 0.66 | | 209 | 165 |
| PFDS (ng/kg/d) | | 0.17 | 0.2 | 0.32 | | 195 | 161 |
| PFHpA (ng/kg/d) | | 0.35 | 0.38 | 0.55 | | 159 | 145 |
| PFHpS (ng/kg/d) | | 0.31 | 0.35 | 0.47 | | 152 | 135 |
| PFHxA (ng/kg/d) | | 0.40 | 0.45 | 0.64 | | 161 | 142 |
| PFHxS (ng/kg/d) | | 0.18 | 0.2 | 0.27 | | 147 | 134 |
| PFNA (ng/kg/d) | | 0.23 | 0.25 | 0.36 | | 159 | 143 |
| PFOA (ng/kg/d) | 200 | 0.33 | 0.38 | 0.51 | 0.3 | 156 | 135 |
| PFOS (ng/kg/d) | 80 | 0.34 | 0.36 | 0.41 | 1 | 121 | 113 |
| PFPA (ng/kg/d) | | 0.75 | 0.78 | 0.87 | | 117 | 112 |
| PFTeDA (ng/kg/d) | | 0.89 | 1.08 | 1.85 | | 208 | 172 |
| PFTTrDA (ng/kg/d) | | 0.55 | 0.62 | 0.86 | | 158 | 139 |
| PFUnA (ng/kg/d) | | 1.51 | 1.67 | 2.16 | | 143 | 129 |
| PHE (ng/kg/d) | | 10.20 | 11.2 | 8.08 | | 79 | 72 |
| PY (ng/kg/d) | | 6.86 | 7.25 | 4.58 | | 67 | 63 |
| Sb (µg/kg/d) | | 0.03 | 0.03 | 0.02 | | 67 | 63 |
| Secoisolariciresinol (ng/kg/d) | | 83.23 | 157.62 | 284.26 | | 342 | 180 |
| Sn (µg/kg/d) | | 1.25 | 3.72 | 4.87 | | 390 | 131 |
| Sr (µg/kg/d) | 600 | 16.84 | 20.36 | 19.65 | 3 | 117 | 96 |
| Te (µg/kg/d) | | 0.03 | 0.04 | 0.03 | | 84 | 70 |
| T2+HT2 toxins (ng/kg/d) | 60 | 31.66 | 34.08 | 36.38 | 61 | 115 | 107 |
| V (µg/kg/d) | | 0.85 | 0.9 | 0.64 | | 76 | 72 |
| Verrucarol (ng/kg/d) | | 8.19 | 8.72 | 7.89 | | 96 | 90 |
| Zearalenone and metabolites (ng/kg/d) | 250 | 64.86 | 67.8 | 66.42 | 27 | 102 | 98 |

The values in red are higher than 100%.



Annex 9. Levels of exposure to pesticides obtained after optimisation according to Scenario B1 in men (substances for which exposure is greater than 10% of the HBGV)

| Pesticide | EU status* | HBGV (µg/kg bw/d) | TDS2 median exposure (µg/kg bw/d) | Average exposure TDS2 (µg/kg bw/d) | Total exposure (µg/kg bw/d) | % HBGV | % median exposure TDS2 | % average exposure TDS2 | FR surveillance and control plans: percentages of detection and contributors | | | | |
|----------------------------|------------|-------------------|-----------------------------------|------------------------------------|-----------------------------|-------------|------------------------|-------------------------|--|------------|------------|------------|--|
| | | | | | | | | | 2010 | 2011 | 2012 | 2013 | Main contributors** and % detection |
| <i>Carbofuran (sum)</i> | NA | 0.15 | 0.06 | 0.06 | 0.08 | 53.4 | 131.6 | 124.4 | 0.1 | 0.1 | 0.3 | 0.2 | Bell peppers and chilli peppers (1-2%), tomatoes (1-3%), green beans (1%) |
| <i>Chlorfenvinphos</i> | NA | 0.5 | 0.05 | 0.06 | 0.06 | 12.7 | 120.6 | 113.8 | 0.1 | 0.02 | 0 | 0 | - |
| Chlorpyrifos-ethyl | A | 1 | 0.06 | 0.07 | 0.11 | 10.6 | 170.2 | 151.9 | 4.2 | 4.6 | 5.3 | 5.7 | Fruits and vegetables (1-50% citrus), tea (2-20%) |
| <i>Coumaphos</i> | NA | 0.5 | 0.02 | 0.03 | 0.07 | 13.3 | 333.8 | 255.0 | 0 | 0 | 0 | 0 | - |
| <i>Diazinon</i> | NA | 0.2 | 0.06 | 0.07 | 0.07 | 36.7 | 116.4 | 111.6 | 0 | 0.02 | 0.1 | 0.1 | Aubergines and bell peppers (<1%) |
| <i>Dieldrin (sum)</i> | POPs | 0.1 | 0.13 | 0.14 | 0.02 | 15.5 | 12.0 | 11.1 | 0.04 | 0.7 | 0.6 | 0.4 | Seafood and freshwater food products (14-20%), courgettes (0-2%) |
| Dimethoate (sum) | A | 1 | 0.55 | 0.61 | 0.66 | 65.8 | 119.0 | 108.5 | 0.8 | 0.6 | 1.0 | 2.4 | Fruits and vegetables (1% strawberries to 50% cherries), tea (1-3%) |
| Dithiocarbamates | A | 6 | 0.80 | 0.85 | 1.04 | 17.3 | 130.5 | 123.1 | 9.9 | 6.2 | 9.5 | 9.5 | Salads (20-35%) |
| <i>Ethoprophos</i> | A | 0.4 | 0.09 | 0.10 | 0.11 | 27.4 | 119.6 | 110.0 | 0 | 0 | 0 | 0 | - |
| <i>Fipronil (sum)</i> | A | 0.2 | 0.02 | 0.02 | 0.04 | 18.9 | 225.0 | 197.7 | 0.03 | 0 | 0.2 | 0.3 | Bell peppers and chilli peppers (1%) |
| <i>Heptachlor (sum)</i> | POPs | 0.1 | 0.12 | 0.13 | 0.02 | 18.7 | 15.9 | 14.9 | 0 | 0.3 | 0.1 | 0.4 | Beef (1%), cucumber (n=1/62) (2013 only) |
| <i>Lindane (HCH-gamma)</i> | POPs | 0.01 | 0.09 | 0.09 | 0.011 | 109 | 11.1 | 12.2 | 0 | 0.1 | 0.04 | 0.1 | Seafood and freshwater food products (0.5-2%) |
| <i>Methamidophos</i> | NA | 1 | 0.16 | 0.17 | 0.20 | 20.1 | 126.3 | 115.5 | 0 | 0.2 | 0.3 | 0.2 | Okra (5-8%) |
| <i>Methidathion</i> | NA | 1 | 0.11 | 0.12 | 0.10 | 10.3 | 92.1 | 86.7 | 0.2 | 0.1 | 0.1 | 0.1 | Grapefruits and oranges (1-6%) |
| <i>Monocrotophos</i> | NA | 0.6 | 0.14 | 0.16 | 0.16 | 27.3 | 114.2 | 102.8 | 0 | 0.03 | 0.3 | 0 | - |
| <i>Parathion (sum)</i> | NA | 0.6 | 0.17 | 0.17 | 0.20 | 33.8 | 121.7 | 117.8 | 0 | 0 | 0 | 0 | - |
| <i>Phorate (sum)</i> | NA | 0.7 | 0.36 | 0.37 | 0.47 | 66.7 | 131.1 | 124.7 | 0 | 0 | 0 | 0 | - |
| <i>Quinalphos</i> | NA | 0.5 | 0.12 | 0.13 | 0.14 | 27.0 | 110.5 | 104.1 | 0 | 0 | 0 | 0 | - |
| <i>Terbufos</i> | NA | 0.6 | 0.04 | 0.04 | 0.07 | 12.2 | 196.0 | 185.7 | 0 | 0 | 0 | 0 | - |

* Regulation (EC) No 1107/2009

A: approved; NA: not approved (in italics)

** Detected for at least 2 years and among more than 100 analyses per foodstuff

Annex 10. Nutrient intakes obtained after optimisation according to Scenario C2 in men

| Nutrient | Intake as absolute value | Lower nutritional constraint | Upper nutritional constraint | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) |
|--|--------------------------|------------------------------|------------------------------|---|---|
| Total energy intake (TEI) (kcal) | 2470 | 2470 | 2730 | 100 | 90 |
| Vitamin A (µg) | 944 | 750 | 3000 | 126 | 31 |
| Vitamin B1 (mg/kcal) | 0.00058 | 0.00058 | - | 100 | - |
| Vitamin B2 (mg/kcal) | 0.00085 | 0.00071 | - | 120 | - |
| Vitamin B3 (mg/kcal) | 0.0114 | 0.0067 | - | 170 | - |
| Vitamin B5 (mg) | 7.4 | - | - | - | - |
| Vitamin B6 (mg) | 2.6 | 1.8 | 25 | 145 | 10 |
| Vitamin B9 (µg) | 520 | 330 | - | 157 | - |
| Vitamin B12 (µg) | 6.7 | 4 | - | 168 | - |
| Vitamin C (mg) | 193 | 110 | - | 176 | - |
| Vitamin D (µg) | 4.3 | 15 | 50 | 29 | 9 |
| Vitamin E (mg) | 15 | - | 300 | - | 5 |
| Calcium (mg) | 1170 | 1000 | 2500 | 117 | 47 |
| Copper (mg) | 2.3 | 1.25 | 5 | 187 | 47 |
| Iodine (µg) | 150 | 150 | 600 | 100 | 25 |
| Iron (mg) | 14 | 11 | - | 124 | - |
| Magnesium (mg) | 444 | 420 | - | 106 | - |
| Manganese (mg) | 5.6 | - | - | - | - |
| Phosphorus (mg) | 1761 | 700 | - | 252 | - |
| Potassium (mg) | 3860 | - | - | - | - |
| Selenium (µg) | 90 | 70 | 300 | 129 | 30 |
| Sodium (mg) | 2276 | - | 2992 | - | 76 |
| Zinc (mg) | 14 | 14 | 25 | 100 | 56 |
| Water (g) | 2375 | 2375 | 2625 | 100 | 90 |
| Proteins (% TEI) | 20 | 10 | 20 | 200 | 100 |
| Fats (% TEI) | 35 | 35 | 40 | 100 | 88 |
| SFA (% TEI) | 12 | - | 12 | - | 99 |
| Lauric + myristic + palmitic acids (% TEI) | 7.9 | - | 8 | - | 98 |
| Linoleic acid (% TEI) | 4.5 | 4 | - | 113 | - |
| Alpha-linolenic acid (% TEI) | 1 | 1 | - | 100 | - |
| EPA + DHA (mg) | 500 | 500 | - | 100 | - |
| Carbohydrates (% TEI) | 42 | 40 | 55 | 104 | 76 |
| Total sugars excluding lactose (g) | 99 | - | 100 | - | 99 |
| Fibres (g) | 30 | 30 | - | 100 | - |

Bold indicates the nutrients whose intake is limited to the lower nutritional constraint

Annex 11. Levels of exposure to additives obtained after optimisation according to Scenario C2 in men

| Substance (unit) | ADI | TDS2 median exposure | TDS2 average exposure | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure |
|-------------------------|-----|----------------------|-----------------------|----------------------------------|-------|------------------------|-------------------------|
| Tartaric acid (mg/kg/d) | 30 | 0.03 | 0.05 | 0.04 | 0.1 | 133 | 70 |
| Nitrites (µg/kg/d) | 60 | 1.33 | 1.65 | 0.20 | 0.3 | 15 | 12 |
| Annatto (µg/kg/d) | 65 | 0.82 | 1.17 | 0.79 | 1 | 96 | 68 |
| Sulphites (mg/kg/d) | 0.7 | 0.15 | 0.22 | 0.02 | 3 | 12 | 8 |

ADI: acceptable daily intake

The values in red are higher than 100%.

