REQUEST FOR INTERNAL REVIEW
UNDER TITLE IV OF THE AARHUS REGULATION

OF COMMISSION IMPLEMENTING DECISION C(2016) 5644
granting an authorisation for six uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red

SUBMITTED BY

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TO

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According to Article 11 of Regulation 1367/2006[1] and Commission Decision 2008/50/EC of 13 December 2007.[2]

[1] 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**").

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[2]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).

INTRODUCTION

1. On 7 September 2016, the European Commission (the "**Commission**") adopted Implementing Decision C(2016)5644 final[3], granting DCC Maastricht BV the authorisation to use *lead sulfochromate yellow* ("**Yellow Lead Chromate**") and *lead chromate molybdate sulphate red* ("**Red Lead Chromate**") (the "**Contested Decision**").

2. Yellow Lead Chromate and Red Lead Chromate were identified in 2010 as substances of very high concern ("**SVHC**") pursuant to Article 57(a) and Article 57(c) of Regulation No 1907/2006[4] (the "**REACH Regulation**") due to their carcinogenicity and reproductive toxicity. Both were then included in the list of substances set out in Annex XIV of the REACH Regulation that can only be used subject to prior authorisation. Yellow Lead Chromate and Red Lead Chromate could thus not be used without the Commission's authorisation after 21 May 2015 (the "**Sunset Date**").

3. DCC Maastricht BV OR (the "**Authorisation Applicant**"), on 19 November 2013, submitted applications for authorisation (the "**Applications for Authorisation**") covering six uses of Yellow Lead Chromate and Red Lead Chromate. These six uses applied for are the same for each substance, and are listed in the table below:

Reference in the Request	Description as presented in the Applications for Authorisation
Use 1	"Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use"
Use 2	"Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)
Use 3	"Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking"
Use 4	"Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use"
Use 5	"Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use"
Use 6	"Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking"

[3] Commission Implementing Decision of 7 September 2016, granting an authorisation for some uses of lead sulfochromate yellow and lead chromate molybdate sulphate red under the REACH Regulation (C(2016) 5644 final), published in the Official Journal of the European Union on 14 September 2009 (OJ C 337 14.09.2016 p. 3-5).
[4] 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).

4. 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 Contested Decision granted the Authorisation Application the authorisation to use Yellow[5] and Red[6] Lead Chromates for all six uses, subject to certain conditions.[7] The authorisation was granted for seven years for all uses, except Uses 3 and 6 for which the review period was reduced to four years.[8]

5. ClientEarth, the European Environmental Bureau ("**EEB**"), the International Chemical Secretariat ("**ChemSec**") and the International POPs Elimination Network ("**IPEN**") request the internal review of the Contested Decision in accordance with Article 11 of the Aarhus Regulation, on the following grounds.

6. First, the Applications for Authorisation failed to provide necessary information on the "*technically required performance characteristics*"[9] of the substances, their function, and raised "*uncertainties*"[10] regarding the alleged lack of technically feasible alternatives. The Applications for Authorisation were thus not in "conformity" in the sense of Article 64(3) of the REACH Regulation. By granting the authorisation, the Contested Decision was therefore taken in breach of Article 60(7) that clearly provides that an authorisation shall be granted only if the application is made in conformity with the requirements of Article 62. Making the authorisation conditional upon further information being provided on "*the status of the suitability and availability of alternatives*" and on "*the description of the authorised uses*"[11] by the end of 2017, is also contrary to Article 60(7). It amounts to giving a blindfolded authorisation. Shortening the review period to remedy a lack of conformity is also in clear contradiction with Article 60(7).

7. Second, the Contested Decision is vitiated by a manifest error of assessment of the risks to human health and the environment: the risks assessed excludes the risk to the aquatic environment, the exposure scenario do no cover the degradation of the Lead Chromate paints or coatings over time once applied, and the "*assessment of the risk of indirect exposure of man through the environment is not performed*".[12]

8. Third, the Contested Decision is vitiated by a manifest error of assessment of the analysis of alternatives in breach of Article 60(5) and Article 60(4):

   (i) The analysis of alternatives provided by the Authorisation Applicant is meaningless as it fails to define the functions that the substances are supposed to achieve, nor the minimum requirements to achieve these functions. The analysis provided thus amounts to solely determining the differences between the Lead

[5] Contested Decision, Article 1(1).
[6] Contested Decision, Article 1(2).
[7] Contested Decision, Article 1(3).
[8] Contested Decision, Article 2.
[9] Contested Decision, §12.
[10] Contested Decision, §9.
[11] Contested Decision, §12.
[12] RAC and SEAC Opinion, Use 3, p. 10.

Chromates and potential alternatives, without explaining why these differences disqualify the alternatives as technically feasible;

(ii) The Contested Decision is vitiated by a confusion between the notion of substitution under merger control rules and the notion of technical feasibility under the REACH Regulation;

(iii) The notion of economically feasible alternative is interpreted in a way that makes the authorisation process meaningless;

(iv) The Contested Decision failed to take into account relevant contributions to the public consultation, that reveal unequivocally that technically and economically feasible alternatives do exist and are currently used. It also failed to critically assess some contributions to the consultation that, contrary to the Authorisation Applicant's assertions, do not demonstrate that there is a lack of suitable alternatives;

(v) The Contested Decision failed to draw the appropriate conclusions from the Authorisation Applicant's claim regarding national legislation on road markings.

9. Fourth, the Contested Decision is vitiated by a failure to state reason within the meaning of Article 296 TFEU: it fails to explain how the Authorisation Applicant has shown that no technically and economically feasible alternative exist and how the public consultation confirms this conclusion. In addition, the Contested Decision draws conclusions on the uncertainties on the risks and the socio-economic factors that is against the precautionary principle which underpins the Authorisation process.

10. Fifth, the Contested Decision erred in concluding that granting authorisation to use lead in paints is compatible with fulfilling the EU commitment under the Strategic Approach to International Chemical Management.

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

A. ADMISSIBILITY

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

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

12. 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.

13. 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.

14. Pursuant to its Articles of Association,[13] 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*".

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

[13] ClientEarth's articles of association; Annex 1.

- *"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 [...]."*

16. 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.[14]

17. ClientEarth's activities regarding chemicals over recent years appear from the annual reports of ClientEarth.[15] 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

18. 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**").

19. ClientEarth is indeed an accredited stakeholder at ECHA[16]. 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;

[14] See Annual Report for 2015; Annex 2.
[15] 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 2 and 3 or available at: <http://apps.charitycommission.gov.uk/Showcharity/RegisterOfCharities/>.
[16] 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.[17]

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

A.1.1.1 Supporting documents of ClientEarth's entitlement to request internal review

21. As required by Commission Decision 2008/50/EC[22], 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 1);
- Annual activity reports of ClientEarth of the last two years (Annexes 2 and 3)
- A copy of the legal registration with the national authority (Annex 4).
- 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 5).

[17] A document further explaining the eligibility criteria and how to fulfil them is available at < http://echa.europa.eu/documents/10162/13559/mb_34_2011_revised_criteria_of_accredited_sh_en.pdf>.
[18] 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>.
[19] 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>.
[20] 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).
[21] More information about CARACAL and its composition can be found at <http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm>.
[22] 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.1.2. European Environmental Bureau fulfils the criteria of Article 10 and 11 of Regulation 1367/2006

22. EEB fulfils the criteria of Articles 10 and 11 of Regulation 1367/2006:

- EEB is an independent non-profit-making legal person in accordance with a Member State's national law or practice;
- EEB has the objective of promoting environmental protection in the context of environmental law;
- EEB has existed for more than 40 years and is actively pursuing the objective of promoting environmental protection;
- The authorisation of continued use of a substance of very high concern, which is the subject matter of the Contested Decision, is covered by EEB's objective and activities.

23. The EEB is a non-profit making, non-governmental environmental organisation with office in Brussels. Created in 1974, the EEB is now Europe's largest federation of environmental organisations with 150+ member organisations who gain their membership from the general public.

24. The EEB works on a vast array of environmental issues its policy officers use experts, scientists, EEB members, and politicians to work towards developing and protecting environmental policies.

25. The Brussels office closely coordinates EU-oriented activities with EEB Members at national level around Europe. The EEB is also part of wider coalitions of NGOs, such as the Green 10 and Spring Alliance, or at a global level through the Global Policies and Sustainability Unit as well as in ad-hoc coalitions with representatives of other interest groups when appropriate.

26. The statutory goals of the EEB, under Article 3, specify the objective of promoting sustainable development, environmental justice, global equity, transparency, participatory democracy and shared but differentiated responsibilities, as well as the principles of prevention, precaution and the polluter pays.

27. In 1979 the EEB created a toxic substances working group and its chemicals policy officers have been extremely active during the entire REACH Regulation process.

28. The EEB work plans for 2014[23] and 2015[24] has allocated time and resources to continue its work on chemicals which includes the following activities:

- Represent environmental interests in the European Chemicals Agency (ECHA) Committees and its Management Board as well as the Competent Authorities' CARACAL meetings;
- Participate actively in REACH implementation, focussing on achieving the substitution of hazardous chemicals, prioritising substances of very high concern (SVHCs) by 2020, ensuring that authorisations are not granted for SVHCs for which feasible alternatives are available in the market and dissemination to the public of information on chemical substances to which they are exposed.

29. Further the EEB activities include work on the EU Directives on access to information and public participation implementing the Aarhus Convention. The EEB is a member and chair of the advisory board of the EU Aarhus Centre that was set up by ClientEarth in 2011.

30. The objective of the Aarhus Convention is stated in Article 1: *"In order to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being, each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention."*

31. The Aarhus Convention is implemented in the EU legal system through Regulation 1367/2006 and Directive 2003/4/EC implements the Aarhus Convention in regards to the first pillar on access to environmental information.

