EUROPEAN COMMISSION

Brussels, 7.12.2016
C(2016) 8454 final

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Subject: **Request for internal review under Article 10 of Regulation 1367/2006 of Commission Implementing Decision C(2016) 3549 granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 (REACH)**

Dear Mr Buonsante,

I am responding to your request of 2 August to the European Commission for an internal review in accordance with Article 10 of Regulation (EC) 1367/2006 of Commission Decision C(2016) 3549 granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP).

Your organisation requests the internal review of that Decision on grounds that it is vitiated by a manifest error of assessment under Article 60(7), 60(2), 60(4), 60(4)(b) and Article 77 of Regulation (EC) No 1907/2006 (REACH), that it infringes an essential procedural requirement under Article 60(4)(b) REACH and that it infringes the Treaty on European Union because of alleged failure to state the reasons, infringement of the precautionary principle and misuse of power.

After careful consideration of the grounds put forward in your request, I have come to the conclusion that the Commission has neither infringed any of the provisions of the REACH Regulation referred to in your request for internal review, neither any of the general principles of law mentioned therein. Accordingly, the grounds put in your request for internal review have to be dismissed as unfounded. The Commission's assessment of each of those grounds is provided in Annex to this letter.

Should you not agree with the present reply, you may make a complaint to the Ombudsman in accordance with Article 228 of the Treaty on the Functioning of the European Union or institute proceedings before the General Court under the conditions laid down in Article 263 TFEU.

For the Commission

Elżbieta Bieńkowska

Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION

ANNEX

Client Earth request to the European Commission for an internal review in accordance with Article 10 of Regulation (EC) 1367/2006 of Commission Decision C(2016) 3549 granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP)

The request for internal review of Decision C(2016) 3549 (hereafter referred to as the "authorisation Decision") is based on the grounds that the Decision is vitiated by a manifest error of assessment under Article 60(7), 60(2), 60(4), 60(4)(b), 64(3) and Article 77 of Regulation (EC) No 1907/2006 (REACH), that it infringes an essential procedural requirement under Article 60(4)(b) REACH and that it infringes the Treaty on European Union because of alleged failure to state the reasons, infringement of the precautionary principle and misuse of power. The following paragraphs provide the Commission's assessment of each of those grounds separately.

1. Alleged manifest error of assessment under Article 60(7) and 64(3) REACH

In your request you contend that the authorisation Decision is in breach of Article 60(7) of REACH because the application for authorisation to which it refers was not in conformity with the requirements of Article 62 of that Regulation. Your conclusion on the lack of conformity is based on the grounds that the application failed to define the use of the substance (required by Article 62(4)(c) REACH, failed to adequately describe the exposure scenarios in the chemical safety report (CSR) (required by Article 62(4)(d)) and failed to assess the alternatives (required by Article 62(4)(e)).

1.1. Alleged failure to define the use

The application for authorisation was submitted for uses of recycled PVC containing DEHP. In your request you contend that since DEHP does not have a technical function for the applicants, the uses for which authorisation was applied for was not covered by the scope of the authorisation requirement in REACH.

As you point out in your request, the applicants mention in the application that "*DEHP does not play any specific functional role for the applicants: it is merely present as a (largely unwanted) impurity in the waste that is collected, sorted, processed and then placed on the market in the form of recyclate.* In line with Article 2(2) of REACH, waste as defined in Directive 2006/12/EC is not a substance, mixture or article within the meaning of REACH and REACH requirements start applying only once the recycled material is no longer waste. The criteria to identify substances which have undergone a recovery process have been clarified in the *Guidance on waste and recovered substances*[1].