Annex 12. Levels of exposure to contaminants excluding pesticides obtained after optimisation according to Scenario C1 in men

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
|---|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| Acrylamide (ng/kg/d) | 406.537 | 406.54 | 474.17 | 224.49 | 55 | 55 | 47 |
| Aflatoxins (ng/kg/d) | 0.454219 | 0.45 | 0.49 | 0.14 | 31 | 31 | 29 |
| Ag (µg/kg/d) | | 1.35 | 1.68 | 1.36 | | 101 | 81 |
| Al (µg/kg/d) | 142.857 | 36.12 | 38.29 | 32.78 | 23 | 91 | 86 |
| AN (ng/kg/d) | | 1.04 | 1.15 | 0.96 | | 92 | 83 |
| Inorganic As (µg/kg/d) | 0.43161 | 0.43 | 0.53 | 0.43 | 100 | 100 | 81 |
| Organic As (µg/kg/d) | | 0.16 | 0.2 | 0.17 | | 104 | 84 |
| Ba (µg/kg/d) | 200 | 6.16 | 6.54 | 8.83 | 4 | 143 | 135 |
| BcFL (ng/kg/d) | | 0.26 | 0.28 | 0.15 | | 59 | 55 |
| BDE-209 = (ng/kg/d) | 0.316157 | 0.32 | 0.37 | 0.32 | 100 | 100 | 85 |
| BghiP (ng/kg/d) | | 0.39 | 0.43 | 0.33 | | 85 | 77 |
| Biochanin A (ng/kg/d) | | 0.00 | 2.04 | 0.60 | | | 29 |
| BjF (ng/kg/d) | | 0.14 | 0.16 | 0.09 | | 62 | 54 |
| BkF (ng/kg/d) | | 0.11 | 0.13 | 0.06 | | 57 | 50 |
| BPA (µg/kg/d) | 0.083 | 0.04 | 0.05 | 0.06 | 67 | 134 | 112 |
| Cd (µg/kg/d) | 0.357143 | 0.15 | 0.16 | 0.13 | 37 | 85 | 82 |
| Co (µg/kg/d) | 1.6 | 0.18 | 0.19 | 0.15 | 9 | 82 | 78 |
| Coumestrol (ng/kg/d) | | 7.46 | 18.37 | 40.17 | | 538 | 219 |
| CPP (ng/kg/d) | | 0.41 | 0.44 | 0.26 | | 63 | 60 |
| CrIII (µg/kg/d) | 300 | 3.95 | 4.08 | 3.61 | 1 | 91 | 88 |
| CrVI (µg/kg/d) | 0.496725 | 0.50 | 0.53 | 0.50 | 100 | 100 | 94 |
| Daidzein (ng/kg/d) | | 68.98 | 2252.04 | 293.29 | | 425 | 13 |
| DAS (ng/kg/d) | | 8.58 | 9.15 | 8.57 | | 100 | 94 |
| DbaeP (ng/kg/d) | | 0.12 | 0.13 | 0.07 | | 54 | 50 |
| DBahA (ng/kg/d) | | 0.07 | 0.07 | 0.04 | | 55 | 56 |
| DbahP (ng/kg/d) | | 0.11 | 0.12 | 0.08 | | 73 | 65 |
| DbaiP (ng/kg/d) | | 0.11 | 0.12 | 0.08 | | 73 | 65 |
| DbalP (ng/kg/d) | | 0.13 | 0.14 | 0.07 | | 58 | 53 |
| Dioxins and furans (pg TEQ05/kg/d) | | 0.15 | 0.16 | 0.15 | | 103 | 94 |
| Dioxins, furans and DL-PCBs (pg TEQ05/kg/d) | 0.7 | 0.36 | 0.41 | 0.42 | 60 | 117 | 102 |
| DOM1 (ng/kg/d) | | 8.24 | 8.8 | 7.51 | | 91 | 85 |
| DON (ng/kg/d) | 1000 | 415.98 | 441.66 | 303.59 | 30 | 73 | 69 |
| Enterolactone (ng/kg/d) | | 10.35 | 57 | 15.36 | | 148 | 27 |
| Equol (ng/kg/d) | | 7.98 | 47.6 | 25.02 | | 314 | 53 |
| FA (ng/kg/d) | | 2.99 | 3.17 | 2.08 | | 69 | 65 |
| FB1+FB2 (ng/kg/d) | 2000 | 23.12 | 28.57 | 21.82 | 1 | 94 | 76 |
| Formononetin (ng/kg/d) | | 0.00 | 14.42 | 0.46 | | | 3 |
| FusX (ng/kg/d) | | 8.58 | 9.15 | 8.57 | | 100 | 94 |
| Ga (µg/kg/d) | | 0.02 | 0.02 | 0.02 | | 91 | 79 |
| Ge (µg/kg/d) | | 0.05 | 0.06 | 0.04 | | 75 | 64 |
| Genistein (ng/kg/d) | | 52.96 | 3092.04 | 330.32 | | 624 | 11 |
| Glycitein (ng/kg/d) | | 11.23 | 498.17 | 41.09 | | 366 | 8 |
| PAH4 (ng/kg/d) | 1.34052 | 1.34 | 1.5 | 0.82 | 61 | 61 | 55 |
| HBCD (ng/kg/d) | 0.155667 | 0.16 | 0.21 | 0.44 | 286 | 286 | 212 |
| Inorganic Ag (µg/kg/d) | 0.571429 | 0.09 | 0.09 | 0.08 | 14 | 90 | 89 |
| IP (ng/kg/d) | | 0.17 | 0.19 | 0.12 | | 67 | 61 |
| Li (µg/kg/d) | | 0.49 | 0.66 | 0.42 | | 85 | 64 |
| MAS (ng/kg/d) | | 8.58 | 9.15 | 7.51 | | 87 | 82 |
| Matairesinol (ng/kg/d) | | 0.00 | 19.95 | 0.37 | | | 2 |
| MCH (ng/kg/d) | | 0.12 | 0.12 | 0.06 | | 49 | 50 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
|---------------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| MeHg (µg/kg/d) | 0.185714 | 0.00 | 0.02 | 0.01 | 5 | 375 | 46 |
| Mo (µg/kg/d) | | 1.34 | 1.43 | 1.82 | | 136 | 127 |
| Ni (µg/kg/d) | 2.8 | 2.28 | 2.38 | 2.56 | 92 | 112 | 108 |
| Niv (ng/kg/d) | 1200 | 28.02 | 31.61 | 35.22 | 3 | 126 | 111 |
| OTA (ng/kg/d) | 17.1429 | 1.02 | 1.08 | 1.13 | 7 | 111 | 105 |
| OTB (ng/kg/d) | | 0.81 | 0.85 | 1.09 | | 135 | 128 |
| Pat (ng/kg/d) | 400 | 8.85 | 10.14 | 17.90 | 4 | 202 | 176 |
| Pb (µg/kg/d) | 0.194746 | 0.19 | 0.21 | 0.17 | 89 | 89 | 82 |
| PBB (ng/kg/d) | 0.0086457 | 0.01 | 0.01 | 0.01 | 62 | 62 | 54 |
| PBDE (7) (ng/kg/d) | 10 | 0.15 | 0.21 | 0.31 | 3 | 200 | 148 |
| PCB indicators (6) (pg/kg/d) | 10000 | 1337.46 | 1821.97 | 2337.69 | 23 | 175 | 128 |
| DL-PCBs (pg TEQ05/kg/d) | | 0.22 | 0.25 | 0.27 | | 125 | 108 |
| PFBA (ng/kg/d) | | 1.29 | 1.35 | 1.23 | | 96 | 91 |
| PFBS (ng/kg/d) | | 0.56 | 0.61 | 0.57 | | 102 | 94 |
| PFDA (ng/kg/d) | | 0.16 | 0.17 | 0.16 | | 99 | 91 |
| PFDoA (ng/kg/d) | | 0.32 | 0.4 | 0.34 | | 106 | 84 |
| PFDS (ng/kg/d) | | 0.17 | 0.2 | 0.16 | | 100 | 82 |
| PFHpA (ng/kg/d) | | 0.35 | 0.38 | 0.36 | | 104 | 95 |
| PFHpS (ng/kg/d) | | 0.31 | 0.35 | 0.31 | | 100 | 89 |
| PFHxA (ng/kg/d) | | 0.40 | 0.45 | 0.38 | | 96 | 85 |
| PFHxS (ng/kg/d) | | 0.18 | 0.2 | 0.17 | | 96 | 87 |
| PFNA (ng/kg/d) | | 0.23 | 0.25 | 0.23 | | 104 | 94 |
| PFOA (ng/kg/d) | 200 | 0.33 | 0.38 | 0.38 | 0.2 | 116 | 101 |
| PFOS (ng/kg/d) | 80 | 0.34 | 0.36 | 0.28 | 0.3 | 82 | 77 |
| PFPA (ng/kg/d) | | 0.75 | 0.78 | 0.57 | | 76 | 73 |
| PFTeDA (ng/kg/d) | | 0.89 | 1.08 | 1.03 | | 116 | 96 |
| PFTrDA (ng/kg/d) | | 0.55 | 0.62 | 0.71 | | 130 | 114 |
| PFUnA (ng/kg/d) | | 1.51 | 1.67 | 1.28 | | 85 | 76 |
| PHE (ng/kg/d) | | 10.20 | 11.2 | 8.00 | | 78 | 71 |
| PY (ng/kg/d) | | 6.86 | 7.25 | 4.72 | | 69 | 65 |
| Sb (µg/kg/d) | | 0.03 | 0.03 | 0.02 | | 58 | 55 |
| Secoisolariciresinol (ng/kg/d) | | 83.23 | 157.62 | 254.94 | | 306 | 162 |
| Sn (µg/kg/d) | | 1.25 | 3.72 | 4.80 | | 384 | 129 |
| Sr (µg/kg/d) | 600 | 16.84 | 20.36 | 20.10 | 3 | 119 | 99 |
| Te (µg/kg/d) | | 0.03 | 0.04 | 0.02 | | 73 | 61 |
| T2+HT2 toxins (ng/kg/d) | 60 | 31.66 | 34.08 | 35.58 | 59 | 112 | 104 |
| V (µg/kg/d) | | 0.85 | 0.9 | 0.59 | | 69 | 65 |
| Verrucarol (ng/kg/d) | | 8.19 | 8.72 | 7.51 | | 92 | 86 |
| Zearalenone and metabolites (ng/kg/d) | 250 | 64.86 | 67.8 | 68.57 | 27 | 106 | 101 |

The values in red are higher than 100%.

