# COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

## Paper for Information:

## UPDATE ON REGULATORY AND BIOMONITORING ACTIVITIES WITH REGARD TO PHTHALATE ESTERS

### Introduction

1. The COT considered the report by the Danish Environmental Protection Agency (EPA) entitled '*Survey and Health Assessment of the Exposure of 2–year olds to Chemical Substances in Consumer Products*' at the February 2010 meeting.* The Committee did not consider that the information presented to the February 2010 meeting (summary and conclusion of the report) raised concerns which required urgent consideration. Members welcomed the approach to studying total exposures from a range of different scenarios. Members asked to see the full report and for further information on the exposure estimates and the basis of the derived no effect level (DNEL). The COT considered the Danish EPA report at the June 2010 meeting. The risk assessments presented in the report focused on realistic worst-case exposure scenarios and were based on EU REACH[1] guidance.

***(Danish Ministry of Environment, EPA report No 102, 2009 http://www.mst.dk/Publikationer/Publications/2009/10/978-87-92548-81-8.htm)**

2. The COT considered a risk assessment of the use of di-n-butyl phthalate (DBP) in children's clogs at the December 2010 meeting. Members noted that the proposed worst-case risk characterisation ratio (i.e RCR>1) was likely to be an over-estimate, due to the conservative nature of the LOAEL ( a dietary level of 20 mg/kg diet for effects on testis and development of mammary glands in offspring (=1.5-3.0 mg/kg bw/day)), and the long duration (10 hours) that was assumed for wearing clogs. Members agreed that direct measurements of systemic uptake of DBP from clogs would be useful, together with information on the prevalence of DBP in the environment and how commonly it occurred in clogs. The Committee agreed that while small children were the critical population subgroup with regard to possible risks from DBP in rubber clogs, there was a need for biomonitoring studies in the UK with particular focus on women of childbearing age. This programme of work should explore the main sources of DBP exposure, and should investigate trends over time as well as patterns and determinants of exposure at baseline.

3. The COT published a statement on the dietary exposure to phthalates- data from total diet study (TDS) in May 2011[2]. Overall the Committee concluded that levels of phthalates that were found in samples from the 2007 TDS do not indicate a risk to human health from dietary exposure alone, either when the compounds are considered individually, or when they are assessed in combination. The Committee considered information on combined effects of phthalate esters, and agreed that, in

[1] Registration, Evaluation, Authorisation & restriction of CHemicals
[2] http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2011/cot201104

view of their similar structure and toxicological effects (the Committee noted that reproductive effects were seen with most, if not all, of the phthalates for which information was available), as a first tier approach, a cumulative risk assessment was appropriate, based on an assumption of dose-additivity. Due to the lack of established TDIs and limited toxicological information for many of the phthalates a hazard index or relative potency factor approach was not possible.

**Proposed Restriction Dossier**

4. The Danish EPA drafted an assessment of risk management options under REACH in November 2010 (Annex 1). It was concluded that restriction - a ban on placing on the market articles containing more than 0.1% of one or more of 4 phthalates (diethyl hexyl phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DiBP)) - was the preferred risk management option. The proposal was based in part on the conclusion that RCR was above 1 when combining the exposure of these 4 phthalates. The decision was made to progress with preparing a restriction proposal under REACH (EC 1907/2006)

[DEHP, DBP, BBP are already covered by legal restrictions in toys and childcare articles]

5. An overview of the Steps to be taken in the restriction process is appended as a flow diagram in Annex 2. The HSE are seeking COT advice on the science underpinning the conclusions in the Restriction Dossier. It is possible this will include a proposed aggregate risk assessment for the four phthalates under consideration. (All of these compounds have reference dose values set (DNEL= (N)LOAEL/Assessment factor (AF)).

6. COT advice will be fed into the UK comments to be submitted during the 6 month Public Consultation period. In this respect The Restriction Dossier is expected sometime in late August-early September and will be circulated by e-mail. It is hoped COT would be able to discuss the dossier at its 1 November 2011 meeting.

**Update on proposed U.K. Biomonitoring study**

7. An overview of the human biomonitoring studies to be undertaken by the U.K. and other participants in the harmonised European pilot study is provided as Annex 3. Members will wish to note that metabolites of the four phthalate esters which have been proposed for restriction within the EU have been selected for biomonitoring studies (i.e. DEHP, BBP. DBP and DiBP). The UK study is currently awaiting ethical clearance.