32. The EEB is accredited stakeholder at the ECHA.[25] Accredited stakeholders need to fulfil the following criteria to be eligible:[26]

- Being legally established within the EU/EEA and having activities at an EU level.
- 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 maintained by the EU. (This criterion only applies if an organisation wishes to participate as an observer in the Committee and Forum meetings of ECHA.)

[23] The EEB 2014 workplan is available at: <http://www.eeb.org/EEB/?LinkServID=A300041E-5056-B741-DB8B65781E9CF702&showMeta=0>.
[24] The EEB 2015 workplan is available at <http://www.eeb.org/index.cfm/library/work-programme-2015/>.
[25] See list of ECHA's accredited stakeholders available at: <http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations>.
[26] For further explanation on the eligibility criteria and how to fulfil them is available at: <http://echa.europa.eu/documents/10162/13559/mb_34_2011_revised_criteria_of_accredited_sh_en.pdf.

33. Further, EEB is listed as an observer in the Risk Assessment Committee[27] in the Socio-Economic Analysis Committee as well as in the Member States Committee of ECHA.[28]

A.1.2.1 Supporting documents of European Environmental Bureau's entitlement to request internal review

34. As required by Commission Decision 2008/50/EC[29], to prove that EEB 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 EEB (Annex 6);
- Annual activity reports of EEB of the last two years (Annexes 7 and 8)
- A copy of the legal registration with the national authority (Annex 9).

A.1.3. The International Chemical Secretariat fulfils the criteria of Article 10 and 11 of Regulation 1367/2006

35. ChemSec 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 ChemSec.

36. ChemSec, the International Chemical Secretariat, is a non-profit organisation dedicated to working towards a toxic free environment.

37. ChemSec is based in Göteborg, Sweden and have for the moment 8 employees. ChemSec was founded in 2002 by four environmental organisations: Swedish Society for Nature Conservation, WWF Sweden, Nature and Youth and Friends of the Earth Sweden.

[27] See 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>.
[28] See 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>.
[29] 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).

These NGOs are the ChemSec member organisations and are represented on the ChemSec board. ChemSec strive to bridge the gap between decision-makers, industry, NGOs and scientists; and offer expertise and guidance on chemical management policies in order to get progressive chemical legislation.

38. Pursuant to its Articles of Association, ChemSecs objectives are to promote environmental and health protection by:

- Monitoring, influencing and providing information about the development of EU and other international policies regarding chemicals, from an environmental and health perspective;
- Functioning as a resource and support in issues relating to chemicals, chiefly for those organisations that stand behind the Association;
- Encouraging and urging foreign and international trade organisations, companies, research bodies and civil society to take a greater interest in the environmental and health aspects of chemicals.

39. All work done by ChemSec aims to speed up the transition to a world free of hazardous chemicals. ChemSec strives to enhance collaboration and open dialogue between all stakeholders interested in phasing out hazardous chemicals. ChemSec is looking to achieve effective solutions and concrete, sustainable results and are especially involved in dialogue with authorities and regulators as well as companies that are interested in taking the lead and phasing out hazardous chemicals ahead of legislation.

40. ChemSec is an accredited stakeholder within a number of policy institutions, committees and initiatives. In all these forums, we use our knowledge and position to influence and improve the way chemicals legislations are implemented in practice.

41. ChemSec's activities regarding chemicals over recent years appear from the annual reports of ChemSec. ChemSec's work can be divided into three parts: policy, business & investors and tools. ChemSec's work on policy is primarily focussed on the implementation of the REACH Regulation.

42. ChemSec Business Group is collaboration among companies working together to inspire concrete progress on toxic use reduction. It gathers market-leading companies, across a diversity of sectors, for the development of effective corporate practice in the substitution of hazardous substances. It also raises public awareness of companies' efforts to be drivers on this issue.

43. ChemSec tools have been created with the aim to speed up the transition to a world free of hazardous chemicals, for example: the SIN (Substitute it Now!) List, the SIN Producers List, SINimilarity, SUBSPORT and the Textile Guide.

44. ChemSec is indeed an accredited stakeholder at ECHA[30]. ChemSec therefore fulfils all the requirements for stakeholders that ECHA has set:

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

45. ChemSec is listed as an observer in the Socio-Economic Analysis Committee ("SEAC") as well as in the Member States Committee of ECHA. ChemSec is also an observer in the meetings of the Competent Authorities for the REACH Regulation and the CLP Regulation ("CARACAL").

A.1.3.1 Supporting documents of the International Chemical Secretariat's entitlement to request internal review

46. As required by Commission Decision 2008/50/EC[31], to prove that ChemSec 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 ChemSec (Annex 10);
- Annual activity reports of ChemSec of the last two years (Annexes 11 and 12)
- A copy of the legal registration with the national authority (Annex 13).

A.1.4. IPEN fulfils the criteria of Article 10 and 11 of Regulation 1367/2006

47. IPEN 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;

[31] 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).

- It has operated for more than two years;

- The subject matter of the Contested Decision is covered by the objectives and activities of IPEN.

48. IPEN is a non-profit network of civil society organizations in more than a 100 countries, legally registered in Sweden in 2008. Its secretariat is based in Gothenburg, Sweden. IPEN brings together leading environmental and public health groups around the world and works to establish and implement safe chemicals policies and practices to protect human health and the environment. It does this by building the capacity of its member organizations to implement on-the-ground activities, learn from each other's work, and work at the international level to set priorities and achieve new policies. Its mission is a toxics-free future for all.

49. IPEN played a critical role in shaping the first treaty to ban the world's most dangerous chemicals – the Stockholm Convention– and remains influential in the implementation of this treaty as well as the Rotterdam and Basel Conventions and the recently adopted Mercury Treaty. IPEN identifies and advocates for adding new chemicals for elimination; brings new scientific information about harmful chemicals to treaty discussions; and builds the capacity of NGOs and governments to advocate for treaty provisions relevant to their national situations.

50. IPEN has been heavily engaged in the Strategic Approach to International Chemical Management's ("SAICM") since 2003 and its global network helped to develop the SAICM international policy framework. IPEN holds public interest, non-governmental organization seat on the SAICM governing bureau, and has substantially influenced SAICM's policies on numerous issues including hazardous chemicals in electronic products, nanotechnology, lead in paint, and chemicals in products.

51. IPEN launched its Global Lead Paint Elimination Campaign in 2008, when NGOs in the IPEN network began to research the lead content of paints sold in the developing world. In response to these studies and other activities, the Second Session of the International Conference on Chemicals Management ("ICCM2") passed a resolution in 2009 identifying lead in paint as an emerging policy issue, endorsed a global partnership to promote phasing out the use of lead in paints, and invited the United Nations Environment Programme ("UNEP") and the World Health Organization ("WHO") to serve as the secretariat for this global partnership. The partnership was named the Global Alliance to Eliminate Lead Paint ("GAELP"). IPEN represents environmental NGOs in GAELP´s Advisory Group.

52. IPEN´s Campaign works at an international level in cooperation with UNEP, WHO and other partners in GAELP, and at the national level with lead paint elimination campaigns and programs led by non-governmental organizations that promote regulatory controls on lead paint and raise awareness among business entrepreneurs, government officials, and consumers about the adverse human health impacts of lead paint, particularly on the

health of children. Since 2008, IPEN has assisted NGOs in sampling and analyzing paints in approximately 40 low and middle income countries and developing national lead paint elimination projects and programs in many of these countries. IPEN implemented the EU-funded Asian Lead Paint Elimination project in 7 Asian countries between 2012-2015, and is currently Executing the Lead Paint Elimination Project in Africa, funded by the global Environment Facility and Executed by UNEP.

A.1.4.1 Supporting documents of IPEN's entitlement to request internal review

53. As required by Commission Decision 2008/50/EC[32], to prove that IPEN 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 IPEN (Annex 14);
- Annual activity reports of IPEN of the last two years (Annex 15)
- A copy of the legal registration with the national authority (Annex 16).

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

54. 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"

55. 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*".

[32] 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).

56. 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."

57. 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.[33]

58. Title VII of the REACH Regulation, "Authorisation", aims at the progressive substitution of substances of very high concern ("**SVHC**").[34] 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.[35] 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 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.

59. To ensure a high level of protection for human health and the environment, the regulation of SVHCs under the REACH Regulation is based on the precautionary principle.[36] This is in line with EU policy on the environment as set out in the Treaty.[37]

60. 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.[38] 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.

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[33] See Case C-558/07 *S.P.C.M. and Others* [2009] ECR I-5783, para. 45.
[34] 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*".
[35] Article 60 REACH with Recital 22.
[36] Article 1(3) REACH with Recital 69.
[37] Article 191(2) TFEU.
[38] See Case C-94/03 *Commission* v *Council*, para. 36 and the case law cited.

61. 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"

62. 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.

63. 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.[39]

64. As stipulated in Article 56(1)(a), a manufacturer, importer and downstream user is prohibited from placing a substance on the market or using that substance, if it has not been authorised in accordance with Articles 60 to 64 of the REACH Regulation. In addition, as stated in Article 56(2), a downstream user may only use a substance in accordance with the conditions of an authorisation granted to an actor up his supply chain.

65. Accordingly, the purpose of the Contested Decision is to apply Article 60 of the REACH Regulation which aims at deciding whether or not an identified substance, could be used in a specific and defined way, by a company applying for this specific use.

66. The scope of the Contested Decision is therefore limited, to six uses, and the Authorisation Applicant and its downstream users, part of its same supply chain. Accordingly, Article 4 of the Contested Decision states that the Decision is specifically addressed to: “DCC Maastricht BV OR”.