Annex 13. Levels of exposure to pesticides obtained after optimisation according to Scenario C2 in men (substances for which exposure is greater than 10% of the HBGV)

| Pesticide | EU status* | HBGV (µg/kg bw/d) | TDS2 median exposure (µg/kg bw/d) | Average exposure TDS2 (µg/kg bw/d) | Total exposure (µg/kg bw/d) | % HBGV | % median exposure TDS2 | % TDS2 average exposure | FR surveillance and control plans: percentages of detection and contributors | | | | |
|----------------------------|------------|-------------------|-----------------------------------|------------------------------------|-----------------------------|-------------|------------------------|-------------------------|--|------------|------------|------------|--|
| | | | | | | | | | 2010 | 2011 | 2012 | 2013 | |
| <i>Carbofuran (sum)</i> | NA | 0.15 | 0.06 | 0.06 | 0.08 | 55.0 | 135.5 | 128.1 | 0.1 | 0.1 | 0.3 | 0.2 | Bell peppers and chilli peppers (1-2%), tomatoes (1-3%), green beans (1%) |
| <i>Chlorfenvinphos</i> | NA | 0.5 | 0.05 | 0.06 | 0.07 | 13.3 | 126.2 | 119.1 | 0.1 | 0.02 | 0 | 0 | - |
| Chlorpyrifos-ethyl | A | 1 | 0.06 | 0.07 | 0.11 | 11.0 | 176.6 | 157.6 | 4.2 | 4.6 | 5.3 | 5.7 | Fruits and vegetables (1-50% citrus), tea (2-20%) |
| <i>Coumaphos</i> | NA | 0.5 | 0.02 | 0.03 | 0.07 | 13.3 | 333.8 | 255.0 | 0 | 0 | 0 | 0 | - |
| <i>Diazinon</i> | NA | 0.2 | 0.06 | 0.07 | 0.08 | 38.6 | 122.3 | 117.2 | 0 | 0.02 | 0.1 | 0.1 | Aubergines and bell peppers (<1%) |
| <i>Dieldrin (sum)</i> | POPs | 0.1 | 0.13 | 0.14 | 0.01 | 11.4 | 8.8 | 8.1 | 0.04 | 0.7 | 0.6 | 0.4 | Seafood and freshwater food products (14-20%), courgettes (0-2%) |
| Dimethoate (sum) | A | 1 | 0.55 | 0.61 | 0.72 | 72.5 | 131.0 | 119.5 | 0.8 | 0.6 | 1.0 | 2.4 | Fruits and vegetables (1% strawberries to 50% cherries), tea (1-3%) |
| Dithiocarbamates | A | 6 | 0.80 | 0.85 | 1.28 | 21.4 | 161.0 | 151.8 | 9.9 | 6.2 | 9.5 | 9.5 | Salads (20-35%) |
| <i>Ethoprophos</i> | A | 0.4 | 0.09 | 0.10 | 0.12 | 30.1 | 131.5 | 121.0 | 0 | 0 | 0 | 0 | - |
| <i>Fipronil (sum)</i> | A | 0.2 | 0.02 | 0.02 | 0.04 | 18.8 | 223.6 | 196.4 | 0.03 | 0 | 0.2 | 0.3 | Bell peppers and chilli peppers (1%) |
| <i>Heptachlor (sum)</i> | POPs | 0.1 | 0.12 | 0.13 | 0.01 | 13.8 | 11.7 | 11.0 | 0 | 0.3 | 0.1 | 0.4 | Beef (1%), cucumber (n=1/62) (2013 only) |
| <i>Lindane (HCH-gamma)</i> | POPs | 0.01 | 0.09 | 0.090 | 0.01 | 95.4 | 11.1 | 10.6 | 0 | 0.1 | 0.04 | 0.1 | Seafood and freshwater food products (0.5-2%) |
| <i>Methamidophos</i> | NA | 1 | 0.16 | 0.17 | 0.22 | 22.3 | 140.4 | 128.4 | 0 | 0.2 | 0.3 | 0.2 | Okra (5-8%) |
| <i>Methidathion</i> | NA | 1 | 0.11 | 0.12 | 0.11 | 11.2 | 100.1 | 94.3 | 0.2 | 0.1 | 0.1 | 0.1 | Grapefruits, oranges (1-6%) |
| <i>Monocrotophos</i> | NA | 0.6 | 0.14 | 0.16 | 0.18 | 30.7 | 128.1 | 115.4 | 0 | 0.03 | 0.3 | 0 | - |
| <i>Parathion (sum)</i> | NA | 0.6 | 0.17 | 0.17 | 0.22 | 36.7 | 132.2 | 127.9 | 0 | 0 | 0 | 0 | - |
| <i>Phorate (sum)</i> | NA | 0.7 | 0.36 | 0.37 | 0.49 | 69.5 | 136.7 | 130.1 | 0 | 0 | 0 | 0 | - |
| <i>Quinalphos</i> | NA | 0.5 | 0.12 | 0.13 | 0.14 | 28.5 | 116.5 | 109.7 | 0 | 0 | 0 | 0 | - |
| <i>Terbufos</i> | NA | 0.6 | 0.04 | 0.04 | 0.07 | 12.1 | 194.7 | 184.4 | 0 | 0 | 0 | 0 | - |

* Regulation (EC) No 1107/2009 per foodstuff

A: approved; NA: not approved (in italics)

** Detected for at least 2 years and among more than 100 analyses

Annex 14. Definition of the size of servings

In the framework of the revision of the food-based dietary guidelines, new quantities of food are proposed as dietary guidelines for different food sub-groups. To be expressed simply and clearly, these quantities must be translated into a given number of servings. The objective of this section is to determine the size of a usual serving of the different food sub-groups.

The consumption data used come from the INCA2 study described in Section 5.5.1.

Method

The serving sizes were estimated for each of the 32 food sub-groups resulting from the food categorisation work described in Section 5.2.2 (see Table 25). These sub-groups are also grouped into 10 food groups.

A food serving has been defined as the total amount consumed (in g) during an act of consumption, i.e. one line from the INCA2 consumption diary. Thus, for example, 3 biscuits consumed in the course of 3 different meals correspond to 3 servings of biscuits (3 different lines in the diary) while 3 biscuits consumed during a single act of consumption (1 line in the diary) correspond to a single serving.

As with the other sections, two populations were considered: women aged 18 to 54 years and men aged 18 to 64 years. The estimates were therefore carried out for each of these populations but also by considering the entire adult sample (women aged 18-54 years and men aged 18-64 years).

Results

After verifying that the average serving sizes were statistically different between the male and female populations, an analysis of the distributions of the serving sizes was conducted separately for men and women. Given the distribution curves observed, a case-by-case approach was followed to determine a serving size that reflected the sizes actually consumed. Depending on the shape of the distributions, the mode or the median were considered more relevant and representative of practices than the average. For sugar-sweetened beverages such as soda, the size of the commercial container was chosen (33 cl).

In some cases, the distribution was bimodal, related to the fact that the sub-group could be consumed as a starter or main course, in different proportions. It thus proved necessary to distinguish the serving sizes according to the consumption occasions (starter or main course). This was the case with vegetables, starchy, savoury/fatty processed products (such as potato chips or French fries) and fish (such as smoked salmon or salmon steaks).

In other cases, the bimodal or multimodal distribution could be explained by the fact that some individuals consume one serving while others consume two or more. In this case, the modes are multiples and the serving selected is the smallest. This explains why the serving sizes selected are often identical for men and women (82%) whereas the average quantities are mostly higher in men. For some sub-groups, the servings are larger in men. This is particularly the case with bread, cheese and starchy, savoury/fatty processed products consumed as a main meal (**Table 38**).

Table 38: Serving size of the sub-groups for men and women and according to the consumption occasions if applicable

| Sub-groups | Consumption occasion | Serving size for men (g) | Serving size for women (g) |
|--|----------------------|--------------------------|----------------------------|
| Vegetables | As a starter | 50 | 50 |
| | As a main dish | 100 | 100 |
| Fresh fruits | - | 150 | 150 |
| Dried fruits | - | 20 | 20 |
| Processed fruits: purees and cooked fruit | - | 100 | 100 |
| Oilseeds | - | 15 | 15 |
| Refined bread and bread products | - | 60 | 50 |
| Wholegrain bread and bread products | - | 60 | 50 |
| Other refined starches | - | 100 | 100 |
| Other wholegrain starches | - | 100 | 100 |
| Starch-based, sweet/fatty processed products | - | 50 | 50 |
| Starch-based, savoury/fatty processed products | As a main dish | 100 | 50 |
| | As a snack | 20 | 20 |
| Pulses | - | 100 | 100 |
| Poultry | - | 130 | 130 |
| Red meat | - | 130 | 130 |
| Delicatessen meats | - | 50 | 50 |
| Oily fish | As a starter | 40 | 20 |
| | As a main dish | 110 | 110 |
| Other fish | As a starter | 40 | 40 |
| | As a main dish | 100 | 100 |
| Eggs | - | 50 | 50 |
| Milk | - | 250 | 250 |
| Plain fresh dairy products | - | 125 | 125 |
| Sweetened fresh dairy products | - | 125 | 125 |
| Sweetened dairy desserts | - | 125 | 100 |
| Cheeses | - | 45 | 30 |
| Butter and reduced-fat butter | - | 10 | 10 |
| Vegetable oils rich in ALA | - | 10 | 10 |
| Vegetable oils poor in ALA and margarines | - | 10 | 10 |
| Sauces, fresh creams and condiments | - | 15 | 15 |
| Sweetened products | - | 15 | 15 |
| Sugar-sweetened beverages such as soda | - | 330 | 330 |
| Fruit juice | - | 150 | 150 |

Annex 15. Nutrient intakes obtained after optimisation according to Scenario A1 in women with high iron requirements

| Nutrient | Intake as absolute value | Lower nutritional constraint | Upper nutritional constraint | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) |
|--|--------------------------|------------------------------|------------------------------|---|---|
| Total energy intake (TEI) (kcal) | 2205 | 1995 | 2205 | 111 | 100 |
| Vitamin A (µg) | 1631 | 650 | 3000 | 251 | 54 |
| Vitamin B1 (mg/kcal) | 0.00058 | 0.00058 | - | 100 | - |
| Vitamin B2 (mg/kcal) | 0.00086 | 0.00071 | - | 121 | - |
| Vitamin B3 (mg/kcal) | 0.0067 | 0.0067 | - | 100 | - |
| Vitamin B5 (mg) | 7.5 | - | - | - | - |
| Vitamin B6 (mg) | 1.9 | 1.5 | 25 | 126 | 8 |
| Vitamin B9 (µg) | 678 | 330 | - | 205 | - |
| Vitamin B12 (µg) | 5.8 | 4 | - | 146 | - |
| Vitamin C (mg) | 114 | 110 | - | 104 | - |
| Vitamin D (µg) | 6.8 | 15 | 50 | 45 | 14 |
| Vitamin E (mg) | 19 | - | 300 | - | 6 |
| Calcium (mg) | 1000 | 1000 | 2500 | 100 | 40 |
| Copper (mg) | 3.1 | 1 | 5 | 307 | 61 |
| Iron (mg) | 16 | 16 | - | 101 | - |
| Iodine (µg) | 150 | 150 | 600 | 100 | 25 |
| Magnesium (mg) | 462 | 360 | - | 128 | - |
| Manganese (mg) | 5.6 | - | - | - | - |
| Phosphorus (mg) | 1767 | 700 | - | 252 | - |
| Potassium (mg) | 3854 | - | - | - | - |
| Selenium (µg) | 109 | 70 | 300 | 156 | 36 |
| Sodium (mg) | 2273 | - | 2273 | - | 100 |
| Zinc (mg) | 11 | 11 | 25 | 100 | 44 |
| Water (g) | 2100 | 1900 | 2100 | 111 | 100 |
| Proteins (% TEI) | 17 | 10 | 20 | 174 | 87 |
| Fats (% TEI) | 35 | 35 | 40 | 100 | 88 |
| SFA (% TEI) | 9.4 | - | 12 | - | 78 |
| Lauric + myristic + palmitic acids (% TEI) | 6.5 | - | 8 | - | 81 |
| Linoleic acid (% TEI) | 4.9 | 4 | - | 122 | - |
| α-linolenic acid (% TEI) | 1 | 1 | - | 100 | - |
| EPA + DHA (mg) | 934 | 500 | - | 187 | - |
| Carbohydrates (% TEI) | 43 | 40 | 55 | 108 | 79 |
| Total sugars excluding lactose (g) | 32 | - | 100 | - | 32 |
| Fibres (g) | 40 | 30 | - | 134 | - |

