AGENCE FRANÇAISE DE SÉCURITÉ SANITAIRE DES ALIMENTS

Maisons-Alfort, 23 October 2007

Opinion

of the French Food Safety Agency (Afssa) on the establishment of relevant maximum levels for non dioxin-like polychlorobiphenyls (NDL-PCB) in some foodstuffs

LA DIRECTRICE GÉNÉRALE

1. CONTEXT OF THE REQUEST AND QUESTIONS RAISED

On 31 October 2006, the French Food Safety Agency (Afssa) was requested by the Directorate General for Food (DGAl) and the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) to give an opinion on the establishment of relevant maximum levels for non dioxin-like polychlorobiphenyls (NDL-PCB) in some foodstuffs.

The request was on the following two questions :

1) Is the consideration of 6 PCB indicators (PCB-28, 52, 101, 138, 153 and 180) instead of the 7 currently used (PCB-28, 52, 101, 118, 138, 153 and 180) a satisfactory and sufficient issue for establishing an appropriate criterion allowing for the subsequent management of contaminations with the aim of protecting public health and minimising consumer exposure?

2) What is Afssa's opinion on the European Food Safety Authority (EFSA) 2005 opinion? Are toxicological data available for each PCB congener and is it presently possible to use such data to determine a Tolerable Daily Intake (TDI) ?

Beyond the strict framework of these questions, Afssa studied the "background" dietary exposure to NDL-PCB of the general population and analysed the relevance of the maximum levels in various foodstuffs which are proposed in a European draft regulation, provided by DGAl and DGCCRF.

2. CONTEXT AND BACKGROUND

The term PCB refers to polychlorobiphenyls which are chlorinated aromatic compounds belonging to a family of 209 compounds or congeners[1]. These 209 congeners occurred in variable amounts in commercial mixtures[2] used for their insulating properties (electrical transformers) and their chemical and physical stability (cutting oils, inks, paints). Such uses were first restricted to closed systems (transformers, capacitors) during the 1970s, and thereafter the production and use of PCB were banned in France in 1987. Chemically stable and of low biodegradability, PCB belong to the category of persistent organic pollutants (POPs). They are also lipophilic substances which concentrate in food chains and are therefore found mainly in animal fats.

2.1 Dioxin-like PCB (DL-PCB)

The notion of dioxin-like PCB (DL-PCB) officially appeared in 1998, when some PCB congeners were included in the assessment of dioxin-related risks[3] (PCDD/F).

[1] For more information, consult i) Afssa's opinion of 8 April 2003 on the possible existence of a significant correlation between levels of different PCB congeners and ii) the report quoted in the opinion entitled "Recent data on the assessment of hazards associated with the presence of PCB in food.", J.P. Cravedi and J.F. Narbonne, December 2002, available on www.afssa.fr

[2] Commercial mixtures: products that used to be marketed, composed of several PCB congeners subject to registered trade marks or names (for example, Aroclor, registered by Monsanto (United States), Phenochlor and Pyralène by Prodelec (France)). In the range of Aroclor compounds (for example Aroclor 1254), the first two figures denote the number of carbon atoms present in the molecule (12 in this case) and the last two indicate the mass percentage of chlorine in the mixture (54% in this case).

[3] Polychlorodibenzodioxins (PCDD) and polychlorodibenzofurans (PCDF) form a group of halogenated polycyclic organic compounds designated under the generic term of dioxins (PCDD/F). For more information, consult Afssa opinion of 9 January 2006 on the

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Unlike PCB, dioxins are not industrial products but combustion residues or by-products of industrial processes. Accordingly, there is no standard mixture for dioxin family, since compound profiles depend on their origin. As it was not feasible to perform toxicological studies on each of the 210 dioxin congeners (PCDD/F), the risk assessment first focused on the 2,3,7,8-TCDD (major congener of the Seveso accident in July 1976), for which a Tolerable Daily Intake (TDI) of 10 pg/kg b.w./d was established.

Then, the concept of toxic equivalency factor (TEF) allowed the application of the TCDD TDI to be extended to all dioxins (10 pg TEQ/kg b.w./d). The TEF is a weighting coefficient which expresses the relative toxicity of each congener considered individually compared to that of TCDD – the reference substance of the family – exhibiting the greatest affinity for the cell receptor Ah (Aryl hydrocarbon). This approach is realistic because, as indicated in the 2005 Afssa's report[3], the toxicity mechanism of dioxins involves the capacity of these molecules to bind to the Ah receptor, inducing changes in the transcription of RNA messengers coding the enzymes involved in cell responses.

Later on, it was known that compounds other than dioxins could also bind to the Ah receptor, such as PAH, indole-3-carbinol and some PCB congeners, which present similar characteristics to dioxins in terms of persistence and accumulation. TEF were therefore attributed to these dioxin-like PCB (DL-PCB). In 1998, WHO redefined the TDI of dioxins by including DL-PCB. Lastly, in 2001, JECFA lowered this TDI to 2.33 pg TEQ/kg b.w./d.

2.2 Non dioxin-like PCB (NDL-PCB)

The notion of non dioxin-like PCB (NDL-PCB) refers to all PCB congeners that are not dioxin-like, as they do not share the same mechanism of toxic action through binding to the Ah receptor. These congeners are mostly found in food matrices so that the reference to sole DL-PCB is not convenient for assessing and managing food risks associated with total PCB.

2.3 PCB indicators (PCBi)

Some PCB congeners present in commercial mixtures are particularly persistent and are therefore recurrently found in the environment (sediments, fish). As a result, they have been considered as PCB tracers, regardless of whether they belong to the group of DL- or NDL-PCB. The study of food matrix contamination profiles then allowed 7 most commonly found congeners to be identified (PCB-28, 52, 101, 118, 138, 153 and 180). As these 7 congeners account for around 50% of all PCB congeners present in foodstuffs of animal origin and in human fat, they were grouped under the term of PCB indicators or PCBi .

PCB-138, 153 and 180 (di-ortho substituted), which are particularly persistent, are also covered by specific regulations in some European countries (PCB-153 in Germany, 3 PCB in the Netherlands). Other PCB which are more intensively metabolised, have been included [PCB-28 and 118 (mono-ortho substituted), PCB-52 and 101 (di-ortho substituted)] as they are also found in significant amounts in some contaminated foodstuffs or are indicators of recent contamination.

In its opinion on 8 April 2003, Afssa suggested to manage the contamination of foods by PCB by taking into account these 7 PCB indicators. In its 2005 report, EFSA recommended the monitoring of 6 PCB indicators, excluding PCB-118 (this congener being a dioxin-like PCB) from the PCBi list. This opinion re-examines Afssa's recommendation regarding the number of congeners to be taken into account.

2.4 Regulatory maximum levels in various foodstuffs

European Regulation (EC) No 1881/2006 sets maximum levels for the sum of dioxins and DL-PCB in some foodstuffs. As the PCB congeners found in food matrices are mainly NDL-PCB, discussions are in progress within Europe in order to set maximum levels for NDL-PCB in some foodstuffs.

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assessment of French population exposure to dioxins, furans and dioxin-like PCB and the attached report of November 2005, available on www.afssa.fr

3. CONCERNING EFSA'S OPINION ON NDL-PCB

3.1 Conclusions of EFSA's opinion

In its assessment on November 2005 concerning NDL-PCB[4], EFSA:

- could not regulate on the toxicity of NDL-PCB congeners, considering that the toxicological effects seen in the studies on NDL-PCB could be attributed to a minor contamination by dioxin-like compounds (around 0.1%) ;
- considered that the lack of mutagenicity potential would allow for a threshold approach to characterise the NDL-PCB hazard, but that the toxicological database was too limited for establishing a health-based value for NDL-PCB.

The European project ATHON (Assessing the Toxicity and Hazard of Non-dioxin-like PCB Present in Food, www.athon-net.eu) was initiated in April 2006 to consolidate knowledge on toxicokinetics and toxicity profiles in the aim of recommending a new strategy for classifying NDL-PCB congeners based on biomarkers of effect. This project also intends to compile and assess data on toxicity and exposure to NDL-PCB and their metabolites.

3.2 Approach based on mixtures

The first PCB toxicological approaches focused on commercial mixtures, by considering each mixture as a specific chemical product (Aroclor 1254, Phenoclor-DP6, for example).

As no official WHO (World Health Organization) human toxicity value was available, several countries adopted Tolerable Daily Intakes (TDI) to set limit levels for PCB in some foodstuffs, particularly fish. Accordingly, in France, the first TDI of 5 µg/kg b.w./d was proposed by the CSHPF (French High Council for Public Hygiene) in 1991 on the basis of Phenochlor-DP6 and toxic effects observed in rats. The same year, Canada proposed its own TDI of 1 µg/kg b.w./d on similar scientific basis and in 1992, Japan adopted the same TDI as the CSHPF.

Mixtures of congeners representative of profiles found in the environment and human milk were then prepared using synthetic congeners. Subsequent experimental studies revealed that adverse effects could be induced following *in utero* exposure, particularly on cerebral development. Moreover, these effects induced by exposure at early stages of the organogenesis, generally appeared at doses lower than the no-effect doses observed in adults.

Relevant data for the establishment of a Tolerable Daily Intake for PCB are presented in table 1.

