



National Research Program "Endocrine Disruptors"

**Consensus Platform
"Brominated Flame Retardants"
Final Document
(July 2007)**



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Editor's Note:

This is an English translation of the original German version. The German version is binding.

Author:

Marcel Trachsel, PhD
Implementation Officer
National Research Program "Endocrine Disruptors"
int/ext Communications AG
Postfach
4004 Basel

marcel.trachsel@int-ext.com

Executive Summary

Introduction

Chemicals with endocrine activity, also termed "endocrine disruptors", can exert a variety of detrimental effects on humans, animals or entire ecosystems. In animals, numerous studies attest negative effects on the reproductive system for broad range of species from fish and birds to marine and terrestrial mammals.

In the year 2000 the Swiss Federal Council mandated the Swiss National Science Foundation (SNSF) to implement the National Research Program 50 "Endocrine Disruptors". This program aims to develop scientific strategies to assess the risks and hazards that arise when endocrine disruptors are processed through ecosystems to cause human and animal exposure. In consensus platforms representatives of the NRP, of the authorities and of the producing and applying industries make recommendations on how to avoid the negative impact of endocrine disruptors.

The methodology of the consensus platform was developed exclusively for the National Research Program "Endocrine Disruptors" on the basis of the objectives defined by the Steering Committee. The consensus platform is a structured, constructive dialogue between industry, the authorities and scientists; it aims to achieve general agreement on the impact of endocrine disruptors on humans, animals and ecosystems and on action to minimize any detrimental effects (see pages 6 f.).

The work of the consensus platform "Brominated Flame Retardants" lasted from May 2006 to June 2007. It involved a total of 19 representatives of the producing and applying industries, the authorities and scientists, in addition to two moderators (see page 8).

With their joint effort to prepare impact and action-related statements, all partners participating in the platform – industry, regulatory authorities and scientists of the National Research Program "Endocrine Disruptors" – expressed their intention to participate in a constructive dialogue, thereby making a valuable contribution towards preventing negative impacts of endocrine disruptors.

Results

The members of the consensus platform accepted and approved 12 impact related statements plus an annex and 19 action related statements/recommendations (see pages 9ff).

The effectiveness of brominated flame retardants as a means of fire protection in materials – mainly in plastics and textiles – is indisputable. When combined with suitable, sensibly selected materials and well thought-out design, these substances help to prevent fires and to mitigate the effects of fire. However, the beneficial protective properties in electrical and electronic equipment, transport devices and in the construction industry also entail some possible hazards. In regard of their presence in the environment, brominated flame retardants – representing high production volume chemicals – are subject of broad controversy. The main substances making up this group of materials are the polybrominated diphenylethers

PentaBDE, OctaBDE and DecaBDE as well as hexabromocyclododecane (HBCD) and tetrabromobisphenol A (TBBPA)

Several brominated flame retardants are chemicals with endocrine activity. Studies conclude that PentaBDE, banned since 2004, has antiandrogenous and estrogenous effects and causes malfunction of the thyroid hormone system. According to the most recent findings, TBBPA and HBCD are considered potential endocrine disruptors. It is still unclear to what extent new-found knowledge from *in vitro* and *in vivo* studies can be applied to humans.

Mindful of the magnitude of the potential hazard posed by endocrine-active substances, the members of the consensus platform believe that scientific uncertainty must not be used to serve as an argument for putting off appropriate action to reduce risk. The problems that these substances are associated with necessitate long-term monitoring and research projects.

Likewise, greater knowledge must be gained of the lifecycle of brominated flame retardants. Efforts must be promoted to search for alternatives to brominated flame retardants that persist in the environment.

Brominated flame retardants can enter the human body by ingestion, i.e. with food, or also by way of house dust and inhalation of indoor air. Workers active in electrical and electronic waste disposal and recycling industries are subjected to high exposure to these substances in their professional activity. There is a need to clarify where these workers incur the highest exposures and whether action is needed to reduce exposure. The processing and disposal industries should investigate jointly whether relevant emission sources of brominated flame retardants exist in Switzerland, and initiate emissions mitigation measures where appropriate.

Based on the current knowledge, TBBPA bonded as a copolymer (for example as epoxy resins in printed circuit boards) is considered harmless in the application phase. On the other hand, industry should dedicate efforts within the scope of exercising self-responsibility to identify areas of application in which DecaBDE and HBCD can be replaced with other flame-retardant systems that possess more favourable risk profiles.

Based on scientifically founded risk assessments, regulatory authorities are reviewing whether to impose further restrictions or bans on persistent brominated flame retardants that are acting as endocrine disruptors. Such review also considers pertinent EU regulations and the availability of substitute substances subject to equally stringent investigation.

