

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on
four phthalates

Draft

15 June 2012

**Opinion of the Committee for Socio-economic Analysis
on an Annex XV dossier proposing restrictions of the manufacture, placing on the
market or use of a substance within the Community**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation [and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation] on the proposal for restriction of

Chemical name(s): *Bis(2-ethylhexyl) phthalate*
EC No.: *204-211-0*
CAS No.: *117-81-7*

Chemical name(s): *Benzyl butyl phthalate*
EC No.: *201-622-7*
CAS No.: *85-68-7*

Chemical name(s): *Dibutyl phthalate*
EC No.: *201-557-4*
CAS No.: *84-74-2*

Chemical name(s): *Diisobutyl phthalate*
EC No.: *201-553-2*
CAS No.: *84-69-5*

This document presents the draft opinion as agreed by SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Denmark has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **16 September 2011**.

Interested parties were invited to submit comments and contributions by **16 March 2012**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on **15 June 2012**.

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at <http://www.echa.europa.eu/web/guest/restrictions-under-consideration> on **6**

July 2012. Interested parties were invited to submit comments on the draft opinion by **3 September 2012.**

OPINION

Taking into account RAC's conclusion that the proposed restriction is not justified because the available data do not indicate that currently (2012) there is a risk from combined exposure to the four phthalates and that the regulatory requirements and consequent reduction in use are further reducing the risk, as will the authorisation requirements imposed on these phthalates in the next few years, SEAC has no basis to support the proposed restriction.

JUSTIFICATION FOR THE OPINION OF SEAC

Justification that action is required on a Community-wide basis

SEAC acknowledged that articles containing phthalates are widely distributed on the EU market. Several Risk Management Measures (RMM) affecting phthalates have been implemented in recent years (incl. restrictions of the use in toys and food contact materials). Consequently, risk management for these chemicals is already taking place at a Community-wide scale and any additional measures, if relevant, would logically be introduced on a Community-wide basis. However, SEAC took note of RAC's conclusion that no further action is justified.

Justification that the suggested restriction is the most appropriate Community-wide measure

Effectiveness in reducing the identified risks, proportionality to the risks

SEAC considered that, due to a trend towards substitution of the four phthalates, existing restrictions under EU legislation and their inclusion in Annex XIV, their amount on the EU market has decreased significantly during the last decade and is expected to further decrease in the period from now until 2020.

According to RAC, this decrease has already reduced and will further reduce the risk for the targeted reprotoxic effect. RAC concluded that the available data do not indicate that currently there is a risk from combined exposure to the four phthalates and considered that the restriction is not justified.

The conclusion of RAC on the proposed restriction is supported by the baseline scenarios of past and future trends regarding amounts of the four phthalates on the EU market. These scenarios in turn partly depend on the future effect of the inclusion of the four phthalates in Annex XIV.

SEAC also underlined that these scenarios only relate to the annual volumes placed on the EU market, and do not take account of initial stocks (present in existing articles) of the four phthalates and their evolution. There is a decline of the stocks of the four phthalates in articles as a consequence of the downward trend of the amount of the four phthalates in articles placed on the market. However, the dynamics of this trend and, therefore, future dates when particular exposure thresholds are reached cannot be assessed quantitatively.

Due to uncertainties over the baseline scenarios, there is a need to collect and review data in the future in order to get a better evidence base for risk management. SEAC recognised that according to Article 69(2)¹ of the REACH Regulation, ECHA shall consider whether the use of the substances in articles poses a risk and if the risk is not adequately controlled, prepare an Annex XV restriction dossier (and therefore will review information on present and future volumes and stocks).

¹ Article 69(2) of the REACH Regulation: "After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV."

a) SEAC views on the proportionality of the proposed restriction

Acknowledging the RAC conclusion that the restriction is not considered to be justified in terms of risk, SEAC had the following views concerning the effectiveness and proportionality of the proposed restriction:

- The four phthalates are classified as reprotoxic chemicals. In addition to potential adverse effects on reproductive health, associations to hormonal cancers and various neurodevelopmental deficits potentially having also social, psychological and behavioural consequences have been reported. The potential health impacts and related uncertainties of the four phthalates are discussed in the Background Document (BD).

However, the benefits of the proposed restriction related to possible health impacts were not demonstrated in the BD, as in particular the distribution of the risk in the EU population was not estimated. Furthermore, the information available to SEAC did not allow for any assessment of potential environmental benefits.

In an attempt to assess the proportionality of the proposed restriction, based on reprotoxic effects, SEAC intended to compare the costs of the proposed restriction, with the benefits in terms of avoided infertility cases in EU couples (see BD), but SEAC found it was not possible to make any comparison between costs and benefits.