Table 1: Relevant data for the establishment of a Tolerable Daily Intake (TDI) for PCB

Mixtures	Species	Exposure	LOAEL (µg/kg/d)	NOAEL (µg/kg/d)	SF	TDI (µg/kg b.w./d)	References
Representative of human milk	Monkey	From birth to 20 weeks old	7.5 neurotoxicity in young monkeys	2.5*	100	0.025	Rice & Hayward 1997, 1999
Aroclor 1254	Monkey	46 weeks during gestation and breastfeeding	5 Dermal and ocular signs, immunotoxicity in young monkeys	1.7*	100	0.02	Arnold *et al.*, 1993a,b, 1995
Aroclor 1254	Monkey	23 and 55 months (capsules)	5 Immunotoxicity in adult monkeys	1.7*	100	0.02	Tryphonas *et al.*, 1989, 91
Human milk	Human	via breastfeeding	- Neurotoxicity children	0.093	6	0.02	Tilson *et al.*, 1990

LOAEL: lowest observed adverse effect level; NOAEL: no observed adverse effect level; SF: safety factor; TDI: tolerable daily intake; *calculated on the basis of the LOAEL with a factor 3.

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[4] EFSA opinion of 8 November 2005 "Opinion of the scientific panel on contaminants in the food chain on a request from the Commission related to the presence of non dioxin like PCB in feed and food".

Based on the studies published by Tryphonas *et al*. (1989, 1991) and Arnold *et al*. (1993a, b), a daily reference dose of 20 ng/kg b.w./d was proposed for the commercial mixture Aroclor 1254 in 1996 by the EPA[5] and for all 209 PCB congeners in 2000 by the ATSDR[6] (validated by a group of international experts during a meeting in Ottawa in 2001[7] and also adopted by the IPCS[8]), on the basis of immunological effects observed in monkeys.

Human data reinforce this reference dose. Following two events of PCB contamination in Asia (1968 in Japan and 1979 in Taiwan [Rogan, 1995]), Tilson *et al*. (1990) studied the relationship between the concentration of PCB in the mother's milk and the neurological development of the child. A non-effect dose of 0.093 µg/kg b.w./d was identified. After applying a safety factor of 6 to take account of the uncertainty and intra-species variation, the corresponding daily reference dose would be 20 ng/kg b.w./d.

In the same populations exposed accidentally to very high doses of PCB, a significant increase in respiratory effects was observed.

In view of all these data and the convergence of different types of toxicological studies towards the same reference value, **a reference dose of 20 ng/kg b.w./d for all 209 PCB congeners** was proposed by WHO at the "2nd PCB workshop" in Brno (Czech Republic, May 2002). This reference dose, expressed in the form of a tolerable daily intake (TDI) was adopted by the RIVM[9] (Netherlands) in 2001 and then Afssa[10] in France in 2003.

Moreover, the sum of 6 or 7 PCB congeners most commonly found in food matrices (PCB-28, 52, 101, 118, 138, 153 and 180) accounts for around 50% of all congeners present, such that a **TDI of 10 ng/kg b.w./d** was adopted for this group of 6 or 7 congeners (RIVM initiative to estimate the risk associated with dietary exposure to NDL-PCB).

3.3 Approach based on mechanisms of toxic action

The term PCB does not refer to one compound, but 209 congeners. To take account of all the congeners as part of a risk assessment, a common mechanism of action may be investigated, as it is done for dioxins, based on the concept of a Toxic Equivalency Factor (TEF). The TEF is a weighting coefficient which expresses the relative toxicity of each congener considered individually compared to a reference congener exhibiting the greatest affinity for a cell receptor. In the case of dioxins, the reference substance is TCDD and the cell receptor is the Ah receptor (Aryl hydrocarbon). In the case of PCB, it remains to be established whether a receptor can fulfil this requirement.

For this purpose, the affinity of PCB for the following receptors was studied *in vitro*: ryanodine receptor (RyR, involved in immunotoxic and neurotoxic effects), transthyretin receptor (TTR, anti-thyroid effects), oestrogen receptors (ER, oestrogen disturbance) and the inhibitory effect on intercellular communication (GJIC, involved in the mechanisms of tumour promotion). Table 2 presents a review of the Toxic Equivalency Factors (TEF) attributed to some PCB depending on their binding affinity *in vitro* with various receptors.

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[5] IRIS-EPA, 1996, Aroclor 1254, http://www.epa.gov/iris/subst/0389.htm

[6] ATSDR - Agency for Toxic Substances and Disease Registry, 2000. *Toxicological profile for Polychlorinated biphenyls (PCBs)*, 948 p

[7] Meeting of the CICAD Final Review Board, Ottawa, Canada, 29 october-1 November 2001.

[8] IPCS: International Programme on Chemical Safety – Concise International Chemical Assessment Document (CICAD) 55, Polychlorinated biphenyls : human health aspects. WHO, Geneva, 2003.

[9] RIVM: RijksInstituut voor Volksgezondheid en Milieu (National Institute of Public Health and the Environment) of the Netherlands) (2001), Baars AJ, Theelen RMC, Janssen PJ, Hesse JM, van Apeldoorn ME, Meijerink MC, Verdam L, Zeilmaker MJ. Re-evaluation of human toxicological maximum permissible risk levels. Report 711701025

[10] Afssa opinion of 8 April 2003 on the possible existence of a significant correlation between the levels of different PCB congeners.

Table 2: Relative potentialities on the basis of which Toxic Equivalency Factors (TEF) are attributed to some PCB congeners according to the different modes of toxic action known (the 6 NDL-PCB are shaded grey), *modified from Marvanova et al., 2006.*

PCB	Relative potentialities					
	AhR	RyR	TTR	GJIC Inh	ER	Anti-ER
18	-	0,174		0,971		
28	-		0.05	0.324	1.65E-07	-
47	-		0.05	1		
49	-	0.226		0.526		
52	-	0.392	0.07	0.414	1.42E-07	-
66	-	0.158		0.623	8.56E-08	-
70	-	0.223		0.534		
74	-			0.886	1.24E-07	-
77	0.0001	-	-	-		
81	0.0001					
95	-	1	0.51	0.594		
99	-		0.2	0.457	-	-
101	-	0,258	0.2	0.627		
105	0.0001		-	0.472	-	-
110	-	0.288	2.6	0.652		
114	0.0005			0.435		
118	0.0001		-	0.587	-	-
123	0.0001					
126	0.1	-	-	-	-	-
128	-		-			
132	-	0.272		0,567		
136	-	1.021	-	0.62		
138	-	0.114	1.76	0.495	-	4.94E-06
149	-	0.7		0.483		
153	-	0.171	0.55	0.66	-	8.50E-06
156	0.0005		-	0.587	-	-
157	0.0005					
163	-	0.182		0.254		
167	0.00001			0.451		
169	0.01		1.15	0		
170	-	0.324		0.162	-	3.12E-06
180	-	0.187	0.07	0.142	-	5.36E-06
187	-	0.268		0.169	-	6.68E-06
189	0.0001			0		

- : no significant affinity ; 0 : no affinity ; white square : data not available

The data presented in table 2 show that:

- NDL-PCB do not present any significant affinity for the Ah receptor. The TEF attributed to DL-PCB, based on affinity for the Ah receptor, cannot be applied to NDL-PCB as a result.
- If the NDL-PCB congeners were contaminated by dioxin-like compounds (around 0.1%), a significant affinity for the Ah receptor should have been observed.
- The NDL-PCB exhibit significant interactions with several receptors (ryanodine, transthyretin, oestrogen), so that no single receptor may act as the Ah receptor and it is therefore not possible to establish a global TEF in this case. However, it would be possible to calculate the specific toxic potentials considering each mechanism of action or particular toxic effect (neurotoxicity, reprotoxicity, immunotoxicity, carcinogenesis).

This conclusion is consolidated by a recent work of Lee *et al.* (2007), according to which the relationships between the POP concentrations (including PCB-126 (DL-PCB), dioxins HPCDD and OCDD, furan HPCDF) in the serum and the prevalence of learning and attention deficit in the child do not correlate with the TEF values, so that the binding to the Ah receptor would not constitute the critical route for neurotoxicity. This hypothesis is corroborated by the fact that ortho-substituted PCB congeners (mainly found in animal matrices) with a low affinity for AhR are neurotoxic, while coplanar congeners (dioxin-like) have a low activity in terms of neurotoxicity.

3.4 Afssa's point of view

The analysis of EFSA's 2005 opinion has not incited Afssa to question its opinion of 8 April 2003 on PCB. Afssa considers that, based on current knowledge, the most appropriate method for assessing PCB-related health risks is based on a tolerable daily intake (TDI) of 20 ng/kg b.w./d for all PCB, derived from of neurological effects observed in monkeys.
The immunological effects observed at low doses only correspond to variations of biological parameters whose significance for human health is unclear (IPCS, 2003).

A TDI of 10 ng/kg b.w./d is adopted for the group of 6 or 7 PCB congeners most commonly found in food matrices (PCB-28, 52, 101, *118*, 138, 153 and 180) as they account for almost 50% of all congeners present.

4. ASSESSMENT OF DIETARY EXPOSURE TO NON DIOXIN-LIKE PCB (NDL-PCB) OF THE FRENCH POPULATION

In a first part, the estimation of dietary exposure to NDL-PCB of the French population is compared depending on whether 6 or 7 congeners are considered.
In a second part, the relevance of establishing maximum NDL-PCB levels in various foodstuffs is analysed, firstly as regards to the maximum levels proposed for some foodstuffs in the European draft regulation (2006) and secondly according to other hypothesis of maximum levels compatible with the TDI of NDL-PCB.

4.1 Consumption data

Food consumption data used are those from the 1999 national and individual food survey called INCA (annex 1).

