The Director General

Maisons-Alfort, 7 July 2014

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

on the restriction proposal under the REACh Regulation: Bisphenol A in thermal paper

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures 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 all necessary information concerning these risks as well as the requisite expertise and scientific 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 made public.

This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 9 july 2014 shall prevail.

1. BACKGROUND AND PURPOSE OF THE REQUEST

In a letter to the Agency dated 4 June 2009, the General Directorate for Health (DGS) made a formal request for an expert appraisal on the health risks to the general population, related to Category 3 reprotoxic substances and/or endocrine disruptors found in products and/or articles on the market, including bisphenol A (BPA) in thermal paper.

The Working Group on Endocrine Disruptors and Category 3 reprotoxic substances (ED WG), of the Expert Committee on "Assessment of the risks related to chemical substances" (CES Chemicals), was appointed by ANSES to respond to this request.

Based on the initial work of the ED WG and the CES Chemicals, in September 2011, the Agency published a collective expert appraisal report on the "Health effects of bisphenol A" and a study report on "Knowledge of the uses of bisphenol A". In March 2013, ANSES published the collective expert appraisal report "Risk assessment of bisphenol A for human health related to dietary and environmental exposure and exposure to consumer goods", in which potential risks were identified for the unborn children of pregnant women, in relation to the handling of thermal paper containing BPA.

Based on the report and on the corresponding ANSES opinion, which identified a potential unacceptable risk for the unborn children of pregnant women exposed to thermal paper containing BPA, the General Directorate for Risk Prevention (DGPR) mandated ANSES, in a formal letter dated 6 May 2013, to prepare a restriction proposal relative to the use of BPA in

thermal paper in Annex XV format of REACh Regulation (EC) No 1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals).

2. ORGANISATION OF THE EXPERT APPRAISAL

In accordance with Annex XV of the REACh Regulation, a restriction dossier must include the following parts:

- The proposal: summary of the justifications, scope and conditions of the restriction
- Information on hazards and risks (including uses)
- Analysis of alternatives (available information and assessment of their availability, their risks, and their technical and economic feasibility)
- Justification that action is required on an EU-wide basis
- Justification that the proposed restriction is the most appropriate EU-wide measure to manage the risk
- Socio-economic analysis of the impact of the restriction (for health, the environment, industry and society as a whole)

This opinion of the Agency summarises the main elements analysed in the restriction dossier.

The Annex XV restriction dossier is based on the conclusions of the following ANSES reports:

- Collective expert appraisal report on "Risk assessment of bisphenol A for human health related to dietary and environmental exposure and exposure to consumer goods", published in March 2013.

- Collective expert appraisal report on "Other compounds of the class of bisphenols (Bisphenol S, F, M, B, AP, AF, and BADGE)" published in December 2012.

- Study report on the "Substitution of bisphenol A: an inventory of alternatives to BPA, identification of the hazards of potential substitutes for bisphenol A", published in March 2013.

These expert appraisals (including the restriction proposal) were carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise – General Requirements of Competence for Expert Appraisals (May 2003)".

The restriction proposal was presented and discussed on 17 September 2013, 22 October 2013, and 17 December 2013, by the Expert Committee on "Assessment of the risks related to chemical substances for the implementation of the REACh and CLP Regulations" (CES REACh-CLP).

Two CES members were appointed as rapporteurs for the socio-economic analysis (SEA) performed in this dossier.

The restriction proposal was prepared using contributions and data collected from the stakeholders consulted during the restriction proposal process:

- A survey was carried out by INERIS in 2013 with thermal paper industry players in the EU (and to a lesser extent from outside the EU), which provided information on the current use of BPA in the thermal paper sector, the concentration of BPA in thermal paper, the consequences for stakeholders of a possible restriction of BPA use in thermal paper and the possible reduction in thermal paper use, the evolution and trends of the thermal paper market, the possible use of alternatives to BPA in thermal paper, and the cost of BPA substitution.

- A questionnaire was sent to the competent authorities for REACh in the EU Member States (MSCAs) addressing issues on the key players of the EU thermal paper market, the use and substitutes of BPA in thermal paper, the risk and exposures related to BPA-containing thermal paper, and the existing/planned national regulations in the MSs.

- Two bodies involved in enforcement and monitoring activities in France were interviewed: the DGCCRF[1] and the SCL[2]. These interviews made it possible to carefully examine the conditions under which the restriction would be enforced and monitored at EU level and to obtain information about the existing analytical methods for measuring BPA content in different materials (XP CEN/TS 13130-13:2005-05-01 and NF EN ISO 18857-2:2012-01) as well as their costs.

3. SCOPE OF THE RESTRICTION

The proposed restriction targets the use of BPA in thermal paper.

BPA is a monomer produced and consumed for a wide range of final products and applications ranging from the synthesis of polymers (such as polycarbonates) and resins (such as epoxy resins) to the manufacture of flame retardants (used as a reagent) and thermal paper. The use of BPA in thermal paper accounts for 0.2% of BPA consumption in the EU (2,400 tonnes in 2013). BPA is widely used as a dye developer in thermal paper in the EU, with a share estimated at around 70%. This use is however decreasing due to its ongoing substitution begun worldwide.

Thermal paper is paper composed of base paper which is coated with at least one chemical layer. This chemical layer is a thermal reactive coating made with binders, dyes and a developer such as BPA. Thermal paper is so called because it is used in direct printing devices, placed under a heating printhead, which allows the images and characters to appear. This is precisely the role of the pigment developer (the BPA) contained in the thermal paper; to make these images and characters visible. Some thermal paper may also include additional coatings depending on the properties and the end-uses sought.

As illustrated below, thermal paper is used in many applications, such as point-of-sales (POS) cash register tickets and receipts, self-adhesive labels, lottery tickets or fax paper.

[1] French Directorate General for Competition, Consumer Affairs and Fraud Control
[2] French Common Laboratories Service

Table 1. Tonnage of BPA-containing thermal paper by application in Europe (2012)

Application	Tonnage of BPA-containing thermal paper
Point-of-sale receipts	351,000t (65%)
Self-adhesive labels	108,000t (20%)
Lottery tickets	54,000t (≈10%)
Fax	27,000t (≈5%)
Other	- (<0.5%)
TOTAL	540,000t (100%)

In principle, all types of thermal papers are likely to contain BPA although the information collected when preparing the restriction dossier indicates that it is mainly POS applications that involve use of BPA. As shown in the table above, these applications account for around 65% of the thermal tickets placed on the EU market. These types of tickets and receipts are made with relatively low-quality thermal paper, namely 'ecopaper', without any protective top-coating, so that the BPA contained in the thermal coating can migrate easily to fingers or any other objects in contact with it.

Although the top coatings of 'protected' thermal paper (most often used for transport tickets, cinema tickets and adhesive labels [food packaging, etc.]) might reduce BPA migration, the possibility of such migration and the risks associated with it cannot be excluded. Therefore, the restriction proposed herein aims to cover all types of thermal paper, from POS applications (namely 'ecopaper') to top-coated 'protected' thermal applications. Nonetheless, due to a greater amount of information collected for POS receipts, the exposure and risk assessments, as well as the socio-economic analysis in the dossier, were carried out considering point-of-sale receipts only.

Moreover, from a control and enforcement perspective, it would be difficult to identify thermal paper produced for one specific application or another, especially because 'thermal paper' is not explicitly defined or categorised as such in the existing classifications for products and articles.

Based on the above points and the analysis presented below, the restriction involves the use of BPA in thermal paper (in the form of a new entry in Annex XVII of the REACh Regulation) under the following terms:

Substance(s)	Conditions
Entry [#]. 4,4'-isopropylidenediphenol (Bisphenol-A) CAS No 80-05-7 EC No 201-245-8	1. Thermal paper shall not be placed on the market 36 months after entry into force of this Regulation if it contains this substance in a concentration equal to or higher than 0.02% by weight[3] 2. The existing standard analytical methods for BPA must be used

[3] For enforcement purposes, the restriction has to contain a concentration limit above 0%. As a result, the limit of BPA has been set at the average of the detection limits of the different existing methods for measuring BPA, calculated at 0.02%. This limit is considered to be the lowest and safest limit.

4. SUMMARY OF THE HEALTH RISK ASSESSMENT

- **Hazard identification**

The health risk assessment was based on two reports published by ANSES. In its reports on the health effects and uses of bisphenol A (September 2011), ANSES showed that there are 'recognised' effects (effects on reproduction, the mammary gland, metabolism, the brain and behaviour) in unborn animals, and other 'suspected' effects in humans (on reproduction, metabolism and cardiovascular diseases). These effects were observed when exposure occurred during sensitive phases of an individual's development, even at low levels of exposure. This led to the identification of vulnerable populations such as pregnant women and their descendants.

In its report on the risk assessment of Bisphenol A on human health (March 2013), ANSES shows that the handling of thermal paper by pregnant women, whether workers or consumers, presents a potential risk for the foetus exposed *in utero*. Four critical effects were identified for the descendants during their lifetime:

- Effects on the female reproductive system: ovarian cysts, disruption of ovarian cycles and endometriosis
- Effects on the metabolism and obesity: increase in cholesterolaemia and increase in body weight
- Effects on the mammary gland: increased vulnerability of mammary glands to subsequent development of tumours during co-exposure to a carcinogenic agent (due to architectural changes such as an increase in terminal ducts (TD), terminal buds (TEB) and hyperplastic ducts (HD))
- Effects on the brain and behaviour: impairment of spatial memory and learning functions

The results of key studies from the 2013 report and the internal derived no-effect levels (DNELs) obtained from the NOAELs are presented below.