In conclusion, although the proposed restriction might have led to benefits, these were not demonstrated in the BD, in terms of their existence, their significance, and magnitude. Therefore, no comparison of the benefits can be made with the costs *a fortiori*.

- Furthermore, SEAC noted that given the very wide scope of the proposal, and given that not all articles are likely to contribute equally to the exposure, it has not been demonstrated and it is doubtful that the proposed restriction would actually be the most appropriate Community-wide measure.
- The proposed restriction could have an adverse economic impact as a result of reduced flows of recycled PVC on the EU market.

These observations should not be understood as questioning any existing or pre-empting of any future risk management measures in relation to the four phthalates.

The following sections b) to d) below provide further justification of the baseline scenarios in more technical terms. They explain in particular why the volumes on the market are expected to decline significantly in the future as a consequence of already implemented/decided risk management measures in the EU. The main reasons for this are the availability and technical feasibility of alternatives as well as the affordability of substitution, and the general trends in the use and substitution possibilities of the four phthalates.

b) Availability and technical feasibility of alternatives

According to the evidence presented in the BD as well as information submitted in the Public Consultation, SEAC concluded that there are technically feasible alternatives available to replace the four phthalates that are subject to the proposed restriction, and to the authorisation procedures for a very significant part of their use.

Section B.2.2.13 of the BD shows that DINP is the major alternative, but that several other alternatives (differing between fields of application) have been reported as available by industrial stakeholders surveyed by the consultant mandated by the dossier submitter.

Industry data² shows that between 2001 and 2010, the market share of DEHP fell from 40% to 10%, while symmetrically the share of three main substitutes (DINP, DIDP, and DPHP) rose from 50% to 80%. In 2009-2010, the use of the four phthalates in articles in the EU was reduced by 35% compared to the use in 2007 (see Table below), indicating that substitution is taking place. Other facts presented in the BD tend to confirm the ongoing shift from the four phthalates to other phthalates (and also to some non-phthalate plasticisers).

Recent regulation is (directly or indirectly, depending on the article) an ongoing driver for this substitution. Although non-phthalate alternatives are still marginal, and have so far mainly been used for applications in toys, medical products and food packaging, there are, nevertheless, indications of significant increases in production capacities in Europe and announcements of new commercial products which show that the use of these alternatives should rise significantly in the EU, including for applications within the scope of the proposed restriction. Therefore, SEAC considered that the number and availability of these alternatives is increasing. Furthermore, although no clear and general conclusion on the suitability of alternative plastics can be made, it is evident that in some cases alternative plastics are possible alternatives further widening the substitution portfolio for industry.

c) Affordability of substitution

Alternative plasticiser price

The BD presents a scenario, in which DEHP in many of the cases is replaced by DINP, which is thought to be a possible substitute for DEHP in PVC. Such a substitution is estimated to increase the costs of the raw material by around 10%. SEAC acknowledged that the substances addressed in the restriction proposal are unlikely to be completely replaced with only one substance (e.g. substitution of DEHP with DINP) but with a combination of alternative non-phthalate and phthalate plasticisers.

Taking into account other alternatives besides DINP, prices of alternatives are 0% - 30% higher in comparison to DEHP. This is based on the scenario suggested in the BD, on the information on alternative plasticisers from past studies, on the recent information retrieved from specialised internet sites for market prices, and taking into account technical substitution factors.

However, given the uncertainty of the available information, and the variety of situations, it is possible that the substitution costs in some cases are outside of this range.

SEAC also noted that plasticiser prices show significant fluctuations that can be of the same order of magnitude as the price differences between phthalates-containing plasticisers and the alternatives.

Reformulation and other costs

There is limited information available to SEAC on other costs such as reformulation of mixtures and materials used for the production of articles, changes in the production process of articles, redesigning and where applicable re-certification or testing of articles,

² European Council for Plasticisers and Intermediates, 2011.

and possible removal and restocking of articles in the supply chain. Similarly, little information is available on possible savings if shorter and more efficient processing can be reached with new plasticisers, as claimed by some manufacturers of alternatives.

Some stakeholders, as reported in the BD, anticipated limited technical problems with regard to reformulation. A flooring company (using both DINP and non-phthalates) and a cable producer (also using both DINP and other plasticised materials) both indicated that the technical changes in the production line are very limited and straightforward. However, it is clear that this example has very limited representativeness given the wide variety of articles produced using soft PVC. Furthermore, in some specific industrial sectors (in particular the aerospace industry) substitution implies the need to conduct research and development, to gain regulatory approval for safety requirements (e.g. flammability) and to distribute alternatives in complex supply chains, which might require more time to carry out.