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

68. Though the CJEU has not clearly defined what constitutes a measure of individual scope, it has considered in further detail what constitutes a measure of general scope. A measure is 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.[40]

69. 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 the Aarhus Regulation.[41] This

[39] See Case T-396/09, para. 26 and the case law cited; Case T-338/08, para. 29 and the case law cited.
[40] Case C-503/07 P, para. 71.
[41] Case C-404/12, paragraph 58; Case T-338/08, para. 38 and 39.

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.

70. 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 uses of Yellow Lead Chromate and Red Lead Chromate by the Authorisation Applicant and the downstream users in its own supply chain for the specific uses applied for.

71. 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 Applicant. These downstream users have to notify the ECHA 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 authorisation granted to an actor up his supply chain. In light of this, it is clear that the Contested Decision is not of general but of individual scope.

72. 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.

73. Furthermore, the Commission has considered admissible[42] 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[43] and Directive 2001/18/EC.[44]

74. 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 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.

[42] 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>.
[43] 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).
[44] 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).

75. 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.

76. 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

77. As required by Article 10(1) of the Aarhus Regulation, this request for internal review is directed to the 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.

78. 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

79. ClientEarth, EEB, ChemSec and IPEN request that the Contested Decision be reviewed on the basis of the following grounds.

B.1. Violations of the REACH Regulation

B.1.1. Breach of Articles 60(7): lack of Conformity of the Application for Authorisation

80. 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) the SEAC and RAC are each required to verify that the application includes all the information specified in Article 62 that is relevant to its remit. When an 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.

81. The Applications for Authorisation in the present case do not provide the information required under Article 62(4) and were not brought into conformity.

a) The Applications for Authorisation do not comply with Article 62(4)(c)

82. Article 62(4)(c) 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*".[45]

83. Contrary to Article 62(4)(c), the Applications 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.

84. First, the Applications for Authorisation failed to define the substances' functions and performance characteristics.

85. Since the final aim of the Authorisation procedure is the substitution of hazardous chemicals, the knowledge of the function of the substance is a condition to be able to identify an alternative substance or technology. ECHA Guidance explaining how to describe uses for authorisation purposes states: "*details on the specific function of the Annex XIV substance would be essential criteria to judge on the suitability of alternatives substances or technologies which can provide an equivalent function*."[46]

86. The Applications for Authorisation failed to detail this essential element. For example, the Application for Authorisation regarding Use 3 (Yellow Lead Chromate) affirms that: "*The yellow is used as a contrast colour on equipment to highlight dangerous moving parts and prevent operator injuries in situations of variable lighting and background. The most common use is in construction and agriculture environments where the background can vary from grey to light yellow with green and browns in between. There is no colour that gives as much contrast in all of those situations as a deep and powerful yellow – since on top of that such uses are subject to extreme wear the paint must also be extremely durable*"[47]. This description does not explain the added value of Yellow Lead Chromate in ensuring safety, compared to other pigments that are also yellow. The Application for Authorisation does not specify which shade of yellow is necessary to achieve these safety needs either. It does not explain either why yellow specifically would be required: the Authorisation Applicant does not provide any supporting evidence showing that yellow painted equipment is safer than equipment in any other colour.

87. The Contested Decision itself acknowledged the failure to define the "*technically required performance characteristics of the pigment premixes, paints and pre-compounds and of*

[45] See also Article 56(1)(a) REACH with Recital 73.
[46] ECHA, "Guidance on the preparation of an application for authorisation", 2011, ECHA-11-G-01-EN, p. xii, available at: <http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf>.
[47] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), pp. 2 - 3.

articles containing them".[48] As explained further below (§102), this flaw in the Applications for Authorisation in breach of Article 62(4)(c), makes the analysis of the alternatives conducted meaningless.

88. Second, the Applications for Authorisation cover "uses" that are too broad in scope which makes the assessment of the application and notably the assessment of alternatives meaningless.

89. ECHA Guidance on the development of the description of uses in the context of authorisation interpreting the requirement in Article 62(4)(c) of the REACH Regulation, states that: "*The level of detail provided in the description of a "use applied for" will be of great importance for the opinion and decision makers to understand how the substance is used in practice"*[49]*.* According to the Guidance, the description of the use should include the following elements: sector use, chemical product category, process category, environmental release category, article category and function.[50] In addition, applicants should refine the description in developing the exposure scenarios and conducting the analysis of alternatives.

90. In the present case, the Applications for Authorisation failed to specify in sufficient detail the scope of the uses applied for. For example, the description of Use 3 ("*Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking")* is overly broad and lacks sufficient detail. The use description defines the product category as "paint" but does not identify the type of paint – e.g. solvent or water based. In addition, the list of article categories that follow is incomplete: "*machines, vehicles, structures, signs, road furniture etc."* The process category also remains undefined and is simply described as "*application*", without specifying the method – such as spraying or brushing.

91. The failure to adequately define the scope of the uses applied for was acknowledged in Article 3(c) of the Contested Decision that requires the Authorisation Applicant to submit a report by 31 December 2017, which, notably, "*shall refine the description of the authorised uses".* This requirement is evidence that the description of the uses is not in conformity with Article 62(4)(c). The rationale of such request would be inexplicable if the Commission did not believe that the scope of the use applied for was too broad and not in line with the provisions of the REACH Regulation.

92. Interestingly, when responding to observations submitted by third parties the Authorisation Applicant indicated that: "*[t]he overwhelming response in support of the applicant's application, numbering in the many hundred, provides ample evidence of the need for*

[48] Contested Decision Recital 12.
[49] ECHA "How to develop the description of uses in the context of Authorisation", 2011, ECHA-11-B-06.1-EN, p. 2.
[50] ECHA "How to develop the description of uses in the context of Authorisation", 2011, ECHA-11-B-06.1-EN, p. 3.

these pigments in the applications applied for. The respondents are for the most part small to medium sized companies providing a specific product for a niche application".[51]

93. This reference to "a niche application" confirms that the use applied for is not in compliance with Article 62(4)(c). The word "application" in the REACH authorisation process only refers to applications for authorisation; however in this context the word application refers to uses of a substance. The reference to a niche application shows clearly that the use applied for actually includes several uses, some of which have alternatives as demonstrated by the large evidence provided in the third party consultation (See Section B.1.3.2) and some of which may not. The Authorisation Applicant should have defined more narrowly the uses applied for because no authorisation can be granted if alternatives exist according to Article 60(4). If this "niche application" or, better, niche use exists and no alternatives are viable, the scope of the Application for Authorisation should have been limited to this "niche".

94. The Contested Decision reached an erroneous conclusion by granting the authorisation despite this obvious lack of conformity with Article 62(4)(c). The possibility to make the authorisation conditional upon the Authorisation Application submitting a report further refining the use descriptions is not provided in the REACH Regulation. What the REACH Regulation provides is that:

- When the SEAC and RAC "*first check that the application includes all the information specified in Article 62*", the Committees have to "*make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62*", if necessary (Article 64(3)).

- "*Authorisations [...] shall normally be subject to conditions, including monitoring*" (Article 60(8)).

95. The Contested Decision interprets these provisions as allowing the Commission to grant an authorisation despite the lack of conformity of an application, by making the authorisation conditional upon fundamental information being provided, i.e. "*description of the authorised uses*". This interpretation is in direct contradiction with Article 60(7) which states that "*an authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.*"

96. Without knowing what the uses applied for actually entail, as required under Article 62, any assessment made is meaningless. The conclusion in the Contested Decision should therefore have been that the authorisation could not be granted since the Applications for Authorisation were not in conformity within the meaning of Article 60(7).

[51] ECHA, "Comments and response to comments on authorisation", applicants reply to comments 260-267 and 362-369 (contributing third party: Akzo).

97. Failing to do so, affects the effectiveness of the authorisation process under REACH: if the use is not described in a way that allows the proper assessment of the conditions for authorisation, and in particular does not allow any meaningful analysis of alternatives, the application cannot be deemed to be in conformity, and the authorisation cannot be lawfully granted. Under the authorisation procedure a use must be clearly defined in relation to a correspondent analysis of the alternatives for those uses.

98. 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. The Contested Decision was therefore taken in breach of Article 60(7) and on that ground should be reviewed.

b) The Applications for Authorisation do not comply with Article 62(4)(e)

99. Article 62(4)(e) of the REACH Regulation provides that an application for authorisation is required to include: "*an analysis of alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate, information about any relevant research and development activities by the applicant*." The Application for Authorisation failed to satisfy this requirement.

100. The Contested Decision acknowledged that the analysis of alternatives for the six uses submitted by the Authorisation Applicant failed to fully assess the technical feasibility of substitution as required in Article 62(4)(e). The deficiencies in the analysis of alternatives were highlighted repeatedly and explicitly in the Contested Decision as follows:

- "*the uncertainties related to the applicant's claim regarding the lack of technical feasibility of alternatives for the road marking sector*";[52]
- "*The difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of the uses covered by the application.*"[53]

101. The authorisation was granted under the condition "*that the performance of the pigment [...] is technically achievable only by using that substance and that such performance is necessary for the intended use.*"[54] The Contested Decision therefore made the authorisation conditional upon the Authorisation Applicant, to "*submit a report on the status of the suitability and availability of alternatives for his downstream users*" before the end of 2017.[55]

102. The Contested Decision reached an erroneous conclusion: due to these "uncertainties", it should have considered that the authorisation could not be granted since the applications were not in conformity with Article 62(4)(c). Failing to do so affects the effectiveness of the REACH Regulation, which seeks to only allow the continued use of a SVHC for a use that

[52] Contested Decision, § 9.
[53] Contested Decision, §§ 12 and 8.
[54] Contested Decision, Article 1 and §12.
[55] Contested Decision, §12.

cannot be provided in a viable way by an alternative substance or technology. As explained above (§94), if the Commission is entitled to impose conditions under Article 60(8), it cannot do so to remedy the lack of conformity of an application, without breaching Article 60(7).

