Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Bis(2-ethylhexyl) phthalate (DEHP)

used in formulation of DEHP in compounds, dry-blends and Plastisol formulations

ECHA/RAC/Opinion N° AFA-O-0000004275-75-12/D

ECHA/SEAC/Opinion N° AFA-O-0000004275-75-12/D

Consolidated version

Date: 23 October 2014

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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) respectively 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 DEHP in compounds, dry-blends and Plastisol formulations.

Intrinsic property referred to in Annex XIV:

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

Applicant

Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.

Reference number

11-0000000324-84-0000

Rapporteur, appointed by the RAC: **Urs SCHLÜTER**

Co-rapporteur, appointed by the RAC: **Norbert RUPPRICH**

Rapporteur, appointed by the SEAC: **Jean Marc BRIGNON**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On **8 August 2013 Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **29 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 24 September 2014.

The draft opinions of RAC and SEAC were sent to the applicant on 24 September 2014.

On **22 October 2014** the applicant informed that it did not wish to comment on the opinions and the draft opinions of RAC and SEAC were therefore considered as the final on **22 October 2014** for RAC and **23 October 2014** for SEAC.

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 ***12 September 2014***.

The draft opinion of RAC was adopted by consensus.

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 22 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***.

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

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 23 October 2014.

THE DRAFT OPINION OF RAC

RAC has formulated its draft 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 to be 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 duration for the review period has been suggested below.

THE DRAFT OPINION OF SEAC

SEAC has formulated its draft 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 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 the applicant's assessment of (a) the potential socio-economic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two is based on acceptable socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment.

The duration for the review period has been suggested below.

Use

The authorisation is considered for the following use:

Formulation of DEHP in compounds, dry-blends and Plastisol formulations.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

The following conditions are recommended in case the authorisation is granted:

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

Monitoring arrangements

The following monitoring arrangements are recommended in case the authorisation is granted:

None.

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 4 years.

JUSTIFICATIONS

Substance name:	Bis(2-ethylhexyl) phthalate (DEHP)
Name of applicant(s):	Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.
Use name:	Formulation of DEHP in compounds, dry-blends and Plastisol formulations
Reference number:	11-0000000324-84-0000

The justifications for the opinion are as follows:

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

☐ Carcinogenic (Article 57(a))

☐ Mutagenic (Article 57(b))

☒ Toxic to reproduction (Article 57(c))

☐ Persistent, bioaccumulative and toxic (Article 57(d))

☐ Very persistent and very bioaccumulative (Article 57(e))

☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

☒ YES

☐ NO

Justification:

For the reproductive toxicity of DEHP, RAC has established reference DNELs (RAC/24/2013/08 rev. 2; Helsinki, 12 April 2013). The critical effects are mediated by an endocrine mode of action, and it has been argued in the public consultation that DEHP therefore should not be regarded as a threshold substance. RAC does acknowledge the mode of action but also recognises that the substance has been put on Annex XIV because of its reproductive effects and not as an Article 57 (f) substance, therefore a threshold approach is warranted.

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

The DNELs from the applicant are not considered appropriate.

Justification

The DNELs from the applicant deviate from the reference DNELs set by RAC on 12 April 2013 without sufficient justification. The deviations between the values derived by RAC and the applicant are due to the application of different oral absorption percentages and application of different assessment factors for intraspecies differences in the case of the worker DNEL. These differences are not based on new information compared to the information used by RAC in setting the reference DNELs which follows current technical

Guidance.

Table 1 compares the respective RAC's and applicant's DNELs. The DNEL values calculated by RAC are lower than the applicant's DNELs. The most obvious difference between the RAC's and applicant's values exists for the oral DNEL for workers which is 94 µg/kg/d derived by RAC and 224 µg/kg/d based on the applicant's calculation (the oral DNEL for workers is needed for comparison with the biomonitoring data).