4.2 Contamination data

PCB-28, 52, 101, 118, 138, 153 and 180 were assayed in 1665 samples of foodstuff (table 3) collected from 2002 to 2006 by food control and food monitoring programmes implemented by the Directorate General for Food (DGAl) for products of animal origin and fishery products.

Contamination profiles in samples from the French western region in 2004 were also considered for cow's milk (n=137).

Concerning plant products, only few contamination results were available from a 2005 programme (determination of profiles/PCBi contamination levels by the LABERCA[11]).

Lastly, contamination data for foodstuffs not analysed in monitoring plans (some types of shellfish) and for processing foods such as tinned fish (tuna, mackerel, sardine, anchovy, crab), smoked fish (salmon, herring) or taramasalata, were taken from the Calipso survey[12].

The contamination levels are presented per food group in tables 3, 4 and 5.

[11] LABERCA (LABoratoire d'Etude des Résidus et Contaminants dans les Aliments), Ecole nationale vétérinaire de Nantes.
[12] Leblanc J.Ch. (Coordinator). CALIPSO : Fish and seafood consumption study and biomarker of exposure to trace elements, pollutants and oméga 3, AFSSA-DGAl-INRA, August 2006, www.afssa.fr

Table 3: Distribution of contamination values for the 7 PCBi per product group (in ng/g of fresh weight for plant products and seafood, in ng/g of fat for animal products, indicated by * and value in italics)

		7 PCBi					
Products	n	min	mean	ET	median	p95	max
*Butter**	37	*0.77*	*3.0*	*2.0*	*2.6*	*8.2*	*10.0*
*Milk**	185	*0.41*	*4.7*	*4.0*	*3.8*	*10.6*	*35.9*
*Egg**	161	*0.39*	*6.1*	*14.0*	*1.9*	*26.3*	*124*
*Livers**	50	*0.50*	*10.3*	*11.6*	*7.7*	*36.5*	*61.5*
*Poultry meat**	50	*0.07*	*5.7*	*8.7*	*2.7*	*26.4*	*42.7*
*Beef**	23	*0.40*	*8.6*	*8.0*	*4.9*	*24.1*	*32.3*
*Lamb**	10	*1.46*	*6.3*	*5.6*	*4.6*	*19.0*	*19.0*
*Pork**	9	*0.59*	*5.1*	*7.8*	*2.1*	*25.2*	*25.2*
*All types of meat**	92	*0.07*	*6.4*	*8.1*	*3.6*	*25.2*	*42.7*
*Total for meat products**	*142*	*0.07*	*7.8*	*9.6*	*4.1*	*26.4*	*61.5*
Cereals	*2*	0.18	0.20	0.03	0.20	0.23	0.23
Bread	*10*	0.03	0.13	0.14	0.05	0.38	0.38
Pasta	*4*	0.03	0.04	0.01	0.04	0.05	0.05
Rice	*5*	0.03	0.71	1.48	0.04	3.36	3.36
Total for plant products	*21*	0.03	0.26	0.72	0.05	0.38	3.36
Cephalopods	81	0.04	4.5	10.0	1.7	11.1	80.7
Shellfish	62	0.14	7.3	7.9	4.2	24.1	36.5
Crustaceans	91	0.02	1.8	3.7	0.69	5.7	25.3
Total for seafood	234	0.02	4.2	7.8	1.7	19.6	80.7
Freshwater fish excluding eel	34	0.28	30.2	83.0	6.0	121	416
Oily freshwater fish (>2% fat)	10	0.28	55.7	127	17.0	245	416
Lean freshwater fish (<2% fat)	24	0..29	19.6	56.0	2.5	31.3	278
Eels	18	1.79	241	451	28.7	1189	1509
Aquaculture fish	212	0.24	11.2	10.6	8.7	27.4	93.4
Oily seafish (>2% fat)	200	0.19	28.8	45.2	11.7	120	343
Lean seafish (<2% fat)	421	0.04	7.6	14.8	1.9	38.2	122
Total for fish	885	0.04	18.9	76.6	5.8	62.3	1509

Table 4: Distribution of contamination values for the 6 NDL-PCB per product group (in ng/g of fresh weight for plant products and seafood, in ng/g of fat for animal products, indicated by* and value in italics)

		6 NDL-PCB					
Products	n	min	mean	ET	median	p95	max
*Butter**	37	*0.61*	*2.4*	*1.6*	*2.1*	*6.3*	*8.1*
*Milk**	185	*0.34*	*3.8*	*3.1*	*3.0*	*8.1*	*28.4*
*Egg**	161	*0.28*	*5.2*	*11.8*	*1.7*	*20.1*	*109*
*Livers**	50	*0.47*	*9.5*	*10.8*	*6.5*	*34.4*	*56.9*
*Poultry meat**	50	*0.06*	*5.2*	*8.1*	*2.4*	*24.3*	*40.8*
*Beef**	23	*0.33*	*7.1*	*6.2*	*4.2*	*20.2*	*21.0*
*Lamb**	10	*1.37*	*5.7*	*5.1*	*4.1*	*17.3*	*17.3*
*Pork**	9	*0.52*	*4.6*	*7.1*	*1.9*	*22.8*	*22.8*
*All types of meat**	92	*0.06*	*5.7*	*7.2*	*3.2*	*21.0*	*40.8*
*Total for meat products**	*142*	*0.06*	*7.0*	*8.8*	*3.6*	*22.8*	*56.9*
Cereals	*2*	*0.18*	*0.20*	*0.03*	*0.20*	*0.21*	*0.21*
Bread	*10*	*0.03*	*0.13*	*0.14*	*0.05*	*0.36*	*0.36*
Pasta	*4*	*0.03*	*0.04*	*0.01*	*0.03*	*0.05*	*0.05*
Rice	*5*	*0.03*	*0.64*	*1.35*	*0.04*	*3.05*	*3.05*

Total for plant products	*21*	*0.03*	*0.24*	*0.65*	*0.05*	*0.36*	*3.05*
Cephalopods	81	0.04	4.1	8.8	1.6	10.5	71.4
Shellfish	62	0.13	6.6	7.4	3.6	23.1	32.7
Crustaceans	91	0.01	1.6	3.3	0.61	4.9	23.3
Total for seafood	234	0.01	3.8	7.0	1.4	18.9	71.4
Freshwater fish excluding eel	34	0.23	26.8	73.3	5.2	106	368
Oily freshwater fish (>2% fat)	10	0.24	49.4	113	15.4	217	368
Lean freshwater fish (<2% fat)	24	0.23	17.3	49.2	2.01	27.7	244
Eels	18	1.55	192	347	24.7	926	1157
Aquaculture fish	212	0.21	9.8	9.4	7.7	23.5	84.2
Oily seafish (>2% fat)	200	0.17	25.8	39.7	10.3	111	286
Lean seafish (<2% fat)	421	0.03	6.9	13.5	1.7	34.0	117
Total for fish	885	0.03	16.4	60.7	5.1	57.9	1157

Table 5: Contamination means of seafood for the 6 and 7 PCB, extracted from the Calipso survey (in ng/g of fresh weight)

Products	n[13]	7 PCBi	6 NDL-PCB
winkle	3	1.0	0.93
whelk	3	1.7	1.6
scorpion fish	1	16	14
taramasalata	1	1.2	0.98
tinned crab	1	0.22	0.16
tinned anchovies	1	1.3	1.20
tinned mackerel	1	6.1	5.5
tinned sardines	1	35	31
tinned tuna	5	1.5	1.4
smoked herring	1	5.0	4.3
smoked salmon	1	13	12

4.3 Methodology

Dietary exposure was calculated using a standard determinist method for determining the exposure to the sum of 7 PCBi and thereafter to the sum of 6 NDL-PCB. Exposure is based on individual consumption data and mean contamination of each foodstuff, related to the declared body weight. The results, expressed per individual, enable the statistic description of the 3 populations studied (namely children (3 to 14 years old), women of childbearing age (19 to 44 years) and adults (> 15 years, excluding women of childbearing age)).

This study concerns the general population and does not focus on locally over-exposed populations.

4.4 Estimations of dietary exposure to the 7 PCBi and 6 NDL-PCB per population group

The mean exposure of children is 14.9 ng/kg b.w./d (P95: 31.3 ng/kg b.w./d) for 7 PCBi and 12.9 ng/kg b.w./d (P95: 27.3 ng/kg b.w./d) for 6 NDL-PCB. The tolerable daily intake (10 ng/kg b.w./d) is therefore exceeded.

[13] For certain products, a single sample was analysed given their consumption on the 4 survey sites of the study (Le Havre, Lorient, La Rochelle, Toulon). Each sample is in fact composed of 5 sub-samples, the origin and distribution of which was determined depending on the place of purchase (selected from the purchase frequency data of the consumption survey) and weighted by the consumption frequencies and quantities consumed. The samples of tinned or smoked products were composed with account taken of the market shares of different brands, from data contained in a list of household purchases compiled by the 2001 Sécodip panel. As a result, they are not composed of 5 sub-samples as fresh products, but of x samples of different brands, covering a maximum of market shares.

Women of childbearing age present an average exposure of 8.7 and 8.8 ng/kg b.w./d to 7 PCBi and of 7.6 and 7.7 to 6 NDL-PCB respectively. The average exposure levels do not exceed the TDI in this case, while the values at P95 are close to 19 ng/kg b.w./d for 7 PCBi (16 ng/kg b.w./d for 6 NDL-PCB) for both populations.