Annex 16. Nutrient intakes obtained after optimisation according to Scenarios B2 and B6 in women with low iron requirements

| Nutrient | Scenario B2 | Scenario B6 | | | Scenario B2 | | Scenario B6 | |
|----------------------------------|--------------------------|--------------------------|------------------------------|------------------------------|---|---|---|---|
| | Intake as absolute value | Intake as absolute value | Lower nutritional constraint | Upper nutritional constraint | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) |
| Total energy intake (TEI) (kcal) | 2039 | 2123 | 1995 | 2205 | 102 | 92 | 106 | 96 |
| Vitamin A (µg) | 822 | 809 | 650 | 3000 | 127 | 27 | 124 | 27 |
| Vitamin B1 (mg/kcal) | 0.00059 | 0.00060 | 0.00058 | - | 102 | - | 103 | - |
| Vitamin B2 (mg/kcal) | 0.00096 | 0.00095 | 0.00071 | - | 135 | - | 134 | - |
| Vitamin B3 (mg/kcal) | 0.0088 | 0.0084 | 0.0067 | - | 131 | - | 125 | - |
| Vitamin B5 (mg) | 5.9 | 6.1 | - | - | - | - | - | - |
| Vitamin B6 (mg) | 2.1 | 2.1 | 1.5 | 25 | 140 | 8 | 143 | 9 |
| Vitamin B9 (µg) | 379 | 417 | 330 | - | 115 | - | 127 | - |
| Vitamin B12 (µg) | 6.5 | 5.6 | 4 | - | 162 | - | 140 | - |
| Vitamin C (mg) | 110 | 110 | 110 | - | 100 | - | 100 | - |
| Vitamin D (µg) | 3.4 | 3.5 | 15 | 50 | 23 | 7 | 24 | 7 |
| Vitamin E (mg) | 14 | 14 | - | 300 | - | 5 | - | 5 |
| Calcium (mg) | 1058 | 1095 | 1000 | 2500 | 106 | 42 | 110 | 44 |
| Copper (mg) | 2 | 2.0138 | 1 | 5 | 190 | 38 | 201 | 40 |
| Iron (mg) | 11 | 12 | 11 | - | 100 | - | 110 | - |
| Iodine (µg) | 150 | 150 | 150 | 600 | 100 | 25 | 100 | 25 |
| Magnesium (mg) | 378 | 403 | 360 | - | 105 | - | 112 | - |
| Manganese (mg) | 4.6 | 4.9 | - | - | - | - | - | - |
| Phosphorus (mg) | 1526 | 1589 | 700 | - | 218 | - | 227 | - |
| Potassium (mg) | 3408 | 3514 | - | - | - | - | - | - |
| Selenium (µg) | 83 | 78 | 70 | 300 | 119 | 28 | 111 | 26 |
| Sodium (mg) | 2010 | 2072 | - | 2273 | - | 88 | - | 91 |
| Zinc (mg) | 11 | 11 | 11 | 25 | 100 | 44 | 100 | 44 |

| Nutrient | Scenario B2 | Scenario B6 | | | Scenario B2 | | Scenario B6 | |
|--|--------------------------|--------------------------|------------------------------|------------------------------|---|---|---|---|
| | Intake as absolute value | Intake as absolute value | Lower nutritional constraint | Upper nutritional constraint | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) | Deviation from the lower nutritional constraint (%) | Deviation from the upper nutritional constraint (%) |
| Water (g) | 2080 | 2100 | 1900 | 2100 | 109 | 99 | 111 | 100 |
| Proteins (% TEI) | 17 | 16 | 10 | 20 | 169 | 84 | 165 | 82 |
| Fats (% TEI) | 35 | 35 | 35 | 40 | 100 | 88 | 100 | 88 |
| SFA (% TEI) | 11 | 11 | - | 12 | - | 94 | - | 92 |
| Lauric + myristic + palmitic acids (% TEI) | 7 | 7 | - | 8 | - | 92 | - | 91 |
| Linoleic acid (% TEI) | 5 | 5 | 4 | - | 116 | - | 124 | - |
| α-linolenic acid (% TEI) | 1 | 1 | 1 | - | 100 | - | 100 | - |
| EPA + DHA (mg) | 500 | 500 | 500 | - | 100 | - | 100 | - |
| Carbohydrates (% TEI) | 45 | 45 | 40 | 55 | 112 | 82 | 113 | 82 |
| Total sugars excluding lactose (g) | 84 | 86 | - | 100 | - | 84 | - | 86 |
| Fibres (g) | 26 | 30 | 30 | - | 85 | - | 100 | - |

Annex 17. Levels of exposure to food additives obtained after optimisation according to the scenarios in women with low iron requirements

| Substance (unit) | ADI | TDS2 median exposure | TDS2 average exposure | Scenario B2 | | | | Scenario B6 | | | |
|-------------------------|-----|----------------------|-----------------------|----------------------------------|-------|------------------------|-------------------------|----------------------------------|-------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure |
| Tartaric acid (mg/kg/d) | 30 | 0.03 | 0.06 | 0.06 | 0.2 | 186 | 105 | 0.08 | 0.3 | 231 | 131 |
| Nitrites (µg/kg/d) | 60 | 1.21 | 1.39 | 0.10 | 0.2 | 8 | 7 | 0.09 | 0.2 | 8 | 7 |
| Annatto (µg/kg/d) | 65 | 0.84 | 1.12 | 0.76 | 1 | 90 | 68 | 0.75 | 1 | 89 | 67 |
| Sulphites (mg/kg/d) | 0.7 | 0.05 | 0.10 | 0.03 | 5 | 60 | 32 | 0.03 | 5 | 61 | 33 |

ADI: acceptable daily intake

Annex 18. Levels of exposure to contaminants excluding pesticides obtained after optimisation according to the scenarios in women with low iron requirements