Table 1

DNELs for DEHP			
	ORAL DNEL µg/kg/d	DERMAL DNEL µg/kg/d	INHALATION DNEL µg/m³
RAC			
WORKERS	94	1882	878
ADULTS	34	672	157
CHILDREN	34	672	118
AfA			
WORKERS	224	3360	1568
ADULTS	48	720	168
CHILDREN	36	720	126
Comparison	RAC values divided by applicant's values		
WORKERS	0.42	0.56	0.56
ADULTS	0.70	0.93	0.93
CHILDREN	0.93	0.93	0.93

Three specific quantitative parameters are responsible for the DNEL differences as described in Table 2.

Table 2

Parameter	*RAC*	*Applicant*
Absorption, oral, rat	*70%*	*75%*
Absorption, oral, workers and adults	*100%*	*75%*
Intraspecies factor for workers	*5*	*3*

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[1] 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 ongoing 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 provided by the applicant and stakeholders during public consultation and finally decided not to deviate from the published reference DNEL in the absence of any new convincing information sufficiently justifying a deviation.

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

☐ *YES*

☒ *NO*

Justification:

As the use applied for is the formulation of DEHP in compounds, dry-blends and plastisol formulations, the exposure assessment concentrates on worker exposure. Exposure of man via environment from this use is also considered.

The applicant assessed the worker exposure by means of biomonitoring data and air concentration measurements. No modelling data was provided by the applicant for this scenario. This generic application for authorisation might have profited from modelling data, provided that the used model was carefully chosen and the chosen input parameters were transparent and well justified. Such modelled exposure data in conformance with measured data (valid for the monitored work places) can support the plausibility of an exposure assessment.

The applicant provided at most a fragmentary description of the activities/tasks and the technologies used for the different formulation processes. The applicant made general claims with respect to the representativeness of the data for the use applied for.

The biomonitoring and air measurements provided for use 1 are of limited informative value. The reasons for these limitations are:

- The applicant used literature data only. None of the measured data presented were generated for this application, either by the applicant or by relevant downstream users.

- The data have limited geographical coverage and are often not recent.

[1] Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health.

Biomonitoring data are available from France (Gaudin et al 2011), the Netherlands (a pilot study by Hines et al 2009), the US (Dirven et al 1993) and Taiwan (Fong et al 2013). Air measurement data are available from Finland (Vainiotalo and Pfäffli 1990), The Netherlands (Dirven et al 1993), France (Protois et al 2007) and Germany (IFA 2012).

- The data have limited coverage concerning the number of monitored workers (an estimated maximum of 500 workers are represented by the measurement data)

- Considering the broadly defined use, the data have only a limited coverage of the many industrial sectors; process technologies (the formulation of DEHP in compounds, dry-blends and plastisol formulations); process categories (PROC 1, 2, 3, 4, 5, 8b, 14, 15), and workers settings in the scope of the use applied for;

- There is limited information concerning the level of risk management measures and operational conditions at the monitored workplaces. For instance, as pointed out by the applicant, none of the biomonitoring studies reported specific RMM;

- The presented data are from European countries with a typically advanced level of occupational hygiene.

In the evaluation of RAC, the exposure data presented in the CSR are not representative for the broad scope of the application. Therefore, a well-founded exposure assessment by RAC is not possible. The following evaluations are only based on a deficient data base and by this of little significance for the risk assessment.

The applicant advocated the use of geometric mean values from biomonitoring exposure estimates for the further risk assessment. RAC considers that 90th percentile values – if available - are more appropriate, especially considering the above limitations of the data. The biomonitoring studies by Hines et al (2009) and Dirven et al (1993) did not report the 90th percentiles. Instead the applicants assumed the 90th percentile was equal to the geometric mean multiplied by four.

If biomonitoring data are used for risk assessment by RAC, the study by Dirven et al (1993) and the creatinine-based approach (instead of the volume-based approach) are appropriate to use. This is consistent with the applicant's approach. The following value could be used:

- **94.0 µg/kg/d** (estimated 90th percentile, creatinine-based approach)

Concerning air monitoring data, the 90th percentiles are not available from most of the literature sources or from the CSR. Therefore RAC has no choice but to select a maximum value for workplace exposure presented in the CSR. The following value could be taken forward for risk assessment:

- **1889 µg/m³** (maximum value)

This value is measured by personal sampling, derived from a compounding process in France in 2005 (Protois et al 2007) and is a worst case assessment (maximum value in the study, no high percentile values are presented) compared to comparable studies. In principle this study seems very relevant for this assessment as it is rather new (data from 2005), from a reliable institute (INRS) and relevant for European workplaces (workplaces in France were monitored).