In terms of contribution of different food groups to NDL-PCB exposure (table 12, annex 3)[14], it can observed that:

- fish products contributes to 49%, 32% and 36% for children, women of childbearing age and adults, respectively
- meat products contributes from 16 to 31%,
- dairy produce (milk, butter, cheese) contributes from 14 to 27%,
- vegetable products contribute from 5 to 12%,
- eggs contribute to 7.5% in children.

4.5 Comparison with other European estimations of dietary exposure

In Europe, 4 studies of dietary exposure to PCB indicators are available (EFSA report, 2005). The average estimated levels for adults from these countries are as follows:

- for the Netherlands in 1998/1999: median of 5.6 ng/kg b.w./d, for 7 congeners (Bakker *et al.*, 2003; Baars *et al.*, 2004) ;
- for Sweden in 1997/1998: medians of 5.5-11.5 and 6.2-9.6 ng/kg b.w./d for women and men, for 23 congeners (Lind *et al.*, 2002);
- for Italy in 2004: average of 10.9 ng/kg b.w./d, for 6 congeners (Fattore *et al*., 2005);
- for Germany in 1998: average of 15.3 ng/kg b.w./d, for 3 congeners (Arnold *et al*., 1998 In EFSA, 2005).

In its 2005 report on NDL-PCB, EFSA proposes an estimation of dietary exposure for a European "average" of 15 ng/kg b.w./d. These levels rise to 20 ng/kg b.w./d for high consumers of meat and 35 ng/kg b.w./d for high consumers of fishery products.

The French estimation of exposure to the 6 NDL-PCB of 7.7 ng/kg b.w./d for the adult average therefore falls within available European estimations[15].

5. CONCERNING THE NUMBER OF PCB (7 PCBi or 6 NDL-PCB) AND THEIR PREDICTIVE CHARACTER

Of the 7 PCBi considered in France, PCB-118 falls into the category of dioxin-like PCB (DL-PCB) because of its planar structure. This congener is an indicator of the level of contamination by PCB as appropriate as the 6 others. According to the type of matrix, the proportion of PCB-118 compared with the 6 others can vary from 6% to 20%.

The correlation between the consideration of 7 congeners (PCBi) and 6 congeners (NDL-PCB) was analysed for different food categories, on the basis of the data extracted from national monitoring and inspection plans. The relative proportion of PCB-118 in the total profile of the 7 PCBi was calculated per food category. Lastly, the possibility of predicting the level of DL-PCB (n=12 congeners) from the measurement of the 6 NDL-PCB in the same food was assessed.

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[14] According to the criterion "exceeds the TDI by more than 5%", defined within the *Codex alimentarius* method for prioritising maximum limit proposals in foods:, CCFAC policy for exposure assessment of contaminants and toxins in foods or food groups, procedure manual, 16th edition, Rome 2006.

[15] The Netherlands' estimation for the sum of 7 PCBi (median of 5.6 ng/kg bw/d) is slightly less than the French estimation (median of 7.4 ng/kg bw/d). Three reasons may explain this difference: 1) the consumption levels of fish and seafood which are the main contributors of PCB appear to be much lower in the Netherlands than in France; 2) the Dutch study used an intra-inidividual variance reduction method to estimate lifetime exposure, which tends to group the values around the median. The high percentiles of exposure are thus overestimated in the French study presented here. Although this overestimation was not quantified here, the sensitivity analysis study conducted by Afssa to assess dioxin exposure through food showed a reduction in intra-individual variance of around 10-20% for high percentiles (Ariane *et al.* 2001). Lastly, 3) in the Dutch study, the under-declarers are not removed in the simulations (unlike in our study), which leads to the high exposure percentiles being underestimated.

5.1 Correlation between 6 and 7 congeners (NDL-PCB vs PCBi)

Data were extracted from the database presented in tables 3 and 4. They originate from three laboratories accredited to conduct monitoring and inspection plans (France, DGAl, 2005-2006) using the methods based exclusively on the GC-HRMS for simultaneous measurements of DL-PCB and the 7 PCBi (table 6).

Table 6: Number of available data according to food type

Products	n
Fish	137
Crustaceans	24
Molluscs	19
Eggs	63
Meat and cow livers	29
Poultry meat	19
Butter	15
Milk	13
TOTAL	319

Whatever the food type studied, a strong correlation is observed between the concentration of the 7 PCBi and 6 NDL-PCB for fish (r>0.999), milk (r>0.997), poultry meat (r>0.999) and eggs (r>0.997) (annex 2A). This correlation between the two expressions of results was also observed for meat and cow's liver, butter, molluscs and crustaceans, on a fewer number of samples. It can be reasonably deduced that not taking PCB-118 into account does not adversely affect the quality of information produced, since this variable is obviously related to the 6 others and is therefore not essential for the relevance, reliability and expression of the result.

5.2 Contribution of PCB-118 to the 7 PCBi

The contribution of PCB-118 to the 7 PCBi is greater for land-based food such as meat, milk and dairy produce, eggs (from 10 to 20%) than for seafood products, whatever it is fish, molluscs or crustaceans (from 6 to 14%, annex 2B).

5.3 Can the DL-PCB contamination levels of a food be predicted on the basis of the measurement of the NDL-PCB profile?

The examination of national data collected in 2005-2006 (annex 2C) shows a strong correlation between contamination profiles for fish (r>0.948), milk (r>0.977), poultry meat (r>0.938) and eggs (0.900). Additional data would nevertheless be needed to reinforce the equations enabling the deduction of DL-PCB values from NDL-PCB, but the feasibility of this approach has been demonstrated.

5.4 Conclusion

1- Lack of consideration of PCB-118 into account does not have any consequence on the quality of information produced, as this variable is obviously related to the 6 other PCB and is therefore not essential for the relevance of the result.

2- The contribution of PCB-118 in the 7 PCBi varies from 6 to 20% depending on foodstuff. It is higher for milk and dairy produce (almost 18% on average), and lower for seafood (molluscs and crustaceans in particular, 10%).

3- A strong correlation of contamination profiles by NDL-PCB (n=6) and DL-PCB is observed for most foodstuffs (r>0.9). Measurement of the 6 NDL-PCB would enable accurate prediction of the DL-PCB level (n=12 congeners) of the same food, and provide an indication of the possible exceedance of the regulatory limits for PCDD/F and DL-PCB in this food at the same time.

Afssa recommends adopting the 6 NDL-PCB from the current list of 7 PCBi to measure and represent the levels of contamination by NDL-PCB.

According to national data collected in 2005-2006, in "background" contamination (without accidents), measurement of the 6 NDL-PCB would enable the DL-PCB level (n=12 congeners) of the same food to be predicted and may give an indication of the possible exceedance of regulatory limits expressed for the sum of PCDD/F and DL-PCB in this food. Afssa points out that additional data are nevertheless needed to reinforce the equations enabling DL-PCB values to be deduced from NDL-PCB.

6. IMPACT OF MAXIMUM NDL-PCB LEVELS IN FOODSTUFFS CONTRIBUTING TO EXPOSURE

The objective of this chapter is to assess the impact of different hypothesis of maximum levels in some foodstuffs on exposure of the French population.

At present (no maximum level), the average exposure to the 6 NDL-PCB shows that the TDI (10 ng/kg b.w./d) is exceeded by 58.4% of children (3 to 14 years old) and by 20% of women of childbearing age (19 to 44 years old) and adults (15 years and over, excluding 19-44 year-old women).

6.1 European draft maximum levels

The setting of maximum NDL-PCB levels in various foodstuffs is currently the focus of European draft regulation. The levels proposed for the 6 congeners correspond to the limits set using the ALARA ("as low as reasonably achievable") principle from contamination data issued by the European Member States (table 7). This principle aims above all to withdraw products presenting very high levels of contamination from the market.
The foodstuffs targeted by the European draft regulation correspond to the main food groups which contribute to French dietary exposure (see paragraph 6.4).
As for vegetable products, French data show a higher contribution than the Codex criterion by 5% of the TDI, but this contribution depends more on high consumption than on high contamination and justifies their exclusion from the draft regulation.

Table 7: Maximum levels proposed by the European draft regulation (2006)

Foodstuffs	Maximum levels proposed Sum of PCB 28, 52, 101, 138, 153, 180
Meat (in ng/g fat)	
ruminants	50
poultry and game	50
pork	50
Livers (in ng/g fat)	200
Fish and fish-based products except * (in ng/g fresh weight)	100
*eel (en ng/g fresh weight)	200
Milk and dairy produce (in ng/g fat)	50
Eggs (in ng/g fat)	50
Oils and fats (in ng/g fat)	
animal	50
vegetable	50
fish	200

An exposure scenario has been developed to simulate the impact of applying the proposed maximum levels (table 8). In practice, contamination values beyond these maximum levels were withdrawn from the distribution of contamination data.

Table 8: Exposure to the 6 NDL-PCB according to the European draft maximum levels, per population group (ng/kg b.w./d), CI = Confidence interval

Exposure scenarios	Children (3 to 14 years)			
	average	p95	% person > TDI [CI]	
Without maximum level	12.9	27.3	58.4	[55.4-61.5]
European draft maximum levels	12.6	25.8	56.8	[53.7-59.8]
	Women of childbearing age [19-44 years]			
	average	p95	% person > TDI [CI]	
Without maximum level	7.6	16.5	19.5	[15.6-23.5]
European draft maximum levels	7.4	16.3	18.3	[14.4-22.1]
	Adults (>15 years. excluding women of childbearing age)			
	average	p95	% person > TDI [CI]	
Without maximum level	7.7	15.8	20.0	[17.6-22.4]
European draft maximum levels	7.5	15.4	19.2	[16.8-21.5]

The results of this simulation show that the application of the European draft maximum levels for NDL-PCB would only have a very limited and insignificant impact on the dietary exposure of the French population compared with the current situation (no maximum level).