Since waste is outside the scope of REACH, the lack of function of the DEHP in the waste material as such ("*it is merely present as a (largely unwanted) impurity in the waste that is collected...*") is not relevant for the purpose of the authorisation. Given that substances constituting waste cannot as such be understood to have a function, the presence of DEHP in waste should be distinguished from the function that the substance has in the recovered material that ceased to be waste. The fact that the applicants consider the presence of DEHP in the recycled material as an "unwanted impurity" is therefore not relevant and it does not

[1] https://echa.europa.eu/documents/10162/13632/waste_recovered_en.pdf

change the Commission's conclusion that the substance does have a function in the material once it has ceased to be waste. Moreover, in the case at hand, the presence of DEHP in recycled soft PVC reduces the amount of plasticisers that needs to be added in the production of soft PVC articles made out of the recycled soft PVC material. The presence of DEHP has, therefore, clearly a function for the production of articles made of soft PVC and therefore for the purpose of the authorised uses.

Should in a hypothetical scenario DEHP be considered, as you claim, an impurity with no function for the recycled soft PVC, the presence of that substance as an impurity (and not as a component of a mixture) would fall outside the scope of the authorisation requirement, in the terms of the current Annex XIV entry for DEHP. However, as explained above, DEHP actually has a function in the recycled PVC and, in any case, is present in concentrations higher than those specified in Article 56(6) of the REACH Regulation. Consequently, mixtures containing DEHP are subject to authorisation and this ground for review must be dismissed.

Should the recycled soft PVC not cease to be waste, the presence of that substance would fall outside the scope of REACH and the authorisation requirement in line with Article 2(2) of that Regulation. However, such a conclusion would not imply that the application for authorisation was not in conformity. On the contrary, it would render the authorisation requirement inapplicable to that material, which would not need an authorisation under REACH for its placing on the market and use.

I recall that within the framework of the REACH authorisation procedure, the Commission needs to check if the conditions for authorisation are fulfilled. The authorisation decision does not need to expressly address the question whether the material concerned has ceased to be waste. The authorisation requirement applies to a substance once it has ceased to be waste. In the absence of end-of-waste criteria at EU level it is for the Member States to decide according to Article 6(4) of Directive 2009/98/EC whether the recycled soft PVC in question has ceased to be waste. Consequently, it would also be for the Member States to decide whether the companies concerned should still operate under the waste regime requirements or be subject to product legislation, including REACH.

In view of the considerations above, this ground for review must be dismissed.

1.2. Alleged failure to adequately describe the exposure scenarios in the chemical safety report (CSR)

In your request you argue that since the CSR, and in particular the exposure assessment, contained deficiencies regarding the exposure of workers to DEHP, the application should have been considered not to be in conformity with Article 62(4)(d) REACH. Whereas indeed the Committee on Risk Assessment (RAC) of the European Chemicals Agency (ECHA) considered in its opinion that the exposure assessment had some deficiencies, it considered that the application included the necessary information specified in Article 62 REACH relevant to their remit and the Commission considered the application in conformity with Article 62. Therefore I consider this ground for review as unfounded.

Furthermore, I would like to draw your attention that the Commission acknowledged the conclusion of the RAC on the deficiencies by, on the one hand, setting a very short review period for the authorisation (expiring on 21 February 2019) and, on the other, by imposing on the holders of the authorisation monitoring arrangements, including the obligation to provide

up-to-date and detailed worker exposure measurement data to the national authorities (upon request) and in the review report. The latter is in particular to address the uncertainties concerning representativeness of the worker exposure data used for the exposure assessment in the application for authorisation.

1.3. Alleged failure to assess the alternatives

In your request you contend that the application for authorisation should have been considered to be not in conformity with the requirement in Article 62(4)(e) because DEHP did not have a function for the applicants, whereas the function of the substance is the basis for identifying possible alternatives to it. In that regard I refer to my conclusion under point 1.1 on the function of DEHP in recycled soft PVC once it ceased to be waste, i.e. that the presence of DEHP in the recycled soft PVC reduces the amount of plasticiser that needs to be added in the production of articles made out of PVC. As already explained above, should the recycled soft PVC not cease to be waste, the presence of that substance would fall outside the scope of REACH and the authorisation requirement in line with Article 2(2) of that Regulation. In the hypothetical case that DEHP were to be considered as an impurity, the placing on the market and use of recycled soft PVC containing that substance would fall outside the scope of the authorisation requirement. Therefore, even if your claim were to be founded (quod non), it would not be a ground for concluding the application was not in conformity, but for dismissing it altogether since no authorisation would be required in that case.