103. In addition to the condition to provide further information, the Contested Decision considered, in order to mitigate the "*difficulties in fully ascertaining the lack of technically feasible alternatives*", that "*the authorisation should be reviewed earlier than recommended by the SEAC*".[56] Once again, the Contested Decision reached a conclusion that is not in line with the REACH Regulation:

- Article 60(8) states that: "*The duration of the time-limit review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate*"

- Article 60(9)(e) providing that the authorisation must specify the time-limited review period does not allow the Commission to use this mechanism to remedy conformity issues.

104. The Contested Decision interprets these provisions as allowing the Commission to grant an authorisation despite the lack of conformity of an application, if it sets a review period that is shorter than the one recommended by SEAC. This interpretation is in direct contradiction with Article 60(7) which states that "*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. The Contested Decision should have therefore concluded that the authorisation could not be granted since the Applications for Authorisation were not in conformity.

105. In line with the principle of industry responsibility at the basis of the REACH Regulation,[57] the applicant for authorisation bears the burden of proof to show that there are no suitable alternatives. This is underscored by the language used in Article 60(4) of Title VII – for example phrases: "*if it is shown*" (Article 60(4)). Consequently, to fulfil the requirements of Article 62(4)(e), an authorisation applicant must demonstrate that adequate steps have been taken to identify possible alternatives and prove whether or not they are suitable and available.

106. As noted in paragraph 100, the Authorisation Applicant did not provide the necessary information regarding available alternatives as it should have under Article 62(4)(e). Hence, the Application for Authorisation was not in conformity and the authorisation was granted in breach of Article 60(7) of the REACH Regulation.

[56] Contested Decision, §§ 6 and 9.
[57] REACH, Article 1(3).

107. In light of the above, by granting an authorisation for applications that were not 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 an error of law. On the basis of this ground, the Contested Decision must be reviewed.

B.1.2. Breach of Article 60(4): manifest error of assessment of the risks to human health and the environment

108. Under Article 60(4), the Commission can only grant an authorisation if "*it is shown that the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance*". The Contested Decision is vitiated by a manifest error of assessment of the risk arising from the uses applied for in breach of this provision.

109. First, the risks assessed only covered two hazards: Carcinogenic and Toxic for reproduction.

110. Under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ("CLP Regulation") both Yellow Lead Chromate and Red Lead Chromate have been classified not only as Carcinogenic (1A) and Toxic to reproduction (1A) but also hazardous to the aquatic environment (Acute 1 and Chronic 1).[58] In other words, both substances have acute and chronic toxic effects on aquatic life, a risk not taken into account in the RAC and SEAC Opinion, and thus neither in the Contested Decision.

111. Under Article 60(4), the risk assessment should cover all hazardous properties of a substance – including the hazards posed to the aquatic environment. This is made explicit in Article 60(5)(a) which requires the Commission to take into account "*whether the transfer to alternatives would result in reduced overall risks to human health and the environment*". ECHA's Guidance on applications for authorisation, concerning the analysis of alternatives repeats the need to demonstrate the: "*Reduction in overall risks to human health and the environment.*"[59] For the sake of consistency, the endpoints to be taken into account for the purpose of the socio-economic assessment under Article 60(4) cannot differ from those assessed in the context of the analysis of alternatives.

112. This is further supported by the construction of Article 62(5)(a) and Annex XVI to the REACH Regulation, which do not specify that the socio-economic assessment is restricted to an examination of the risks arising from the properties of a substance that lead to its

[58] ECHA, Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) - Yellow Lead Chromate, available at: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/5938>; ECHA, Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – Red Lead Chromate, available at: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/19257>.

[59] ECHA Guidance on the preparation of an application for authorisation, p. 90, available at: <https://www.echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf>

inclusion in the authorisation list. By comparison, Article 60(2) clearly states that an analysis of all the risks is not necessary *"if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled".* The legislators' intention is clear, if there is no risk from the use of the substance for the property for which it was included in Annex XIV (i.e. "intrinsic properties"), no other consideration should be taken into account when assessing an application for authorisation. Yet, under Article 60(4) a comprehensive assessment is necessary because the substance included in Annex XIV will always be used in ways that do not exclude a risk for human health and the environment.

113. Second, in the Applications for Authorisation the assessment made of the risk of release in the environment is limited to the risk of release during the "application" of the paint or mixture[60] and does not, for example, assess exposure due to paint degrading with time or due to heat. The Authorisation Applicant argues in its analysis of alternatives that Yellow and Red Lead Chromates are more durable and resistant to heat.[61] However, that does not mean that they do not degrade at all.

114. In fact, as clearly laid out on the ECHA website in the Profile Brief of Red and Yellow Lead Chromate there is a risk of release to the environment of these substances:

"*Release to the environment of this substance is likely to occur from industrial use: in the production of articles, formulation in materials and formulation of mixtures. Other release to the environment of this substance is likely to occur from: indoor use, outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) […] and outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives).*"[62]

115. These releases into the environment should have been taken into account in the risk assessment.

116. Furthermore, according to the RAC and SEAC Opinion "*the assessment of the risk of indirect exposure of man through the environment is not performed, as it is considered to be not applicable due to very low predicted environmental exposure levels which are much lower than the background environmental concentration*".[63] This is contrary to the letter of Article 60(4) that requires an assessment of "*the risk to human health or the environment*".

[60] See, Section 9 and 10 of the CSR (non-confidential report), Use 3, available at: <https://echa.europa.eu/documents/10162/9cd8cf27-3bfe-4e5c-b929-8b535f9ba6ec>; Section 9 and 10 of the CSR (non-confidential report), Use 6, available at: <https://echa.europa.eu/documents/10162/658e1448-362b-4016-9dcb-b5493307cb7f>.
[61] See, Analysis of alternatives (non-confidential report), Use 6, p. 21–22, available at: <https://echa.europa.eu/documents/10162/fc5e664d-91a3-4a42-9a39-425219755e65>.
[62] ECHA, Brief Profile, Yellow Lead Chromate, available at: <https://echa.europa.eu/brief-profile/-/briefprofile/100.014.267>.
[63] Compiled RAC and SEAC Opinion, Use 3 (Red and Yellow Lead Chromate), p. 10, available at: <https://echa.europa.eu/documents/10162/ad1b0af9-01c4-4ec0-9200-16e39ad2211c>.

117. The Contested Decision is therefore vitiated by a manifest error of assessment of the risk to human health and the environment within the meaning of Article 60(4)(a). On that ground, the Contested Decision must be reviewed.

B.1.3. Breach of Article and 60(4) and 60(5): errors in the Analysis of Alternatives

118. According to Article 55 of the REACH Regulation: "*the aim of [the Authorisation 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*".

119. In line with this objective, Article 60(4) provides that for an authorisation to be granted under the socio-economic route, the following conditions need to be fulfilled: "*if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies*." In other words, an authorisation cannot be granted under this provision if it is not shown that there are no suitable alternative substances or technologies.

120. According to Article 60(5), "*when assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including [...] (b) the technical and economic feasibility of alternatives for the applicant."*

121. Article 60(4) specifies that "*The decision shall be taken after consideration of all the following elements [...] (c) the analysis of alternatives submitted by the applicant [...] and any third party contributions submitted*."

122. As further explained below, the Contested Decision is vitiated by 1) an error of law in the interpretation of the notion of suitable alternative within the meaning of Articles 60(4) and 60(5), REACH; and 2) a manifest error of assessment of the information submitted by third parties under Article 64(2).

B.1.3.1. Error of law in interpreting the notion of suitable alternative

123. The Contested Decision erred in law by endorsing the Authorisation Applicant's erroneous interpretation of the notion of (a) technical feasibility and (b) economic feasibility.

a) Error of law in interpreting the notion of technical feasibility

i) Technically feasible does not mean technically identical

124. The Applications for Authorisation conclude that "*In the end none of the alternatives can substitute or form an alternative […] as they always fail multiple tests of technical feasibility and availability and even those that come closest then turn out to have completely unacceptable other characteristics*"[64]. When taking a closer look at the analysis, the Authorisation Applicant disqualifies each alternative on the basis that it does not fulfil some criteria. In other words, it excludes any alternative that would not achieve all the technical criteria of Red and Yellow Lead Chromate at the same level of performance. The RAC and SEAC opinion endorse the approach: "*None of the alternatives identified by the applicant meets the same technical requirements as [Yellow Lead Chromate*]".[65] The Contested Decision does not question this interpretation.