6.2 Hypothesis of maximum levels compatible with the NDL-PCB TDI

Three exposure scenarios have been developed to simulate the impact of applying lower maximum levels than those envisaged by the European Commission: namely 50, 25 and 10 ng/g of fresh weight or fat, similar for all products targeted (table 9). As previously, contamination values above these maximum levels have been withdrawn from the distribution of contamination data.

Table 9: Hypothesis of maximum levels adopted in the 3 exposure scenarios

	Sum of PCB 28, 52, 101, 138, 153, 180		
Foodstuffs	Maximum levels at 50 ng/g	Maximum levels at 25 ng/g	Maximum levels at 10 ng/g
Meat (in ng/g fat)			
ruminants	50	25	10
poultry and game	50	25	10
pork	50	25	10
Livers (in ng/g fat)	50	25	10
Fish and fish-based products (including eel) (in ng/g fresh weight)	50	25	10
Milk and dairy produce (in ng/g fat)	50	25	10
Eggs (in ng/g fat)	50	25	10
Oils and fats (in ng/g fat)			
animal	50	25	10
fat	50	25	10
fish	50	25	10

The simulation study with these 3 scenarios (table 10) shows that the scenario involving a maximum contamination limit at 25 ng/g for all the foodstuffs targeted significantly reduces exposure for children and adults. However, only the last scenario with a maximum limit for all products **at 10 ng/g of foodstuff would have a significant impact on the overall exposure of all populations**. This scenario would reduce exposure in children by around 65% on average and 60% at p95 compared with the current situation (no maximum level).

However, the application of a limit at 10 ng/g of foodstuffs would not guarantee that the TDI is not exceeded for almost 30% of children, 4% of women of childbearing age and adults. *It* *should nevertheless be noticed that this study probably overestimates the highest exposure levels by not correcting the variability of exposure from week to week.*

Table 10: Exposure to the 6 NDL-PCB depending on the different scenarios, per population group (ng/kg b.w./d), CI = Confidence interval, in bold = significantly different from exposure with no maximum level

Exposure scenarios	Children (3 to 14 years old)			
	average	p95	% person > TDI [CI]	
No maximum level	12.9	27.3	58.4	[55.4-61.5]
European draft maximum levels	12.6	25.8	56.8	[53.7-59.8]
Maximum levels at 50 ng/g	12.4	25.8	56.4	[53.3-59.4]
Maximum levels at 25 ng/g	**11.6**	**23.5**	**52.0**	**[48.9-55.0]**
Maximum levels at 10 ng/g	**8.4**	**16.3**	**27.9**	**[25.1-30.7]**
	Women of childbearing age [19-44 years old]			
	average	p95	% person > TDI [CI]	
No maximum level	7.6	16.5	19.5	[15.6-23.5]
European draft maximum levels	7.4	16.3	18.3	[14.4-22.1]
Maximum levels at 50 ng/g	7.3	16.0	15.9	[12.3-19.6]
Maximum levels at 25 ng/g	6.8	14.1	12.6	[9.3-15.9]
Maximum levels at 10 ng/g	**4.9**	**9.6**	**3.9**	**[1.9-5.8]**
	Adults (>15 years old. excluding women of childbearing age)			
	average	p95	% person > TDI [CI]	
No maximum level	7.7	15.8	20.0	[17.6-22.4]
European draft maximum levels	7.5	15.4	19.2	[16.8-21.5]
Maximum levels at 50 ng/g	7.3	14.9	17.8	[15.5-20.1]
Maximum levels at 25 ng/g	**6.7**	**13.3**	**13.8**	**[11.8-15.9]**
Maximum levels at 10 ng/g	**4.8**	**9.0**	**3.3**	**[2.3-4.4]**

In view of all these data, the maximum level proposal of 10 ng/g for the targeted foodstuffs appears to be most compatible with the NDL-PCB TDI.

However, as shown in table 13 (annex 3), the application of such a limit would lead to reject from the market 21.4% of the targeted products compared with 1.3% according to the European draft regulation. The food groups that would be the most targeted by the application of such a limit are fish and meat products with a rejection percentage of around 33 and 37% respectively, compared with 2% for fish alone with the European draft regulation.

7. COMPARISON BETWEEN A RISK ASSESSMENT BASED ON NDL-PCB AND ONE BASED ON DL-PCB

This paragraph seeks to compare the assessment of PCB-related risks depending on whether it is based on DL-PCB or NDL-PCB contamination measurements.

Dioxin-like PCB (DL-PCB)

The risk assessment based on DL-PCB requires the application of a TDI specific to DL-PCB. But at present, they share a TDI with dioxins of 2.33 pg TEQ/kg b.w./d. Depending on their relative contribution in the DL-PCB/dioxin mixture (around 70%), a theoretical TDI of 1.63 pg TEQ/kg b.w./d could be attributed to DL-PCB.

In 2006, Afssa conducted a study of French population dietary exposure to dioxins and DL-PCB using the same methodology as that used in this NDL-PCB assessment (Afssa opinion of 9 January 2006; Tard *et al.*, 2007). Exposure to dioxins and DL-PCB has been estimated at 1.8 pg TEQ/kg b.w./d for the adult average. Still according to the hypothesis that DL-PCB account for 70% of the total TEQ, the exposure would then correspond to 77% of the DL-PCB TDI[16].

[16] (1.8 pg TEQ/kg bw/d x 70%) / 1.63 pg TEQ/kg bw/d = 77.3 %

Non dioxin-like PCB (NDL-PCB)
Estimates of dietary exposure to the 6 NDL-PCB in this assessment are 7.7 ng/kg b.w./d for the adult average. These exposure levels correspond to 77% of the TDI of 10 ng/kg b.w./d.

Conclusion
The assessment of PCB-related risks based on NDL-PCB does not underestimate the risk compared with the DL-PCB approach, as the calculation leads in both cases to an average dietary exposure for adults corresponding to 77% of the TDI.

8. ASSESSMENT OF THE RISK ASSOCIATED WITH EXCEEDING THE PCB TDI

The assessment of the health risks associated with exceeding the TDI has been discussed in several international meetings and reports (particularly ILSI Workshop[17] in 1998).

First of all, it should be remembered that a TDI is based on a theoretical approach affecting safety factors by "prudence" to take account of uncertainties surrounding the extrapolation of effects observed in animals to possible effects in humans and of the potential susceptibility differences between individuals.
A TDI corresponds to a maximum amount of contaminant that experts consider may be eaten over a lifetime, without fearing adverse effects on human health. Toxicologists agree that for toxic agents causing long-term effects, a short-term exposure exceeding a human toxicity value based on chronic exposure does not necessarily pose a significant health risk.

Nevertheless, when the dietary exposure estimation exceeds the reference value established for the long term, the critical toxic effects and safety factors considered should be examined in-depth.

In this regard, this opinion applied two approaches :

- the approach based on Margins Of Exposure (MOE) is the ratio between the no-observed-adverse-effect level in a test animal (NOAEL) and the actual exposure of populations (food intake, for example);
- the approach based on Margins Of Body Burden (MOBB) is the ratio between the body burdens associated with toxic effects in test animals and body burdens observed in humans. Indeed, body burdens (or body impregnations) are good exposure markers for persistent contaminants in the body and can be used for intra- and inter-specific comparisons. This approach gets rid of the need for inter-specific toxicokinetic variability.

Both these approaches were also developed in EFSA's 2005 report on NDL-PCB.

To estimate the health risk associated with PCB exposure levels identified in this opinion, the population can be split into **2 groups**: adults/children over 3 years of age and women of childbearing age/children under 3 years of age.

<u>For adults and children over 3 years of age</u>
The critical effect to be considered is a hepatic effect, identified from experimental studies performed on the weaned rat, for doses exceeding those leading to neurotoxic effects in the foetus. The key studies on the monkey for establishing the TDI of 20 ng/kg p.c./j are not taken into account here as a result.

The risk assessment according to the MOE approach can then be based on data on the most toxic PCB congener (PCB-153). The lowest no-observed-adverse-effect level (NOAEL) is 34 µg/kg b.w./d, after a 90-day intoxication in the rat (Chu *et al.*, 1996). The MOEs for dietary exposure[18] in adults compared with this NOAEL are around **4400** on average and **2000** at P95. For children, the MOEs are **2600** and **1200** respectively.

[17] ILSI Europe Workshop on Significance of Excursions of Intake above the Acceptable Daily Intake (ADI), April 21-23, 1998, Milan, Italy, publications dans *Regul Toxicol Pharmacol*. 1999, 30(2 Pt 2).
[18] Current situation with no maximum level, data in Table 8

For women of childbearing age

Women of childbearing age are of particular interest because fœtal exposure to PCB depends not on daily intake but on the content of PCB in the umbilical cord blood, which itself depends on the mother's body burden as a result of the accumulation of PCB between her birth and the conception of the child, and the number of previous children for mothers who have had more than one child.

The risk assessment according to the MOBB approach is more appropriate. The comparison of human body burdens and test animal body burdens can then be based on data on the most toxic PCB congener (PCB-153), as in the previous case. The burdens corresponding to the NOAEL and lowest-observed-adverse-effect level (LOAEL) are 1200 and 9000 µg/kg b.w. respectively in the rat after a 90-day intoxication (Chu *et al*., 1996).

