Substance name: Dibutyl phthalate (DBP)
EC number: 201-557-4
CAS number: 84-74-2

JUSTIFICATION FOR THE DRAFT RECOMMENDATION OF INCLUSION IN ANNEX XIV

14 January 2009

CONTENTS

1. Identity of the substance

Substance name:	Dibutyl phthalate (**DBP**)
IUPAC name:	Dibutyl phthalate
Chemical name:	Dibutyl phthalate
EC number:	201-557-4
CAS number:	84-74-2

2. Intrinsic properties of the substance

DBP was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified as Toxic to Reproduction, Category 2 and included in the candidate list for authorisation by the ECHA's decision ED/67/2008 on 28 October 2008, after agreement of the Member State Committee.

Possible route for authorisation:
The substance meets the criteria in Article 57(c) and according to available information, it is possible to determine a toxicological threshold. Therefore, if the risk to human health from the use of the substance arising from its toxicity to reproduction is adequately controlled in accordance with Section 6.4 of Annex I and this is documented in the applicant's chemical safety report, an authorisation will be granted in accordance with Article 60(2) ('adequate control route'); if not, an authorisation may be granted in accordance with Article 60(4) ('socio-economic route').

3. Proposed transitional arrangements

Proposal:

- *Latest application date*:
  30 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  48 months after the entry into force of the Decision to include the substance in Annex XIV

Justification:

Complexity of the supply chain:

According to the available information, DBP is manufactured at 2 sites within EU. Furthermore, there is a net export of DBP.

DBP is either processed - mainly as gelling aid and plasticiser - in various types of polymers (PVC and other polymers) or formulated as component in preparations (e.g. adhesives, grouting agents, paints). These different applications and relatively high amounts of DBP used may indicate that a large number of companies are involved in the further processing and formulation of DBP down into the supply-chains. A wide range of end-products containing DBP are produced and used by potentially high

number of users. Furthermore, users of the end products containing DBP represent several different industry sectors and professional user groups.

As conclusion, according to available information, many different types of industries and activities involving a large number of actors may be affected by the possible authorisation requirement and may need to get involved directly or indirectly in the preparation of applications.

Hence, based on the available information, it is anticipated that the preparation of applications for authorisation will require a considerable collaborative effort by various actors, involved both within the same or different supply chains, which justifies a longer period for preparing applications than the minimum.

Furthermore, some of the uses and potentially affected user groups are the same as for DEHP, which backs setting the same applications date for these substances.

Availability of alternatives:

There appears to be information on alternative substances to DBP and alternative materials to polymers containing DBP for many of the uses. Furthermore the available information indicates substitution of DBP is already ongoing for certain uses. The available information on potential alternatives and experiences in their use in comparable applications and/or as substitutes to similar substances facilitates preparing an analysis of alternatives for the uses for which actors wish to apply for

On the other hand, some of the available information on alternatives suggests that the potential applicants may need to assess a more complicated situation to conclude whether or not the transfer to alternatives is feasible. This is the case, for instance, where the identified potential alternative may have an impact on the specific properties that DBP confers to certain end products affecting, e.g., the maintenance.

Consequently, the available information suggests that the preparation of the application, in particular the analysis of alternatives, may require more time. Hence, the available information justifies a longer period for preparing applications than the minima.

Conclusion:

The available information on the complexity of the supply chains and the availability and nature of alternatives provides reasons to propose a longer time for preparing applications.

4. Proposed review periods for certain uses

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5. Proposed exempted (categories of) uses

Proposal:

To exempt from the authorisation requirement the placing on the market of DBP in preparation for the supply to general public for the use as artists' paints when these are covered by Directive 1999/45/EC.

Justification:

DBP is substance which use is restricted by Directive 76/769/EEC. This restriction can be found in entries 30 and 51 of that Directive as well as in entries 30 and 51 of Annex XVII of the REACH Regulation. Annex I of Directive 76/769/EEC permits use of DBP under the conditions set out below.

First, pursuant to entry 30 of Annex I of Directive 76/769/EEC substances (e.g., DBP) which appear in Annex I to Directive 67/548/EEC classified as toxic to reproduction category 1 or 2, shall not be placed on the market for supply to the general public as a substance on its own or in preparations when equal to or greater than either the relevant concentration specified in Annex I to Directive 67/548/EEC, or the relevant concentration specified in Directive 1999/45/EC (i.e., is equal to or greater than 0.5%). Thus, use of DBP in concentrations lower than 0.5% is permitted.

Article 56(6)(b) of REACH provides that the authorisation requirement does not apply to the use of substances in preparations below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC. Accordingly, the concentration limits specified for DBP in Directive 76/769/EEC (and in Annex XVII of REACH) are in fact the same as the concentration limits referred to in Article 56(6)(b). Therefore, the use of DBP below the concentration limits set out in Directive 76/769/EEC (and Annex XVII of REACH) does not need to be subject to an exemption from authorisation.

Second, pursuant to entry 30 the concentration limits described above do not apply to medicinal or veterinary products, cosmetic products, motor fuels, mineral oil products intended for use as fuel, fuels sold in closed systems, and artists' paints.

Pursuant to Articles 2(5)(a), 56(4) (c) and (d) and 56(5)(a) the provisions on authorisation under REACH do not in any event apply to medicinal or veterinary products, cosmetic products[1], motor fuels, mineral oil products intended for use as fuel and fuels sold in closed systems. Use of DBP in these products therefore does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

However, the use of DBP in artists' paints covered by Directive 1999/45/EC is not automatically exempted from authorisation under the REACH Regulation. In light of the fact that such use was already permitted under Directive 76/769/EEC which is legislation imposing minimum requirements relating to the protection of human

[1] In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health.

health, the use of artists' paints can be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation.

Third, pursuant to entry 51 of Annex I of Directive 76/769/EEC DBP shall not be placed on the market or used as a substance on its own or in a preparation, at concentrations greater than 0.1% by mass of the plasticised material, in toys and childcare articles.

The concentration limits set out in this entry are lower than the concentration limits set out in Article 56(6)(b). Use of DBP in these products therefore does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

It should be noted that it is not possible to grant an authorisation that would constitute a relaxation of a restriction set out in Annex XVII (Art 60(6) of REACH). Therefore, it is not possible to authorise, and by that not meaningful to apply for an authorisation for, the use of DBP in plasticised materials intended for the use in toys and childcare articles or the placing on the market of preparation for the supply for generic public.