Additionally it is described in the CSR that a survey of the European PVC processing industry involving 30 companies, largely confirmed these data on inhalation exposure (Cadogan 2010). Generally, from this survey only individual samples were available and

the highest concentration obtained for some mixing operations was 1200 µg/m³. A study by Fong et al. (2013) from Taiwan describes a maximum value of about 1600 µg/mg³ for single workers.

In summary the value of 1889 µg/m³ is a worst case value for the two companies that were sampled in Protois et al (2007). However, considering the important limitations in the representativeness of the information, and the fact that it seems the value is supported by additional relevant information (Cadogan 2010; Fong et al 2013), RAC considers the value appropriate to be used. As RAC does not have task-based or even PROC-specific information on exposure (the description in the CSR does not give this information) it is not possible to attempt a further differentiation of the different tasks / technologies.

Exposure of man via environment from this use is considered to be adequately described on the basis of biomonitoring data. However, data presented in the DEMOCOPHES layman's report indicate higher average exposure levels in several European countries compared with the overall average for the 17 participating countries. The highest average exposure level is reported for the Slovak Republic and is roughly 1.7 times higher than the European average.

However, for this risk assessment, 90th percentile values are considered more relevant than average levels. Thus, the overall 90th percentile value for mothers and children was used for the risk assessment (no 90th percentile values were reported for the individual countries).

Conclusion and Summary

Taking into account the limitations of the exposure data for workers outlined above, RAC is of the opinion that the data is not representative for the use applied for. The reason is that the exposure data is fragmentary and not clearly linked to the many process technologies; process categories; worker settings within each process category that are covered by the broadly defined exposure scenarios in the applied for use.

If despite of these principle deficiencies exposure values are to be selected for workers, the values reported in table 4 can be used by RAC for risk assessment.

Table 4 Relevant exposure values for RAC assessment

	Workers	**Man via environment**
Applicant	Biomonitoring: 92 µg/kg/day	Biomonitoring: 9 µg/kg/day (Adults) 10 µg/kg/day (Children)
RAC	Biomonitoring: 94 µg/kg/day Air monitoring: 1889 µg/m³	Biomonitoring: 9 µg/kg/day (Adults) 10 µg/kg/day (Children)

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☒ NO

Justification:

The use applied for is the formulation of DEHP in compounds, dry-blends and plastisol formulation. For this use risk assessment needs to be performed for workers and the general population (man via environment).

Risk assessment for the general population is based on biomonitoring data: the exposure estimates from biomonitoring data include all sources of exposure, thus including the exposure of man via the environment. Using the reference DNEL and 90th percentile exposure levels RAC calculated an RCR of 0.3 both for adults and children. As discussed in section 4, the data reported in the DEMOCOPHES layman's report indicates (up to roughly 1.7 times) higher average exposure levels in several European countries compared with the overall average for the 17 participating countries. It is considered plausible that high average exposure estimates for individual participating countries are to a large extent reflected in the overall 90th percentile estimates. RAC considers that the available data supports the conclusion that RCRs for the general population are below 1 also for individual European countries. Thus, RAC agrees with the applicant's conclusion of RCRs lower than 1 for the general population.

However, RAC does not agree to the applicant's conclusion for workers. For workers the applicant calculated an RCR of 0.4 (an estimated 90th percentile exposure level from biomonitoring data). Using the reference DNEL, RAC calculated a higher RCR for workers: the comparison of the reasonable worst case DEHP intake of 94 µg/kg/d from biomonitoring data (creatinine-based approach) with the oral reference DNEL of 94 µg/kg/d results in an RCR of 1. RAC additionally used a measured maximum value for inhalation exposure of 1889 µg/m³; this exposure level compared to the inhalation reference DNEL of 878 µg/m³ results in an RCR of 2.2. A 90th percentile value for the selected study was not available from the CSR or the original literature.

