REQUEST FOR INTERNAL REVIEW UNDER TITLE IV OF THE AARHUS REGULATION

OF COMMISSION IMPLEMENTING DECISION C(2016)3549

granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 16 June 2016[1]

SUBMITTED BY

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TO

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According to Article 11 of Regulation 1367/2006[2] and Commission Decision 2008/50/EC of 13 December 2007.[3]

[1] Summary of European Commission Decisions on authorisations for the use of substances listed in Annex XIV to
[2] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13–19) (the "**Aarhus Regulation**")
[3] Commission Decision 2008/50/EC of 13 December 2007 laying down detailed rules for the application of Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the Aarhus Convention as regards requests for the internal review of administrative acts, (OJ L 13, 16.1.2008)

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INTRODUCTION

1. On 16 June 2016, the European Commission (the "**Commission**"), and more specifically the Growth Directorate-General, adopted the Implementing Decision C(2016)3549 final, granting an authorisation to three companies for uses of bis(2ethylhexyl) phthalate ("**DEHP**") until 21 February 2019[4] (the "**Contested Decision**").[5]

2. DEHP was identified in 2008 as a substance of very high concern ("**SVHC**") pursuant to Article 57(c) of Regulation (EC) No 1907/2006[6] (the "**REACH Regulation**") due to its reproductive toxicity. For that reason DEHP has been included in the list of substances subject to authorisation set out in Annex XIV of the REACH Regulation. The authorisation process aims to ensure that the risks of SVHCs are properly controlled and that these substances are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.

3. Pursuant to Article 58(1)(c)(i) of REACH, due to its inclusion in Annex XIV of REACH, DEHP cannot be used without an authorization after 21 January 2015 (the "**Sunset Date**"). Further, since December 2014, DEHP has also been classified as a SVHC for its endocrine disrupting properties pursuant to Article 57(f) of REACH.

4. On 13 August 2013, an application for authorisation (the "**Application for Authorisation**") was jointly submitted by three companies (the "**Authorisation Applicants**") - three waste recyclers - for two uses of DEHP described at Article 1 of the Contested Decision and summarised as follows in the Contested Decision: (i) the formulation of recycled soft poly vinyl chloride ("**PVC**") containing DEHP in compounds and dry-blends and (ii) the industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles.[7]

5. Following the opinions of the scientific committees of the European Chemicals Agency ("**ECHA**"), the Committee for Risk Assessment ("**RAC**") and the Committee for Socio-economic Analysis ("**SEAC**"), the authorisation was granted conditional upon some monitoring arrangements.[8]

6. In addition, as the REACH Regulation does not apply to waste,[9] the Contested Decision specified that "*the authorisation to place on the market and use recycled soft PVC*

[4] i.e. four years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006 for DEHP
[5] Commission Implementing Decision of 16 June 2016, granting an authorisation for the use of DEHP under the REACH Regulation (C(2016)3549 final); Annex 1.
[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 200 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency, (OJ L 396 30.12.2006, p. 1).
[7] Contested Decision, §2.
[8] Compiled RAC and SEAC opinion on the Application for Authorisation dated 27 January 2015 (CAS number 117-81-7); Annex 2.
[9] Recital 11 of the REACH Regulation states that "to ensure workability and to maintain the incentives for waste recycling and recovery, wastes should not be regarded as substances, mixtures or articles". This approach is further confirmed by Article 2(2) of the Regulation.

compounds and dryblends containing DEHP [...] applies to the extent that those compounds and dry-blends have ceased to be waste in accordance with Article 6 of [the Waste Directive][10]". [11]

7. ClientEarth requests the internal review of the Contested Decision on the following grounds. First, the Contested Decision is vitiated by numerous manifest errors of assessment under the REACH Regulation calling into question the effectiveness of the authorisation process.

8. The Commission granted the authorisation to use DEHP despite the fact that the Application for Authorisation was not in conformity with the requirements set out at Article 62 of the REACH Regulation. The Application for Authorisation indeed (i) failed to correctly define the scope of the application (i.e. definition of the uses which are the subject matter of the authorisation), (ii) failed to properly describe the exposure scenarios in relation to the uses applied for, and (iii) failed to submit a valid analysis of alternatives.

9. The authorisation was granted under Article 60(4) (i.e. the socio-economic assessment route or "**SEA route**") despite the fact that the Application for Authorisation was submitted under Article 60(2) (i.e. the "**Adequate Control**" route). The information provided within the Application for Authorisation was therefore not in line with the requirements under Article 60(4). The Commission also failed to properly assess the economic feasibility of the alternatives as well as justify the deviation from the Guidance document in relation to economic feasibility.

10. The Contested Decision is also vitiated due to the breach of an essential procedural requirement provided under the REACH Regulation as third parties were not consulted to provide socio-economic input.

11. Finally, the Contested Decision was adopted in violation of the Treaty. In particular, it was taken in breach of an essential procedural requirement for failure to state reason. Furthermore it ignored the precautionary principle and is vitiated by a misuse of power.

12. Before developing these substantive grounds (**B.**), the admissibility of the Request is discussed hereunder (**A.**).

[10] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3) (the "**Waste Directive**").
[11] Contested Decision, §8.

A. ADMISSIBILITY

A.1. Eligibility of the Applicant pursuant to Article 10 of Regulation 1367/2006

A.1.1. ClientEarth fulfils the criteria of Article 10 and 11 of Regulation 1367/2006

13. ClientEarth fulfils the criteria of Articles 10 and 11 of Regulation 1367/2006:

- It is a non-profit organization;
- It is dedicated to the protection of the environment;
- It has operated for more than two years;
- The subject matter of the Contested Decision is covered by the objectives and activities of ClientEarth.

14. ClientEarth is a non-profit making, non-governmental environmental law, science and policy organisation with offices in Brussels, London and Warsaw. It opened in London and Brussels in 2008 and currently counts around 80 employees, of whom more than half have legal qualifications. ClientEarth works to protect the environment through advocacy, litigation and research. ClientEarth provides public interest legal capacity for the environment, working in its own right and with environmental NGOs and other stakeholders; acting as legal advocates for environmental objectives. The statutory goals of ClientEarth specify the objective of promoting and encouraging the conservation and protection of the environment, including the protection of human health.

15. Pursuant to its Articles of Association,[12] ClientEarth's activities focus on promoting, assisting, undertaking and commissioning research into law, practice and the administration of justice in connection with the environment and matters relating thereto including the impact, direct or indirect, of any human activity on the environment. Article 4.1. of the Articles of Association provides that the objective of the organisation is "*to promote and encourage the enhancement, restoration, conservation and protection of the environment, including the protection of human health, for the public benefit*".

16. According to Article 5 of its Articles of Association, ClientEarth has power to:

- "*provide expert legal advice, assistance, and representation in connection with the management, administration regulation, and protection of the environment, and the prudent and rational utilisation of land and other natural resources, including the*

[12] ClientEarth's Articles of Association; Annex 3.

development of policy or law, the drafting of laws, the implementation thereof, the institution of proceedings, conduct of litigation and resolution of disputes";

- *"subject to any consent required by law, to institute legal proceedings, conduct litigation and participate in alternative forms of dispute resolution";* and,

- *"alone or with other organisations to seek to influence governmental and other bodies and institutions regarding the reform, development and implementation of appropriate policies, legislation and regulations [...]."*

17. Since 2010, ClientEarth has had initially one and, since 2012, two lawyers working to use appropriate and available legal tools to protect human health and the environment from the harmful effects of chemicals. ClientEarth has allocated time and resources from its 2015 budget to continue this project.[13]

18. ClientEarth's activities regarding chemicals over recent years appear from the annual reports of ClientEarth.[14] In a nutshell, ClientEarth's work on chemicals is primarily focussed on the implementation of the REACH Regulation. Further activities of ClientEarth in relation to chemicals are focussed on product specific legislation regarding for example plant protection products, biocides and cosmetics. ClientEarth works, both in its own right and with other environmental organisations, to identify and apply legal principles and mechanisms set within the EU chemicals legislation, with the objectives, in particular, to secure the underpinning precautionary approach to decision making, to ensure that the hazard-based approach to the identification of chemicals is upheld and to place responsibility on producers to demonstrate the safety of the products involved, as foreseen by European legislation on chemicals. In order to achieve its goals, ClientEarth strives for full transparency and accountability of the regulatory process on chemicals, to improve the quality and increase the availability of data on chemicals, to ensure use of the latest scientific research to support a precautionary approach to regulation and to support innovation and the substitution of non-harmful alternatives. Key activities involve legal actions, including litigation, the provision of legal advice and supporting studies and reports

19. Furthermore, ClientEarth has stakeholder engagements with Member States, the European Parliament, the European Commission, and its Agencies such as ECHA and the European Food Safety Authority ("**EFSA**").

