

RoHS dossier on small brominated alkyl alcohols – project description

27-05-2016

The Danish EPA hereby welcome tenders on the preparatory works for a RoHS dossier on small brominated alkyl alcohols.

The project should not amount to more than [REDACTED].

Background

The use of brominated flame retardants in electric and electronic equipment

In 2014 the Danish EPA performed a survey on brominated flame retardants (BFRs) (<http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-90-2.pdf>). BFRs are added to polymers that are applied in electric and electronic equipment (EEE) in order to enhance the ability to resist heat and sparks without starting a fire. All BFRs follow the same mechanism, which consist of releasing bromine hydrogen when the material is ignited. The survey identified approximately 70 BFRs, which have been pre-registered under REACH and/or are produced by the major international manufacturers of BFRs. The survey presents figures on production and use patterns for the identified substances. Further, various exposure routes and their effect on human health and the environment is described. Finally, non-brominated alternatives are described. The major use for BFRs is in EEE.

Grouping of BFRs

Based on the Danish EPA survey on BFRs the Danish Technical University – National Food Institute (DTU Food) has investigated the possibilities of grouping BFRs. Based on their chemical structures 15 preliminary groupings were identified. (Q)SAR predictions for a number of environmental and health effects within these initial groupings were investigated (The draft version of the report ‘Category approach for selected brominated flame retardants’ can be obtained by contact to the Danish EPA).

One of the groupings; the small linear and branched brominated alkyl alcohols, consisting of 2,3-dibromo-1-propanol (2,3-DBPA) and 2,2-bis(bromomethyl)-1,3-propanediol (DBNPG) and 2,2-bis(bromomethyl)-3-bromo-1-propanol (TBNPA), was chosen for further investigation and the grouping was extended to include also theoretical compounds. The category, defined as having 3-5 carbons, 2-3 bromine atoms and 1-2 alcohol groups comprised 61 members, with 24 of the members having a registered CAS RN.

Read Across for Small Brominated Alkyl Alcohol

(Q)SAR predictions were performed for the members of the category of small brominated alkyl alcohols. Predictions for carcinogenic and genotoxic properties indicated that the 61 members in the category of small brominated alkyl alcohols have a carcinogenic potential with a possible mutagen-

ic/genotoxic mode of action. The estimated specificities of the applied (Q)SAR models as established by leave-many-out cross-validations are between 85.9% and 95.1%, i.e. the overall false positive rates of the models are around 5% - 14%.

A literature search was performed to collect experimental data on human health effects for the 24 category members with a CAS RN assigned. Relevant experimental data on human health effects were only retrieved for the three category members identified in the preliminary structural grouping, i.e. 2,3-dibromo-1-propanol (2,3-DBPA) and 2,2-bis(bromomethyl)-1,3-propanediol (DBNPG) and 2,2-bis-(bromomethyl)-3-bromo-1-propanol (TBNPA).

The critical effect of these three members of the category with relevant experimental data on human health effects is the multiple-organ carcinogenic effect, most probably exerted by a genotoxic mode of action either by the parent compound itself (2,3-DBPA) or by a metabolite of the parent compound (DBNPG and TBNPA). Furthermore, 1,3-dibromo-2-propanol (1,3-DBPA), a REACH pre-registered compound for which no experimental data on human health effects were retrieved, has a notified classification for a possible carcinogenic potential (Carc. 2 H351).

Possible read-across for the critical effect from the three category members with experimental data and the one member with classifications for the identified critical effect to the remaining 57 structurally similar target analogues in the category is supported by the following observations:

- a) The experimental data show comparable toxicological effects for the three members of the category identified in the preliminary structural grouping (2,3-DBPA, DBNPG and TBNPA), i.e. carcinogenic and mutagenic/genotoxic effects.
- b) The classifications (harmonized or notified) as Muta. 1B H340 / Muta. 2 H341 and/or Carc. 1B H350 / Carc. 2 H351 for these three members and for 1,3-DBPA.
- c) The (Q)SAR predictions for carcinogenic and mutagenic/genotoxic properties indicate that the 61 category members have a carcinogenic potential with a possible mutagenic/genotoxic mode of action. However, the structural alerts identified in the OECD (Q)SAR Application Toolbox indicate that members may exert their effects by a number of different mechanisms.

If the category were extended to include small brominated alkyl alcohols with 2-6 carbon atoms, tree more compounds (CAS RN 540-51-2, 4286-55-9, 488-41-5) with experimental data pointing towards carcinogenic effects would have been included.

