Draft recommendation of the European Ombudsman in the inquiry into complaint 2186/2012/FOR against European Chemicals Agency Made in accordance with Article 3(6) of the Statute of the European Ombudsman

Recommendation
Case 2186/2012/FOR - **Opened on** 29/11/2012 - **Recommendation on** 12/12/2014 - **Decision on** 16/06/2015 - **Institution concerned** European Chemicals Agency (Draft recommendation accepted by the institution) |

The background to the complaint

1. The complainant, the British Union for the Abolition of Vivisection (BUAV), alleges that the European Chemicals Agency (ECHA) wrongfully refused to give public access to documents relating to proposals for testing of chemicals using animals.

2. ECHA deals with the registration, evaluation, authorisation and restriction of chemicals in compliance with the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (known as the REACH Regulation). The REACH Regulation aims to improve the protection of human health and the protection of the environment through the better and earlier identification of the main properties of chemical substances. In this context, Article 40 of the REACH Regulation requires ECHA to examine proposals for testing of certain chemicals produced in or imported into the EU. Proposals for testing may include tests using animals.

3. If a proposal for testing is submitted to ECHA, ECHA first produces a draft decision which proposes the approval, modification or rejection of the proposal for testing. The company putting forward the proposal (the registrant) then has the opportunity to comment on the draft. The dossier is then sent to the Member States' competent authorities (MSCAs), each of which may comment thereon. Eventually, a decision on the testing proposal is taken by the Member State Committee (MSC) of ECHA.

4. On 21 June 2012 the complainant, in an effort to understand why testing proposals that included tests using animals were approved, asked ECHA to give it public access [1] to certain documents, namely:

1) Draft Decision letters relating to testing proposals for three named chemical substances;

2) Registrant comments relating to the same three substances;

3) MSCA proposals for amendments relating to the three substances;

4) Final decisions and cover letters relating to the three substances;

5) The "compliance check" for a fourth substance (CETIOL CC) discussed at the 19th MSC meeting.

5. ECHA then sent the cover letters and the redacted final decisions referred to in point 4) of paragraph 4 above to the complainant. However, it refused to grant access to the other documents. It sought to justify its decision by arguing that disclosing the documents would give a "misleading picture" of a long and complex scientific discussion with different parties. Further, it argued, disclosure of the documents would undermine the independence of ECHA, MSCAs and the MSC, as it would allow pressure to be put on them.

6. The complainant then made a confirmatory application for access to the draft Decision letters, registrant comments and MSCA proposals for amendments relating to two of the three substances (namely, those relating to ECHA references TPE-D-0000001417-76-06/F and TPE-D-0000001517-74-06/F).

7. ECHA replied stating that releasing the documents would 1) give a misleading picture to those that would not have followed the entirety of the discussion; 2) undermine the independence of ECHA, MSCAs and the MSC; 3) limit the space to think of the MSC; 4) enable Member State positions to be identifiable, including positions that were contrary to the final "unanimous" decision of the MSC (reaching unanimity and compromise would thus, it argued, be more difficult if Member State initial decisions were made public, thus damaging scientific debate); 5) Members (of the MSC) could be subject to external pressure, which could hamper consensus and seriously undermine the MSC's decision-making process; 6) there was no overriding public interest in disclosure since a) stakeholders can take part in non-confidential discussions at the MSC and the complainant has availed itself of that opportunity, b) MSC minutes are subsequently publicised, and c) the complainant was given access to the final decisions and cover letters.

8. The complainant then turned to the Ombudsman.

The inquiry

9. The complainant alleges that ECHA wrongly refused to give public access to documents relating to proposals for testing of chemicals under ECHA references TPE-D-0000001417-76-06/F and TPE-D-0000001517-74-06/F. It claims that the ECHA should give public access to the documents.

10. In the course of the inquiry, the Ombudsman received the opinion of ECHA on the complaint and, subsequently, the comments of the complainants in response to ECHA's opinion. Her services also carried out an inspection of ECHA's file on the case. The Ombudsman's draft recommendation takes into account the arguments and opinions put forward by the parties.