20. ClientEarth is indeed an accredited stakeholder at ECHA[15]. ClientEarth therefore fullfills all the requirements for stakeholders that ECHA has set:

- being legally established within the EU/EEA and having activities at a European level;

[13] See Annual Report for 2015 ; Annex 4.
[14] Annual Report for 2011 (p. 9), Annual Report for 2012 (p. 9), Annual Report for 2013 (p. 10-11), Annual Report for 2014 (p. 11-12); Annual Report for 2015 (p. 13-14); Annexes 4 and 5 or available at: <http://apps.charitycommission.gov.uk/Showcharity/RegisterOfCharities/>.
[15] List of ECHA's accredited stakeholders available at <http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>.

- having a legitimate interest in ECHA's areas of work;
- being representative in the field of its competence;
- being non-profit making and not exclusively representing individual companies;
- being registered in the Transparency Register of the European Union.[16]

21. ClientEarth is listed as an observer in ECHA's Risk Assessment Committee ("**RAC**"),[17] in the Socio-Economic Analysis Committee ("**SEAC**") as well as in the Member States Committee of ECHA.[18] ClientEarth is also an observer in the meetings of the Competent Authorities for the REACH Regulation and and the CLP Regulation[19] ("**CARACAL**"). CARACAL is an expert group that advises the European Commission and ECHA on questions related to REACH and CLP.[20]

A.1.2. Supporting documents of ClientEarth's entitlement to request internal review

22. As required by Commission Decision 2008/50/EC[21], to prove that ClientEarth meets the criteria listed under Article 11(1) of the Aarhus Regulation, the following documents are provided as Annexes to the Request:

- Articles of Association of ClientEarth (Annex 3);
- Annual activity reports of ClientEarth of the last two years (Annexes 4 and 5)
- A copy of the legal registration with the UK authority (Annex 6).
- ClientEarth has previously been acknowledged by the Commission as being entitled to make a request for internal review: see the Decision C(2009)3337) dated 27 April 2009 (Annex 7).

[16] A document further explaining the eligibility criteria and how to fulfill them is available at <http://echa.europa.eu/documents/10162/13559/mb_34_2011_revised_criteria_of_accredited_sh_en.pdf>.
[17] List of stakeholder organisations regarded as observers of the Committee for Risk Assessment (RAC) available at <http://echa.europa.eu/documents/10162/13579/rac_loa_sto_en.pdf>.
[18] List of stakeholder organisations regarded as observers of the Committee for Socio-Economic Analysis (SEAC) available at <http://echa.europa.eu/documents/10162/13580/list_of_sto_participation_in_seac_en.pdf>.
[19] Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).
[20] More information about CARACAL and its composition can be found at <http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm>.
[21] Commission Decision of 13 December 2007 laying down detailed rules for the application of Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the Aarhus Convention as regards requests for the internal review of administrative acts (OJ L 13, 16.1.2008, p. 24–26).

A.2. The Contested Decision is an "administrative act" in the sense of the Aarhus Regulation

23. The Contested Decision falls within the scope of an administrative act as described in Article 2(1)(g) of the Aarhus Regulation, i.e. "*any measure of individual scope under environmental law, taken by the Community institution or body, and having legally binding and external effect*", as detailed below.

A.2.1. The Contested Decision was issued "under environmental law"

24. The Contested Decision falls within the scope of environmental law as defined by Article 2(1)(f) of the Aarhus Regulation, i.e. "*legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of Community policy on the environment as set out in the Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources, and promoting measures at international level to deal with regional or worldwide environmental problems*".

25. The Contested Decision was issued under Article 60 of the REACH Regulation. Article 1 of the REACH Regulation leaves no doubt with regard to the objective of this regulation:

> *"Article 1 Aim and scope*
>
> *The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."*

26. The Court of Justice of the European Union ("**CJEU**") has affirmed that protection of human health and the environment are the primary objectives of REACH, while the functioning of the internal market is a secondary objective.[22]

27. Title VII of the REACH Regulation, "Authorisation", aims at the progressive substitution of substances of very high concern ("**SVHC**").[23] The Commission may only grant an authorisation if the risk to human health and the environment is adequately controlled, or on the basis of socio-economic reasons only when no suitable alternatives are available.[24] Hence, the decision to grant an authorisation is clearly based on the requirement to protect human health and the environment. As stipulated in Article 60(5), where alternatives are

[22] See Case C-558/07 *S.P.C.M. and Others* [2009] ECR I-5783, para. 45.
[23] Article 55: "*The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution*".
[24] Article 60 with Recital 22.

available, their suitability is to be assessed according to whether the use of the substances would reduce the risk to human health and the environment.

28. To ensure a level of protection for human health and the environment, the regulation of SVHCs under the REACH Regulation is based on the precautionary principle.[25] This is in line with EU policy on the environment as set out in the Treaty.[26]

29. Article 2(1)(f) of the Aarhus Regulation states that the scope of environmental law is to be considered "irrespective of its legal basis". Therefore, though the REACH Regulation takes Article 95 EC Treaty, now Article 114 TFEU, as its legal basis – it does not follow that REACH does not fall under the scope of environmental law as defined in Article 2(1)(f) of the Aarhus Regulation. Moreover, case-law has confirmed that where an act pursues a number of objectives that cannot be disassociated, the act may be said to be based on simultaneous legal bases.[27] Therefore, despite the reference to Article 95 EC as the legal basis, it is made clear via the legal text and Title VII of the REACH Regulation that the authorisation process pursues the twin objectives of harmonisation and environmental protection.

30. For the reasons set out above, it cannot be reasonably argued that the Contested Decision was not issued "under environmental law".

A.2.2. The Contested Decision is an administrative act of "individual scope"

31. Case law, the legal text of the REACH Regulation and previous decisions taken by the Commission concerning internal reviews all lead to the conclusion that the Contested Decision is of "individual scope" in the sense of Article 2(1)(g) of the Aarhus Regulation.

32. Measures of individual scope are not defined under the Aarhus Regulation or any other sources of EU law. However, according to the CJEU in order to determine the scope of a measure, account should first be taken of its purpose and its content.[28]

33. The purpose of the Contested Decision is to apply Article 60 of the REACH Regulation, i.e. to decide whether or not to grant an authorisation to use DEHP to the Authorisation Applicants - VinyLoop Ferrera S.p.A, Stena Recycling AB and Plastic Planet srl - who submitted a joint application for specific uses. The content of the Contested Decision stipulates the uses, conditions and monitoring of the uses of DEHP for the holders of the authorisation. The scope of the Contested Decision is therefore limited, by definition, primarily, to the Authorisation Applicants and their downstream users being part of the same supply chain.

34. Therefore, in light of the purpose and content of the Contested Decision, this administrative act can only be considered as being of "individual scope".

[25] Article 1(3) with Recital 69.
[26] Article 191(2) TFEU.
[27] See Case C-94/03 *Commission* v *Council*, para. 36 and the case law cited.
[28] See Case T-396/09, para. 26 and the case law cited; Case T-338/08, para. 29 and the case law cited.

35. Though the CJEU has not clearly defined what constitutes a measure of individual scope, the Court has considered in further detail what constitutes a measure of general scope/application. A measure will be considered to be of general scope where: 1) it applies to objectively determined situations and; 2) it entails legal effects for categories of persons envisaged generally and in the abstract.[29]

36. Applying these criteria, the CJEU held that Regulation No 149/2007, which sets maximum residue levels for active substances when applying pesticides, was not a measure of individual application for the purposes of Article 2(1)(g) of Regulation No 1367/2006.[30] This was on the basis that Regulation No 149/2007, 1) applied to an objectively determined situation and 2) entailed legal effects for categories of persons envisaged generally and in the abstract – i.e. economic operators covered by the annexes to Regulation No 396/2005 and any holders of market authorisations for plant protection products containing substances covered by those annexes.

37. By contrast, the Contested Decision does not satisfy the criteria of a measure of general scope. It does not apply to objectively determined situations: the scope of the authorisation is specifically limited to the use of the substance DEHP by the Authorisation Applicants, in the specific supply chain for the uses (products) applied for, the Authorisation Applicants being the only companies allowed to be at the top of the supply chain for the fabrication of recycled products containing DEHP as described in Article 1 of the Contested Decision.

38. For this reason, the Contested Decision only entails legal effects in a specific supply chain, on specific economic operators. The Contested Decision has only legal effect for producers acting within the supply chain of the Authorisation Applicants. These downstream users have to notify according to Article 66 of the REACH Regulation, so that ECHA can verify whether the use by a downstream user is in accordance with the conditions of an authorization granted to an actor up his supply chain. In light of this, it is clear that the Contested Decision in not of general but of individual scope.