Regulation of hazardous substances in EEE

Hazardous substances in EEE are regulated in the RoHS Directive 2011/65/EU (RoHS 2). According to articles 6(1) it is possible for member states to submit a proposal for adding new substances to the list of restricted substances in Annex II of the directive. Article 6(1) and 6(2) describe the criteria and requirements for proposals for restrictions respectively.

In 2014 the Commission published the study, 'Study for the Review of the List of

Restricted Substances under RoHS 2 - Analysis of impact from Possible Restriction of several new Substances under RoHS 2', performed by the Öeko-Institute. The aim of the study was to evaluate the prioritized substances for the RoHS Directive (<http://www.umweltbundesamt.at/rohs2> and <https://circabc.europa.eu/sd/a/0ee53cdd-5807-4679-a88c->

[3cabe30162f6/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf](#)). In the study the Öeko-Institute provided input concerning quantitative usage data for the 21 priority substances in EEE identified by the Austrian Umweltbundesamt GmbH, or where this is not possible, a magnitude ranking, with a view to a refined prioritization. From the table below it can be seen that the Austrian Umweltbundesamt GmbH prioritized two small brominated alkyl alcohols to be in the group of substances with the highest priority.

The Substances with Priority as Indicated by the Austrian Umweltbundesamt GmbH

Substance Name	CAS-No.
Highest priority	
Diisobutylphthalate (DIBP)	84-69-5
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8
Dibromo-neopentyl-glycol	3296-90-0
2,3-dibromo-1-propanol (Dibromo-propanol)	96-13-9
Second highest priority	
Antimontrioxid	1309-64-4
Diethyl phthalate (DEP)	84-66-2
Tetrabromobisphenol A	79-94-7
MCCP (medium chained chlorinated paraffins, C14 – C17)	85535-85-9
Third highest priority	
Polyvinylchloride (PVC)	9002-86-2
Fourth highest priority	
Nickel sulphate	7786-81-4
Nickel bis(sulfamidate); Nickel sulfamate	13770-89-3
Beryllium metal	7440-41-7
Beryllium oxide (BeO)	1304-56-9
Indium phosphide	22398-80-7
Fifth highest priority	
Di-arsenic pentoxide; (i.e. Arsenic pentoxide; Arsenic oxide)	1303-28-2
Di-arsenic trioxide	1327-53-3
Cobalt dichloride	7646-79-9
Cobalt sulphate	10124-43-3
Sixth highest priority	
Cobalt metal	7440-48-4
Nonylphenol (4-Nonylphenol, branched and linear)	84852-15-3 and 25154-52-3

Proposals for restriction of substances by the Commission and other Member States

Since RoHS 2 came into force the Commission has proposed the restriction of four phthalates. The so- called RoHS dossiers for these four phthalates can be found on the Commission Homepage (http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm).

Further KEMI in Sweden has commissioned the consultancy Risk & Policy Analysts Ltd (RPA) (e.g. <http://rpald.co.uk/projects/mccp> or <https://chemicalwatch.com/43145/sweden-to-prepare-rohs-restriction-for-mccps>) to prepare a [RoHS Annex II Dossier/Restriction proposal for MCCP in electric and electronic equipment regulated by ROHS](#).

Project Aim

The aim of this project is to collect, assess and present scientific data to support a proposal for restriction of small brominated alkyl alcohol in the RoHS Directive, if the data prove to be adequate. The category can be defined as having 3-5 carbons, 2-3 bromine atoms and 1-2 alcohol groups.

Projectdescription

In the application for the project the consultant should explain which data they intent to collect and how they intent to structure the scientific information.

Beside the Article 6 in the RoHS directive, there is no detailed guidance concerning the scientific data to be collected, assessed and structured in order to support a restriction under the RoHS Directive. However, the consultant should draw on relevant parts of the four dossiers on the phthalates restricted in RoHS and the methodology applied when establishing the dossiers (<http://www.umweltbundesamt.at/rohs2>). Further the Tender from KEMI (http://www3.kemi.se/Documents/Om_Kemi/Docs/Upphandlingar/upphandling-rohs-150710.pdf) can serve as inspiration.

In the approach of the Umweltbundesamt GmbH applied in the preparation of the phthalates dossier a mass flow analysis is performed. The mass flow analysis is applied in order to enable an assessment of the exposure to workers and surrounding environment during waste treatment and recycling operations. A similar approach may also be relevant for the small brominated alkyl alcohols.

At least it should be evaluated whether the small brominated alkyl alcohols:

- Could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
- Could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
- Could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;
- Could be replaced by substitutes or alternative technologies which have less negative impacts.