125. However, this interpretation means in essence that for any alternative to be considered "technically feasible", it would have to have the exact same characteristics as the original substance. This makes the analysis of alternatives meaningless and clearly against Article 55 of the REACH Regulation which provides that substitutes can be both substance and also technologies. As explained by the Authorisation Applicant, this approach is even more problematic in relation to paint: "*the choice of any pigment is a complex compromise between several factors*", and "*a one for one substitution will never be possible. Not one single pigment is known to be identical to another and the choice of pigment regardless of the application is made on the basis of several criteria all of which together dictate the final choice*".[66]

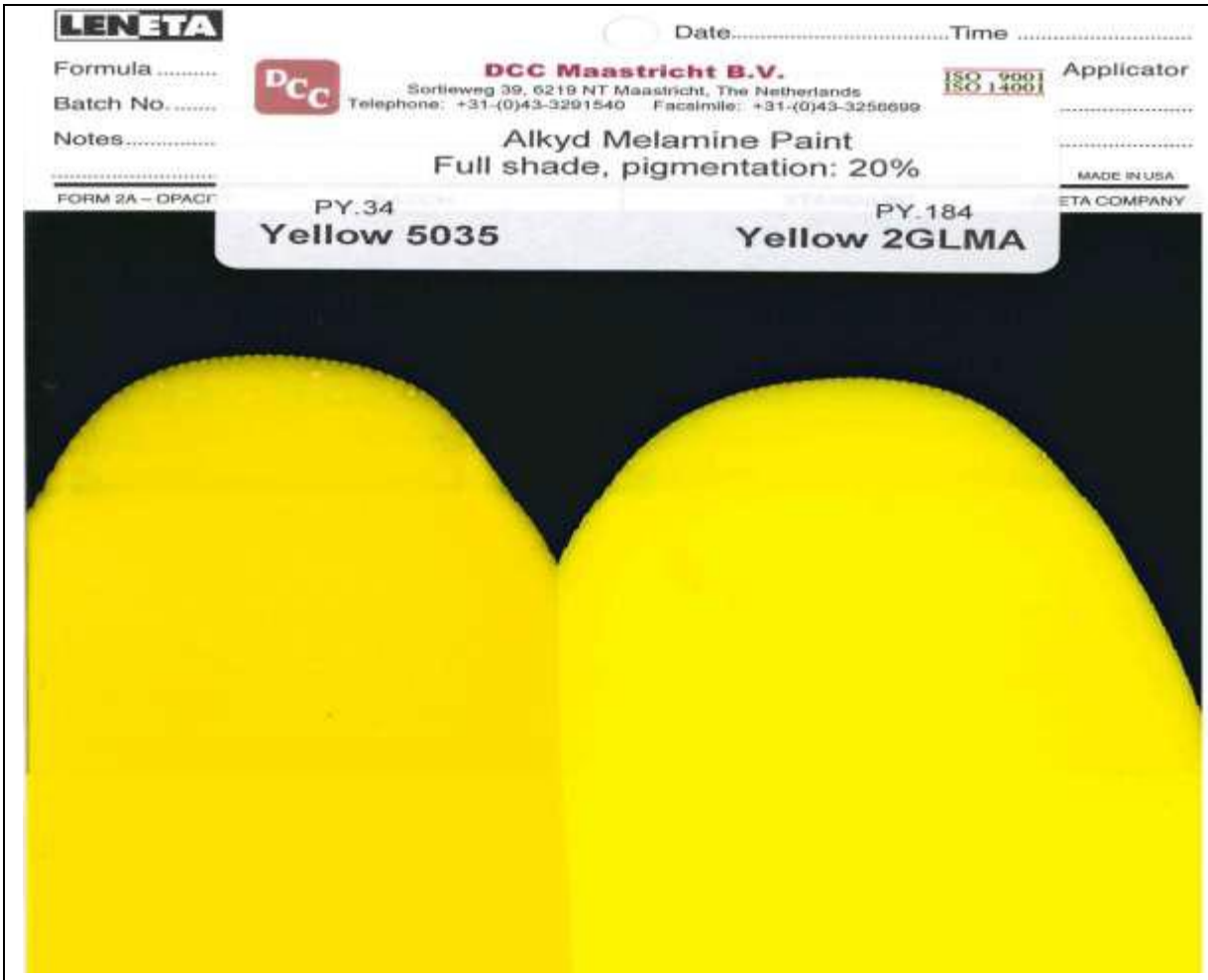
126. In addition, the interpretation is not in line with ECHA's Guidance which explains that: "*An alternative is a possible replacement for the Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs. The alternative could be another substance or it could be a technique (e.g. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance function altogether.*"[67] What should be assessed and used as a comparison point is thus the characteristics of the substance necessary for its function, and not all its individual properties irrespective of the function of the substance.

127. However, the Applications for Authorisation do not define what levels of performance, for the criteria listed, are necessary to achieve the function that Red and Yellow Lead Chromate perform. Even though the Applications for Authorisation list the relevant

[64] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), p. 107.
[65] Compiled RAC and SEAC Opinion, Use 3 (Red and Yellow Lead Chromate), p. 13.
[66] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), p. 3.
[67] ECHA, "Guidance on the preparation of an application for authorisation", 2011, pp. 89-90.

technical criteria: shade, opacity, chroma, durability or heat stability, they do not set the standard required for the function to be achieved. For example, the Authorisation Applicant assesses whether chroma and opacity are "similar", or if durability and heat stability is "poorer".

128. Concerning shade, the Authorisation Applicant affirms that: "*The yellow is used as a contrast colour on equipment to highlight dangerous moving parts and prevent operator injuries in situations of variable lighting and background. [...] There is no colour that gives as much contrast in all of those situations as a deep and powerful yellow – since on top of that such uses are subject to extreme wear the paint must also be extremely durable*"[68]. However, if we could understand that the colour yellow may be efficient to achieve safety, the Authorisation Application does not specify which shade of yellow is necessary to achieve these safety needs.



"From this comparison it is obvious why PY. 184 is the closest possible alternative from a technical perspective (it has many other good characteristics) to PY.34 and is therefore the

[68] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), pp. 2-3.

> *pigment we deem the least bad alternative to PY.34. Nevertheless even to the naked eye the lighter shade of the pigment is obvious and this translates into a great difficulty in obtaining a deeper, more powerful yellow colour with PY. 184."*[69]

129. In this analysis, the lighter shade of the pigment is not that "obvious" and the necessity to achieve "deeper, more powerful yellow" is not demonstrated. The British Coatings Federation during the public participation raised this point very clearly: "*We fail to see how lead chromates could be considered 'safety critical'. Whilst the yellow colour offered by lead chromates is recognised as a safety colour, the exact shade of paint is not that important*."[70]

130. Furthermore, the function of the substance is not even clear in the first place. For example, it is affirmed on the one hand that: "*The coatings produced from PY.34 and PR. 104 never only have a decorative function*",[71] and on the other hand: "*PY.34 and PR. 104 are particular in that they are in part of the spectrum that allows good mixing with other colours to create powerful colour effects. This shade functionality makes them essential for colour matchers who have to juggle a palette of thousands of colours*"[72].

131. Comparing a substance's technical characteristics with the technical characteristics of other substances, without knowing the function that the substance is supposed to achieve, nor the minimum requirements to achieve this function, is meaningless. Such a comparison inevitably leads to the finding that the substitute substance cannot be considered technically feasible.

132. By endorsing this erroneous interpretation of the notion of technical feasibility, the Contested Decision is thus vitiated by an error of law in breach of Article 60(5).

ii) The notion of substitution under EU competition law rules cannot legally be taken into account when implementing the REACH Regulation

133. The SEAC opinions assessing the technical feasibility of Red and Yellow Lead Chromate state that: "*[European Commission]'s recent conclusion related to a merger between two big manufacturers of chemicals, coatings and plastics indicates that organic and inorganic pigments should be further segmented by class, since – according to their characteristics (different chemistry, features, colour, shade and performance), they are not interchangeable from either the supply-side or the demand-side point of view (based on markets investigation). Furthermore, [the European Commission] concludes in its document that certain pigments cannot be used in all applications as there are different*

[69] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), p. 10.
[70] ECHA, "Comments and response to comments on authorisation", British Coatings Federation.
[71] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), p. 2.
[72] Analysis of alternatives - non-confidential report, Use 3 (Red and Yellow Lead Chromate), p. 22.

relevant product markets e.g. for Bismuth Vanadate and for lead chromates, which would further confirm the applicant's view that currently, substitution is not possible."[73] This reasoning was not called into question by the Commission in the Contested Decision.

134. However, deducting from a market definition within the context of merger control, the lack of technically feasible alternatives under REACH constitutes an error of law. The analysis of whether two products can be "substituted" in the context of merger control and the analysis of alternatives under the REACH Regulation have different objectives and different meanings.

135. Merger control aims at ensuring that competition in the market is not distorted due to corporate reorganisations, such as mergers.[74] In order to assess whether a merger may raise competition issues, it is necessary to define first whether the companies that want to merge are selling competing products or not. Products will be considered as competing, i.e. on the same "relevant market", if they are substitutable from a competition perspective: will consumer switch between products in case of a small but permanent price increase. This assessment of substitutability is not limited to an analysis of product characteristics and functions.

136. Indeed, as explained by DG Competition: "*product characteristics and intended use are insufficient to show whether two products are demand substitutes. Functional inter-changeability or similarity in characteristics may not, in themselves, provide sufficient criteria, because the responsiveness of customers to relative price changes may be determined by other considerations as well*" [75].

137. By contrast, the notion of alternative within the meaning of REACH does not aim at defining the boundaries of competition but the boundaries of what is technically feasible. What matters is whether the alternative can fulfil the same function. It is therefore a broader concept. The REACH Regulation aims at pushing companies to abandon the use of substances of very high concern and replace them with technically and economically feasible alternatives. Only considering as alternatives within the meaning of REACH, the substances that are considered as "competing" within the meaning of merger control is contrary to this objective.

138. Therefore, it cannot be deducted from a merger decision that concludes that *Bismuth Vanadate* and lead chromates are not competing on the same market, that *Bismuth Vanadate* does not constitute a technically feasible alternative to lead chromates within the meaning of REACH. Quite the opposite, the fact that *Bismuth Vanadate* is even considered in the merger assessment, means that it is in "*the field of investigation of*

[73] Compiled SEAC and RAC opinion, Use 3 (Red and Yellow Lead Chromate), p.14.
[74] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings, OJ L 24, 29.1.2004, p. 1–22.
[75] Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997, p. 5–13, §36.

possible substitutes"[76], and therefore that it is considered as fulfilling the same function as lead chromates.

139. The Contested Decision did not contradict the RAC and SEAC Opinion in that regard, and is thus vitiated by an error of law in interpreting the notion of technical feasibility.

b) Error of law in interpreting the notion of economic feasibility

140. The Authorisation Applicant's assessment of the economic feasibility of alternatives, endorsed by the Contested Decision, is based on an erroneous interpretation of the notion of economic feasibility.

141. In the ECHA Guidance on the preparation of an application for authorisation, ECHA 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*".[77] 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.