8. The Consortium to Perform Human Biomonitoring on a European scale (COPHES) has a timeline running from December 2009-to November 2012 and will establish the framework for harmonised approach to biomonitoring. DEMOCOPHES is a collaborative pilot study of 120 mother child pairs in each participating EU member state. There are 16 participating member states in DEMOCOPHES. The timeline for DEMOCOPHES is from September 2010 to November 2012.

**COMMENT**

9. The COT will be asked for an opinion on the scientific basis underpinning the EU restriction dossier on phthalate esters currently being prepared by the Danish Compete Authority.

**Secretariat**
**August 2011**

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### UPDATE ON REGULATORY AND BIOMONITORING ACTIVITIES WITH REGARD TO PHTHALATE ESTERS

Danish EPA assessment of risk management options under REACH

**Secretariat**
**August 2011**

November 4, 2010

# ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION FOR 4 PHTHALATES (RMO ANALYSIS)

**Substance name: Bis(2-ehtylhexyl)phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP)**

**IUPAC Name: Bis(2-ethylhexyl) phthalate**
**EC NUMBER: 204-211-0**
**CAS NUMBER: 117-81-7**

**IUPAC Name: Benzyl butyl phthalate**
**EC NUMBER: 201-622-7**
**CAS NUMBER: 85-68-7**

**IUPAC Name: Dibutyl phthalate**
**EC NUMBER: 201-557-4**
**CAS NUMBER: 84-74-2**

**IUPAC Name: Diisobutyl phthalate**
**EC NUMBER: 201-553-2**
**CAS NUMBER: 84-69-5**

**Submitted by: Denmark**
**Date: November 4, 2010**

## 1. Background

The RMO addresses the exposure due to emissions from articles that emit the phthalates DEHP, DBP, BBP and DIBP to the indoor environment as well as from articles where there is a direct exposure to humans. Especially exposure to children is in focus.

3 of the substances are already addressed via the authorisation procedure. The coming proposal for restriction will, however, address the effects to human health (REP 2) due to the combined (cumulative) exposure to the 4 classified phthalates and emissions to indoor environment and direct exposure from certain articles. This approach is not addressed by the authorisation process, as this process only addresses the use of the individual phthalate in individual articles.

3 of the phthalates (DEHP, DBP and BBP) are already covered by legal restrictions in toys in REACH Annex XVII, entry 51, which stipulates: "[DEHP, DBP and BBP] shall not be used as substances or as constituents of preparations, at concentrations higher than 0.1 % by mass of the plasticised material, in toys and childcare articles (5). Toys and childcare articles containing these phthalates in a concentration higher than 0.1 % by mass of the plasticised material shall not be placed on the market."

The proposal will therefore not touch upon a ban in articles already covered by this entry in REACH Annex XVII.

## 2. Objectives for risk management

The overall objective is a restriction for certain products based on the combined exposure of the 4 classified phthalates. The 4 phthalates are all classified based on their reproductive toxicity (Rep Cat 2 according to Dir. 67/548/EEC). The risk characterisation is based on exposure from food, indoor environment and direct exposure from consumer products.

Therefore the restriction will address the exposure due to emissions from articles that emit the phthalates to the indoor environment, and also from articles where there is a direct exposure to humans. Especially exposure to children is in focus.

The main groups of articles – based on existing data from surveys done in the last 10 years on uses – are for example:

- PVC wall covering and flooring.
- PVC insulation on wires and cables.
- PVC coated fabric and film/sheets used for furniture.
- PVC coated fabric and film/sheets used for bags and brief/suitcases and similar items.
- PVC coated fabrics and film/sheets used for tablecloth, curtains, shower curtains and similar items (non-industrial uses).
- Carpet tiles/squares produced with PVC-foam as back cover.
- PVC water- and air mattresses.
- Wallpaper/tapestry made of or coated with PVC.
- PVC footwear.
- Textiles (T-shirts and similar items) with PVC-print.
- PVC bathing equipment (swim-jackets/wings/belts and pools - inflatable and others).
- PVC erasers.
- Lacquer for wooden floors and furniture.
- Balance balls of PVC for playing (not toys) and physical exercises.

## 3. Available information

The 4 phthalates in question are all classified as Rep Cat 2 according to Dir. 67/548/EEC.

Denmark is currently gathering information on the uses and imports of the 4 phthalates into the EU and at the same time collecting information on available alternatives. In this respect Denmark is looking at the primary exposure routes for the 4 phthalates, exposure of phthalates from indoor environment, food and consumer products. Preliminary results indicate that the Risk Characterisation Ratio (RCR) is above 1 when combining exposure from the 4 phthalates.

