The Director General

Maisons-Alfort, [date]

Note
on the results of the call for contributions following publication of the reports on the health effects and uses of bisphenol A (BPA) (September 2011) and on the inventory of alternatives to and/or substitutes for BPA

The purpose of this note is to present the responses to the publication and call for contributions issued by ANSES in September 2011 based on the expert work done on bisphenol A, through two reports on the health effects and uses of bisphenol A. This call for contributions sought in particular to collect all scientific data or useful information, specifically in relation to available alternatives to BPA according to use.

1. BACKGROUND AND PURPOSE OF THIS NOTE

In response to solicited requests from the French Ministries of Health (2009) and Ecology (2010) on endocrine disruptors, including bisphenol A (BPA), ANSES published two initial reports in September 2011, one on the health effects of bisphenol A, and the other on its uses. This work identified the effects considered as recognised in animals and suspected in humans, even at low exposure levels. These effects could also be highly dependent on exposure periods with respect to different phases of individual development, leading to the identification of particularly susceptible populations. ANSES then considered that there was sufficient scientific information to identify prevention of exposure in the most susceptible populations, i.e. infants, young children, and pregnant and breastfeeding women, as the chief objective. This objective requires reducing exposure to BPA, principally by replacing it in food contact materials, which may be the main source of exposure in the most susceptible populations.

These two reports mark a first step in the expert appraisal currently being conducted by an *ad hoc* working group on the assessment of the health risks related to BPA.

From September to November 2011, in conjunction with this publication, the Agency issued a call for contributions in order to collect scientific data specifically on available alternatives to BPA and, if possible, on their safety and effectiveness. Since the end of 2011, in compliance with the request of its supervisory ministries, ANSES also compiled an inventory of different alternatives to BPA, identifying the available data on their toxicity.

A detailed presentation of all data will be set down in the collective expert report on the assessment of the health risks of BPA scheduled before the end of 2012. In the interim, a summary of the inventory of substances or alternatives to BPA is presented in an annex to this document.

Finally, in September 2011 the Agency sent the report on the health effects of BPA to the European authorities concerned (European Food Safety Authority [EFSA], European Chemicals Agency [ECHA], etc.), to consider the advisability of revising the reference doses used for regulatory purposes.

2. RESULTS OF THE CONSULTATION

Following the above mentioned consultation process, ANSES received about twenty responses from national agencies, associations, companies, professional federations, and French, European and international universities (see Annex 1). Among these responses, nine contributions related to alternatives to BPA and nine others concerned the report on its health effects.

The nine contributions related to substitution of BPA are of different types: feedback on actual alternatives from industrial companies or universities, or general considerations from organisations or federations. These contributions do not include any toxicological data that had not already been identified by the Agency from among the data available in the public domain, which are listed below.

Some comments on the report on the health effects of BPA refer to the methodology used by the expert group for analysing the published data on BPA toxicity, while others refer to certain scientific publications cited in the report and their interpretation. On the whole, the contributions received reflect current scientific debates and for some of them, differences of opinion within the scientific community about the effects of BPA at low doses.

ANSES wishes to thank all the contributors who submitted their comments on these reports.

3. METHODOLOGY OF THE STUDY ON THE INVENTORY OF ALTERNATIVES TO BPA

The search for alternatives to BPA was undertaken along three different, complementary lines:

- call for contributions (issued in September 2011);
- review of the literature (until February 2012);

- telephone interviews with industrial companies, separate from the call for contributions.

The call for contributions, open until the end of November 2011, aimed to collect scientific data on available alternatives and data relating to their safety and effectiveness. Several French and European companies responded to this call and some of them provided data on their alternatives.

A review of the literature, carried out until February 2012, led to the identification of industrial manufacturers or users of alternatives to BPA, which were then contacted. Some of the information in this document was also derived from interviews the Agency conducted with these companies, separate from the call for contributions.

To date, 73 alternatives to BPA have been identified including:

- 21 for polycarbonates;
- 18 for epoxy resins;
- 34 for thermal paper.

Summary tables showing the various alternatives to BPA in polycarbonates, epoxy resins and thermal paper, as well as the available toxicity data, are presented in Annex 2. More detailed information on these alternatives will be available in the collective expert report on the assessment of the risks of BPA scheduled for publication by the end of 2012.

