

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Bis(2-ethylhexyl) phthalate (DEHP) use:

**Formulation of recycled soft PVC containing DEHP in
compounds and dry-blends**

ECHA/RAC/SEAC Opinion N° AFA-O-0000004151-87-16/D

Consolidated version

Date: 22 October 2014

Consolidated version of the
Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis
on an Application for Authorisation

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 Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) of the REACH Regulation with regard to an application for authorisation for:

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

for the following use:

Formulation of recycled soft PVC containing DEHP in compounds and dry-blends

Intrinsic property referred to in Annex XIV:

Toxic to reproduction (Article 57 (c) of the REACH Regulation)

Applicants and reference numbers:

VINYLOOP FERRARA S.p.A., 11-0000000327-78-0000
Stena Recycling AB, 11-0000000327-78-0002
Plastic Planet srl, 11-0000000327-78-0004

Rapporteur, appointed by the RAC: **Betty HAKKERT**

Rapporteur, appointed by the SEAC: **Cees LUTTIKHUIZEN**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 13 August 2013 VINYLOOP FERRARA S.p.A.; Stena Recycling AB and Plastic Planet srl submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **31 October 2013** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation> on **13 November 2013**. Interested parties were invited to submit comments and contributions by **8 January 2014**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant as well as third parties to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

Due to the need to ensure the efficient use of resources, and in order to synchronise the public consultation with the plenary meetings of the Committees the time limit set in Article 64(1) for the sending of the draft opinions to the applicant has been extended until 01 October 2014.

The draft opinions of RAC and SEAC were sent to the applicant on **01 October 2014**.

On **09 October 2014** the applicants informed that they did not wish to comment on the opinions and the draft opinions of RAC and SEAC were therefore considered as the final on **10 October 2014**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **13 August 2014** via Written Procedure.

The draft opinion of RAC was adopted by a simple majority of all members having the right to vote.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **10 October 2014**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **12 September 2014** at the SEAC-24 plenary meeting.

The draft opinion of SEAC was adopted by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **10 October 2014**.

THE OPINION OF RAC

RAC has formulated its opinion on the risks arising from the use applied for and the appropriateness and effectiveness of the described risk management measures, and on the assessment of the risks related to the alternatives as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC confirmed that it is possible to determine a DNEL for the reproductive toxicity properties of the

substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that there appear not to be [any] suitable alternatives that further reduce the risk.

RAC confirmed that the risk assessment based on the limited exposure data in the application does not demonstrate adequate control of risks for workers from the use applied for.

RAC's assessment based on these limited exposure data in the application showed a risk for the use applied for.

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC took note of RAC's confirmation that it is possible to determine a DNEL for the reproductive toxicity properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC took note of RAC's confirmation that the risk(s) to human health or the environment from the use of the substance is not demonstrated to be adequately controlled.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.

SEAC considered that there were significant deficiencies in the socio-economic analysis presented by the applicant, including a health impact assessment identifying the remaining risks to workers health.

However, based on a qualitative analysis that incorporated relevant uncertainties, SEAC considered that authorisation of the use would be proportional.

The duration for the review period has been suggested below.

Use

The authorisation is considered for the following use:

- Formulation of recycled soft PVC containing DEHP in compounds and dry-blends

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

No additional conditions to those described in the application are proposed.

Monitoring arrangements

No additional monitoring arrangements to those described in the application are proposed.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use the duration of the review period for the use is recommended to be **seven years**.

JUSTIFICATIONS

Substance name: Bis(2-ethylhexyl) phthalate (DEHP)
Name of applicants and reference numbers: VINYLOOP FERRARA S.p.A., 11-0000000327-78-0000
Stena Recycling AB, 11-0000000327-78-0002
Plastic Planet srl, 11-0000000327-78-0004
Use name: Use 1: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property/properties:

- C
 M
 R
 PBT/vPvB
 Other [please specify]:

2. Is the substance a threshold substance?

- YES
 NO

Justification:

Reproductive toxicity is the most sensitive toxicological endpoint for DEHP. For DEHP there is no evidence of genotoxicity. Reproductive toxicity of DEHP is mediated by a depression of testosterone levels in the developing male reproductive system resulting in, amongst other effects, testicular dysgenesis syndrome. Based on this toxicological endpoint, RAC has previously established reference Derived No Effect Levels (DNELs; RAC/24/2013/08 rev. 2; Helsinki, 12 April 2013) and considers DEHP to be a threshold substance. In the public consultation, it was argued that DEHP is a recognised endocrine disrupting substance (EDC) and therefore should not be considered as a threshold substance.

