Danish Ministry of the Environment
Environmental Protection Agency

Background for national legislation on bisphenol A (BPA) in EU and EFTA countries

Environmental Project No. 1552, 2014

Title:

Background for national legislation on bisphenol A (BPA) in EU and EFTA countries

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Published by:

The Danish Environmental Protection Agency
Strandgade 29
1401 Copenhagen K
Denmark
www.mst.dk/english

Year:

2014

ISBN no.

978-87-93178-18-2

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Preface

Bisphenol A (BPA) is included in the Danish Environmental Protection Agency's List of Undesirable Substances (LOUS), as it is i) included in the EU list of potential endocrine disruptors in category 1 and ii) classified for reproductive toxicity in category 2.

Therefore, BPA has been subject to a survey to provide basis for an assessment of whether there is a need for further information generation, legislation and/or other risk reduction measures[1].

Based on the survey, the Danish EPA has on 31 May 2013 issued a strategy for risk management of BPA in Denmark[2]. One of the initiatives suggested in the BPA strategy is the present study seeking clarification of the differences in regulatory approaches in the EU and EFTA Member States and providing basis for an evaluation regarding future legislation on BPA in Denmark.

The Danish EPA has commissioned the study to COWI A/S having carried out the project during July-December 2013.

Danish EPA, December 2013

[1] http://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-14-8.pdf
[2] http://www.mst.dk/NR/rdonlyres/39F6C09F-EB54-4EFD-BC6B-7C893337D852/156361/3BPAstrategifinal1.pdf (in Danish)

Executive summary

Background

Bisphenol A (BPA) is included in the Danish Environmental Protection Agency's List of Undesirable Substances (LOUS), as it is i) included in the EU list of potential endocrine disruptors in category 1 and ii) classified for reproductive toxicity in category 2.

Based on a survey of BPA, the Danish EPA on 31 May 2013 issued a strategy for risk management of BPA in Denmark[3], suggesting among others, the current study seeking clarification of the differences in regulatory approaches in the EU and EFTA Member States. This should provide an input to the basis for an evaluation regarding future legislation on BPA in Denmark.

BPA has been the subject of intense research and debate over the last decade, not least due to suspected low-dose effects (endocrine disrupting properties and developmental neurotoxicity) of the chemical and its presence in food contact materials resulting in exposure of vulnerable groups such as infants and young children.

The 2003 (updated in 2008) EU risk assessment under the Existing Chemicals programme concludes that there is no consumer risk associated with the use of BPA. The EFSA evaluation of 2006 established a Tolerable Daily Intake (TDI) of 0.05 mg/kg body weight/day based on "traditional" multigeneration toxicity studies. EFSA reviewed new scientific information on BPA in 2008, 2009, 2010 and 2011 and concluded on each occasion that they could not identify any new evidence which would lead them to revise the TDI. Based on this TDI, a migration level of 0.6 mg BPA/kg food is specified in the EU plastic food contact materials regulation. An EU Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 (inhalable dust), has been established based on an opinion from the Scientific Committee on Occupational Exposure Limits (SCOEL) opinion of 2004. SCOEL considers on the basis of an inhalation study from 2004 irritation to be the critical effect. SCOEL is currently updating its recommendation and the current draft suggests using a higher assessment factor in relation to the same inhalation study (a new OEL of 2 mg mg/m^3 is suggested). Overall, existing EU authoritative assessments do not find the sufficient evidence for BPA low-dose effects in humans.

On the other side, some Member States find that the increase in data indicating low-dose effects of BPA is sufficient to take precautionary measures in relation to human exposure, in particular in relation to foetuses and exposure of small children. Partly triggered by pressure from Member States, an EU ban on BPA in baby bottles (already in place in several Member States) was introduced as an EU Commission regulation in 2011.

Some EU Member States keep pursuing (tighter) legislation on BPA via a number of activities:

- The national BPA legislations, which will be the subject of this report;
- A REACH Substance Evaluation, which might lead to further action at EU level (Germany is the rapporteur Member State);
- A recently suggested harmonised classification and labelling for BPA (Reprotoxic Category 1B) tabled by France, and
- A REACH restriction proposal, expected early 2014, aiming at limiting/banning BPA in thermal paper (France is the rapporteur Member State).

[3] http://www.mst.dk/NR/rdonlyres/39F6C09F-EB54-4EFD-BC6B-7C893337D852/156361/3BPAstrategifinal1.pdf (in Danish)

Based on recent scientific findings and possibly triggered by several Member States aiming at further restrictions on the use of BPA in food contact materials, EFSA is currently undertaking a full re-evaluation of the human risks associated with exposure to BPA through the diet, also taking into consideration the contribution of non-dietary sources to the overall exposure to BPA. The exposure part of this re-evaluation was published as a draft opinion for public consultation on 25 July 2013 with a 15 September 2013 deadline for commenting[4]. The second part of the re-evaluation concerning health effects of bisphenol A is expected to be published for public consultation in December 2013. Adoption of the final risk assessment is expected by May 2014.

Objective

The objective of this study is to seek clarification of the reasons behind the differences in national regulatory approaches to BPA in EU and EFTA Member States. The analysis should be based on evidence in exposure and risk assessments, alternatives/impact assessments, legal analyses, and other information used as background information/justifications for the national legislations.

Approach

The following information sources, organisations and Member States were contacted in identifying national provisions and for collecting relevant background information:

- The European Commission web-portal for EU notifications of national legislation (TRIS);
- The European Food Safety Authority (EFSA), communication with desk officer;
- The European Chemicals Agency (ECHA), communication with desk officer;
- European Commission, DG SANCO[5], communication with desk officer;
- DG SANCO web-site with "Legislative overview" (on EU and national laws);
- The Danish EPA, communication with desk officer;
- Danish Veterinary and Food Administration, communication with desk officer;
- European Commission Joint Research Centre, communication with desk officer;
- Direct request to the rapporteur member state for the REACH substance Evaluation (Germany) regarding possible legislative overviews generated;
- Direct request to the rapporteur member state preparing REACH Annex XV dossiers for harmonised EU classification and restriction proposal for BPA (France) regarding possible legislative overviews generated, and
- Competent authorities in relation to food contact material legislation, REACH and occupational exposure limits in Denmark, Sweden, Finland, Germany, Belgium, France, Austria and Switzerland as appropriate.

The above was supplemented with targeted Internet searches. As further specified in the report, these activities were designed to identify existing and possibly upcoming national BPA legislation. Main sources for identification/collection of background information were: i) the public version of the EU notification web-site, ii) a survey of national food contact material legislation conducted by the Danish Veterinary and Food Administration, iii) a survey of BPA legislation prepared for the German authorities preparing the REACH Substance Evaluation, and not the least iv) direct correspondence with the relevant competent authorities in the relevant Member States (Denmark, Sweden, Finland, Germany, Belgium, France, Austria and Switzerland).

Results and discussion

Scope of national legislation – implemented or in the pipeline

In relation to banning BPA in food contact materials, Denmark and Belgium generally bans BPA in food contact materials intended for the 0-3 year olds. Sweden has a narrower scope, banning BPA in varnish and coatings in food contact materials intended for the 0-3 year olds. France has implemented a general ban for all food contact materials (covering all ages) from January 2015, with a

[4] http://www.efsa.europa.eu/en/consultationsclosed/call/130725.htm
[5] Directorate General for Health and Consumers

two years earlier implementation for food contact materials intended for infants and small children. Until the ban enters into force, France has also implemented a provision for labelling food contact material packaging containing BPA with a health warning advising against their use by pregnant women, breastfeeding women, infants, and small children. However, a separate EU notification for the decree with the modalities for implementing this provision has been subject to a number of comments/opinions launched by the EU Commission and other Member States. France is therefore currently considering whether/how to proceed with this decree.

In relation to food contact materials, Germany has implemented (in a legally non-binding Recommendation) a migration limit for recycled fibres used for paper/cardboard food contact materials. The migration limit (0.6 mg BPA/kg food) is adopted from the harmonised EU migration limit in the plastic food contact material regulation.

Belgium is considering national measures to reduce BPA exposure to pregnant women, but is currently awaiting the upcoming EFSA re-evaluation foreseen early 2014. In direct oral correspondence, several Member States and EU institutions note that there is an implicit 'ceasefire' in relation to new national regulation in the food contact materials area, until EFSAs re-evaluation is tabled.

An EU Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 exists. A number of Member States operate with lower national OELs: Denmark (3 mg/m^3), Finland (5 mg/m^3), Germany (5 mg/m^3), Austria (5 mg/m^3) and Switzerland (5 mg/m^3). It can be noted that, the EU Scientific Committee on Occupational Exposure Limits (SCOEL) in an on-going process has recommended lowering the EU OEL to 2 mg/m^3.

France and Austria have implemented bans on BPA in pacifiers and teething rings with the slight difference that the Austrian ban addresses BPA in the manufacturing of such items.

Sweden has prepared national provisions for banning BPA in thermal paper for cash receipts, but is currently awaiting an EU REACH restriction proposal to be submitted by France on the same issue.

Sweden is in the early stages looking into BPA in tap water linings and France might at some point address BPA in medical devices.

Scientific background

Bans of BPA in food contact materials, thermal paper, as well as pacifiers and teething rings are all by-and-large supported by the scientific argument that there are uncertainties related to the possible low-dose effects (endocrine disrupting properties/development neurotoxicity) of BPA, in particular in relation to infants/small children/pregnant women. The increasing evidence of such possible effects is used as the main argument for excluding/minimising exposure to BPA as a precautionary measure. In relation to the Swedish proposed ban on BPA in thermal paper, a quantitative risk assessment showing risks for dermal as well as oral exposure scenarios (reference dose based on low-dose effects). However, in general the scientific justifications for this type of legislation is driven by precaution rather than quantitative exposure/risk assessments.

The national OELs in Germany, Switzerland and Austria (all based on the German MAK[6] documentation) are based on the same inhalation study as the EU IOEL showing irritation following inhalation (NOAEL 10 mg/m^3). Although discussing the issue of endocrine/low-dose effects, the MAK documentation does not find sufficient evidence for these effects in humans. The Danish and Finnish deviations from the EU IOEL are partly based on the fact that the national OELs for biological dust are lower than the EU OEL for BPA and it is for precautionary reasons not found justified us-

[6] Maximale Arbeitsplatz-Konzentration

ing higher OELs for BPA. Finland highlights the on-going discussions regarding possible low-dose effects of BPA and that their OEL will soon be re-evaluated.

Assessment of alternatives/assessment of wider impacts
The impression from identified background material is that alternatives and wider impacts are generally not addressed in great detail in relation to these national BPA provisions.

However, to this end, it should be stressed:

- Results from analyses/assessments might be available that have not been provided to the project;
- The project has not had access to the comments and opinions provided in response to the respective EU notifications, as well as responses to such comments/opinions and subsequent negotiations, and
- In relation to food contact materials, it seems that BPA for some applications is already substituted; e.g. as specified in relation to the Swedish ban on BPA in varnish and coatings, indicating that substitution has already taken place due to national provisions in other countries.

Legal analysis vis-à-vis EU legislation
In line with the scientific background analysis, bans of BPA are largely justified by the will to reduce the BPA exposure as it is considered to possibly pose a fundamentally detrimental effect on health. In their argumentation for national legislation for BPA, Denmark and France explicitly refer to Article 9, Paragraph 7 of the Information Procedure Directive (Directive 98/34/EC)[7], whereas e.g. Sweden refers to several European court decisions.

Sweden also notes the difference of views between the European Commission and a number of Member States in relation to whether Member States can table national bans for applications/chemicals which fall under the scope of REACH.

No legal arguments supporting national deviations from the EU IOEL have been identified. This appears logic given Article 3 of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, which provide justification for such deviations. In the same vein, no legal arguments has been identified in relation to the German non-legally binding migration limit for BPA in recycled fibres to be used for food packaging.

Legal analysis in relation to the choice of legal national instrument
Background documents on this issue have generally not been identified/provided to the project, the only exemption being the background document on the proposed Swedish ban on BPA in thermal paper.

Possible reasons for this could be:

- such analyses have not been forwarded to the authors of the report, and
- in most cases, the national implementation seems rather logical/straightforward (OELs implemented in national OEL lists and BPA bans in food contact materials in national food contact materials legislation).

[7] Providing for urgent national action in case of serious and unforeseeable circumstances relating e.g. to the protection of public health or safety.

Sammenfatning

Baggrund

Bisphenol A (BPA) er inkluderet i Miljøstyrelsens liste over uønskede stoffer (LOUS), fordi BPA: i) er optaget på EU's liste over potentielt hormonforstyrrende stoffer i kategori 1 og ii) klassificeret som reproduktionstoksisk i kategori 2.

Baseret på en kortlægning af BPA har Miljøstyrelsen den 31. maj 2013 udsendt en "Strategi for risikohåndtering i Danmark af bisphenol A (BPA)". En af strategiens anbefalinger er gennemførelse af nærværende projekt for at afklare forskellene i baggrunden for nationale reguleringer af BPA i EU- og EFTA-medlemsstater. Dette skulle give input til en vurdering af fremtidig regulering af BPA i Danmark.

Bisphenol A (BPA) har været genstand for intens forskning og debat i det sidste årti, ikke mindst på grund af formodede lav-dosis effekter (hormonforstyrrende egenskaber og udviklingsmæssig neurotoksicitet) af kemikaliet og dets tilstedeværelse i fødevarekontaktmaterialer, der medfører eksponering af sårbare grupper, såsom spædbørn og små børn.

EU's risikovurdering fra 2003 (opdateret i 2008) under programmet for eksisterende kemikalier konkluderer, at der ikke er nogen risiko for forbrugere forbundet med anvendelsen af BPA. Den Europæiske Fødevareautoritets (EFSAs) vurdering af BPA fra 2006 fastsatte et tolerabel daglig indtag (TDI) på 0,05 mg/kg legemsvægt/dag baseret på "traditionelle" multigenerations toksicitetsundersøgelser. EFSA gennemgik nye videnskabelige oplysninger om BPA i 2008, 2009, 2010 og 2011 og konkluderede i alle tilfælde, at de ikke kunne identificeres ny evidens, som ville føre til en revision af den fastsatte TDI værdi. Baseret på denne TDI værdi specificerer EU's forordning om fødevarekontaktmaterialer af plast en migrationsgrænse på 0,6 mg BPA/kg fødevare. En vejledende EU grænseværdi for erhvervsmæssig eksponering (IOEL) på 10 mg/m^3 er fastsat baseret på en udtalelse (opinion) fra 2004 fra Den Videnskabelige Komité for Grænseværdier for Erhvervsmæssig Eksponering (SCOEL). SCOEL anser på grundlag af et inhalationsstudie fra 2004 irritation som den kritiske effekt. SCOEL er for øjeblikket ved at revidere sin anbefaling, og det nuværende udkast foreslår at anvende en højere vurderings-faktor i forhold til det samme inhalationsstudium, som anbefalingen fra 2004 er baseret på (en ny grænseværdi på 2 mg/m^3 er foreslået). Samlet set finder eksisterende EU autoritative vurderinger ikke tilstrækkelige beviser for lavdosis-effekter af BPA i mennesker.