142. The economic assessments of the alternatives presented in the Applications for Authorisation did not determine whether revenue minus cost would be positive. The Applicant focused on estimating the higher cost and thus higher price of the alternatives and subsequent anticipated drop in market share due to this higher price: "*[the alternative] costs approximately six times more than the pigments it could potentially replace – a more macro level examination of the substitution effect is given in the SEA analysis. Taking into account the [price] elasticities detailed above this would cause a drop in demand of between 20-90% depending on the exact market and replacement.*"[78] This does not mean that the alternatives would not generate gross profit. It only means that the alternatives are estimated to be more expensive.

143. The SEAC endorsed this interpretation and noted for Use 3 for example that the alternatives were "*much more costly*",[79] and that comments received by interested parties "*tend to confirm that the alternatives are, in most cases, more expensive*".[80] The SEAC thus followed the applicant's erroneous interpretation of the notion of economic feasibility based on a pure cost comparison.

144. This interpretation is contrary to the objective of the authorisation process, i.e. to ensure "*that substances of very high concern [...] are progressively replaced by suitable*

[76] Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997, p. 5–13, §36.
[77] ECHA, "Guidance on the preparation of an application for authorisation", 2011, p. 75.
[78] Analysis of alternatives – non-confidential report, Use 3 (Yellow Lead Chromate), pp. 39-41 – Section 4.2.3.1 Bismuth Vanadate PY. 184.
[79] Compiled RAC and SEAC Opinion, Use 3 (Red and Yellow Lead Chromate), p.16.
[80] Compiled RAC and SEAC Opinion, Use 3 (Red and Yellow Lead Chromate), p.16.

alternatives substances or technologies where these are economically and technically viable"[81].

145. This price comparison approach leaves Article 60(5) without any meaning, as no businesses would need to apply for an authorisation if the non-hazardous alternative was cheaper than the substance for which the application for authorisation was sought.

146. The Contested Decision, which endorsed this analysis of the economic feasibility, is therefore vitiated by an error of law.

B.1.3.2. Manifest error of assessment of the information submitted by third parties under Article 64(2)

147. Article 60(4) specifies that: "*The decision shall be taken after consideration of all the following elements [...] (c) the analysis of alternatives submitted by the applicant [...] and any third party contributions submitted*." The Contested Decision was taken in breach of this provision as: a) it failed to take properly into account crucial information submitted during the public consultation; and b) it is vitiated by an error of assessment of certain submissions from downstream users.

a) Failure to take properly into account relevant contributions to the public consultation

148. The Contested Decision did not give sufficient weight to key submissions to the public consultation that unequivocally revealed that technically and economically feasible alternatives are available on the market, and have been for years.

149. For instance, BASF participated in the public consultation and affirmed unequivocally that:[82]

> "*Most of our customers have either successfully converted to lead chromate free formulations or are prepared to do so because they have already worked out alternative recipes, partly even earlier than 2012. Thus the reformulation cost is spent already. [...]*
>
> *Our expectation is that for lead chromate alternatives sufficient production capacities exist worldwide and the components are available broadly. All under Chapter 2 mentioned pigments are available on European and/or global market. Most of the substances are available from more than one manufacturer / supplier.*

[81] Article 55 REACH.
[82] BASF, Third party submission of information on alternatives for applications for authorisation, p.15, available at: <https://echa.europa.eu/documents/10162/18074545/a4a_comment_375_1_attachment_en.pdf>.

> *In the pigment industry, decent paints or plastic parts or other applications are in all known cases formulated at the downstream user with pigment combinations from one or several suppliers rather than with a single pigment. The future recipes thus will consist of different combinations of pigments without usage of [Yellow or Red Lead Chromate]. We, other competitors and even the applicant offer a range of products which, depending on the specific use, contribute to all needs of the [downstream users] in achieving formulations without lead chromate. There is a lot of established experience, especially in substituting [Yellow and Red Lead Chromate] by organic and/or inorganic pigments. [...] Depending on shade and performance lead chromate free formulations could be more cost efficient than lead chromate containing paints and coatings*".

150. The Authorisation Applicant responded to this submission that "*This means that SOME of their customers have not and are unable to transition*"[83]. This response does not contradict BASF's affirmation that alternatives are used by most of their customers, thereby revealing that "*technically and economically feasible alternatives*" have already replaced lead chromates. This unconvincing response echoes the Authorisation Applicant's allegation of the existence of "niche" applications for which Lead Chromates could not be substituted. However, as explained above, if these niche applications exist and require Lead Chromate, the application for authorisation should have been limited to these specific "niche" uses (see §93) as opposed to covering many uses for which it has been shown - and not contradicted by the Authorisation Applicant - that suitable alternatives exist.

151. Akzo Nobel, also highlighted, without ambiguity, the existence of technically and economically feasible alternatives for the uses applied for:[84]

> "*A range of suitable and safer alternatives to lead chromate pigments have been commercially available in the European Union and throughout the world for many years. Examples include:*
> - *Bismuth vanadates*
> - *Mixed metal oxides/iron oxides*
> - *Organic pigments (eg Diketopyrrolo-pyrrole (DPP), azos, Isoindoline, benzimidazolones)*
>
> *These pigments can be used alone, as hybrids or in formulated mixtures with other pigments to obtain the desired coating product characteristics and performance at an acceptable cost. Different formulation solutions are often required for different product types, depending on the end-use involved.*
>
> *Since the complete withdrawal from the use of lead compounds from all products across AkzoNobel at the end of 2011, it is clear that the performance achieved with lead*

[83] "Comments and response to comments on authorisation", applicants reply to comments 370-375 and 380-385 (contributing third party: BASF).
[84] Comments from AkzoNobel on applications made for an authorization under REACH for the use of lead sulfochromate yellow (C.I Pigment yellow) and lead chromate molybdate sulphate red (C.I. Pigment red 104) in industrial and professional coatings, pp.2-4.

chromate-free products has met the requirements of the customers in our markets. In transition we experienced no resistance to the introduction of lead chromate-free coatings from customers, neither have we lost business on account of being free of products containing lead chromate. [...]

On the basis of experience in the markets in which we operate, AkzoNobel maintain that technically effective, economically feasible and safe products are available that do not contain lead chromate pigments.

These products meet our customer requirements, are available globally and include the following uses relevant to the application for authorization:

- *Production of yellow and red colour paste/dispersions for use in manufacture of solvent-based coloured paints*
- *Industrial application of coatings to metal surfaces of non-consumer articles including high grade steel-based products (eg. Piping used in the petrochemical industry, crane arms, agricultural machinery, steel bridges, construction arches and coil coating for roofing, ships and boats).*
- *Professional application of coatings to metal surfaces of non-consumer articles including high grade steel-based products (eg. Piping used in the petrochemical industry, crane arms, agricultural machinery, steel bridges, construction arches, ships and boats).*

As regards coatings used for road marking on public roads, in car-parks and airports we do not believe use of lead chromates is technically necessary and believe that continued use is undesirable from a human exposure and environmental perspective (flaking)."

152. Once again, the Authorisation Applicant responded to this submission by insisting on the existence of "niche" applications and: *"the over whelming response in support of the applicant's application, numbering in the many hundred, provides ample evidence of the need for these pigments in the applications applied for. [...] The respondents are for the most part small to medium sized companies providing a specific product for a niche application. This is the main issue in regards to Akzo's comments*."[85] This does not contradict Akzo's demonstration that technically and economically feasible alternatives exist for the uses applied for and are available on the market. If these downstream users need lead chromate for a "*specific product for niche application*", then the scope of the application for authorisation should have been limited to these specific uses. The alleged "overwhelming" support from downstream users is, in addition, misleading as explained further below (see §§160-165).

153. In addition to the submissions from major and credible actors on the market, it is also worth noting that the comments submitted by downstream users were not given adequate

[85] "Comments and response to comments on authorisation", applicants reply to comments 260-267 and 362-369 (contributing third party: Akzo).

weight in the assessment. For example, Product Markings,[86] a downstream user in the United Kingdom that manufactures and supplies all types of materials for marking roads and car parks, affirmed during the public consultation that: "*There are many viable safe alternatives to red, primrose and yellow lead chromates for roadmarkings. Product markings as a responsible manufacturer has ceased to use them for six months and experienced no problems. […] Plenty of time has been given to find alternatives and if that time has not been utilized then that is the fault of the companies involved. Red alternative PR170 Napthol red is used in preference to lead chromate by many companies at present*."[87]

154. The British Coatings Federation, the UK Trade Association representing the interests of the decorative, industrial and powder coatings, printing inks and wallcovering manufacturers, representing 95% of the UK sales of coatings, inks and wallcoverings, submitted the following comments:[88]

> *"Many of these alternatives have been covered in detail in the DCC Application for Authorisation, but we disagree with their conclusion that lead chromate pigments are irreplaceable. Many of our members have already replaced them in their industrial coatings ranges.*
>
> *Lead Chromates enable clean bright colours of paint and powder coatings to be made, however, they are essentially used to impart colour and are not truly functional pigments. For instance, they do not impart corrosion protection, film preservation or adhesion properties to coatings.*
>
> *We fail to see how lead chromates could be considered 'safety critical'. Whilst the yellow colour offered by lead chromates is recognised as a safety colour, the exact shade of paint is not that important."*

155. Overall, these submissions from the public consultation are unequivocal: technically and economically feasible alternatives exist and have been used to substitute Yellow and Red Lead Chromate. Had these submissions been properly taken into account, they would have led ECHA's committees and the Commission to conclude that it was not "*shown that* [...] *there are no suitable alternative substances or technologies*" within the meaning of Article 60(4).