RAC does acknowledge the endocrine mode of action of DEHP but also recognises that it has been included in Annex XIV because of its reproductive toxicity classification (Art. 57c) and not on the basis of endocrine disrupting properties (Art. 57f). As a consequence, the current assessment is limited to the reproductive toxicity of DEHP.

3. Hazard assessment. Are the DNEL(s) appropriate?

The DNELs from the applicants deviate from the DNELs set by RAC at 12 April 2013.

Justification:

The DNEL values from the applicant deviate from the DNEL values set by RAC on 12 April 2013. Table 1 compares the respective RAC and applicant DNEL values. RAC DNEL values are lower than those provided by the applicant. The most significant difference between the RAC and applicant values is for the oral DNEL for workers which is 94 µg/kg/d derived by RAC and 224 µg/kg/d derived by the applicant (the oral DNEL for workers is needed for comparison with the biomonitoring data).

Table 1: Comparison of DNEL values derived by the applicant and those set as reference DNELs by RAC.

DNEL	Value applicant	Value RAC	Cause deviation	Factor difference
Worker - inhalation	1.6 mg/m ³	0.88 mg/m ³	Oral abs. rat 75% vs 70% Intraspecies AF 3 vs. 5	1.8
Worker-dermal	3.4 mg/kg bw/d	1.88 mg/kg bw/d	Oral abs. rat 75% vs 70% Intraspecies AF 3 vs. 5	1.8
Worker-oral (biomonitoring)	0.23 mg/kg bw/d	0.094 mg/kg bw/d	DNEL worker-inh. 1.6 vs. 0.88 mg/m ³ Oral abs. adult 75% vs. 100%	2.4
GP Child - oral	0.036 mg/kg bw/d	0.034 mg/kg bw/d	Oral abs. rat 75% vs 70%	1.1
GP Adult- oral	0.048 mg/kg bw/d	0.034 mg/kg bw/d	Oral abs. rat 75% vs 70% Oral abs. adult 75% vs. 100%	1.4

GP = general population. All DNELs are external doses.

RAC has carefully considered the arguments as provided by the applicant. There is some evidence that the oral DEHP absorption in humans might be slightly

higher than in the rat. This is reflected in the oral absorption percentages used by RAC. In the ECHA guidance document for DNEL derivation the default intraspecies extrapolation factor for workers is agreed to be 5. Because there are no specific DEHP data indicating the need for a substance-specific modification of the default intraspecies factor, RAC decided not to deviate from the default intraspecies factor of 5 for workers.

RAC is aware of the uncertainties regarding the DNEL derivation for DEHP; these uncertainties have been addressed in the RAC document establishing reference DNELs for DEHP (RAC/24/2013/08 rev. 2, 12 April 2013). There are extensive research activities with respect to DEHP toxicology; thus there are many recent publications on DEHP toxicity following finalisation of the RAC reference DNEL document. One specific area of DEHP research focusses on possible interspecies differences. RAC considered the corresponding arguments as provided by the applicant and stakeholders during public consultation and finally decided not to deviate from the published reference DNEL in absence of any new convincing information sufficiently justifying a deviation.

4. Exposure assessment. Is the exposure from the use adequately described?

YES

NO

The applicant describes one use, or exposure scenario (ES):

Use1 – Formulation of recycled soft PVC containing DEHP in compounds and dry-blends

The applicants indicate that cable waste is mainly used as basis for the recycled soft PVC (so called recyclate), containing a maximum 20% DEHP. The recyclate is transported to downstream users where it is processed to produce PVC articles. The scope of the application for authorisation is very broad as several processes are included which may take place by numerous downstream users across the whole of Europe (the applicants estimated fewer than 100 sites, but the exact locations and number of sites is not available). The applicants provided short descriptions of the Exposure Scenarios, including operational conditions (OCs) and risk management measures (RMMs).

To cover the broad scope of the application, the applicants mainly used data from biomonitoring studies and provided supporting data from air monitoring studies. The applicants stated that the available monitoring data (biomonitoring or air monitoring) did not cover the transfer of recyclate by small or big bags and therefore modelled the exposure for these activities: PROC 8a (small bags) and PROC 8b (big bags). In addition, one applicant separately provided measurement data for PROC 8b.