Table 5 summarises the risk-related key data for the workers and the general population. DEHP uptake is calculated based on the urinary DEHP metabolite concentrations reported in the CSR. The final results, but not interim results, were rounded.

Table 5

Use 1				WORKERS			
					Expo	DNEL	RCR
	Formulation	RAC	BM	P90	94 µg/kg/d	94 µg/kg/d	**1.0**
		RAC	AIR	INH	1889 µg/m³	878 µg/m³	**2.2**
		AfA	BM	P90	94 µg/kg/d	224 µg/kg/d	**0.4**

Use 1				GENERAL POPULATION			
					Expo	DNEL	RCR
	Formulation	RAC	BM (A)	P90	9 µg/kg/d	34 µg/kg/d	**0.3**
		RAC	BM (C)	P90	10 µg/kg/d	34 µg/kg/d	**0.3**
		AfA	BM (A)	P90	9 µg/kg/d	48 µg/kg/d	**0.2**
		AfA	BM (C)	P90	10 µg/kg/d	36 µg/kg/d	**0.3**

There are both DNEL- and exposure-related uncertainties in this DEHP risk assessment. However, it is the basic understanding of RAC that REACH risk assessments have to be based on the principles and assumptions laid down in the corresponding REACH guidance, which refers both to DNEL derivation and exposure assessment. The basic principle to be followed is covered by the term “reasonable worst case”.

The critical risk profile to be evaluated refers to developmental toxicity; it is DEHP toxicity to pregnant women being occupationally exposed during a critical time window of foetal testis development. The critical time window for foetal testis development is considered to be gestational weeks 8-14. RAC considers this exposure scenario relevant.

RAC considered that due to the exposure-related uncertainties in this specific case, RAC should not quantify the human health impacts. An attempt was made to describe the possible human health consequences qualitatively:

1) It appears from the available (bio)monitoring data that worker exposure can be expected to be adequate controlled in many, possibly even the majority of workplaces.

2) For workers RAC calculated a risk characterisation ratio of about 1 to 2 (reasonable worst case exposure). The most sensitive DEHP study resulting in the lowest NOAEL of 4.8 mg/kg/d was used for the establishment of the DNEL. In this 3-generation rat study low incidences of testicular effects were observed in the offspring exposed to 14 mg/kg/d and above. Thus the experimental LOAEL is a factor of 3 above the experimental NOAEL. Assuming that this experimental animal relationship of NOAEL and LOAEL in principle is valid for humans as well, the described reasonable worst case exposure level for workers can be considered to be located somewhere between the no adverse effect and low adverse effect level for fertility impairment assumed for the male offspring of pregnant workers.

RAC’s conclusion is that the applicant did not demonstrate adequate control. This conclusion is primarily based on RAC’s opinion that the description of worker exposure is not adequate. Secondly, RCRs for workers range from about 1 to 2 when using high percentile occupational exposure levels (biomonitoring and air-monitoring data) and the RAC reference DNEL.

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

Justification and concluding on the remaining risk:

The exposure assessment of the applicant is not considered to be adequate to describe the exposure situation at workplaces covered by this use in the whole of Europe (see section 4 of the justification). However, it is shown by the exposure data for e.g. dry blending and preparation of plastisols that the exposures indeed were adequately controlled in several of the monitored workplaces. However, as the data indicates that this seems not to be the case for all affected workplaces, the remaining risk is therefore not reduced to as low a level as is technically and practically possible for all industrial sectors; process technologies; process categories, and workers settings within each process category covered by the use.

7. Justification of the suitability and availability of alternatives

7.1 Would the alternatives lead to overall reduction of risk?

☒ YES

☐ NO

☐ NOT APPLICABLE

The applicant concluded that based on similar or higher DNELs and a lower hazard profile in terms of classification of the evaluated alternative substances, and assuming similar exposure levels, the alternatives appear to constitute a lower risk to consumers compared to DEHP (some caveats nevertheless were expressed regarding DEHA and DEHS).