På den anden side finder nogle medlemsstater, at den stigende evidens for lavdosis-effekter af BPA er tilstrækkelig til at tage forholdsregler i forhold til menneskers eksponering, især i forhold til eksponering af fostre og små børn. Delvist udløst af pres fra medlemsstaterne blev der i 2011 indført et EU- forbud mod BPA i sutteflasker i en Kommissions-forordning (et forbud som allerede eksisterede i flere medlemsstater).

Nogle EU-medlemsstater søger strammere regulering af BPA via en række aktiviteter:

- De nationale BPA-lovgivninger, som adresseret i denne rapport;
- En REACH stofvurdering, som kan føre til yderligere handling på EU-plan (Tyskland er 'rapporteur' medlemsstat);
- En nyligt foreslået harmoniseret klassificering for BPA (reproduktionstoksisk kategori 1B) fremsat af Frankrig, og

- Et REACH anvendelsesbegrænsnings-forslag, som forventes i begyndelsen af 2014, og som sigter mod at begrænse/forbyde BPA i termopapir (Frankrig er 'rapporteur' medlemsstat).

Baseret på den seneste videnskabelige evidens, og muligvis udløst af flere medlemsstaters ønske om begrænsning af brugen af BPA i fødevarekontaktmaterialer, er EFSA i øjeblikket i gang med en fuldstændig revurdering af de humane risici forbundet med eksponering for BPA gennem kosten. Vurderingen tager også hensyn til bidraget fra andre (ikke-fødevare) kilder til den samlede eksponering for BPA. Eksponerings-delen af denne revurdering blev offentliggjort som et udkast til en udtalelse, som var i offentlig høring fra den 25. juli 2013 til den 15. september 2013. Anden del af revurderingen (farevurderingen) forventes publiceret og sendt i offentlig høring i december 2013. Vedtagelse af den endelige risikovurdering forventes i maj 2014.

Formål

Formålet med dette projekt er en afklaring af baggrundene for de forskelle tilgange til national regulering af BPA i EU- og EFTA-medlemsstater. Analysen skal adressere eksponerings- og risikovurderinger, vurderinger af alternativer, konsekvensanalyser, juridiske analyser og andre oplysninger, der bruges som baggrundsinformation/begrundelser for de nationale lovgivninger.

Tilgang og metode

Følgende informationskilder, organisationer og medlemsstater blev kontaktet for at identificere de nationale bestemmelser og for at indsamle relevante baggrundsoplysninger:

- Europa-Kommissionens web-portal for EU-notifikationer af national lovgivning (TRIS);
- Den Europæiske Fødevareautoritet (EFSA), kommunikation med sagsbehandler;
- Det Europæiske Kemikalieagentur (ECHA), kommunikation med sagsbehandler;
- Europa-Kommissionen, DG SANCO, kommunikation med sagsbehandler;
- DG SANCOs website med "Legislative overview" (over EU og national lovgivning);
- Miljøstyrelsen, kommunikation med sagsbehandler;
- Fødevarestyrelsen, kommunikation med sagsbehandler;
- Europa-Kommissionens Fælles Forskningscenter (JRC), kommunikation med sagsbehandler;
- Direkte anmodning til 'rapporteur' medlemsstat for stofevalueringen af BPA under REACH (Tyskland) vedrørende eventuel genereret oversigt over BPA lovgivning;
- Direkte anmodning til 'rapporteur' medlemsstat for forberedelse af anvendelsesbegrænsningsforslag under REACH og harmoniseret EU-klassificering for BPA (Frankrig) vedrørende eventuel genereret oversigt over BPA lovgivning, og
- De relevante kompetente myndigheder i relation til fødevarekontaktmaterialer, REACH og grænseværdier i Danmark, Sverige, Finland, Tyskland, Belgien, Frankrig, Østrig og Schweiz.

Ovenstående blev suppleret med målrettede søgninger på internettet. Som yderligere uddybet i rapporten blev disse aktiviteter designet til at identificere eksisterende og eventuelt kommende nationale reguleringer af BPA. Vigtigste kilder til identifikation/indsamling af baggrundsoplysninger var: i) den offentlige version af EU's notificerings-website, ii) en undersøgelse af de nationale lovgivninger vedr. fødevarekontaktmaterialer gennemført af Fødevarestyrelsen, iii) en undersøgelse af BPA-lovgivning udarbejdet for de tyske myndigheder, der forbereder stofvurderingen under REACH, og ikke mindst iv) direkte korrespondance med de relevante kompetente myndigheder i Danmark, Sverige, Finland, Tyskland, Belgien, Frankrig, Østrig og Schweiz.

Resultater og diskussion

Omfanget af nationale lovgivninger - gældende eller i støbeskeen

Hvad angår forbud mod BPA i fødevarekontaktmaterialer, er der i Danmark og Belgien forbud mod BPA i fødevarekontaktmaterialer beregnet til de 0-3 årige. Sverige har et mere snævert anvendelsesområde, idet der i Sverige er forbud mod BPA i 'varnish og coatings' i fødevarekontaktmaterialer beregnet til de 0-3 årige. Frankrig har gennemført et generelt forbud mod BPA i alle fødevarekontaktmaterialer (for alle aldre), som træder i kraft to år tidligere for fødevarekontaktmaterialer be-

regnet til spædbørn og små børn. Indtil forbuddet træder i kraft har Frankrig også indført en bestemmelse om mærkning af fødevarekontaktmaterialer med en helbredsadvarsel, der fraråder gravide, ammende kvinder, spædbørn og små børn at anvende sådanne materialer. Imidlertid har en efterfølgende særskilt EU-notificering af bekendtgørelsen med de konkrete bestemmelser for gennemførelse af mærkningen været genstand for en række bemærkninger/udtalelser fra Europa-Kommissionen og de øvrige medlemsstater. Frankrig overvejer således i øjeblikket, hvordan de kommer videre med denne bekendtgørelse.

Tyskland har endvidere gennemført en migrationsgrænse for genanvendte fibre, der anvendes til papir/pap til fødevarekontaktmaterialer. Migrationsgrænsen er angivet i en juridisk ikke-bindende henstilling/bestemmelse. Der anvendes samme migrationsgrænse (0,6 mg BPA/kg fødevare) som den harmoniserede EU migrationsgrænse i forordningen for fødevarekontaktmaterialer af plastik.

Belgien overvejer nationale foranstaltninger for at reducere BPA-eksponeringen af gravide, men afventer i øjeblikket den kommende revurdering fra EFSA, som forventes i begyndelsen af 2014. Flere medlemsstater og EU-institutioner bemærker i forbindelse med direkte mundlig korrespondance, at der er en implicit 'våbenhvile' i relation til ny national regulering af fødevarekontaktmaterialer indtil EFSAs revurdering foreligger.

Der foreligger en vejledende EU grænseværdi for erhvervsmæssig eksponering (IOEL) på 10 mg/m^3. En række medlemsstater opererer med lavere nationale grænseværdier: Danmark (3 mg/m^3), Finland (5 mg/m^3), Tyskland (5 mg/m^3), Østrig (5 mg/m^3) og Schweiz (5 mg/m^3). Det skal bemærkes, at EUs Videnskabelige Komité for Grænseværdier for Erhvervsmæssig Eksponering (SCOEL) i en igangværende revurdering anbefaler at sænke EU grænseværdien til 2 mg/m^3.

Frankrig og Østrig har gennemført forbud mod BPA i sutter og bideringe med den lille forskel, at det Østrigske forbud vedrører brugen af BPA i fremstillingen af sådanne produkter.

Sverige har udarbejdet nationale bestemmelser om forbud mod BPA i termisk papir til kasseboner, men afventer i øjeblikket et fransk anvendelsesbegrænsnings-forslag under REACH (for hele EU) om samme emne.

Sverige gennemfører forberedende studier vedr. BPA i foringer i drikkevandsledninger og Frankrig vil muligvis på et tidspunkt lave lovgivning vedrørende BPA i medicinsk udstyr.

Videnskabelig baggrund
Forbud mod BPA i fødevarekontaktmaterialer, termisk papir samt sutter og bideringe er alle stort set støttet af det videnskabelige argument, at der er usikkerhed forbundet med mulige lavdosis-effekter af BPA (hormonforstyrrende egenskaber /neurotoksicitet), især i forhold til spædbørn, små børn og gravide. Den stigende evidens for sådanne mulige effekter bruges som det vigtigste argument for at udelukke/minimere eksponeringen for BPA som en forebyggende foranstaltning. I forhold til det svenske udkast til forbud mod BPA i termisk papir foreligger der desuden en kvantitativ risikovurdering, der viser risiko ved dermal og oral eksponering (baseret på lavdosis-effekter). Generelt er de videnskabelige begrundelser for disse typer af regulering dog udelukkende drevet af forsigtighed snarere end kvantitative eksponerings- og risikovurderinger.

De nationale grænseværdier i Tyskland, Schweiz og Østrig (alle baseret på den tyske MAK-/grænseværdi-dokumentation) er baseret på den samme inhalationsstudie som EU's vejledende grænseværdi (IOEL), der viser irritation efter inhalation (NOAEL 10 mg/m^3). Baggrunds-dokumentationen berører spørgsmålet om hormonforstyrrende/lavdosis-effekter, men finder ikke tilstrækkelige evidens for disse effekter i mennesker. De danske og finske afvigelser fra EU's IOEL er delvist baseret på den kendsgerning, at de nationale grænseværdier for biologisk støv er lavere end EU's IOEL for BPA, og det er af forsigtighedsgrunde ikke fundet berettiget at fastsætte højere

grænseværdier for BPA. Finland fremhæver de igangværende drøftelser om mulige lavdosis-virkninger af BPA, og at den finske OEL snart vil blive revurderet.

Vurdering af alternativer / vurdering af videre konsekvenser
Indtrykket fra det identificerede baggrundsmateriale er, at alternativer og videre konsekvenser generelt ikke behandles i detaljer i forhold til de adresserede nationale BPA bestemmelser.

Det skal dog understreges at:
- der kan forefindes analyser/vurderinger, som ikke har været tilgængelige for projektet;
- projektet har ikke haft adgang til de kommentarer og udtalelser som svar på de respektive EU-notificeringer, samt svar på sådanne bemærkninger/udtalelser og efterfølgende forhandlinger, og
- i forhold til fødevarekontaktmaterialer forekommer det, at BPA i nogen omfang allerede er substitueret, som f.eks. specificeret i relation til det svenske forbud vedr. 'varnish og coatings', hvor det indikeres, at substitution allerede har fundet sted på grund af de nationale bestemmelser i andre lande.

Juridisk analyse vis-à-vis EU-lovgivning
I tråd med den videnskabelige baggrundsanalyse er forbud mod BPA i høj grad begrundet i viljen til at reducere BPA eksponeringen, da den anses for muligvis at kunne have en grundlæggende skadelig virkning på helbredet. I deres argumentation for national regulering af BPA henviser Danmark og Frankrig eksplicit til artikel 9, paragraf 7 i informationsproceduredirektivet (direktiv 98/34/EF)[8], mens f.eks. Sverige henviser til flere afgørelser fra EU-domstolen.

Sverige noterer desuden den uenighed, der eksisterer mellem Europa-Kommissionen og en række medlemsstater i relation til, om medlemsstaterne kan indføre nationale forbud for anvendelser/kemikalier, der falder ind under anvendelsesområdet for REACH.

Der er ikke fundet juridiske argumenter til støtte for nationale afvigelser fra EUs IOEL. Dette synes logisk da nationale afvigelser tillades via Artikel 3 i Rådets direktiv 98/24/EF om beskyttelse af arbejdstagernes sikkerhed og sundhed under arbejdet mod risici i forbindelse med kemiske agenser. I tråd med dette, er der ikke blevet fundet juridiske argumenter for den tyske ikke-juridisk bindende migrationsgrænse for BPA i genbrugsfibre, der skal anvendes til fødevareemballager.

Juridisk analyse i relation til valg af nationalt lovgivnings-instrument
Baggrundsdokumenter om dette spørgsmål er generelt ikke blevet identificeret med undtagelse af baggrundsdokumentet for det foreslåede svenske forbud mod BPA i termisk papir.

Mulige årsager til dette kan være:
- sådanne analyser er ikke blevet delt med forfatterne af denne rapport, og
- i de fleste tilfælde synes den nationale gennemførelse logisk og ligetil (grænseværdier implementeres i de nationale grænseværdi-lister og forbud mod BPA i fødevarekontaktmaterialer implementeres i national lovgivning vedrørende fødevarekontaktmaterialer).

[8] Som åbner mulighed for uopsættelige nationale initiativer i tilfælde af alvorlige og ikke forudsebare omstændigheder, f.eks. relateret til beskyttelse af befolkningens sikkerhed og sundhed.

1. Introduction

1.1 Background

Bisphenol A (BPA) has been the subject of intense research and debate over the last decade, not least due to suspected endocrine disrupting properties of the chemical and its presence in food contact materials resulting in exposure of vulnerable groups such as infants and children. Scientific discussions are on-going specifically regarding the reliability and relevance of studies reporting effects at low doses and their use in risk assessments.

As BPA is included in the EU list of potential endocrine disruptors in category 1 covering substances for which endocrine activity has been documented in at least one study of a living organism[9] and classified for reproductive toxicity in category 2, it included in the Danish Environmental Protection Agency's List of Undesirable Substances (LOUS)[10].

Substances on LOUS are in the period 2012-2015 subject to surveys to provide basis for an assessment of whether further information generation, legislation and/or other risk reduction measures should be undertaken. BPA was included in the first round of surveys and DEPA has on 31 May 2013 issued a strategy for risk management of BPA in Denmark[11]. One of the initiatives suggested in the BPA strategy is the present study seeking clarification of the differences in regulatory approaches in the EU and EFTA Member. It is foreseen that a possible new restriction in Denmark should be risk-based.

In 2010 Denmark decided to invoke the principle of precaution and introduce a temporary national ban on BPA in materials in contact with food for children aged 0 – 3 years (infant feeding bottles, feeding cups and packaging for baby food). Other Member States (Belgium, France, Sweden and Austria) have also notified national legislation to the 98/34-procedure outlined in Directive 98/34/EC, from now on referred to as the "EU notification procedure".

In the EU, a range of activities addressing BPA have taken place. An EU risk assessment under the existing substances programme was published in 2003, concluding a.o. that "There is need for further information and/or testing" for developmental toxicity[12]. A 2-generation study in mice according to OECD 416 (with some specific modifications) was requested. When the results of this study were made available in 2008, the human health part of the risk assessment was updated[13]. This concluded the need for risk reduction for workers (manufacture of epoxy resins and other occupational work with the potential for direct skin contact). At the same time, the risk assessment concluded that there is no risk for consumers, a conclusion which is still being debated. For example, with reference to the available data regarding development neurotoxic effects, Denmark, Norway and Sweden did not agree with the EU risk assessment conclusion[14].