Exposure of humans via the environment is assessed by biomonitoring data covering all sources of DEHP to the general public.

RAC assessment:

RAC previously considered exposures to DEHP for the general population from the current range of articles to cause an acceptable health risk in the opinion on an Annex XV dossier proposing restrictions on four phthalates (adopted 15 June 2012, ECHA/RAC/RES-O-0000001412-86-07/F). The data in the present application for authorisation also do not indicate a health risk for consumers from the present range of articles. With the concentration of DEHP in the incoming recyclate limited to 20%, it is not expected that the future range of articles covered by the broad scope of this authorisation will increase exposure of the general population to an extent that would result in an unacceptable health risk. RAC therefore agrees with the applicants that risks to the general population as a result of Use 1 are adequately controlled.

For the exposure assessment of workers from use 1, the applicant provided measured data (biomonitoring and air measurements) that were considered to be of limited informative value. The reasons for this are, as follows:

- The biomonitoring data for workers are very limited, consisting of information from only two Member States, of which one study is quite old (1993).
- Limited air monitoring data are available from four Member States (France, Germany, Finland and the Netherlands). None of these data are specifically related to the use of recyclates.
- The short descriptions provided in the Exposure Scenarios (PROCs) do not match the operational conditions and risk management measures described when obtaining the monitoring data, e.g. the use of risk management measures described by the applicants in their exposure scenarios do not seem to be in place at real workplaces.

With the exception of the transfer of recyclate in bags described above, no workplace exposure modelling data is provided by the applicant. A very generic application like this might have profited from carefully considered and transparently reported exposure modelling. Modelled exposure data (in principle valid for all work places concerned) that is consistent with measured data (valid for the monitored work places) support the plausibility of an exposure assessment.

Taking into account these limitations, RAC is of the opinion that the presented exposure assessment for the worker population is not representative for this application for authorisation. This is because the application covers several process technologies (compounding and dry-blending), process categories (PROC 1, 2, 3, 4, 8a*, 8b, 14, 15) and many worker settings within each process category. The authorisation is also requested for application across all EU Member States and EEA countries.

Despite the abovementioned limitations, RAC considered the available exposure information. Based on the available but limited dataset on biomonitoring, the applicants used the highest reported median value from biomonitoring data multiplied by four, to obtain an approximation of the 90th percentile of worker exposure, i.e. 94 µg/kg bw/d. In the view of the applicants, it is generally

acknowledged that mean values from biomonitoring studies are better indicators of long-term exposure than upper percentile values. In contrast with the applicant's opinion, the RAC does not consider long-term exposure as the appropriate dose metric for developmental toxicity. The testicular dysgenesis syndrome is considered to be caused by DEHP exposure during a critical window during gestation. It cannot be excluded that short-term exposure or peak exposure on a single day (compared to mean longer term repeated exposure) could trigger the relevant adverse effect. Therefore, RAC considers high end percentiles of exposure on any given workday to be relevant for developmental toxicity and thus it is crucial to have information on exposure variability between tasks, workers and days. The long-term repeated exposure 90th percentile as presented by the applicants will average out this variability; hence the exposure estimate provided by the applicants does not address high exposures from specific short-term processes or activities, that are considered to be most relevant for the risk assessment of DEHP.

RAC's only alternative for the exposure estimate based on biomonitoring data by the applicants is to resort to the maximum values reported in air monitoring studies as they were considered to potentially present a better representation of high exposures during a specific process or task than the available biomonitoring data. The highest reported maximum value was 1889 µg/m³ for compounding.

Both values, i.e. 94 µg/kg bw/d and 1889 µg/m³, are taken forward for comparison with the DNELs (see 5 below).

*: The applicants subsequently indicated that PROC 8a (transfer of small bags) does not occur in their facilities nor by their downstream users. Therefore, it is their wish to withdraw this specific process activity from the application.

Note: there is no registration dossier on recycled soft PVC containing DEHP. This means that all uses and information needs to be provided in the application for authorisation. It is noted that for non-recycled material, there is a REACH registration dossier that provides information on, amongst others, the intended uses.