Overall, considering the above information, and also some partial qualitative information present in the BD (impact of substitution costs on article price for final consumers, qualitative information of the feasibility of substitution), SEAC estimated that alternatives are currently technically available at an affordable cost for a majority of situations.

d) Future decline in volumes put on the EU market annually

According to Section B.2.1 of the BD, articles placed on the market for the use indoors and/or in direct human skin/mucous membranes contact were estimated to contain 255,000 tonnes of the four phthalates in total in 2007. DEHP represents 95% of this amount. The imported articles represent at least 44,000 tonnes (17%).

Based on the information from registrations submitted by producers and importers, the content of the four phthalates in articles is estimated to rapidly decrease, having reached 165,000 tonnes by 2009-10. It is not known to what extent the registered reduction is a real decline and to what extent it reflects different approaches in collecting data. The numbers above do not include potential volumes from recycling. Other information present in the BD indicates a decreasing trend in the consumption³ of DEHP, DIBP and DBP in Europe between 2000 and 2010.

The information presented in the BD shows that the four phthalates are still used in large quantities in articles for indoor use and/or with direct human contact. But for many fields of application, voluntary phasing out of the four phthalates and/or phthalates in general has already taken place, or is underway. For the phasing out process there are several drivers: the classification of the four phthalates as reprotoxic, the EU legislation restricting their use in toys and childcare articles, and the recent EU regulation on food contact materials. The substitution process seems to be continuing after the inclusion of the four phthalates in Annex XIV to REACH.

Substitution of the four phthalates with other plasticisers is expected to continue due to information requirements (triggered by the fact that the four phthalates have been identified as substances of very high concern (SVHCs) under the REACH Regulation). The information requirements are set in REACH for the supplier of an article containing one or more of the four phthalates in a concentration of more than 0.1% to inform the recipient and (upon request) the consumer if the article contains one or more of the four phthalates. It is therefore assumed that the amount of articles containing the four phthalates will clearly decrease, even if the direct effects of their inclusion in Annex XIV are not taken into account. As shown in the Table below, the decrease in EU production from 2007 to 2020 is

³ Consumption = production in the EU – export + import.

projected to be 60%. The total decrease is somewhat less (56%) due to a smaller decline in imports. The BD contains a more detailed description of these scenario calculations.

On top of this, the baseline scenarios are constructed taking into account the direct effects of the inclusion of the four phthalates in Annex XIV. The inclusion of the four phthalates in Annex XIV will have an influence as in order to use the four phthalates after the sunset date (21 February 2015), an authorisation will be needed. The authorisation procedure incurs non-negligible costs to industry that could be higher than substitution costs in a number of situations. Furthermore, not necessarily all requested authorisations will be granted. These factors encourage industry to find and use suitable alternatives and, therefore, it can be assumed that the use of the four phthalates within Europe will decline even more than projected without the authorisation effect (see above).

Considering information on the availability and on the costs of alternatives as well as the evidence that substitution has already started (see sections above), for the purpose of developing the baseline, SEAC assumed that authorisations will only be applied for and granted in a moderate number of cases. This is reflected in the strong decline in volumes placed on the market by EU manufacturers in the baseline scenario⁴.

Authorisation does not directly restrict the import of articles containing the four phthalates, however, certain obligations due to the Annex XIV listing cause additional tasks (and costs) to importers. Nevertheless, it could be expected that volumes of the four phthalates in imported articles may increase after authorisation takes place compared to the projected amount without the authorisation effect, as imports could replace some of the EU production. On the other hand, some uses could also be replaced by other phthalate and non-phthalate alternatives by non-EU-producers, which in turn would decrease the imported amounts. Overall, the increase of phthalates in imports in the future is considered to be limited.

Based on these basic assumptions, three scenarios are developed in the BD. Having three scenarios instead of a single one aims to provide a more robust estimation with an interval of projected volumes instead of a single value.