Table 2. Effects and related DNELs selected for the Health Risk Assessment

Critical effects	Study reference	Route of exposure	NOAEL (µg/kg/d)	Internal NOAEL** (µg/kg/d)	Internal DNEL (µg/kg/d)
Brain and behaviour	Xu *et al.*, 2010a	oral	**50**	**1.5**	**0.005**
Female reproductive system	Rubin *et al.*, 2001**Erreur ! Signet non défini.**	oral	**100**	**3**	**0.01**
Metabolism and obesity	Miyawaki *et al.*, 2007**Erreur ! Signet non défini.**	oral	**87***	**2.6**	**0.009**
Mammary gland	Moral *et al.*, 2008	oral	**25**	**0.75**	**0.0025**

*: NOAEL calculated from the LOAEL.
**: internal NOAEL calculated from the NOAEL using a 3% value for systemic bioavailability following cutaneous absorption in animal tests

- **Exposure assessment**

Exposure via handling of thermal paper was modelled for female workers (tellers/cashiers) and consumers. A probabilistic approach was adopted to characterise exposure doses of BPA. On the basis of toxicokinetic parameters (or assumptions), internal dose (ID) equivalents of unconjugated BPA were calculated for the relevant target population(s). The different values that the ID can take, given the variability of the values exhibited by the different parameters used in its calculation, resulted in a dose distribution.

The results of the probabilistic assessment of internal doses associated with the handling of BPA-containing thermal paper were then used to determine the median and average values of exposure and the 95th percentile was used to characterise the risk to pregnant women (Table 3).

Table 3. Internal doses (ID) associated with the handling of thermal receipts for a population of pregnant women

Exposure scenarios	Internal exposure dose in µg.kg^{-1}.d^{-1}		
	Median	Average	95th percentile
Thermal receipts - female workers (cutaneous absorption flow approach)	0.20	0.21	0.43
Thermal receipts - consumers (cutaneous absorption rate approach)	0.01	0.02	0.08

- **Assessment of the health risks associated with BPA**

The risk is considered adequately controlled if 95% of the internal doses calculated are lower than the four DNELs (one for each type of effect mentioned above), i.e. P95 lower than the four DNELs. Figures 1 and 2 show the position of the P95 of the ID distribution (for female cashiers/tellers and consumers) compared with the DNELs associated with the four types of effects, showing that in all cases the P95 exceeds the DNELs.

Handling of thermal receipts leads to exposure levels for which a potential risk has been identified for the four types of effects considered, both for pregnant women cashiers and tellers as well as more generally for pregnant consumers handling thermal receipts.

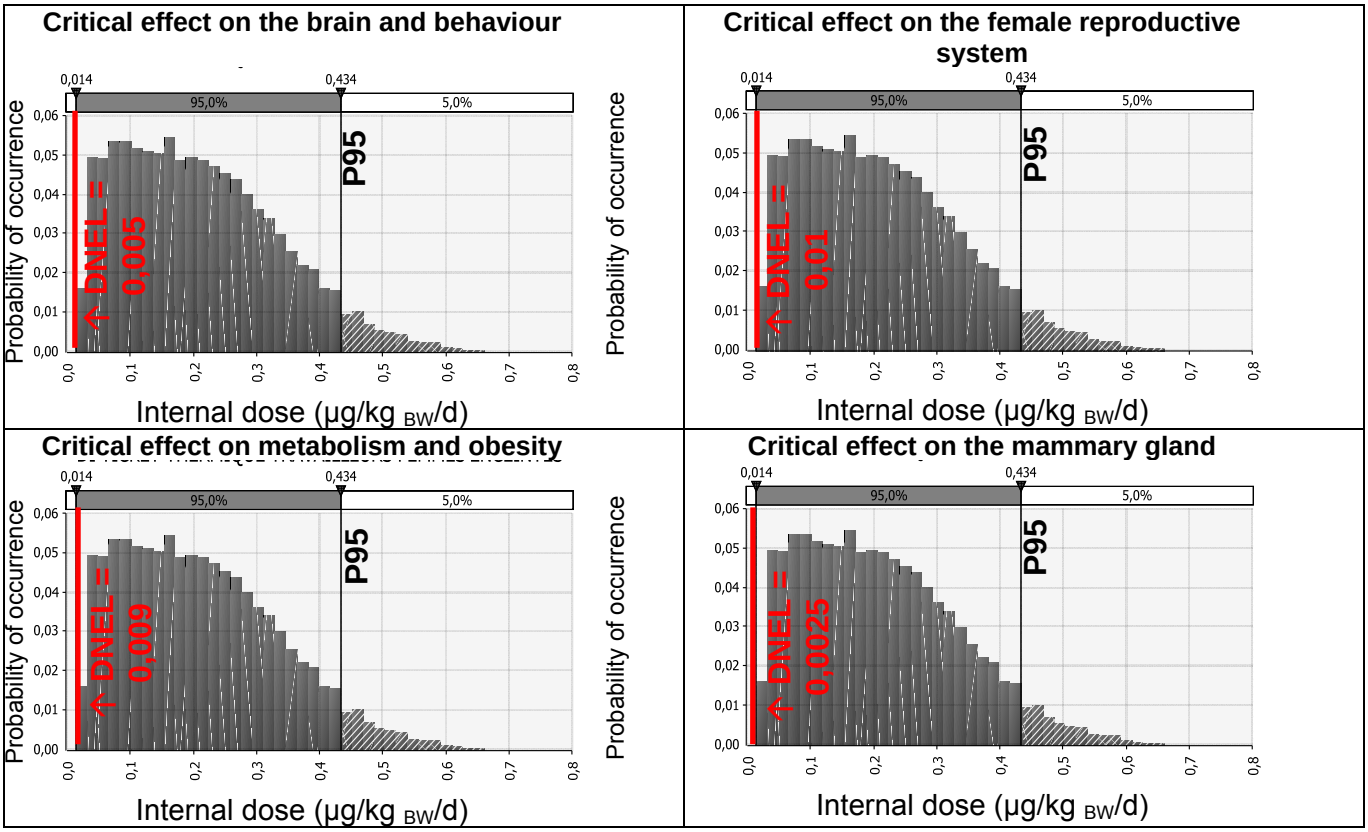
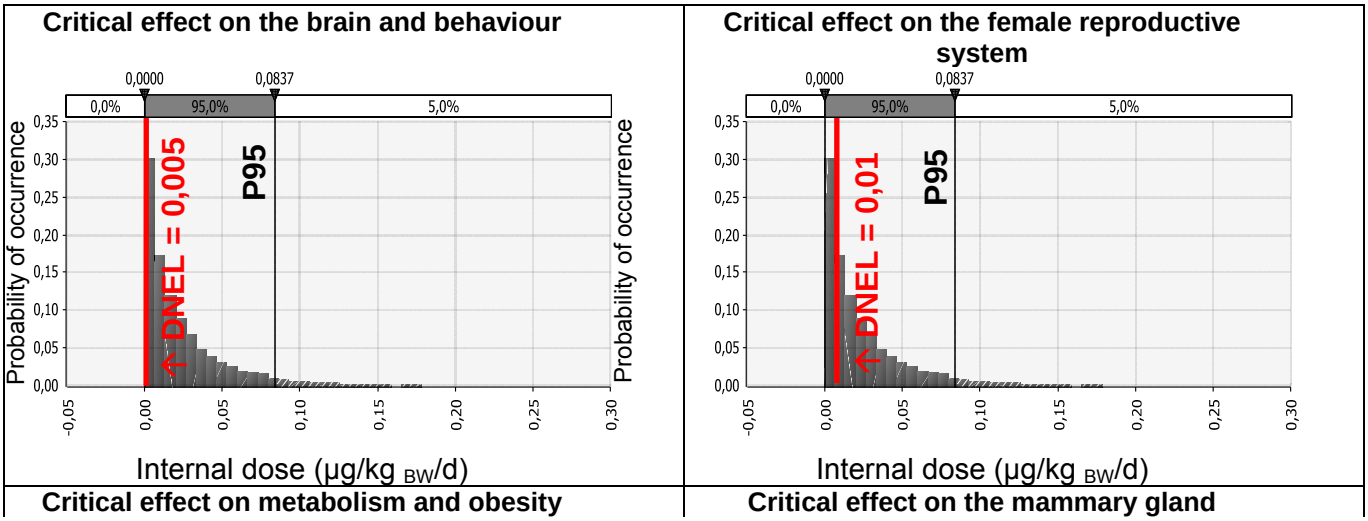


Figure 1. Characterisation of the risks associated with handling thermal receipts containing BPA – "Female Cashier/Teller" scenario