Allegation of failure to give public access to documents

Arguments presented to the Ombudsman

11. The complainant argues that there is no reason to believe that the disclosure of the documents would mislead. If anything, disclosure is likely to throw light on the final decision of ECHA. The complainant adds that it is the final decision of ECHA which gives an incomplete picture, and which therefore misleads. It adds that the complainant, as an expert organisation with many years of experience in animal experimentation, with extensive experience in REACH discussions, can fully understand complicated scientific discussions. The complainant states that access to the requested documents would make it better able to understand what ECHA does. Access would also avoid the public having to guess what happens behind closed doors at ECHA. It added that secrecy makes the public suspicious that ECHA have something to hide and damages public confidence in ECHA's regulatory work.

12. The complainant goes on to argue that even if some persons might be misled by the documents that are disclosed, the disclosure of the documents would not seriously undermine ECHA's decision-making. In this respect, the complainant argued, it is inherent in the public access transparency regime that a person requesting access to documents might not understand the disclosed document. The person might even misrepresent the documents in the public sphere. However, this does not justify refusing to disclose documents. The complainant also said that, in any case, ECHA always has the option to publish, together with the information it releases, whatever explanations or additional information it wishes if it considers that the release of the document would create misunderstandings.

13. The complainant also points out that disclosure is in fact likely to enhance the public's understanding of ECHA's processes and the careful consideration ECHA gives to decisions, especially those requiring animal tests.

14. The complainant adds that if disclosure were to reveal any flaw in ECHA's decision making, public discourse in relation to that flaw would in fact lead to an improvement in ECHA's decision-making.

15. As regards the argument that disclosure would undermine the independence of ECHA, MSCAs and the MSC as result of external pressure being exerted as a result of disclosure, the complainant argues that this argument is misconceived. It points out that it is the very essence of democracy that ECHA should be subject to lobbying by citizens. It refers to Recital 2 of Regulation 1049/2001 which states that "openness enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system. Openness contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in Article 6 of the EU Treaty and in the Charter of Fundamental Rights of the European Union."

16. The complainant thus argues that ECHA should be open to lobbying. It adds that lobbying is likely to be more useful (for ECHA) if it is well-informed.

17. The complainant adds, notwithstanding the above general comments, that lobbying could not be used to influence the specific decisions dealt with by the requested documents since the decision-making process in question has already finished. The only effect of disclosure would be to reveal something which might be the subject of legitimate lobbying in the future, thereby improving the quality of ECHA's decision-making and ensuring that it complies with the REACH Regulation.

18. As regards the ECHA argument that consensus from Member States would be difficult to achieve if Member State positions were made known, the complainant states that the fact that a Member State may be seen to have changed its position in a process is not a bad thing. This simply reflects the fact that science, and toxicology in particular, is complicated. Reasonable toxicologists may disagree as regards what tests are appropriate in particular circumstances. Equally, a person may become convinced by another person's view, and therefore change his/her mind, during a process. The system is working properly, the complainant insists, when dialogue leads to such outcomes. Disagreements about scientific matters are, the complainant argues, both expected and healthy. There is no reason, the complainant insists, why the iterative path which discussions take should be hidden from the public, especially after the decision has been taken, when the participants no longer require a "space to think". Thus, Member State positions should be identified (the complainant, however, does not object to the names of the persons representing identified Member States (MSCA and MSC members) being redacted).

19. As regards the issue of overriding public interest, the complainant makes detailed arguments in relation to a position taken by ECHA in relation to carrying out a particular type of test using animals. The complainant has concerns that these animal tests are unnecessary and contrary to a factsheet previously produced by ECHA (it argues that if the factsheet were followed it would save the lives of 4.5 million animals (the tests use 480 animals per substance). It is in relation to this problem that the complainant wishes to see the documents at issue. It wishes to check if there is anything about the two chemicals which would justify the use of animal tests.

20. In this respect, the complainant argues that there is an overriding public interest in the disclosure of the documents in relation to animal testing. The complainant notes that animal testing is a matter of acute public controversy. While there is, the complainant states, public support for animal testing when it is used to find cures for serious human illness, there is less public support for the use of animal testing when it is used to demonstrate the safety of non-medical chemicals. In this respect, the complainant points out that Article 25 of the REACH Regulation states that animal testing should be a last resort [2] .