RAC considered that this conclusion could be extended also to the risks to workers if the exposure of the alternatives would be comparable to DEHP. This would be the case if the following conditions are fulfilled:

- the same activities and tasks are performed with the alternatives,
- the amount and concentration (including the matrix) of the alternatives are comparable,
- the ambient conditions of the workplaces are similar,
- the physico-chemical characteristics (e.g. vapour pressure, dustiness) of the alternatives are alike,
- the workplaces (including technologies, operational conditions, risk management measures in place, level of occupational hygiene) are similar.

The applicant concluded that considering the similar environmental effect profiles and comparable PECs, none of the alternative substances should be ruled out as a substitute for DEHP based on environmental risks. The applicant had a reservation regarding TOTM as it has been listed on the CoRAP for environmental concerns/suspicion of PBT properties.

Overall, the applicant did not discard any of these alternatives on the basis of risk considerations from further assessment (with the necessary caveats regarding uncertainties and reservations regarding DEHA, DEHS and TOTM). RAC can agree with the applicant's conclusions but stressed that this conclusion needs to be interpreted with caution, considering the uncertainties resulting from the different level of information available on the (eco)toxicological properties of the alternatives compared with DEHP as well as the absence of a full risk assessment for each of the alternatives.

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

☐ YES

☒ NO

☐ NOT APPLICABLE

RAC recognizes that the applicant submitted an extensive assessment of the hazard profiles of alternative substances and calculated PECs for the environment. The risk comparison can be considered adequate and fit for purpose for the general population and for the environment. However, the applicant did not include a risk comparison for workers.

7.2 Are the alternatives technically and economically feasible?

☐ YES

☒ NO

Justification:

General comments to the applicant's approach

The applicant discarded alternative materials, substances and techniques in the analysis of alternatives on grounds that

- he technically cannot produce these alternative substances or materials (he doesn't have the adequate equipment or knowledge); or

- alternatives would not be economically feasible and available for him as a manufacturer (e.g. he would have difficulties penetrating the market; would be impacted by the higher price of feedstock for alternative plasticizers in comparison with DEHP; and he would need to invest in significant modifications in the plant in order to produce the alternatives); or

- he has accessibility problems to the feedstock for alternative plasticizers.

The applicant shortlisted 11 chemicals for a (limited) assessment of the technical and economic feasibility of substitution for downstream users. For each alternative, the applicant concludes that there are no technically and economically feasible alternatives available for him as a manufacturer of DEHP.

However, the authorisations under REACH are sought for uses and not for the manufacture of chemicals. The analysis of alternatives should focus on the function of the substance in the uses applied for, which relate to soft PVC compounding and soft PVC article manufacturing, and not to plasticizer production.

The economic feasibility for the applicant to change to the manufacturing of an alternative to DEHP depends on the market for the alternative, which was evaluated from a survey in the supply chain of the three applicants (ARKEMA FRANCE, Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s.). The assessment is limited in capturing the evolution in downstream users' use of plasticisers and the possibility to modify the customers base was not covered by the scope of the survey. SEAC acknowledges however that the potential market for the applicant is closely linked to its current customers base and their customers current plasticiser use.

It is plausible that the applicant will incur significant costs in case authorisation is not granted. These costs are considered in the SEA. The substitution costs claimed by the applicants in the non-use scenario are also partially attributable to other factors than the authorization such as the declining market of DEHP and their own strategy.

Overall, SEAC considers that the conclusion of the applicant regarding the suitability and availability of alternatives, which is primarily based on his perspective as a manufacturer of DEHP, is not sufficiently justified.

<u>General remarks on the downstream user survey</u>

When confronting the Analysis of Alternatives with other sources of information from manufacturers of alternatives it appears that the potential of some alternatives (for instance some bio-based alternatives) might have been somewhat downplayed in terms of their range of applications, their ability to be used as primary plasticizers, or their future availability on the market.