Under REACH, BPA is currently subject to a REACH substance evaluation with Germany as the rapporteur Member State. This activity may lead to proposals for further action at the EU level. France has recently suggested harmonised classification and labelling for BPA (Reprotoxic Category 1B) and France is also working on a REACH restriction proposal expected early 2014, aiming at limiting/banning BPA in thermal paper.

[9] http://www.mst.dk/English/Chemicals/endocrine_disruptors/the_EU_list_of_potential_endocrine_disruptors/
[10] http://www.mst.dk/English/Chemicals/assessment_of_chemicals/lous_list_undesirable_substances_2009/
[11] http://www.mst.dk/NR/rdonlyres/39F6C09F-EB54-4EFD-BC6B-7C893337D852/156361/3BPAstrategifinal1.pdf (in Danish)
[12] http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/phenolreport060.pdf
[13] http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/15069/1/lbna24589enn.pdf
[14] For further details: http://www.mst.dk/Publikationer/Publications/2013/April/978-87-93026-14-8.htm

If the French classification proposal is adopted (Reprotoxic Category 1B), BPA could be included in the candidate list[15] based on this property. Alternatively, a Member State might suggest inclusion in the candidate list based on properties of 'equivalent level of concern' "such as endocrine disrupting properties" (REACH article 57(f)).

EFSA completed its full risk assessment of BPA in 2006[16] setting a Tolerable Daily Intake (TDI) of 0.05 milligrams/kilogram of body weight (mg/kg bw/day), derived by applying a 100-fold uncertainty factor to an overall NOAEL of 5 mg/kg bw/day. This NOEAL is based on a NOAEL of 5 mg BPA/kg bw/day (liver effects) in a two-generation reproductive toxicity study in mice following OECD test guideline 416 and performed under GLP (Tyl et al., 2006[17]) and a NOAEL of 5 mg BPA/kg bw/day (reductions in adult bodyweight and pup body and organ weights) from a 'comprehensive' three-generation study in the rat (Tyl et al., 2002[18]). EFSA reviewed new scientific information on BPA in 2008, 2009, 2010 and 2011: EFSA's experts concluded on each occasion that they could not identify any new evidence which would lead them to revise the TDI for BPA of 0.05 mg/kg bw/day[19].

Based on new scientific findings and possibly triggered by several Member States aiming at further restrictions on the use of BPA in food contact materials, EFSA is currently undertaking a full re-evaluation of the human risks associated with exposure to BPA through the diet, also taking into consideration the contribution of non-dietary sources to the overall exposure to BPA. The exposure part of this re-evaluation was published as a draft opinion for public consultation on 25 July 2013 with a 15 September 2013 deadline for commenting[20]. The second part of the re-evaluation concerning health effects of bisphenol A is expected to be published for public consultation in December 2013. Adoption of the final risk assessment is expected by May 2014.

In recognition of the uncertainty as to the effect associated with possible low-dose exposure of BPA and following pressure from several Member States, an EU ban prohibiting the use of BPA for the manufacture of polycarbonate infant feeding bottles was adopted in January 2011 (Commission Directive 2011/8/EU); a ban which was already implemented in national legislation in various EU member states.

In general however, BPA is permitted for use in food contact materials in the European Union (EU) under Regulation 10/2011/EU, relating to plastic materials and articles intended to come into contact with foodstuffs (from now on "the plastic food contact material regulation"). Annex 1 of the regulation specifies a maximum migration limit of 0.6 mg BPA/kg food (this migration value is derived from the TDI of 0.05 mg/kg bw/day established in the EFSA opinion).

A European Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 (8-hour TWA[21]; as inhalable dust) is in place based on a SCOEL (Scientific Committee on Occupational Exposure Limits) recommendation from 2004 (SCOEL/SUM/113, May 2004).

SCOEL arrived at the recommended OEL based on the foll0wing:

- an observed NOAEL of 10 mg/m^3 from a 13 weeks inhalation study in rats (Nitschke et al 1985b, 1988)[22]

[15] http://echa.europa.eu/da/candidate-list-table
[16] http://www.efsa.europa.eu/en/efsajournal/doc/428.pdf
[17] Tyl RW, Myers CB, Marr MC. 2006. Draft Final Report: Two-generation reproductive toxicity evaluation of Bisphenol A (BPA; CAS No. 80-05-7) administered in the feed to CD-1® Swiss mice (modified OECD 416). RTI International Center for life Sciences and Toxicology, Research Triangle Park, NC, USA.
[18] Tyl RW, Myers CB, Marr MC, Thomas BF, Keimowitz AR, Brine DR, Veselica MM, Fail PA, Chang TY, Seely JC, Joiner RL, Butala JH, Dimond SS, Cagen SZ, Shiotsuka RN, Stropp GD, Waechter JM. 2002. Three-generation reproductive toxicity study of dietary bisphenol A in CD Sprague-Dawley rats. Toxicol Sci 68, 121-46.
[19] http://www.efsa.europa.eu/en/topics/topic/bisphenol.htm
[20] http://www.efsa.europa.eu/en/consultationsclosed/call/130725.htm
[21] Time Weighted Average
[22] Referred to as follows in the SCOEL documentation:
Nitschke K.D, Quast J.F, Schuetz D.J and Wolfe E.L (1985b) Bisphenol-A: 2 week aerosol toxicity study with Fischer 344 rats. Dow Chemical Company unpublished report

- mild nasal olfactory epithelium inflammation observed at 50 mg/m^3 in the same study
- the prediction that humans could be less sensitive than rats to this effect
- a 50/kg/day NOAEL established in a standard (oral) multigeneration study in rats (although noting the dispute relating to possible developmental toxicity/endocrine-modulating activity of BPA, SCOEL regarded this NOAEL as the most appropriate)
- worst case calculations showing that inhaling 10 m^3/day of BPA with a concentration of 10 mg/m^3 (repeated inhalation NOAEL) and considering 100% absorption would lead to a body burden of 1 mg/kg/day, which is well below the NOAEL of 50 mg/kg/day from the multigeneration study

Recently, SCOEL has updated its recommendation and recommends an OEL of 2 mg/m^3 for BPA (8-hour TWA; as inhalable dust) in a draft document which was for consultation until September 2013 (SCOEL/SUM/113; March 2013).

This new recommended OEL is based on:

- the same NOAEL of 10 mg/m^3 as in the 2004 recommendation
- dividing this NOAEL with as assessment factor of 3 (to cover the uncertainties related to the inter-species extrapolation) resulting in an OEL of 3 mg/m3, which is in turn rounded to 2 mg/m^3
- the consideration that there is no need for specific adjustment for inter-species differences in toxicokinetics[23]
- the notion that the 2 mg/m^3 leaves almost a 25-fold safety margin to the systemic liver effects seen in rats at the oral dose levels of > 5 mg/kg bw/day (the NOAELs used as the starting point by EFSA for setting an oral reference dose. In that study mild liver hypertrophy, increased liver weights and reductions in weight gain are seen at 50 mg/kg bw/day for mice and rats)
- that there is currently no concluding evidence showing that suggested "low-dose effects" (developmental neurotoxicity/possible prostate effects) are real and relevant for humans

Further details on Danish and EU legislation for BPA can be found in the Survey of Bisphenol-A and Bisphenol A diglycidylether polymer[24].

1.2 Scope and objective

As already noted, one of the initiatives suggested in the Danish EPA BPA strategy is to seek clarification of the reasons behind the differences in national regulatory approaches of BPA in EU and EFTA Member States.

Thus, the overall objective of this study is to identify the specific national regulatory initiatives pertaining to BPA in the EU Member States, and to provide insight into the scientific and legal background behind these initiatives. To the extent possible, it will also be attempted to identify other/upcoming activities or draft legislations, which may come into effect at a later stage. The ambition level for upcoming activities will merely be to provide a status and overall risk considerations as available.

In Member States where national regulatory initiatives are taken, the aim is to identify and describe possible risk assessments carried out, the background for the risk assessment, the NOAELs/LOAELs that have been used and how the exposure has been calculated. If restrictions are suggested on the basis of the precautionary principle, the reasoning behind the initiative and the

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Nitschke K.D, Lomax L.G, Schuetz D.J, Hopkins P.J and Weiss S.W (1988)
Bisphenol-A: 13 week aerosol toxicity study with Fischer 344 rats. Dow Chemical
Company unpublished report

[23] "Enterohepatic circulation in rats results in a longer half-life of BPA in rats when compared to that in humans. On the other hand, the glucuronidation rate in rats is higher than in humans. Regardless of these apparent differences in BPA toxicokinetics, it has been noted that internal exposures to free BPA are rather similar in rodents and humans reducing the need for allometric scaling" (WHO, 2011. Toxicological and health aspects of bisphenol-A. Report of joint FAO/WHO expert meeting, 2-5 November, 2010.)

[24] http://www.mst.dk/Publikationer/Publications/2013/April/978-87-93026-14-8.htm

use of the precautionary principle must be described, to the extent the principle is revoked. In addition to scientific justifications provided, justifications for choice of legal instrument and justifications vis-à-vis EU legislation will be analysed where available.

The aim is also to clarify whether differences in approaches to regulating BPA in Member States are due to different assessments of an identical scientific documentation or if differences arise from use and assessment of different information, e.g. national surveys, assessments and monitoring programmes.

Where national restrictions have been adopted, the legal basis must be identified and it must be specified whether national restrictions are notified according to the *Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations*. Notifications can be searched in the 98/34 Database[25].

Furthermore, it will be noted if there as part of the EU notification process were comments launched by the European Commission or other Member States. Due to confidentiality, the content of such comments cannot be addressed in this report. This is of course a limitation in the applicability of the study, since discussions regarding the legal basis and/or clarifications of the justifications for national provisions following the EU notifications are thus not part of the analysis presented in this report.

1.3 Approach

The project has been carried out on the basis of the following partly overlapping activities:

- Identification of national BPA legislation and initiatives;
- Collection of relevant background information;
- Analysis of the scientific and legal background behind national BPA legislation and initiatives, and
- Discussion/comparison of national initiatives.

1.3.1 Identification of national BPA legislation

The objective of this phase was to identify existing and upcoming national EU and EFTA Member State legislation and initiatives regarding risk reduction of BPA.

The following organisations and information sources have been consulted:

- The European Commission web-portal for EU notifications of national legislation[25];
- The European Food Safety Authority (EFSA), communication with desk officer;
- The European Chemicals Agency (ECHA), communication with desk officer;
- European Commission, DG SANCO[26], communication with desk officer;
- DG SANCO web-site with "Legislative overview" (on EU and national laws);
- The Danish EPA, communication with desk officer;
- Danish Veterinary and Food Administration, communication with desk officer;
- European Commission Joint Research Centre, communication with desk officer;
- Direct request to the rapporteur member state for the REACH substance Evaluation (Germany) regarding possible legislative overviews generated, and
- Direct request to the rapporteur Member States preparing REACH Annex XV dossiers for harmonised EU classification and restriction proposal for BPA (France) regarding possible legislative overviews generated.

[25] http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?lang=EN
[26] Directorate General for Health and Consumers

This was where relevant complemented with targeted Internet searches, primarily in relation to national Occupational Exposure Limits (OELs) for BPA, which were not believed to be comprehensively covered by information from the above sources.

It was originally planned to consult all national food and REACH competent authorities, including stakeholder observers to the competent authority groups, with a general request/questionnaire regarding national BPA legislation.

It was however agreed with the Danish EPA to skip these requests for the following reasons:

- Since BPA is in regulatory focus, there have been numerous questionnaires circulated to national competent authorities in relation to various projects;
- Such requests generally give a rather low response rate, which would likely also be the case here (in particular considering the fatigue triggered by the numerous previous BPA questionnaires).

As will be evident from the results chapter, it was during the process of the project assessed that the project had by-and-large captured national BPA legislation without the need to contact all Member States.

1.3.2 Collection of relevant background information

Based on the identified national BPA legislations and activities, the following activities were undertaken:

- For legislation where notifications have been filed, relevant documents from the EU notification web-site were downloaded;
- The web-sites of the relevant national authorities/agencies were searched in order to identify any relevant material (legislation, assessments, impact assessments, stakeholder comments), and
- Direct focused follow-up questions via phone and e-mail to these national authorities (this turned out to be necessary in all cases to request and/or acquire all relevant information, which could be made available to the project).

1.3.3 Scientific and legal background of national BPA legislation and initiatives

The background information collected was analysed and a summary for each identified legal provision was prepared. The summary addressed to the extent possible scientific reasoning, alternatives/impact assessment, legal analyses and other justifications based on the collected information.

1.3.4 Discussion/comparison of national initiatives

Based on the analysis of the background information for each national provision, a comparative analysis/discussion was undertaken.

2. Identification of national BPA legislation and initiatives

This chapter focuses on existing and proposed/upcoming national legal provisions on BPA. Please refer to Chapter 1 for an overview of existing EU legislation. Where relevant, national provisions will be compared/related to the EU provision(s).

2.1 Food contact materials

Prior to the EU provisions banning BPA in baby bottles, several member states had introduced national bans, e.g. Denmark and France. However, as this is currently implemented in EU law, it has not been the aim of the current project to identify such historical provisions.

2.1.1 National legislation in place

The following main sources provided an initial overview of information on food contact material legislation in place: i) a recent survey on this issue conducted by the Danish Veterinary and Food Administration (provided directly to the project) and ii) the public access to EU notifications[27]. Subsequent correspondence with European institutions (EFSA, ECHA, Joint Research Centre and DG SANCO) involved in BPA research, assessment and legislation, as well as consultation of a review of national BPA provisions prepared for the German authorities conducting the BPA REACH substance evaluation (provided by Germany), did not identify any further national BPA legislation in place. Altogether, we are therefore confident that we have identified relevant national food contact material provisions and these are listed in Table 1 in Section 3.1.

2.1.2 National provisions in the pipeline

Two proposed and/or upcoming national provisions have been identified; a French initiative on modalities for labelling food contact materials containing BPA (until a ban is fully implemented by 1. January 2015) and Belgian considerations regarding measures for the protection of pregnant women, see Table 1 in Section 3.1. These were identified through the EU notification web-site and via direct dialogue with the EU institutions and the Member States most active in the area (Austria, France, Germany, Sweden, Denmark, and Belgium). We cannot exclude that other Member States have activities on-going that could lead to national BPA legislation, but as we have been in direct dialogue with the most active Member States, we assume that we have good coverage. Further, several Member States and EU institutions note that in the food/food contact materials area there is an implicit agreement, a “ceasefire”, that no new national legal provisions are tabled before the updated EFSA opinion is in place (draft opinion expected beginning 2014, see Introduction).