4. ANSES'S RESPONSE TO COMMENTS RECEIVED ON THE REPORT ENTITLED "HEALTH EFFECTS OF BPA"

Comments received following the consultation cover different areas. Some refer to the methodology used by the expert group for analysing the published data on BPA toxicity, while others refer to certain publications cited in the report and their interpretation.

For reference, this report on the "Health effects of BPA" (September 2011) was an interim report aimed solely at identifying effects and qualifying them as 'recognised', 'suspected', 'controversial' or 'effects for which no conclusion can be drawn on the basis of the available data'. This report is the first step of the expert appraisal and does not pre-empt the findings of the ongoing process of health risk assessment (HRA) related to BPA, which will culminate in the publication of a collective expert report in the last quarter of 2012.

1. Studies analysed

Some of the comments received considered the choice of studies cited in the expert appraisal report and indicated that major studies or significant data were not included. Therefore, ANSES's expert appraisal report makes specific reference to previous expert appraisal reports prepared by other national and international bodies, and specifically the French National Institute for Health and Medical Research [INSERM] collective expert report (2011), as called for by the Agency's supervisory ministries in their letter of request. Publications subsequent to these expert appraisals were considered when at least one of the doses tested was less than 5 mg/kg/d, the current reference dose for deriving EFSA's tolerable daily intake (TDI). Accordingly, the objective of ANSES's expert appraisal was specifically to verify whether or not the toxicity data would lead to revision of this reference value proposed by EFSA in 2007 and also used in the European risk assessment report (European Commission, 2010).

2. Consideration of studies using non-oral routes of exposure

A discussion was initiated that was prompted by the comments received concerning the advisability of using animal studies conducted using non-oral routes of exposure (subcutaneous injection, for example). ANSES considered that at the stage of identification of hazards associated with a substance, all routes of exposure should be taken into account. This approach can, in fact, identify effects that could be specific to one route of exposure or those that might be common to several routes. A route other than the route of exposure may be used for the HRA (route-to-route extrapolations are common in HRAs), provided that the absence of an effect's qualificative specificity is ensured for a route when comparing it to the route of exposure in humans, and when the equivalence of internal doses among different routes of exposure can be established. To do so, the Agency has begun working to develop a physiologically-based pharmacokinetic (PBPK) model that will be used to interpret studies by subcutaneous injection.
Finally, ANSES considers that the available data thus far cannot rule out non-oral routes of exposure to BPA. BPA detected in thermal receipts or in dust particles in indoor environments supports this analysis.

3. Levels of evidence considered

The approach used by ANSES's experts is quite similar to the 'weight of evidence' approach used in some expert appraisal work (ECHA, 2010; European Centre for Ecotoxicology and Toxicology of Chemicals [ECETOC], 2009, etc.). Rather than conducting the HRA on the basis of a single study considered to be *a priori* of good quality (according to criteria in compliance with Organisation for Economic Cooperation and Development [OECD] guidance documents and carried out under Good Laboratory Practices (GLP) for example), the expert group chose to analyse all the available data, in view of the considerable number of publications arising mainly from the academic sector showing the effects of BPA at low doses.

This approach can identify bodies of epidemiological or experimental evidence for a same type of effect.

The studies selected by the experts were therefore analysed in terms of protocol quality, power of the study, consideration of confounding factors, reproducibility of effects observed by other similar studies and discussed in working group meetings. Studies with methodological limitations were therefore included for analysis to the extent that they were supported by other comparable studies. A study's statistical power is a key parameter to consider. However, when an effect is observed in spite of low statistical power, the level of proof is enhanced.

The applicability of effects observed in animals to humans was assessed on the basis of data found in the literature. Inter-species differences that limit the direct transposition of data derived from rodents to humans were taken into account during analysis of the experimental data.

However, the fact that a mechanism of action is not identified is not sufficient reason for failing to take into account a given effect when assessing the health impacts in humans. Most of the observations aimed at assessing the consistency of effects observed in various experimental models (epidemiological, animal, *in vitro* data, etc.) were assessed and used to classify the effects.

4. Differences between the conclusions of ANSES's interim report compared to other expert appraisals

In some comments, differences were highlighted between the conclusions of the ANSES's expert appraisal and those of other reports, such as those by EFSA, 2010; the European Union Risk Assessment Report (EU RAR), 2010; the National Toxicology Program - Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR), 2008; the US Food and Drug Administration (FDA), 2008; and the Food and Agriculture Organization (FAO)/World Health Organization (WHO), 2010. It should be emphasised that the conclusions of the various expert appraisal reports are not directly comparable, since these assessments had different objectives, i.e., expert appraisals with the aim of deriving an acceptable daily intake (ADI) by EFSA, the FDA, etc., or expert appraisals aimed at assessing certain specific effects on health (NTP-CERHR, etc.). Observable differences between these expert appraisals were recently analysed by Beronius *et al*. (2010). ANSES considers that they reflect the uncertainly within the scientific community concerning the effects of endocrine disruptors at low doses, and of BPA in particular. Other comments the Agency received on the interim report concur with this analysis.