21. Finally, as regards the fact that the complainant's representative is allowed to attend the non-confidential part of MSC meetings, the complainant states that the complainant's representative is bound by a confidentiality requirement which prevents her from making public the information discussed in that meeting. Thus, the public's interest in public access is not satisfied by the limited access given to the complainant's representative.

22. In its opinion ECHA, by way of background information, first details the steps of the procedure which is followed when a testing proposal is submitted to ECHA. It says that this procedure and its related decision-making process is characterised by transparency. Disclosure of documents is an important part of this process. It notes that the outcome of consultation with third parties, including ECHA's responses to these consultations, is available on ECHA's website. Further, the Final Decisions are also available, with a link to the corresponding disseminated registration dossiers submitted by the registrant. The minutes of MSC meetings are also published online. Moreover, ECHA states, stakeholders can take part in non-confidential discussions at the MSC. Indeed, it notes, that the complainant has availed itself of such an opportunity. In addition, ECHA states, the complainant could also have access to confidential information through its sister organization (ECEAE - European Coalition to End Animal Experiments), which is an accredited stakeholder that attends MSC meetings regularly.

23. ECHA notes that the Ombudsman posed six questions when opening the inquiry. ECHA was asked 1) to explain why, in light of the specific content of each of the documents at issue, it considers that the disclosure of each document would seriously undermine the ECHA's decision-making process; 2) to explain precisely the nature of the pressure it considers would be placed on the decision-makers who took part in the deliberations at issue, in particular when such deliberations have now ended; 3) to explain why it considers that such pressure would be considered "undue pressure"; 4) to explain precisely how such pressure would "seriously undermine" its decision making process, in particular after the decision at issue has been taken; 5) to provide its views on the arguments raised by the complainant in relation to an overriding public interest in disclosure; and 6) to take a view, in light of its knowledge of the content of the undisclosed documents, on whether there are other public interests which should also be taken into consideration when determining whether there is an overriding public interest in disclosure.

24. In response to the first question, ECHA maintains that the access to the requested documents should be denied on the basis of the second paragraph of Article 4(3) of Regulation 1049/2001, which states that "access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure". It argues that ECHA's decision-making process would be hampered if the documents were disclosed, as the disclosure would shift from decision-making based on the efficient provision of objective scientific and technical advice to decision-making based on policy considerations. In ECHA's view, disclosing such documents would 1) prevent the reaching of a unanimous agreement in the MSC, 2) reduce the quality of debates, and 3) lead to subjective decisions. Indeed, ECHA maintains, ECHA, MSC and MSCAs would, in order to avoid being pressured by interest groups, self-censor. They would discuss the topics on the basis of pre-prepared statements, without any debate.

25. ECHA also says, again, that the disclosure of individual documents would give a misleading picture of a case. Persons examining such documents would not be able understand the outcome of a long and complex scientific discussion. ECHA maintains that

even the complainant itself misunderstood the status of notification letters. ECHA pointed out, in this respect, that such letters have no binding value nor are they part of the final decision.

26. In response to the second question, with regard to the nature of the pressure that the disclosure would exert upon the decision-makers, ECHA argues that such pressure would derive from the fact that the decision-makers would restrict themselves in the debate about a sensitive matter, because of pressure from industry and NGOs.

27. As regards the third question, about the reason why such pressure would be "undue", ECHA says that, in the event of disclosure of the requested documents, the position defended by MSC members would become identifiable, as the list of MSC members is available on ECHA's website. Therefore, the MSC committee members would no longer be free to present their positions and would suffer from pressure by NGOs and interest groups, thus transforming a scientific debate into a political debate.

28. In response to the fourth question, ECHA reiterates that, if committees are not able to propose and discuss frankly the testing proposals on animals, the objective to address adequately the properties of chemicals may not be addressed. As a consequence, the objective of the REACH Regulation (to protect human health and the environment) would be put at risk. Moreover, a decision in one case may cause pressure to be applied on future similar cases. This could endanger the quality and solidity of forthcoming decisions.

29. In relation to the fifth question, about the provision of arguments related to ECHA's claimed lack of an overriding public interest in the complainant's request, ECHA argues that the requested notification letters contain information of a general nature, which does not emanate from the decision-making process on testing proposals. Moreover, notification letters have no binding value. Therefore, the disclosure of notification letters would not add substantively to what was already in the public domain. Furthermore, ECHA considered that the complainant, through ECEAE, has already had access to the required information and, accordingly, there is no overriding public interest served by disclosure of the documents.