5. If a threshold substance, is adequate control demonstrated?

YES

NO

See point 4. Since worker exposure is not described in sufficient detail relative to the broad scope of the application, adequate control cannot be demonstrated for workers, and therefore also for the total application for authorisation. Moreover, when using the RAC reference DNELs, RCRs equal to or greater than one are calculated using 90th-percentile exposure data from the CSR. In addition, the air monitoring data provided further substantiate that air concentrations above the DNEL value could occur under certain circumstances.

Use 1		WORKERS					
				Expo	DNEL		RCR
	Formulation	RAC	BM	P90	94 µg/kg/d	94 µg/kg/d	1,0
		RAC	AIR	INH	1.889 µg/m ³	878 µg/m ³	2,2
		AfA	BM	P90	94 µg/kg/d	224 µg/kg/d	0,4

In conclusion:

Based on the RAC opinion that the description of worker exposure is not adequate and that RCR values for workers (based on the limited exposure information and the RAC reference DNELs) range from about 1 to 2, it is the conclusion of RAC that the applicant did not demonstrate adequate control for workers for the use applied for (as defined in Annex I of the REACH regulation).

The critical effect of DEHP, on which the DNEL is based, is reproductive toxicity in males exposed *in utero* during a critical window during gestation. The effects are mediated by a depression of testosterone levels in the developing male reproductive system, resulting in, amongst other effects, testicular dysgenesis syndrome. The clinical effects (as required by SEAC for their opinion development) to be expected from these pathological effects, are fertility problems and in a worst case infertility (depending on the magnitude of exposure) in men exposed prenatally to DEHP.

The exposure to the general population via the environment is adequately described and results in RCR values below 1, indicating that risks to the general population via the environment are adequately controlled.

6. If adequate control is not demonstrated, is the remaining risk reduced to as low a level as is technically and practically possible?

Based on the information provided this cannot be assessed.

Justification:

In section four of this opinion it is concluded that the exposure assessment of the applicant is not adequate to describe the exposure situation at workplaces for the whole of Europe. In view of the broad scope of the application for authorisation and in view of the lack of detailed and appropriate exposure data, adequate control could not be demonstrated. As a consequence, it cannot be assessed whether the remaining risk is reduced to as low level as is technically and practically possible.

7. Justification of the suitability and availability of alternatives

The applicants present three alternatives, including a socio-economic analysis of these alternatives. The consequences of selection of each one of these alternatives and/or a non-use scenario are given. Further justification is given

below.

7.1 Would the alternatives lead to overall reduction of risk?

- YES
- NO
- NOT APPLICABLE / UNKNOWN

7.1.1 Are the risks of alternatives adequately described and compared with the Annex XIV substance?

- YES
- NO
- NOT APPLICABLE

7.2 Are the alternatives technically and economically feasible for the applicant?

- YES
- NO

The applicants present three alternatives. Two of the alternatives outline different processes for the production of recyclate from post-consumer PVC waste containing DEHP. The third alternative describes the use of an alternative waste PVC feedstock to produce recyclate.

The two process alternatives describe different means to remove DEHP from the waste PVC feedstock before it enters the recycling process. The third alternative describes the use of post-industrial PVC waste as an alternative feedstock material, as it is known to have lower DEHP levels than post-consumer waste PVC feedstock.

The first alternative describes the screening of the incoming PVC waste stream to exclude wastes with a DEHP content of >0.3% from the recycling process. Screening can be done by separating the incoming waste streams based on either visual observation or analytical testing.

According to the applicants, a separation process on an automated level is not technically available at an industrial scale. Chemical testing of the incoming bulk waste would have serious problems because of the lack of homogeneity of the waste stream (necessitating excessive numbers of samples for monitoring the variability of DEHP levels) and waiting time for the results of the analyses (with consequent requirements for waste storage). No statements opposing these statements from the applicants were received in the public consultation.

Overall, SEAC evaluates the analysis of this alternatives presented by the

applicant to be plausible. SEAC therefore agrees with the applicants that waste segregation is not technically or economically feasible. The alternative is not considered to be economically feasible because of the perceived costs associated with the necessary chemical testing, storage capacity and waiting time in the testing scenario.

The second alternative stated by the applicants, solvent extraction of DEHP, has been demonstrated to be technically possible at the laboratory scale, but it remains uncertain whether this could also be technically feasible at an industrial scale. The applicants argue that the transition into industrial scale is highly uncertain. SEAC is not aware of any solvent extraction process for DEHP at an industrial scale at this moment.