Furthermore, the application, as evaluated by the two ECHA Committees, does contain an assessment of the suitability of possible alternatives from the applicants' perspective in accordance with Article 60(5). It also contains an assessment from the downstream users' (flexible PVC converters') perspective – namely, assessment of the impacts in case of substituting recycled soft PVC with virgin PVC. Therefore I consider this ground for review as unfounded.

1.4. Alleged breach of Article 60(7)

Article 60(7) requires that for an authorisation to be granted, all the elements in Article 62 must be submitted in the application. When an application for authorisation is not in conformity, Article 64(3) provides that the ECHA Committees may request additional information from the applicant in order to bring the application into conformity with the requirements of Article 62. The fact that Article 64(3) does not expressly provide that the Committees may make further requests for information after considering the application to be in conformity does not imply in any way that the Committees are prohibited from making such requests to the applicant, where such information is relevant for the assessment of the application. In your request you have not provided any justification supporting your understanding of this provision as excluding the possibility for the ECHA Committees to request additional information after considering the application to be in conformity. Since I do not see any reason why such requests for additional information should not be allowed, I consider your claim that the requests for further information made by the Committees leads the authorisation decision to infringe Article 60(7) REACH as unfounded.

2. Alleged manifest error of assessment under Article 60(2) REACH

2.1. Alleged infringement of Article 60(2) and 60(4)

In your request[2] you state that "*Where an application for authorisation submitted via the Adequate Control route does not satisfy the conditions set out at Article 60(2), it must be rejected. The REACH Regulation does not allow for the same application to be then approved under the SEA [socio-economic] route.*" This assertion has no basis in the REACH Regulation. The conditions for granting an authorisation are set out in Article 60 (2) and (4) REACH, and indeed are commonly referred to as two different "routes" to authorisation. Those conditions are either that the risk to human health or the environment from the use of the substance is adequately controlled in accordance with Section 6.4 of Annex I (Article 60(2), commonly referred to as "adequate control route") or if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and there are no suitable alternative substances or technologies (Article 60(4), commonly referred to as "socio-economic route"). The REACH Regulation does not prevent an applicant from including in his application supporting evidence to meet the conditions of both paragraphs 2 and 4 of Article 60. The application for authorisation at the basis of the authorisation Decision contained elements supporting that the conditions in Article 60(2) and (4) were met. Based on that information, the RAC considered that the conditions under Article 60(2) were not satisfied as the risk was not adequately controlled, but based on the relevant available information the SEAC concluded that the conditions in Article 60(4) were satisfied.

Furthermore in your request you state[3] that "*by granting the authorisation via Article 60(4), when the Application for Authorisation was submitted under Article 60(2) the Contested Decision was in breach of both provisions and the general principle of equal treatment*". However, an application for authorisation is not submitted under a given route, but it should contain all the information necessary to meet the conditions set out in Article 60(2) and/or Article 60(4). In the case at hand, the information submitted by the applicants in support of their application was relevant under both paragraphs 2 and 4 of Article 60, and hence the Committees assessed it in the light of both sets of conditions. Therefore the claim that Article 60(2) was infringed must be dismissed.

2.2. Alleged manifest error of assessment of the conditions for authorisation under Article 60(2)

Firstly, in your request you claim that the scientific information provided in the application for authorisation did not substantiate the finding that DEHP is a threshold substance (i.e. substance for which a Derived No-Effect Level can be derived in accordance with Section 6.4 of Annex I to the REACH Regulation) and, therefore, you suggest that the Commission should have questioned that conclusion by the RAC.