156. However, SEAC did not draw any conclusions from the submissions from the public consultation and simply summarised them. Similarly, the SEAC merely summarised the Authorisation Applicant's response, without any critical assessment and concluded, without any scientific and technical assessment, that: "*SEAC tends to agree with the*

[86] See, Product Markings, available at <http://www.productmarkings.co.uk/>.
[87] Comments from Product Markings, available at: <https://www.echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/comments-public-consultation-0012-05>.
[88] "Comments and response to comments on authorisation", British Coatings Federation.

applicant that from the perspective of technical feasibility, no suitable alternatives are available".[89]

157. The Contested Decision only concluded that there were "*difficulties in fully ascertaining the lack of technically feasible alternatives*" and, as a result reduced the review period recommended by the SEAC. However, when submissions from the public consultation reveal that technically and economically feasible alternatives are available, the Commission cannot lawfully grant an authorisation without breaching Article 60(4)(c). By ignoring the evidence that suitable alternatives exist for some or all the uses (or functions) covered by the uses applied for the Commission makes the consultation provided by Article 64(2) meaningless. In addition, it breaches Article 60(4) by granting authorisations for uses for which suitable substitutes exist.

158. The Contested Decision is thus vitiated by a manifest error of assessment of the information submitted during the public consultation and breaches as a result Article 60(4)(c).

b) Failure to critically assess certain contributions to the public consultation

159. Article 60(4) provides that "*The decision shall be taken after consideration of all the following elements [...] (c) the analysis of alternatives submitted by the applicant [...] and any third party contributions submitted*." However, that does not mean that the submissions should not be assessed with a critical eye. In that regard, the Contested Decision is vitiated by a manifest error of assessment of certain submissions to the public consultation, i.e. the "*Many hundred EU downstream user comments [...] received supporting the applicant's authorization application*."[90] These submission present obvious flaws that should have caught the attention of the SEAC and RAC and ultimately of the Commission and led to their exclusion from the assessment.

160. First, many of these submissions were submitted by companies that requested to stay anonymous. Anonymity does not seem justified in this case since no confidential information was submitted via the public consultation. The confidentiality creates doubts as to the legitimacy and credibility of these submissions.

161. Second, many of these submissions were very similar in wording and content, which creates even more doubts as to their source, legitimacy and genuineness.

162. Third, if it is true that these comments were submitted in the "several hundred", this does not mean that each submission comes from a different company, nor that these submissions are representative of the opinion of downstream users. When looking at these submissions in detail, this number ("several hundred"), repeatedly mentioned by the

[89] Compiled SEAC and RAC Opinions, Use 3 (Red and Yellow Lead Chromate), pp. 13-16.
[90] "Comments and response to comments on authorisation", applicants reply to comments 370-375 and 380-385 (contributing third party: BASF).

Authorisation Applicant in its applications and response to the submission to the public consultation is misleading. In fact, only 6 companies that submitted comments in support of the Applications for Authorisation, actually, disclosed their name. These companies have in most cases sent several (for some around 10) submissions for each application. There have also been around 150 confidential comments from companies supporting all 12 applications. It is difficult to ascertain how many companies are actually responsible for these 150 comments. If we assume that each anonymous company has submitted the same number of submissions for each application as the 6 companies that disclosed their identity, it seems reasonable to argue that only around 10 companies sent these 150 comments. On this basis, the total number of individual companies that have actually submitted comments in support of the Applications can be estimated at around 16 companies.

163. Fourth, in any event, the main arguments of the comments submitted in support of the Authorisation Application should have been considered irrelevant. In a nutshell, these downstream users argued that the non-lead pigments are not of equivalent performance as the lead pigments and are more expensive. As explained above (see Section B.1.3.1) these arguments are based on an erroneous interpretation of the notion of alternative. In addition, it was consistently raised that if the lead pigments were banned in the EU, it would mean that their company would need to exit the EU market. This argument is irrelevant to the question of whether technically and economically feasible alternatives are available. In addition, it amounts to an illegitimate threat solely aiming at putting political pressures on ECHA's and the Commission's staff, pushing for an erroneous interpretation of the notion of alternative.

164. These numerous submissions from anonymous companies demonstrate that there is resistance in transitioning to safer alternatives, but do not demonstrate that there is a lack of suitable alternatives available. The role of the SEAC is not to weigh the number of supporting statements from third parties but to critically analyse and assess from a scientific perspective the evidence that is presented to it.

165. The SEAC Opinion did not question the legitimacy or relevance of these submissions. The Contested Decision did not either. The Contested Decision is therefore vitiated by a manifest error of assessment of the information submitted by third parties in breach of Article 60(4)(c) and on that ground must be reviewed.

B.1.3.3. Manifest error of assessment of the national rules relating to roadmarkings

a) The alleged obligation at national level to use lead paint for roadmarkings

166. The Application for Authorisation for the use on road markings claimed for example that:

"*pigments that are suitable with a lower content cannot reach the (legally) required yellow spectrum.*"[91]

"several governments require the use of bright yellows and reds in roadmarkings. [...] At this moment only certain countries mandate yellow/red for road safety and this requirement goes hand in hand with a requirement for the markings to be durable, weather fast and on-fading"[92].

167. This allegation raises three issues. First, a requirement to use "bright yellow or reds" does not mandate the use of Lead Chromate.

168. Second, as raised by the Swedish Chemical Authority during the public consultation, the accuracy of these claims is not demonstrated:[93]

> *"1) Airports do not need to use any substances from the candidate list. In 2013, none of the substances on the candidate list was used by Swedavia in the operation of 8 Swedish airports out of 10.*
>
> *2) Long term use of yellow and red paints is not necessary for the safety on public roads. The national legislation on road markings in Sweden requires white paint. Red markings are not normally used.*
>
> *3) Standards and other requirements for road markings are not verified. We were not able to find any references to the national regulations in the application on which the applicant bases the need for authorisation".*

169. In its response to the Swedish Chemical Agency, the Authorisation Applicant stated: "*In the Guide to Airfields Pavement Maintenance from the British (Defence Works Functional Standards), Ministry of Defense (page 134) it is stated that in replacing airfield markings in a similar colour as the original one, Requirements of MOD Specification TS10080 should be followed and "…..yellow paint shall contain at least 27% by mass of lead chromate*"".[94]

[91] Analysis of alternatives – non-confidential report, Use 6 (Yellow Lead Chromate) p. 3, available at: <https://echa.europa.eu/documents/10162/fc5e664d-91a3-4a42-9a39-425219755e65>.
[92] Analysis of alternatives – non-confidential report, Use 6 (Yellow Lead Chromate) p. 26.
[93] KEMI (Swedish Chemical Agency), Comments from the Swedish Chemical Agency on the authorisation consultation no 0012-12, p. 1, available at: <https://www.echa.europa.eu/documents/10162/18074545/a4a_comment_520_1_attachment_en.pdf>.
[94] "Comments and response to comments on authorisation", applicants reply to comments 519 and 520 (contributing third party: KEMI (Swedish Chemical Agency)).

170. However, it is unclear which document the Authorisation Applicant is referring to, as this particular document does not seem to be publicly available. There is also a possibility that the Authorisation Applicant is actually referring to an out-dated guide.[95] The Authorisation Applicant's claim regarding national requirements is therefore not supported by clear reference to national legislation.

171. Third, the fact that no submission in the public consultation was made by the national bodies that allegedly impose the use of lead chromate, casts additional doubts as to the accuracy of the Authorisation Applicant's claim. In any event, ultimately, national standards cannot prevail over EU law.

172. The Contested Decision did not exclude these unsupported claims from its assessment. They may have been taken into account as an "uncertainty" that led to the review period to be shortened. As explained previously, shortening a review period cannot lawfully remedy the flaws of an application for authorisation. These "uncertainties" should have led the Commission to conclude that it was not shown, by the Application for Authorisation, "*that there are no suitable alternative substances or technologies*" in breach of Article 60(4). On this ground, the Contested Decision must be reviewed.

b) The prohibition in some Member States of the use of Yellow and Red Lead Chromate for road marking

173. The Contested Decision acknowledged that: "*the use of the two substances in road marking has been substituted or is prohibited in some Member States.*"[96] However, the Contested Decision granted the authorisation and stated that this authorisation would not apply in Member States where a national measure in force on the date of the Decision prohibits the use of the substances in road marking applications.[97]

174. The fact that Member States banned these substances in road marking is, on its own, sufficient proof that alternative substances, which are technically and economically feasible, exist to fulfil the same function. This contradicts the Authorisation Applicant's demonstration that no viable alternatives exist. The Contested Decision should have concluded that, in view of the national prohibition of these substances, the Authorisation Applicant failed to show "*that there are no suitable alternative substances*" within the meaning of Article 60(4).

175. The Contested Decision is thus vitiated by a manifest error of assessment, and on this ground must be reviewed.

B.3. Breach of the Treaty and general principles of EU law

[95] NBS, Guide to airfield pavement maintenance, Chapter 10 - Maintenance of airfield ground markings, available at: <https://www.thenbs.com/PublicationIndex/documents/details?Pub=MOD&DocID=261578>.
[96] Contested Decision, §9.
[97] Contested Decision, Article 1(4).

B.3.1. Failure to State Reason

176. 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.*"[98]

177. Contrary to this obligation, the Contested Decision does not present an assessment of how the Authorisation Applicant has shown that no suitable alternative exist within the meaning of Article 60(4) and 60(5). The Contested Decision does not detail any assessment of whether the information submitted via the public consultation contradicted or supported the Applications for Authorisation. The Contested Decision merely summarises the conclusions of the SEAC and RAC Opinion without detailing the reasoning that led to the authorisation.[99] The only "assessment" in the Contested Decision relates to the "*uncertainties*" or "*difficulties in fully ascertaining the lack of technically feasible alternatives*"[100].