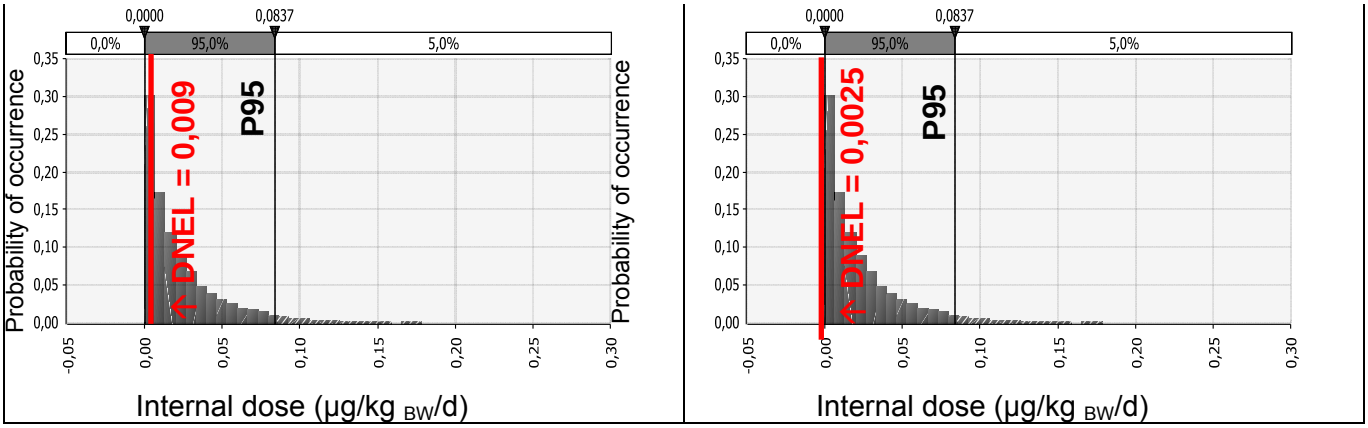


Figure 2. Characterisation of the risks associated with BPA from handling thermal receipts – "Female Consumer" scenario

A sensitivity analysis for exposure scenarios regarding the handling of thermal receipts containing BPA by pregnant workers showed that there is always a potential risk for the four critical effects with a systemic bioavailability factor following cutaneous absorption varying between 5 and 75 %, with the other parameters of the model remaining constant. For pregnant consumers, it appears that for all five tested values for systemic bioavailability following cutaneous absorption (5%, 10%, 30%, 50% and 75%), risk situations exist with regard to the critical effect on mammary glands; and for the 30%, 50% and 75% systemic availability values, risk situations exist for the four critical effects studied.

5. ANALYSIS OF ALTERNATIVES

An extensive analysis of alternatives to BPA was performed in the framework of this proposal. The analysis evaluated both chemical and technical alternatives.

Regarding the analysis of alternative dye developers, a three-step approach was followed:

- firstly, the identification of potential alternatives to BPA in thermal paper;
- secondly, selection from among the identified alternatives based on the technical feasibility criteria described below, and
- thirdly, an assessment of these alternatives according to the criteria of their availability, their hazards for human health and the environment, and their technical and economic feasibility.

The identification of potential alternatives to BPA in thermal paper was based on the review of the available literature (RPA, 2003; ANSES, 2011; US EPA, 2012 (update of US EPA,2010), INERIS, 2010; ANSES, 2013; Danish EPA., 2013; Kemi, 2013) and the data gathered from the stakeholders and MSCAs consulted. These two channels of information led to the preliminary conclusion that many other chemicals can in principle be used in thermal paper to replace BPA. Thirty 'potential' substitutes to BPA in thermal paper were identified.

From these 30 identified substitutes, alternatives were then selected, based on the following exclusion and inclusion criteria:

- **Exclusion criterion**: unknown or very unlikely use of the chemical in thermal paper

- **Inclusion criteria:**
  - **1**: actual and known commercial use of the chemical in thermal paper
  - **2**: possible alternative (very similar properties) or alternative recently placed or about to be placed on the market as a dye developer in thermal paper

From these criteria, ten alternative dye developers were considered as potential 'realistic' substitutes to BPA in thermal paper: 3 bisphenols (BPS, BPF, BPA), 5 phenolic compounds (D8, D90, TGSA, DD70, 1,2-diphenoxyethane) and 2 urea-based chemicals (UU and Pergafast).

These 10 alternative chemicals were then assessed according to the criteria of availability, hazards for human health and the environment, and technical and economic feasibility, based on the review of the available literature as mentioned above and the data collected from the players consulted. As presented in the table below, this assessment showed that some of them are available and already being used as a replacement for BPA (and thus are also, in principle, technically feasible) and some seem to be economically feasible. Nevertheless, many uncertainties surround the alternatives selected and a significant lack of data was noted, on their hazard profiles in particular, preventing a clear-cut conclusion from being reached about them. Indeed, none of them have a totally safe toxicological or ecotoxicological profile, making it impossible to recommend just one of them. However, the reliability and accuracy of information about alternatives are of prime importance since the substitution of BPA by other bisphenols is highly likely and these chemicals could be hazardous. BPS in particular is already largely used in thermal paper worldwide and appears to be the most technically and economically feasible "drop-in" alternative. **Nevertheless, given the toxicological profile of BPS, this substitute might cause very similar adverse health effects to BPA**.

Table 4. Comparison of alternative dye developers selected and assessed

Alternative chemicals	CAS number	EC number	Hazards HH/ENV	CLP	Registered	Availability	Technical feasibility	Economic feasibility
BPS	80-09-1	201-250-5	Not data for cutaneous absorption. Oestrogenic properties, Anti-androgenic activity, Uterotrophic effect, Effects on reproduction and development at maternal toxic doses (300 mg/kg/d), Discrepancies between genotoxicity studies. (ANSES; study report on the bisphenol family compounds, 2012)	No harmonised classification; 209 registrants are not classified; Number of different aggregated notifications: 7; Proposed notifications: Aquatic chronic 3, H412; Eye irrit. 2, H319; Skin irrit. 2, H315; STOT SE 3 resp. irrit., H335;	yes >1000t	+++	+++	+2,920-4,2000€/t

BPF	620-92-8	210-658-2	Difficult to decide on the toxicity for the reproductive organs; Endocrine disruption activity via oestrogen receptors; Direct genotoxic effect by DNA strand break. (ANSES; study report on the bisphenol family compounds, 2012)	No harmonised classification; 5 registrants are not classified; Number of different aggregated notifications: 6; Proposed notifications: Aquatic chronic 3, H412; Eye irrit. 2, H319; Skin irrit. 2, H315; STOT SE 3 resp. irrit., H335; Skin sens. 1, H317;	no	+ ?	+ +	?
BPAP	1571-75-1	433-130-5	Oestrogenic activity, Not possible to conclude on the endocrine disruption activity. No toxicokinetic data, no data on toxicity for the reproductive organs. (ANSES; study report on the bisphenol family compounds, 2012).	Yes, harmonised classification: Aquatic acute 1 H400; Aquatic chronic 1 H410;	no	+ ?	+ +	?
1,2-diphenoxyethane	104-66-5	203-224-9	Not evaluated by ANSES. -Data only from the disseminated data from the registration dossier: -No oral acute toxicity -Eye irritation -Not skin sensitiser -Low repeated dose toxicity -not toxic for development -Non mutagenic -short term toxicity to fish: NOEC = 0.40 mg/l *- Short term toxicity to aquatic invertebrates: NOEC = 0.40 mg/l* *- Long-term toxicity to aquatic invertebrates: NOEC = 0.54 mg/l* *-Toxicity to aquatic algae and cyanobacteria: NOAEL = 0.40 mg/l*	No harmonised classification Nb of aggregated notifications: 1 Proposed notification: Aquatic chronic 2 H411;	yes >1000t	+	+ +	?
Pergafast (DP 201) (N-(p-Toluenesulfonyl)-N'- (3-p-toluenesulfonyloxyphenyl) urea)	232938-43-1	432-520-2	Not evaluated by ANSES. -not thought to be absorbed through the skin. Absorption expected by inhalation and by gastro-intestinal tract (US EPA) -low toxicity by oral route and dermal route (US EPA and disseminated data) -not irritant for skin (US EPA) -low eye irritant (US EPA) -low skin sensitising (US EPA) -moderate repeated dose toxicity (US EPA) -reprotoxicity (fertility and development) estimated as moderate (US EPA) -low genotoxicity estimated -No data on carcinogenicity -not expected to be neurotoxic based on structural alert (US EPA) -no oestrogenic activity (US EPA) -uncertainty for immunotoxicity *-strong persistence in the environment and may be toxic to aquatic organisms*	Yes, harmonised classification: Aquatic chronic 2 H411;	yes confid.	+ ?	+ +	-15,000€-30,000€/t

D8 (or DD8 or ALD-2000) (4-(4-isopropoxyphenylsulfonyl)phenol)	95235-30-6	405-520-5	Not evaluated by ANSES. -not thought to be absorbed through the skin (US EPA) -no data on acute toxicity -No data on carcinogenicity -Moderate concern for genotoxicity based on an analog (US EPA) -Moderate concern for reprotoxicity based on an analog (BPS ((US EPA) -Neurotoxicity: moderate based on the phenol structural alert (US EPA) -high hazard concern for repeated dose toxicity by analogy to BPS (US EPA) -low hazard concern for skin sensitisation, eye irritation and dermal irritation (US EPA) -no data for respiratory sensitization or immunotoxicity -endocrine activity: limited evidence (US EPA); but discrepancy between two studies: ER binding study and anti-oestrogenic binding assay. *-significant hazard for aquatic life (US EPA)*	Yes, harmonised classification: Aquatic chronic 2 H411;	yes (NONS) confid.		+	- 1 1 , 3 9 0 - 1 5 , 1 0 4 € /t
D90 (Phenol, 4,4'-sulfonylbis-, polymer with 1,1'-oxybis[2-chloroethane])	191680-83-8	Not assigned	Not evaluated by ANSES. -No data concerning dermal absorption -Low oral and dermal concern based on good quality studies (US EPA) -No data on carcinogenicity (US EPA) -Estimated to be of low genotoxicity -low potential for developmental toxicity ((US EPA) Moderate potential for neurotoxicity (US EPA) -Low hazard for repeated dose toxicity -Low hazard for skin sensitisation -eye irritant -No data for respiratory sensitisation or immunotoxicity *- low concern for acute Ecotoxicity (US EPA)* *- low hazard concern for chronic Ecotoxicity (US EPA)* *- low mobility in soil based on its expected strong absorption to soil (US EPA)* *- Very high persistence (US EPA)*	No	no	+ ?	+ ?	