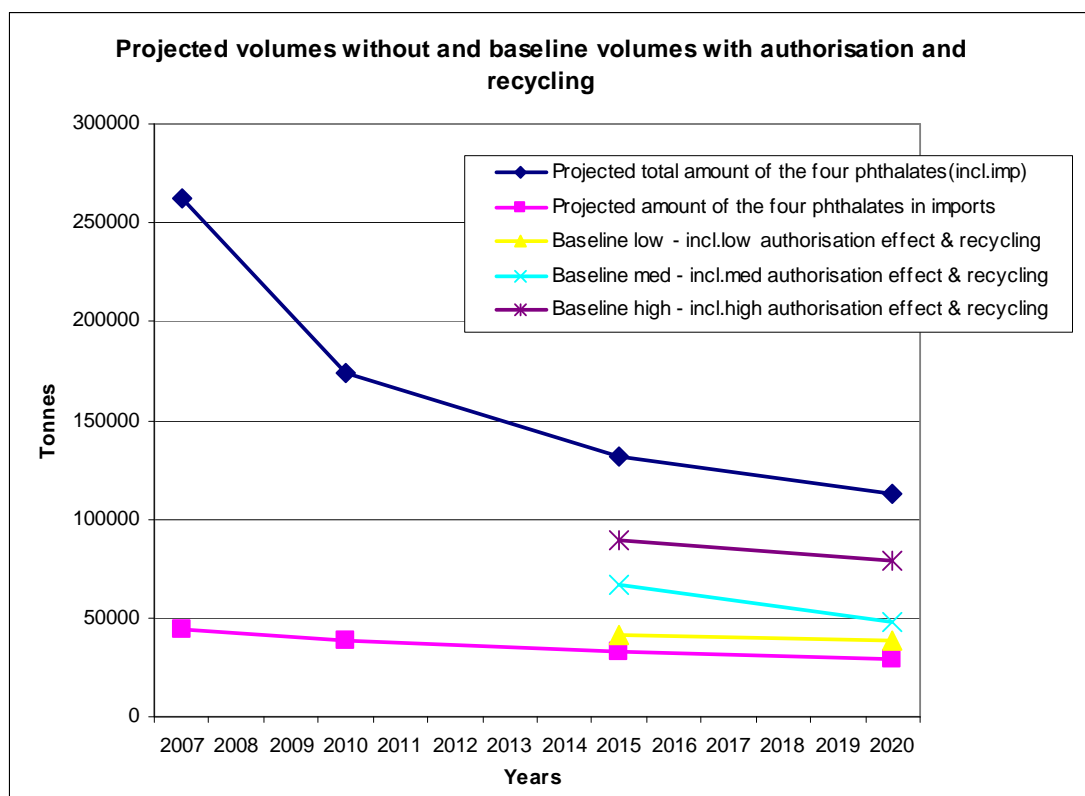
The discussion above concentrates on virgin materials and thus the amounts mentioned above do not include phthalates that are contained in recyclates recovered from used soft PVC. The BD details an estimation of volumes coming from recyclates which need to be added to the amounts. Based on industry information (BD and Public Consultation), it can be estimated that there was an additional amount of 5,000 tonnes in 2010 and there will be 6,900 tonnes in 2015 and 8,400 tonnes in 2020 of the four phthalates included in the scope of the proposed restriction through recyclates.

For a final baseline volume estimate, the amounts from the three scenarios and the estimated amount of phthalates in the recyclates from mechanical recycling have been summed, and the results range from 38,000 to 79,000 tonnes. The baseline scenarios are presented in Table 1 and in the graph below with the original market projections without authorisation and recycling.

⁴ SEAC clarifies that this general assessment is independent from its future assessments and opinions on individual authorisation dossiers submitted by industry.

Table 1 Estimated amounts of the four phthalates in articles marketed in the EU in 2007 and 2009-2010, and projected amounts for 2015 and 2020 including the projected baseline volumes for three alternative baseline scenarios.

	2007	2009-10	2015	2020
Projected volumes without authorisation and recycling:				
<i>EU production (kt)</i>	211	127	98	84
<i>decrease since 2007</i>		-40%	-54%	-60%
<i>imports to EU (kt)</i>	44	38	33	29
<i>decrease since 2007</i>		-13%	-25%	-35%
Total (kt)	255	165	131	113
<i>decrease since 2007</i>		-35%	-49%	-56%
Baseline scenarios with authorisation effect:				
<i>"low" scenario (kt)</i>			35	30
<i>"low" scenario (decrease since 2007)</i>			-86%	-88%
<i>"med" scenario (kt)</i>			59	39
<i>"med" scenario (decrease since 2007)</i>			-77%	-84%
<i>"high" scenario (kt)</i>			82	71
<i>"high" scenario (decrease since 2007)</i>			-68%	-72%
Baseline scenarios with authorisation effect and amounts from recycling:				
<i>"low" scenario (kt)</i>			42	38
<i>"low" scenario (decrease since 2007)</i>			-84%	-85%
<i>"med" scenario (kt)</i>			66	48
<i>"med" scenario (decrease since 2007)</i>			-74%	-81%
<i>"high" scenario (kt)</i>			89	79
<i>"high" scenario (decrease since 2007)</i>			-65%	-69%



The aforementioned information on volumes and baseline estimates have been used by RAC, together with other information, to assess the future risk of the exposure to the four phthalates proposed to be restricted.

Practicality, including enforceability

Given that SEAC has no basis to support the proposed restriction, its practicality (including enforceability) is no longer relevant.

Monitorability

Given that SEAC has no basis to support the proposed restriction, its monitorability is no longer relevant.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinion.

SEAC has no basis to support the proposed restriction as proposed in the Annex XV restriction dossier submitted by Denmark.