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B2 | | | | Scenario B6 | | | |
|------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| Acrylamide (ng/kg/d) | 339.469 | 339.47 | 446.23 | 315.96 | 93 | 93 | 71 | 316.56 | 93 | 93 | 71 |
| Aflatoxins (ng/kg/d) | 0.404236 | 0.40 | 0.43 | 0.05 | 12 | 12 | 12 | 0.05 | 12 | 12 | 12 |
| Ag (µg/kg/d) | | 1.43 | 1.72 | 1.82 | | 127 | 106 | 1.69 | | 118 | 98 |
| Al (µg/kg/d) | 142.857 | 38.72 | 42.18 | 42.37 | 30 | 109 | 100 | 46.14 | 32 | 119 | 109 |
| AN (ng/kg/d) | | 0.96 | 1.01 | 0.89 | | 93 | 88 | 0.88 | | 92 | 87 |
| Inorganic As (µg/kg/d) | 0.506682 | 0.51 | 0.61 | 0.93 | 183 | 183 | 152 | 0.78 | 153 | 153 | 127 |
| Organic As (µg/kg/d) | | 0.18 | 0.23 | 0.38 | | 209 | 165 | 0.32 | | 173 | 137 |
| Ba (µg/kg/d) | 200 | 6.02 | 6.30 | 8.45 | 4 | 140 | 134 | 9.51 | 5 | 158 | 151 |
| BcFL (ng/kg/d) | | 0.25 | 0.26 | 0.17 | | 68 | 66 | 0.17 | | 66 | 64 |
| BDE-209 = (ng/kg/d) | 0.303109 | 0.30 | 0.34 | 0.27 | 89 | 89 | 79 | 0.27 | 88 | 88 | 78 |
| BghiP (ng/kg/d) | | 0.37 | 0.41 | 0.41 | | 111 | 100 | 0.39 | | 105 | 94 |
| Biochanin A (ng/kg/d) | | 0.00 | 6.66 | 21.60 | | | 324 | 65.46 | | | 983 |
| BjF (ng/kg/d) | | 0.13 | 0.16 | 0.17 | | 129 | 107 | 0.13 | | 101 | 83 |
| BkF (ng/kg/d) | | 0.11 | 0.13 | 0.13 | | 118 | 98 | 0.10 | | 92 | 76 |
| BPA (µg/kg/d) | 0.083 | 0.04 | 0.04 | 0.06 | 76 | 160 | 158 | 0.07 | 90 | 189 | 186 |
| Cd (µg/kg/d) | 0.357143 | 0.14 | 0.15 | 0.17 | 48 | 120 | 114 | 0.17 | 48 | 121 | 114 |
| Co (µg/kg/d) | 1.6 | 0.17 | 0.18 | 0.18 | 11 | 106 | 102 | 0.20 | 13 | 116 | 112 |
| Coumestrol (ng/kg/d) | | 9.37 | 32.85 | 56.25 | | 600 | 171 | 56.25 | | 600 | 171 |
| CPP (ng/kg/d) | | 0.39 | 0.42 | 0.32 | | 83 | 77 | 0.31 | | 81 | 75 |
| CrIII (µg/kg/d) | 300 | 3.73 | 3.85 | 4.10 | 1 | 110 | 106 | 4.22 | 1 | 113 | 109 |
| CrVI (µg/kg/d) | 0.509611 | 0.51 | 0.56 | 0.55 | 108 | 108 | 98 | 0.56 | 110 | 110 | 100 |
| Daidzein (ng/kg/d) | | 85.60 | 3632.05 | 2399.69 | | 2803 | 66 | 7085.48 | | 8277 | 195 |
| DAS (ng/kg/d) | | 7.46 | 7.82 | 8.44 | | 113 | 108 | 8.44 | | 113 | 108 |
| DbaeP (ng/kg/d) | | 0.11 | 0.12 | 0.08 | | 69 | 66 | 0.08 | | 67 | 64 |
| DBahA (ng/kg/d) | | 0.07 | 0.07 | 0.04 | | 65 | 63 | 0.04 | | 61 | 59 |
| DbahP (ng/kg/d) | | 0.10 | 0.11 | 0.08 | | 81 | 76 | 0.08 | | 79 | 75 |
| DbaiP (ng/kg/d) | | 0.10 | 0.11 | 0.09 | | 82 | 77 | 0.08 | | 80 | 76 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B2 | | | | Scenario B6 | | | |
|---|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| DbalP (ng/kg/d) | | 0.12 | 0.13 | 0.08 | | 71 | 65 | 0.08 | | 70 | 64 |
| Dioxins and furans (pg TEQ05/kg/d) | | 0.14 | 0.15 | 0.17 | | 120 | 113 | 0.17 | | 121 | 113 |
| Dioxins, furans and DL-PCBs (pg TEQ05/kg/d) | 0.7 | 0.34 | 0.40 | 0.51 | 73 | 150 | 128 | 0.51 | 73 | 151 | 129 |
| DOM1 (ng/kg/d) | | 7.27 | 7.57 | 7.60 | | 105 | 100 | 7.61 | | 105 | 101 |
| DON (ng/kg/d) | 1000 | 336.28 | 357.17 | 297.45 | 30 | 88 | 83 | 296.73 | 30 | 88 | 83 |
| Enterolactone (ng/kg/d) | | 15.91 | 70.37 | 216.70 | | 1362 | 308 | 225.56 | | 1418 | 321 |
| Equol (ng/kg/d) | | 12.97 | 58.78 | 183.00 | | 1411 | 311 | 198.16 | | 1527 | 337 |
| FA (ng/kg/d) | | 2.81 | 3.00 | 2.21 | | 79 | 74 | 2.08 | | 74 | 69 |
| FB1+FB2 (ng/kg/d) | 2000 | 17.21 | 23.25 | 11.67 | 1 | 68 | 50 | 11.13 | 1 | 65 | 48 |
| Formononetin (ng/kg/d) | | 0.19 | 24.75 | 30.44 | | 15665 | 123 | 64.50 | | 33198 | 261 |
| FusX (ng/kg/d) | | 7.46 | 7.82 | 8.44 | | 113 | 108 | 8.44 | | 113 | 108 |
| Ga (µg/kg/d) | | 0.02 | 0.02 | 0.02 | | 100 | 93 | 0.02 | | 101 | 94 |
| Ge (µg/kg/d) | | 0.05 | 0.06 | 0.04 | | 83 | 74 | 0.04 | | 83 | 74 |
| Genistein (ng/kg/d) | | 65.64 | 4907.47 | 3097.19 | | 4719 | 63 | 9292.42 | | 14157 | 189 |
| Glycitein (ng/kg/d) | | 13.90 | 704.40 | 446.83 | | 3214 | 63 | 1249.66 | | 8988 | 177 |
| PAH4 (ng/kg/d) | 1.30359 | 1.30 | 1.48 | 1.29 | 99 | 99 | 87 | 1.09 | 83 | 83 | 73 |
| HBCD (ng/kg/d) | 0.137901 | 0.14 | 0.18 | 1.61 | 1167 | 1167 | 894 | 1.64 | 1192 | 1192 | 913 |
| Inorganic Ag (µg/kg/d) | 0.571429 | 0.10 | 0.10 | 0.10 | 17 | 101 | 97 | 0.10 | 17 | 101 | 96 |
| IP (ng/kg/d) | | 0.17 | 0.19 | 0.16 | | 96 | 87 | 0.15 | | 86 | 78 |
| Li (µg/kg/d) | | 0.61 | 0.73 | 0.44 | | 72 | 61 | 0.47 | | 77 | 64 |
| MAS (ng/kg/d) | | 7.77 | 8.12 | 7.60 | | 98 | 94 | 7.61 | | 98 | 94 |
| Matairesinol (ng/kg/d) | | 0.00 | 25.98 | 18.03 | | | 69 | 45.52 | | | 175 |
| MCH (ng/kg/d) | | 0.11 | 0.11 | 0.05 | | 51 | 50 | 0.05 | | 49 | 48 |
| MeHg (µg/kg/d) | 0.185714 | 0.01 | 0.02 | 0.04 | 21 | 731 | 199 | 0.03 | 14 | 494 | 135 |
| Mo (µg/kg/d) | | 1.24 | 1.34 | 1.94 | | 156 | 145 | 2.82 | | 227 | 210 |
| Ni (µg/kg/d) | 2.8 | 2.19 | 2.33 | 2.75 | 98 | 126 | 118 | 3.21 | 115 | 147 | 138 |
| Niv (ng/kg/d) | 1200 | 21.93 | 25.13 | 32.03 | 3 | 146 | 127 | 32.00 | 3 | 146 | 127 |
| OTA (ng/kg/d) | 17.1429 | 0.90 | 0.95 | 1.07 | 6 | 120 | 113 | 1.07 | 6 | 119 | 113 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B2 | | | | Scenario B6 | | | |
|--------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| OTB (ng/kg/d) | | 0.73 | 0.77 | 1.01 | | 138 | 131 | 1.01 | | 138 | 131 |
| Pat (ng/kg/d) | 400 | 9.30 | 11.01 | 15.41 | 4 | 166 | 140 | 15.29 | 4 | 164 | 139 |
| Pb (µg/kg/d) | 0.174303 | 0.17 | 0.19 | 0.20 | 117 | 117 | 107 | 0.21 | 122 | 122 | 112 |
| PBB (ng/kg/d) | 0.0085212 | 0.01 | 0.01 | 0.01 | 67 | 67 | 57 | 0.01 | 70 | 70 | 59 |
| PBDE (7) (ng/kg/d) | 10 | 0.14 | 0.21 | 0.34 | 3 | 248 | 163 | 0.38 | 4 | 279 | 183 |
| PCB indicators (6) (pg/kg/d) | 10000 | 1256.39 | 1822.04 | 3080.69 | 31 | 245 | 169 | 3182.68 | 32 | 253 | 175 |
| DL-PCBs (pg TEQ05/kg/d) | | 0.20 | 0.25 | 0.34 | | 173 | 138 | 0.34 | | 173 | 138 |
| PFBA (ng/kg/d) | | 1.23 | 1.29 | 1.73 | | 140 | 134 | 1.89 | | 153 | 146 |
| PFBS (ng/kg/d) | | 0.55 | 0.59 | 0.81 | | 148 | 137 | 0.90 | | 165 | 152 |
| PFDA (ng/kg/d) | | 0.17 | 0.18 | 0.29 | | 171 | 159 | 0.30 | | 178 | 166 |
| PFDoA (ng/kg/d) | | 0.35 | 0.45 | 0.81 | | 229 | 179 | 0.85 | | 241 | 188 |
| PFDS (ng/kg/d) | | 0.19 | 0.21 | 0.37 | | 199 | 177 | 0.38 | | 206 | 182 |
| PFHpA (ng/kg/d) | | 0.38 | 0.44 | 0.63 | | 164 | 142 | 0.66 | | 173 | 150 |
| PFHpS (ng/kg/d) | | 0.32 | 0.37 | 0.53 | | 168 | 144 | 0.56 | | 177 | 152 |
| PFHxA (ng/kg/d) | | 0.41 | 0.47 | 0.73 | | 177 | 155 | 0.78 | | 189 | 165 |
| PFHxS (ng/kg/d) | | 0.19 | 0.21 | 0.30 | | 161 | 144 | 0.32 | | 172 | 155 |
| PFNA (ng/kg/d) | | 0.23 | 0.25 | 0.41 | | 177 | 163 | 0.44 | | 192 | 177 |
| PFOA (ng/kg/d) | 200 | 0.35 | 0.40 | 0.58 | 0.3 | 168 | 145 | 0.66 | 0.3 | 192 | 166 |
| PFOS (ng/kg/d) | 80 | 0.34 | 0.35 | 0.50 | 1 | 148 | 142 | 0.51 | 1 | 151 | 145 |
| PFPA (ng/kg/d) | | 0.72 | 0.75 | 0.99 | | 137 | 132 | 1.06 | | 147 | 141 |
| PFTeDA (ng/kg/d) | | 1.04 | 1.18 | 2.08 | | 200 | 177 | 2.15 | | 206 | 182 |
| PFTrDA (ng/kg/d) | | 0.63 | 0.67 | 0.95 | | 151 | 141 | 0.98 | | 156 | 146 |
| PFUnA (ng/kg/d) | | 1.50 | 1.64 | 2.51 | | 167 | 153 | 2.69 | | 179 | 164 |
| PHE (ng/kg/d) | | 9.07 | 9.83 | 7.40 | | 82 | 75 | 7.17 | | 79 | 73 |
| PY (ng/kg/d) | | 6.44 | 6.76 | 4.78 | | 74 | 71 | 4.58 | | 71 | 68 |
| Sb (µg/kg/d) | | 0.03 | 0.03 | 0.02 | | 66 | 67 | 0.02 | | 69 | 70 |
| Secoisolariciresinol (ng/kg/d) | | 92.94 | 220.94 | 376.46 | | 405 | 170 | 483.38 | | 520 | 219 |
| Sn (µg/kg/d) | | 1.36 | 3.56 | 5.15 | | 378 | 145 | 5.19 | | 381 | 146 |
| Sr (µg/kg/d) | 600 | 19.63 | 24.32 | 22.62 | 4 | 115 | 93 | 24.09 | 4 | 123 | 99 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B2 | | | | Scenario B6 | | | |
|---------------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| Te (µg/kg/d) | | 0.03 | 0.04 | 0.03 | | 89 | 75 | 0.03 | | 93 | 78 |
| T2+HT2 toxins (ng/kg/d) | 60 | 27.58 | 28.64 | 33.84 | 56 | 123 | 118 | 33.81 | 56 | 123 | 118 |
| V (µg/kg/d) | | 0.77 | 0.82 | 0.73 | | 95 | 89 | 0.74 | | 96 | 90 |
| Verrucarol (ng/kg/d) | | 7.26 | 7.51 | 7.60 | | 105 | 101 | 7.61 | | 105 | 101 |
| Zearalenone and metabolites (ng/kg/d) | 250 | 60.42 | 62.90 | 62.70 | 25 | 104 | 100 | 63.99 | 26 | 106 | 102 |

The values in red are higher than 100%.

Annex 19. Levels of exposure to pesticides obtained after optimisation according to the scenarios in women with low iron requirements (substances for which exposure is greater than 10% of the HBGV)