UU (Urea Urethane Compound)	321860-75-7	Not assigned	Not evaluated by ANSES. -Not absorbed by skin based on an analog (US EPA) -Low hazard for oral acute toxicity (US EPA) -Lack of data for carcinogenicity (US EPA) -Low concern for genotoxicity potential (US EPA) -Low hazard concern for developmental toxicity (US EPA) -Low neurotoxicity hazard (US EPA) -low hazard concern for repeated dose toxicity (US EPA) -Not skin sensitising, low concern for dermal and eye irritation (US EPA) -no data for endocrine activity -no data for immunotoxicity *-Low hazard concern for acute Ecotoxicity (US EPA)* *-Low hazard concern for chronic Ecotoxicity* *- partition predominantly to soil and sediment* *- Very high persistence potential* *- Low potential of bioaccumulation*	No	n o	+ ?	+ ?	
TGSA (2,2'-diallyl-4,4'-sulfonyldiphenol)/notified substance subject to transitional measures	41481-66-7	411-570-9	Not evaluated by ANSES. -not thought to be absorbed through the skin (US EPA) -low oral and dermal acute toxicity based on studies on TGSA (US EPA) -Moderate concern estimated for carcinogenicity (US EPA) -Low concern exists for genotoxicity -moderate hazard concern for developmental effects based on data existing for analog BPS (US EPA) -Moderate hazard for neurotoxicity (US EPA) -A classification as STOT RE 2 might be obtained according to US EPA. -skin sensitizer; moderate concern for respiratory sensitisation; low eye irritant; no dermal irritant. -No evidence of endocrine activity *- high concern exists for acute toxicity based on experimental acute aquatic toxicity values for fish and Daphnia which are in the range of 1-10 mg/L (US EPA).* *-high concern for chronic toxicity* *- partition primarily to soil.* *-low bioaccumulation potential*	Harmonised classification: index nb: 016-075-00-8 Skin Sens. 1; H317 Aquatic Chronic 2; H411 Seveso substance: 9ii (toxic to aquatic org and long term effects)	Y e s	+ ?	+ ?	?

DD70	93589-69-6 407-480-4		-Not evaluated by ANSES. -Not thought to be absorbed through the skin (US EPA) -Low acute toxicity (US EPA) -Potential carcinogen or estimated tumour promoter (US EPA) -No genotoxicity data -No data on reprotoxicity but estimated to be moderately toxic for reproduction (US EPA) -No data on repeated toxicity but moderate hazard is estimated (US EPA) -Moderately neurotoxic based on the phenol structural alert (US EPA) -Moderate hazard identified for skin sensitization and dermal irritation reported for an analog (US EPA) -Concern exists for corrosion for eyes (US EPA) -No data for respiratory sensitization or immunotoxicity (US EPA) -endocrine activity: no data (US EPA) *- high concern for acute ecotoxicity* *- high concern for chronic aquatic toxicity* *- partition primarily to soil* *- high persistency, no bioaccumulation*	Yes. Harmonised classification: Aquatic chronic 2 – H411				

Regarding alternative techniques, alternative printing techniques were analysed, such as matrix printing, inkjet printing and thermal transfer printing, as well as paper-free techniques such as e-tickets and mobile payments. The European print market is currently shrinking due to lower print pricing, reduced printing practices, tough competition and innovation. The sector is under transformation and e-technologies are growing. These alternative techniques were also assessed according to the criteria of their availability and their technical and economic feasibility. However, it was not possible to assess their hazards and risks for human health and the environment due to a lack of data. As shown in the table below (Table 5), the assessment is qualitative and concludes that, wide-scale, affordable replacement of direct thermal printing with these alternative techniques is probably not feasible . This is mainly due to the fact that direct thermal printing is far more efficient and advantageous in terms of quality and costs than other technologies which, additionally, have rather limited (for now) availability and acceptability.

Table 5. Comparison of alternative techniques selected and assessed

Alternative techniques		**Risks for human health/ the environment**	**Availability**	**Technical feasibility**	**Economic feasibility**	**Consumer acceptability**
Alternative printing techniques	matrix printing	No data	+↓	+	- -	+
	inkjet printing	No data	++	+	- -	+

	laser printing	No data	++	+	- -	+
	thermal transfer printing	No data	++	++	-	+
Paper-Free techniques		No risks expected	+↑	+↑	++	-

The arrows express trends (↓: expected to decrease; ↑: expected to increase)

6. JUSTIFICATION FOR THE NEED FOR A REACH RESTRICTION

A REACh restriction proposal is justified for the following reasons.

- There is a need for action since a risk has been demonstrated
- There is a need for EU-wide action
- The restriction is the most appropriate way of managing the risk

There is a need for action since a risk has been demonstrated

As presented above, the risk assessment has demonstrated that BPA might cause multiple adverse effects to the health of the unborn children of pregnant workers and consumers. This risk is not addressed anywhere in Europe since no EU country has yet implemented any national legislation related to thermal paper. Sweden and Belgium recently proposed a restriction for that purpose, but these proposals have not yet been adopted. As a result, the anticipated exposures and risks for human health are expected to continue until regulatory action has been implemented.

Risks for the environment are not included in the proposal although it has been shown that the restriction could also bring some benefits to the environment, avoiding in particular the release of BPA in aquatic compartments from thermal paper recycling. Indeed, up to 50% of thermal paper is currently recycled in the EU, and is re-used to produce other paper-based products such as recycled paper, napkins, toilet paper, paper towels, newspapers or magazines (Gehring, 2004). Those products might thus contain BPA traces and contribute to secondary contamination.

Because of the toxicity of BPA and the repeated criticism from public opinion, the media and health and environment agencies all over the world, substitution of BPA in thermal paper is already underway (see the analysis of alternatives above). However, the rate and efficiency of substitution in the absence of regulatory obligation remain uncertain and there is thus a need for regulation.

There is a need for EU-wide action

Thermal paper is extensively manufactured, traded and used all over Europe. It is also imported from outside the EU. The analysis of several hundred tickets as well as the consultations carried out during the drafting of this proposal have demonstrated that BPA is still widely used in thermal paper in the EU, in particular in ecopaper used for POS receipts as described above. According to the stakeholders and MSCAs consulted, the share of BPA-containing thermal paper compared to thermal paper as a whole is claimed to be at least 70%, the BPA concentration being around 1-2% by mass. As a consequence, exposure is likely to concern all EU countries. Moreover, the populations at risk are any pregnant workers likely to handle thermal tickets (such as cashiers) and any pregnant consumers receiving a ticket or receipt after a purchase, a cash withdrawal or a credit card payment. In principle, this means that every EU pregnant woman is concerned by the risk.

Finally, the REACh restriction proposal is also justified by EU common market considerations. Indeed, it would prevent the EU Member States from adopting different legislative requirements which could potentially be in conflict and/or create unequal market conditions for those involved in the thermal paper supply chain. The proposed restriction would remove any distorting effect that national restrictions might have on the free circulation of goods in the common market. This equal treatment would enable the creation of a level playing field for all EU manufacturers and all importers of thermal paper into the EU. An EU-wide restriction would also give a clear message on the status of the obligations to be complied with and would facilitate communication between the different supply chain players, especially suppliers outside the EU.

The restriction proposed is the most appropriate way of managing the risk

As required by Annex XV of the REACh Regulation, the restriction proposal has been assessed according to the criteria of effectiveness, practicality and monitorability.

The ***effectiveness*** of the restriction is defined such as the measure must be targeted to the effects or exposures that cause the identified risks, and must be assessed based on two subcriteria (ECHA, 2007):

- Its *risk reduction capacity*: ability of the measure to reduce the demonstrated risks to an acceptable level within a reasonable period of time

  Regarding this first subcriterion, the restriction proposed for the use of BPA in thermal paper is considered as *effective in reducing the identified risks*. The concentration limit proposed is very low and at this level, based on the stakeholder consultation, the thermal paper would no longer be effective. The restriction is thus equivalent to a total ban. As a result, it is expected that BPA will have been fully phased out by the date the restriction enters into force and thus exposure will have been totally eliminated, along with the associated adverse effects. Moreover, the proposed transitional period of 3 years (36 months) is deemed to be reasonable in terms of timing and manageability in order to give the supply chain enough time to comply and begin (or keep on) substituting, and for the control authorities to organise controls. These considerations are linked to the practicality and monitorability criteria (presented below).

- Its *proportionality to the risk*: the proportionality of the restriction is considered regarding its economic and technical feasibility. The economic feasibility of the restriction is

regarded from the perspective of the costs and benefits expected from its implementation. When both can be assessed and valued, the costs and benefits can be compared in order to decide on their relative magnitude. The technical feasibility of the restriction is analysed considering the practical feasibility of substitution as well as compliance by the supply chain with the new obligations.