2.2 Occupational Exposure Limits

A European Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 (8-hour TWA[28]; as inhalable dust) is in place based on a SCOEL (Scientific Committee on Occupational Exposure Limits) recommendation from 2004 (SCOEL/SUM/113, May 2004). Recently, SCOEL has updated its rec-

[27] http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?lang=EN
[28] Time Weighted Average

ommendation and recommends an OEL of 2 mg/m^3 for Bisphenol A (8-hour TWA; as inhalable dust) in a draft document which was for consultation until September 2013 (SCOEL/SUM/113; March 2013).

Via the legislative overview prepared in support of the German REACH substance evaluation and via searches on the Internet, including the IFA web-site[29], it was identified that a number of countries deviate from the current EU IOEL of 10 mg/m^3, see Table 2 in Section 3.2.

2.3 Other national legislation

From consultation and direct contact with the information sources outlined in Section 1.3.1, the Austrian and French provisions regarding pacifiers and teething rings have been identified.

In addition - based on the sources outlined in Section 1.3.1, Internet searches and direct follow-up contact with Member States already addressing BPA in national legislation - a number of upcoming/on-going activities have been identified. Overall, we assess that this gives a comprehensive overview of possibly upcoming areas within which national BPA legislation may appear at a later stage. However, we cannot exclude that other activities are on-going in other Member States. Table 3 in Section 3.3 provides an overview of identified other national legislation (in place and possibly upcoming).

[29] IFA - Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS International Limit Values. Available at: http://limitvalue.ifa.dguv.de/Webform_gw.aspx (last accessed September 2013).

3. Collection of relevant background information

The aim of this section is to provide an overview of what information has been collected. This is done in table format for food contact materials, OELs and other legislation, respectively, outlining what legislation is in place or possibly upcoming and what background material has been identified/acquired.

3.1 Food contact materials

TABLE 1
IDENTIFIED EXISTING AND POSSIBLE FUTURE NATIONAL FOOD CONTACT MATERIAL LEGISLATION REGARDING BPA AND OVERVIEW OF BACKGROUND INFORMATION ACQUIRED

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Responses to EU notification from Commission and/or Member States*	Background information collected	Comments
Denmark	Statutory Order on food contact materials No. 822 June 26th 2013 (Bekendtgørelse om fødevarekontaktmaterialer nr 822 af 26/06/2013) Formerly Statutory Order No. 579 June 1th 2011 (BEK nr 579 af 01/06/2011)	Ban on BPA in food contact materials intended to come into contact with food for 0-3 year olds	Yes (2010/294/DK) *No comments from the European Commission or other EU member States provided in response to the Danish notification.* *However, subsequently an opinion from the Commission was received by the Danish authorities.*	1. Evaluation from the National Food Institute (DTU Food). This evaluation was provided as "Impact assessment" as part of the EU notification 2. The EU notification "message" summarising context and justification of the national legislation	

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Responses to EU notification from Commission and/or Member States*	Background information collected	Comments
Belgium	Law of 4 September 2012 modifying the Law of 24 January 1977 concerning protection of consumers in relation to BPA in food contact materials (4 Septembre 2012.—Loi modifiant la loi du 24 janvier 1977 relative à la protection de la santé des consommateurs en ce qui concerne les denrées alimentaires et les autres produits, visant à interdire le bisphénol A dans les contenants de denrées alimentaires)	Ban on BPA in food contact materials intended to come into contact with food for 0-3 year olds	Yes (2012/141/B) *Issue of comments by: The Commission, Italy* *Issue of a detailed opinion by: Czech Republic, United Kingdom*	1. Belgian health scientific committee opinion (CSS_BPA_8697_avis_2010). "Bisphenol A" (Submitted from Belgian authorities and also available on EU notification website) 2. The EU notification "message" summarising context and justification of the national legislation	
Sweden	Swedish Food Decree (2006:813) (Livsmedelsförordning (2006:813))	Ban on BPA in varnish and coating in the packaging of food intended for 0-3 year olds	Yes (2012/241/S) *Issue of comments by: The Commission* *Issue of a detailed opinion by: Czech Republic, Spain, United Kingdom*	1. An Impact assessment available on the EU notification website 2. Supplemented by an e-mail from the Swedish authorities 3. The EU notification "message" summarising context and justification of the national legislation	

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Responses to EU notification from Commission and/or Member States*	Background information collected	Comments
France	Law 2012-1442 of 24 December 2012 on the suspension of BPA in food contact materials (LOI n° 2012-1442 du 24 décembre 2012 visant à la suspension de la fabrication, de l'importation, de l'exportation et de la mise sur le marché de tout conditionnement à vocation alimentaire contenant du bisphénol A)	Banning BPA in any food packaging by 1 January 2015 Banning BPA in food packaging for infants and young children by 1. January 2013 Also provides for labelling/warning advising against the use by pregnant women, breastfeeding women and infants and young children of the above packing until such packaging is suspended from the market (NB! The decree with modalities for implementing this provision is discussed further down in this table) Finally, also BPA in pacifiers and teething is banned via this legislation. As this provisions is not related to food contact materials, it is addressed under "Other legislation", see Table 3	Yes (2011/529/F) *Issue of comments by: The Commission, Italy, Slovenia* *Issue of a detailed opinion by:Czech Republic, Spain, The Netherlands, United Kingdom*	1. Opinion published by French Agency for Food, Environmental and Occupational Health & Safety (ANSES): Health effects of Bisphenol A. Collective Expert Report. Request nos. 2009-SA-0331 and 2010-SA-0197 2. An alternatives/ impact assessment referred to as part of the EU notification (identified via Internet search) 3. The EU notification "message" summarising context and justification of the national legislation	

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Responses to EU notification from Commission and/or Member States*	Background information collected	Comments
Germany	Recommendation XXXVI (Paper and board for food contact) from the Federal Institute for Risk Assessment (BfR* Empfehlung XXXVI. Papiere, Kartons und Pappen für den Lebensmittelkontakt (Stand vom 01.06.2013)). *BfR: Bundesinstitut für Risikobewertung	Migration limit of 0.6 mg/kg foodstuff for recycled fibres used as raw materials for the production of paper and board for food contact materials	Notification not required as such a "Recommendation (Emphelung)" is not legally binding[30].	Justification provided in an e-mail from the German authorities	
National legislation in pipeline					
France	In preparation/consideration Proposed to be implemented as a decree, specifying the modalities for affixing the health warnings as specified in Article 2 of the LOI n° 2012-1442 (see above)	Concerning health warnings against the use of packaging containing bisphenol A intended to enter into direct contact with foodstuffs	Yes (2013/230/F) *Issue of comments by: Denmark* *Issue of a detailed opinion by: Belgium, Czech Republic, the Commission, Spain, Italy, The Netherlands, United Kingdom*	1. The EU notification "message" summarising context and justification of the national legislation	In e-mail correspondence with the French authorities, it is stated in relation to the EU notification: "We received many comments and need to think of all of it"

[30] See e.g. http://www.packaginglaw.com/3214_.shtml, stating: "*The German BfR Recommendations are not legally binding. They are, however, widely respected by industry throughout the European Union (EU), particularly in areas where harmonized EU legislation has not yet occurred, such as the regulation of paper and paperboard for food contact.*"

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Responses to EU notification from Commission and/or Member States*	Background information collected	Comments
Belgium	In preparation/consideration	"Some measures for the protection of pregnant women"	Not applicable	Belgian Health Scientific opinion 8732, 2012 "Bisphenol A – dietary and non-dietary routes of exposure"	Belgian authorities note that legal action will probably await the updated EFSA opinion (expected early 2014) These possible upcoming provisions will thus not be addressed further in this report.

3.2 Occupational Exposure Limits

As set out in the Introduction, an EU Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 exists. As member states are allowed to deviate from IOELs, no EU notification is required for such deviations. This notification column is therefore taken out of the table.

TABLE 2
IDENTIFIED OCCUPATIONAL EXPOSURE LIMITS FOR BPA AND OVERVIEW OF BACKGROUND INFORMATION ACQUIRED

Country	Legal Act/Provision	Scope	Background information collected	Comments
Denmark	Statutory order 507 of 17/05/2011 (Bekendtgørelse om grænseværdier for stoffer og materialer, nr. 507 af den 17. maj 2011 med senere ændringer)	National OEL: 3 mg/m^3 (8h TWA, as inhalable dust fraction)	No background document available, but justification provided in E-mail from the Danish Working Environment Authority	

Country	Legal Act/Provision	Scope	Background information collected	Comments
Germany	Standards for Hazardous Substances (TRGS* 900) (Arbeitsplatzgrenzwerte (TRGS* 900)) TRGS: Technischen Regeln für Gefahrstoffe	National OEL (MAK*): 5 mg/m3 (8h TWA, as inhalable dust fraction) *MAK: Maximale Arbeitsplatz-Konzentration	MAK documentation for Bisphenol A (4,4'-Isopropylidenediphenol) from 1996 (http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb8005e0013/pdf)	Amendment of the MAK documentation in 2011 did not lead to any change in the value as no new BPA inhalation studies were available Germany notes the ongoing SCOEL re-evaluation of the EU BPA IOEL
Austria	Austrian OEL regulation as adapted in 2011 (GKV 2011) (Verordnung des Bundesministers für Arbeit, Soziales und Konsumentenschutz über Grenzwerte für Arbeitsstoffe sowie über krebserzeugende und über fortpflanzungsgefährdende (reproduktionstoxische) Arbeitsstoffe (Grenzwerteverordnung 2011 – GKV 2011 - BGBl II Nr. 429/2011))	National OEL (MAK): 5 mg/m3 (8h TWA, as inhalable dust fraction) (= German MAK)	Austrian authorities note that that value is based on the German MAK documentation, see under “Germany”	
Finland	Act 1213\2011 (Social- och hälsovårdsministeriets förordning om koncentrationer som befunnits skadliga, 1213/2011)	National OEL: 5 mg/m3 (8h TWA, as inhalable dust fraction)	Justification given in a note provided in response to request	Finland awaits the outcome of the current SCOEL re-evaluation of the EU BPA IOEL, whereafter the Finnish OEL will be re-evaluated
Switzerland	Fact sheet - Swiss occupational exposure limits (latest edition: January 2013) (Grenzwerte am Arbeitsplatz" (German) or "Valeurs limites d'expositions aux postes de travail" (French), according to Article 50, §3 VUV (Ordinance regulating accident prevention and occupational diseases))	National OEL (MAK): 5 mg/m3 (8h TWA, as inhalable dust fraction) (= German MAK)	Swiss authorities note that that value is based on the German MAK documentation, see under “Germany”	

3.3 Other legislation

TABLE 3
OTHER IDENTIFIED EXISTING AND POSSIBLY UPCOMING NATIONAL LEGSILATION REGARDING BPA AND OVERVIEW OF BACKGROUND INFORMATION ACQUIRED

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Comments to proposal?*	Background information collected	Comments
Austria	Federal law gazette – Part II No 327/2011 (Bundesgesetzblatt für die republic Österreich - Teil II - Ausgegeben am 6. Oktober 2011) (BGBl. II Nr. 327/2011)	Ban on BPA in the manufacture of pacifiers and teething rings	Yes (2011/50/A) *Issue of comments by: The Commission* *Issue of a detailed opinion by: Czech Republic, The Netherlands, United Kingdom*	1. Risk assessment provided under confidentiality 2. An Impact assessment available on the EU notification website (among others summarising the above risk assessment) 3. The EU notification "message" summarising context and justification of the national legislation	In a recommendation of the Austrian Codex-Commission one can find information on how to (analytical) verify that BPA was not used in the manufacture of these products. http://www.bmgf.gv.at/cms/home/attachments/3/5/2/CH1252/CMS1167208341459/gg_bisphenol_a.pdf
France	Law 2012-1442 of 24 December 2012 on the suspension of BPA in food contact materials specifying that Article L.5231-2 from the Code of Public Health should be adapted (LOI n° 2012-1442 du 24 décembre 2012 visant à la suspension de la fabrication, de l'importation, de l'exportation et de la mise sur le marché de tout conditionnement à vocation alimentaire contenant du bisphénol A and Code de la santé publique - Article L5231-2)	Banning BPA in pacifiers and teething rings	See Table 1 (Implemented as part of law already addressed in Table 1)	See Table 1 (Implemented as part of law already addressed in Table 1)	

Country	Legal Act/Provision	Scope	Notified with the EU (File number) *Comments to proposal?*	Background information collected	Comments
National legislation in pipeline					
Sweden	In preparation/consideration. Suggested to be implemented in the Swedish Environmental Code 1998:808 (Miljöbalken – SFS 1998:808) Proposal for legal text on p. 48 of the background report mentioned in the column "Background information collected"	Ban of BPA in Thermal paper	Not applicable	Background report prepared by the Swedish Chemicals Agency (KEMI) with health, environmental and alternatives considerations (Bisfenol A i kassakvitton– rapport från ett regeringsuppdrag) (http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport4_12.pdf)	The Swedish authorities state that the proposal is on hold awaiting the French REACH Restriction proposal on this issue – expected early 2014
France	In preparation/consideration	BPA in medical devices	Not applicable	French authorities state: "French law mentions the need for studying the alternatives before taking interdiction measures"	These possible upcoming provisions will not be addressed further in this report.
Sweden	In preparation/consideration (early phase)	BPA in relining of tap water pipes	Not applicable	Not (yet) available	The Swedish Chemicals Agency (KEMI) is currently working on a commission from the Government on this issue. These possible upcoming provisions will thus not be addressed further in this report.

4. Scientific and legal background behind national BPA legislation and initiatives

4.1 Food contact materials

4.1.1 Denmark – Ban on BPA in food contact materials intended to come into contact with food for 0-3 year olds

The scientific background for the Danish national ban on BPA in food contact materials intended to come into contact with food for 0-3 year olds is an assessment from the Danish National Food Institute, Technical University of Denmark (NFI, 2010). This assessment was also provided as the "Impact Assessment" in support of the EU notification. The assessment specifically assesses a by then new developmental neurotoxicity study in rats (According to OECD Test Guideline 426) provided by the industry in response to the increasing concern related to possible low-dose effects of BPA on the development of the nervous system or behaviour (Stump, 2009[31]; Stump et al. 2010[32]). The assessment discusses the new study in relation to other studies addressing developmental neurotoxicity of low-dose exposure to BPA.

The assessment identifies several weaknesses in the industry study, including: "*A very significant weakness of the study is that it has not been designed based on the observations of harmful effects of BPA, at low doses, on the development of the nervous system or behaviour, as found in previous limited experiments, such as effects on some aspects of learning and memory (avoidance learning, schedule-controlled behaviour and impulsiveness), anxiety-related behaviour and gender-specific behaviour. As a result of this, the study cannot clarify the uncertainty with respect to such effects on the development of the nervous system*."

Overall, it is therefore concluded that the industry study: "*...does not clarify or change the uncertainty with respect to BPA's effects on development of the nervous system or behaviour of rodents at low dosages of BPA*."