National Research Program 50 "Endocrine Disruptors" (NRP 50)

Chemicals with endocrine activity, also termed "endocrine disruptors", can exert a variety of detrimental effects on humans, animals or entire ecosystems. In animals, numerous studies attest to reproductive disturbances across a broad species spectrum ranging from fish and birds to marine and terrestrial mammals. Various solvents, insecticides, pesticides, combustion products, certain drugs, cosmetics and even plant products are suspected of interfering with the endocrine system of humans and animals.

In 2000, the Swiss Federal Council mandated the Swiss National Science Foundation (SNSF) to implement the National Research Program 50 "Endocrine Disruptors". The scientific program, with total funding of CHF 15 million, started in 2002 and will end in 2007. The international Steering Committee approved a total of 30 research projects in three program phases.

The National Research Program "Endocrine Disruptors" aims to develop scientific strategies to assess the risks and hazards that arise when endocrine disruptors are processed through ecosystems to cause human and animal exposure. In consensus platforms representatives of the NRP, of the authorities and of the producing and applying industries make recommendations on how to avoid the negative impact of endocrine disruptors.

Methodology of the Consensus Platforms

The methodology of the consensus platform was developed by the Implementation Officer of the National Research Program "Endocrine Disruptors", Dr. Marcel Trachsel, in cooperation with the consultancy int/ext Communications AG, Basel. It was based on the objectives defined by the Steering Committee.

The consensus platform is a structured, constructive dialogue between industry, the authorities and scientists; it aims to achieve general agreement on the impact of endocrine disruptors on humans, animals and ecosystems and on action to minimize any detrimental effects. The methodology is based on a series of meetings and individual preparatory reflection.

A successful consensus platform requires certain conditions to be met:

- The issue to be treated must be defined as narrowly as possible.
- The members are willing to cooperate within the limits of the process, to accept divergent interests and viewpoints and work together to achieve agreement.
- The meetings are moderated professionally.
- All developments and interim results are treated as confidential until the consensus platform is completed. On termination of the work, only approved results are communicated.

Step 1: On the basis of their knowledge the members define their individual position, or that of the organization they represent, on the impact and action of endocrine disruptors.

Step 2: At the first joint meeting the members of the consensus platform put across their position on the impact and action and respond to questions on their position from other members of the consensus platform (hearing). On the basis of this meeting *a list of impact related statements and one of action related statements/recommendations are compiled*. These lists are then made available to the members of the consensus platform.

Step 3: In this step each member decides on *acceptance, conditional acceptance or non-acceptance of each impact related statement*. In the event of conditional acceptance, conditions must be defined. The results are collected and categorized centrally as follows:

- Category i1: generally accepted >>> immediate inclusion in the final list of accepted statements
- Category i2: accepted or conditionally accepted, no more than one non-acceptance >>> to be discussed at the joint meeting
- Category i3: more than one non-acceptance >>> is not further pursued

Step 4: At the joint meeting, the Category i2 impact related statements are subjected to further discussion in order to find a formulation that is acceptable to all members of the consensus platform. The outcome of this meeting, together with the Category i1 statements, yields *the final list of accepted impact related statements*. These are set out in a logical sequence and approved by the consensus platform.

Step 5: In this step each member of the consensus platform decides on *the acceptance, conditional acceptance or non-acceptance of each action related statement/recommendation*. In the event of conditional acceptance, condition must be defined. The results are collected and categorized centrally as follows:

- Category a1: generally accepted >>> immediate inclusion in the final list of accepted statements
- Category a2: accepted or conditionally accepted, no more than one non-acceptance >>> to be discussed at the joint meeting
- Category a3: more than one non-acceptance>>> is not further pursued

Step 6: At the joint meeting, the Category a2 action related statements are subjected to further discussion in order to find a formulation that is acceptable to all members of the consensus platform. The outcome of this meeting, together with the Category a1 statements, yields *the final list of accepted action related statements*. These are set out in a logical sequence and approved by the consensus platform.

Step 7: The approved lists of impact and action related statements are set out *in a final document* and made available for communication to other stakeholders.

Members of the Consensus Platform "Brominated Flame Retardants"

The following persons have kindly accepted the invitation of the National Research Program "Endocrine Disruptors" to play an active role in the consensus platform "Brominated Flame Retardants". The persons in charge of the National Research Program wish to thank the members of the consensus platform for their valued participation.