Regarding this second subcriterion, the restriction proposed is considered as economically and technically feasible and, as a whole, *under reasonable assumptions, as proportionate to the risks*:

- The *costs* of the restriction mainly consist of substitution costs and compliance control costs (see section on the socio-economic analysis below). Given the range of costs assessed and the fact that the substitution of BPA in thermal paper is already underway, the restriction is considered as *economically feasible*.
- As regards the *health benefits* expected from the restriction, they correspond to the costs avoided due to the reduction in adverse effects for human health described in the risk assessment. The health benefits were assessed for female workers as well as for female consumers (see section on the socio-economic analysis below).
- Taking as granted that the proposal is equivalent to a total ban on BPA in thermal paper, the technical feasibility of the restriction is analysed in terms of the technical feasibility of the substitution. As shown in the dossier, there are technically and economically feasible chemical alternatives available, and some of them are already being used as dye developers in thermal paper (see analysis of alternatives above). No significant changes are therefore expected to be made to the technical processes or existing equipment except for some adjustments possibly related to reformulations of the thermal coatings. As a consequence, the restriction proposed, considered as a strong regulatory incentive to substitute, is deemed to be technically feasible.

*The **practicality*** of the restriction refers to whether the measure is implementable, enforceable and manageable (ECHA, 2007):

- A proposed measure's *implementability* means that the players involved are capable in practice of complying with it. To achieve this, the techniques and/or chemical alternatives should be available and economically feasible within the timeframe set in the restriction.

  As regards this criterion, *the restriction proposed is considered to be implementable*: industry players concerned by the proposed restriction would be capable of complying with the requirements in practice since concentration tests and alternatives are available as well as technically and economically feasible. The thermal paper supply chain is concentrated around a small number of players in the EU. In particular, the few producers are large companies, and are thus not expected to encounter major difficulties in complying with the new obligations. The only SMEs likely to be concerned by the restriction are retailers such as corner shops, which will have to buy BPA-free thermal paper rolls for their till receipts. However, it is considered that they are unlikely to face major additional costs (due to the higher price of thermal paper following substitution) since the cost of the rolls they buy from suppliers should be a very small share of their total operating costs and consumables.

- *Enforceability* means that the authorities responsible for implementing restriction must be able to check the compliance of relevant players with the restriction. The resources needed for enforcement have to be proportional to the risks avoided.

  Regarding this criterion, *the restriction proposed is considered to be enforceable:* First of all, a limit above zero has been set for the substance instead of a ban,which should enable the enforcement body to question whether the content is below the authorised limit. There is currently no standard analytical method for measuring the content of BPA in thermal paper in the EU, however several methods are available for other materials and could be used for that purpose (such as the XP CEN/TS 13130-13:2005-05-01 and NF EN ISO 18857-2:2012-01 methods). The establishment of an EU standard method would facilitate the routine implementation of these tests but it would also require time and money. Therefore, given that methods do exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

- *Manageability* means that the restriction should take into account the characteristics of the sectors concerned (for instance, the number of SMEs) and be understandable to the affected parties. The means by which the restriction will be implemented should be clear to the players involved and the enforcement authorities, and access to the relevant information should be easy. Furthermore, the level of administrative burden for the players concerned and for the authorities must be proportional to the risk avoided.

  Regarding this criterion*, the restriction proposed is considered to be manageable*: the means of implementation of the proposed restriction (concentration tests, substitution of BPA, etc.) are clear and understandable to the players involved, in particular because substitution of BPA in thermal paper is already underway and the information about the concerns relating to BPA seems to be communicated smoothly along the supply chain, at least down to the distributors. As regards the end-users, in particular the SMEs such as corner shops and single-proprietor businesses, some effort may be needed to access this information from their suppliers. One issue regarding manageability of the restriction could however be related to the fact that there is no EU standard method of measuring BPA content in thermal paper, as explained above. The market players would thus have to obtain information themselves and undergo additional training in order to be able to carry out the compliance tests needed. This would mainly be the case with manufacturers of thermal paper, and SMEs might not be affected.

The ***monitorability of the restriction*** means that it must be possible to monitor the results of implementation of the restriction. Monitoring has a broad definition and may cover any means of following up the effect of the restriction in reducing exposure. This may include, for example, follow up of the amounts of substance manufactured and imported, follow up of the amounts of substance used for different uses, measuring of the concentration of the substance in preparations or articles, measuring of the relevant emission and/or exposure levels, biomonitoring, etc.

Regarding this criterion, the *restriction proposed is considered as monitorable*: given that there are several analytical methods for measuring BPA content in thermal paper, it is considered that the restriction proposed can be monitored by the control authorities and customs services. As regards thermal paper imported into the EU, a problem regarding

definition could occur, since no specific existing TARIC[4] code has been assigned to this type of product. Several TARIC codes could in principle cover 'thermal paper'.

In conclusion, the restriction proposed is considered as effective, practicable and monitorable.

It should be noted that another option for restriction had been considered, which was based on limiting the migration of BPA in thermal paper. Indeed, since the demonstrated risk comes from exposure to BPA via dermal contact, the BPA migration rate could be considered as the most relevant indicator to describe potential exposure from thermal paper handling. However, such an option did not seem to be the most appropriate. Indeed, no correlation could be determined between the quantity of BPA likely to end up on the fingers and the quantity of BPA contained in the thermal ticket handled (and therefore likely to migrate). It is thus not possible to define a 'safe' level of BPA content that would allow 'safe' migration from the thermal paper. The only way to limit the migration of BPA and ensure the reduction of the risks addressed would be either to limit the content of BPA as much as possible (this is proposed by the restriction dossier), or to create a technical 'barrier' to BPA migration on (or in) the thermal paper itself. While this technical 'barrier' is theoretically feasible, no study was able to verify its efficiency and appears to be more difficult to monitor on an analytical level. As a consequence, although additional coatings might reduce the migration of BPA from tickets, it cannot be excluded that BPA might still migrate. Furthermore, applying such a protective coating on all types of thermal paper, especially on (cheap) ecopaper which is widely used for POS receipts, would probably imply a significant cost for industry and is not considered as economically feasible. As a whole, although this option could have been enforceable, manageable and able to be monitored, it has been discarded based on the lack of knowledge about its technical feasibility and efficiency.

7. SOCIO-ECONOMIC ASSESSMENT OF THE PROPOSED RESTRICTION

As required by Annex XV of the REACh Regulation, and to support the assessment of the proportionality of the restriction, a socio-economic analysis (SEA) was included in the proposal.

The SEA aimed at documenting and assessing the expected impacts from the restriction proposed. The assessment included the 'negative' impacts of the restriction, namely the costs, and the 'positive' impacts, namely the benefits. The costs mainly refer to the compliance costs expected to be borne by the markets and supply chains concerned by the restriction, including the substitution costs (costs associated with the adoption of alternatives) and the compliance control costs (cost of testing the compliant products). When relevant, some possible additional adverse effects for human health and/or the environment can also be assessed (e.g. in the case of hazardous substitutes). The benefits relate to the 'positive' impacts of the restriction (considered as avoided costs) and include mainly the adverse effects to human health and/or the environment avoided thanks to the restriction. When relevant, some possible economic benefits can be assessed as well (e.g. increased profits in the market of alternatives). The social impacts of the restriction can also be included in the assessment.

[4] TARIC: Integrated Tariff of the European Communities

In the case of the restriction proposed on the use of BPA in thermal paper, the analysis consisted of the evaluation on the one hand, of the economic and social impacts for the affected supply chains and the markets, from upstream to downstream, and on the other hand, of the health benefits for humans (based on the four critical effects addressed in the risk assessment). The assessment carried out was semi-quantitative. Most of the expected impacts were quantified and valued (monetised). Some others were qualitatively analysed. As regards the values quantified and monetised, a cost-benefit approach was followed. This is an approach whereby the costs and the benefits are compared with each other in order to decide on their relative order of magnitude and in doing so, on the proportionality of the restriction.

Regarding the *economic impact* (costs) assessment of the proposed restriction, these were assessed for 4 interlinked EU markets: the BPA market, the thermal paper market, the market of alternative dye developers and the market of alternative techniques.

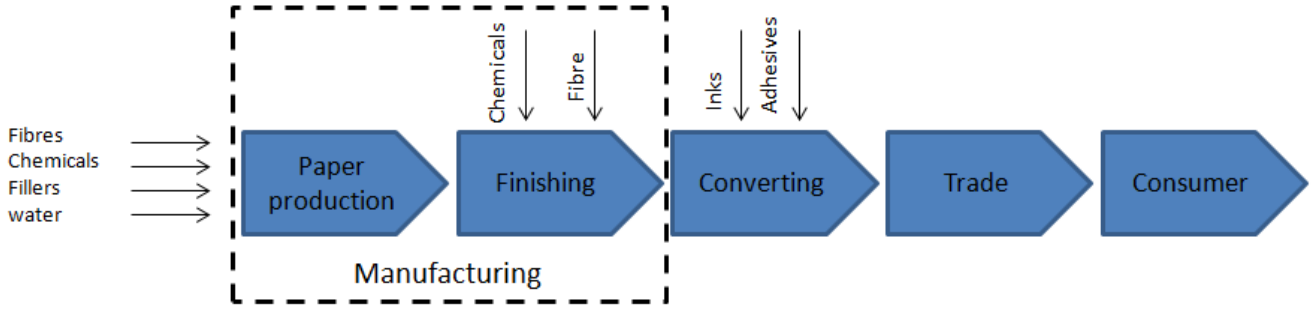
- ***Economic impacts for the BPA market***

  Given the very marginal use of BPA to manufacture thermal paper in the EU (0.2% of EU consumption of BPA), the BPA market is not expected to be significantly impacted by the restriction. Considered as insignificant, these impacts were only qualitatively analysed.