39. In Cases T-396/09 and T-338/08, the General Court excluded that measures of general application can be regarded as measures of individual scope for the purposes of Article 2(1)(g) of Regulation No 1367/2006. It is thus clear that the Contested Decision is of individual scope.

40. On the same basis, the Commission has considered admissible[31] the requests for internal review of decisions of the Commission to authorise the placing of GMO food and feed on the market pursuant to Regulation (EC) No 1829/2003[32] and Directive 2001/18/EC.[33]

[29] Case C-503/07 P, para. 71.
[30] Case C-404/12, paragraph 58; Case T-338/08, para. 38 and 39.
[31] Commission Decision dated 26 May 2008 (SANCO/E1/CV/al D(2008)510302) available at: <http://ec.europa.eu/environment/aarhus/pdf/title_iv/Reply%20to%20J_E.pdf>; Commission Decision dated 6 July 2010 (C(2010)4632) available at: <http://ec.europa.eu/environment/aarhus/pdf/requests/9_reply%20.pdf>.
[32] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1–23).

41. There are clear parallels between the procedures provided for in Regulation (EC) No 1829/2003 and Directive 2001/18/EC for the placing of GMOs on the market and the authorisation process for substances on the Authorisation List under the REACH Regulation. Indeed, under Regulation (EC) No 1829/2003, the market authorisation 1) is addressed to a specific legal entity and 2) will permit the authorisation holder to market or import any food or feed produced from a GMO into the EU. Therefore, it would create unjustified inconsistency in the decision-making practice of the Commission under the Aarhus Regulation if the Contested Decision was considered as being of general scope while decisions authorising the placing of GMO food and feed on the market pursuant to Regulation (EC) No 1829/2003 are acknowledged to be of individual scope.

42. In light of the Commission's decision-making practice under the Aarhus Regulation, the case law of the CJUE, and the objective and content of the Contested Decision, the Contested Decision is a measure of "individual scope" in the sense of Article 2(1)(g) of the Aarhus Regulation.

A.2.3.The Contested Decision was taken by a Community institution or body

43. As required by Article 10(1) of the Aarhus Regulation, this request for internal review is directed to the European Commission, the institution that adopted the Contested Decision. The Decision was signed by Commissioner Elżbieta BIEŃKOWSKA, member of the European Commission and responsible for the Growth Directorate-General.

44. In light of the above, the Contested Decision meets the criteria of an administrative act according to Article 2(1)(g) of the Aarhus Regulation. The Request must therefore be held admissible. The substantive grounds for the review are set out below.

B. GROUNDS FOR REVIEW

45. ClientEarth requests that the Contested Decision be reviewed on the basis of the following grounds.

46. The Contested Decision is vitiated by manifest errors of assessment and a violation of an essential procedural requirement under the REACH Regulation. The Contested Decision specifically breaches a number of substantial and procedural provisions under Title VII (Authorisation) of the REACH Regulation. More specifically, the Contested Decision is requested to be reviewed on the following grounds:

[33] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC OJ (L 106, 17.4.2001, p. 1–39).

(1) Manifest error of assessment under Article 60(7) as the Commission granted the authorisation despite the fact that the **Application for Authorisation was not in conformity** with the requirements of Article 62. In fact, the Application for Authorisation was deemed in conformity under Article 64(3) despite not containing the minimum information necessary to carry out an assessment. Indeed, the committees requested additional information necessary to adopt their opinion, after deeming the Application in conformity. In particular, the Application was not in conformity with:

- Article 62(4)(c) for failing to correctly define the scope of the application/definition of the use;
- Article 62(4)(d) for failing to properly describe the exposure scenarios in relation to the uses applied for DEHP;
- Article 62(4)(e) for failing to submit a valid analysis of alternatives;

(2) Manifest error of assessment under Article 60(2) for **granting an authorisation under Article 60(4)**, (i) while the Authorisation Applicants did not submit the Application under Article 60(4) and (ii) despite the fact that the Authorisation Applicants did not prove that the risk to humans and the environment is adequately controlled in accordance with Section 6.4 of Annex I;

(3) Manifest error of assessment under Article 60(4) for (i) **granting an authorisation despite the fact that the Applicants did not prove that benefits for society outweigh the risks** and no substitutes exists for the uses for which DEHP is requested; (ii) and **failing to take into account relevant information** to the socio-economic assessment;

(4) Violation of an essential procedural requirement for **failure to invite third parties to provide socio-economic input** under Article 60(4)(b);

(5) Manifest error of assessment under Article 60(5)(b) and Article 77**, for failure to properly take into account the economic feasibility of the alternatives** as well as justify the deviation from the Guidance document on socio-economic analysis in relation to economic feasibility.

47. Furthermore, the Contested Decision was adopted in breach of the Treaty. In particular:

(1) It violates an essential procedural requirement by **failing to state reason**;

(2) It violates the **precautionary principle**; and,

(3) It is vitiated by a **misuse of power**.

B.1. Violations of the REACH Regulation

B.1.1. Absence of Conformity of the Application for Authorisation (Article 60(7) and 64(3))

Article 60(7) of the REACH Regulation provides that an authorisation shall be granted only if the application is made in conformity with the requirements of Article 62 which provides for the necessary information to be included in an application for authorisation. According to Article 64(3) each Committee (SEAC and RAC) is required to check that the application includes all the information specified in Article 62 that is relevant to its remit. When the application is not deemed in conformity the committees must, in consultation with each other, make a joint request to the applicant for additional information to bring the application into conformity.

a) The Application for Authorisation does not comply with Article 62(4)(c)

48. The Contested Decision was adopted in breach of Article 62(4)(c) which provides that: "*the application for authorisation shall include [...] a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant*".[34] The Application for Authorisation failed to satisfy these requirements in two regards.

49. First, contrary to this definition, the authorisation applied for by the Authorisation Applicants relates to the use of a material containing DEHP that is incorporated as part of a plastic waste stream where DEHP does not have a technical function. The authorisation therefore does not seek to allow the applicant to continue to use DEHP on its own, in a preparation or to incorporate it in an article.

50. Second, the Application for Authorisation failed to define the "use of the substance" as that term needs to be understood to achieve the objectives of the authorisation mechanism under the REACH Regulation. The term “use” is defined in Article 3(24) of the REACH Regulation as: “*any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization*”. It is clear from Article 56(1)(a) of the REACH Regulation that the function of the substance is central to the authorisation process. Moreover, in the context of an authorisation via the SEA route, the precise function of the substance is the cornerstone of the assessment of the benefits to society.

51. In the Application for Authorisation, the key elements of the conditions of uses and functional requirements include:

- *"Process temperatures in closed systems: 100-150 ˚C.*

[34] See also Article 56(1)(a) of the REACH Regulation with Recital 73.

- *Process temperatures during activities involving operator's action: < 40 ˚C.*

- *The solid recyclates contain typically less than 10% of DEHP with maximum concentrations below 20%.*

- *Technical function: 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. Nevertheless, the limited presence of DEHP in the recyclate may facilitate its processing into new PVC articles by reducing the amount of pure (or 'virgin') DEHP or other plasticizers that can be added to the compounds before new flexible PVC articles are produced. The use of pure DEHP is not covered by this application for authorisation*".[35]

52. As is clear in this description, DEHP serves no function for the purposes of the authorisation. This fact was confirmed by the Authorisation Applicants in the Analysis of Alternatives:

> "*The substance [DEHP] is not used per se by the applicants. It is rather present in post-consumer flexible PVC waste that the applicants process into PVC recyclate which in turn is placed on the market for use in the manufacture of new PVC articles. Therefore, 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*."[36]

53. The use covered in the Application for Authorisation is therefore clearly not within the scope envisaged by the relevant provision of the REACH Regulation. This was highlighted by the RAC rapporteur in their first comments on the Application:

> "*I question whether this application should have passed the conformity check according to REACH article 62(4)(c) – because the scope and use that the application concern is unclear*."[37]

54. The Authorisation Applicants failed to define the scope and use of the substance in breach of Article 62 of the REACH Regulation. This affects the very objective of the Regulation which is to seek to only allow the continued use of a SVHC for a function or use that cannot be provided in a viable way by an alternative substance or technology. Without any function, there should not be any authorisation.

[35] Application for Authorisation available at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/1621/term>
[36] Analysis of Alternatives – non-confidential report, p.1; Annex 8.
[37] Comments and response to comments on the Application for Authorisation on bis(2-ethylhexyl) phthalate (DEHP), p.2; Annex 9.

55. Despite this clear breach as to the conformity of the Application for Authorisation with the requirements of Article 62(4)(c), the authorisation was granted in violation of Article 60(7).

b) The Application for Authorisation does not comply with Article 62(4)(d)

56. The Application is not in conformity with Article 62(4)(d) which provides that: "*An application for authorisation shall include [...]a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV*". The Application indeed failed to adequately describe the exposure scenarios in reference to the uses applied for.