Further, the following should be delivered

- a. precise and clear description of the group of substances,
- b. references and scientific evidence for the restriction – if adequate,
- c. information on the use of the small brominated alkyl alcohols in EEE,
- d. information on detrimental effects and exposure in particular during waste EEE management operations,
- e. information on possible substitutes and other alternatives, their availability and reliability

a. In this regard the following should be considered:

i. Their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II of the RoHS Directive is scientifically or technically impracticable.

ii. The reliability of substitutes.

iii. Whether the total negative environmental, health and consumer safety impacts caused by substitution outweigh the total environmental, health and consumer safety benefits or not.

f. justification for considering a Union-wide restriction as the most appropriate measure – if adequate,

g. socioeconomic assessment,

h. evaluation on whether the inclusion of the small brominated alkyl alcohol in the lists in Annexes III and IV in the RoHS Directive would weaken the environmental and health protection afforded by the REACH Regulation (EC) No 1907/2006.

Further, the consultant should consider the relevance of identifying the most critical and thus most relevant steps in the waste treatment process in order to support or refine the assessment.

If possible a quantitative risk assessment should be performed. If lack of data prevents a quantitative assessment relevant assumptions should be made and arguments for the assumptions presented.

Stake holder consultation

In the application the consultants should discuss the relevance of a stakeholder consultation and perform such a consultation if relevant. The consultant can consider consulting various interested parties, including economic operators, recyclers, treatment operators, environmental organizations and employee and consumer associations.

Additive effects

If relevant the consultants should consider additive effects.

Read across

Optionally: If the consultant has any knowledge on additional possible read across options to small brominated alkyl alcohol, this should be described in the dossier

Data

Data can be collected from various sources. The following sources of information should be applied:

- The Danish EPA's survey on brominated flame retardants (BFR)
 - o Here information of use and consumption might be found.
- The Danish EPA's investigation of the possibilities of grouping BFRs (performed by The Danish Technical University Food – National Food Institute). Here hazard information and information on read across can be found.
- The Commission reports (1 and 2) on the prioritization of substances

The relevant web addresses has already been included in the tender description and is not repeated here

If the Consultant have knowledge of other important data sources these should be described in the application.

The following data should - at least if possible - be presented in the dossier:

- The amount of small brominated alkyl alcohols produced and marketed globally and in the EU on an annual basis for the last 10 years.
- The amount applied in EEE on a global scale and in the EU.
- The collection rates of WEEE.
- The number of WEEE treatment facilities in the EU.
- The waste treatment of the components where BFRs are applied.

Results

The result should be a clear recommendation on whether or not to include the small brominated alkyl alcohols in the RoHS Directive.

Delivery

The final delivery is a report in English using the Danish EPA's design for reports (<http://mst.dk/service/om-miljoestyrelsen/designguide-og-publikation/>).

Deadline

The project will start up in June 2016 and end by December 31th 2016. The final report must be delivered by November 30th 2016 and approved by December 15th 2016.

Economy

The project should not amount to more than [REDACTED]. The tender must contain all expenditure that the consultant expects in relation to the project and all expenditures must be specified.

All expenses for travel and meeting must be explicit in the tender.

Application

The tender shall contain the following:

- **Approach.** In the application for the project the consultant should explain which data they intent to collect and how they intent to structure the scientific information.
- **Work plan.** The work plan describes how the project is conducted, the time schedule and deadlines. The Danish EPA suggests at least a face to face start up meeting as well as a mid-way face-to-face meeting, where relevant decisions that has come up during the work can be taken. For additional meetings videoconferences can be arranged.**CV.** The consultant shall include CV of all staff members who would be assigned to work on the project. The consultant must describe the work assignment for each participant and indicate the number of hours assigned. Should the consultant want to replace the staff during the project, the new staff should be approved by the Danish EPA.
- **Expertise.** The following expertise is expected: Knowledge on the RoHS Directive, experience with risk assessment, socio-economic assessment, waste treatment, manufacturing processes and mass flow analysis as well as the ability to compile relevant information in written reports.
- **Budget.** In the budget the expenses of the main activities should be specified including hours.
- **Derivations.** If the consultant chooses to work differently than suggested here. It should be justified in the application.
- **Language.** The application should be written in English.

Here you can find the [Tender specifications for advertisement of contract](#).

Here is a copy of the [Danish EPA standard draft contract](#). When submitting a tender the draft contract should NOT be filled in or attached to the application

The application should be submitted to the Danish EPA:

, att. Dorte Lerche and to before June 16th 2016 at 10.00. The tender should be marked with the following number: MST-652-00134.

Contact person for the tender is Dorte Lerche (). Any question concerning the tender should be in writing and be submitted to at least 48 hours before June 13th 2016 kl. 10.00. All questions and replies will be published on the website of the Danish EPA.