With no French data on the impregnation levels of women of childbearing age, the risks may be estimated by taking the average and extreme values measured in European populations, 240 ng/g fat (or 48 µg/kg body weight) and 1000 ng/g fat (or 200 µg/kg b.w.) respectively (EFSA report, 2005). Sparse data observed in France do not allow for the national population to be considered different from the European population. To compare data concerning rats and humans, a correction factor of 2 corresponding to the differences in body fat is used. Accordingly, the MOBBs compared with the NOAEL are around **50** for average values and **12** for values exceeding impregnation[19]. Regarding the LOAEL, the margins are 375 and 90 respectively.

For children under 3 years of age

It is accepted that maternal milk contributes to 5-10% of the body burden observed in adult age. Considering that a significant proportion of children under 3 years of age are breastfed and that their brain is not mature, they should be placed in the same group as women of childbearing age.

Conclusion

For the group of adults and children over 3 years of age, the estimated daily intakes[16] lead to MOEs exceeding 1000, on the basis of a critical hepatic effect. The establishment of regulations setting limit values of NDL-PCB would further increase this margin of exposure.

However, for women of childbearing age, the low MOBBs would justify the monitoring of impregnation levels (for example, regular measurement of contamination levels in human milk, as is done in other European countries[20]). Additional epidemiological studies are recommended to improve understanding of dose-response relationships between exposure levels *in utero* and potential health effects, particularly to identify intervention limits (for example, within the cohort ELFE[21]).

9. CONCLUSIONS AND RECOMMENDATIONS

After consulting the scientific panel "Chemical and Physical Contaminants and Residues", which met on 18 September 2007, the French Food Safety Agency issues the following conclusions and recommendations :

1. Concerning the number of congeners making up the group of PCB indicators

Afssa assumes that consideration of 6 NDL-PCB (PCB 28, 52, 101, 138, 153 and 180) is satisfactory and sufficient for managing the contamination of foodstuffs by PCB. This approach is consistent with the future European regulations on non dioxin-like PCB (NDL-PCB).

2. Concerning the method for assessing health risks associated with NDL-PCB

The recommendations issued in Afssa's opinion of 8 April 2003 can be renewed, namely :

- the tolerable daily intake (TDI) of 20 ng/kg b.w./d proposed by the ATSDR (2000) and RIVM (2001) for all PCB is adopted as the human health-based value, on the basis of neurological effects observed in monkeys ;

[19] 1200*2/48 = 50 ; 1200*2/200 = 12

[20] Belgium, Czech Republic, Croatia, Denmark, Finland, Germany, Hungary, Norway, Slovakia, Spain and the Netherlands in 1988, 1993 and 2001 (EFSA report, 2005).

[21] ELFE: Etude Longitudinale Française depuis l'Enfance (French Longitudinal Study since Childhood), coordinated by the INED and InVS.

- the risk assessment based on dietary exposure for the sum of 6 NDL-PCB should consider a TDI of 10 ng/kg b.w./d.

3. Concerning dietary exposure to NDL-PCB of the French population

At present (no maximum level), average exposure to 6 NDL-PCB is 12.9 ng/kg b.w./d for children, 7.7 ng/kg b.w./d for adults and 7.6 ng/kg b.w./d for women of childbearing age.

4. Concerning management options which can be proposed regarding dietary exposure to NDL-PCB of the French population

- First of all, it should be pointed out that, unlike dioxins, action on PCB contamination sources is very limited since it mostly results from environmental pollution (sediments) associated with past use of these compounds until the 1980s. As a result, the management of risks associated with these two families of chlorinated compounds (PCB and dioxins) is necessarily distinct.

- The risk assessment based on NDL-PCB (through 6 congeners) does not underestimate the risks associated with dietary exposure, compared with the DL-PCB approach.

- The maximum levels for NDL-PCB proposed in the European draft regulation (2006) would only have a very limited impact on the dietary exposure to NDL-PCB of the French population.

- Establishment of maximum limits compatible with the TDI of NDL-PCB would lead to exclusion levels of foodstuff of around 20 to 40% depending on the food group.

- Estimation of average exposure in France is comparable to exposure levels reported in the other European countries.

- The TDI has been exceeded for all 3 populations studied (children, adults and women of childbearing age).

- Concerning women of childbearing age and children under 3 years of age, the safety margins are considered insufficient to guarantee their safety. As a result, Afssa recommends finding out more about impregnation levels of women of childbearing age in France. Considering the nutritional interest[22] of fish consumption, Afssa, like other health agencies[23], recommends consuming different species of fish from different fishing areas to avoid exclusively consuming oily fish from the most contaminated fishing areas in PCB.

- Concerning adults and children over 3 years of age, the safety margins are considered to be sufficient, since the neurological effect on which the TDI is based is not critical for this population group.

- According to national data collected in 2005-2006, it would be possible to predict DL-PCB (n=12 congeners) levels from NDL-PCB (n=6 congeners) concentrations in the same foodstuff*.* **The assay of these 6 congeners is therefore adapted to the routine monitoring of “background” contamination (excluding accidents) by all PCB, whether they be NDL-PCB or DL-PCB.** However, additional data are still needed to confirm the reliability of equations for predicting DL-PCB contamination levels from only 6 NDL-PCB. In view of the low number of data available in meat, although this food group constitutes the second highest contributor to dietary exposure after fish, Afssa recommends completing measurements in meat and offal.

- The recommendations issued in this opinion, drawn up on the basis of current knowledge, still sparse on these compounds, may be changed as knowledge is gained through research projects and studies, such as the European project ATHON.

[22] Fish is a key source of essential fatty acids, necessary for the development of the nervous system and the establishment of cognitive functions, proteins, vitamins and trace elements (such as selenium) and fatty acids presenting antithrombotic and antiarrythmic properties, particularly omega 3 polyunsaturated fatty acids.
[23] These recommendations are drawn up for methylmercury, PCB and dioxins which are lipophilic contaminants liable to become concentrated in animal fats, particularly oily fish and carnivores with a long life expectancy. Accordingly, Afssa has already issued this type of recommendation in its opinions on methylmercury.

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13. KEY WORDS

NDL-PCB, PCB indicators, PCBi, PCB, polychlorobiphenyls

The Director General of the French Food Safety Agency

Pascale BRIAND

Annex 1: Consumption data used in the assessment of dietary exposure to NDL-PCB

The INCA survey[24] was conducted by the CREDOC in 1998-99. It gathers all of the food intakes of individuals over a whole week. The food consumption data were obtained using food records, filled in over a period of 7 consecutive days, which facilitate the identification of food and portion sizes with photographs. The list of foods referred to in this survey was based on the one used in composition tables and contains almost 1,000 codes and 44 food groups.
The survey was conducted among 3,003 individuals, children and adults, representative of the French population. National representativeness was ensured by stratification (age, sex, individual body weight and size of household).

The sample of adults comprises 1,985 individuals over 15 years of age. Calculations only concern adults who have correctly assessed their individual case. This sample comprises 1,474 individuals.

The sample of children comprises 1,018 individuals aged from 3 to 14 years. With no method for selecting under-estimating individuals, this sample was not adjusted.
In this study, the weight of almost all participants was recorded, enabling exposure per kg of body weight (kg b.w.) to be calculated.

The groups of individuals studied in this survey are children aged 3 to 14 years (n=1018), women of childbearing age (19-44 years) (n=389) and adults over 15 years of age (n=1085). The category of women aged between 19 and 44 years was studied separately so as to be able to observe this at-risk group concerning PCB and more generally POPs more carefully.

Recipes

Using this food survey, the ingredients contained in the foods consumed in the surveys were quantified by the Afssa Observatory of Food Consumptions team. This led to the RECIPE base[25] of the foods included in the INCA list, which was set up as a reference for exposure studies. The recipes included in this base correspond to foodstuffs defined as complex, i.e. made up of several ingredients.

On the basis of RECIPE, the link between the recipes of complex foodstuffs (i.e. with the description of their ingredients) and products consumed in the INCA survey could be established. This gave a consumption total for each survey, no longer by food type (sweet pastries, savoury pastries, ready meals, etc.) but by ingredient category (vegetables, cereals, meat, etc.).

This improved consideration of an individual's diet enabled the dietary exposure of each person to be calculated more accurately by taking account of not just foods as they were consumed (beef burger for example) but also ingredients (butter in a pastry).
Tables 11a, b and c present the consumption data of 7 food categories for the 3 population groups studied.