The survey of downstream users is limited to clients of the applicant, i.e., converters/article manufacturers that are currently using DEHP. Although it might be difficult for manufacturers to obtain information from outside their supply chains, it would have been of interest for the assessment of alternatives in the applicants' supply chain to have a picture of the reasons why former DEHP users have changed to alternatives. In addition, there were only 50 surveyed downstream users over around 21 000 PVC converters in the EU. For these reasons, it is unsure whether the surveyed downstream users are representative for this sector in the EU.

Another caveat is that surveyed downstream users have tested few alternatives, and that they appear to have a low knowledge of alternatives.

Therefore, the reason why downstream users do not report alternatives as technically feasible might be in several cases that their information and experience on alternatives is deficient.

Searches of the literature and of substitution-specialised websites carried out by the applicant to complement the downstream user survey seem to have been very limited.

<u>Feasibility for the Downstream Users</u>

Technical feasibility

The applicant excluded assessing alternatives per application type in the Analysis of Alternatives, as he considers a combination of substances not being an economically viable option from his manufacturer's point of view. The possibility for supply chains to use a combination of substances is therefore not assessed in the Analysis of Alternatives. On the other hand, the non-use scenario in the SEA considers a combination of alternatives that replaces DEHP fully (this is used by the applicant to assess the substitution costs). The SEA also reports that many downstream users informed that

they would move to a combination of alternatives plasticizers in case DEHP is no longer available.

SEAC therefore considers that in some cases, replacing DEHP with a combination of alternatives is technically possible.

The applicant excluded alternative materials and alternative techniques from the assessment. However, from the point of view of the function of the endproduct, alternative materials are in some cases suitable alternatives. Indeed, the SEA reports that in a few cases compounders answered they would shift some of their production to other materials if the authorization is not granted.

The technical feasibility for downstream users of the shortlisted 11 alternatives is acknowledged by the applicant. The applicant considered that there are several general plasticizers that could technically replace DEHP potentially in a very significant proportion of its downstream users' applications. Some limitations are mentioned, but the information provided in the Analysis of Alternatives remains generic and fails to identify those cases (article types), for which alternatives are not suitable to its downstream users.

To conclude, the assessment of alternatives does not address specifically the varied situations covered by the very broad scope of this application and therefore does not demonstrate that alternatives are not technically feasible. Overall, in the absence of information on the contrary, SEAC considers that general purpose alternatives combined with specialized plasticizers, or alternative materials, can cover all technical requirements for downstream users.

This conclusion is in line with the opinion of SEAC on the DK restriction proposal for four phthalates (including DEHP and for a similar scope), the view that "alternatives are currently technically available […] for a majority of situations".

Economic feasibility.

As reported in section 8 below, SEAC confirmed the order of magnitude of the substitution costs for downstream users (see more information on substitution costs in section 8).

Since the alternatives are in general more expensive, a significant increase of the soft PVC production costs in the EU would result from using alternative plasticizers.

Switching to any alternative would incur substitution costs to a significant proportion of downstream users, and incur at least some adaptation/transaction costs to all downstream users.

1. Impacts to compounders

For compounders, the economic impact can be looked at through the impact on PVC compound price.

The substitution cost for compounders is equivalent to a mean increase of around 10% of the PVC compound price (based on SEAC estimate of substitution costs and recent ICIS data for PVC compound price). This increase varies between ~0 and ~50% across the different alternatives.

Comparing the reported profit margins for compounders in the supply chain of the three applicants (ARKEMA FRANCE, Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s.) with ranges with the impact on PVC compound prices suggests that

the economic impacts are likely to be significant for a proportion of the article compounders.

The economic impact of these substitution costs depends in part on the ability of compounders to pass on costs to their suppliers (article manufacturers). This ability probably depends on the same ability for article manufacturers to pass on costs to their customers.

The proportion of the applicants' downstream users who are compounders only (i.e. not article manufacturers) is somewhat unclear in the Application, but thought to represent between [redacted] of DEHP consumption in the supply chain of ARKEMA FRANCE, Grupa Azoty Zakłady Azotowe Kędzierzyn S.A. and DEZA a.s..