57. As a result of the broad description of the uses in the Application, the exposure scenarios did not correspond to the risk of the continued use of DEHP. The absence of adequate evidence to substantiate the claim that the risks to workers were adequately controlled was highlighted by the RAC, which stated that the data on biomonitoring and air measurements was of "limited informative value."[38]

58. The RAC opinion also concludes that the exposure from the use of the substance is not adequately described. It adds that "*[f]or 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*." Therefore the RAC concludes that "*[t]aking 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*".[39]

59. Moreover, the failure to fully describe the exposure scenarios in the Application for Authorisation was even emphasised in the Contested Decision:

> *"[…] the SEAC recognised the deficiencies in the workplace exposure assessment identified by the RAC and the lack of health impact assessment in the socio-economic analysis*"[40]

60. Hence, the Commission acknowledged that the Application for Authorisation was not submitted in conformity with the requirements in Article 62(4)(d). There is therefore no doubt that the authorisation was granted in breach of Article 60(7) of the REACH Regulation.

[38] Compiled RAC and SEAC Opinion, page 7; Annex 2.
[39] Compiled RAC and SEAC Opinion, page 7; Annex 2.
[40] Contested Decision, §9.

c) The Application for Authorisation does not comply with Article 62(4)(e)

61. The Contested Decision failed to assess the alternatives in breach of Article 62(4)(e) of the REACH Regulation.

62. The term "alternative" is not defined in the legal text of the REACH Regulation. However the stated intention of the authorisation process is very clear: the substitution of SVHCs with "*alternative safer substances or technologies*".[41] It therefore follows that in an application for authorisation, which aims to secure the use of Annex XIV substances, an analysis of alternatives would entail an evaluation of how the substance functions and the impact of replacing it with another.

63. This is consistent with the interpretation made by ECHA in its Guidance, which describes an alternative as: "*a possible replacement for the Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs*."[42] Accordingly, the analysis of alternatives as described in the Guidance is focused on the function of the particular substance: a suitable alternative will be one that is deemed to provide "*an equivalent function to that provided by the substance or makes the substance's use redundant*".[43]

64. However, contrary to the very premise of the analysis of alternatives that is aimed at substituting the function of an Annex XIV substances, in the non-confidential analysis of alternatives the Authorisation Applicants state:

> "*The substance is not used per se by the applicants. It is rather present in post-consumer flexible PVC waste that the applicants process into PVC recyclate which in turn is placed on the market for use in the manufacture of new PVC articles. Therefore, 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*."[44]

65. The RAC Rapporteur highlighted the failure to fully analyse alternatives in the initial comments to the Application for Authorisation, and stated that:

> "*The application only presents an assessment of alternatives for how DEHP can be excluded from the waste. I therefore find the assessment of alternatives lacking as the applicant has not included an assessment of alternatives for the use of recycled PVC further down the production chain such as for instance when a shoe or bag is manufactured*."[45]

[41] Article 55, with Recital 74 REACH Regulation.
[42] ECHA, Guidance on the preparation of an application for authorisation, 2011, available at: <http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf>, p.41.
[43] ECHA, Guidance on the preparation of an application for authorisation, 2011, p.42.
[44] Analysis of Alternatives – non-confidential report, p.1; Annex 8
[45] Comments and response to comments on application for authorisation on bis(2-ethylhexyl) phthalate (DEHP), p.2 ; Annex 9.

66. The analysis of alternatives was not valid, as it did not provide the necessary information to assess the alternatives as required under Article 62(4)(e). Hence, the Application for Authorisation was not in conformity and was granted in breach of Article 60(7) of the REACH Regulation.

d) Conclusion: the Contested Decision breaches Article 60(7)

67. Overall, the Contested Decision was granted in breach of Article 60(7) of the REACH Regulation, which stipulates that an application will be permitted "*only if it is made in conformity*" with the requirements of Article 62.

68. Despite the Application for Authorisation lacking substantive information that was necessary for the Commission to carry out its obligations under Article 60, the RAC and SEAC did not bring the Application into conformity according to the procedure laid out in Article 64(3) of the REACH Regulation.

69. According to Article 64(3), the committees must ('shall') check that 'all' the information required by Article 62 is provided and they must ('shall') require additional information to be provided to bring an application into conformity prior to the application being declared in conformity. Therefore, once an application is held to be in conformity, Article 64(3) does not foresee that the RAC may request further information from the applicant.

70. However, contrary to the REACH Regulation, once the Application for Authorisation was already deemed in conformity, further information was requested from the Authorisation Applicants. In the minutes of the 27th Meeting of the Committee for Risk Assessment, it is noted that:

> "*The RAC agreed with the Rapporteurs that all seven applications [including the application submitted by Vinyloop Ferrara SpA, Plastic Planet SRL, Stena Recycling AB] for authorisation are in conformity. The teams of Rapporteurs also reported on some issues which could be relevant to the evaluation of the applications. They will formulate their questions to the applicants for further clarification*."[46]

71. The RAC therefore simultaneously deemed the Application for Authorisation to be in conformity with the requirements in Article 62(4) and sought to request further substantive information.

72. Moreover, the failure to follow the procedure laid out in Article 64(3) means that the substantive information that was subsequently provided by the Authorisation Applicants was outside the formal process and cannot be deemed to form part of the Application for Authorisation. Therefore, the Contested Decision is based on irrelevant information and is vitiated by a manifest error in assessment.

[46] Minutes of 27th Meeting of the Committee for Risk Assessment (RAC/M/27/2013), 2 – 5 December 2013, p.18 -19, available at: <https://echa.europa.eu/documents/10162/13579/rac_meeting_27_minutes_final_en.pdf>.

73. According to Article 60(7), the Commission has the final decision as to whether an application has been made in conformity: "*An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62*". It flows from this provision that where an application is not brought into conformity the Commission is required to reject the application. The word "only" leaves no room for interpretation: this condition is absolute.

74. In light of the above, by granting an authorisation for an application that was never formally made in conformity with the requirements of Article 62, the Commission violated Article 60(7) of the REACH Regulation. The Contested Decision is therefore vitiated by a manifest error of assessment. On the basis of this ground, the Commission is requested to review the Contested Decision.

B.1.2. Breach of Article 60(2) (the Adequate Control route)

a) Violation of Article 60(2) and Article 60(4)

75. The REACH regulatory framework foresees two routes to the authorisation of a SVHC. Article 60(2) establishes the "**Adequate Control route**", whereby the use of a substance may be authorised if the risks to human health and the environment are adequately controlled. Article 60(4) lays out the "socio-economic route" ("**SEA route**") according to which a SVHC may be authorised where: 1) there are no suitable alternative substances and technologies which are economically and technically viable and; 2) the socio-economic benefits outweigh the risks.

76. The Contested Decision was adopted in breach of Article 60(2) and 60(4) as it granted an authorisation under Article 60(4) while the Authorisation Applicant submitted the Application under Article 60(2).

77. 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 via the SEA route.

78. As stipulated in Article 60(1) of the REACH Regulation, the Commission is required to adhere to the provisions in Title VII when deciding to grant an authorisation. Therefore, the decision making process must be in line with the language, structure and intention of Title VII, Chapter 2, especially Article 60(2) and Article 60(4), which lay out the respective procedures for taking a decision on an application made via the Adequate Control route or the SEA route.

79. According to Article 60(2) and 60(4) REACH Regulation, the Adequate Control route and SEA route are two distinct means to authorise a SVHC. This is evident by the different intention and focus of the two routes - adequate control is concerned with the risks of a particular substance, whereas the SEA route is based on an assessment of the benefits to society. Moreover, whereas an authorisation can be granted even when a suitable

alternative exists under Adequate Control route, it can never be granted if a suitable alternative exists under the SEA route.[47]

80. Treating an application for authorisation submitted under the Adequate Control route the same as an application under the SEA route cannot be objectively justified, as the two routes have different purposes and require different evidence. Not treating differently applications submitted under the different routes for approval therefore breaches the principle of equal treatment.[48]

81. Hence, by granting the authorisation via Article 60(4), when the Application for Authorisation was submitted via Article 60(2) the Contested Decision was in breach of both provisions and the general principle of equal treatment. On the basis of this manifest error of assessment, the Commission is requested to review the Contested Decision.

b) Manifest error of assessment of the conditions for authorisation under Article 60(2)

82. First, it is questionable whether the authorisation via the Adequate Control route was open to the Applicants at all. As stipulated in Article 60(3)(a) of the REACH Regulation (read in conjunction with Article 57), an authorisation cannot be granted via the Adequate Control route if it relates to substances (that meet the criteria for classification in the hazard class "carcinogenicity", "germ cell mutagenicity", "reproductive toxicity", or which give rise to "an equivalent level of concern" within the meaning of Article 57(f)) for which it is not possible to determine a "threshold" (or for which a "**DNEL**" cannot be determined) in accordance with Section 6.4 of Annex I. The RAC concluded that "*it is possible to determine a DNEL for the reproductive toxicity properties [of DEHP]*"[49] and on that basis, the Commission did not question whether the Adequate Control route was even applicable.