It is correct that in its opinion, the RAC did dismiss the arguments provided by the applicants in support of the DNEL values in the application, and consequently assessed the application using the reference values which the RAC itself had published in April 2013[4]. Since in relation to those reference values the applicants did not demonstrate adequate control in

[2] Par. 77

[3] Par. 81

[4] https://echa.europa.eu/documents/10162/13579/rac_24_dnel_dehp_comments_en.pdf

accordance with Article 60(2), an authorisation could not be granted on the basis of that Article of REACH. However, in your request you do neither refer to nor question the scientific basis used by the RAC itself when it identified and published reference DNEL values for DEHP and, implicit in those values, RAC's conclusion that DEHP is a threshold substance with regard to toxicity for reproduction, which is the only effect relevant intrinsic property in the context of the application received. Since the values proposed by the applicants were rejected by the RAC, but your request does not question the scientific basis of the reference values derived by the RAC itself, your claim on the non-threshold nature of DEHP with regard to its reprotoxic properties is unfounded.

Secondly, in your request you claim that the applicants failed to provide the required information under Article 60(2), because of the limited worker exposure data submitted in the application. Again, there is no contradiction between your claim and the conclusions of the RAC, which were duly reflected in the authorisation Decision through additional monitoring and reporting obligations. In its justification of the opinion, the RAC noted that "*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.*"[5] Accordingly, the RAC (and the Commission in its Decision[6]) concluded that the conditions for granting an authorisation under Article 60(2) were not met and that it was not appropriate to grant the authorisation based on that Article. In view of this, this ground for review must be dismissed.

3. Alleged manifest error of assessment under Article 60(4) REACH

In your request you claim that the authorisation Decision, in granting an authorisation on the basis of Article 60(4) REACH, on the one hand did not respect the conditions set out in that Article and on the other failed to take into account relevant information omitted from the application for authorisation.

3.1. Compliance with the conditions of Article 60(4) REACH

For an authorisation to be granted on the basis of Article 60(4) REACH, two cumulative conditions have to be met, namely the applicant must demonstrate that the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, and that there are no suitable alternative substances or technologies.

i) Alleged failure to demonstrate that the socio-economic benefits outweigh the risk to human health or the environment

Your claim that the first condition under Article 60(4) has not been met in the present case is based on three grounds:

- Firstly, that no socio-economic benefits can result from the use of a substance which serves no function. However, as clarified under point 1.1 above, provided that recycled PVC with DEHP has ceased to be waste and thus, falls under the REACH authorisation requirement, the presence of DEHP in recycled PVC described in the

[5] RAC opinions, section 5 of the Justification (https://echa.europa.eu/documents/10162/b50d9fc3-f6db-4e91-8a95-c8397bb424d2, https://echa.europa.eu/documents/10162/8d9ee7ac-19cf-4b1a-ab1c-d8026b614d7a)
[6] Recital 5

authorisation Decision does fulfil a function, i.e. it reduces the amount of plasticisers that needs to be added in the production of soft PVC articles made of recycled soft PVC. Furthermore, Article 60(4)(b) requires consideration of the socio-economic implications of a refusal to authorise. DEHP is already present in the recycled soft PVC material, in variable quantities. Thus, a refusal to authorise would have had socio-economic implications as demonstrated in the application, assessed by the SEAC, and taken into consideration in the Decision.

- Secondly, the incorrect assumption in the socio-economic analysis submitted as part of the application for authorisation, that there are no risks from the use of DEHP in the case at hand. The authorisation Decision does recognise[7] that the applicants did not demonstrate adequate control of the risks and that the RAC could not quantify the remaining risks for workers. However, the Decision recognises that the SEAC concluded that benefits of continued use outweigh the risks on the basis of a qualitative analysis of the available information. The fact that the applicants' claim for adequate control and 'no risks from continued use' was dismissed by the RAC does not prevent the conclusion that benefits of continued use outweigh the risks. In fact, the information at hand was sufficient for the SEAC to unanimously conclude that the benefits of continued use outweigh the remaining risks.