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[24] Volatier, J.L. (Coordinator). INCA survey (2000) CREDOC-AFSSA-DGAL, French national survey on food consumptions, Tech & Doc Lavoisier

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Table 11: Consumption data per population and per food group (in g/person/day):

a. children

products	average	median	ET	p90	p95	Consumer level
	(in g/person/d)					(in %)
plant products	496.2	467.2	198.6	750.5	847.1	100.0
dairy produce	385.1	379.5	168.5	583.8	679.5	100.0
meat	124.3	115.6	57.0	195.9	230.8	99.9
eggs	25.7	22.7	17.9	49.5	58.8	99.3
fish	18.8	13.8	19.1	42.0	54.7	89.7
seafood	2.2	0.0	5.9	7.1	12.6	30.8
total	1052.3	1032.1	296.0	1403.4	1587.9	100.0

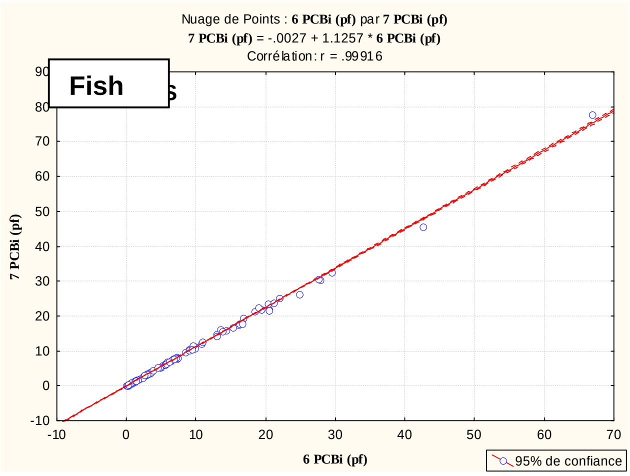
b. women of childbearing age

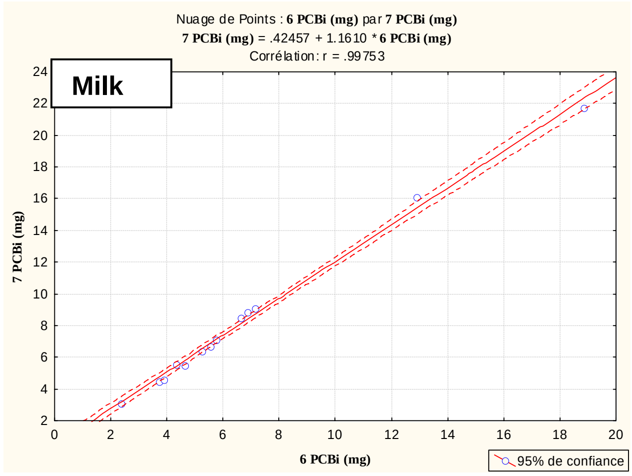
products	average	median	ET	p90	p95	Consumer level
	(in g/person/d)					(in %)
plant products	629.8	595.8	223.6	927.8	1042.4	100.0
dairy produce	313.4	292.9	153.5	510.6	602.6	100.0
meat	145.8	140.7	58.9	218.3	254.1	99.5
eggs	26.1	22.6	17.3	48.8	58.8	99.5
fish	26.0	20.0	25.6	65.9	77.8	89.2
seafood	5.3	0.0	11.6	16.9	23.0	44.7
total	1146.4	1109.8	287.7	1547.9	1663.9	100.0

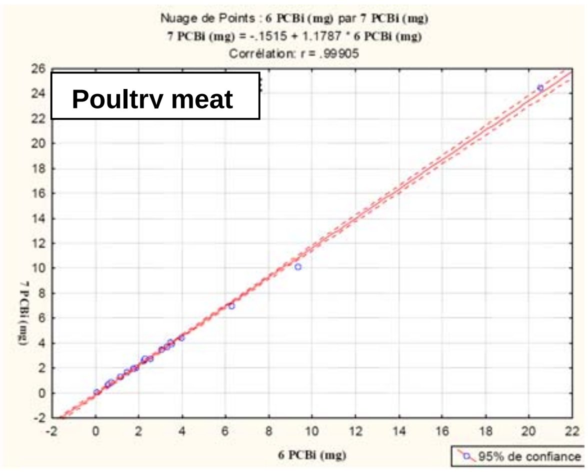
c. Adults

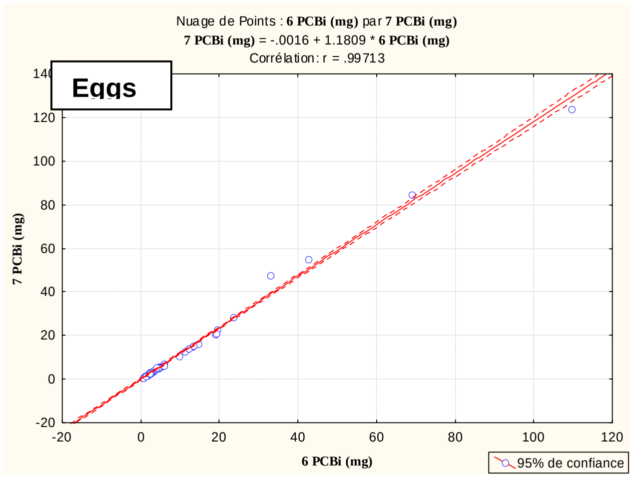
products	average	median	ET	p90	p95	Consumer level
	(in g/person/d)					(in %)
plant products	828.6	756.8	364.1	1290.4	1495.9	100.0
dairy produce	288.2	261.8	158.1	505.2	577.9	100.0
meat	179.0	166.1	82.6	282.4	325.0	100.0
eggs	31.6	24.8	31.8	67.3	89.1	90.0
fish	30.0	25.7	23.7	58.9	75.2	98.6
seafood	4.9	0.0	10.0	15.8	24.3	41.5
total	1362.2	1298.1	406.9	1895.1	2076.6	100.0

Annex 2:
A- Correlations between PCBi (n=7) and NDL-PCB (n=6) in 4 food categories

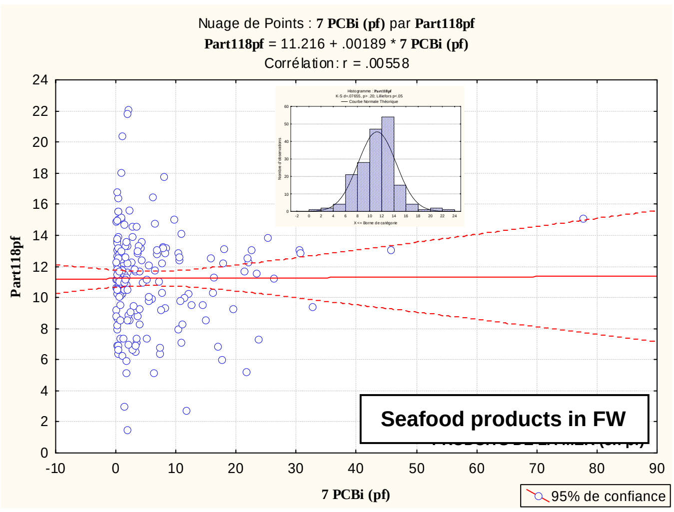


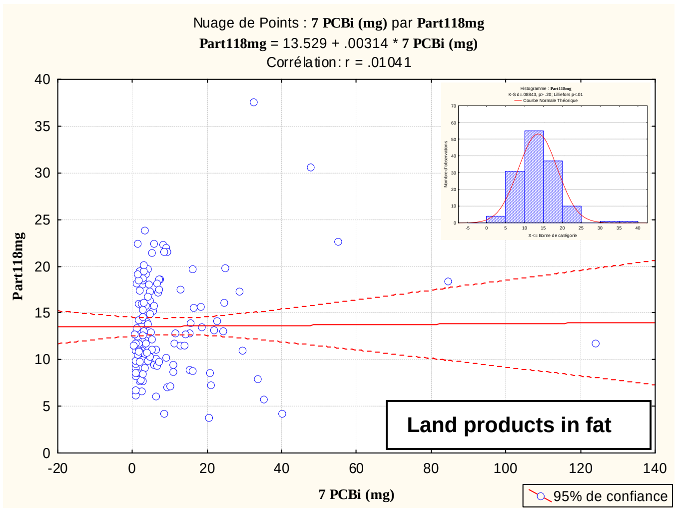




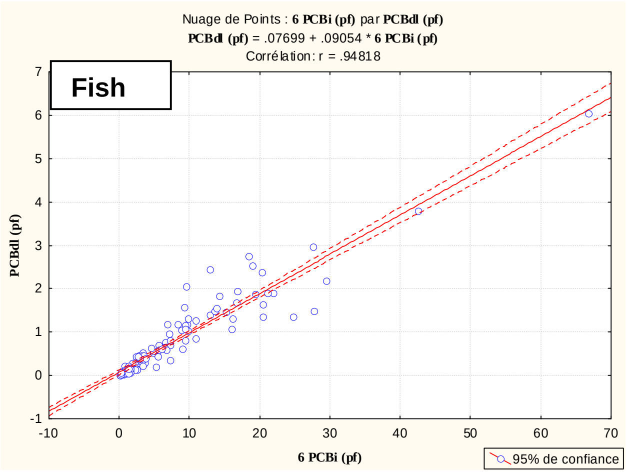


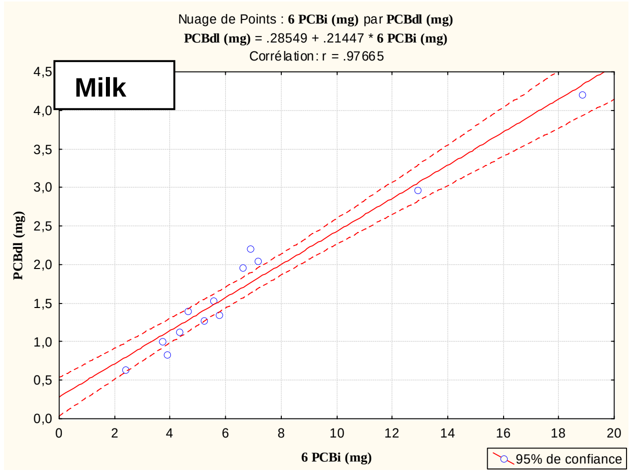
B- Contribution of PCB118 in the group of 7 PCBi