Producing Industry

Dr. Paul Vesel, Swiss Society of Chemical Industries, Zurich
Dr. Urs Friederich, Dr. Claude Bastian, Dow (Europe) GmbH, Horgen
Dr. Adrian Beard, Clariant GmbH, Huerth-Knapsack (D)
Dr. Klaus Rothenbacher, Bromine Science and Environmental Forum (BSEF), Brussels (B)

Applying Industry

Dr. Juergen Baumann, Siemens Schweiz AG, Zurich
Dr. Ferdinand Quella, Siemens AG, Munich (D)

Authorities

Prof. Georg Karlaganis, Dr. Josef Tremp, Federal Office for the Environment, Bern
Dr. Beat Brueschweiler, Dr. Steffen Wengert, Federal Office of Public Health, Bern/Zurich
Dr. Christoph Rueegg, State Secretariat for Economic Affairs, Bern/Zurich

National Research Program "Endocrine Disruptors"

Dr. Martin Kohler, Dr. Andreas Gerecke, Dr. Peter Schmid, Christian Bogdal, Empa Materials Science & Technology, Duebendorf
Prof. Dr. Walter Giger, Dr. Hans-Peter Kohler, Swiss Federal Institute of Aquatic Sciences and Technology, Duebendorf
Dr. Leo Morf, Andreas Buser, GEO Partner AG, Zurich

Moderation and Editing

Prof. Felix R. Althaus, President of the Steering Committee NRP „Endocrine Disruptors“, University of Zurich
Dr. Marcel Trachsel, Implementation Officer NRP "Endocrine Disruptors", int/ext Communications AG, Basel

The work of the consensus platform "Brominated Flame Retardants" lasted from May 2006 to June 2007.

Results of the Consensus Platform "Brominated Flame Retardants": Impact Related Statements

Statements regarding flame retardants

- Fire is a major source of hazards to life and property. The use of flame retardants, in addition to the selection of suitable materials and designs, constitutes an essential element of fire prevention.
- Fire protection shall be considered in a total view. Benefits as well as impacts shall be considered. Investigation must not be limited to certain specific flame-retardant classes or substance groups.
- Flame retardants originating from various chemical classes exist. Brominated flame retardants display beneficial formulation and material properties for certain specific applications such as in plastic housings of electrical and electronic equipment, printed circuit boards and polystyrene foams.
- As a general rule, brominated flame retardants are not the best or most effective flame retardants. Over time, alternative solutions have been developed for many applications.
- Alternative flame retardants must likewise meet stringent requirements governing environmental compatibility and health hazards.
- For various applications, there are currently still no alternatives to brominated flame retardants. This is the case, for example, where laws or customers stipulate particular flame-retardant requirements, such as in the United States. Among other materials, this affects non-polar plastics such as foamed polystyrene.

Statements regarding brominated flame retardants

- Substance flow analysis is one suitable tool for weighting the effect of substance flows with respect to emissions to the environment. The results of such analysis can serve as the basis for planning actions and measures to reduce environmental emissions.
- Risk assessment of brominated flame retardants must be based on investigation of all components of the technical product (including stereoisomers and byproducts).
- Occupational exposure of workers to brominated flame retardants shall be considered in dedicated studies separate to those targeting effects on consumers. High occupational exposures to brominated flame retardants have been verified among workers in particular in production, disposal and recycling industries.
- TBBPA: Based on our knowledge today, tetrabromisphenol-A chemically bonded as a copolymer (for example as epoxy resins in printed circuit boards) is considered harmless in the application phase.

Statements regarding the endocrine activity of chemicals

- Both natural as well as synthetic chemicals exist that have endocrine activity.

Statements regarding the endocrine activity of brominated flame retardants

- Certain brominated flame retardants have endocrine activity (see the annex in this regard).

Annex to "Impact Related Statements"

The terms "endocrine disruptor" and "potential endocrine disruptor" are used in accordance with the definitions spelled out in the WHO/IPCS report "Global assessment of the state-of-the-science of endocrine disruptors":

Endocrine disruptor:

*An **endocrine disruptor** is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.*

Potential endocrine disruptor

*A **potential endocrine disruptor** is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations.*

The statement in the main document, that "certain brominated flame retardants with endocrine activity exist", is expressed in such broad and general terms that the consensus platform believes it is in need of certain supplementary explanations:

- *In recent years, the possible impacts of individual brominated flame retardants on human and animal hormone systems have been the subject of increasing investigation. These studies have revealed that various flame retardants have broadly differing impacts on hormone systems.*
- *PentaBDE is an endocrine disruptor, as antiandrogenous and estrogenous effects were identified in vitro as well as in vivo. Likewise, adverse effects on the thyroid hormone system were observed in several studies.*
- *Besides foodstuffs, it has been determined that house dust and indoor air are significant sources of PentaBDE ingested and inhaled by humans.*
- *Based on the data available today, DecaBDE is not an endocrine disruptor, as studies yielded no impacts – neither in vitro nor in vivo – that are directly due to hormone system disruption.*