83. However, the RAC justification for DEHP being a threshold substance is not convincing. The RAC opinion states that "*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*."

84. The fact that the assessment is limited to the reproductive toxicity of DEHP does not mean that the Applicants' obligation to prove that DEHP is a threshold substance is waived. Nowhere in the REACH Regulation, it is stated that substances classified with reproductive toxicity must be considered automatically as being "threshold" substances. The RAC should have taken into consideration the scientific evidence submitted in order to

[47] See Article 60(2) and Article 60(4) REACH Regulation.
[48] Case C-154/04 *Alliance for Natural Health* [2005] ECR I-6461, para. 115: "*comparable situations must not be treated differently and that different situations must not be treated in the same way unless the treatment is objectively justified."*
[49] Compiled RAC and SEAC Opinions, p. 4; Annex 2.

determine whether DEHP could be considered as a threshold substance. However, the scientific evidence provided in the Application for Authorisation does not substantiate the finding that DEHP is a threshold substance.[50] As a result, the Commission should have questioned the RAC's reasoning and its conclusion that DEHP can be considered as a threshold substance.

85. In light of this, the Commission should have drawn the conclusion that the Adequate Control route was not applicable and then should have altogether rejected the Application for Authorisation. By failing to do so, the Commission violated Article 60(3)(a) of the REACH Regulation. The Contested Decision is therefore vitiated by this manifest error of assessment.

86. Second, the Authorisation Applicants failed to provide the required information under Article 60(2), i.e. under the Adequate Control route, in violation of Section 6.4 of Annex 1. In line with the so-called principle of industry responsibility as the basis of the REACH Regulation,[51] the applicant bears the burden of proof to establish the requirements for authorisation under the Adequate Control route. This is underscored by the language used in Article 60(2) of Title VII – for example phrase: "*as documented in the applicant's chemical safety report*" (Article 60(2)).

87. The elements and documentation that the Commission must take into account in assessing whether an application has provided sufficient information is clearly laid out in Article 60(2): an authorisation will be granted only "*if the risk to human health and the environment […] is adequately controlled […] as documented in the applicant's chemical safety report"* (emphasis added).[52] According to the language used, an authorisation cannot be granted if the Commission is not persuaded that the all requirements for granting authorisation have been fulfilled.

88. However, in the present case, the RAC found that the limited exposure data submitted by the Authorisation Applicants failed to demonstrate adequate control of risks for workers.[53] If an application is submitted via Article 60(2) and it fails to demonstrate that the risks are adequately controlled – it must be rejected (and the application cannot be considered for authorisation via the SEA route as explained above). Accordingly, the Commission was required, in line with Article 60(2) to reject the Application for Authorisation via the Adequate Control route.[54]

89. Hence, the Contested Decision was adopted in breach of Article 60(2) of the REACH Regulation. On the basis of these manifest errors of assessment, it is requested that the Contested Decision be reviewed.

[50] Compiled RAC and SEAC Opinions, p. 7; Annex 2.
[51] Article 1(3) of the REACH Regulation.
[52] Article 60(2) REACH Regulation emphasis added.
[53] Compiled RAC and SEAC Opinions, p.3; Annex 2.
[54] Contested Decision, Preamble, §5.

B.1.3. Breach of Article 60(4) (the SEA route)

90. In violation of Article 60(4), the authorisation was granted despite:

- The Application for Authorisation failing to prove that benefits for society outweigh the risks (Article 60(4)(b)), and that no substitutes exist for the use for which DEHP is requested (Article 60(4)(c));
- The Commission's failure to take into account relevant information omitted from the Application for Authorisation.

a) Insufficiencies of the Application for Authorisation under Article 60(4)

91. In line with the so-called principle of industry responsibility as the basis of the REACH Regulation,[55] the applicant for authorisation bears the burden of proof to show that the requirements for authorisation under the SEA route are fulfilled. This is underscored by the language used in Article 60(4) of Title VII – for example phrases: "if it is shown" (Article 60(4)) and "as demonstrated" (Article 60(4)(b)).

92. Where an application is submitted via the SEA route, the authorisation can "only" be granted if two conditions are met at the same time: 1) benefits for society outweigh the risks (Article 60(4)(b)), and 2) no substitutes exists for the use for which DEHP is requested (Article 60(4)(c)). According to the language used, the authorisation cannot be granted if the application does not show that these requirements have been fulfilled. The Contested Decision is vitiated by manifest errors of assessment of these two conditions.

i) The Application failed to demonstrate that the benefits outweigh the risks

93. The Contested Decision was made in breach of Article 60(4)(b) as the applicants failed to demonstrate that the benefits of the continued use of DEHP outweigh the risks.

94. First, in the context of authorisation via the SEA route, the applicant must prove that a substance has a defined function that brings a benefit to society. Accordingly, as stipulated in Article 60(4)(b) of the REACH Regulation, the SEA is focused on "use" of the substance. However, this exercise could not be effectively undertaken in the present case as, according to the Authorisation Applicants, DEHP has no function. As described in the non-confidential analysis of alternatives submitted by the applicants: *"[a]t the waste stage, the plasticisers are effectively impurities which do not display critical properties or meet quality criteria of relevance to the recycling process*".[56] Pointing to the potential use or benefits for customers, applicants continue: "*PVC compounders or converters using the recyclate do not place specific requirements on the presence of DEHP in the product*"[57] (see §64

[55] Article 1(3) REACH Regulation.
[56] Analysis of Alternatives – non-confidential report, p.4; Annex 8.
[57] Analysis of Alternatives – non-confidential report, p.5 (emphasis in the original) ; Annex 8.

above). Since the Authorisation Applicants claim that DEHP has no function, its presence cannot bring any benefits to society. As provided by Article 60(4)(b) of REACH, the burden to prove such benefits lies on the Authorisation Applicants.

95. Second, the SEA submitted by the Authorisation Applicants does not demonstrate that the benefits outweigh the risks since it is based on the assumption that there are "*no risks from continued use*"[58]. This is because the Application for Authorisation was submitted via the Adequate Control route (Article 60(2)). The discrepancies between the information required under the two routes for authorisation was highlighted by the RAC and SEAC in the final report, which stated:

> "*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*."[59] (emphasis added)

96. Third, the SEA was submitted within the context of an application for authorisation under Article 60(2) as opposed to 60(4). As explained in the Guidance on the preparation of socio-economic analysis as part of an application for authorisation prepared by ECHA, the SEA can have multiple purposes in an application for authorisation depending on the basis of the application. Under the SEA route "Purpose 1", the SEA must demonstrate that socio-economic benefits outweigh the risks. Under the Adequate Control route, "Purpose 2", the SEA may provide "*socio-economic information, which can be used by the Agency committees and the Commission in setting conditions for the authorisation or defining the review period*."[60]

97. As stated by the Applicants, the SEA was not submitted pursuant to "Purpose 2" and never sought to provide evidence for the granting of an authorisation via the SEA route: "*Although an SEA is not required in such situations [in an application for authorisation via Article 60(2)], the aim here has been to illustrate the impacts of a refused Authorisation on the companies forming the Soft PVC recyclate Authorisation Consortium (SPAC). The SEA is also intended to support arguments as to an appropriate review period for Authorisation*."[61] The SEA was therefore narrowly focused on the impact of not granting the authorisation.

98. As argued above, the Commission committed a manifest error of assessment in considering whether the authorisation could be granted via Article 64(4) – the SEA route. This is because the two routes serve distinct purposes, require separate documentation and demand the applicant prove different substantive elements. Therefore, the Application for Authorisation submitted via Article 60(2) did not satisfy the conditions necessary for an

[58] Compiled RAC and SEAC Opinions, p. 21; Annex 2.
[59] Compiled RAC and SEAC Final Opinion, p. 16; Annex 2.
[60] ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation, 2011, pp.5-6.
[61] Socio–economic assessment - non-confidential report, p.2; Annex 10.

authorisation under Article 60(4) – especially regarding the SEA submitted for the purpose of Article 60(4)(b) which must substantiate how the benefits outweigh the risks.

99. Overall, the Authorisation Applicants failed to demonstrate that the socio-economic benefits of the continued use of DEHP outweighed the risks within the meaning of Article 60(4), since 1) the substance does not a serve a function; 2) the Authorisation Applicants incorrectly claimed that there were no risks of using DEHP and 3) the SEA was narrowly focused on the impact of not granting the authorisation.