Based on this assessment, the following 'Statement of grounds' was provided as part of the Danish EU notification message: "*The regulations prohibiting Bisphenol A in all products specifically for 0-3 year olds are issued as a result of new, extensive rat experiments on the substance. The exper-*

[31] Stump (2009) study report. A Dietary Developmental Neurotoxicity Study of Bisphenol A in rats. October 2009. Submitted by Polycarbonate/BPA Global Group American Chemistry Council, Arlington, VA, USA. (NB! Later published as Stump et al., 2010).

[32] Stump DG, Beck MJ, Radovsky A, Garman RH, Freshwater L, Sheets LP, Marty MS, Waechter JM, Dimond SS, Van Miller JP, Shiotsuka RN, Beyer D, Chappelle AH and Hentges SG. 2010. Developmental neurotoxicity study of dietary bisphenol A in Sprague-Dawley rats. Toxicological Sciences 115, 167-182.

iments have been assessed by The Ministry of Food's adviser on risk evaluations, The National Food Institute, The Technical University of Denmark. The Institute considers that findings of impaired learning capacity in young males at low dosages can be an indication of a low dosage effect, but can also be an incidental finding. The new investigations are therefore considered to raise uncertainties with respect to the harmful effects in particular on children. Ensuring acceptable safety levels is very important, in particular for the section of the population that is as vulnerable as small children. A prohibition of the use of the substance Bisphenol A in materials which come into contact with food which are marketed in particular for 0-3 year olds, or which are already in contact with food particularly destined for babies and small children has therefore been prepared.

Evaluations show that other substances will be able to replace Bisphenol A in materials which come into contact with food."

Thus, the justification for implementing a national BPA legislation is based on uncertainty with regard to the effect in the hazard data base and does not explicitly address exposure or quantitative risk characterisation.

An assessment addressing wider impacts has not been identified in/provided to the project.

The EU notification lists the following 'Grounds of the Emergency' for implementing national legislation: "*Article 9, Paragraph 7 of the Information Procedure Directive, opens the opportunity for a Member State, on the grounds of urgency due to a serious, unpredictable situation which relates to the protection of human health, etc., to not be required to postpone the implementation of a technical regulation, but to adopt the regulation immediately. The enclosed impact analysis from the Technical University of Denmark, cf. point 15, concludes that there can be a serious, health threatening effect which the authorities do not dare ignore. The evaluation points to the possibility of an effect which can threaten the health of one of the most vulnerable groups in society*".

No justification for the choice of legal instrument has been identified. However, the provision seems logically implemented in the Statutory Order concerning food contact materials No. 822 June 26th 2013[33] (formerly Statutory Order No. 579 of June 1th 2011). Article 7(3) states: "Bisphenol A and all compounds in which it is embedded must not be used in materials, which are intended to come into contact with food specifically intended for 0-3 year olds"[34].

The EU notification web-site does not list comments or opinions from the European Commission or other Member States. However, in March 2011 the EU Commission sent a detailed opinion to the Danish food authorities[35]. The details of the opinion are confidential, but the European Commission generally questioned the timing and justification of the Danish restriction. In response, the Danish authorities point out that dead-lines and notification procedures have been adhered to and that the scientific analysis provided by The National Food Institute, The Technical University of Denmark is still valid and thus that the legislation is justified. Further correspondence is not available and the file is now indicated as "Closed".

4.1.2 Belgium - Ban on BPA in food contact materials intended to come into contact with food for 0-3 year olds

The scientific background to the national legislation is based on an opinion launched by the Belgian Superior Health Council (CSS) from October 2010. The CSS is composed from experts within gen-

[33] Bekendtgørelse om fødevarekontaktmaterialer nr 822 af 26/06/2013
[34] Own translation. Original Danish text: "Bisphenol A og alle de forbindelser, det indgår i, må ikke anvendes i materialer, der er beregnet til at komme eller være i kontakt med fødevarer specielt rettet mod 0-3 årige".
[35] http://www.euo.dk/dokumenter/efdomstolen/aabn/aabnanl/2011/0422/ (in Danish)

eral and paediatric nutrition, general chemistry and medicinal chemistry, physiology and pathophysiology of nutrition, food science, toxicology, additives, residues, contaminants, industrial microbiology and technology, preventive medicine and public health. They analyse scientific opinions issued from various national and international bodies and base their opinion on the results from these analyses. The scientific opinions reviewed in this context by CSS were:

- Scientific Committee for Food (SCF) and the European Food Safety Authority (EFSA): Scientific Opinion on Bisphenol A: Evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A. EFSA Journal 8(9):1829 (2010)
- French Agency for Food Safety (AFSSA[36]): Opinion of the French Food Safety Agency on the critical analysis of the results of a study of the toxicity of bisphenol A on the development of the nervous system together with other recently-published data on its toxic effects (2010)
- Bundesinstitut für Risikobewertung (BfR): Bisphenol A: Studies by Stump et al. (2010)[37] and Ryan et al. (2010)[38] provide no indications for adverse effects on neurological development and behaviour. BfR Opinion No. 035/2010 (2010)
- Santé Canada (SC) (Health Canada): Health Canada. Assessment of health risks associated with BPA in food packaging (2008)
- Japanese national Institute of Advanced Industrial Science and Technology (AIST): Bisphenol A (BPA) Risk Assessment Document. AIST Research Center for Chemical Risk Assessment (2005)
- National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP – CERHR) (USA): NTP - CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. No. 08-5994 (2008).
- International Food Safety Authorities Network (INFOSAN): Bisphenol A (BPA) - Current state of knowledge and future actions by WHO and FAO. INFOSAN Information Note No. 5/2009 (2009)

The CSS opinion includes summaries/assessments of each of the above mentioned international scientific opinions, which all address the issue of low-dose effects.

The CSS opinion does not conduct its own exposure assessment, but refer, as an example, to TDI data from the National Toxicological Programme (NTP) (2008).

The opinion does address specific Belgian exposures or risks.

At the end of the opinion, alternatives to BPA are very briefly addressed. This focuses on BPA in baby bottles (banned in the EU after this opinion). CSS points out that polycarbonate bottles may be replaced with polypropylene or polyether sulfone bottles. Glass bottles are, however, mentioned as the best alternative to BPA. BPA in other plastics/food contact materials is not addressed.

In conclusion, the CSS opinion states that the published opinions (listed above) indicate that the exposure of the population, including small children, to BPA does not seem to cause health concerns. However, since the same opinions agree, that there are still uncertainties concerning the neurotoxicity of BPA, the toxicokinetics, the effects at low doses, the effects on the immune system, the effect on development, and the possibility of an increased risk of cancer in the mammary glands following exposure in the uterus or during lactation, CSS recommends, based on the precautionary principle, that the exposure of young children to BPA should be as low as possible.

[36] Now ANSES (French Agency for Food, Environmental and Occupational Health & Safety)
[37] Stump DG, Beck MJ, Radovsky A, Garman RH, Freshwater L, Sheets LP, Marty MS, Waechter JM, Dimond SS, Van Miller JP, Shiotsuka RN, Beyer D, Chappelle AH and Hentges SG. 2010. Developmental neurotoxicity study of dietary bisphenol A in Sprague-Dawley rats. Toxicological Sciences 115, 167-182
[38] Ryan BC, Hotchkiss AK, Crofton KM, Gray Jr. LE. 2010. In Utero and Lactational Ex-posure to Bisphenol A, in contrast to Ethinyl Estradiol, Does not Alter Sexually Dimorphic Behavior, Puberty, Fertility and Anatomy of Female LE Rats. Toxicol. Sci. 114(1), 133-148.

Thus, the justification for implementing a national ban is based on hazard uncertainties and consequently the wish to minimise exposure.

An impact assessment addressing wider impact has not been identified in/provided to the project.

A legal analysis vis-à-vis EU law has not been identified/provided and no legal analysis for the choice of legal instrument has been found. However, we assess that the provision is logically implemented in the Belgian Law on consumer health protection with regard to foodstuff and other products (Act of 24 January 1977, last amended by the Act of 19 May 2010). It states that a new article (3/1) is added, saying that "sale or placement on the market and manufacture of materials which are intended to hold foodstuffs for children of 0 to3 years old and containing bisphenol A are prohibited"[39]

As can be seen from Table 1, comments to the Belgian EU notification were received from the Commission and Italy, and detailed opinions were launched by the Czech Republic and the UK.

4.1.3 Sweden - Ban on BPA in varnish and coating in the packaging of food intended for 0-3 year olds

No actual risk assessment has been identified /provided for the Swedish ban on BPA in food contact materials intended for 0-3 year olds.

However, the Impact Assessment submitted as part of the EU notification of the Swedish national legislation highlights (without going into detail) the uncertainties related to the possible toxic effects of BPA, in particular for children as a sensitive group.

It is noted that the EU prohibition of BPA in baby bottles is based on this uncertainty and it is stated: "*It is therefore appropriate and justified to adopt, as a preventive measure, rules which prohibit the use of BPA in baby food packaging and thus to reduce the exposure of small children as far as possible.*"

In direct correspondence with the Swedish Ministry for Rural Affairs, Animal and Food Division, it is further stated that: "*The ban of BPA in the packaging of food intended for small children is in line with the Swedish national action plan for a toxic-free everyday environment. The goal is to ensure that BPA is not present in such packaging and thereby minimising the exposure for small children.*"

Thus, the national Swedish legislation is based on preventing exposure based on uncertainty as to the effect of exposure in the hazard data base and does not explicitly address exposure levels or quantitative risk assessment/characterisation.

The impact assessment considers the impacts on industry and concludes that the proposed ban will not entail any additional costs or other unwanted consequences for industry as substitution has already taken place on the Swedish market. It is noted that this substitution was triggered by the similar Danish ban in 2010 (addressed in Section 4.1.1).

The impact assessment goes on with addressing the scope for national legislation vis-à-vis EU legislation. It recognises that there is no legal scope for issuing national bans or other restrictions on BPA in plastic products which fall within the field of application of the plastics food contacts regulation (10/2011/EU), but notes that: "*...in the field of varnish and coating there is a lack of detailed EU legislation, and consequently this field is not regarded as being fully harmonised. This means that there is legal scope for taking national measures if the prerequisite conditions for this are*

[39] Own translation. French text: "Art. 3/1. Le commerce ou mise dans le commerce et la fabrication de contenants destinés aux denrées alimentaires pour les enfants de 0 à 3 ans et contenant le bisphénol A sont interdits".

judged to be in place. Any national measures must meet the requirements set in the common foodstuffs legislation and in the treaties".

No legal analysis regarding choice of legal instrument has been identified. However, we assess that the provision is logically implemented in the Swedish Food Decree (2006:813). Article 6b states: "Bisphenol A, and compounds containing bisphenol A, must not be used in varnish and coating in the packaging of food particularly intended for children between 0 and 3 years of age." [40]

It is interesting to note that this scope is more limited than e.g. the Danish ban on BPA in food contact materials intended for the 0-3 year olds.

As can be seen from Table 1, comments to the Swedish EU notification were received from the Commission and detailed opinions launched by the Check Republic, Spain and the UK.

4.1.4 France - Ban on BPA in food contact materials

The scientific background for the national suspension of the manufacture, import, export and placement of the market of all food packaging products containing BPA is a report published in 2011 by the French National Agency for Food Safety and Occupational and Environmental Health (ANSES, 2011[41]). The report was prepared upon request from the French Directorate General for Health (DGS), requesting an expert assessment on BPA, taking into account all types of toxic effects (not only reprotoxic effects and/or effects related to endocrine disruption).

The report was drawn up by a working group of experts appointed by ANSES. The assessment relied on the review of publications made by national and international expert assessment authorities (EU-RAR, (2002-2008)[42], JRC (2010)[43], NTP-CERHR (2008)[44], Health Canada (2008)[45], OEHHA (2009)[46], AFSSA (2010)[47], INSERM (2010)[48]) and by 'Expert panels' such as Chapel Hill (2007)[49].

Original research papers that were considered as key studies for certain types of effects linked to BPA were also analysed by the working group, with particular focus on epidemiological studies and experimental animal studies conducted using low doses of BPA. "*The experts especially focused on studies assessing the effects of BPA at doses lower than the NOAEL of 5 mg/kg/day, which was used to establish EFSA's current Tolerable Daily Intake (TDI) (0.05 mg/kg/day) (2006, confirmed in 2010).*" (ANSES, 2011).

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[40] Own translation. Original Swedish text: "Bisfenol A, och föreningar där bisfenol A ingår, får inte användas i lack och ytskikt i förpackningar för sådana livsmedel som är särskilt avsedda
för barn mellan 0 och 3 år."

[41] ANSES (2011): Health effects of Bisphenol A. Collective Expert Report. Request nos. 2009-SA-0331 and 2010-SA-0197. Available online: http://www.anses.fr/sites/default/files/documents/CHIM-Ra-BisphenolAEN.pdf

[42] http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/phenolreport060.pdf
and
http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/15069/1/lbna24589enn.pdf

[43] Not specified, but we assume:
http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/14221/1/eur%2024389_bpa%20%20baby%20bottles_chall%20%20persp%20(2).pdf

[44] National Toxicology Program (NTP)(2008): NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. NIH, No. 08-5994 (NIH, Research Triangle Park, NC)

[45] Health Canada (2008): Évaluation préalable finale pour le défi concernant le Phénol, 4,4-(1-méthyléthylidène)bis (Bisphenol-A). Health Canada, (Health Canada, Ottawa)

[46] Office of Environmental Health Hazard Assessment California Environmental Agency (OEHHA) Reproductive and Cancer Hazard Assessment Branch (2009): Evidence on the developmental and reproductive toxicity of Bisphenol A. OEHHA, (OEHHA, Sacramento)

[47] Agence française de sécurité sanitaire des aliments (AFSSA) (2010a) Annexe de l'avis de l'AFSSA du 29 janvier 2010 relatif a l'analyse critique des résultats d'une étude de toxicité sur le développement du système nerveux ainsi que d'autres données publiées récemment sur les effets toxiques du bisphenol A. AFSSA, (AFSSA, Maisons-Alfort)

[48] Since the final report from the INSERM expert assessment was published in June 2011 (Collective expert assessment on Reproduction and the Environment), the Working Group's experts referred to the preliminary version of the INSERM report (June 2010).

[49] vom Saal FS, Akingbemi BT, Belcher SM *et al.* (2007): Chapel Hill bisphenol A expert panel consensus statement: integration of mechanisms, effects in animals and potential to impact human health at curren levels of exposure. *Reproductive Toxicology* **24,** 131-138.

The health effects investigated were

- Information from epidemiological studies
- Effects on the male reproductive system
- Effects on the female reproductive system
- Effect on the brain and behaviour
- Effects on metabolism and cardiovascular system
- Effects on the thyroid
- Effects on the immune system
- Effects on the intestine
- Effects on the prostate
- Effects on the breasts
- Information from ecotoxicological studies

For each type of effect, the working group characterised and qualified these effects in terms of:

- Recognised effects
- Suspected effects
- Controversial effects
- Effects for which no conclusion can be drawn on the basis of the available data.