Denmark has asked industry organisations as well as individual companies the following general questions in relation to use of the 4 phthalates and the alternatives in the articles mentioned above (which has been followed up by more specific questions):

- Which products are produced within the EU or imported to the EU containing the phthalates in question? To what extent are these products manufactured using the phthalates in question,

other phthalates or other plasticisers? What is the concentration of phthalates or other plasticisers typically used in the products?

- Which trends regarding the use of the phthalates in question and other plasticisers can be assumed in case no further restrictions are introduced?
- Which alternatives to the phthalates in question are available on the market, and which alternatives are today employed by the industry in EU?
- For which products are alternatives to the phthalates in question currently unavailable?
- Costs of alternatives compared to the phthalates in question?

***Denmark would like to take this opportunity to ask the same questions to member states. If member states have other relevant information (e.g. information on exposure, other important articles than listed above etc.), this is of course also welcomed and much appreciated.***

***Denmark would also like to take this opportunity to ask member states to comment on the approach taken (a general ban for articles intended for indoor use).***

## 4. Identification of risk management options

The chosen RMO shall address emissions to indoor environment and direct exposure as well as the combination thereof.

The following RMOs have been identified:

a. Voluntary agreements with importers on not to place the articles in question on the EU market.

b. Information – Campaigns aimed at consumers and retailers to avoid the articles in question.

c. Authorisation route. Imposing a ban on the use of the 4 phthalates within the EU, unless an authorisation has been issued. This RMO will not cover imported articles.

d. Labelling. Required labelling of all articles (in the covered product types) that contain more than a certain percentage (e.g. 0.1 %) of phthalates in question and that the article should be avoided in indoor environment. For other articles there should also be a warning on the risk arising from direct contact.

e. Restriction - ban on the placing on the market of articles intended for indoor use containing more than 0.1 % of one or more of the 4 phthalates

The identified options are discussed in chapter 5.

## 5. Assessment of the identified risk management options

The knowledge already available indicates clearly that alternatives already exist for most if not all articles/groups of articles – and that the alternatives are already on the market indicating that the economic impacts are small.

Re. 4a. Voluntary agreements.

It does not seem feasible to establish a functioning agreement due to the large number of importers and because the sector is not organised. This is also true for the plastic industry in Europe as quite a few of the downstream users are not organised (e.g. in Denmark).

Re. 4b. Information to consumers and retailers.
The message could be:
*To retailers – Avoid selling the articles in question.* This RMO does not seem to be sufficiently effective. Although the classification of the substances as Rep Cat 2 according to Dir. 67/548/EEC has been in force for many years, the articles still contain the substances.

*To consumers – Avoid buying the articles in question.* This RMO does not seem to be sufficiently effective. For the consumer it will be difficult to identify the articles containing the substances. Even if the articles are labelled (cf. RMO 4d) it is a problem that some of the articles have a long lifetime, e.g. PVC flooring, and a house might change owners/tenants. Therefore the person that is exposed might be another than the one taking the buying decision.

*To consumers – Ensure sufficient ventilation.* Calculations show that this will not be effective as the concentration in indoor air still will be too high when the exposures from other sources are taken in to account. This RMO will not cover direct exposure from articles from e.g. skin contact. However this RMO would address risks from articles already in use. The RMO can be supplementary to a restriction in relation to existing articles. Such advice can be given on national/local level.

Re. 4c Authorisation
The authorisation route only addresses use within the EU. This means that risks related to imported articles are not addressed. Furthermore the timeframe for the proposal will probably be much shorter than what can be achieved via the authorisation route. Furthermore the authorisation route would look upon the individual substances and in individual articles while this proposal will look into the combined effects of the phthalates from a broad range of articles.

Re. 4d Labelling
As mentioned under RMO 4b it is not considered that the risk is addressed effectively by requiring labelling of articles

Re. 4e. Restriction - ban on placing on the market of articles containing more than 0.1 % of one or more the 4 phthalates (the proposed RMO)

This seems to be the most effective RMO. So far alternatives seem to be available.

Restrictions set out a level playing field for all stakeholders and give both producers and importers the same obligations.

No major costs in relation to enforcement have so far been identified. The restriction should be based on a limit value as is the case for the existing entry 51 in Annex XVII of the REACH regulation in order to make enforcement easier.

## 6. Conclusions on the most appropriate (combination of) risk management option(s)

It is expected that the restriction dossier will consist of a ban of (types of) articles and include limit values on the content of the 4 phthalates.