100. As a consequence, the Application for Authorisation failed to demonstrate that the benefits outweigh the risk as required under Article 60(4)(b) of the REACH Regulation. The Contested Decision is therefore vitiated by a manifest error of assessment and on that ground must be reviewed.

ii) The Application failed to demonstrate that DEHP could not be substituted

101. The Contested Decision was adopted in breach of Article 60(4)(c) of the REACH Regulation, which prohibits the authorisation of non-adequately controlled substances where the applicant fails to demonstrate no suitable alternatives exist.

102. First, as discussed in paragraphs 66, the analysis of alternatives did not examine alternative substances but focused on substituting the waste stream – which is not foreseen in the REACH regulatory framework.

103. The Authorisation Applicants submitted information about two alternative processes for the production of recyclate from post-consumer PVC waste containing DEHP and one alternative that describes the use of an alternative waste PVC feedstock to produce recyclate. This does not comply with the requirement to assess the feasibility of using an alternative substance to fulfil the function of DEHP. For this reason alone the Application for Authorisation did not comply with the information requirements.

104. As acknowledged in the non-confidential analysis of alternatives submitted, DEHP serves no function and "*is simply present in the processed waste*".[62] If the substance has no function, the analysis of alternatives is meaningless to satisfying the test of "no suitable alternative" in Article 60(4)(c). Examining the viability of eliminating DEHP from the recycling process is not relevant.[63]

105. The failure of the Authorisation Applicants to assess the suitability of different substances was highlighted by the RAC, which commented that: "*After discussing the alternatives, the RAC agreed that alternatives relate to different processing options of the same substance*

[62] Analysis of Alternatives – non-confidential report, p.4; Annex 8.
[63] Analysis of Alternatives – non-confidential report, p.5; Annex 8.

and the Committee was not able to assess whether the exposure and the risks could be reduced when using the alternatives."[64]

106. Second, the analysis submitted by the applicants failed to compare the risks of using DEHP with the risks of using any alternatives. This is because the analysis was based on the false assumption that the risks of using DEHP were adequately controlled. Therefore, the Authorisation Applicants were able to assert that all three alternatives identified presented "*no discernible benefit to workers' health*".[65] However, this assessment was unsubstantiated as the RAC later concluded that the Application had failed to demonstrate that risk to workers was adequately controlled.

107. In light of this, the Application for Authorisation did not comply with Article 62(4)(e) of the REACH Regulation which requires an application to include an assessment of the risks in using an alternative and the technical and economic feasibility of "substitution". The Contested Decision was therefore taken in breach of Article 60(4)(c) of the REACH Regulation and is vitiated by manifest errors of assessment. On the basis of this ground, the Contested Decision must be reviewed.

b) Failure to take into account relevant information omitted from the Application for Authorisation

108. Beyond the deficiencies of the Application for Authorisation that the Contested Decision ignored, it also failed to take into account relevant information, omitted from the Application, relating to 1) the risks covered and 2) the consequences of not granting the authorisation.

i) Failure to take into account the risks posed by other endpoints

109. DEHP is currently included in Annex XIV as being toxic for reproduction in application of Article 57(c) of the REACH Regulation. This constitutes its "intrinsic property" within the meaning of Annex XIV. However, as highlighted by the European Parliament in the non-legislative resolution concerning the authorisation of DEHP,[66] DEHP is also recognised as a substance having endocrine disrupting properties.

110. Under the SEA route, the risk assessment should cover all hazardous properties of a substance. This flows from ECHA's guidance which specifies, concerning the analysis of alternatives, that: "*The alternatives should result in reduced overall risks to human health and the environment. Therefore, it is important not only to consider the risks arising from the Annex XIV endpoint but also on all other possible risks from the Annex XIV substance*

[64] Minutes of 29th Meeting of the Committee for Risk Assessment (RAC/M/29/2014), 2 – 6 June 2016, p.19, available at: < http://echa.europa.eu/documents/10162/13579/rac_29_minutes_en.pdf>.
[65] Analysis of Alternatives – non-confidential report, p. 1; Annex 8.
[66] European Parliament Resolution dated 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) (P8_TA(2015)0409).

and the alternatives."[67] (emphasis added). For the sake of consistency, the endpoints to be taken into account for the purpose of the SEA under Article 60(4) cannot differ from those assessed in the context of the analysis of alternatives. Indeed, there is no legitimate reason to only cover the risks arising from a single endpoint when conducting the socio-economic assessment while taking into account all endpoints to assess alternatives.

111. This interpretation is also supported by the wording and structure of Title VII Chapter 2 of the REACH Regulation. According to Article 60(2), under the Adequate Control route, an authorisation will be granted if the "*use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled*" (emphasis added). By contrast, Article 60(4), setting out the conditions for an authorization under the SEA route, refers more generally to the "*risk […] arising from the use of the substance*" without further precision. It flows from this that, under the SEA route, the authorisation applicant, third parties, the SEAC and the Commission, are required to consider all the hazardous properties of a substance beyond the risk arising from its "*intrinsic properties specified in Annex XIV*". This is further supported by the construction of Article 62(5)(a) and Annex XVI to the REACH Regulation, which does not specify that the SEA is restricted to an examination of the risks arising from the intrinsic properties of a substance.

112. The issue is that the Application for Authorisation and the SEAC limited the SEA to the risks arising from DEHP's "intrinsic property", i.e. toxic for reproduction, without considering the other "end points" such as its endocrine disrupting properties.

113. As a consequence, the Commission failed to take into account relevant information as required in Article 60(4) of the REACH Regulation. The Contested Decision is vitiated by a manifest error of assessment.

ii) Omitted consequences of not granting the authorisation

114. In reaching its decision on the socio-economic costs and benefits, the Commission is not required to focus strictly on the costs or benefits to the applicant. This is made clear in Article 60(4)(b) of the REACH Regulation, which stipulates that the Commission must also consider information submitted by interested parties. Moreover, whereas the REACH Regulation states that the Commission's assessment of suitable alternatives must include the technical and economic feasibility of alternatives "for the applicant"[68] – there is no such condition when assessing socio-economic factors.

115. This interpretation is supported by the guidelines in Annex XVI to the REACH Regulation, which extend to the analysis of the socio-economic impact of an Application for Authorisation being granted or refused to a range of stakeholders. Therefore, despite Annex XVI, first indent, being focused on the impact on "the applicant(s)", the following provisions in Annex XVI address the impact on multiple actors – including other businesses and consumers. Though the elements listed in Annex XVI are not mandatory

[67] ECHA Guidance on application for authorisation available at: <http://echa.europa.eu/support/qas-support/browse/-/ga/70Qx/view/scope/reach/authorisation>.
[68] Article 60(5)(b).

and the Annex is addressed to an applicant, the Annex to the REACH Regulation remains the only guide to the substantive requirements of a SEA in the legal text.

116. However, contrary to the guidance, Article 60(4)(b) and Annex XVI to the REACH Regulation, the Contested Decision does not take into account all the socio-economic consequences of not granting the authorisation – to the applicant or other stakeholders.

117. Had the authorisation not been granted, the Authorisation Applicants would still have been able to sell the recycled soft PVC as waste. In accordance with Article 2(2), REACH registration requirements, evaluation, authorisation and restrictions do not apply to waste. As DEHP is classified as toxic for reproduction under Article 57(c) of the REACH Regulation, it therefore falls under the definition of "hazardous waste" under the Annex III to the Waste Framework Directive 2008/98/EC.[69] However, classification as "hazardous waste" for the purposes of the Waste Framework Directive 2008/98/EC does not mean that a substance is banned. Instead a stricter control regime would apply.

118. Therefore, the Contested Decision ignored the possibility for the Authorisation Applicants to sell their product under the legal framework of the Waste Directive and relied solely on the opinion from SEAC that not granting the authorisation would mean that the Authorisation Applicants would no longer be able to use DEHP and incur significant costs.[70] By omitting these elements of fact, the Contested Decision is vitiated by a manifest error of assessment and as such must be reviewed.

B.1.4. Violation of an essential procedural requirement: absence of third party consultation

119. As described above, the Contested Decision failed to take into account key information relevant to the SEA, e.g. the fact that, in absence of authorisation, the Authorisation Applicants would have been able to sell their products as waste. These elements pointing towards a negative SEA and potentially other socio-economic elements not covered by the Application for Authorisation, would have arguably affected the outcome of the Contested Decision should they have been brought to the attention of the Commission.

120. However, neither ECHA nor the Commission have an open channel to receive this socio-economic information. There is no official public consultation in place to invite third parties to provide socio-economic input. As a result the Commission and the SEAC were not in a position to consider relevant information from third parties.