| Pesticide | EU status* | HBGV (µg/kg bw/d) | TDS2 median exposure (µg/kg bw/d) | TDS2 average exposure (µg/kg bw/d) | Scenario B2 | | | | Scenario B6 | | | | FR surveillance and control plans: percentages of detection and contributors | | | | |
|----------------------------|-------------|-------------------|-----------------------------------|------------------------------------|-----------------------------|--------------|------------------------|-------------------------|-----------------------------|--------------|------------------------|-------------------------|--|------------|------------|------------|--|
| | | | | | Total exposure (µg/kg bw/d) | % HBGV | % TDS2 median exposure | % TDS2 average exposure | Total exposure (µg/kg bw/d) | % HBGV | % TDS2 median exposure | % TDS2 average exposure | 2010 | 2011 | 2012 | 2013 | Main contributors** and % detection |
| <i>Carbofuran (sum)</i> | NA | 0.15 | 0.063 | 0.067 | 0.09 | 60.2 | 142.8 | 134.3 | 0.092 | 61.4 | 145.5 | 136.9 | 0.1 | 0.1 | 0.3 | 0.2 | Bell peppers and chilli peppers (1-2%), tomatoes (1-3%), green beans (1%) |
| <i>Chlorfenvinphos</i> | NA | 0.5 | 0.054 | 0.059 | 0.071 | 14.3 | 131.8 | 121.0 | 0.073 | 14.5 | 134.1 | 123.1 | 0.1 | 0.02 | 0 | 0 | - |
| Chlorpyrifos-ethyl | A | 1 | 0.068 | 0.079 | 0.126 | 12.6 | 184.4 | 160.6 | 0.127 | 12.7 | 186.2 | 162.1 | 4.2 | 4.6 | 5.3 | 5.7 | Fruits and vegetables (1-50% citrus), tea (2-20%) |
| <i>Coumaphos</i> | NA | 0.5 | 0.026 | 0.031 | 0.078 | 15.6 | 300.2 | 253.8 | 0.078 | 15.6 | 300.2 | 253.8 | 0 | 0 | 0 | 0 | - |
| <i>Diazinon</i> | NA | 0.2 | 0.062 | 0.066 | 0.079 | 39.6 | 126.8 | 119.5 | 0.081 | 40.7 | 130.5 | 122.9 | 0 | 0.02 | 0.1 | 0.1 | Aubergines and bell peppers (<1%) |
| Dieldrin (sum) | POPs | 0.1 | 0.129 | 0.142 | 0.017 | 17.2 | 13.4 | 12.2 | 0.017 | 17.4 | 13.5 | 12.3 | 0.04 | 0.7 | 0.6 | 0.4 | Seafood and freshwater food products (14-20%), courgettes (0-2%) |
| Dimethoate (sum) | A | 1 | 0.572 | 0.619 | 0.72 | 72 | 125.9 | 116.3 | 0.725 | 72.5 | 126.8 | 117.0 | 0.8 | 0.6 | 1 | 2.4 | Fruits and vegetables (1% strawberries to 50% cherries), tea (1-3%) |
| Dithiocarbamates | A | 6 | 0.669 | 0.712 | 1.125 | 18.7 | 168 | 158.0 | 1.163 | 19.4 | 173.8 | 163.5 | 9.9 | 6.2 | 9.5 | 9.5 | Salads (20-35%) |
| Ethoprophos | A | 0.4 | 0.095 | 0.103 | 0.123 | 30.7 | 129.2 | 119.3 | 0.125 | 31.3 | 131.4 | 121.4 | 0 | 0 | 0 | 0 | - |
| Fipronil (sum) | A | 0.2 | 0.018 | 0.019 | 0.04 | 20 | 227.2 | 206.2 | 0.041 | 20.6 | 234.5 | 212.9 | 0.03 | 0 | 0.2 | 0.3 | Bell peppers and chilli peppers (1%) |
| Heptachlor (sum) | POPs | 0.1 | 0.128 | 0.134 | 0.022 | 22.3 | 17.4 | 16.7 | 0.023 | 22.6 | 17.6 | 16.9 | 0 | 0.3 | 0.1 | 0.4 | Beef (1%), cucumber (n=1/62) (2013 only) |
| Lindane (HCH-gamma) | POPs | 0.01 | 0.083 | 0.087 | 0.010 | 103.6 | 12.4 | 11.9 | 0.011 | 108.3 | 12.9 | 12.4 | | | | | Seafood and freshwater food products (0.5-2%) |
| <i>Methamidophos</i> | NA | 1 | 0.168 | 0.182 | 0.227 | 22.7 | 135.5 | 124.7 | 0.228 | 22.8 | 136 | 125.2 | 0 | 0.2 | 0.3 | 0.2 | Okra (5-8%) |
| <i>Methidathion</i> | NA | 1 | 0.11 | 0.119 | 0.113 | 11.3 | 102.5 | 94.7 | 0.118 | 11.8 | 107.5 | 99.4 | 0.2 | 0.1 | 0.1 | 0.1 | Grapefruits and oranges (1-6%) |
| <i>Monocrotophos</i> | NA | 0.6 | 0.15 | 0.165 | 0.182 | 30.3 | 121.4 | 110.3 | 0.183 | 30.5 | 121.9 | 110.8 | 0 | 0.03 | 0.3 | 0 | - |
| <i>Parathion (sum)</i> | NA | 0.6 | 0.163 | 0.172 | 0.214 | 35.7 | 131.3 | 124.9 | 0.221 | 36.8 | 135.2 | 128.6 | 0 | 0 | 0 | 0 | - |
| <i>Phorate (sum)</i> | NA | 0.7 | 0.339 | 0.359 | 0.469 | 67 | 138.2 | 130.8 | 0.493 | 70.4 | 145.2 | 137.3 | 0 | 0 | 0 | 0 | - |
| <i>Quinalphos</i> | NA | 0.5 | 0.123 | 0.132 | 0.15 | 30 | 121.9 | 113.6 | 0.155 | 31 | 126.2 | 117.6 | 0 | 0 | 0 | 0 | - |
| <i>Terbufos</i> | NA | 0.6 | 0.038 | 0.041 | 0.081 | 13.6 | 215.8 | 197.8 | 0.084 | 14 | 222.7 | 204.1 | 0 | 0 | 0 | 0 | - |

* Regulation (EC) No 1107/2009

A: approved; NA: not approved (in italics)

** Detected for at least 2 years and among more than 100 analyses per foodstuff

Annex 20. Nutrient intakes obtained after optimisation according to Scenarios B3, B4 and B5 in women with high iron requirements

| Nutrient | Intake as absolute value Scenario B3 | Intake as absolute value Scenario B4 | Intake as absolute value Scenario B5 | Lower nutritional constraint | Upper nutritional constraint |
|--|--------------------------------------|--------------------------------------|--------------------------------------|------------------------------|------------------------------|
| Total energy intake (TEI) (kcal) | 2205 | 2108 | 2091 | 1995 | 2205 |
| Vitamin A (µg) | 957 | 937 | 935 | 650 | 3000 |
| Vitamin B1 (mg/kcal) | 0.00072 | 0.00075 | 0.00075 | 0.00058 | - |
| Vitamin B2 (mg/kcal) | 0.00109 | 0.00108 | 0.00111 | 0.00071 | - |
| Vitamin B3 (mg/kcal) | 0.0119 | 0.0115 | 0.0118 | 0.0067 | - |
| Vitamin B5 (mg) | 7.6 | 6.9 | 7.1 | - | - |
| Vitamin B6 (mg) | 2.6 | 2.5 | 2.5 | 1.5 | 25 |
| Vitamin B9 (µg) | 431 | 423 | 424 | 330 | - |
| Vitamin B12 (µg) | 8.2 | 9.66 | 8.6 | 4 | - |
| Vitamin C (mg) | 105 | 110 | 110 | 110 | - |
| Vitamin D (µg) | 4.2 | 5.7 | 5.2 | 15 | 50 |
| Vitamin E (mg) | 15 | 15 | 15 | - | 300 |
| Calcium (mg) | 950 | 1000 | 1000 | 1000 | 2500 |
| Copper (mg) | 2.2 | 2.0 | 2.0 | 1 | 5 |
| Iron (mg) | 15 | 15 | 15 | 16 | - |
| Iodine (µg) | 160 | 168 | 156 | 150 | 600 |
| Magnesium (mg) | 394 | 381 | 378 | 360 | - |
| Manganese (mg) | 3.5 | 3.1 | 3.0 | - | - |
| Phosphorus (mg) | 1695 | 1611 | 1603 | 700 | - |
| Potassium (mg) | 3701 | 3672 | 3669 | - | - |
| Selenium (µg) | 106 | 108 | 96 | 70 | 300 |
| Sodium (mg) | 2141 | 2165 | 2056 | - | 2273 |
| Zinc (mg) | 12 | 12 | 11 | 11 | 25 |
| Water (g) | 2100 | 2100 | 2100 | 1900 | 2100 |
| Proteins (% TEI) | 20 | 19 | 19 | 10 | 20 |
| Fats (% TEI) | 35 | 38 | 38 | 35 | 40 |
| SFA (% TEI) | 11 | 12 | 12 | - | 12 |
| Lauric + myristic + palmitic acids (% TEI) | 7.5 | 7.9 | 8.0 | - | 8 |
| Linoleic acid (% TEI) | 4.5 | 5.0 | 5 | 4 | |
| α-linolenic acid (% TEI) | 1 | 1 | 1 | 1 | - |
| EPA + DHA (mg) | 475 | 854 | 745 | 500 | - |
| Carbohydrates (% TEI) | 42 | 40 | 40 | 40 | 55 |
| Total sugars excluding lactose (g) | 85 | 100 | 100 | - | 100 |
| Fibres (g) | 26 | 26 | 26 | 30 | - |

Annex 21. Levels of exposure to additives obtained after optimisation according to the scenarios in women with high iron requirements

| Substance (unit) | ADI | TDS2 median exposure | TDS2 average exposure | Scenario B3 | | | | Scenario B4 | | | | Scenario B5 | | | |
|-------------------------|-----|----------------------|-----------------------|----------------------------------|-------|------------------------|-------------------------|----------------------------------|-------|------------------------|-------------------------|----------------------------------|-------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % ADI | % TDS2 median exposure | % TDS2 average exposure |
| Tartaric acid (mg/kg/d) | 30 | 0.03 | 0.06 | 0.08 | 0.3 | 230 | 130 | 0.09 | 0.3 | 263 | 149 | 0.09 | 0.3 | 263 | 149 |
| Nitrites (µg/kg/d) | 60 | 1.21 | 1.39 | 0.48 | 1 | 39 | 34 | 0.73 | 1 | 60 | 52 | 0.77 | 1 | 64 | 56 |
| Annatto (µg/kg/d) | 65 | 0.84 | 1.12 | 0.77 | 1 | 92 | 69 | 2.62 | 4 | 313 | 234 | 2.61 | 4 | 311 | 233 |
| Sulphites (mg/kg/d) | 0.7 | 0.05 | 0.10 | 0.04 | 6 | 78 | 42 | 0.06 | 9 | 117 | 63 | 0.06 | 9 | 114 | 61 |

ADI: acceptable daily intake

Annex 22. Levels of exposure to contaminants excluding pesticides obtained after optimisation according to the scenarios in women with high iron requirements