One applicant has provided a confidential detailed cost estimation of this technique at industrial scale in order to assess its economic feasibility. This estimate showed high investment (amounting to several million Euros) and operational costs. Furthermore, the applicant states that the resulting product is of less economic value due to the loss of quality and volume of the final recyclate associated with the use of a non-specific solvent extraction method (which, in addition to DEHP, also removes desired components of the PVC). SEAC could not check the estimated investment costs in detail (confidential). The calculation of the operational cost is based on the use of methanol as an example non-specific solvent and uses several sub scenarios on solvent regeneration. Basic assumptions and calculations on the amount of solvent required, solvent price, energy consumption for the regeneration of solvent or energy generation due to onsite burning of the solvent were checked. SEAC finds that the operational costs could add up to additional costs of at least 45% of the current selling price based on the most favourable conditions in this simplified cost calculation [calculation based on confidential data]. SEAC notes that the most favourable economic option involves the regeneration of used solvent. In this scenario, most of the operational costs are for the energy required to regenerate the solvent. This cost estimate is sensitive to the amount of solvent required per tonne of treated soft PVC waste and the heat of evaporation of the specific solvent. The current ratio chosen is based on the experience of the applicant. The solvent used for this cost estimation (methanol) has an average heat of evaporation.

One applicant currently uses a solvent-based production process for the production of the recyclate, including the regeneration of the solvent through evaporation. It is therefore SEAC's understanding that, depending on the physical-chemical properties of the specific solvent and the ratio between solvent and feedstock, a solvent-based production process is economically feasible. However, it is SEAC's understanding of current techniques that no solvent is currently available with a selected specificity for DEHP. Therefore, any solvent extraction that will extract DEHP will also have an effect on the content of other plasticizers, stabilisers or other components in the PVC matrix in addition to DEHP. The resulting product will therefore be of lower volume and might need additional chemicals to be added by downstream users before re-use.

Considering the above, SEAC agrees with the estimate provided by the applicant

that this alternative process is technically challenging and economically unrealistic at this moment. Whether this alternative is technically and economically feasible in a longer timeframe is currently not clear and will depend on several factors such as the availability of a cheap specific solvent for DEHP extraction, the amount of this solvent needed for extraction, the heat of evaporation of this solvent and the market conditions.

The final alternative, the use of DEHP-free post-industrial waste as a feedstock to the recycling process, is technically feasible according to the applicants. Using this alternative, the applicants would only recycle DEHP-free post-industrial soft PVC waste instead of post-consumer waste. According to the applicants, post-industrial flexible PVC waste has a considerably higher market price (€250-450 per tonne) than post-consumer PVC waste (<€50 per tonne). The applicants state that post-industrial PVC waste would likely be of better quality than post-consumer PVC waste. The applicants provided a quick calculation containing confidential information to SEAC. SEAC could not check the price range of these waste streams as they were unable to find adequate information in the public domain. The applicant stated these numbers in the public version of the analysis of alternatives and the public consultation did not yield contradictory information regarding these estimates. Therefore, SEAC assumes these numbers are realistic.

The calculation containing confidential information provided a cost estimate in which the increase in costs of a scenario switching to post-industrial flexible PVC waste as a source would be comparable with the current combined turnover of the applicants. SEAC notes that the higher quality of the post-industrial waste could also increase the quality of the produced recyclates and this could increase the market value of the recyclates produced from post-industrial waste, which would in turn dampen the inflated cost of the raw material (i.e. post-industrial PVC). However, given the information that the downstream users tend to produce articles that are at the lower end of the value spectrum for flexible PVC recyclate, the probability to pass on a price increase for better quality recyclate to the downstream users seems unlikely. Furthermore, post-industrial PVC waste may be in short supply as only a small fraction (few percent) of industrial production is estimated to result in post-industrial waste. SEAC has received no indications contradicting the assessment made by the applicants that this alternative is economical unfavourable.

In addition, if PVC waste streams with a DEHP content of >0.3% would not be authorised for recycling following the adoption of alternatives one and three, SEAC is aware that this would imply a significant reduction in the volume of post-consumer flexible PVC waste that would be recycled. Non recycled post-consumer flexible PVC containing DEHP would find its way towards waste incineration or landfill. Although this reduction in recycling potential does not influence the technical and economic feasibility of these alternatives to the applicants, it does influence the overall risk benefit analysis for society as a whole (as is described in section 10 of this opinion).