- Thirdly, the fact that the socio-economic analysis was submitted by the applicants "in the context of an application for authorisation under Article 60(2)", not Article 60(4). As already stated in point 2.1 above, applications for authorisation are not submitted under a given route. Based on the evidence provided in the application, the RAC and the SEAC assess, within the remit of their respective tasks, 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 and the socio-economic factors and the availability, suitability and technical feasibility of alternatives. These elements feed into the Commission assessment of whether the conditions for an authorisation are met, be it under Article 60(2) or (4). Even if the applicants considered that the socio-economic analysis was not aimed at demonstrating that the conditions of Article 60(4) were met because they assumed that an authorisation could be granted under Article 60(2) (which was subsequently rejected by the RAC), the inclusion in that analysis of information relevant under Article 60(4) enabled the SEAC to assess the application on the basis of the latter provision.

In view of the above, the Commission did not breach the conditions in Article 60(4) REACH when granting the authorisation.

ii) Alleged failure to demonstrate lack of suitable alternatives

In your request you claim that the authorisation Decision breached Article 60(4)(c) because the applicants did not demonstrate that there were no suitable alternatives for the uses applied for.

Firstly, you argue that DEHP does not have a function in recycled soft PVC. As pointed out under point 1.1 above, provided that recycled PVC with DEHP has ceased to be waste, the presence of DEHP in recycled PVC described in the authorisation Decision did fulfil a

[7] Recitals 5 and 6

function, i.e. it reduces the amount of plasticisers that needs to be added in the production of soft PVC articles from recycled soft PVC. This argument has therefore already been dismissed.

Secondly, you argue that the analysis of alternatives submitted by the applicants failed to compare the risks of using DEHP with those from using the alternatives, and this failure is due to the fact that the application for authorisation was based on the assumption that the risks for workers were adequately controlled. In that regard, it should be pointed out that, as mentioned in the ECHA *Guidance on the preparation of an application for authorisation*[8], for the purpose of demonstrating that an alternative does not lead to an overall reduction of risks it is not necessary to assess the risks from the alternatives in the same detail as the risks associated with the use of the Annex XIV substance. The level of detail of analysis is a matter of judgment for the applicant in each case, which will then be scrutinised by RAC and SEAC. It is clear, that in particular in cases where one of the aspects of the feasibility of an alternative is excluded, the other aspects do not need to be assessed. In particular the Guidance clarifies that if one of the elements of the feasibility analysis (e.g. reduction of overall risks) is not met by a particular alternative, there would be little merit in detailed analysis of other feasibility aspects. In the case at hand, the SEAC concurred with the applicants that the identified alternatives are not technically and economically feasible. As a result, it was not necessary to also assess those alternatives from the point of view of the reduction of the risks.

3.2. Alleged failure to take into account relevant information omitted from the application

In your request you contend that the authorisation Decision did not take into account an important piece of information relating to the risks arising from other hazards of DEHP and on the consequences of not granting an authorisation.

i) Alleged failure to take into account the risks related to other properties of the substance

As one of the grounds for the request for a review you refer to the fact that, subsequent to the inclusion of DEHP in Annex XIV to REACH, that substance has also been identified under Article 57(f) REACH because of its endocrine disrupting properties for the environment. In your request you claim that under Article 60(4) REACH, the risk assessment should cover all hazardous properties of a substance, hence also those arising from the endocrine disrupting properties for the environment. In that regard, it should be noted that the identification of DEHP under Article 57(f) due to endocrine disrupting properties for the environment only occurred in December 2014, whereas the application for authorisation had been submitted in August 2013. One could not have expected the applicants to anticipate the identification of an additional hazardous property of DEHP when preparing the application for authorisation, in the course of 2012-2013, when such properties where only identified 15 months later. Such an approach would be contrary to the principle of legal certainty and cannot be supported. Changes in the hazards related to a substance should be relevant at the time of the review of the authorisation, as foreseen in Article 61 REACH. In view of this, this ground for review cannot be accepted.