121. The SEAC has a duty to take into account information submitted by third parties relating to the SEA. This is made clear in Recital 81: "*In order to provide a harmonised approach to the authorisation of the uses of particular substances, the Agency should issue opinions*

[69] Annex III of the REACH Regulation, replaced by Commission Regulation (EU) No 1357/2014.
[70] Contested Decision, §9.

on the risks arising from those uses, including whether or not the substance is adequately controlled and on any socio-economic analysis submitted to it by third parties. These opinions should be taken into account by the Commission when considering whether or not to grant an authorisation."

122. According to Article 64(3), the RAC and SEAC are required to "*take into account any information submitted by third parties*" when preparing their opinion. Therefore, according to the REACH Regulation, in addition to the elements listed in an application for authorisation, the SEAC is required to also assess information on socio-economic factors submitted by third parties.

123. Similarly, Article 60(4)(b) provides that the Commission must take into account "*the socio-economic benefits [...] as demonstrated by the applicant or other interested parties*" (emphasis added).

124. The absence of procedure in place to invite third parties to provide information relevant to the SEA raises a serious legal issue as it renders the obligation of the Commission and the committees to take into account this information meaningless.

125. According to settled case-law, failure to comply with a procedural rule "*can render the final decision of the institution concerned unlawful only if it is sufficiently substantial and has a detrimental effect on the legal and factual situation of the party alleging a procedural irregularity*".[71]

126. The fact that third parties are not consulted on the SEA in the context of authorisation procedures, prevents the Commission or the SEAC from taking into account any socio-economic input coming from third parties. This inherently prevents the Commission "*[from delivering] its opinion in full knowledge of the facts, that is to say, without being misled in a material respect by inaccuracies or omissions*"[72] As described above (§§56-60), the Application for Authorisation in the present case was incomplete and deficient. The fact that third parties could not provide their views on the socio-economic impact to remedy these gaps or bias, calls into question the "*effet utile*" of the entire authorisation process under the REACH Regulation.

127. In light of this, the absence of consultation process to invite third parties to provide socio-economic input violates an essential procedural requirement of the REACH Regulation. On that ground, it is requested that the Contested Decision be reviewed.

[71] Case T-443/11, para. 98.
[72] Case T-443/11, para. 99.

B.1.5. Breach of Article 60(5) (Availability of Alternatives)

128. The Contested Decision violates Article 60(5)(b) and Article 77 of the REACH Regulation. This is because the Commission 1) adopted an approach that was contrary to the REACH Regulation and ECHA Guidance in relation to economic feasibility 2) based its assessment on information that was not reliable and 3) ignored information revealing the existence of suitable alternatives submitted by third parties.

a) Failure to take into account guidance on economic feasibility

129. In accordance with the REACH Regulation, economic feasibility entails an assessment of whether the applicant can switch to alternatives. The language in Article 60(5)(b) is clear: "*the technical and economic feasibility for the applicant*". In other parts of the REACH regulation, the term feasible is replaced with "viable".[73] The wording of Article 62(4) read together with Recital 72 of the REACH Regulation, lays out the obligation on authorisation applicants to analyse the "*suitability of alternatives with regards to their economic feasibility*". As per Article 62(4)(e) of the REACH Regulation, an applicant is required to submit an "*analysis of the alternatives considering their risk and the technical and economic feasibility of substitution*". Furthermore, Article 62(4)(f) foresees that where the analysis "*shows that suitable alternatives are available*", a substitution plan should also be included in the application.

130. In light of these provisions, to use higher net costs as the standard to assess economic feasibility would mean that these provisions have no meaning, as no businesses would need to request an authorisation if that the alternative was cheaper than the substance which is the subject matter of the application for authorisation. In particular, it would be incompatible with the obligation on the applicant to provide a substation plan if the standard of higher net costs was chosen.

131. In the ECHA Guidance on the preparation of an application for authorisation, the Agency identifies that "[*o]ne criterion for an alternative to be economically feasible is whether the net present value of the revenues minus costs is positive. In other words, the issue is that using the alternative should result in generating gross profit*".[74] The Guidance recommends for the applicant to prepare a cost-benefit analysis to quantify the direct and indirect economic costs and benefits of continuing to use the Annex XIV substance. Hence, economic feasibility is focused on the "changes" to costs and revenues, as opposed simply an increase in net costs incurred by substitution.[75]

132. However, the Contested Decision did not properly take into account the economic feasibility of the alternatives in that sense, or justify the deviation from the Guidance document on socio-economic analysis in relation to economic feasibility.

[73] See Article 55 and Recital 12 and Recital 22.
[74] ECHA, "Guidance on the preparation of an application for authorisation", 2011, ECHA-11-G-01-EN, p. 75
5 Ibid., p. 1.
[75] ECHA, "Guidance on the preparation of an application for authorisation", 2011, ECHA-11-G-01-EN, p. 74.

133. In fact, the SEAC substituted the test of "economic feasibility" by concluding that the third (more expensive) alternative to DEHP was "economically unfavourable".[76] The reference to (un)favourability indicates that a "higher net costs" approach was used as the standard to assess economic feasibility. This standard of "favourability" is not mentioned anywhere in the legal text of the REACH Regulation, and is obviously more lenient for applicants than the "feasibility" standard provided in the Regulation and described in the Guidance.

b) Assessment of Alternatives based on unreliable information

134. Moreover, the Commission based its decision on information provided in the Application for Authorisation which was not reliable.

135. In the Opinion, the SEAC states:

> *"[t]he 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*."[77]

136. The data on which the Authorisation Applicants relied should have been independently scrutinised, however, it is clear that the SEAC and the Commission could not and did not test the reliability and credibility of the information in the Analysis of Alternatives submitted by the Authorisation Applicants.

137. The Commission did not independently assess whether the Authorisation Applicants had discharged their obligation to prove that alternatives were not feasible. Instead, the Contested Decision relied on the opinion of the SEAC to reach its conclusion that no economically feasible alternatives to DEHP existed.[78] In addition, the Opinion applied the wrong standard to assess feasibility and the information relied upon was not credible, and as a consequence the Contested Decision was taken in breach of Article 60(5)(b).

c) Failure to take into account information submitted by third parties

138. The Commission failed to take into account third party contributions submitted under Article 64(2), in violation of Article 60(4)(c).

139. Indeed, during the public consultation required under Article 64(2) of the REACH Regulation, the Director of the Chemicals Policy and Science Initiative of the Lowell Center for Sustainable Production at the University of Massachusetts Lowell submitted information on suitable alternatives. Research conducted by the Center and the Massachusetts Toxics Use Reduction Institute, documented that safer, cost-effective and

[76] Compiled RAC and SEAC opinions, p.12; Annex 2.
[77] Compiled RAC and SEAC opinion, p.12; Annex 2.
[78] Contested Decision, §§6-7.

functional alternatives to DEHP as a plasticizer in PVC applications are available for most applications.[79] According to these documented responses to the public participation, “suitable alternatives” to DEHP are in fact available.

140. The Contested Decision was therefore adopted in breach of Article 60(4) of the REACH Regulation, which prohibits the authorisation of non-adequately controlled substances where an alternative exists.

B.2. Breach of the Treaty and general principles of EU law

B.2.1. Failure to State Reason

141. The Contested Decision failed to provide a clear statement of the reasoning leading to the authorisation in breach of the duty to state reasons.

142. The duty to give reasons for decisions arises from Article 296(2) TFEU and is recognised as a right under Article 41(2)(c) of the Charter of Fundamental Rights of the European Union as well as being an essential component of the right to an effective remedy recognised in Article 47 of the Charter of Fundamental Rights of the European Union. According to settled case law, "*the duty to state [...] is an essential procedural requirement.*"[80]

143. Furthermore, "*the obligation to state reasons laid down in Article [296 TFEU] requires that the reasons on which a decision is based be clear and unequivocal. Thus, the reasoning on which a measure is based must be logical and contain no internal inconsistency that would prevent a proper understanding of the reasons underlying the measure*."[81]

144. Contrary to this obligation, the Contested Decision merely summarises the conclusions of the opinion of SEAC[82] without setting out the legal reasoning that led to the authorisation. In addition, the Contested Decision contains internal inconsistencies. For example, it is difficult to comprehend how the Commission could conclude at paragraph 7 that "it is therefore appropriate to authorise these two uses based on Article 60(4)" while acknowledging at paragraph 9 that "*the SEAC recognised the deficiencies in the workplace exposure assessment identified by the RAC and the lack of a health impact assessment in the socio-economic analysis*."