5. Exclusion of the study by Tyl *et al*. (2002, 2008)

Some of the comments received deemed that the expert appraisal did not give due consideration to the results of the work by Tyl *et al*. (2002, 2008) in which reprotoxic effects were not the most sensitive effects, in contrast to other systemic

effects which allowed the determination of NOAEL (No Observed Adverse Effect Level).

Since these studies were conducted in compliance with OECD guidelines and according to GLP, based on these comments, they should discredit 'academic' studies showing effects. ANSES experts consider that the protocols currently used in studies that follow the OECD 416 guidance documents are not the most suitable for the study of substances that cause changes in the biological system linked to endocrine disruption. In particular, they are ill suited to assessing the effects of a substance that emerge following exposure during a particularly sensitive period (during pregnancy, for example) and whose effects are observed much later. Carcinogenesis studies carried out according to OECD protocols do not cover exposure during the *in utero* period, for example. Moreover, effects other than those commonly assessed in regulatory toxicity studies may be associated with exposure to endocrine-disrupting substances (changes in mammary gland architecture and maturation for example). Lastly, at this early stage of the expert appraisal, studies judged to be of intrinsic good scientific quality were selected *a priori* for conducting the HRA.

6. Effects of low doses of BPA on development and reproduction

Some of the comments received cite studies emphasising the lack of evidence supporting the hypothesis that low doses of BPA would result in effects on reproduction and development (Gray *et al.,* 2004; Goodman *et al.*, 2006, Sharpe, 2010). Here again, ANSES considers that this review of the scientific literature reflects the uncertainties and controversies on the subject. Other journals and/or recent studies show effects of low doses of BPA on reproduction or development as well, particularly those of Golub, 2010; Jenkins, 2011; Ayyaanan *et al*., 2011; Braun, 2011; and Salian *et al*., 2011.

Finally, ANSES analysed the comments received on more specific points relating to certain publications cited in the interim report and submitted them, as appropriate, to the expert group for discussion. They may be taken into account when characterising the hazards and dose-effect relationships of BPA that will be the subject of the collective expert report on the BPA HRA. Publication of this report is scheduled for the last quarter of 2012.

The Director General

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KEY WORDS

Bisphenol A (BPA), health effects, reprotoxicity, uses, substitution, contributions, alternatives, endocrine disruptor

ANNEXE(S)

Annex 1

List of organisations, federations, companies and universities that responded to the call for contributions

Annex 2

List of alternatives to BPA and available toxicity data

Annex 3

List of references

Annex 1: List of organisations, federations, companies and universities that responded to the call for contributions

- Chair, Sustainable Chemistry, *Ecole Nationale Supérieure de Chimie de Montpellier*
- Greiner Packaging
- French Food Industries Association (ANIA)
- EcoAid
- Technical University of Denmark (DTU)
- PlasticsEurope
- Antidote Europe
- German Federal Institute of Risk Assessment (BfR)
- German Federal Environment Agency (UBA)
- Topas Advanced Polymers
- Consumer and veterinary affairs department of the canton of Vaud, Switzerland
- Verdex Limited
- National Public Health Institute of Quebec (INSPQ)
- US National Institute of Environmental Health Sciences (NIEHS)
- Frederick vom Saal, Missouri University, and a panel of American, Canadian and European scientists
- Eastman Chemical Company

Annex 2: **List of alternatives to BPA and available toxicity data**

The summary tables below show the alternatives identified to date for the replacement of BPA in polycarbonates, epoxy resins and thermal paper, as well as available toxicological data on these alternatives. The information in blue shows those obtained from the call for contributions. The other substitutions listed were taken from the literature and interviews with other industrial companies, separately. All the information relating to the description of uses associated with each alternative will be developed in the BPA HRA collective expert report scheduled for publication in the last quarter of 2012.