[8] https://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf, section 3

ii) Alleged failure to take into account information on consequences of not granting an authorisation

In your request you also contend that the Commission failed to take into consideration all the socio-economic consequences of not granting the authorisation. In particular, you note that if the authorisation had been refused, the applicants could have continued to sell the recycled soft PVC material as waste.

This claim is incorrect. The application does consider the option: *'to sell its products as a waste with the related consequences (the customer must have an environmental permit enabling him to handle waste and must fulfil waste legislation requirements'*, but it is then dismissed as unfeasible: *'latter option is unrealistic as converters will not want to meet the requirements of waste legislation and this would further erode the margins that recyclers can earn on their recyclate, making it uneconomic to continue. They have therefore been left with no alternative but to apply for Authorisation'*[9].

Furthermore, the *Guidance on the preparation of socio-economic analysis as part of an application for authorisation*[10] (SEA Guidance) acknowledges that for a given use there may be different non-use scenarios possible, and in such cases the applicant may choose to develop all of them or only choose the most likely one(s). Thus the non-consideration by the applicant (and subsequently by SEAC and the Commission) of a particular (unlikely) non-use scenario under the socio-economic analysis cannot vitiate the authorisation Decision. Therefore this ground for review must be dismissed.

4. Alleged infringement of essential procedural requirement under Article 60(4)(b)

In relation to the previous ground for review addressed under point 3.2 ii) above, you claim in your request that the non-use scenario referred to therein was not put forward by interested parties at the time the application for authorisation was being assessed because *"neither ECHA nor the Commission have an open channel to receive this socio-economic information"*[11]. In your view third parties are not consulted on the socio-economic analysis, and, consequently, the SEAC and the Commission are prevented from taking into account any socio-economic input from third parties, thereby infringing the obligation set out in Article 60(4)(b) and Article 64(3) REACH.

This is incorrect. The procedure set out in Article 64 REACH for assessing applications for authorisation specifically provides (in paragraph 2) for a public consultation to be conducted by ECHA at the beginning of the process. The legislator did not foresee a separate public consultation for obtaining other types of information from interested parties. Therefore, although the main focus of the consultation under Article 64(2) is to obtain information from third parties on possible alternatives, third parties may also comment on other parts of the application, and in practice they have done so in the public consultations conducted so far. Comments received in public consultations so far by the Agency, including those which were not specifically referring to the alternatives, were considered by the Committees. The public summary of the SEA part of this particular application was made available during the public

[9] Socio-economic analysis, page 3 (https://echa.europa.eu/documents/10162/0aaf5968-a5d2-41ed-b488-be971af6e6e9)
[10] https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf, section 1.4.3
[11] Par. 120

consultation and ECHA did not restrict commenting on SEA-related issues. On the contrary, the possibility to provide comments on aspects other than the alternatives has been communicated by the Agency in the webinars it organises to inform stakeholders on how to contribute in public consultations under Article 64(2)[12]. In the case at hand, a number of the comments put forward by interested parties during the public consultation did indeed concern other elements than the alternatives (e.g. the definition of the uses applied for, hazards of DEHP, the exposure assessment). In view of the above, I must conclude that this ground of review is unfounded.

5. Alleged manifest error of assessment under Articles 60(5) and 77 REACH

Your request for review also contends that the authorisation Decision infringes Articles 60(5) and 77 of REACH because it did not take into account the SEA Guidance, the assessment of the alternatives was based on unreliable information and the assessment did not take into account information submitted by third parties.