- *TBBPA is a potential endocrine disruptor . Multiple in-vitro studies yielded impacts on the thyroid hormone system. However, these findings were not confirmed for TBBPA in vivo.*
- *HBCDs are potential endocrine disruptors, as several in-vitro studies produced low-level interactions with the thyroid hormone system. These findings are currently the subject of experimental testing in vivo.*
- *The knowledge gained from cell and animal testing within the scope of these studies cannot be directly applied to human beings. The relevance of experimental findings for human health has therefore not yet been comprehensively clarified.*
- *As in-vitro and in-vivo investigations have demonstrated, certain brominated flame retardants (PentaBDE, HBCD and DecaBDE) are capable of disrupting neuron development in experiments conducted with test animals. To what extent this knowledge is transferable to humans is currently the subject of scientific study.*
- *Risk assessments of major brominated flame retardants (TBBPA und HBCD) are currently underway in the EU; conclusive reports on individual substances (DecaBDE, OctaBDE and PentaBDE) have already been completed. An addendum on DecaBDE is currently being prepared to the report on the environmental risk assessment from the year 2004. Knowledge gaps still exist with respect to the possible impacts that the remaining brominated flame retardants (besides PentaBDE, DecaBDE, TBBPA and HBCDs) have on endocrine systems.*

Results of the Consensus Platform "Brominated Flame Retardants": Action Related Statements/Recommendations

Statements on general actions to be taken with regard to endocrine disruptors

- The problems created by endocrine active substances necessitate long-term monitoring and research projects.
- Mindful of the magnitude of the potential hazard posed by endocrine-active substances, we believe that scientific uncertainty must not be allowed to serve as an argument for putting off appropriate action to reduce risk.

Statements on general actions to be taken with regard to brominated flame retardants

- Efforts in search of alternatives to brominated flame retardants that persist in the environment must be promoted.
- Endocrine disruptors are covered in, among other legislation, the European chemical regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). Brominated flame retardants are used worldwide. It is therefore inappropriate to make do with a focal point that considers Switzerland alone.
- We must improve our knowledge of the lifecycle of brominated flame retardants.
- Investigations must focus on the substance flows and lifecycles of brominated flame retardants. This also includes production data, substance quantities in products, recycling and in particular the emissions occurring during use.
- Analysis of the occupational exposures of recycling industry workers to brominated flame retardants shall serve to clarify where exposures are highest and whether action to reduce exposure is needed.
- DecaBDE: Emissions to the environment of DecaBDE within the course of product technical lifecycle must be investigated.
- DecaBDE: Detailed information on the production of DecaBDE and its use in various materials as well as its consumption must be made known (substance flow analysis).
- DecaBDE: In order to better understand the enrichment of DecaBDE and other brominated flame retardants along food chains, birds of prey, their eggs and their prey must be studied and tested for the presence of these substances and their related degradation products.
- HBCD: Giving due consideration to ongoing scientific investigations, it must be clarified whether alpha-HBCD is formed in the environment from technical HBCD or is selectively transported and/or ingested, inhaled or absorbed by living organisms.
- TBBPA, HBCD and DecaBDE: To enable better assessment of the exposures incurred by living organisms in aquatic and terrestrial ecosystems, the degradation behaviour of substances and their degradation products in sewage

sludge, sediments and soil should be more thoroughly investigated taking into account scientific studies presently already underway.

- alpha-HBCD: Owing to the significant enrichment of alpha-HBCD in the Biota (in the biological environment) and the hazards this substance is known to pose today, appropriate measures must be considered with the goal of reducing emissions.

Statements on regulatory authority actions to be taken with regard to brominated flame retardants

- Based on scientifically based risk assessments, regulatory authorities are reviewing whether to impose further restrictions or bans on persistent and hormone-active brominated flame retardants. Such review also considers pertinent EU regulations and the availability of substitute substances subject to equally stringent investigation.
- DecaBDE and TBBPA: A risk assessment report on DecaBDE and TBBPA has been completed. Based on the investigations called for in this report and on the outcome of current, ongoing research work, the regulatory authorities aim to introduce, where needed, regulation of these substances and/or measures to reduce risk. This is being done in coordination and agreement with the corresponding EU regulations.

Statements on industry actions to be taken with regard to brominated flame retardants

- The processing and disposal industries are investigating whether relevant emission sources of brominated flame retardants exist in Switzerland, and initiating emissions mitigation measures where appropriate.
- DecaBDE: Emissions to the environment of DecaBDE within the course of the technical lifecycle of products must be reduced. Industry has introduced a voluntary initiative, VECAP, for the very purpose of reducing emissions.
- DecaBDE: Efforts being made for the Product Stewardship Programme with respect to DecaBDE should be fostered and supported. This applies in particular to cooperation between producers and user industries, as well.
- DecaBDE and HBCD: Industry is dedicating efforts within the scope of exercising self-responsibility to identify areas of application in which DecaBDE and HBCD can be replaced with other flame-retardant systems possessing more favourable risk profiles.