[79] See Report from Lowell Center for Sustainable Production at the University of Massachusetts Lowell from 2011, "Phthalates and Their Alternatives:Health and Environmental Concerns" (Annex 11); See Report from the Green Chemistry and Commerce Council from 2013, "Chemical Hazard Assessments of Alternative Plasticizers for Wire & Cable Applications" (Annex 12).
[80] Case C-535/14 P, para. 37.
[81] Case T-406/09, para. 28.
[82] Contested Decision, §7.

145. Therefore, in addition to the numerous manifest errors of assessment described previously (See Section B.1), the Commission has violated its obligation to state reasons under Article 296 TFEU. On that ground, it is requested that the Contested Decision be reviewed.

B.2.2. Violation of the Precautionary Principle

146. The Contested Decision was adopted in breach of the precautionary principle. The precautionary principle is recognized under Article 191 of TFEU and underpins the REACH Regulation.[83] The precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty.[84]

147. The substance DEHP is recognized as being toxic for reproduction and is classified as an SVHC on this basis. In addition, DEHP also has endocrine disrupting properties. Indeed, as stated by the European Parliament in its Resolution dated 25 November 2015: "*the Member State Committee ("MSC") unanimously agreed to the identification of DEHP as a substance giving rise to an equivalent level of concern due to its endocrine disrupting properties in the environment; […] the MSC unanimously acknowledged that, in the case of DEHP, there is scientific evidence on endocrine disrupting activity and on the causal link between this activity and adverse effects on human health*".[85]

148. Furthermore, the Parliament reminded the Commission that: "*scientific evidence on DEHP shows that exposure during sensitive time windows of development may cause irreversible developmental programming effects leading to severe effects on development and reproduction, regarded as particularly serious in relation to human health and wildlife species, also because these adverse effects may first manifest themselves in later life stages as a consequence of exposure during early life stages*." [86]

149. To date, despite this scientific evidence, due to a lack of a consensus, the EU legal framework does not provide for specific scientific criteria to identify endocrine disruptors that may cause adverse harm to human health and the environment yet.

150. In light of this uncertainty, and taking due account of the fact that, on the basis of scientific and objective evaluation endocrine disruptors such as DEHP may have dangerous effects, the precautionary principle should be invoked to ensure that the use of DEHP is restricted in order to prevent the potential damage to human health and the environment.

[83] Article 1(3).
[84] Communication from the Commission of 2 February 2000 on the precautionary principle (COM(2000)1 final)
[85] European Parliament Resolution dated 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) (P8_TA(2015)0409).
[86] European Parliament Resolution dated 25 November 2015, Ibid.

151. In a similar case relating to the approval of active substances in pesticides in application of Regulation No 1107/2009[87], a complaint was filed to the Ombudsman on the ground that in certain cases, the Commission approved active substances for pesticides despite the fact that the legal requirements were not met, in particular despite insufficient data allowing it to exclude risks for human health, animal health, groundwater and the environment. In that case, the Ombudsman "*considered that the Commission, which has the duty to ensure that the active substances it approves are not harmful for human health, animal health, or the environment, may be too lenient in its practices and might not be taking sufficient account of the precautionary principle*".[88]

152. There is a clear parallel with the Contested Decision: by granting the authorisation despite the fact that the Application for Authorisation was not in conformity, and did not satisfy the legal requirements under the REACH Regulation, the Commission has been too lenient and did not take sufficient account of the precautionary principle.

153. On that ground, it is requested that the Contested Decision be reviewed.

B.2.3.Misuse of power

154. In the context of its Circular Economy Package, the Commission acknowledged that "*the presence of hazardous chemical additives can pose technical difficulties*" and announced that it "*will prepare a strategy addressing the challenges posed by plastics throughout the value chain and taking into account their entire life-cycle*".[89] While this initiative should be encouraged, adopting such a commitment in this Action Plan does not entitle the Commission, in the meantime, to misuse the REACH authorisation process for the purpose of implementing policy objectives and key priorities that it defined on its own.

155. According to settled case-law: "*an act is vitiated by misuse of powers only if it appears, on the basis of objective, relevant and consistent evidence, to have been taken with the exclusive or main purpose of achieving an end other than that stated or evading a procedure specifically prescribed by the Treaty for dealing with the circumstances of the case*".[90] The Contested Decision is, in application of this case-law, vitiated by misuse of power for the following reasons.

[87] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009 L 309 p. 1.
[88] European Ombudsman, Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides) available at: <http://www.ombudsman.europa.eu/en/cases/decision.faces/en/64069/html.bookmark>.
[89] See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 2 December 2015, "Closing the loop - An EU action plan for the Circular Economy" (COM(2015) 614 final).
[90] Case C-342/03 *Spain* v *Council*, paragraph 64 and the case-law cited.

156. First, the content of the Contested Decision and of the SEAC report strongly suggests that the authorisation was granted with the main purpose of encouraging the economic activity of recycling.

157. Indeed, as pointed out by the European Parliament in its Resolution regarding the Contested Decision "*one of the arguments given by the SEAC in favour of granting authorisation is that 'there is a political and societal incentive to promote recycling as a sustainable way to handle natural resources'*".[91] These arguments set out in the SEAC report are also summarized quite clearly in the Contested Decision itself: "*SEAC considered the significant economic costs for the applicants and their downstream users of no longer being able to use the substance resulting from PVC waste recycling, the probable loss of jobs and the external costs for society associated with the environmental and human health damage due to increased landfilling and incineration, reduced recycling rates in case of no authorisation*"[92]. This statement reveals how much weight was given to the benefits of recycling in the overall assessment.

158. These considerations, focusing on the benefits of recycling in general, have undoubtedly played a decisive role in the outcome of this case. The Contested Decision and the SEAC report do not list any other "benefit" to society that may have outweighed the risks to human health. Therefore, it seems clear that without this policy objective, the sole existence of known "*deficiencies in the workplace exposure assessment identified by the RAC and the lack of a health impact assessment in the socio-economic analysis*,"[93] would have led to the inevitable rejection of the Application for Authorisation.

159. Second, the stated purpose of the Contested Decision was to implement the authorisation process under the REACH Regulation. The stated purpose of the REACH Regulation is to "*ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation*."[94] This does not include the promotion of recycled materials containing hazardous substances.

160. As explained previously, the Commission granted the authorisation despite the fact that the Application for Authorisation:

    (i) was not in conformity with the requirements of Article 62 of the REACH Regulation;

    (ii) did not prove that the risk to humans and the environment is adequately controlled under Article 60(2); and,

[91] 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)), P8_TA(2015)0409, Recital X.
[92] Contested Decision, §9.
[93] Contested Decision, §9, *in fine.*
[94] Article 1 of the REACH Regulation.

(iii) did not prove that benefits for society outweigh the risks and no substitutes exist for the use for which DEHP is requested under Article 60(4).

161. By making the promotion of recycling the decisive factor leading to the authorisation, despite the Application for Authorisation obviously not fulfilling the conditions under Article 60, the Commission misused its power of implementation granted under the REACH Regulation to achieve an aim different from the one stated in the legislation.

162. In light of this, there is "*objective, relevant and consistent evidence*" that the Commission excused, without the authority to do so, the deficiencies of the Application for Authorisation in order to implement its own policy objectives regarding recycling. The Commission hence misused its power of implementation conferred under Article 291(2) TFEU. On that ground, it is requested that the Contested Decision be reviewed.

Brussels, 2 August 2016

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SCHEDULE OF ANNEXES

No. of Annexes	Description
1.	The Contested Decision : Commission Implementing Decision C(2016)3549 of 16 June 2016 granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) under the REACH Regulation
2.	The compiled RAC and SEAC Opinions 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, dated 22 October 2014
3.	Articles of Association of ClientEarth
4.	ClientEarth's Annual Report for 2015
5.	ClientEarth's Annual Report for 2014
6.	Proof of registration from the Regulator for Charities in the United Kingdom
7.	Commission Decision C(2009)3337) from 27 April 2009 acknowledging ClientEarth as being entitled to make a request for internal review
8.	Non-confidential version of the Analysis of Alternatives submitted by the Authorisation Applicants
9.	Comments and Response to Comments on authorisation (CAS number: 117-81-7; Consultation number: 0008-01) relating to the consultation period between 13/11/2013 and 08/01/2014
10.	Non-confidential Summary of the SEA submitted by the Authorisation Applicants
11.	Report from Lowell Center for Sustainable Production at the University of Massachusetts Lowell from 2011, "Phthalates and Their Alternatives:Health and Environmental Concerns"
12.	Report from the Green Chemistry and Commerce Council from 2013, "Chemical Hazard Assessments of Alternative Plasticizers for Wire & Cable Applications"

ClientEarth is a non-profit environmental law organisation based in London, Brussels and Warsaw. We are activist lawyers working at the interface of law, science and policy. Using the power of the law, we develop legal strategies and tools to address major environmental issues.

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