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B3 | | | Scenario B4 | | | Scenario B5 | | | | | |
|------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| Acrylamide (ng/kg/d) | 339.469 | 339.47 | 446.23 | 99.09 | 29 | 29 | 22 | 98.60 | 29 | 29 | 22 | 100.06 | 29 | 29 | 22 |
| Aflatoxins (ng/kg/d) | 0.404236 | 0.40 | 0.43 | 0.08 | 20 | 20 | 19 | 0.08 | 21 | 21 | 20 | 0.11 | 28 | 28 | 26 |
| Ag (µg/kg/d) | | 1.43 | 1.72 | 1.94 | | 136 | 113 | 2.21 | | 155 | 129 | 2.00 | | 140 | 116 |
| Al (µg/kg/d) | 142.857 | 38.72 | 42.18 | 43.83 | 31 | 113 | 104 | 49.98 | 35 | 129 | 118 | 48.58 | 34 | 125 | 115 |
| AN (ng/kg/d) | | 0.96 | 1.01 | 0.73 | | 76 | 72 | 0.77 | | 80 | 76 | 0.76 | | 80 | 76 |
| Inorganic As (µg/kg/d) | 0.506682 | 0.51 | 0.61 | 1.15 | 228 | 228 | 189 | 1.44 | 284 | 284 | 236 | 1.16 | 228 | 228 | 190 |
| Organic As (µg/kg/d) | | 0.18 | 0.23 | 0.48 | | 262 | 207 | 0.60 | | 329 | 260 | 0.48 | | 262 | 207 |
| Ba (µg/kg/d) | 200 | 6.02 | 6.30 | 8.58 | 4 | 143 | 136 | 8.54 | 4 | 142 | 136 | 8.53 | 4 | 142 | 135 |
| BcFL (ng/kg/d) | | 0.25 | 0.26 | 0.18 | | 71 | 69 | 0.18 | | 72 | 69 | 0.17 | | 70 | 67 |
| BDE-209 (ng/kg/d) | 0.303109 | 0.30 | 0.34 | 0.26 | 85 | 85 | 76 | 0.34 | 112 | 112 | 100 | 0.36 | 118 | 118 | 106 |
| BghiP (ng/kg/d) | | 0.37 | 0.41 | 0.27 | | 74 | 66 | 0.27 | | 75 | 67 | 0.25 | | 68 | 62 |
| Biochanin A (ng/kg/d) | | 0.00 | 6.66 | 33.38 | | | 501 | 65.46 | | | 983 | 65.46 | | | 983 |
| BjF (ng/kg/d) | | 0.13 | 0.16 | 0.19 | | 140 | 116 | 0.23 | | 174 | 144 | 0.18 | | 136 | 113 |
| BkF (ng/kg/d) | | 0.11 | 0.13 | 0.14 | | 127 | 106 | 0.17 | | 158 | 131 | 0.13 | | 124 | 103 |
| BPA (µg/kg/d) | 0.083 | 0.04 | 0.04 | 0.07 | 88 | 185 | 182 | 0.09 | 104 | 219 | 216 | 0.08 | 101 | 212 | 209 |
| Cd (µg/kg/d) | 0.357143 | 0.14 | 0.15 | 0.16 | 44 | 111 | 105 | 0.17 | 46 | 117 | 110 | 0.15 | 42 | 107 | 101 |
| Co (µg/kg/d) | 1.6 | 0.17 | 0.18 | 0.19 | 12 | 109 | 104 | 0.22 | 14 | 125 | 120 | 0.21 | 13 | 124 | 119 |
| Coumestrol (ng/kg/d) | | 9.37 | 32.85 | 56.25 | | 600 | 171 | 56.25 | | 600 | 171 | 56.25 | | 600 | 171 |
| CPP (ng/kg/d) | | 0.39 | 0.42 | 0.29 | | 74 | 68 | 0.28 | | 71 | 66 | 0.27 | | 69 | 64 |
| CrIII (µg/kg/d) | 300 | 3.73 | 3.85 | 4.17 | 1 | 112 | 108 | 4.09 | 1 | 110 | 106 | 4.11 | 1 | 110 | 107 |
| CrVI (µg/kg/d) | 0.509611 | 0.51 | 0.56 | 0.57 | 111 | 111 | 101 | 0.56 | 110 | 110 | 100 | 0.56 | 111 | 111 | 101 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B3 | | | | Scenario B4 | | | | Scenario B5 | | | |
|---|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| Daidzein (ng/kg/d) | | 85.60 | 3632.05 | 3675.38 | | 4294 | 101 | 7100.54 | | 8295 | 195 | 7102.11 | | 8297 | 196 |
| DAS (ng/kg/d) | | 7.46 | 7.82 | 7.58 | | 102 | 97 | 5.92 | | 79 | 76 | 5.87 | | 79 | 75 |
| DbaeP (ng/kg/d) | | 0.11 | 0.12 | 0.08 | | 67 | 63 | 0.08 | | 67 | 63 | 0.07 | | 66 | 62 |
| DBahA (ng/kg/d) | | 0.07 | 0.07 | 0.05 | | 72 | 69 | 0.05 | | 78 | 75 | 0.05 | | 72 | 69 |
| DbahP (ng/kg/d) | | 0.10 | 0.11 | 0.07 | | 72 | 68 | 0.07 | | 72 | 68 | 0.07 | | 72 | 68 |
| DbaiP (ng/kg/d) | | 0.10 | 0.11 | 0.08 | | 73 | 70 | 0.08 | | 74 | 70 | 0.08 | | 74 | 70 |
| DbalP (ng/kg/d) | | 0.12 | 0.13 | 0.08 | | 64 | 58 | 0.08 | | 64 | 58 | 0.07 | | 63 | 58 |
| Dioxins and furans (pg TEQ05/kg/d) | | 0.14 | 0.15 | 0.19 | | 136 | 128 | 0.20 | | 139 | 130 | 0.19 | | 133 | 125 |
| Dioxins, furans and DL-PCBs (pg TEQ05/kg/d) | 0.7 | 0.34 | 0.40 | 0.60 | 86 | 177 | 151 | 0.63 | 89 | 183 | 157 | 0.58 | 83 | 170 | 145 |
| DOM1 (ng/kg/d) | | 7.27 | 7.57 | 7.51 | | 103 | 99 | 5.92 | | 81 | 78 | 5.87 | | 81 | 78 |
| DON (ng/kg/d) | 1000 | 336.28 | 357.17 | 228.96 | 23 | 68 | 64 | 142.79 | 14 | 42 | 40 | 141.18 | 14 | 42 | 40 |
| Enterolactone (ng/kg/d) | | 15.91 | 70.37 | 226.75 | | 1425 | 322 | 228.34 | | 1435 | 324 | 228.64 | | 1437 | 325 |
| Equol (ng/kg/d) | | 12.97 | 58.78 | 202.01 | | 1557 | 344 | 207.15 | | 1597 | 352 | 208.11 | | 1604 | 354 |
| FA (ng/kg/d) | | 2.81 | 3.00 | 2.26 | | 80 | 75 | 2.40 | | 85 | 80 | 2.29 | | 81 | 76 |
| FB1+FB2 (ng/kg/d) | 2000 | 17.21 | 23.25 | 4.94 | 0.2 | 29 | 21 | 6.18 | 0.3 | 36 | 27 | 6.24 | 0.3 | 36 | 27 |
| Formononetin (ng/kg/d) | | 0.19 | 24.75 | 39.86 | | 20516 | 161 | 64.50 | | 33198 | 261 | 64.50 | | 33198 | 261 |
| FusX (ng/kg/d) | | 7.46 | 7.82 | 7.58 | | 102 | 97 | 5.92 | | 79 | 76 | 5.87 | | 79 | 75 |
| Ga (µg/kg/d) | | 0.02 | 0.02 | 0.02 | | 102 | 94 | 0.02 | | 94 | 88 | 0.02 | | 94 | 87 |
| Ge (µg/kg/d) | | 0.05 | 0.06 | 0.05 | | 85 | 76 | 0.05 | | 85 | 76 | 0.05 | | 85 | 76 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B3 | | | | Scenario B4 | | | | Scenario B5 | | | | |
|------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|-----|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | |
| Genistein (ng/kg/d) | | 65.64 | 4907.47 | 4767.04 | | 7263 | 97 | 9299.90 | | | 14169 | 190 | 9300.69 | | 14170 | 190 |
| Glycitein (ng/kg/d) | | 13.90 | 704.40 | 665.61 | | 4787 | 94 | 1251.58 | | | 9002 | 178 | 1251.78 | | 9003 | 178 |
| PAH4 (ng/kg/d) | 1.30359 | 1.30 | 1.48 | 1.33 | 102 | 102 | 90 | 1.56 | 120 | 120 | 105 | 1.28 | 99 | 99 | 87 | |
| HBCD (ng/kg/d) | 0.137901 | 0.14 | 0.18 | 1.53 | 1106 | 1106 | 847 | 1.55 | 1122 | 1122 | 860 | 1.57 | 1141 | 1141 | 874 | |
| Inorganic Ag (µg/kg/d) | 0.571429 | 0.10 | 0.10 | 0.10 | 17 | 104 | 99 | 0.10 | 18 | 106 | 101 | 0.10 | 17 | 103 | 98 | |
| IP (ng/kg/d) | | 0.17 | 0.19 | 0.14 | | 81 | 73 | 0.15 | | 88 | 79 | 0.13 | | 76 | 69 | |
| Li (µg/kg/d) | | 0.61 | 0.73 | 0.45 | | 74 | 62 | 0.42 | | 68 | 57 | 0.41 | | 67 | 57 | |
| MAS (ng/kg/d) | | 7.77 | 8.12 | 7.51 | | 97 | 93 | 5.92 | | 76 | 73 | 5.87 | | 76 | 72 | |
| Matairesinol (ng/kg/d) | | 0.00 | 25.98 | 25.50 | | | 98 | 45.52 | | | 175 | 45.52 | | | 175 | |
| MCH (ng/kg/d) | | 0.11 | 0.11 | 0.05 | | 48 | 47 | 0.06 | | 51 | 50 | 0.05 | | 51 | 50 | |
| MeHg (µg/kg/d) | 0.185714 | 0.01 | 0.02 | 0.05 | 28 | 941 | 256 | 0.07 | 38 | 1307 | 356 | 0.05 | 28 | 941 | 256 | |
| Mo (µg/kg/d) | | 1.24 | 1.34 | 2.03 | | 164 | 152 | 2.63 | | 212 | 196 | 2.63 | | 212 | 196 | |
| Ni (µg/kg/d) | 2.8 | 2.19 | 2.33 | 2.80 | 100 | 128 | 120 | 3.26 | 116 | 149 | 140 | 3.27 | 117 | 149 | 140 | |
| Niv (ng/kg/d) | 1200 | 21.93 | 25.13 | 30.25 | 3 | 138 | 120 | 15.51 | 1 | 71 | 62 | 15.09 | 1 | 69 | 60 | |
| OTA (ng/kg/d) | 17.1429 | 0.90 | 0.95 | 1.00 | 6 | 112 | 105 | 0.81 | 5 | 90 | 85 | 0.83 | 5 | 92 | 87 | |
| OTB (ng/kg/d) | | 0.73 | 0.77 | 0.99 | | 135 | 128 | 0.80 | | 109 | 104 | 0.82 | | 112 | 106 | |
| Pat (ng/kg/d) | 400 | 9.30 | 11.01 | 15.17 | 4 | 163 | 138 | 13.34 | 3 | 143 | 121 | 13.24 | 3 | 142 | 120 | |
| Pb (µg/kg/d) | 0.174303 | 0.17 | 0.19 | 0.19 | 111 | 111 | 102 | 0.21 | 121 | 121 | 111 | 0.21 | 118 | 118 | 108 | |
| PBB (ng/kg/d) | 0.0085212 | 0.01 | 0.01 | 0.01 | 89 | 89 | 76 | 0.01 | 88 | 88 | 75 | 0.01 | 83 | 83 | 71 | |
| PBDE (7) (ng/kg/d) | 10 | 0.14 | 0.21 | 0.49 | 5 | 358 | 235 | 0.52 | 5 | 376 | 247 | 0.50 | 5 | 364 | 239 | |
| PCB indicators (6) (pg/kg/d) | 10000 | 1256.39 | 1822.04 | 4151.29 | 42 | 330 | 228 | 4486.90 | 45 | 357 | 246 | 4115.08 | 41 | 328 | 226 | |
| DL-PCBs (pg TEQ05/kg/d) | | 0.20 | 0.25 | 0.41 | | 208 | 165 | 0.43 | | 217 | 172 | 0.39 | | 199 | 158 | |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B3 | | | | Scenario B4 | | | | Scenario B5 | | | |
|---------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| PFBA (ng/kg/d) | | 1.23 | 1.29 | 1.73 | | 140 | 134 | 1.88 | | 152 | 145 | 1.94 | | 157 | 150 |
| PFBS (ng/kg/d) | | 0.55 | 0.59 | 0.72 | | 131 | 122 | 0.79 | | 144 | 133 | 0.81 | | 148 | 137 |
| PFDA (ng/kg/d) | | 0.17 | 0.18 | 0.26 | | 157 | 146 | 0.27 | | 164 | 153 | 0.28 | | 167 | 155 |
| PFDaA (ng/kg/d) | | 0.35 | 0.45 | 0.69 | | 198 | 154 | 0.72 | | 204 | 159 | 0.74 | | 212 | 165 |
| PFDS (ng/kg/d) | | 0.19 | 0.21 | 0.34 | | 182 | 161 | 0.35 | | 188 | 166 | 0.36 | | 193 | 171 |
| PFHpA (ng/kg/d) | | 0.38 | 0.44 | 0.60 | | 157 | 136 | 0.63 | | 166 | 144 | 0.64 | | 168 | 146 |
| PFHpS (ng/kg/d) | | 0.32 | 0.37 | 0.50 | | 159 | 136 | 0.53 | | 168 | 144 | 0.54 | | 170 | 146 |
| PFHxA (ng/kg/d) | | 0.41 | 0.47 | 0.69 | | 167 | 146 | 0.73 | | 176 | 155 | 0.74 | | 181 | 158 |
| PFHxS (ng/kg/d) | | 0.19 | 0.21 | 0.29 | | 152 | 136 | 0.30 | | 160 | 144 | 0.31 | | 164 | 147 |
| PFNA (ng/kg/d) | | 0.23 | 0.25 | 0.37 | | 159 | 147 | 0.39 | | 170 | 157 | 0.40 | | 175 | 161 |
| PFOA (ng/kg/d) | 200 | 0.35 | 0.40 | 0.57 | 0.3 | 164 | 142 | 0.63 | 0.3 | 182 | 157 | 0.64 | 0.3 | 186 | 161 |
| PFOS (ng/kg/d) | 80 | 0.34 | 0.35 | 0.49 | 1 | 144 | 139 | 0.54 | 1 | 159 | 154 | 0.52 | 1 | 154 | 148 |
| PFPA (ng/kg/d) | | 0.72 | 0.75 | 0.94 | | 131 | 125 | 1.00 | | 139 | 134 | 1.02 | | 142 | 137 |
| PFTeDA (ng/kg/d) | | 1.04 | 1.18 | 1.88 | | 180 | 159 | 1.94 | | 186 | 165 | 2.06 | | 197 | 174 |
| PFTrDA (ng/kg/d) | | 0.63 | 0.67 | 0.83 | | 131 | 123 | 0.89 | | 141 | 132 | 0.95 | | 151 | 141 |
| PFUnA (ng/kg/d) | | 1.50 | 1.64 | 2.37 | | 157 | 144 | 2.53 | | 168 | 154 | 2.60 | | 173 | 159 |
| PHE (ng/kg/d) | | 9.07 | 9.83 | 7.75 | | 85 | 79 | 8.14 | | 90 | 83 | 7.98 | | 88 | 81 |
| PY (ng/kg/d) | | 6.44 | 6.76 | 4.57 | | 71 | 68 | 4.53 | | 70 | 67 | 4.53 | | 70 | 67 |
| Sb (µg/kg/d) | | 0.03 | 0.03 | 0.02 | | 70 | 71 | 0.02 | | 71 | 72 | 0.02 | | 71 | 71 |
| Secoisolaricire sinol (ng/kg/d) | | 92.94 | 220.94 | 413.46 | | 445 | 187 | 483.07 | | 520 | 219 | 482.57 | | 519 | 218 |
| Sn (µg/kg/d) | | 1.36 | 3.56 | 4.09 | | 300 | 115 | 3.58 | | 263 | 101 | 3.55 | | 260 | 100 |
| Sr (µg/kg/d) | 600 | 19.63 | 24.32 | 23.22 | 4 | 118 | 95 | 25.54 | 4 | 130 | 105 | 24.58 | 4 | 125 | 101 |