A restriction is seen as the most appropriate and effective legal measure in order to protect consumers from being exposed to the 4 phthalates from a variety of articles used indoor and/or with direct exposure.

As mentioned above, Denmark would like to take this opportunity to place the questions mentioned in section 3 to Member States. If Member States have other relevant information, this is of course also welcomed and much appreciated. If information could be made available **before December 15**, Denmark would be very grateful. If information cannot be made available at that time, please indicate when information could be sent.

Please send your comments to Mr. Frank Jensen on e-mail fje@mst.dk – if you have any questions or need further information please contact Mr. Frank Jensen by e-mail or by phone (+45 7254 4423 / mobile +45 4061 3832).

The expected date for submission of the proposal is January 21, 2011.

**References**

Danish EPA 2009: Survey and Health Assessment of the exposure of 2 year-olds to chemical substances in Consumer Products, Survey of Chemical Substances in Consumer Products, 102, 2009, http://www.mst.dk/Publikationer/Publications/2009/10/978-87-92548-81-8.htm

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Restriction Process: Steps

**Secretariat**
**August 2011**

# Restriction process: Steps

The adoption of a new restriction on the manufacturing, placing on the market or use of substances involves the following main steps:

**1. Preparatory work**

A Member State or the European Commission may have a concern that a certain substance poses a risk to human health or the environment. If so, it would undertake preparatory work to investigate the problem further.

**2. Notify the intention to prepare a restriction dossier**

If the Member State or the Commission concludes that a restriction appears to be the best way forward, it has to notify its intention to prepare a restriction dossier. ECHA maintains a Registry of Intentions (RoI) which is publicly available on ECHA's website. It enables the stakeholders to prepare their contributions to the process.

- Registry of Intentions

**3. Prepare the restriction dossier**

The restriction dossier shall include information on hazards and risks, available information on alternatives and a justification for restrictions at EU-wide level. The dossier needs to demonstrate that the restriction is the most appropriate risk management instrument to address the identified risk or risks. The restriction dossier may also include an analysis of the socio-economic impacts. The proposal needs to be prepared according to the requirements given in Annex XV of REACH. The dossier needs to be submitted within 12 months of the notification in the Registry of Intentions.

- Reporting format
- Guidance for the preparation of an Annex XV dossier for restrictions
- Guidance on Socio-Economic Analysis - Restrictions

**4. Submit the restriction dossier**

Currently Member States can submit restriction proposals by e-mail. In 2010, Members States will have the possibility to submit restriction dossiers through REACH-IT.

**5. Check conformity**

The Committees check whether the submitted restriction dossier conforms with the requirements of Annex XV of the REACH Regulation.

- Template for checking conformity 

**6. Public consultation on the restriction report**

Conforming restriction reports will be published on ECHA's website, excluding any confidential information. Interested parties may submit comments on the restriction report and supporting documentation within six months of the date of their publication.

**7. Advice from the Forum**

The Forum may provide advice to RAC and SEAC on the enforceability of the proposed restriction.

**8. Prepare and adopt the opinion of RAC**

Within nine months of the date of the publication of the restriction report, RAC prepares and adopts an opinion based on the restriction dossier and comments received during the public consultation.

**9. Prepare and adopt the draft opinion of SEAC**

Within nine months of the date of the publication of the restriction report, SEAC prepares and adopts a draft opinion based on the restriction dossier, the socio-economic impacts, and the comments and socio-economic information received during the public consultation

**10. Public consultation on SEAC draft opinion**

The draft opinion of SEAC and the final opinion of RAC will be placed on ECHA's website. Interested parties may submit comments on the SEAC draft opinion within 60 days from publication.

**11. Prepare and adopt the opinion of SEAC**

SEAC prepares and adopts the final opinion taking into account the comments on its draft opinion.

**12. Send the opinions to the Commission**

ECHA sends the opinions of RAC and SEAC along with relevant background documents to the European Commission. These are also published on ECHA's website.

**13. Prepare and adopt the restriction decision**

Within three months of receipt of the Committees' opinion, the Commission prepares a draft amendment of the list of restrictions.

If the Council or the European Parliament do not oppose to the restriction, the Commission adopts it. The decision to restrict is published in the Official Journal as an amendment Annex XVII of the REACH.