Table 1: Potential alternatives to BPA-based polycarbonates and available toxicological data

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Polyphenylsulfone	-	-	-	-	-	-	-	-	TDS
Polyethersulfone	-	-	-	-	-	-	-	-	No
Polyamide 6,6	-	-	-	-	-	-	-	-	No
Polyamide 11	-	-	-	-	-	-	-	-	No
Polyamide 12	-	-	-	-	-	-	-	-	MSDS + TDS
High-density polyethylene	-	-	-	-	-	-	-	-	No
Low-density polyethylene	-	-	-	-	-	-	-	-	No
Polypropylene	-	-	-	-	-	-	-	-	No
Copolyester Tritan®	-	-	-	-	-	-	-	-	**MSDS**
Polyethylene terephthalate (PET)	-	-	-	-	-	-	-	-	No
Isosorbide 652-67-5	NC	NC	NC	Lacking detailed studies; only a summary of toxicological studies is available	No	No	No	No	MSDS
Ecozen®	-	-	-	-	-	-	-	-	MSDS
Polyetherimide	-	-	-	-	-	-	-	-	No
Polylactic acid (PLA)	-	-	-	-	-	-	-	-	No
TOPAS IT X1	-	-	-	-	-	-	-	-	**MSDS + TDS**

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Melamine 108-78-1	NC	NC	NC	OECD test 414 + reproduction (one-generation) and development studies	IUCLID (2000)	Yes	No	No	No
Acrylonitrile-butadiene-styrene (ABS)	-	-	-	-	-	-	-	-	No
Glass	-	-	-	-	-	-	-	-	No
Stainless steel	-	-	-	-	-	-	-	-	No
Silicone	-	-	-	-	-	-	-	-	No
Ceramics	-	-	-	-	-	-	-	-	No

-: information unavailable due to missing CAS number
NC: non-classified compound
OECD 414: Prenatal Development Toxicity Study
MSDS: Material Safety Data Sheet submitted by manufacturers
TDS: Technical Data Sheet submitted by manufacturers

Table 2: Potential alternatives to epoxy resins and available toxicological data

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Polyesters	-	-	-	-	-	-	-	-	No
Polykoat®	-	-	-	-	-	-	-	-	MSDS
Polypropylene carbonate	-	-	-	-	-	-	-	-	No
Oleoresins	-	-	-	-	-	-	-	-	No
Chemsud resin	-	-	-	-	-	-	-	-	No
Biolignin™	-	-	-	-	-	-	-	-	MSDS
Souplethane WP	-	-	-	-	-	-	-	-	No
Verdanol	-	-	-	-	-	-	-	-	MSDS
UVL Eco-Resin	-	-	-	-	-	-	-	-	No
SPR resins	-	-	-	-	-	-	-	-	No
Isosorbide 652-67-5	NC	NC	NC	Lacking detailed studies; only a summary of toxicological studies is available	No	No	No	No	No
Polyacrylates	-	-	-	-	-	-	-	-	No
Polyethylene terephthalate (PET)	-	-	-	-	-	-	-	-	No
Acrylic	-	-	-	-	-	-	-	-	No
Vinyl	-	-	-	-	-	-	-	-	No
Glass	-	-	-	-	-	-	-	-	No
TetraPack®	-	-	-	-	-	-	-	-	No

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Doypack®	-	-	-	-	-	-	-	-	No
BPA migration reduction	-	-	-	-	-	-	-	-	No

-: information unavailable due to missing CAS number
NC: non-classified compound
MSDS: Material Safety Data Sheet submitted by manufacturers
TDS: Technical Data Sheet submitted by manufacturers

Table 3: Potential substitutes for BPA in thermal paper and available toxicological data

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Bisphenol S 80-09-1	NC	NC	NC	One OECD test 421	No	No	Yes	Yes (24/06/2011)	No
Bisphenol F (para) 620-92-8	NC	3	3b	No	No	No	Yes	Yes (15/07/2011)	No
Bisphenol F (ortho) 2467-02-9	NC	NC	NC	No	No	No	No	No	No
Bisphenol AP 1571-75-1	H400, H410	3	NC	No	No	No	Yes	Yes (03/02/2012)	No
2,2'-diallyl-4,4'-sulfonyldiphenol (TGSA) 41481-66-7	H317, H411	NC	NC	No	No	No	Yes	No	No
4-(4-isopropoxy-phenylsulfonyl)phenol (D8) 95235-30-6	H411	NC	NC	No	No	No	Yes	No	No
Phenol, 4-[[4-(2-propen-1-yloxy)phenyl]sulfonyl] (BPS-MAE) 97042-18-7	NC	NC	NC	No	No	No	Yes	No	No
4-4'-methylenebis-(oxyethylenethio)diphenol 93589-69-6	H411	NC	NC	No	No	No	Yes	No	No
Phenol, 4,4'-sulfonylbis-, polymer with 1,1'-oxybis[2-chloroethane] (D90) 191680-83-8	NC	NC	NC	No	No	No	Yes	No	No