The alternatives presented in the application all reflect alternatives from the perspective of the applicants (manufacturer). SEAC notes that an additional alternative could have been identified from the perspective of downstream users

that was not included in the analyses for alternatives. However, the applicants do reflect on this matter in their socio-economic analysis.

For the downstream converters of the DEHP-containing recycled soft PVC, a possible alternative would be the use of virgin PVC with (a mixture of) other, non-SVHC plasticisers as feedstock rather than recycled material. The applicants state that, for the uses covered by this application for authorisation, the downstream users tend to produce articles that are at the lower end of the value spectrum. Due to the high level of competition within the sector and from imports into the EU from Asia, some downstream users (converters) of the applicants indicate that they might not remain competitive after incurring the additional cost of using virgin PVC.

The price of flexible PVC recyclate is lower than the cost of virgin PVC and if profit margins are not sufficient, converters could withdraw from the market, although virgin PVC would be available. SEAC recognises that from the point of view of the applicants, this is not an alternative and that even from the point of view of (some of) the downstream user(s), this alternative might not be economically feasible. Limited research undertaken by SEAC supports the claim by the applicants that the price of flexible PVC recyclate (confidential information) is lower than the cost of virgin PVC (range of 900-1500 euro/tonne).

7.2.1 Are the technical and economic feasibility of alternatives adequately described and compared with the Annex XIV substance?

YES

NO

Justification:

7.3 If alternatives are suitable, are they available to the applicant?

YES

NO

NO SUITABLE ALTERNATIVES EXIST

Justification:

See under section 7.2 above.

8. For non-threshold substances, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

- YES
 NO
 NOT RELEVANT QUESTION

Justification:

9. Do you propose additional conditions or monitoring arrangements

- YES
 NO

Detailed description for additional conditions and monitoring arrangements:

The applicant did not demonstrate adequate control because the worker exposure assessment was not adequate to cover the broad scope of the application. RAC therefore concluded that it could not propose sufficiently specific additional conditions or monitoring arrangements that could justify a conditioned adequate control.

10. Proposed review period:

- Normal(7 years)
 Long (12 years)
 Short (4 years)
 Other:

Justification for the suggested review period:

Based on the deficiencies in the workers exposure assessment, in the event that the authorisation should be granted, RAC recommended a short review period. Should a review report be submitted for this use RAC expects this to contain relevant exposure information from downstream user workplaces, including:

- representative exposure assessments and descriptions of operational conditions for key workplaces and technologies
- measurement data that allows the evaluation of worker exposure at relevant downstream user workplaces
- information about the situation in different affected industry sectors, Member States, stages of the life cycle.

The applicants did not specifically request a review period in their SEA, although a period of 30 years is mentioned. In their request for additional information, SEAC asked the applicants what length of review period would be required and what data would be available to underpin the requested period. Although no specific timeframe was stated, the applicants argued that the length of the authorisation should be longer rather than shorter. According to the applicants, if recycling is to continue, in line with several EU objectives, a normal review period of seven years would be too short to encourage investments in further recycling capacity. SEAC used the following information provided by the applicants to evaluate the required review period of this application:

- Availability of alternatives currently and in the future
- Expected future concentrations of DEHP in the PVC waste stream
- Typical investment cycles of the applicants
- The estimated risk benefit balance of this application

These aspects will be further explained in the sections below. Note that some of these aspects were included in the RAC/SEAC working procedure to determine the length of the review period others should be seen as specifically relevant for this application.

As concluded in section 7.2 of this opinion, there are no alternatives foreseen in the near future that are economically as well as technically feasible. There is a possibility that alternative two (i.e. solvent extraction of DEHP) will become technically and economically feasible in the longer term. However, based upon the information that is available to SEAC, this is not considered likely to happen within at least the coming decade.