- Comitology procedure with scrutiny
- List of restrictions (Annex XVII)

**14. Comply with restriction**

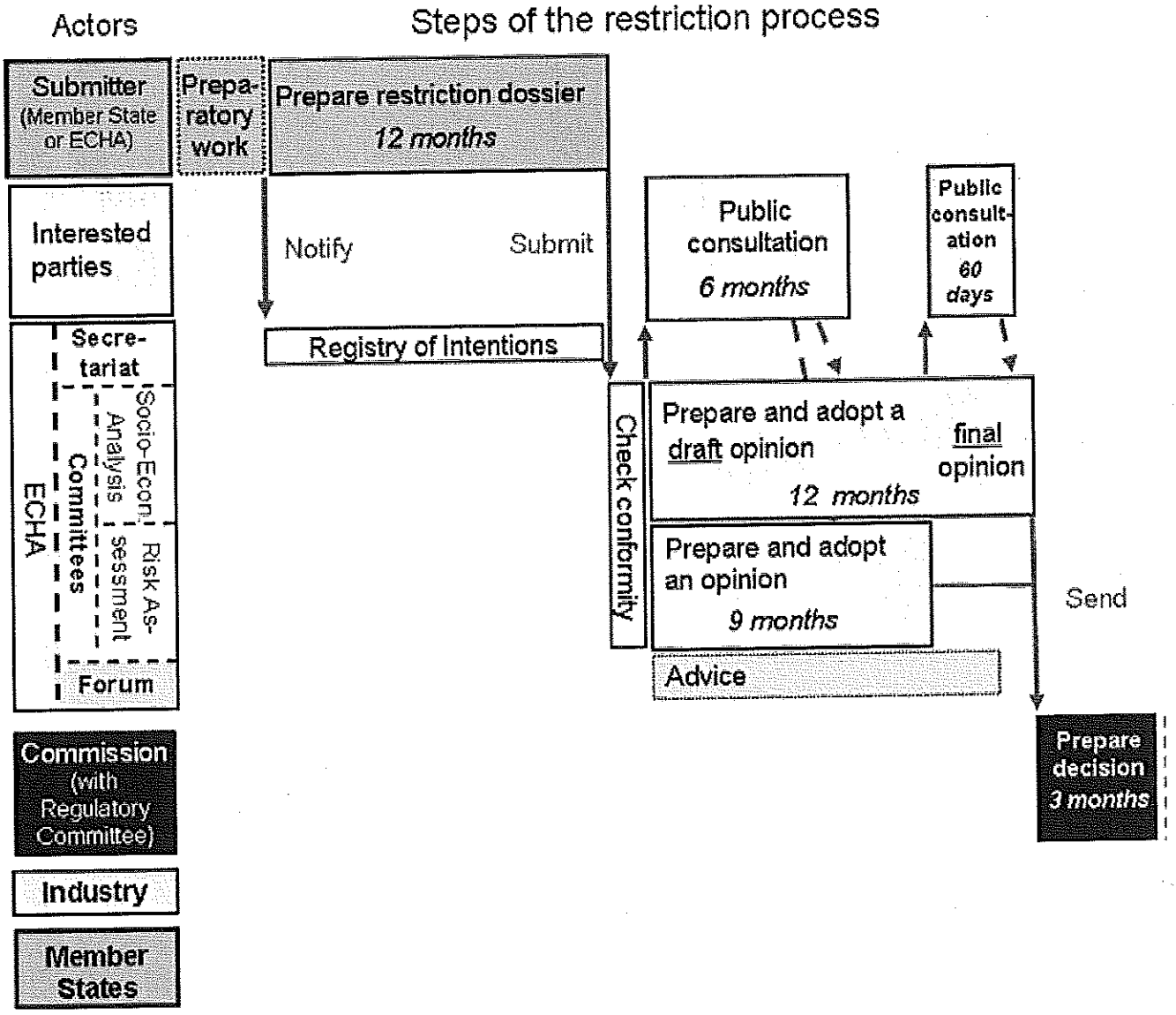
Once the substance restriction has been adopted industry needs to comply with it. By industry we mean anyone addressed in the ristriction, such as manufacturers, importers, distributors, downstream users or retailers.

**15. Enforce the restriction**

Member State Competent Authorities are responsible for enforcing the restriction.

# Restriction process

Restriction process has several actors and steps. This graph gives you an overview of the process. By clicking at actors or specific steps you can get further information.



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### UPDATE ON REGULATORY AND BIOMONITORING ACTIVITIES WITH REGARD TO PHTHALATE ESTERS

Human Biomonitoring For Europe: A Harmonised Approach

**Secretariat**
**August 2011**