| Substance (unit) | Toxicological constraint | TDS2 median exposure | TDS2 average exposure | Scenario B3 | | | | Scenario B4 | | | | Scenario B5 | | | |
|---------------------------------------|--------------------------|----------------------|-----------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|----------------------------------|----------------------------|------------------------|-------------------------|
| | | | | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure | Total exposure as absolute value | % toxicological constraint | % TDS2 median exposure | % TDS2 average exposure |
| Te (µg/kg/d) | | 0.03 | 0.04 | 0.03 | | 83 | 69 | 0.03 | | 83 | 69 | 0.03 | | 83 | 69 |
| T2+HT2 toxins (ng/kg/d) | 60 | 27.58 | 28.64 | 31.84 | 53 | 115 | 111 | 20.33 | 34 | 74 | 71 | 19.96 | 33 | 72 | 70 |
| V (µg/kg/d) | | 0.77 | 0.82 | 0.71 | | 93 | 87 | 0.68 | | 89 | 83 | 0.66 | | 87 | 81 |
| Verrucarol (ng/kg/d) | | 7.26 | 7.51 | 7.51 | | 103 | 100 | 5.92 | | 82 | 79 | 5.87 | | 81 | 78 |
| Zearalenone and metabolites (ng/kg/d) | 250 | 60.42 | 62.90 | 61.28 | 25 | 101 | 97 | 48.51 | 19 | 80 | 77 | 49.63 | 20 | 82 | 79 |

Annex 23. Levels of exposure to pesticides obtained after optimisation according to the scenarios in women with high iron requirements (substances for which exposure is greater than 10% of the HBGV)

| Pesticide | EU status* | HBGV (µg/kg bw/d) | TDS2 median exposure (µg/kg bw/d) | TDS2 average exposure (µg/kg bw/d) | Scenario B3 | | | | Scenario B4 | | | | Scenario B5 | | | |
|---------------------------------------|-------------|-------------------|-----------------------------------|------------------------------------|-----------------------------|--------------|------------------------|-------------------------|-----------------------------|--------------|------------------------|-------------------------|-----------------------------|--------------|------------------------|-------------------------|
| | | | | | Total exposure (µg/kg bw/d) | % HBGV | % TDS2 median exposure | % TDS2 average exposure | Total exposure (µg/kg bw/d) | % HBGV | % TDS2 median exposure | % TDS2 average exposure | Total exposure (µg/kg bw/d) | % HBGV | % TDS2 median exposure | % TDS2 average exposure |
| <i>Carbofuran (sum)</i> | NA | 0.15 | 0.063 | 0.067 | 0.090 | 60.3 | 143.0 | 134.5 | 0.088 | 58.7 | 139.1 | 130.9 | 0.088 | 58.7 | 139.3 | 131.0 |
| <i>Chlorfenvinphos</i> | NA | 0.5 | 0.054 | 0.059 | 0.071 | 14.3 | 132.0 | 121.2 | 0.070 | 14.0 | 129.4 | 118.8 | 0.070 | 14.0 | 129.7 | 119.1 |
| Chlorpyrifos-ethyl | A | 1 | 0.068 | 0.079 | 0.126 | 12.6 | 184.6 | 160.8 | 0.118 | 11.8 | 172.4 | 150.2 | 0.118 | 11.8 | 172.0 | 149.8 |
| <i>Coumaphos (not detected)</i> | NA | 0.5 | 0.026 | 0.031 | 0.078 | 15.6 | 300.2 | 253.8 | 0.069 | 13.7 | 264.4 | 223.6 | 0.068 | 13.6 | 262.6 | 222.1 |
| <i>Diazinon</i> | NA | 0.2 | 0.062 | 0.066 | 0.079 | 39.5 | 126.5 | 119.2 | 0.076 | 38.1 | 122.0 | 115.0 | 0.077 | 38.3 | 122.6 | 115.6 |
| <i>Dieldrin (sum)</i> | POPs | 0.1 | 0.129 | 0.142 | 0.018 | 18.5 | 14.3 | 13.0 | 0.019 | 19.3 | 15.0 | 13.6 | 0.020 | 19.8 | 15.4 | 14.0 |
| Dimethoate (sum) | A | 1 | 0.572 | 0.619 | 0.725 | 72.5 | 126.8 | 117.1 | 0.710 | 71.0 | 124.2 | 114.6 | 0.710 | 71.0 | 124.3 | 114.7 |
| Dithiocarbamates | A | 6 | 0.669 | 0.712 | 1.036 | 17.3 | 154.8 | 145.6 | 0.827 | 13.8 | 123.5 | 116.2 | 0.818 | 13.6 | 122.3 | 115.0 |
| <i>Ethoprophos (not detected)</i> | A | 0.4 | 0.095 | 0.103 | 0.124 | 30.9 | 130.1 | 120.1 | 0.121 | 30.2 | 127.0 | 117.3 | 0.121 | 30.2 | 126.8 | 117.1 |
| <i>Fipronil (sum)</i> | A | 0.2 | 0.018 | 0.019 | 0.039 | 19.6 | 223.1 | 202.6 | 0.032 | 15.8 | 180.2 | 163.6 | 0.031 | 15.7 | 178.3 | 161.8 |
| <i>Heptachlor (sum)</i> | POPs | 0.1 | 0.128 | 0.134 | 0.024 | 24.0 | 18.7 | 17.9 | 0.025 | 25.0 | 19.5 | 18.7 | 0.025 | 25.4 | 19.8 | 19.0 |
| Lindane (HCH-gamma) | POPs | 0.01 | 0.083 | 0.087 | 0.014 | 142.0 | 17.0 | 16.3 | 0.015 | 146.9 | 17.6 | 16.8 | 0.015 | 154.5 | 18.5 | 17.7 |
| <i>Methamidophos</i> | NA | 1 | 0.168 | 0.182 | 0.230 | 23.0 | 137.1 | 126.2 | 0.226 | 22.6 | 134.9 | 124.2 | 0.226 | 22.6 | 134.9 | 124.2 |
| <i>Methidathion</i> | NA | 1 | 0.11 | 0.119 | 0.112 | 11.2 | 102.4 | 94.7 | 0.115 | 11.5 | 104.4 | 96.5 | 0.115 | 11.5 | 104.8 | 96.9 |
| <i>Monocrotophos</i> | NA | 0.6 | 0.15 | 0.165 | 0.185 | 30.9 | 123.5 | 112.2 | 0.186 | 30.9 | 123.7 | 112.5 | 0.186 | 31.0 | 123.9 | 112.6 |
| <i>Parathion (sum) (not detected)</i> | NA | 0.6 | 0.163 | 0.172 | 0.217 | 36.1 | 132.7 | 126.3 | 0.208 | 34.6 | 127.3 | 121.1 | 0.211 | 35.2 | 129.3 | 123.0 |
| <i>Phorate (sum) (not detected)</i> | NA | 0.7 | 0.339 | 0.359 | 0.464 | 66.3 | 136.8 | 129.4 | 0.408 | 58.3 | 120.3 | 113.8 | 0.410 | 58.5 | 120.7 | 114.2 |
| <i>Quinalphos (not detected)</i> | NA | 0.5 | 0.123 | 0.132 | 0.149 | 29.9 | 121.4 | 113.2 | 0.147 | 29.5 | 119.9 | 111.8 | 0.148 | 29.6 | 120.3 | 112.1 |
| <i>Terbufos (not detected)</i> | NA | 0.6 | 0.038 | 0.041 | 0.080 | 13.3 | 212.0 | 194.4 | 0.069 | 11.6 | 184.3 | 168.9 | 0.069 | 11.5 | 183.1 | 167.8 |

* Regulation (EC) No 1107/2009

A: approved; NA: not approved (in italics)

** Detected for at least 2 years and among more than 100 analyses per foodstuff





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