

March 15, 2017

*Annex XV dossier to identify Bisphenol A (BPA) as SVHC based on alleged endocrine disrupting properties for human health available for public consultation*

### **French initiative contradicts recent conclusion of European food safety authority**

The members of the PC/BPA group note that the French authorities have submitted to ECHA an Annex XV dossier for BPA, proposing the identification of BPA as a substance of very high concern (SVHC) under REACH, based on alleged endocrine disrupting properties for human health with equivalent level of concern to human health to those of other substances as set out in REACH Article 57. The dossier was published on March 9, 2017 and is subject to a public consultation open until April 24, 2017. The PC/BPA group is evaluating the dossier and will provide comments within the timeframe of the public consultation.

### **Based on the widely accepted WHO criteria EFSA concludes BPA is not an Endocrine Disruptor**

For BPA, a comprehensive scientific evaluation, which follows weight-of-evidence principles, was carried out by the European Food Safety Authority (EFSA) and published in 2015. It investigated the substance's intrinsic properties together with the actual exposure of humans in order to determine appropriate measures to ensure safe use. In their assessment, EFSA's independent researchers reviewed all available scientific studies on BPA, including the literature on potential endocrine-related effects of BPA. On endocrine disruption EFSA's expert panel concluded that *"based on the WHO criteria, it is not possible to conclude that BPA is an endocrine disruptor"*.

### **Consumer safety of BPA confirmed for food contact applications and beyond**

With respect to consumer safety, the European Food Safety Authority (EFSA) concluded that current consumer exposure to BPA poses no health risk to any age group. This is because the exposure via food, but also via a combination of different sources (food, dust, cosmetics, thermal paper) is far below the newly derived tolerable daily intake (TDI). Of note, in the derivation of the TDI, EFSA already factored in remaining uncertainties regarding potential mammary gland and reproductive, metabolic, neurobehavioural and immune system effects. *"Given the clear safety conclusion of EFSA, and in view of the European Commission's roadmap for BPA in food contact materials, and their work towards a harmonised measure on the use of BPA in plastics, coatings and varnishes in food contact, we do not see a logical basis for the new French initiative,"* says Jasmin Bird of the PC/BPA-group.

### **Potential additional SVHC-identification: no implications for BPA-based applications expected**

Since January 2017 BPA is already included in the SVHC Candidate List based on its 1B reprotoxic classification. This listing triggers communication and notification obligations for companies under certain conditions. Furthermore, identification as an SVHC could be the entry point into a potential Authorisation under REACH at a later stage.

The new dossier correctly reflects that the large majority of BPA-uses are intermediate uses, which would not be subject to Authorisation under REACH. Therefore, a potential later Authorisation would only apply to very few uses of BPA as monomer. *"We are concerned that the French initiative will produce increasing uncertainty and induce additional workload among all partners without having meaningful practical consequences,"* says Jasmin Bird of the PC/BPA-group.

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