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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
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Directors-General

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Mr Geert Dancet
Executive Director
European Chemicals Agency
Annankatu 18
P.O. Box 400
FI – 00121 Helsinki

Dear Mr. Dancet,

We are writing to set out our strategy for managing the risks associated with the substance deca-BDE, also known as bis(pentabromophenyl)ether or decabromodiphenyl ether. We want to avoid a repetition of the difficulties recently encountered in relation to the substance HBCDD, where a proposal to list the substance under the Stockholm Convention on Persistent Organic Pollutants (POP) coincided with the authorisation procedure under REACH. Fortunately, in the case of deca-BDE the REACH situation is not as advanced and we have time to ensure an adequate interface between both regulatory frameworks at an early stage.

The background to this issue is annexed to this note.

Following a proposal by Norway to list deca-BDE under the Stockholm Convention, our services consider that the authorisation route under REACH is not the most appropriate risk management measure for the following reasons:

1) Our experience with HBCDD (which had already been included in Annex XIV when a global ban with one exemption was proposed under the Stockholm Convention) highlights the difficulties presented by simultaneous POP elimination and REACH authorisation procedures.

The timing of the procedures under the Stockholm Convention and REACH authorisation makes it very likely that a similar situation could arise in relation to deca-BDE.

2) One of the conclusions of the REACH review is to address legislative duplication or divergence and our services are determined to act on this.

During the recent discussion with UK, Norway and ECHA, our services expressed these concerns.

In order to address the risks presented by deca-BDE pending the listing of the substance under the Stockholm Convention, the option of preparing an Annex XV dossier for restriction was also analysed and discussed. Norway expressed its willingness to work with ECHA on this

and to share data and information collected in relation to the Stockholm Convention procedures.

Proposed action

It is crucial to be clear about the regulatory approach towards this substance and to communicate it to industry and stakeholders as soon as possible. At the RiME (Risk Management Expert) meeting on 4 June, our services presented the recent discussion on deca-BDE and the change of risk management option on this substance as a consequence of recent developments under the Stockholm Convention.

Our services would ask ECHA to ensure that deca-BDE will not be considered for inclusion in the 5th draft recommendation of substances to be included in Annex XIV and will not form part of the subsequent public consultation. This early step would prevent a replication of the problems encountered when regulating HBCDD.

In order to clearly signal the intention with regard to the most appropriate risk management measure, the Commission is therefore officially asking ECHA to develop an Annex XV restriction dossier and to put this substance in the Register Of Intentions of restriction proposals upon receipt of this note.

Further details of the content of the Annex XV dossier for restriction will be discussed between our services and ECHA in the coming weeks.

Daniel Calleja
DG Enterprise & Industry

Karl Falkenberg
DG Environment

[redacted]

Encl.: 1

ANNEX

BACKGROUND

About decaBDE

Deca-BDE is a flame retardant used in many applications including electronics, wire and cable insulation, textiles, automobiles and airplanes. It was identified as a priority substance under Regulation (EEC) No 793/93. A risk assessment was published in the OJ L 84, 5.4.1993, p. 1 and the Commission Communication on the strategy for limiting the risks was published in the OJ 2008/C 131/04, on 29 May 2008. The EU risk assessment showed that further information and/or testing were needed in relation to both human health (of workers and persons exposed via the environment) and the environment (the aquatic and terrestrial ecosystems). The neurotoxic effects of the substance also required further investigation.

Deca-BDE has been restricted under the RoHS Directive since 1 July 2008 with no applications exempted.

In September 2009, the UK Environment Agency reviewed all new data on the environmental risks posed by deca-BDE and prepared an addendum to the EU RAR. According to its report, deca-BDE is very persistent and widely dispersed in the environment. The Agency expresses concern about the presence of the substance in the food chain and the unknown significance of degradation into more hazardous substances (with PBT/vPvB properties), although deca-BDE itself does not meet the PBT/vPvB or POP criteria.

VECAP Programme

In 2004 a Voluntary Emissions Control Action Programme (VECAP) was set up to promote new codes of good practice for the use of deca-BDE in the plastics and textile industries. VECAP does not address the emission of deca-BDE from treated articles but only industrial emissions.

This ongoing industry monitoring programme lasts ten years and industry has undertaken to report the results on a yearly basis in accordance with Commission Regulation (EC) No 565/2006.

On 17 December 2009, several companies (manufacturers and importers) announced, as a result of negotiations with the US Environmental Protection Agency (EPA), that they would phase-out deca-BDE by 31st December 2012 for most uses and end all uses by the end of 2013.

The European Brominated Flame Retardant Industry Panel (EBFRIP) issued a progress report on deca-BDE in January 2010 and presented it at the Meeting of Competent Authorities for REACH and CLP (CARACAL) of 2 February 2010. According to that report, the disposal of used packaging containing the substance was much more important than had been realised and a best practice for the disposal of used packaging was adopted in 2009. Until then, only emissions to air and water had been considered. There was a reduction in the level of potential emissions reported for 2009 compared to 2008 and this in spite of a rise in deca-

BDE sales in 2009. Between 2008 and 2009, the overall potential emissions of deca-BDE fell from 3432 kg to 1220 kg in Europe.

Recent developments

In February 2010, the 4th CARACAL meeting concluded that further risk management measures on deca-BDE were needed and that the best instrument for risk management under REACH (restriction or authorisation) for deca-BDE could not be determined without more information.

In August 2012, the UK Authorities submitted an Annex XV dossier to ECHA proposing deca-BDE as a substance of very high concern under REACH.

In its report, the focus was on the transformation of deca-BDE into more hazardous substances, since deca-BDE itself meets neither the PBT or vPvB criteria nor POP on the basis of its intrinsic properties. However concerns were raised about the toxicity of deca-BDE. Bioaccumulation data for deca-BDE were equivocal.

On 29 November 2012, the Member State Committee concluded that deca-BDE is considered to meet the definition of a PBT/vPvB substance in accordance with Annex XIII to REACH and thereby fulfils the criteria in Article 57(d) and (e).

On 19 December 2012, by a decision of ECHA, deca-BDE was included in the Candidate List of Substances of Very High Concern for eventual inclusion in Annex XIV to REACH.

On 02 May 2013, Norway proposed adding deca-BDE to Annex A to the Stockholm Convention.

According to the Norwegian proposal, the versatility of deca-BDE has resulted in a range of end uses, leading to a complex life cycle. It concludes that deca-BDE meets the criteria of Annex D to the Stockholm Convention on persistence, bioaccumulation, long-range transport and adverse effects to human health and/or the environment. It expresses concern about the potential debromination of deca-BDE to other POPs, the possibility of combined effects and about deca-BDE being a potential endocrine disruptor.