In their conclusion, the working group recommends that the following effects should be considered in a human health risk assessment:

"Recognised in animals":

- Increased incidence of ovarian cysts on pre- and postnatal exposure,
- Hyperplastic changes in the endometrium on pre- and postnatal exposure,
- Advancement of the age of puberty on early pre- and postnatal exposure,
- Impairment of sperm production on exposure in adults,
- Histological changes in neurogenesis on pre- and perinatal exposure,
- Effects on lipogenesis following prenatal, perinatal, or adult exposure,
- Effects on the mammary gland: acceleration of structural maturation of the mammary gland in adults and development of hyperplastic intraductal lesions associated with pre- or perinatal exposure to BPA.

"Suspected in humans":

- Effects on oocyte maturation in women in the case of medically-assisted procreation,
- Effects on cardiovascular disease (coronary disease) and diabetes.

Data on recognised effects in humans are lacking, but "*the working group considered that the effects observed in animals can be transposed to humans, except in cases where it has been demonstrated that these effects observed in animals are specific to the species in question*" (ANSES, 2011).

In the 'Brief Statement of Grounds' in the EU notification message, several findings from the ANSES report are repeated:

- Health effects in animals found at low levels of exposure (below regulatory reference levels (a NOAEL of 5 mg/kg bw/day used by EFSA to establish the current TDI (ANSES, 2011))
- The possibility of a non-threshold dose-effect relationship
- Difficulty in finding a no-effect-level on the basis of the available scientific data
- The existence of exposure windows corresponding to periods of susceptibility to the effects of BPA
- The existence of susceptible groups (young children, pregnant women, infants)

and it is stated:

"*In consideration of these new findings, the conclusion reached by Anses is that sufficient scientific evidence has been found to immediately prioritise the prevention of exposure of the most susceptible groups: infants, young children, pregnant women and breastfeeding mothers*".

Thus, the justification for implementing a national suspension of the use of BPA in food contact materials is based on hazards indications and not on quantitative exposure or risk assessment. Specific exposure/risk assessment of the French population is not part of the background report.

A report assessing the current use of BPA in food contact materials/products and the availability of alternatives was referred to as part of the EU notification[50]. A literature study and an industry survey were conducted in order to obtain information on BPA containing products and alternatives to BPA for articles in contact with foodstuff.

The results from the study showed, that some alternatives to BPA exist and that for food contact materials intended for children under 3 years of age, the replacement of polycarbonate is already widely accepted by market agents. The most frequently used alternatives to polycarbonate are polypropylene (PP), polyphenylsulfone (PPSU) and Tritan™ copolyester. For other product types, such as the lining of cans using epoxy resins, no suitable alternative was found. The lids of glass jars and baby food jars also contains epoxy resins, but for these product types, a PVC film could be used to isolate the migration of BPA, even though it was noted that the effectiveness of this is still being questioned.

No specific investigation of the impact on industry was assessed in the study. However, the responses from the industry survey show that since the use of BPA has been prohibited in baby bottles since 2010, further prohibition of use in all tableware for children does not seem to pose any particular problem to the industry.

Some conclusions are also made regarding the socio-economic effects of an implementation of cardboard packages as alternatives to cans. It was found that they are currently not marketed in France, since they do no appeal to the French consumers at the moment.

A legal analysis vis-à-vis EU law is provided under 'Grounds of the Emergency' in the EU notification message: "*Article 9.7 of Directive 98/34 permits Member States, for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health (...) to prepare technical regulations in a very short space of time in order to enact and introduce them immediately. The opinions expressed by Anses, communicated by the French authorities in support of this notification, disclose the health effects of bisphenol A found in animals and suspected in humans, some of which occur at low levels of exposure.*"

No legal analysis for choice of legal instrument has been identified. The provision is implemented in the French Act (Loi no. 2012-1442, amending Loi no 2010-729 of 30 June 2010). Article 1 is intended to suspend manufacture, import, export and placement on the market of any packaging, container or utensil containing bisphenol A that is intended for food use, as of 1 January 2015.

It is stated in the act that said suspension shall take effect from the first day of the month following the enactment of law (i.e. 1 January 2013) if such packaging, containers and utensils are intended for use with foodstuffs for infants and young children.

Furthermore, it is stated that all packaging containing bisphenol A and which is intended to come into direct contact with foodstuffs must include a health warning advising against their use by preg-

[50] Rapport D´Étude 20/08/2011. N° DRC-11-115721-08982A - Identification d'actions de réduction des usages pour le Bisphénol A (BPA). Focus sur les articles en contact avec les aliments (notamment pour les enfants, hors biberons). Available online: http://www.ineris.fr/substitution-bpa/sites/default/files/documents/rapport%20substitution%20BPA.pdf

nant women, breastfeeding women and infants and young children. NB! The decree suggested for implementing the modalities for this provision is addressed in section 4.1.6 (below).

In article 2 part II it is stated that a subsection (1 bis) should be inserted in Article L.5231-2 from the Code of Public Health[51]. Article L.5231-2 then states that manufacture, selling, exposure and import of pacifiers and teething rings containing bisphenol A is banned. As this is not food contact materials, this provision will be further addressed in section 4.3.2.

As can be seen from Table 1, comments to the French EU notification were received from the Commission, Italy and Slovenia and detailed opinions were launched by the Czech Republic, Spain, the Netherlands, and the UK.

4.1.5 Germany – migration limit for paper/board of recycled fibres used for food contact materials

Food contact materials (and their chemical content) are subject to the general provisions of the "framework" regulation for food contact materials (Regulation EC/1935/2004), specifying that materials and articles that come into contact with food shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health. For a number of specific materials[52], further legislation specifically identify migration limits of contained substances, e.g. the plastic food contact materials regulation with a specific migration level of 0.6 mg BPA/kg food (see also Introduction). Chemicals in paper/board used for food packaging are not subject to specific harmonised EU legislation.

The Federal Institute for Risk Assessment (BfR - Bundesinstitut für Risikobewertung) informs in an e-mail that the BPA migration level for paper/board based on recycled fibres used for food contact materials is adopted from the plastic food contact material regulation (10/2011) and is thus implicitly based on the same scientific evidence[53]. BfR points out that the migration level will be reconsidered as soon as the EFSA re-evaluation of BPA is finalised (see Introduction). BfR further notes that BPA in recycled fibres may originate from BPA in thermal paper.

The national migration limit is implemented in a non-legally binding Recommendation (Empfehlung) and thus not subject to EU notification.

4.1.6 Preparation/consideration France – modalities for implementing labelling/warnings

Article 2 of the LOI n° 2012-1442 (the French national provisions discussed in Section 4.1.4) specifies a labelling requirement for food contact materials until such material is eventually suspending given the ban of such product by 2015.

These provisions are suggested to be implemented as a decree, specifying the modalities for affixing the health warnings. This decree is subject to EU notification procedure "2013/230/F".

No specific scientific background document is available for this proposed legal provision. However, as indicated, the decree should be seen in the context of the background information submitted as part of the ban on BPA in food contact material's (discussed in Section 4.1.4).

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[51] http://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006690335&dateTexte=&categorieLien=cid

[52] http://ec.europa.eu/food/food/chemicalsafety/foodcontact/spec_dirs_en.htm

[53] http://www.efsa.europa.eu/en/efsajournal/pub/428.htm

The EU notification message provides the following 'Brief Statement of Grounds': "*Health warnings are to be displayed over the transitional period running up to 1 January 2015, prior to the suspension of the manufacture, import, export and marketing either free of cost or for profit of packaging, containers or utensils containing bisphenol A intended to enter into direct contact with food products.*

Its purpose is to inform consumers of food packaging that still contains bisphenol A and to warn against their use for pregnant and breast-feeding women and infants and young children."

In response to the EU notification, comments were received from Denmark and detailed opinions were launched from Belgium, the Czech Republic, the Commission, Spain, Italy, the Netherlands, and the UK.

As set out in Table 1, we have as part of this project received the following statement from the French authorities in relation to the on-going EU notification procedure: "*We received many comments and need to think of all of it*". Thus, it appears that France is currently considering whether and if so how to progress with this decree.

4.2 Occupational Exposure Limits

As set out in the introduction, a European Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 (8-hour TWA[54]; as inhalable dust) is in place based on a SCOEL (Scientific Committee on Occupational Exposure Limits) recommendation from 2004 (SCOEL/SUM/113, May 2004).

According to Article 3 of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, IOELs are non-binding, although member states shall implement an OEL for substances with IOEL taking into account the Community limit value, as well as the national legislation and practice. Thus, deviations from an IOEL would not require the national legal provision to be submitted as an EU notification.

Recently, SCOEL has updated its recommendation and recommends an OEL of 2 mg/m^3 for Bisphenol A (8-hour TWA; as inhalable dust) in a draft document which was for consultation until September 2013 (SCOEL/SUM/113; March 2013).

As set out in the "Introduction", the updated recommendation is based on the same inhalation study as the original value, but with a higher assessment factor and thus lower recommended OEL.

4.2.1 Denmark

The Danish Working Environment Authority informs that the Danish OEL of 3 mg/m^3 for BPA is based on the general national OEL for organic dust of 3 mg/m^3. Based on precaution this value was kept when the EU IOEL of 10 mg/m^3 for BPA was established, also to avoid unnecessary exposure to substances where the EU IOEL is higher.

4.2.2 Germany, Switzerland, Austria

The German, Swiss and Austrian OELs are all based on the German MAK[55] Documentation of 1996[56] prepared by the Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (the "MAK Commission").

The MAK value is based on the NOAEL of 10 mg/m^3 from the same 13 week inhalation study/studies as the OEL recommended by SCOEL. It is stated that: "A MAK value of 5 mg/m^3 can be set on the basis of a no effect concentration of 10 mg/m^3." Thus although not stated explicitly, an assessment factor of 2 has been applied to arrive at the MAK/OEL.

[54] Time Weighted Average
[55] MAK: Maximale Arbeitsplatz-Konzentration.
[56] http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb8005e0013/pdf (official English translation)

The NOAEL from the repeated inhalation study is compared with the NOAEL from other oral studies (including a multigenerational study) and considered the most conservative.

The MAK documentation was amended in 2011[57] where it was noted in the conclusion that the relevant mode of action for of BPA is the local effect on the respiratory tract. At the same time it is noted that the weak oestrogenic activity of BPA and thereby its possible reproductive activity is up for discussion. As no new inhalation studies are available the OEL/MAK-value of 5 mg/m^3 from 1996 is maintained.

4.2.3 Finland

The current Finnish OEL entered into force in 2011. In a note received from the Ministry of Social Affairs and Health Department for Occupational Safety and Health, reference is made to the studies considered critical by EFSA (NOAEL 5 mg/kg bw/day) and SCOEL (10 mg/m^3) and it is noted that "*Although the experts in this field have not come to a consensus on the critical dose and effect, it is clear that doses lower than 10 mg/m^3 might cause adverse effects.*" It was therefore concluded that the Finnish OEL should be lower than the EU IOEL. It was decided to set the OEL for BPA at 5 mg/m^3 (which corresponds to the Finnish OEL for organic dust of substances without a substance-specific OEL), but it was concluded that the situation regarding BPA has to be followed, and the OEL should be re-evaluated within a near future.

Currently, Finland is awaiting the new SCOEL recommendation and after the finalization of that, the national OEL will be re-evaluated.

Finally, it can be noted that the Finnish authorities informed that: "*The Finnish OEL-values are not binding, but according to our national legislation, the employers have to take them into account when carrying out the mandatory risk assessments at the workplaces*".

4.3 Other Legislation

4.3.1 Austria - pacifiers and teething rings

The scientific basis for national BPA legislation relating to pacifiers and teething rings is laid down in a Scientific Statement from the Austrian Agency for Health and Nutrition[58]. This statement has been provided to the project under confidentiality and can therefore not be summarised. However, key findings/extracts from this statement are presented as part of the Impact Assessment available at the EU notification web-site and will be summarised here.

The impact assessment highlights the conflicting evidence and opinions regarding the toxicity/low-dose toxicity of BPA; EU risk assessment and EFSA opinion versus e.g. German (BfR), French (AFSSA/ANSES) and Danish (Technical University of Denmark) studies/opinions highlights hormone-like effects and ambiguity in existing evidence. It is also pointed out that a number of new studies have become available after the tolerable daily intake (TDI) was established by EFSA. Reference is also made to an assessment from the US National Toxicology Program giving rise to concern regarding negative effects on the brain, behaviour and the prostates of foetuses, infants and babies, and that Canada and several states in the US have found it necessary to take measures to reduce infant BPA exposure.

Overall, it is argued that these uncertainties were the drivers for implementing the EU ban on BPA in baby bottles and that banning/reducing BPA in pacifiers and teething rings would follow the

[57] http://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb8005d0050/full (available in German only)
[58] AGES-DSR: Wissenschaftliche Stellungnahme: Bewertung von BPA und Handlungsoptionen zur Reduktion im kindernahen Bereich. 22 October 2010.
AGES: Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH. DSR: Daten, Statistik und Risikobewertung.

same logic as in the case of infants exposed to baby bottles. Thus, using pacifiers/teething rings fall "*... into precisely this developmental phase*".

Conclusions regarding the impacts on government, employment and companies are summarised as follows in the provided impact assessment:

- Financial effects: This will not result in any additional costs to the Federal Government and the Federal States;
- Effects on the administrative burdens for companies: The legislation does not contain any duties to provide information, and
- Impacts on employment in Austria and on the business location of Austria: None.

These conclusions are not further elaborated.

The EU notification message does not add any details to the above, but states as 'Brief Statement of Grounds': "*The enactment of this Regulation is necessary in the sense of preventative health protection*".

No legal analysis vis-à-vis EU legislation has been identified.

No legal analysis regarding choice of legal instrument has been identified. The national provision is implemented as a so-called Bundesgesetzblatt (Teil II, No. 327/2011) on the basis of Section 19, Paragraph 1 of the Food Safety and Consumer Protection Act (*Lebensmittelsicherheits- und Verbraucherschutzgesetz* – LMSVG), Federal Law Gazette I No 13/2006, last amended by Federal Act Federal Law Gazette I No 95/2010). The legal text specifies: "It is prohibited to manufacture pacifiers and teething rings with bisphenol A or place them on the market."[59]

Comments to the EU notification were launched by the Commission and detailed opinions by the Check Republic, the Netherlands and the UK.

4.3.2 France – ban on pacifiers and teething rings

As noted in Section 4.1.4, this provision was implemented via the same act (Loi no. 2012-1442) as the food contact material provisions.

We have not identified specific background documentation (risk assessment, alternatives/impact assessment nor legal analysis) related to this provision. As Loi no. 2012-1442 was the outcome of the EU notification process "2011/529/F", it must implicitly be assumed that this provision is covered by that process, although the documentation available on the public EU notification site does not clearly state that a ban of BPA in pacifiers and teething rings is part of the notification.