According to the applicants, the presence of DEHP in soft PVC waste streams that are used for PVC recycling is expected to continue for many years. This is because of the relatively long lifetime of the DEHP containing materials and articles, import of DEHP containing articles from outside the EU and direct recycling of DEHP containing soft PVC waste into articles inside the EU. The applicants estimate that DEHP may still be found in end-of-life flexible PVC waste streams in 2045, suggesting that authorisation will be required for over 30 years, mainly based upon the lifetime of various PVC articles. Depending on the outcomes of the applications for authorisation for other DEHP uses currently being considered, the required timeframe could eventually be longer. An estimate of the future use of DEHP in PVC articles in Europe was also provided in the SEAC opinion for the restriction proposal on DEHP and three other phthalates in indoor articles in Europe submitted by Denmark. The baseline trend that was estimated for that context shows that although quantities of DEHP used in Europe are expected to decline substantially, the total quantities used in PVC articles will remain significant at least up to 2020 (no further predictions were made by SEAC). Note that this baseline was produced for the use of four different phthalates. However, the majority of phthalate use was considered to be of DEHP (95%). Furthermore, although the scope of this baseline estimate is somewhat different compared to the authorisation application evaluated here e.g. in terms

of PVC articles covered, the baseline produced by SEAC gives a rough indication that the estimate of the applicants that concentrations of DEHP will continue to persist for a relatively long timeframe is reasonable. SEAC therefore considers the estimate of the applicants regarding the continued presence of DEHP in the PVC waste stream to be plausible.

Upon request of SEAC, the applicants have provided additional confidential information concerning the typical investment cycles of their processes. Here, distinction is made between technical and financial lifetimes and they vary roughly between 15 and 25 years. Furthermore, the years of capital investments and start of production differ among the applicants and lie between 2003 and 2009.

Following the standard criteria to underpin the length of the review period (SEAC/20/2013/3), the estimated balance between socio-economic benefits and risks might provide an additional argument for setting the length of the review period. If risks are indicated to be low and socio-economic benefits are estimated to be high, and if this is not likely to change in the next decade, that could be a justification for a longer review period.

Opinion on benefits and risks of continued use

RAC has concluded that adequate control has not been demonstrated by the applicant. Consequently, this application for authorisation can only be granted according to REACH art. 60.4. Therefore, SEAC has to form an opinion on the socio-economic benefits and the risks to human health of continued use. The applicant did not provide a full socio-economic analysis as it was anticipated by the applicant to demonstrate adequate control. Consequently, no health impact assessment has been performed and the analysis lacks the methodology to compare the health impacts of continued use to the socio-economic benefits. However, the applicant did perform economic and social impact analysis. SEAC assessed the economic and social impact analysis as provided by the applicant.

Socio-economic benefits

The socio-economic benefits of the 'applied for use' scenario can be expressed as the avoided socio-economic costs that were estimated by the applicants for the non-use scenario. The total socio-economic cost of the non-use scenario is estimated by the applicants to be around 210 – 275 million euros over the time period of 2015-2020. These costs reflect the following:

Costs to the applicants:

- Losses in turnover by waste recyclers. SEAC notes that losses in turnover are not the same as costs to the applicants or costs to society as a whole. Costs to the applicants or 'added value foregone' resulting from closure of the applicants activities might in principle be estimated by taking the production value (turnover) of the companies involved and subtracting from this figure the costs of all inputs except capital and labour. As the latter figure has not been provided by the applicants, the turnover figure presented in the SEA can according to SEAC not be used in the context of this cost analysis. It can also not be included in the analysis as societal

costs, as the loss in turnover for the applicants will very likely result in an increase in turnover of other market actors (e.g. so-called integrated PVC recycling operators). Whether such a shift in activity and turnover from the applicants to other market actors will result in a net societal cost or benefit, cannot be concluded based on the available information.

Costs to downstream users and other supply chain actors:

- Costs of replacing recyclate with virgin PVC. This estimate is based upon the difference between the publicly available price of virgin PVC and the price of recyclate as indicated by the applicants. As the latter could not be checked by SEAC as no publicly available data was found indicating the price of recyclate, it is not possible to scrutinize the given estimate. Furthermore, it is noted that to be fully correct, such a price difference should be corrected for the difference in quality between the two PVC materials. SEAC realises that recycled PVC material can be of lower quality compared to virgin PVC due to the presence of impurities. However, the PVC can also be valued higher by DUs compared to virgin PVC as some softeners and stabilisers are already included in the recycled PVC. Overall, however, SEAC sees the price difference between virgin PVC and recycled PVC as a rough cost indicator that can be used in this cost analysis.
- Costs of increased landfilling and incineration for waste collectors or recyclers. This estimate consists of gate fees that the applicants would have to pay to dispose the PVC waste that was previously recycled and cost of transport and other costs. It is not clear to SEAC where these costs are based upon as no reference is given to the used figures. However, the Committee observes that gate fees vary widely throughout Europe (http://ec.europa.eu/environment/waste/pdf/final_report_10042012.pdf). Nevertheless, SEAC considers it likely that such costs would be substantial.

