France prepared a restriction report on bisphenol A in thermal paper [1]

SUMMARY

France has submitted a proposal for the placing on the market of thermal paper containing bisphenol A (BPA) in a concentration equal or higher than 0.02% by weight.

Thermal paper is a paper coated with a reactive layer that changes colour when exposed to heat. Thermal paper is used in many applications such as point-of-sales tickets and receipts, self-adhesive labels, lottery tickets or fax paper. BPA is the most common dye developer in such paper.

The restriction proposal aims to address the risks to pregnant workers and consumers from dermal exposure to BPA in thermal paper. More precisely, risks are identified for children exposed through their pregnant mothers. The risks are identified for effects on the female reproductive system; effects on brain and behaviour; mammary gland changes; as well as effects on metabolism and obesity.

The public consultation on the restriction report starts 18 June 2014 and will end on 18 December 2014. ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) welcome any comments already by 1 September 2014 to assist them in their first discussions of the proposal.

GENERAL REMARKS

The Annex XV restriction report, prepared by France, has been published on ECHA's website. It is open to public consultation for a period of six months[2] to allow stakeholders[3] to submit their comments, as well as additional information relevant to the proposal. Comments are welcomed from the EU or beyond.

At a later stage in the RAC's and SEAC's opinion making process, a 60 days public consultation will be held specifically on the draft SEAC opinion.

The opinions of RAC and SEAC will take into account the comments received in the public consultation. ECHA will publish the responses of the dossier submitter and the Committees' rapporteurs to these comments on its website.

The final opinions of both Committees are scheduled to be adopted by 18 June 2015. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

[1] The information note has been prepared based on the Annex XV report prepared by France.
[2] The duration of the public consultation is six months according to Article 69(6) of REACH.
[3] Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities.

SUGGESTED RESTRICTION (SCOPE)

France has submitted a proposal to restrict the placing on the market of thermal paper containing bisphenol A (BPA; 4,4'-isopropylidenediphenol) in a concentration equal or higher than 0.02% by weight. This concentration limit is considered to equal a total ban of BPA in thermal paper. According to the proposal, the existing standard analytical methods for BPA have to be used to establish the concentration of BPA in thermal paper.

France proposes that the restriction will apply 36 months after the amendment to Annex XVII to REACH comes into force. It has not proposed any derogations.

BISPHENOL A IN THERMAL PAPER

Thermal paper is a paper coated with a reactive layer that changes colour when exposed to heat. Thermal paper is used in many applications such as point-of-sales tickets and receipts, self-adhesive labels, lottery tickets or fax paper. BPA is the most common dye developer in thermal paper, although substitution is picking up speed. BPA is typically present in a concentration of 1-2% by weight.

Around 65% of thermal paper placed on the EU market are point-of-sales tickets and receipts and are thought to represent the main source of BPA exposure to workers and consumers. These type of tickets and receipts are typically made of thermal paper without topcoating and thus can result in dermal exposure to BPA. Topcoatings might prevent or reduce migration of BPA from the thermal coating layer to the skin. There are indications that BPA might not be used anymore in topcoated thermal paper.

Although most information is available for point-of-sales tickets and receipts, the restriction proposal covers all thermal papers.

REASONS FOR ACTION

BPA is primarily used in the manufacture of polycarbonate and epoxy resins. In comparison, the use in thermal papers is minor (about 0.2% of the total volume of BPA used in the EU). Exposure to BPA from thermal papers is considered of concern since BPA is present as a free monomer that can migrate from the paper to the skin upon contact.

A risk from BPA in thermal paper has been identified on the basis of effects on the female reproductive system; effects on brain and behaviour; mammary gland changes; as well as effects on metabolism and obesity. The identified risk is Union-wide and considered to be potentially severe. These risks are identified for children exposed *in utero*.

A restriction is proposed aiming to address the risks to pregnant workers (e.g., cashiers) and consumers from dermal exposure to BPA in thermal paper they may handle.

