

## EFSA's Risk Assessment on Brominated Flame Retardants (BFRs)

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### Introduction

The European Food Safety Authority (EFSA) was established in January 2002 as an independent body providing scientific advice and communication on risks associated with the food chain (Regulation (EC) No 178/2002). As a risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission (EC), European Parliament and EU Member States in taking effective and timely risk management decisions. EFSA can be tasked by the EC, the Members States, the European Parliament, or on its own initiative.

The European Commission requested EFSA to prepare a scientific opinion on the risks to human health related to the presence of brominated flame retardants (BFRs) in food. EFSA has been asked to consider all relevant toxicological information available and to identify congeners of toxicological relevance with particular reference to those occurring in food. In addition, EFSA has been asked to carry out an exposure assessment considering the dietary exposure situation for the general population and specific groups of the population and provide an indication of the relative importance from non-dietary sources. Biomonitoring data for these compounds, if available, will also be taken into account.

### Background

The group of the BFRs consists of different groups of chemicals with a variety of physicochemical properties and use. The main BFRs are the polybrominated diphenyl ethers (PBDEs), tetrabromobisphenol A (TBBP-A), hexabromocyclododecane (HBCD), polybrominated biphenyls (PBBs) and other brominated compounds. The occurrence of BFRs in the environment, feed and food, and in humans has raised concern in the last years. In order to protect health and the environment, Directive 2003/11/EC banned the placing on the market and the use as a substance or as a constituent of substances or of preparations of two PBDEs commercial mixtures, *i.e.* pentabromodiphenylether (PentaBDE) and octabromodiphenylether (OctaBDE), in concentrations higher than 0,1 % by mass. Since July 2006, new electrical and electronic equipment put on the market should not contain PBBs or PBDEs as laid down in Directive 2002/95/EC on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment. The application of the commercial mixture decabromodiphenylether (DecaBDE) in polymeric applications was specifically exempted from the requirements. However, as of July 2008, DecaBDE can no longer be used in electronics and electrical applications as decided by the European Court of Justice (2008).

Risk assessments on BFRs have been carried out by various international bodies such as the Joint FAO/WHO Expert Committee on Food Additives on PBDEs (JECFA, 2006) and the Agency for Toxic

Substances and Disease Registry on PBDEs and PBBs (ATSDR, 2004). The European Chemicals Bureau (ECB) has published environmental and health risk assessment reports on PentaBDE (ECB, 2000), OctaBDE (ECB, 2003), DecaBDE (ECB 2004), TBBP-A (ECB, 2006) and HBCD (ECB, 2008).

In 2006, the EC asked EFSA advice on the relevant chemical compounds in the group of BFRs for monitoring in feed and food. The EFSA's Panel on Contaminants in the Food Chain (CONTAM Panel) concluded in its advice of 24 February 2006 that the available occurrence data on BFRs in feed and food did not allow a comprehensive assessment of contamination in all feeds and foods and identified the following compounds as the most important ones to be monitored based on knowledge at that time on the analytical feasibility to measure them in accredited laboratories, the production volumes, their occurrence in food and feed, their persistence in the environment and their toxicity:

- PBDEs: BDE-28, -47, -99, -100, -153, -154, -183 and -209,
- HBCD total amount (isomer specific analysis of a limited number of samples and/or pools in case of significantly elevated levels or increasing trends),
- PBBs: BB-153

Optionally, the following BFRs were recommended to be monitored: decabromodiphenyl ethane, hexabromobenzene and bis(2,4,6-tribromophenoxy)ethane. Subsequently, an EU-wide monitoring of these compounds was organised as of October 2006.

#### **EFSA's risk assessments on BFRs**

EFSA will tackle the risk to human health related to the presence of BFRs in food considering the following classes of BFRs in different scientific opinions: (1) PBDEs, (2) PBBs, (3) HBCD; (4) TBBP-A and other phenols and (5) Other BFRs, including emerging BFRs. This task was allocated to the CONTAM Panel and a Working Group was established for this purpose. The scientific opinions will be issued by the end of 2010 (for PBDEs and PBBs) and during 2011 (for HBCD, TBBP-A and other phenols, and Other BFRs).

The assessment of the risk will be done following the four pillars of risk assessment, *i.e.* hazard identification, exposure assessment, hazard characterization and risk characterization. The exposure situation for specific groups of the population as well as the relative importance from non-dietary sources will be considered. Toxicological data on these compounds and biomonitoring data, if available, will be taken into account in the evaluations. In addition, the risk assessment will explore whether individual compounds can be used as markers for dietary exposure to the specific groups of BFRs and will identify potential data gaps for the specific groups of BFRs.

The exposure assessment will combine the data on human consumption for the different food categories with the occurrence data on BFRs in the respective food categories. A range of intake/exposure scenarios estimates are foreseen so that special subgroups of the population (e.g. children, vegetarians) that may be considered as high consumers are covered. Food consumption at the individual level is usually estimated through food consumption surveys. National consumption surveys

have been routinely conducted in many European countries as part of surveillance programs on nutrition. The “*Concise European food consumption database*” (Concise Database) was established by EFSA to provide data on the average daily consumption of foods per person in the adult population of 17 different MS, Iceland and Norway. It comprises 15 broad food categories (*e.g.* milk and dairy-based products) and 21 food subcategories (*e.g.* cheese). The Concise Database constitutes the first European database with dietary information from the majority of EU MS and it provides a first screening tool to EFSA, and its Scientific Panels, to help carry out preliminary exposure assessment calculations, being also a first step towards generating a more comprehensive database (<http://www.efsa.europa.eu/en/datex/datexfooddb.htm>).

The occurrence data from the EU-wide monitoring recommended by the EC in 2006 based on the outcome of the EFSA’s advice was made available to EFSA. In addition, since more data appeared to be of importance for a comprehensive human exposure assessment, EFSA launched a call for data.

### **EFSA’s call for data on BFRs**

EFSA launched in December 2009 a call for data to collect all the available data on BFRs analysis carried out from 2000 to 2009 (included), and especially on the following compounds:

- PBDEs, *e.g.* BDE-28, -47, -99, -100, -153, -154, -183 and -209.
- PBBs, *e.g.* BB-3, -15, -29, -49, -52, -80, -101, -103, -153, -180, -194, -206 and -209.
- HBCD (total amount of HBCD and isomer specific analysis, if available).
- TBBP-A and other phenols.
- Emerging BFRs, *e.g.* decabromodiphenyl ethane (DeBDethane), hexabromobenzene and bis(2,4,6-tribromophenoxy)ethane) (TBE).

The following closing dates for data submission were set: (1) data on PBDEs and PBBs: 26 February 2010, (2) data on HBCD: 2 July 2010 and (3) data on TBBP-A, other phenols and emerging BFRs: 20 December 2010 (<http://www.efsa.europa.eu/en/data/call/datex091215.htm>).

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