2. Impacts to combined compounders/articles manufacturers

For combined compounders/articles manufacturers, the economic impact on article price is thought to be lower than the impact for "pure" compounders, since the cost penalty is diluted in other raw materials and processes not impacted by the substitution.

3. Impacts to article manufacturers

Some information given by downstream users in the SEA indicate that the DEHP cost is a marginal to significant proportion of the article production costs. This suggests that significant economic impacts are likely in the non-use scenario for a proportion of the article manufacturers, especially when they are competing with imported articles manufactured with DEHP.

Overall, there are consistent indications that to a significant proportion of compounders and article manufacturers alternatives are not economically feasible. SEAC considers that, as a whole, alternatives are not economically feasible.

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

☒ YES

☐ NO

Justification:

In terms of information, the applicant provided significant and relevant assessment of the technical economic feasibility of the alternatives.

SEAC has reservations regarding how the applicant concludes on the suitability of alternatives, but the survey of alternatives in supply chains is regarded as adequate (given however some caveats that are discussed above in section 7.2).

7.3 If alternatives are suitable, are they available?

☐ YES

☐ NO

☒ NO SUITABLE ALTERNATIVES EXIST

Justification:

Based on Section 7.2 above, SEAC concluded that there are no suitable alternatives at the present moment.

8. For substances for which adequate control is not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT QUESTION

Justification:

Risks of continued use

RAC considered there is adequate control for the general population and consumers.

For workers RAC considered the exposure data in the application limited and therefore considered the applicant does not demonstrate adequate control of risks for workers. RAC's assessment based on these limited exposure data in the application showed a risk for the use applied for.

Regarding the alternatives, RAC considered that under the assumption that exposure conditions do not change significantly when moving to alternatives, their adoption would lead to an overall reduction of risk (from RCRs already just slightly above 1, therefore very low or no risk can be anticipated with current knowledge and assessment of alternatives).

The applicant considered that there are no risks from continued use. Nevertheless he carried out a monetary assessment of health impacts of continued use, relying on the assumption that a fraction of idiophatic male infertility cases reported in the EU for the general population are attributable to chemicals, and that another fraction of these could theoretically be attributable to DEHP.

SEAC considers this health impact analysis is not fully adequate, in particular because the DEHP-related fertility problems fractions are calculated for the general population but applied to the workers population. SEAC therefore had to consider and adapt its results for the assessment of the authorisation.

SEAC assessed the social cost of continued use per case of fertility impairment. For that purpose, SEAC used information from the applicant's SEA and other sources of economic information on valuation of fertility impairment. Both tangible (cost of Assisted Reproductive Technology) and intangible economic issues (intangible value of fertility) are taken into account.

The SEA reported a range of 32,500 € to 77,500 € per fertility impairment case, combining both ART costs and willingness to pay (WTP) for having a baby with ART. SEAC reviewed this assessment and proposes a similar range of 58 200 € to 67 200 € per case. The difference lies in additional indirect costs of ART (Connelly et al., 2010) that were included by SEAC, and also the use of a different upper bound for the range of WTP for having a baby with ART.

There are significant uncertainties and information gaps regarding this assessment, and it is difficult to prefer one range over another. However, the fact that the ranges assumed by SEAC and the applicant are similar gives some confidence in the order of magnitude (confidence to the point set by the limitations of the available scientific literature on the economic value of fertility).

Benefits

The applicant based his assessment of these costs mainly on the loss of revenue from the cessation of DEHP manufacturing and on substitution costs for downstream users.

Avoided costs for DEHP manufacturers

The main argument for the cessation of DEHP production is the non-availability of some DEHP precursors, which has not fully been demonstrated.

The costs of cessation were fully attributed to the non-use scenario. This approach is, however, questionable since part of them could be attributed to other factors than the authorisation (decline of DEHP sales in the EU).

Other possible sources of overestimation have been identified, e.g., the reference price of DEHP for valuing the lost DEHP sales, the DEHP sales future decline rate, and the discount rate.