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
p-phenylphenol 92-69-3	NC	3	1	No	No	No	No	No	No
4,4'-thiobisphenol 2664-63-3	NC	NC	NC	No	No	No	Yes (uterotrophic assay)	No	No
p-tert-butylphenol 98-54-4	NC	2	2	OECD tests 414, 416 and 422 + 1 Three-generation study	EU RAR (2008); IUCLID (2000)	No	Yes	In progress	No
Benzyl 4-hydroxybenzoate 94-18-8	NC	NC	NC	No	No	No	Yes	No	No
Ethyl 4-hydroxybenzoate 120-47-8	NC	NC	1	No	No	No	Yes (uterotrophic assay)	No	No
Dimethyl 4-hydroxyphthalate (DMP-OH) 22479-95-4	NC	NC	NC	No	No	No	No	No	No
3.5-bis-tert-butylsalicyclic acid 19715-19-6	NC	NC	NC	No	No	No	No	No	No
3,5-bis-α-methylbenzylsalicyclic acid non-specified CAS No.	-	-	-	-	-	-	-	-	No
N-(p-toluenesulfonyl)-N'-(3-p-toluenesulfonyloxyphenyl) urea 232938-43-1	H411	NC	NC	No	No	No	Yes	No	No
p-[[p-benzyloxyphenyl] sulfonyl]phenol 63134-33-8	NC	NC	NC	No	No	No	Yes	No	No

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Urea urethane compound 321860-75-7	NC	NC	NC	No	No	No	Yes	No	No
4,4'-bis(N-carbamoyl-4-methylbenzenesulfonamide)diphenylmethane 151882-81-4	H351	NC	NC	No	No	No	Yes	No	No
o-[(4-hydroxyphenyl)sulfonyl]phenol 5397-34-2	NC	NC	NC	No	No	No	Yes	No	No
4,4'-isopropylidenedi-o-cresol 79-97-0	NC	NC	NC	No	No	No	Yes	No	No
Methyl bis(4-hydroxyphenyl) acetate (MBHA) 5129-00-0	NC	NC	NC	No	No	No	Yes	No	No
4,4'-Isopropylidenebis(2-phenylphenol) 24038-68-4	NC	NC	NC	No	No	No	Yes	No	No
6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol 85-60-9	NC	NC	NC	No	No	No	Yes	No	No
2,6-di-tert-butyl-p-cresol 128-37-0	NC	NC	NC	OECD tests 414 and 416 + development studies, on one, two and three generations and on fertility	IUCLID (2000)	Yes	Yes	No	No

Name and CAS number of the potential substitute	Classification under the CLP Regulation	Classification		Reprotoxicity data available under REACH	Existing toxicological assessments			ANSES toxicological profile	MSDS/TDS
		BKH	DHI		ESIS	NTP	US EPA		
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate 2082-79-3	NC	NC	NC	OECD tests 414 and 416	IUCLID (2000)	No	Yes	No	No
Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) 6683-19-8	NC	NC	NC	OECD tests 414 and 416	IUCLID (2000)	No	Yes	No	No
4,4',4''-(1-methylpropanyl-3-ylidene)tris[6-tert-butyl-m-cresol 1843-03-4	NC	NC	NC	No	No	No	Yes (uterotrophic assay)	No	No
1,2-diphenoxyethane 104-66-5	NC	NC	NC	No	No	No	No	No	No

-: information unavailable due to missing CAS number
NC: non-classified compound
H317: may cause an allergic skin reaction
H351: suspected of causing cancer
H400: very toxic to aquatic life
H410: very toxic to aquatic life with long lasting effects
H411: toxic to aquatic life with long lasting effects
OECD 414: Prenatal Development Toxicity Study
OECD 416: Two-Generation Reproduction Toxicity
OECD 421: Reproduction/Developmental Toxicity Screening Test
OECD 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test
MSDS: Material Safety Data Sheet submitted by manufacturers
TDS: Technical Data Sheet submitted by manufacturers

Annex 3: List of references

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