178. 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*."[101]

179. The Contested Decision lacks logic and contains internal inconsistencies. For example, it is difficult to comprehend how the Contested Decision could conclude that despite the "uncertainties" and "difficulties in fully ascertaining the lack of technically feasible alternatives" the authorisation could be granted. Such an approach undermines the entire authorisation procedure as it is for the applicants to demonstrate that no suitable alternatives exist for all the uses they applied for. It also raises questions, as highlighted in this request for an internal review, as to the accuracy and level of scrutiny that the SEAC has put into discharging its duties foreseen in Article 64(4)(b) of REACH. Therefore, the only legal consequence of these uncertainties is that the authorisation should not have been granted due to the inability of the applicant to prove that suitable alternatives do not exist.

180. The lack of reasoning, and the lack of logic, prevents a proper understanding of the reasons underlying the Contested Decision within the meaning of the case law cited above. Furthermore, the RAC and SEAC Opinion relied upon extensively in the Contested Decision fails to provide any additional clarity. For example, as explained above (§156), the Opinion does not provide sufficient explanation as to why "*SEAC tends to agree with*

[98] Case C-535/14 P, para. 37.
[99] Contested Decision, §§6 and 7.
[100] Contested Decision, §§8-9.
[101] Case T-406/09, para. 28.

the applicant that from the perspective of technical feasibility, no suitable alternatives are available."[102] Instead of assessing the validity of the arguments made in the Applications of Authorisation against the "conflicting comments received" during the public consultation, the SEAC merely summarised these comments and concluded that there was an "uncertainty". In addition, instead of leading to the rejection of the authorisation, this "uncertainty" only led to a shorter review period and conditions being imposed. It is difficult to consider such a conclusion the result of a rational assessment.

181. 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, the Contested Decision must be reviewed.

B.3.2. Violation of the Precautionary Principle

182. 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.[103] 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.[104]

183. In a case relating to the approval of active substances in pesticides in application of Regulation No 1107/2009[105], 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*".[106]

184. 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 raised "*uncertainties*" or "*difficulties in fully ascertaining the lack of technically feasible*

[102] Compiled SEAC and RAC Opinion, Use 3 (Red and Yellow Lead Chromate), p. 16.
[103] Article 1(3) REACH.
[104] Communication from the Commission of 2 February 2000 on the precautionary principle (COM(2000)1 final).
[105] 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.
[106] 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>.

alternatives"[107], the Contested Decision lost sight of the precautionary principle which underpins the authorisation process under the REACH Regulation.

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

B.4 Incompatibility with the Dubai Declaration on International Chemicals Management

186. According to Recital 6 of REACH, the Regulation "*should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai*." The Contested Decision is incompatible with SAICM for the reasons set out below.

187. The Strategic Approach to International Chemical Management ("SAICM") was adopted at the International Conference on Chemicals Management in February 2006 in Dubai to implement the commitments contained in the Johannesburg Plan of Implementation of the World Summit on Sustainable Development ("WSSD"). The Johannesburg Plan of Implementation consists, in particular, in a move towards the eradication of the use of lead, and a commitment to: *"Phase out lead in lead - based paints and in other sources of human exposure, work to prevent, in particular, children's exposure to lead and strengthen monitoring and surveillance efforts and the treatment of lead poisoning."*[108]

188. In recognition of the global emergency caused by the presence of lead in paint, in 2009, the International Conference on Chemicals Management passed Resolution II/4/B and established the Global Alliance to Eliminate Lead in Paint ("GAELP"). The goals and objectives of the GAELP are: "*to prevent children's exposure to paints containing lead and to minimize occupational exposures to lead paint. In this context, the Alliance is committed to efforts that support primary prevention, seeking to reduce or eliminate the conditions that give rise to environmental lead exposure before such exposures can occur. Its broad objective is to achieve the phase-out of the manufacture and sale of paints containing lead and to eventually eliminate the risks that such paints pose*."[109]

189. In other words, within the context of SAICM, the GAELP is an international initiative designed to eradicate the use of lead in paints. In the EU, the REACH Regulation is key to implementing these commitments.

190. The Contested Decision contradicts these international commitments since it allows the use of lead paint in roadmarkings and on "metal surfaces" such as machines vehicles, thus allowing the risk that occupational exposure to lead paint increases.

[107] Contested Decision, §§8-9.
[108] Johannesburg Plan of Implementation of the World Summit on Sustainable Development, §57.
[109] Global Alliance to Eliminate Lead Paint, Business Plan, 24 August 2012, p.2, available at: <http://www.who.int/ipcs/assessment/public_health/business_plan_en.pdf?ua=1>.

191. The Contested Decision argues that: *"This authorisation is not incompatible with the primary goal of the GAELP because the uses applied for do not concern consumers and therefore should not lead to their exposure to the substances. Furthermore, proper control of occupational risks will be ensured via the authorisation conditions."*[110]

192. This statement is erroneous for the following reasons.

193. First, the Contested Decision replicates the erroneous argument set out in the Applications for Authorisation that presents the GAELP as aiming to eliminate only consumer direct exposure to lead, i.e. prevent lead in *decorative* paint. Not only does this approach disregard the overall broad objective to "*promote a phase-out of the manufacture and sale of paints containing lead and eventually to eliminate the risks that such paints pose*"[111], it also completely disregards the information provided in the second foundational document of GAELP, its Business Plan.

194. Although this document also mentions "*a special attention to the elimination of lead decorative paints and lead paints for other applications most likely to contribute to childhood lead exposure*", this cannot be reasonably interpreted as limiting the goal to only decorative or consumer paints. Not only have the EU and its Member States committed to achieving the SAICM goals through the Dubai Declaration, they have also supported the unanimous decisions at the second[112], third[113] and fourth[114] International Conference on Chemicals Management ("ICCM") to endorse resolutions to achieve the global phase-out of lead in paint. None of these resolutions include a limitation on the types of paint, nor did the interventions and discussions leading up to these resolutions included any limitation on the type of paint.

195. Finally, the Authorisation Application and subsequent submissions from the Authorisation Applicant state that their customers need to have access to the lead-containing products to be able to compete on non-EU markets. In low and middle income countries (or countries where lead content of products is not regulated), there is very little distinction between products markets for consumer use and markets for non-consumer use.[115] Therefore, it is naïve to believe that exported lead-containing products, because they officially "do not concern consumers", will not contribute to direct consumer (and *a fortiori* children) exposure at least outside the EU in breach of the EU commitments to achieving SAICM goals.

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[110] Contested Decision §15.
[111] Global Alliance to Eliminate Lead Paint, Operational Framework, 2012, p.3, available at : <http://www.unep.org/chemicalsandwaste/Portals/9/Lead_Cadmium/docs/GAELP/GAELP_operational-framework[1]-FULL-JM131017>.
[112] <http://www.saicm.org/images/saicm_documents/iccm/ICCM2/emerging%20issues/ICCM2%20Outcomes/Emerging%20issues/Omnibus%20resolution%20II_4.doc>.
[113] <http://www.saicm.org/images/saicm_documents/iccm/ICCM3/Meeting%20documents/iccm3%2024/K1283429e.pdf>
[114] <http://www.saicm.org/images/saicm_documents/iccm/ICCM4/Re-issued_mtg_report/K1606013_e.pdf>.
[115] see e.g. <https://www.ncbi.nlm.nih.gov/pubmed/23472856>; <http://thestandard.com.ph/news/metro/207406/-toxic-paints-used-in-schools-.html>.

196. Second, it is inaccurate to affirm that the uses applied for "*should not lead to [consumer] exposure to the substances".* As explained previously (Section B.1.2.), the Contested Decision is vitiated by a manifest error of assessment of the risks to human health and the environment.

197. Third, as highlighted above, one of the priority objectives of the GAELP is to minimize occupational exposure to lead in paints. The authorisation conditions do not ensure such minimization. Indeed these conditions heavily rely on the use of personal protective equipment, which are the least protective mean of controlling exposure to chemicals in the workplace that are foreseen by Article 4 and 5 of the Carcinogens and Mutagens Directive. The RAC expressed its doubts concerning the suitability and effectiveness of the risk management measure proposed. Indeed, in the Minutes of the 30th Meeting of the Committee for Risk Assessment, it was observed that:

"*Several RAC Members raised questions regarding the effectiveness of the personal protective equipment (which seemed to offer unusually high levels of protection), other risk reduction measures described for the different uses in the application for authorisation, as well as combined exposure*."[116]

198. In light of this, the Contested Decision authorising the use of Red and Yellow Lead Chromate in the EU for seven additional years runs contrary to the international commitments made by the EU.

199. According to Recital 6, the REACH Regulation "*should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai*." Although SAICM is a declaration that does not have direct legal effects into EU law, the Contested Decision should have recognized that granting authorisation to uses of lead in paints is not compatible with fulfilling the EU commitment under this international framework. Therefore, for the reasons stated above, the Contested Decision is contrary to the SAICM and must be reviewed.

Brussels, 26 October 2016

[116] Minutes of the 30th Meeting of the Committee for Risk Assessment (RAC-30) 8 – 12 September 2014, p. 20, available at: <https://echa.europa.eu/documents/10162/21961120/rac_30_minutes_en.pdf/7fa6f99d-6c41-4e8f-a24b-ca813a9258dd>.

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SCHEDULE OF ANNEXES

No. of Annexes	Description
1.	ClientEarth articles of association
2.	ClientEarth annual activity report (2015)
3.	ClientEarth annual activity report (2014)
4.	Client Earth legal registration with the national authority
5.	Commission Decision C(2009)3337) dated 27 April 2009
6.	EEB articles of association
7.	EEB annual activity report (2014)
8.	EEB annual activity report (2015)
9.	EEB legal registration with the national authority
10.	ChemSec articles of association
11.	ChemSec annual activity report (2014)
12.	ChemSec annual activity report (2015)
13.	ChemSec legal registration with the national authority
14.	IPEN articles of association
15.	IPEN annual activity report (2012-2015)
16.	IPEN legal registration with the national authority

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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