30. As regards the sixth question as to whether there were other public interests to be taken into consideration when determining whether there is an overriding public interest in disclosure, ECHA did not identify any.

31. ECHA also states that account should be taken of the interests of MSC members to ensure their own safety and privacy. ECHA states, in this respect, that if the names of MSC members are made public, they could be linked to the opinions they express on animal testing in the MSC. ECHA also refers to the need to protect the interests of registrants. It states that if comments of registrants in support of animal testing are made public, these comments could affect the privacy and safety of individuals in those companies. Further, companies that are associated with animal testing could lose their customers.

32. Finally, ECHA says that the administrative burden involved, if it had to redact the documents in advance of disclosure, would affect adversely its capacity to evaluate the safe

use of substances.

33. In its observations to the Ombudsman on the ECHA's opinion, the complainant states that ECHA has not given any reason why Article 4(3) of Regulation 1049/2001 applies to the request for disclosure of the documents. It maintains that the argument that the requested documents would mislead if disclosed is irrelevant. It insists that the rationale of Regulation 1049/2001 does not encompass ensuring that persons will not be misled by the disclosure of documents. Furthermore, the complainant states, ECHA has not explained why such a risk can exist when the documents are disclosed together and as a whole.

34. The complainant also argues that Article 4(3), second indent of Regulation 1049/2001 is not applicable since the documents were not simply for internal use of the ECHA (the complainant states that the documents emanated from outside ECHA and were shared with persons outside ECHA).

35. The complainant also argues that disclosure can have no effect on the behaviour of the parties taking part in a decision-making process when that decision-making process has already ended. It states that, since the deliberations have ended in this specific decision-making process, no pressure can be exerted on that process. In the complainant's view, ECHA's statements that pressure will be exerted on the decision-making process are merely speculative, unsupported by any evidence and insulting to the integrity of ECHA staff.

36. The complainant adds that MSC and MSCA members take part in a regulatory process by giving scientific advice. The argument that individuals involved in the regulatory process would misrepresent or suppress their true scientific opinion, simply because preliminary documents might become available after the decision-making process, misrepresents the nature of their involvement in the process.

37. The complainant also insists that NGOs and industry representatives, insofar as they engage in lobbying, are actors within the normal democratic process. It added that registrants are free to lobby the Member States with their scientific case. Further, it is difficult to see how documents relating to a different substance could assist a registrant with the evaluation of its own chemical product. Therefore, in the complainant's view, ECHA has given no evidence about how pressure could undermine the decision-making process in question.

38. Furthermore, ECHA's claim that the possibility of later publication could affect the chances of finding a compromise on Draft Decisions within the MSC, in other cases, is similarly without substance: this position neglects to consider that, where there is disagreement which cannot be resolved during the normal decision-making process, ECHA's legislative policy provides that a centralised procedure should be followed, and the decision is taken by the Commission in accordance with Recital 67 of the REACH Regulation.

39. As regards whether there is an overriding public interest in disclosure, the complainant argues that transparency itself constitutes an overriding public interest. It adds that even if a notification letter has no binding value, it does not mean that it is not relevant, especially when it may contain some elements that confirm the importance of the public interest at

stake.

40. The complainant also argues that ECHA has not made any observation on the "Honeywell decision" by the ECHA Board of Appeal [3] , where the Board of Appeal ruled that ECHA had failed to comply with the REACH Regulation's provisions about animal tests. The "Honeywell decision" by the ECHA Board of Appeal demonstrates, in the complainant's view, the relevance of the public interest in access to the requested documents.

41. The complainant states that no EU institution or agency can prevent documents from being disclosed under Regulation 1049/2001 by simply stating that it is willing to disclose other documents..

42. As regards the right to privacy, the complainant argues that MSCA and MSC members perform a public role and that, in any case, there is no risk to their safety. However, the complainant does not oppose the anonymisation of MSCA and MSC members' names. Further, it does not oppose the redaction of any business information in the documents.