5.1. Alleged failure to take into account the ECHA Guidance on authorisation applications

In your request you contend that the authorisation Decision did not properly take into account the economic feasibility of one of the alternatives, namely the use of DEHP-free post-industrial waste as a feedstock for the recycling process, in accordance with the ECHA Guidance, in particular by simply using higher net costs as the standard to assess economic feasibility instead of following the recommendation of the guidance (cost-benefit analysis). Furthermore, you claim that SEAC substituted the test of 'economic feasibility' with a more lenient approach of 'economically unfavourable' based on the use of a so-called *'standard of higher net cost'*.

Please note that the ECHA Guidance *on the preparation of an application for authorisation* stipulates (p. 75): *'The basis of determining the economic feasibility of alternatives can be called a cost analysis. This identifies the costs associated with the Annex XIV substance and compares this to possible alternatives, calculating the comparative costs between them. The analysis should also include possible changes in revenues due to substitution. Such revenues would be deducted from the costs.'* Furthermore, according to the *ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation* (p. 73) *'"net costs" should take into account both additional costs to actors if an authorisation is not granted and possible cost savings caused by the transfer to alternatives'*. Thus the net cost of substituting with an alternative in the context of applications for authorisation is the gross cost of the substitution reduced by the revenue incurred due to the substitution. This means that the *'standard of higher net costs'* (referred to in your claim and whose appropriateness for the assessment of economic feasibility you question) is actually inherent in the approach that is recommended by the ECHA Guidance. Accordingly, the SEAC assessment applied the approach suggested by the ECHA Guidance by considering the higher market price of the alternative feedstock but also the higher market value of the recyclates if using the alternative, as well as other economic consequences for the applicants and their downstream users.

[12] https://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/applications-for-authorisation-how-to-respond-during-public-consultation

Hence, from the above it can be concluded that the approach used by SEAC in their assessment is in line with the ECHA Guidance and that the SEAC conclusion that the alternatives are not economically feasible is valid. All of the above renders your claims moot, thus this ground for review must be dismissed.

5.2. Assessment of the alternatives based on allegedly unreliable information

In your request you also contend that the information used by the SEAC for concluding that the price range of the waste streams (post-industrial soft PVC waste as compared to post-consumer waste) provided by the applicant in its analysis of alternatives is unreliable because it was not scrutinised by an independent party. In that regard, it should be noted that the applicants did provide the calculation at the basis of those figures to the SEAC (which is confidential business information), but, as reported by the SEAC in its opinion, the Committee was unable to find adequate information in the public domain. Since the public consultation did not yield contradictory information regarding the figures put forward by the applicant, the SEAC concluded they were realistic. Given the limited public information available on the price of the waste streams in question, and the fact that no contradictory information was submitted in the public consultation, the conclusion reached by the SEAC was justified. Requiring the Committee to undertake an independent search for this specific data would be disproportionately burdensome on the procedure and unrealistic given the number and complexity of elements to be assessed by the Committees and the limited time frame provided in REACH for the assessment (i.e. 10 months). Therefore I must conclude that this ground for review is unfounded.

5.3. Alleged failure to take into account information submitted by third parties

In your request you also contend that the authorisation Decision did not take into account one particular comment from the public consultation which identified possible alternatives to DEHP as a plasticiser in PVC. Contrary to this claim, the applicants provided responses to the comments of this particular stakeholder, which are publicly available on ECHA's website[13]. The comments and the related responses were considered by SEAC during the opinion-making as appropriate.