Overall, it remains unclear that the closure of the facility is necessary, and the costs for the applicant of non-use are probably overestimated.

For these reasons, SEAC only took account qualitatively of these costs in the assessment, and further concentrated on substitution costs for downstream users.

Avoided costs for downstream users

The costs calculated for downstream users were based on the price differences between DEHP and potential alternatives, and these were overall consistent with those that were found by SEAC during the assessment of the Danish restriction proposal.

In order to confirm firmly the order of magnitude of the substitution costs for downstream users, SEAC carried out another assessment based on the same method, but using detailed and traceable price information from different quotation or economic sites, and recently published information on major alternatives from ICIS.

Costs calculated by SEAC were around 65% of the costs calculated by the applicant, and therefore the order of magnitude could be considered as consistent between the two estimates. The substitution costs for downstream users as calculated by SEAC were used in the break-even analysis below.

In the future, increasing production capacities and offer for alternative plasticizers on the market could also decrease the price of some if not a majority of alternatives. The above cost figures also probably do not take into account commercial reductions that are classically granted to compounders by plasticizer manufacturers (ICIS, personal communication to SEAC rapporteur).

These figures were also based on the market shares for alternatives in 2012. However there are several indications of changes in market shares for some alternatives since 2012, and in the near future.

The costs are sensitive to assumptions regarding market shares and DIDP prices (found

to be very variable). Based on slightly revised 2014 market shares and using the alternative price information mentioned above, costs of around 25% of those calculated by the applicant can be calculated. Since this calculation was based on scarce information, it was not used in the comparison of break-even analysis, but it was taken into account qualitatively when deciding on the review period (see section 10).

Break-even analysis

Given the limitations in the available information on risks, it was not possible to carry out a realistic assessment of the human health impact of the continued use scenario. However, the benefits (avoided costs in terms of substitution costs for downstream users) and the estimate of the monetary value of infertility cases could be used to carry out a break-even analysis.

To compare the break-even numbers with a number of infertility cases, SEAC did not use the applicant's SEA because it was relying on arbitrary assumptions regarding the relation between exposure and effect, and because these assumptions made for the general population were applied to the workers population.

SEAC made a worst case scenario calculation of possible number of infertility cases among female workers' future male babies. The calculation estimates a number of male babies born from female workers working in uncontrolled workplaces and exposed to DEHP. Severe worst case assumptions are then made about the fraction of such workers exposed above the DNEL and about the future consequence in terms of reprotoxic impacts on their male babies. SEAC also took account of RAC's view that in comparison with DEHP, substitution with alternatives seems to constitute a lower risk (with caveats expressed in section 7.1).

The number of infertility cases calculated in the worst case scenario was below the range derived in the break-even interval. SEAC reviewed qualitatively the uncertainties on costs and benefits and concluded that they did not affect significantly the break-even analysis. Therefore, SEAC concluded that the analysis indicated that the benefits of continued use of DEHP outweigh the risks.

9. Do you propose additional conditions or monitoring arrangements

☐ YES

☒ NO

Justification for additional conditions and monitoring arrangements:

10. Proposed review period:

☐ Normal (7 years)

☐ Long (12 years)

☒ Short (4 years)

☐ Other:

Justification for the suggested review period:

See section 6. A shorter than standard review period was recommended by RAC

because:

RAC has strong indications that adequate control can be achieved by many downstream users in a variety of workplaces. As adequate control appeared not to have been achieved in several workplaces, or at least it has not been demonstrated with an adequate assessment, there is clearly no minimisation of exposure nor of risks.

SEAC took note of the recommendation of RAC and additionally took the following into account in their recommendation for the review period:

- There is supporting information (e.g., ICIS) that substitution costs have been decreasing between 2012 and 2014 and will continue to do so, and SEAC would therefore need to confirm or revise its assessment of the socio-economic costs and benefits within a relatively shorter period of time;

- There were deficiencies in the Analysis of Alternatives and the SEA that create uncertainties in SEAC assessment.

- Confidential information given by the applicant.

SEAC proposed a short review period of 4 year.