The Ombudsman's assessment leading to a draft recommendation

The argument that the release of the document might mislead the public

43. As regards the argument that public disclosure of the documents might mislead the public, the Ombudsman first notes that her services have inspected the documents at issue. On the basis of this inspection, the Ombudsman notes that while the documents are technical, she does not consider that they would be likely to mislead any reasonably well-informed interested person.

44. In any event, the Ombudsman does not consider that the complexity of a document is a justification for refusing to grant public access to that document. It may well be true that certain highly technical documents in the possession of EU institutions might be fully understood only by experts. However, such an eventuality cannot, in isolation, justify refusing to grant public access to such documents. Indeed, the Ombudsman notes, many highly complex documents are published daily by the EU institutions.

45. The Ombudsman notes that, in any event, an EU institution can, if it deems it necessary when it discloses a document, provide, with that document, whatever additional explanations are necessary and useful in order to promote the better understanding of that document. This principle applies to any document the institutions proactively make available as part of their normal communication policy and to any document they make available as a result of a request for public access to documents. In the event misunderstanding persists in relation to a document, and that such a misunderstanding results in pressure (see below) being placed on the institutions concerned, there is nothing to prevent the institutions concerned from clarifying the misunderstanding that has occurred.

46. The Ombudsman believes not only that this argument is wrong, but that invoking it carries the risk that the institution will be seen as appearing both overbearing and paternalistic towards the public.

The decision-making process

47. ECHA's main argument of relevance relates to the protection of its decision-making processes. An institution's decision-making processes may be undermined, during the period before a decision is taken, due to the possibility that third parties will, as a result of having access to the document which will be used by decision-makers to take their decision, exert "undue pressure" on the decision-makers. According to ECHA, that "undue pressure" on decision-makers might be directed at altering the timing (for example, putting undue pressure on the decision-makers to cease deliberating and to take a quick decision) or at altering the content of the decision (for example, by lobbying for alternative outcomes). However, in order to prove that such a risk exists, the institution concerned must provide an explanation which would demonstrate that such undue pressure on decision-makers is reasonably foreseeable, and not purely hypothetical. This explanation should relate not only to the likely existence of undue pressure on decision-makers, but also to the likelihood that such undue pressure on decision-makers would be of such a nature and intensity as to undermine seriously the decision-making process.

48. The release of a document used in a particular decision-making process cannot, after the decision has been taken, give rise to **direct pressure** on decision makers to alter the timing or the content of that specific decision.

49. The requested documents are the following:

1) Draft Decision letters of ECHA relating to testing proposals for two named chemical substances;

2) Registrant comments relating to the draft decision letters;

3) MSCA proposals for amendments relating to the draft decision letters.

50 . The Ombudsman has inspected the documents in question [4] . She can confirm that the information contained therein may indeed be characterised as "opinions for internal use as part of deliberations and preliminary consultations within the institution". The views expressed therein are certainly "opinions". Further, those views were intended to be used, and in fact were used, in the internal decision-making process of ECHA [5] .

51. Having established that the documents contain "opinions for internal use" in the decision-making process of ECHA, it must be examined if the release of the documents, after the ECHA decision making process has ended, would seriously undermine that decision-making process.

52. According to ECHA, access to the requested documents would give rise to a shift, from

decision-making based on the efficient provision of objective scientific and technical advice, to decision-making based on policy considerations. This would, in ECHA's view, reduce the quality of debates and lead to subjective decisions. ECHA maintains that the authors of such documents would self-censor in order to avoid being pressured by interest groups, such as industry interests and NGOs. The authors of such documents would, instead, choose to discuss the topics on the basis of pre-prepared statements, without any debate.

53. The Ombudsman recognises that ECHA must, in order properly to carry out its complex technical role of assessing the hazards of chemical substances, take all the necessary measures to ensure that its decision-making processes are capable of obtaining the full and frank scientific views of those participating in that process. Indeed, the Ombudsman's examination of the documents reveals that the decision-making processes at issue were indeed characterised by a broad and in-depth scientific discussion.