Although, pacifiers and teething rings are not explicitly addressed, the scientific aspect regarding low-dose effects of BPA, in particular in relation to infants/small children, must be assumed to implicitly address the pacifier and teething ring exposure scenario as well.

The provision is implemented via article 2 part II of Act 2012-1442 (Loi no. 2012-1442) specifying that Article L.5231-2 in the Code of Public Health[60] should be adapted to state that manufacture, selling, exposure and importation of pacifiers and teething rings containing bisphenol A is banned[61].

[59] English text taken from proposed legal text in the in EU notification. Original text: "Es ist verboten, Beruhigungssauger und Beißringe mit Bisphenol A herzustellen oder in Verkehr zu bringen."

[60] http://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006690335&dateTexte=&categorieLien=cid

[61] Original text: "Sont interdites la fabrication, la vente, la mise en vente, l'exposition et l'importation: ... 1° bis Des collerettes de tétines et de sucettes et des anneaux de dentition comportant du bisphénol A"

4.3.3 Preparation/consideration Sweden – Ban on BPA in thermal paper in receipts

The Swedish Chemicals Agency (KEMI) was commissioned by the Swedish Government to prepare a proposal for a Swedish ban on BPA in thermal paper used in cash receipts, tickets, etc.

Addressing this, KEMI has prepared the background report "Bisphenol A in cash receipts – report from a government assignment[62]" addressing, among others, risks, alternatives, impact assessment, legal analysis and a proposal for a legal text.

The risk assessment constitutes a quantitative exposure, hazard (reference dose) and risk characterisation and addresses dermal exposure and oral exposure (children licking receipts), respectively, with focus on the dermal exposure.

As this is the only identified background report carrying out a full and quantitative risk assessment, this will be summarised in some detail.

Risk assessment - dermal exposure. A worst case **internal exposure (following dermal contact)** is estimated to be **in the range of 1 µg/kg body weight/day**, considering:

- thermal paper for receipts contain about 1-2% BPA (Biedermann et al, 2010[63], Östberg and Noaksson, 2010[64]);
- a dermal uptake of about 10% (conservative estimate based on weight-of-evidence considering Biedermann et al. 2010[63], Kaddar et al. 2008[65], EU RAR, 2003[66] and Zalko et al., 2010[67] and the fact that BPA has a relatively high fat solubility and small molecule size);
- an estimated maximum human absorption of 0.25 µg/cm^2/hour (based on in vitro penetration studies performed by Marquet et al., 2011[68] – showing inter alia that human dermal absorption is 10 times slower than for rats and that there is high human variability);
- exposed skin is assumed to be 200 cm^2 (both hand palms), and
- 60 kg body weight.

It is noted that estimating BPA exposure is highly uncertain considering various aspects such as uncertainty and inter-human variability regarding dermal BPA absorption, number of receipts handled per day, handling time, how receipts are handled (with fingers or with entire palm), etc. Overall, the estimated exposure is considered worst case.

Regarding hazards, focus is on neurotoxicological low-dose effects. It is estimated that by May 2012 about 60 such studies are available. Although it was outside the scope of the analysis to go through these studies in detail, the following arguments/analyses are presented:

- about 54 (of the 60) studies indicate BPA effects and are thus considered as an indication for the ability of BPA exposure to affect the development of the brain in test foetus animals (it is noted that the test design of these studies can be criticised as well as the more traditional multigeneration studies of BPA);
- Effect levels in these studies vary between 0.25 and 200.000 µg/kg/day (median 40 µg/kg/day);

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[62] Own translation. Original title: "Bisfenol A i kassakvitton – rapport från ett regeringsuppdrag – Rapport Nr. 4/12". Avaialble at (only available in Swedish): http://www.kemi.se/en/Content/News/Proposal-for-a-Swedish-ban-on-bisphenol-A-in-receipts/

[63] Biedermann S, Tschudin P, Grob K. 2010. Transfer of bisphenol A from thermal printer paper to the skin. Anal Bioanal Chem 398: 571-576.

[64] Östberg T, Noaksson E. (2010), BPA i svenska kvitton, Jegreliusinstitutet för tillämpad grön kemi, Jämtlands läns landsting.

[65] Kaddar N, Harthé C, Déchaud H, Mappus E, Pugeat M. 2008. Cutaneous penetration of bisphenol A in pigskin. J Toxicol Environ Health A 71: 471-473

[66] http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/phenolreport060.pdf

[67] Zalko D, Jacques C, Duplan H, Bruel S, Perdu E. 2011. Viable skin efficiently absorbs and metabolizes bisphenol A. Chemosphere 82: 424-430.

[68] Marquet F, Payan JP, Beydon D, Wathier L, Grandclaude MC, Ferrari E. 2011. In vivo and ex vivo percutaneous absorption of 14C-bisphenol A in rats: a possible extrapolation to human absorption? Arch Toxicol 85: 1035-1043.

- Although not applicable for risk assessment, it is noted that 3 of 4 available epidemiological studies indicate a correlation between BPA exposure and change in behaviour;
- 33 studies address oral exposure during pregnancy and lactation, where the brain function of the foetuses have been investigated;
- Of these, three studies are chosen for deriving (alternative) reference values. The corresponding dose descriptors are:
  - LOAEL[69]: 500 µg/kg/day (Xu et al 2010[70]; male offspring mice; study considered robust)
  - LOAEL[69]: 200 µg/kg/day (Ryan and Vandenberg, 2006[71]; female mice; study considered robust)
  - NOAEL: 5 µg/kg/day (Jones et al, 2011[72], effects seen in male rats, study considered uncertain), and
- By applying the REACH default assessment factors (3 for LOAEL to NOAEL extrapolation, 4(rats)/7(mice) for allometric scaling, 2.5 for other interspecies variation and 10 for human intraspecies variation), gives the following (alternative) reference values:
  - **0.05 µg/kg/day**
  - **0.4 µg/kg/day**
  - **0.95 µg/kg/day**

The risk characterisation is presented as risk quotients (exposure/reference value), where values above 1 would indicate a risk. The risk characterisation is presented in Table 4 (adapted and translated from the KEMI report). The final row addresses for comparison a risk characterisation considering the EFSA reference value.

TABLE 4
KEMI RISK CHARACTERISATION FOLLOWING DERMAL EXPSORUE TO BPA IN CASH RECEIPTS

Exposure (systemic/internal; µg BPA/kg bw/day)	Reference dose (µg BPA/kg bw/day)	Risk quotient (Exposure/ref. dose)	Reference
1	0.05	20	Jones et al., 2011
1	0.4	2.5	Ryan and Vandenberg, 2006
1	0.95	1.05	Xu et al., 2010
1	50	0.02	EFSA TDI

The table shows that all the alternative scenarios based on neurotoxicological effects give rise to concern as opposed to the scenario applying the EFSA TDI.

Please note that the reference value is based on oral studies (as no appropriate dermal studies were assessed to be available for risk assessment).

Risk assessment - Oral exposure. A scenario is presented considering that a child could lick on a receipt. Estimating that a receipt weighs 100 mg, a 10 kg child would maximally be exposed to 1-2 mg BPA corresponding to an **oral exposure of 100-200 µg/kg bw/day.**

[69] LOAEL is preferred rather than the NOAEL due to large spans in dosing
[70] Xu XH, Zhang J, Wang YM, Ye YP, Luo QQ. 2010. Perinatal exposrue to bisphenol A impairs learning-memory by concomitant down regulation of N-methyl_D_aspartate receptors of hippocampus in male offspring mice. Hormones and behavior 58: 326-333.
[71] Ryan BC, Vandenbergh JG. 2006. Developmental exposure to environmental estrogens alters anxiety and spatial memory in female mice. Hormones and behavior 50(1): 85-93.
[72] Jones BA, Shimell JJ, Watson NV. 2011. Pre- and postnatal bisphenol A treatment results in persistent deficits in the sexual behavior of male rats, but not female rats, in adulthood. Hormones and behavior 59(2): 246-251.

Applying a NOAEL of 320 µg/kg bw/dag (Viberg et al, 2011[73]; young mice exposed orally to BPA) and an assessment factor of 175 (allometric scaling mice: 7; other intraspecies uncertainties: 2.5; intraspecies uncertainties: 10) gives a **reference dose of 1.8 µg/kg bw/day**.

Comparing these figures indicate a **risk quotient > 50** and thus a relatively high risk.

Alternatives/impact assessment. The assessment shows that thermal paper alternatives not containing BPA are commercially available and concludes that substitution is possible. At the same time, the assessment points out that it cannot be assured that increased use of alternatives would lead to a higher safety level in the short term as the alternatives (several of which are also bisphenols) also possess undesired health and environmental properties. In the longer term, however, it is assessed that banning BPA might motivate innovation/product development and the transfer to digital solutions[74]. It is also noted that national initiatives might impact on the EU legislation.

In terms of wider impacts, it is assessed that some market reorganization will take place, including new possibilities for suppliers of alternatives and that there will be increased administrative costs related to transferring information in the supply chain. Further, it is concluded that there will be increased costs for the inspecting authorities (costs for analyses/tests, inspection, for providing information and for dialogue with enterprises).

Legal analysis. The legal analysis contain a discussion of how regulating the use of products containing BPA is addressed in existing EU legislation (with focus on REACH, CLP and the Product Safety Directive) and concludes that these instruments are not regulating BPA in thermal paper. It is also concluded that a national Swedish restriction would have to be notified to the EU as well as to WTOs[75] TBT[76] agreement. It is assessed that Sweden should be able to argue that a national BPA ban in receipts is compliant with EU provisions; i.e. that it will protect health, it is objectively motivated, proportionate and necessary. In this context, various references to European court decisions are referenced, please see the KEMI report for details.

Interestingly, the legal analysis also notes that the European Commission has recently claimed (with reference to the 98/34/EU notification process and Article 69.4 in REACH) that EU Member States cannot implement national restrictions for chemicals, unless the country first prepares a REACH restriction dossier. However, Sweden and a number of other Member States do not agree with the Commission pointing to the shared legislative competence as e.g. evident from REACH Article 128.2.

The legal analysis logically suggests including the ban in the [Swedish] Environmental Code (Miljöbalken – SFS 1998:808), which is generally used as the legislative instrument regarding national restrictions related to handling, import and export of chemicals; as well as for the transposition of EU provisions into Swedish law. The suggested legal text specifies that undertakings which according to Swedish legislation are obliged to provide documentation for receipts for payment of goods are not allowed to use cash receipts to which BPA has been added[77].

Dialogue with representatives from the Swedish Environmental Ministry, informs that the legislative process is currently on hold, awaiting the French REACH restriction proposal regarding BPA in thermal paper, foreseen early 2014.

[73] Viberg H, Fredriksson A, Buratovic S, Eriksson P. 2011. Dose-dependent behavioural disturbances after a single neonatal Bisphenol A dose. Toxicology 290: 187-194.

[74] Please note that the Danish EPA in a parallel with the current project has commissioned a project, among others, looking into technological alternatives such as e-receipts.
[75] World Trade Organisation
[76] Technical Barriers to Trade
[77] Original Swedish text: "Verksamhetsutövare som omfattas av dokumentationsskyldigheten i 39 kap. i skatteförvaltningslagen (2011:1244) ifråga om kassaregister får inte tillhandahålla kassakvitton som innehåller tillsatt bisfenol A."

5. Discussion/comparison of national initiatives

The findings from the analysis of scientific and legal background information presented in Chapter 4 are summarised in Table 5 and will be subject to a comparative discussion in this chapter.

5.1 Scope of national provisions

In relation to banning BPA in food contact materials, Denmark and Belgium generally bans BPA in food contact materials intended to come into contact with food for the 0-3 year olds. Sweden has a narrower scope, banning BPA in varnish and coatings in food contact materials intended for the 0-3 year olds (see also below section "Legal analysis vis-à-vis EU legislation).

France implements a general ban for all food contact materials (intended for all ages), although it is implemented two years earlier for food contact materials intended for infants and small children. Until the ban enters into force, France has also implemented a provision for labelling food contact material packaging containing BPA with a health warning advising against their use by pregnant women, breastfeeding women, and infants and young children. However, the separate EU notification for the decree with the modalities for implementing this provision has been subject to a number of comments/opinions for the Commission and other Member States. France is therefore currently considering whether/how to proceed with this decree.

In relation to food contact materials, Germany has implemented (in a non-legally binding Recommendation) a migration limit for recycled fibres used for paper/cardboard food contact materials. The migration limit (0.6 mg BPA/kg food) is adopted from the harmonised EU migration limit in the plastic food contact material regulation.

An EU Indicative Occupational Exposure Limit (IOEL) of 10 mg/m^3 exists. A number of Member States operate with lower national OELs: i) Denmark (3 mg/m^3), Finland (5 mg/m^3), Germany (5 mg/m^3), Austria (5 mg/m^3) and Switzerland (5 mg/m^3). It can be noted that in an on-going process, the EU Scientific Committee on Occupational Exposure Limits (SCOEL) has recommended lowering the EU OEL to 2 mg/m^3.

France and Austria have implemented bans on pacifiers and teething rings with the slight difference that Austria refers to banning BPA in the manufacturing of such items.

Sweden has prepared a national provision for banning BPA in thermal paper for cash receipts, but is currently awaiting a French REACH restriction proposal on the same issue.

5.2 Scientific background

It can be seen that the implemented or proposed bans of BPA in food contact materials, thermal paper, as well as pacifiers and teething rings are all by-and-large supported by the scientific argument that the uncertainties related to the possible low-dose effects (endocrine disrupting properties/development neurotoxicity) of BPA, in particular in relation to infants/small children/pregnant women. The increasing evidence of such possible effects is used as the main argument for exclud-

ing/minimising exposure to BPA as a precautionary measure. In addition to this, Sweden (proposed ban on BPA in thermal paper) presents a quantitative risk assessment showing risks (risk characterisation quotients above 1) for dermal as well as oral (children licking cash receipts) exposure scenarios. We have not identified exposure/risk assessments specifically addressing the situation in countries were the national bans are implemented or suggested. The issue of possible low-dose effects of BPA is foreseen to be (one of) the main issue addressed in the upcoming EFSA re-evaluation of BPA (see "Introduction").

In essence, these national legislations can be seen in the light of the precautionary principle (PP) as described in the Commission Communication on the PP[78], i.e. that scientific uncertainty with possibly significant risks of effects can lead to (legal) interventions. However, it is outside the scope of this report and the information available to analyse whether all elements as required in the PP communication have been addressed in relation to the individual national legislations. The Swedish background document for banning BPA in thermal paper analyses the PP as defined in the communication.