6. Alleged failure to state the reason

In your request you contend that the authorisation Decision did not provide a clear statement of the reasoning supporting the granting of the authorisation, because it "merely summarises the conclusions of the opinion of the SEAC without setting out the legal reasoning that led to the authorisation"[14]. This claim is unfounded in the light of the text of the authorisation Decision. In particular with regard to the SEAC opinion, the Decision[15] indeed refers to the conclusions reached in that document, and on that basis it concludes: "It is therefore appropriate to authorise these two uses based on Article 60(4) of Regulation (EC) No 19072006 provided that the risk management measures and operational conditions described in the application (...) are fully applied" [16] (emphasis added). The wording of this Recital

[13] Comments and response to comments on authorisation, https://echa.europa.eu/documents/10162/17cf3d83-502b-4bd3-9450-eb7cc0cb52a3
[14] Par. 144
[15] Recital 6
[16] Recital 7

makes it clear that the Commission reviewed and agreed with the SEAC conclusions referred to in the previous Recital. By referring in this manner to the SEAC opinion the Decision provided a clear and sufficient motivation of the aspects of why it considered that the conditions for granting an authorisation under Article 60(4) REACH were met. In view of this, this ground for review must be dismissed.

7. Alleged infringement of the precautionary principle

In your request you claim that the authorisation Decision infringes the precautionary principle because "on the basis of scientific and objective evaluation" endocrine disruptors such as DEHP may have dangerous effects, and therefore restricting the use of DEHP would prevent the potential damage to human health and the environment[17].

Firstly it should be noted that the use of DEHP has so far only been restricted for specific applications under EU law (e.g. toys and childcare articles, cosmetic products). With the inclusion of DEHP in Annex XIV to REACH, uses of this substance which are not expressly restricted have been made subject to the authorisation requirement under REACH. An authorisation is granted if either the conditions of Article 60(2) or Article 60(4) are met. If based on the precautionary principle all uses of a substance listed in Annex XIV had to be prohibited because that substance has been identified as an endocrine disruptor, the whole purpose and effectiveness of the authorisation requirement would be nullified. This would in turn be in contradiction with the recognition, under Article 57(f) REACH, of endocrine disrupting properties as a hazard whose effects may be identified as being of equivalent level of concern to those listed in Article 57 (a) to (e) REACH. In other words, the legislator considered that also endocrine disruptors can be subjected to the authorisation requirement, which implies that a general ban of all uses of substances having such properties on the basis of the precautionary principle does not find a basis in the REACH Regulation. Therefore I find this ground for review unfounded.

8. Alleged misuse of power

Lastly, in your request you contend that by adopting the authorisation Decision the Commission misused its powers because, on the one hand, "*the authorisation was granted with the main purpose of encouraging the economic activity of recycling*"[18] and, on the other, the "*promotion of recycled materials containing hazardous substances*" is not among the purpose of the REACH Regulation[19].

In order to support your first statement, you refer to the Resolution of the European Parliament of 25 November 2015 on the draft authorisation Decision[20], which stated as one of the reasons for objecting to the draft Decision the reference in the SEAC opinion to recycling as a policy goal. The fact that the authorisation application in question is about a substance in

[17] Par. 150
[18] Par. 33
[19] Par. 159
[20] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting an authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (D041427 – 2015/2962(RSP))

recycled PVC was indeed an important element considered in the authorisation Decision, namely for the assessment of the alternatives for the applicant as well as with regard to the societal cost of disposing rather than recycling the material. The external costs to society due to potential risks to human health and the environment in case of no authorisation are a very relevant element for one of the Article 60(4) criteria, namely whether benefits of continued use outweigh the risks to human health and environment. However the fact that this particular element is relevant does not amount to the Commission misusing its powers in any way, since those elements were only part of the overall assessment of the application in the light of the conditions set for granting an authorisation under Article 60(4) REACH and setting the review period under Article 60(9) REACH. Therefore I find this ground for review unfounded.

Conclusion

For the afore-mentioned reasons, the internal review of Decision C(2016) 3549 has led to the conclusion that the Commission has neither infringed any of the provisions of the REACH Regulation referred to in the request for internal review, neither any of the general principles of law mentioned therein. Accordingly, the grounds put in the request for internal review have to be dismissed as unfounded.