- ***Economic impacts for the EU thermal paper market***

  The economic impacts for the thermal paper market are considered to be the most significant. These impacts were assessed for the different segments of the thermal paper supply chain in the EU, as presented in the figure below: the manufacturers, convertors, traders (distributors) and consumers (end-users) as well as for the importers of thermal paper in the EU. The assessment focused on the substitution costs and the compliance control costs, related to the testing of BPA content in thermal paper. As mentioned above, the data used for the assessment came from consultations carried out for the purposes of the proposal and a review of publicly available data.

Figure 3. Supply chain of the thermal paper market



(Source :Jeffs, 2011)

- **Substitution costs**

Substitution costs are expected to mainly affect thermal paper manufacturers. The 'direct' costs of substitution (the costs of alternatives) were evaluated, while the indirect costs (the other costs associated with substitution) were not quantified since they were not regarded as significant. As shown in Tables 6-8, the substitution costs have been estimated for 3 alternative chemicals based on the only quantitative data collected during preparation of the dossier, especially on their price (also indicated in Table 4).

The 3 scenarios established (min, medium, max) for the substitution cost assessment are based on a 70% EU market share of paper containing BPA as stated by industry (ETPA[5] in particular), a quantity of thermal paper produced in the EU of 540,000 tonnes (as presented in Table 1) as well as other assumptions presented in Table 6.

Table 6. Overview of the assumptions made and the input data taken into consideration in the substitution cost calculation

Input data	Min	Max	Medium
Price of BPA (€/tonne)	1,263	1,906	1,585
Price of BPS (€/tonne)	2,920	4,200	3,583
Price of D8 (€/tonne)	11,390	15,104	12,938
Price of Pergafast (€/tonne)	15,000	30,000	22,500
Concentration of BPA in thermal paper	1%	2%	1.5%
Concentration of alternative developers in thermal paper	1%	2%	1.5%
Grammage of thermal paper	48g/m²	200g/m²	55g/m²
Price of thermal paper (2013)	€0.066/m²	€0.074/m²	€0.069/m²

It should be noted that the price of Pergafast is very high compared to the other alternatives and it proportionally contributes to the high level of the upper bound of the substitution costs.

[5] European Thermal Paper Association

Nevertheless, this price is likely to be overestimated since it has been estimated ten times higher than BPA and up to €30,000/tonne based on one claim only. Moreover, although this alternative dye developer is currently manufactured by a monopoly in the EU, it may be expected that its price will decrease as demand for it increases due to the ban on the use of BPA in thermal paper.

The substitution cost assessment over time is then based on the following assumptions:

- The price of BPS, currently the cheapest alternative, is estimated to decrease over time, reaching the 2013 price of BPA within 10 years. This represents a decrease of 8% per year between 2013 and 2023. From 2023, it will be then considered that the extra cost due to the use of BPS is zero.
- In the meantime, it is considered that the prices of the other (initially more expensive) alternatives will also decrease at the same rate as BPS over 2013-2023, all other things being equal, and will then decrease more slowly (by a rate of 5%) over 2024-2030.
- The growth rate of thermal paper production is based on the information provided by the industry players consulted. The thermal paper market has grown by around 10% per year for the last ten years and is still resilient and growing. However, it is suffering from tough competition (from Asia and to a lesser extent from paper-free alternatives and mobile payment) and decreasing profits, and is therefore expected to grow more slowly in the future. The annual growth of thermal paper over 2019[6]-2030 is thus estimated to be between 5% (low range) and 7% (high range).
- The costs of substitution are considered to be borne by the thermal paper manufacturers not only in the first year of substitution but also to some extent every subsequent year, compared to the (lower) costs they faced before substitution. However, due to the decreasing prices of alternatives, the extra cost is expected to decrease over time. Although substitution is already underway and will probably accelerate before the entry into force of the restriction, it is considered that by 2019 it will be complete.
- Finally, the substitution costs have been discounted (with a discount rate of 4%) for the 2019-2030 period and expressed in average annual value.

Table 7. Average annual chemical substitution cost of BPA over 2019-2030 – annual growth in thermal paper production of 7%

[6] 2019 is the expected date that the restriction will enter into force, based on the proposed 3-year transition period

[6] Discounting is a financial mechanism which consists in estimating the present value of a future amount of money in order to reflect its current value, as if it existed today. One euro today is worth more than one euro tomorrow due to a time preference for the present.

Alternative	Substitution cost (min)	Substitution cost (max)	Substitution cost (medium)	Period
BPS	€597,966	€6 390 201	**€1,211,343**	For 2019-2023 then zero
D8	€9,629,818	€113 459 640	**€19,193,862**	For 2019-2030
Pergafast 201	€13,798,488	€274 419,227	**€39,341,185**	For 2019-2030

Table 8. Average annual chemical substitution cost of BPA over 2019-2030 – annual growth in thermal paper production of 5%

Alternative	Substitution cost (min)	Substitution cost (max)	Substitution cost (medium)	Period
BPS	€524,122	€5,615,738	**€1,062,880**	For 2019-2023 then zero
D8	€7,866,679	€92,779,025	**€15,691,408**	For 2019-2030
Pergafast 201	€11,254,909	€223,604,469	**€32,066,838**	For 2019-2030

The substitution cost assessment underwent a sensitivity analysis performed in order to address uncertainties related to certain parameters: the market share of thermal paper containing BPA. The share used in the calculation was 70%. It might be overestimated given that this data could not be double-checked and that substitution of BPA is already underway. For the purposes of the sensitivity analysis, costs were recalculated with a 50% and 30% share (as well as, for illustrative purposes, an 85% share). As a result, the lower the share of thermal paper containing BPA on the market today, the lower the quantity of BPA to be substituted and the lower the substitution costs will be.

Considering the likely overestimation of the share of thermal paper currently containing BPA in the EU and the likely overestimation of the price of Pergafast, the conclusion is that the upper bound of the substitution costs may be largely overestimated**. As a whole, taking into account the decreasing trend of the prices of alternatives and depending on the annual growth rate of the production of thermal paper in the EU, the annual substitution cost ranges from around €0.5 million to €274 million with a (probably**

more realistic) average between €1 million and €39 million over 2019-2030 (Tables 7 and 8).

- **Compliance control (testing) costs**

The compliance costs are likely to be borne by convertors and traders to ensure the compliance of the thermal paper they use and place on the EU market. As shown in the table below, the evaluation of these costs was based on the cost of available analytical methods to measure BPA content (estimated at €260, as indicated in Table 9) and realistic assumptions made about the frequency of testing over the period 2019-2030, the size of jumbo rolls (before conversion) and the annual growth rate of the thermal paper market (as used in the assessment of the substitution costs above). The results are presented in Table 10.

Table 9. Summary of input data used for the assessment of compliance control costs

Assumptions/input data	Value
Test frequency first year, one per 1000 jumbo rolls (2019)	0.001
Test frequency for the 5 subsequent years, one per 10000 jumbo rolls (2020-2024)	0.0001
Test frequency for the 6 subsequent years, one per 100000 jumbo rolls (2025-2030)	0.00001
Assumed growth rate in production volume of thermal paper in the EU	5%-7%
Cost per test (SCL)[7]	€260
average weight of a jumbo roll (assumption)	50kg-100kg

Table 10. Compliance control costs expected from the restriction

Input data	Compliance control costs (Discount rate 4%)
Low range values: 5% annual growth 50 kg weight of a jumbo roll	€1,755,056 over 2019-2030 (€146,255 per year)
High range values: 7% annual growth 100 kg weight of a jumbo roll	€ 3,053,666 total over 2019-2030 (€254,472 per year)

[7] The costs associated with the XP CEN/TS 13130-13:2005-05-01 and NF EN ISO 18857-2:2012-01 methods are related firstly, to the equipment used for measuring (respectively LC-DAD and GC-MS) and secondly, to the cost of the tests themselves. As regards the former, equipment based on LC-DAD or GC-MS is common in chemical analysis laboratories and costs from €50,000 and €100,000. Given that EU laboratories are already equipped with such technical devices, these costs are not considered as extra costs resulting from the proposed restriction. Regarding the unit cost of testing thermal paper samples, information has been collected from the SCL providing a unit cost of €260 (excluding VAT) for one sample (based on pricing by private laboratories using the GC-MS technique).

As a whole, the total costs of compliance control tests can be estimated at between €1,755,056 and €3,053,666 over 2019-2030, or between €146,255 and €254,472 per year.

The impact of these costs on the average price of thermal paper was then calculated based on the following input data and assumptions:

- the surface area of thermal paper contained in one single jumbo roll: this data is not available as such. This surface area was thus inferred from the 2006 production of $2.4x10^9$ m² of thermal paper which is equivalent to approximately 168,000 tonnes of paper (EC, 2008) or 0.07 kg/m². Related to an average weight of one jumbo roll of between 50 kg and 100 kg, the surface area of one jumbo roll was estimated at between 714 m² and 1,429 m².
- the average price of thermal paper: €0.069/m² (INERIS, 2013).
- the unit cost of a test: €260 (SCL).