The EU IOEL (based on a SCOEL recommendation), as well as deviating national OELs in Germany, Switzerland and Austria (all based on the German MAK documentation) are based on the same inhalation study showing irritation following inhalation (NOAEL 10 mg/m^3). Although discussing the issue of endocrine/low-dose effects, these background documentations do not find sufficient evidence for these effects. The same is the case for a recently suggested update of the SCOEL recommendation (public hearing just finalised), which suggests a lower OEL, but still based on the same inhalation, just with a higher assessment factor. This higher assessment factor is not justified based on possible low-dose-effects.

The Danish and Finnish deviations from the EU IOEL are partly based on the fact that the national OELs for biological dust are lower than the EU OEL for BPA and it is for precautionary reasons not found justified using higher OELs for BPA. In direct correspondence, Finland further notes the on-going discussions regarding possible low-dose effects of BPA. Germany and Finland specifically note that they are awaiting the outcome of the on-going SCOEL update of the EU OEL.

5.3 Assessment of alternatives/assessment of wider impacts

In relation to information identified in/provided to the project, the following implemented or possibly upcoming provisions have addressed availability of alternatives/wider impacts in the background documentation:

- Denmark (food contact): Alternatives briefly addressed
- Belgium (food contact): Alternatives briefly addressed
- Sweden (food contact): Assessment of alternatives and wider impacts addressed in some detail
- France (food contact): Assessment of alternatives addressed in quite some detail and some wider impacts addressed
- Austria (pacifiers and teething rings): Conclusions regarding impacts very briefly summarised (actual background analysis not available to project)
- Sweden (proposed ban on BPA in thermal paper): Rather detailed analysis of alternatives and wider impacts

Thus, the impression is that alternatives and wider impacts are generally not addressed in great detail in relation to these national BPA provisions.

[78] Communication from the Commission on the precautionary principle. COM(2000) 1. European Commission. Brussels, 02.02.200.

However, to this end, it should be stressed:

- Analyses/assessments might be available that have not been provided to the project;
- The project has not had access to the comments and opinions provided in response to the respective EU notifications, as well as responses to such comments/opinions and subsequent negotiations, and
- In relation to food contact materials, it seems that BPA to a large extent is already substituted; e.g. as specified in relation to the Swedish ban indicating that substitution has already taken place due to national provisions in other countries.

5.4 Legal analysis vis-à-vis EU legislation

In their EU notification messages, Denmark and France explicitly justify their notifications based on Article 9, Paragraph 7 of the Information Procedure Directive (Directive 98/34/EC) as they consider that BPA poses a serious health threatening effect. It should be noted that the Danish and French bans are applicable to all types of materials. Interestingly, Sweden also pointing to the possible serious health threatening effects of BPA (although not explicitly pointing to Article 9, Paragraph 7 of the Information Procedure Directive), does not find scope for implementing a national ban in plastic food contact materials as this is considered EU harmonised via the plastic food contact materials regulation. The Swedish ban is therefore limited to 'varnish and coatings' (for which EU rules are not considered harmonised) in food contact materials.

In relation to a possible upcoming Swedish ban on BPA in thermal paper, a rather detailed legal analysis is available. Existing EU legislation is reviewed and it is concluded that existing EU legislation will not reduce BPA exposure in thermal paper. Reference is made to several European court decisions in relation to implementing national bans, and it is concluded that Sweden should be able to argue that a national BPA ban in cash receipts is compliant with EU provisions; i.e. that it will protect health, it is objectively motivated, proportionate and necessary.

Interestingly, the legal analysis also notes that the European Commission has recently claimed (with reference to the 98/34/EU notification process and Article 69.4 in REACH) that EU Member States cannot implement national restrictions for chemicals, unless the country first prepares a REACH restriction dossier. However, Sweden and a number of other EU Member States do not agree with the Commission pointing to the shared legislative competence as e.g. evident from REACH article 128.2.

As noted elsewhere, the legal process in relation to implementing the Swedish national ban is currently on hold as France in the meantime is preparing an EU restriction dossier on this issue (expected early 2014).

No legal analyses have been provided for the deviations from the EU IOEL, but this appears logical as Article 3 of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, provides for such deviations. In the same view no legal analysis has been identified in relation to the German non-legally binding migration limit for BPA in fibres to be used for food packaging.

5.5 Legal analysis in relation to choice of legal national instrument

Background documents on this issue have generally not been identified in/provided to the project, the only exemption being in relation to the proposed Swedish ban on BPA in thermal paper.

Possible reasons for this could be:

- Such analysis have not been provided to the project
- In most cases, the national implementation seems rather logical/straightforward (OELs implemented in national OEL lists and BPA bans in food contact materials in national food contact materials legislation)

TABLE 5
COMPARATIVE SUMMARY OF ANALYSIS OF BACKGROUND DOCUMENTATION FOR NATIONAL BPA PROVISIONS

	Based on precaution with reference to BPA low dose effects	Quantitative hazard, exposure , risk assessment	Assessment of alternatives	Assessment of impacts on government, industry, ...	Legal analysis – vis-à-vis EU legislation	Legal analysis – choice of national instrument	Comment
Denmark – Ban of BPA in food contact materials intended to come into contact with food for 0-3 year olds	Yes	Not available/identified	(Yes): Briefly mentioned that alternatives are available	Not available/identified	Yes. Based Article 9, Paragraph 7 of the Information Procedure Directive. *"...serious, health threatening effect which the authorities do not dare ignore..."*	No	
Belgium – Ban of BPA in food contact materials intended to come into contact with food for 0-3 year olds	Yes	Not available/identified	(Yes)/no: Briefly mentioned that replacement of polycarbonate bottles with polypropylene or polyether sulfone bottles is possible (opinion published prior to the EU ban). Alternatives to other BPA applications not addressed.	Not available/identified	Not available/identified	Not available/identified	

	Based on precaution with reference to BPA low dose effects	Quantitative hazard, exposure , risk assessment	Assessment of alternatives	Assessment of impacts on government, industry, …	Legal analysis – vis-à-vis EU legislation	Legal analysis – choice of national instrument	Comment
Sweden – Ban of BPA in varnish and coatings food contact materials intended for 0-3 year olds	Yes	Not available/identified	Yes: "Substitution has already taken place"	Yes: "not entail any additional costs or other consequences for industry"	Yes: i) no legal scope for issuing national bans or other restrictions on BPA in plastic articles (considered harmonized via plastic food contact material regulation), but ii) "…*in the field of varnish and coating there is a lack of detailed EU legislation, and consequently this field is not regarded as being fully harmonised*	Not available/identified	NB! Legal analysis seems to conflict with national legislation in e.g. Denmark, Belgium and France, also banning BPA in food contact materials made of plastic
France – ban in all food contact materials	Yes, although it the underlying opinion is more explicitly convinced of demonstrated low-dose-effects than other several other BPA opinions	Not available/identified	Yes: A report assessing the current use of BPA in food contact products and the availability of alternatives was provided from the EU notification site	Yes: an industry survey was a part of a report provided from the EU notification site. " *since the use of BPA have been prohibited sin baby bottles since 2010, further prohibition of use in all tableware for children does not seem to pose any particular problem for the industry."* Cardboard boxes as alternatives to cans) was found not to be available on the French market.	Yes. Based Article 9, Paragraph 7 of the Information Procedure Directive. "*The opinions expressed by Anses, communicated by the French authorities in support of this notification, disclose the health effects of bisphenol A found in animals and suspected in humans, some of which occur at low levels of exposure."*	Not available/identified	

	Based on precaution with reference to BPA low dose effects	Quantitative hazard, exposure , risk assessment	Assessment of alternatives	Assessment of impacts on government, industry, ...	Legal analysis – vis-à-vis EU legislation	Legal analysis – choice of national instrument	Comment
Germany – BPA migration limit for recycled fibres used for food contact materials	No, based on the EFSA Tolerable Daily Intake	(Hazard - Yes) Transfer of the migration level from plastic contact materials to paper/board; i.e. implicitly based on TDI established by EFSA	No – not applicable	Not available/identified	Not available/identified, but implicitly not required as migration limit is not legally binding	Not available/identified	The migration limit will be re-evaluated based on the upcoming EFSA re-evaluation
France – modalities for implementing labelling/warnings (possibly upcoming)	Yes. (Not directly stated, but implicitly assumed as it should be seen in context with the above discussed French ban on BPA in food contact materails)	Not available/identified	(Yes, see above entry regarding French BPA ban in food contact materials)	(Yes, see above entry regarding French BPA ban in food contact materials)	Not available/identified	Not explicitly identified, but naturally suggested implemented in relation to French BPA ban in food contact materials (see above)	
Denmark - OEL	Yes, but not to address the possible developmental neurotoxicity of BPA	No. It is assessed as not justified to establish a higher value for BPA than the Danish OEL for organic dust	Not available/identified	Not available/identified	Not explicit, but implicitly a Member State has to implement a national OEL when an EU IOEL is established and deviations are allowed taking into account national practice and legislation	Not explicit, but logically implemented as part of national OEL list	

	Based on precaution with reference to BPA low dose effects	Quantitative hazard, exposure , risk assessment	Assessment of alternatives	Assessment of impacts on government, industry, ...	Legal analysis – vis-à-vis EU legislation	Legal analysis – choice of national instrument	Comment
Germany, Switzerland, Austria – OEL **(all based on German MAK documentation)**	No	OEL is quantitatively derived from the same inhalation study as used by SCOEL for the EU IOEL, but with a higher assessment factor	Not available/identified	Not available/identified	Not explicit, but implicitly a Member State has to implement a national OEL when an EU IOEL is established and deviations are allowed taking into account national practice and legislation	Not explicit, but logically implemented as part of national OEL lists	Germany notes the upcoming new SCOEL IOEL
Finland - OEL	Partly and will be re-evaluated once the work with the SCOEL revision is completed	Based on weight-of-evidence taking into account the current Finnish OEL for organic dust and awaiting new IOEL based on SCOEL re-evaluation	Not available/identified	Not available/identified	Not explicit, but implicitly a Member State has to implement a national OEL when an EU IOEL is established and deviations are allowed taking into account national practice and legislation	Not explicit, but logically implemented as part of national OEL list	
Austria – Ban of BPA in the manufacture of pacifiers and teething rings	Yes	No	Not available/identified	Briefly addressed in EU notification material, generally concluded no/very limited impacts	Based on the arguments: - Basically having the same intention and scope of protecting infants as the EU ban on BPA in baby bottles *- The enactment of this Regulation is necessary in the sense of preventative health protection*	Not available/identified	
France – Ban of BPA in pacifiers and teething rings	Yes	Not identified/available	Not identified/available	Not identified/available	Not identified/available	Not identified/available	

	Based on precaution with reference to BPA low dose effects	Quantitative hazard, exposure , risk assessment	Assessment of alternatives	Assessment of impacts on government, industry, ...	Legal analysis – vis-à-vis EU legislation	Legal analysis – choice of national instrument	Comment
Sweden – possibly upcoming BPA ban in thermal paper	Yes - background material indicate that the performed quantitative risk assessment is based on an "alternative" no effect level from the non-guideline developmental neurotoxicity studies	Yes, fully quantitative risk assessment based on worst case exposure estimation and NOAELs/LOAELs from neurotoxicological low-dose effects. Risk quotients above one (for dermal as well as oral exposure) are estimated, indicating that there is a risk. It is acknowledged that exposure estimates are conservative and the controversies related to neurotoxic effects.	Yes, it is assessed that alternatives are available and that substitution is possible. However, health and environmental issues with alternatives are highlighted and thus a ban might not in the short term lead to reduced health impacts.	Yes: - some market reorganization will take place, including new possibilities for suppliers of alternative - increased administrative costs related to transferring information in the supply chain - increased costs for the inspecting authorities - in the longer term a ban might trigger innovation/product development and impact on the EU legislation	Yes - Existing EU legislation will not reduce BPA exposure in thermal paper - EU (and WTO) notifications assessed to be required - Sweden should be able to argue that a national BPA ban in receipts is compliant with EU provisions; i.e. that it will protect health, it is objectively motivated, proportionate and necessary. Reference is made to several European court decisions. - NB! Sweden points to the different view between the European Commission and several Member States in relation to whether member states can implement bans for applications of chemicals within the scope of REACH	Yes Such a ban would logically be implemented in the [Swedish] Environmental Code.	

List of abbreviations

AFSSA	French Agency for Food Safety, now ANSES
AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH.
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety)
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)
BPA	Bisphenol A
bw	body weight
CERHR	Center for the Evaluation of Risks to Human Reproduction
CLP	Classification, Labelling and Packaging (acronym for the EU classification and labelling legislation)
CSS	Conseil Supérieur de la Santé (Belgian Superior Health Council)
Danish EPA	Danish Environemntal Protection Agency
DGS	French Directorate General for Health
DG SANCO	Directorate General for Health and Consumers (European Commission)
DSR	Daten, Statistik und Risikobewertung (Department/group in AGES)
DTU/TUD	Technical University of Denmark
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization
GKV	Grenzwerteverordnung
GLP	Good Laboratory Practice
h	hour
IFA	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung
INSERM	Institut national de la santé et de la recherche médicale
IOEL	Indicative Occupational Exposure Limit
JRC	Joint Research Centre
KEMI	Kemikalieinspektionen (Swedish Chemicals Agency)
LMSVG	Lebensmittelsicherheits- und Verbraucherschutzgesetz
LOAEL/C	Lowest Observed Adverse Effect Level/Concentration
LOUS	List of Undesirable Substances
MAK	Maximale Arbeitsplatz-Konzentration
NFI	(Danish) National Food Institute
NOAEL/C	No Observed Adverse Effect Level/Concentration
NTP	National Toxicology Program
OECD	The Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment California Environmental Agency
(I)OEL	(Indicative) Occupational exposure Limit

REACH	Registration, Evaluation, Authorisation and restriction of CHemicals (acronym for the EU chemicals legislation)
PPS	PolyproPylene or Precautionary Principle
PPSU	PolyPhenylSUlfone
RAR	Risk Assessment Report
SC	Santé Canada
SCF	Scientific Committee for Food
SCOEL	Scientific Committee on Occupational Exposure Limits
TBT	Technical Barriers to Trade
TDI	Tolerable Daily Intake
TG	Test Guideline
TRGS	Technischen Regeln für Gefahrstoffe
TRIS	Technical Regulations Information System (used for EU notifications of national legislation)
TWA	Time Weighted Average
WHO	World Health Organization
WTO	World Trade Organisation

Background for national legislation on bisphenol A (BPA) in EU and EFTA countries

The objective of this study is to seek clarification of the reasons behind the differences in national regulatory approaches to bisphenol A (BPA) in EU and EFTA Member States. Bans of BPA in food contact materials, thermal paper, as well as pacifiers and teething rings are all by-and-large supported by the scientific argument that there are uncertainties related to the possible low-dose effects (endocrine disrupting properties/development neurotoxicity) of BPA, in particular in relation to infants/small children/pregnant women. The increasing evidence of such possible effects is used as the main argument for excluding/minimising exposure to BPA as a precautionary measure.

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