External costs to society:

- Costs associated with environmental and human health damage due to increased landfilling or incineration of flexible PVC wastes, increased production of virgin flexible PVC and reduced recycling. The applied LCA methodology in this estimate seems plausible and the input data used for the analysis seems sufficient for the analysis. Although SEAC did not scrutinise the full analysis in detail, the order of magnitude of this analysis this seems to be reasonable.

The contribution of the various cost elements to the total cost estimate is presented in the confidential part of the SEA and can therefore not be presented here. The actual costs of the non-use scenario might in fact be somewhat lower than those that are presented as part of the costs included as losses in turnover should rather be subtracted from the total cost figure. SEAC, however, expects that based on the information provided by the applicants, overall costs will still be substantial. As alternatives are not likely to become available in at least the coming decade, this socio-economic cost estimate is not likely to change significantly in the foreseen future.

Besides the total cost estimate, the applicants provide an estimate of the social impacts of the non-use scenario as loss of jobs in the recycling sector. These are estimated to range between 150-200 jobs in different parts of the value chain. SEAC finds the underpinning provided in the confidential SEA reasonable and considers the estimate to be plausible although the basic assumptions could not be checked.

Health impact

The risk assessment of the applicants has been evaluated by RAC. Contrary to the applicant's assessment, RAC has concluded, on the basis of deficiencies in the exposure assessment provided, that the remaining risks for workers have not been demonstrated to be adequately controlled and for this application it is not possible to perform a quantitative health impact assessment as the remaining potential risks could not be fully assessed as the exposure assessment of the applicant is not adequate to describe the exposure situation at workplaces for the whole of Europe. At request of SEAC, the applicants in SPAC provided information that roughly between 80 and 160 workers would be directly exposed to plasticised PVC containing DEHP. Although the worker population potentially at risk is therefore more or less defined, it still cannot be assessed whether the remaining risk to those workers has been reduced to as low level as is technically and economically feasible.

Conclusion benefits and risks of continued use

In this case, SEAC cannot quantitatively conclude on the proportionality of continued use (i.e. do the benefits of continued use exceed the costs to society) as information on the remaining risks to workers health cannot be quantified.

Alternatively, SEAC needs to justify their opinion on other, qualitative, socio-economic arguments. SEAC has considered the following arguments:

- The expected clinical health effects for which workers are at risk concern fertility problems and in worst case infertility (depending on the magnitude of exposure) in men exposed prenatally to DEHP.
- Fertility problems and infertility are considered of very high concern by society.
- The expected clinical health effects for which workers are at risk are irreversible, non-lethal and have a long latency period.
- The exposed worker population is estimated by the applicants to be between roughly 80 and 160 workers directly exposed and this number could increase or decrease with production volumes.
- It cannot be assessed whether the remaining risk could be reduced to as low level as is technically and economically feasible.
- There is a political and societal incentive to promote recycling as a sustainable way to handle natural resources.
- There are significant economic costs, compared to the assumed turnovers, in case of non-authorisation for the applicants and their downstream users.
- It is probable that there will be a loss of up to 200 jobs in case of non-authorisation.
- There are external costs for society associated with environmental and

human health damage due to increased landfilling or incineration of flexible PVC wastes, increased production of virgin flexible PVC and reduced recycling rates.

- Alternatives are not likely to become available, in at least the coming decade; therefore the socio-economic costs are not likely to change significantly in the foreseen future.

Based on a qualitative assessment of the above mentioned arguments, SEAC considers authorisation proportional.

Overall conclusion

SEAC acknowledges that alternatives to the use applied for will not be available for at least the coming decade, that the presence of DEHP in waste streams will continue and that the investment cycles in the recycling industry are long. SEAC notes that RAC recommended a "short" review period and that RAC could not assess if the remaining risk was reduced to as low a level as is technically and practically possible. SEAC notes that there were significant deficiencies in the socio-economic analysis provided by the applicant, such as the lack of a health impact assessment. Therefore, on balance, SEAC considers a normal review period of 7 (seven) years to be appropriate in this case.