Table 11. Relative price impact on thermal paper due to compliance control costs – illustrative examples

Test frequency	Surface area of thermal paper in one single jumbo roll	Relative impact on the price of one thermal paper jumbo roll
1 per 1,000	714m²	0.53%
	1,429m²	0.26%
1 per 10,000	714m²	0.05%
	1,429m²	0.03%
1 per 100,000	714m²	0.01%
	1,429m²	0.003%

The relative impact of testing costs on thermal paper prices appears thus to be moderate, even very moderate for the highest surface area assumed (0.003%-0.26%). Given that the restriction also covers other types of thermal paper than ecopaper, these other types would in principle need to be tested as well. Due to the lack of data on the price of these other types of thermal paper, the cost of these potential additional tests has not been calculated.

For the convertors that are not in full control of their supply chain, testing may be the only option to ensure due diligence that they are in compliance with the proposed restriction. It is also likely that these costs will be split between convertors and traders downstream in the supply chain. However, given the concentrated (oligopolistic) structure of the production market in the EU, it may be expected that convertors and manufacturers have trust and transparent relationships which may facilitate information disclosure on products (ecopaper and other types) along the supply chain. Taking this aspect into consideration, the compliance control costs assessed might be overestimated.

It should be noted that importers of thermal paper in the EU are also expected to carry out some tests on the products they place on the EU market. However, these costs could not be quantified due to a lack of data, especially on the volume of thermal paper imported. Furthermore, some tests are also expected to be conducted by the customs services and the control authorities after the entry into force of the restriction. These costs have only been qualitatively analysed since no robust data is available on the frequency and regularity of these tests.

Finally, regarding consumers, these are not expected to be significantly affected by the extra costs faced by the manufacturers. The 'consumers' of thermal paper are the downstream end-users (such as large retailers, corner shops or banks) that use thermal paper for the tickets or receipts they provide to their clients. The extra costs borne by the manufacturers upstream are likely to be either passed on along the supply chain or entirely absorbed by the manufacturers themselves over the full range of products they supply. Exactly how this would be done has not been communicated by industry. However, there is no indication that the downstream users would face major additional costs from the restriction, since the cost of the thermal paper rolls they buy from distributors is likely to be a very small share of their total operating costs.

Overall, the total costs of the restriction proposed for the thermal paper market (substitution and compliance control costs) are estimated to range from around €0.6 million (low range) to around €274.2 million (high range, probably overestimated) with a more realistic average estimate between €1.1 million and €39.2 million per year over 2019-2030. These average costs account for between 0.18% and 5.85% of the total production value of thermal paper manufactured for POS applications over 2019-2030.

- ***Economic impacts for the markets of alternative dye developers***

The market of alternative dye developers is expected to grow and capture the demand created by the 'non use' of BPA after the entry into force of the restriction. The main impacts expected are: an increase in demand for alternatives, higher profitability, a corresponding downward trend in prices over time as demand grows, and the arrival of new comers attracted into these markets. These markets may also benefit from some positive impact in terms of "green" image, and the development of new patents could lead to competitive advantages.

The alternative markets may not all be equally affected, depending on the alternative(s) chosen by the thermal paper manufacturers. These impacts were qualitatively analysed.

- ***Economic impacts for the markets of alternative techniques***

The market of alternative printing techniques is not expected to be significantly affected by the proposed restriction. As explained above, these techniques are quite different from direct thermal printing systems and might not meet the same technical requirements for end-users. These machines are generally bigger, slower and more expensive and used for very different purposes (offices, for example). In that respect, replacing all direct thermal printers in the whole EU is not considered to be economically feasible. As regards the paper-free alternatives, they are expected to grow in the future but the extent of this growth is uncertain. The markets for e-tickets and mobile payments are new and increasing but they might not be considered as suitable alternatives in the short or medium-term. Indeed, they might not achieve general acceptability (at least in the short term) and might thus be difficult to adopt at the EU scale. Overall, the paper-free alternatives are expected to grow independently of whether or not BPA is used in thermal paper.

As a whole, the impacts of the restriction on the markets of alternative techniques are considered to be rather marginal.

Regarding the social impacts of the restriction, no major change in employment is expected to occur in the BPA market since, as explained above, the BPA market itself might not be significantly affected by the proposed restriction. Nevertheless, some increase in employment (R&D, production, marketing, etc.) may be observed in the markets of alternative dye developers due to the increase in demand for these chemicals and the expected growth of these markets.

Regarding the human health impact (benefits) assessment (HHIA), the benefits expected from the restriction were assessed based on the four adverse effects to human health demonstrated in the risk assessment. The assessment was performed in three steps: firstly, the estimation of the population at risk in the EU; secondly, the calculation of the excess risks corresponding to each critical effect due to BPA exposure from thermal paper and finally, the evaluation of the impact on human health (through its economic valuation, when possible, or its qualitative analysis).

- **Estimation of the population at risk**

  This calculation consisted in estimating the EU population of female workers (based on the 'cashier' occupation, extrapolated from France) and consumers of childbearing age exposed to thermal paper containing BPA. The assessment took into account occupational and demographic indicators such as INSEE classifications, the number of live births per gender, the EU annual birth rate and the number of women of working age in the EU. Based on these indicators, the population exposed to BPA from thermal paper at doses that could lead to a risk was inferred from the cumulative probability distributions of internal dose established in ANSES's 2013 report (see Figures 1 and 2). It was estimated that 95% of workers could be at risk for all critical effects and 55%, 58% and 81% of consumers could be at risk, respectively for the effects on the female reproductive system, on the metabolism and obesity, and on the mammary gland.

  As a result, taking into account that 70% of thermal paper on the market contains BPA and 65% of POS applications use thermal paper, the annual number of unborn children in the EU considered to be at risk through their mother's exposure was estimated in workers at 32,378 (for all critical effects) and in consumers respectively at:
  - 1,338,364 for the effects on the female reproductive system,
  - 1,408,791 for the effects on the metabolism and obesity,
  - 1,965,168 for the effects on the mammary gland.

- **Calculation of the excess risks corresponding to each critical effect due to BPA exposure from thermal paper**

  This calculation was performed for each critical effect for which the economic valuation was considered as relevant due to reliable information on the type of effect and outcome expected. This was modelled based on the raw data from the key animal studies selected for the risk assessment (listed in Table 2) in order to assess the probability of

occurrence of each effect within the exposed 'at risk' human population. This approach is similar to the one used for cancer risk assessment. It consists in adjusting animal doses to equivalent human doses, then deriving the point of departure by fitting a mathematical model to the data, and finally linearly extrapolating from the point of departure to lower doses. Using this approach, the probability (risk) of an individual with an adverse level of exposure could be estimated directly as a function of the dose. It was assumed that the relationship between exposure and response observed in animals is similar to that in humans. The excess risk values calculated are shown in Table 13. The differences between excess risks calculated for female workers and consumers are explained by the different average BPA internal doses based on the above-mentioned cumulative probability distribution (Table 3), and used in the calculation. The average BPA internal dose is 0.21 µg/kg bw/d for workers and 0.02 µg/kg bw/d for consumers.

From the probability of occurrence assessed, the fraction of the targeted population (namely the number of unborn children) likely to develop each effect was inferred and is also shown in Table 13.

- **The economic evaluation of the impacts on human health**

The analysis performed was semi-quantitative and is detailed in the table below. Most of the health benefits were quantified and monetised. In order to assess the economic value of an effect, data from the scientific literature linking effects (sometimes preliminary) in animal models and their occurrence in humans (ideally adverse effects) is necessary. The different human health outcomes corresponding to the critical effects in animals may indeed be expressed in a great variety of forms, from slight discomfort to severe disability, from temporary to whole-lifetime disorders in humans. As a result, these differences generate uncertainties regarding monetisation that might have made the systematic economic evaluation of all the impacts somehow random and not robust enough for the purposes of the restriction proposal. Hence, some impacts were qualitatively analysed when reliable information on their actual effects, duration and/or severity in humans were missing.

For the impacts that were economically valued, the assessment was based on the review of the economic literature for the corresponding effects and diseases. Studies were selected from among all the available literature in order to take into account their consistency with the concern addressed in the dossier, the age and gender of the population studied and the relevance for the European population. The economic studies finally selected are shown in Table 12. Depending on the study selected, the economic evaluation was based on a cost-of-intervention approach (only including direct medical treatment costs) or a cost-of-illness approach (also including indirect costs such as the social costs of disease, loss of incomes, etc.). The economic values used in the evaluation for each disease are shown in Table 13.