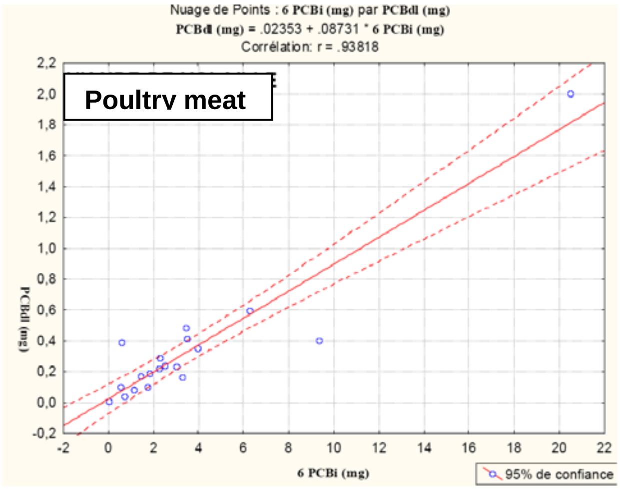


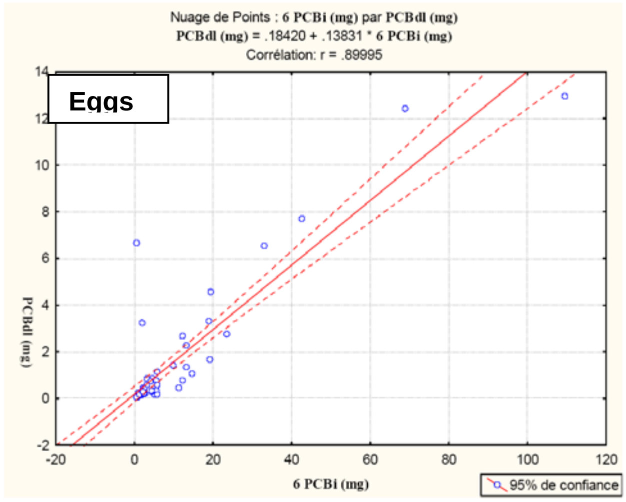


C- Correlation of PCBi and DL-PCB in 4 food categories









Annex 3:
Detailed estimations of dietary exposure to the 6 NDL-PCB for each population, for different scenarios

Table 12: Exposure to the 6 NDL-PCB per food group and for each population group, for different scenarios (ng/kg b.w./d)

a. children

	No maximum level		EU maximum levels		Maximum levels at 50 ng/g		Maximum levels at 25 ng/g		Maximum levels at 10 ng/g	
	average	% TDI	average	% TDI	average	% TDI	average	% TDI	average	% TDI
fish	4.9	49.0	4.7	47.1	4.5	45.3	4.0	39.8	2.4	24.3
meat	3.1	31.0	3.1	31.0	3.1	31.0	3.0	30.0	1.7	16.9
dairy produce	2.7	27.4	2.7	27.4	2.7	27.4	2.7	26.7	2.5	25.3
plant products	1.2	11.8	1.2	11.8	1.2	11.8	1.2	11.8	1.2	11.8
eggs	0.8	7.6	0.6	6.0	0.6	6.0	0.5	4.9	0.3	3.0
seafood	0.2	2.5	0.2	2.4	0.2	2.4	0.2	2.4	0.2	2.4
Total	12.9	129.2	12.6	125.7	12.4	123.9	11.6	115.6	8.4	83.8

b. women of childbearing age [19-44 years old]

	No maximum level		EU maximum levels		Maximum levels at 50 ng/g		Maximum levels at 25 ng/g		Maximum levels at 10 ng/g	
	average	% TDI	average	% TDI	average	% TDI	% TDI	average	% TDI	average
fish	3.2	31.7	3.1	30.9	2.9	29.4	2.6	25.8	1.6	16.1
meat	1.7	16.7	1.7	16.7	1.7	16.7	1.6	16.1	0.9	9.1
dairy produce	1.5	15.1	1.5	15.1	1.5	15.1	1.5	14.8	1.4	14.0
plant products	0.6	6.1	0.6	6.1	0.6	6.1	0.6	6.1	0.6	6.1
eggs	0.3	3.5	0.3	2.8	0.3	2.8	0.2	2.2	0.1	1.4
seafood	0.3	2.5	0.3	2.5	0.3	2.5	0.3	2.5	0.3	2.5
Total	7.6	75.7	7.4	74.2	7.3	72.6	6.8	67.6	4.9	49.2

c. adults

	No maximum level		EU maximum levels		Maximum levels at 50 ng/g		Maximum levels at 25 ng/g		Maximum levels at 10 ng/g	
	average	% TDI	average	% TDI	average	% TDI	% TDI	average	% TDI	average
fish	3.6	35.9	3.4	34.4	3.2	32.4	2.8	28.2	1.7	17.1
meat	1.7	16.6	1.7	16.6	1.7	16.5	1.6	15.9	0.9	9.0
dairy produce	1.4	14.1	1.4	14.1	1.4	14.1	1.4	13.8	1.3	13.1
plant products	0.5	5.0	0.5	5.0	0.5	5.0	0.5	5.0	0.5	5.0
eggs	0.3	3.2	0.3	2.6	0.3	2.6	0.2	2.1	0.1	1.3
seafood	0.2	2.3	0.2	2.3	0.2	2.3	0.2	2.3	0.2	2.3
Total	7.7	77.1	7.5	75.0	7.3	73.0	6.7	67.4	4.8	47.8

Table 13: Percentages of samples exceeding the maximum levels for the 4 scenarios studied

	EU maximum levels	Maximum levels at 50 ng/g	Maximum levels at 25 ng/g	Maximum levels at 10 ng/g
fish	2.0	6.0	12.0	33.1
meat	0	1.1	6.5	37.0
dairy produce	0	0	0.5	2.3
plant products	0	0	0	0
eggs	1.9	1.9	4.3	13.0
seafood	0	0	0	0
Total	1.3	3.6	7.3	21.4

Table 14: Exposure (ng/kg b.w./d) and percentages of samples exceeding the maximum levels for the 4 scenarios studied, per species (>5% TDI), in each of the 3 major food groups and for the 3 populations studied

	No maximum level			EU maximum levels				Maximum levels at 50 ng/g				Maximum levels at 25 ng/g				Maximum levels at 10 ng/g			
	children	women	adults	children	women	adults	% rejection	children	women	adults	% rejection	children	women	adults	% rejection	children	women	adults	% rejection
FISH																			
Salmon	1.550	0.984	0.970	1.550	0.984	0.970	0	1.550	0.984	0.970	0	1.338	0.849	0.838	6.9	0.725	0.460	0.454	49.4
Tinned sardine*	1.331	0.709	0.965	1.331	0.709	0.965	13.9	1.331	0.709	0.965	33.3	1.068	0.569	0.774	61.1	0.427	0.228	0.310	80.6
MEAT																			
Pork	1.286	0.726	0.741	1.286	0.726	0.741	0	1.286	0.726	0.741	0	1.286	0.726	0.741	0	0.647	0.365	0.372	20.0
Beef and veal	1.253	0.584	0.539	1.253	0.584	0.539	0	1.253	0.584	0.539	1.6	1.253	0.584	0.539	6.3	0.749	0.349	0.322	36.5
DAIRY PRODUCE																			
Cheese	0.727	0.529	0.568	0.727	0.529	0.568	0	0.727	0.529	0.568	0	0.723	0.510	0.548	0.5	0.723	0.469	0.504	2.7
Butter	0.723	0.439	0.406	0.723	0.439	0.406	0	0.723	0.439	0.406	0	0.701	0.438	0.406	0	0.644	0.438	0.406	0

*other types of sardines than tinned ones are not considered to be among the main contributors of the fish group. However, since the contamination average of tinned sardines comes from the Calipso survey, the rejection percentage presented here for the different scenarios corresponds to fresh sardines analysed in monitoring plans.

Within each group, table 14 shows that:

- for fish, salmon and tinned sardines would be targeted in particular because of their high contribution to exposure, whatever the population studied (for children, the proportions are 15.5 and 13.3% respectively in the 49% contribution to the TDI). Other fish contribute less than 5% to the TDI in each of the populations studied. The rejection percentage among the foodstuff analyses would be around 50% for salmon and 80% for sardines. Lastly, it should be pointed out that other fish species, such as eel, mackerel, horse mackerel and anchovies that are not high contributors (<5% TDI) on the basis of data currently available, would be concerned by a high market rejection percentage: 83%, 64%, 77% and 76% respectively, based on the high observed contamination levels.

  Consumption of oily fish (> 2% fat, list appended) contributes significantly to exposure and represents an average of 75.5% of contribution of the fish group for adults and 73.4% for children. For women of childbearing age, the distribution oily fish-lean fish is 69%-31%.

- For meat, pork and beef contribute more than 5% of the TDI, 12.8 and 12.5% respectively in children and 7 and 5.5% for the 2 adult populations. These data should nevertheless be interpreted with caution, because of the poor number of analyses available for these types of meat. Other meat, such as poultry, contributes to less than 5% of the TDI, whatever the population groups.

- For dairy produce, cheese and butter contribute to 7% of the TDI for children and around 5 and 4% for the 2 other populations. Yoghurts are the 3rd highest contributor (<5% TDI).

Annex 4:
List of fish present in the INCA survey and used to estimate exposure to NDL-PCB with the distinction between "oily" fish and "lean" fish.

"Oily" fish (>2% fat)
Tinned anchovies
eel
carp
swordfish
herring
smoked herring
mackerel
tinned mackerel
plaice
sardine
tinned sardine
salmon
smoked salmon
sea bass
mullet
turbot

"Lean" fish (<2% fat)
angler
pike
pollock
lemon sole
ling
whiting
hake
cod
perch
skate
scorpion fish
dogfish
sole
tuna
tinned tuna