BROADER CONTEXT

RAC has recently adopted an opinion to strengthen the existing harmonised classification and labelling (CLH) of BPA from a category 2 to a category 1B reproductive toxicant regarding the adverse effects on sexual function and fertility. This classification was in

line with a proposal from the French Competent Authority[4]. In comparison with the classification proposal, the restriction proposal concentrated on effects seen at low doses, and assessed effects on brain and behaviour, mammary gland changes and effects on the metabolism in addition to adverse effects on sexual function and fertility.

A substance evaluation of BPA was carried out by the German Competent Authority in 2012. As a result of this evaluation, ECHA issued a decision in December 2013 to request further data from the registrants of BPA on skin absorption and environmental exposure[5]. Furthermore, a drop-in alternative for BPA, called BPS, is currently being evaluated by the Belgian Competent Authority[6].

The European Food Safety Authority (EFSA) recently published two draft opinions on BPA, one on exposure and one on human health risks[7]. In its draft opinion on human health risks EFSA considered that "*the exposure even for the highest exposed groups in the population is well below the t-TDI of 5 µg/kg bw per day, indicating that the health concern for BPA is low at the current level of exposure*"[8]. In its draft opinion, EFSA also considered exposure from thermal paper. The differences in the conclusions in the draft opinion of EFSA and of the French restriction proposal are due to differences in assumptions and methods used.

CONSEQUENCES OF THE ACTION

According to the French restriction report, the proposed restriction is expected to result in a full phase-out of BPA in thermal paper by the date of entry into force of the restriction. Thus, the corresponding exposures and associated adverse effects would be avoided. France estimated the total quantified potential health benefits of the proposed restriction to range from €1.8 million to €12.6 million per year over 2019-2030. Not all the benefits have been valued, though.

The substitution of BPA by BPS or other bisphenols is likely, should the restriction be adopted. Indeed, BPS is already widely used in thermal paper worldwide and appears to be the most technically and economically feasible "drop-in" alternative. BPS might cause very similar adverse health effects as BPA and as a consequence the estimated health benefits due to the restriction of BPA in thermal paper could be lower than estimated by France.

France has considered the option to restrict all bisphenols that are likely to be used in thermal paper. However, it discarded this restriction option because it views that there is a lack of toxicological data for some of these alternatives. In contrast, France considers that risks from BPA have already been demonstrated.

The costs of a restriction would mainly consist of substitution costs, namely costs associated with the replacement of BPA with another chemical dye developer and compliance control costs, related to the testing of BPA content in thermal paper. France

[4] http://echa.europa.eu/en/view-article/-/journal_content/title/rac-proposes-to-strengthen-the-classification-of-bisphenol-a
[5] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/substance/178/search/201-245-8/term
[6] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/substance/181/search/201-250-5/term
[7] http://www.efsa.europa.eu/en/topics/topic/bisphenol.htm
[8] http://www.efsa.europa.eu/en/consultationsclosed/call/140117.pdf

estimated the costs to be between €1.1 million[9] and €39.2 million[10] per year over 2019-2030 depending on the drop-in alternative that would be used as a substitute.

SPECIFIC INFORMATION REQUESTED

Any information or comments on the restriction proposal are welcomed. Derogations to the proposed restriction can also be suggested. Please provide any evidence or justification to support your proposals or comments. Specific information is requested on:

1) the hazardous properties of alternatives (human and environmental hazards);
2) the technical and economic feasibility as well as the availability of alternatives (including information on prices and volumes manufactured or placed on the market as well as trends in these prices and volumes);
3) biomonitoring studies targeting exposure to BPA in thermal paper (e.g. exposure of cashiers).

COMMENTS PREFERABLY BY 1 SEPTEMBER 2014

Although the public consultation concludes on 18 December 2014, RAC and SEAC encourage comments already by 1 September 2014 to assist them in their first discussions of the proposal.

[9] Assuming 100% substitution of BPA with BPS
[10] Assuming 100% substitution of BPA with Pergafast 201