Table 12. Effects and economic studies selected for the human health impact assessment

Critical effects	Type of effect	Human health impact assessed (economic evaluation/qualitative analysis)	Population considered for the Human Health Impact Assessment	Economic studies used for the evaluation
Brain and behaviour	Alteration of spatial memory and of learning functions	No economic evaluation / qualitative analysis	Pregnant women and offspring (both sexes)	-
Female reproductive system	Increase in the occurrence of ovarian cysts	No economic evaluation / qualitative analysis	Pregnant women and offspring (girls only)	-
	Endometrial hyperplasia	Economic evaluation of endometriosis	Pregnant women and offspring (girls only)	Simoens, 2012
	Disruption of ovarian cycles	No economic evaluation / qualitative analysis	Pregnant women and offspring (girls only)	-
Metabolism and obesity	Increase in body weight	Economic evaluation of obesity	Pregnant women and offspring (both sexes)	Brown III, 2007
	Increase in cholesterolaemia	Economic evaluation of the increase in cholesterol	Pregnant women and offspring (both sexes)	Benner, 2005 Lachaine, 2007 Grabowski, 2012
Mammary gland	Increase in the number of terminal end buds and terminal ducts of the mammary glands	Economic evaluation of the increase in breast cancer occurrence	Pregnant women and offspring (girls only)	Gruber, 2012 Campbell, 2009 Marino, 2003 Radice, 2003

Table 13. Summary of the human health impact assessment due to the BPA restriction in thermal paper for workers and consumers

Critical Effect	Adverse health outcomes	Excess Risk		Number of unborn children likely to develop each critical effect		Economic values (from the economic studies shown in Table 12)	Annual health benefit (female workers+consumers)
		workers	consumers	workers	consumers		
Female reproductive system	Increase in ovarian cysts	-	-	-	-	-	>0 Qualitatively analysed
	Endometriosis	0.07% (female only)	0.0064%	11	42	€9,579 per woman per year	€107,677 + €399,377
	Disruption of ovarian cycles	-	-	-	-	-	>0 Qualitatively analysed
Mammary gland	Increase in vulnerability to breast cancer (due to increase in TEB, TD and/or HD)	0.61% (TEB) 0.55% (TD) 0.055% (HD) (female only) Worst-case: ∑= 1.22%	0.059% (TEB) 0.053% (TD) 0.005% (HD) (female only) Worst-case: ∑= 0.117%	96 87 9 Worst-case: ∑= 191	564 507 48 Worst-case: ∑= 1,119	[€3,000; €25,000] per woman per year	[€288,413; €2,403,440] + [€1,693,096; €14,109,132] (TEB) [€260,044; €2,167,036] + [€1,520,917; €12,674,305] TD) [€26,004; €216,704] + [€143,483; €1,195,689] (HD) Worst case: [€574,462; €4,787,180] + [€3,357,495; €27,979,126]
Metabolism and obesity	Increase in body weight	0.33%	0.032%	107	451	€3,760 per avoided case per year	$B^{w}_{bw} + B^{c}_{bw}$ = €401,751 + €1,695,058
	Increase in Cholesterol	0.73% (then adjusted to the general population fraction of 54%)	0.07% (then adjusted to the general population fraction of 54%)	128	533	€11 or €42.5 per % of decreased LDL-cholesterol for one person treated/year Or €123 per % of decreased LDL-cholesterol for one person treated/year	[€8,424; €94,195] + [€35,147; €393,002]
Brain and behaviour	Spatial memory	-	-	-	-	-	>0 Qualitatively analysed
	learning functions	-	-	-	-	-	>0 Qualitatively analysed
TOTAL for the year 2013							**>[€2,814,920; €19,601,632]**
Annual TOTAL over 2019-2030 (discounted 4%)							**>[€1,809,489; €12,600,332]**

The total quantified potential human health benefits of the proposed restriction are estimated to range from (at least) €1.8 million to €12.6 million per year over 2019-2030, keeping in mind that not all the benefits have been valued.

The Human Health Impact Assessment underwent a sensitivity analysis to address uncertainties intrinsic to some uncertain parameters and to decide on their influence on the overall health benefits (female workers and consumers):

- As already mentioned above, the market share of BPA-containing thermal paper in the EU used in the assessment is 70% which might be overestimated. The impact of this share in our analysis was evaluated by modifying its level to 30%, 50% and 85% (the latter for illustrative purposes); all other values were unchanged. As expected, the higher the share of BPA-containing thermal paper on the market, the higher the health benefits of the restriction.
- The number of cashiers in the EU compared to the general population was inferred from the French situation, where 0.42% of the population is a cashier (less than one cashier for 100 people). it was not possible to double-check this percentage on the labour market and it was varied to 0.2%, 1% and 2% in order to take into account the uncertainty related to the possible exclusion of some workers likely to handle BPA-containing thermal paper but not referenced strictly within the 'cashiers' occupation, e.g. the owners of single-proprietor or small enterprises (craftsmen, owners of corner shops) who are at the same time owners, sellers and cashiers. As one may expect, the higher the number of cashiers (or more generally workers likely to handle BPA-containing thermal paper) in the EU, the greater the health benefits.
- As regards the economic evaluation of the increase in body weight, the number of children likely to be affected by overweight or obesity was estimated to be 558 (107 for workers' children and 451 for consumers' children; see Table 13). It was implicitly assumed that any increase in body weight would lead to overweight or obesity, which is an overestimating assumption. The effect of these numbers on the impact assessment was evaluated arbitrarily (no other data available), varying them to 210 and 350 respectively. Moreover, according to the WHO, 20% of children and adolescents are currently overweight in Europe. This data can thus also be taken into account for the sensitivity analysis, assuming that these children would be overweight anyway independently of their exposure to BPA *in utero* from thermal paper. For the sake of completeness, the value of 446 was also used (corresponding to 558 children less 20% considered as overweight anyway); all other values remained unchanged. As a result, the lower the number of unborn children at excess risk, the lower the health benefits. It is worth noting that even with half the number of children likely to be affected, the benefits would remain fairly close to the results shown in Table 13.

  In addition to this sensitivity analysis, other uncertainties can be highlighted:

  - Some uncertainties might cause the benefits to be overestimated: in particular, the impacts on human health of alternatives to BPA in thermal paper were not assessed and the assumption was made that the health benefits related to the BPA restriction are 'absolute'. Indeed, it has been assumed that thanks to the restriction, the adverse effects will disappear. However, this might not be entirely valid if some substitutes (such as BPS) had similar adverse effects on human health.

- Some uncertainties might cause the benefits to be underestimated:
  - the health benefits related to critical effects on brain and behaviour and some for the female reproductive system were not quantified for the reasons explained above.
  - The health benefits for the unborn children of female workers other than those who work in commercial establishments and who may handle thermal paper were not taken into account in the evaluation. This is the case with medical staff who may handle thermal paper from, for example, ECG or ultrasound medical tests. Compared to cashiers, this might concern a relatively low number of persons but including them in the HHIA would most likely increase the health benefits.
  - A collateral benefit from the restriction could be also the reduction in risks for female workers exposed to BPA during the production of BPA-containing thermal paper. Including these avoided cases of adverse exposure would also in principle increase the total health benefits of the restriction.

- Other uncertainties can also be reported:
  - It is unclear to what extent the health benefit calculations carried out based on US studies (such as Grabowski, 2012, Radice, 2013 or Campbell, 2009) can be extrapolated to the EU.
  - There is an inherent uncertainty related to the calculation of the excess risks used as a basis for the HHIA. Indeed, the excess risks were modelled based on studies from which the proportion of affected animals was inferred. This proportion was then extrapolated to humans. Although some uncertainty factors were applied in order to take into account this uncertainty, one has to be aware of this methodological limitation. Moreover, the calculated values of excess risk and health benefits related to the increase in vulnerability of the mammary gland are uncertain due to the low number of animals tested in the studies selected for this effect and the lack of information on the causal link between the increase in TEB, TD and HD and the occurrence of breast cancer.
  - The health benefits were assessed assuming that one alternative would totally replace the BPA contained in thermal paper in the EU. It might be more realistic to consider that several alternatives may replace it, depending on the choice of the players in the supply chain.

Finally, considering the delay in preparing the Annex XV dossier, it is acknowledged that the ANSES Expert Committee (CES) on REACh and CLP Regulations was not able to challenge in detail the (original) method for modelling the excess risks in support of the calculation of the human health impacts.

8. CONCLUSION

The restriction proposal followed previous ANSES reports demonstrating the existence of a risk for pregnant women (workers and consumers) when exposed to BPA-containing thermal paper, for four types of effects:

- Effects on the brain and behaviour
- Effects on the mammary gland

- Effects on the female reproductive system
- Effects on the metabolism and obesity

The restriction under REACh has been demonstrated to be the most appropriate risk management option for addressing the risk generated by BPA contained in thermal paper. It is indeed effective, practical and able to be monitored.

This restriction would be equivalent to a total ban on the use of BPA in thermal paper and is considered to be technically and economically feasible.

> Technically, several alternatives have been identified as substitutes for BPA in thermal paper and some are already used in the market. Substitution is already underway in Europe. Nevertheless, the use of an alternative such as BPS confers no obvious benefit to human health. Given the uncertainties surrounding in particular their hazard profiles, it has not been possible to recommend any one chemical as an ideal (and safer) substitute for BPA.
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> Economically, the costs expected from this restriction (including substitution costs and compliance control costs) are estimated to range from around €0.6 million (low range) to around €274.2 million (high range, probably overestimated) with a more realistic average estimate between €1.1 million and €39.2 million per year over 2019-2030. These average costs account for between 0.18% and 5.85% of the total production value of thermal paper manufactured for POS applications over 2019-2030. Regarding the health benefits associated with the restriction, they would amount to (at least) between €1.8 million and €12.6 million per year over 2019-2030, keeping in mind that not all the benefits have been valued. As a result, under reasonable assumptions, the restriction is thus considered to be proportionate to the risks.

The analysis carried out in the restriction proposal, in particular the socio-economic analysis and the assessment of costs and benefits, paid particular attention to the uncertainties. This was achieved through several sensitivity analyses, aiming to make the assessment as transparent and robust as possible.

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