54. The Ombudsman agrees that the issue of animal testing for the purposes of authorising the use of chemicals is a particularly sensitive issue. It is reasonably foreseeable that civil society actors, especially those that have as their primary objective the protection of animals, may seek to put pressure on the ECHA decision-making process for the purposes of ensuring that few or no tests using animals are approved. Further, it is reasonably foreseeable that industry interests may seek to pressure ECHA not to impose an obligation to carry out certain tests on animals, given the additional substantial costs that such tests may imply for an industry.

55. It should be noted that interested parties will seek to impose pressure on the ECHA decision-making process irrespective of whether or not the documents relating to that process are made public.

56. It should also be noted that all pressure from third parties, who seek to engage with ECHA on issues of science alone, is entirely legitimate and useful pressure. Indeed, such pressure can seek to improve the decision-making of ECHA by identifying alternative options that were overlooked, and even errors that may have occurred, in the ECHA decision-making process.

57. As regards the specific case at hand, a careful examination of the various MSCA documents inspected by the Ombudsman leads her to conclude that the Member States concerned may have no objections to its MSCA's proposals for amendments being released. ECHA has not, moreover, produced any evidence that it has consulted with the Member States to determine if they do in fact have concerns as regards the disclosure of the documents [6] .

58. As regards the comments of registrants, the comments express a scientific view on the need for further testing. Even in the event the disclosure of such views would give rise to pressure from third parties, who seek to engage with ECHA on issues of science alone, such pressure is entirely legitimate and useful pressure. Indeed, such pressure can seek to improve the decision-making of ECHA by identifying alternative options that were overlooked, and even errors that may have occurred.

59. As regards the non-disclosure of the Draft Decisions, the Ombudsman sees no reason why ECHA cannot release these documents. She notes that many Draft Decisions may support the use of tests using animals, and may thus give rise to pressure from interest groups. However, the very same comment could be made for many Final Decisions of ECHA, given that these may also support the use of tests using animals. These Final Decisions are, of course, made public, without any fear by ECHA that their publication will give rise to self-censorship on the part of ECHA. It is thus not credible for ECHA to argue that it would self-censor if Draft Decisions are made public after a decision-making process has ended.

60. It must also be underlined that disclosure of such Draft Decisions are vital to the understanding of ECHA's decision-making process, since they reveal the starting point for ECHA's deliberations.

61. The very same points can be made as regards registrant comments, which are also vital to the understanding of ECHA's decision-making process.

62. In light of the above, the Ombudsman will make a draft recommendation in accordance with Article 3(6) of the Statute of the European Ombudsman.
The draft recommendation
On the basis of the inquiry into this complaint, the Ombudsman makes the following draft recommendation to ECHA:

ECHA should disclose the requested Draft Decisions.

ECHA should disclose the registrant comments.

ECHA should disclose the MSCA proposals for amendments.

ECHA and the complainant will be informed of this draft recommendation. In accordance with Article 3(6) of the Statute of the European Ombudsman, ECHA shall send a detailed opinion by 31 March 2015. The detailed opinion could consist of the acceptance of the draft recommendation and a description of how it has been implemented.

Emily O'Reilly

Done in Strasbourg on 12 December 2014

[1] The request for access to documents was made under Regulation 1049/2001 on public access to documents, which is applicable to documents held by ECHA by virtue of Article 118(1) of the REACH Regulation (see OJ L 396, 30.12.2006, p. 1–849). See also Decision on the implementation of Regulation 1049/2001 adopted by the ECHA Management Board on 23 April 2008.

[2] Article 25 of the REACH Regulation states that "in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests."

[3] See Decision of the Board of Appeal of 29 April 2013 in Case number A-005-2011 (available at https://echa.europa.eu/documents/10162/13575/a_005_2011_boa_decision_en.pdf).

[4] The draft decision letters are documents drawn up by ECHA for internal use in the process of deciding on the testing proposals. The registrant comments and the MSCA proposals are documents drawn up by third parties and submitted to ECHA. However, they are nonetheless, "opinions" on a matter under consideration by ECHA (the testing proposals). Further, they will be used, internally, by ECHA for the purposes of assisting ECHA to take a decision on the testing proposals.

[5] The fact that the Draft Decision letters were sent to registrants for comments and to the MSCAs for their deliberations and proposals for amendments, does not alter the fact that the Draft Decisions can constitute "opinions" that are (eventually) used in the context of informing the internal decision-making process of ECHA. These Draft Decisions, along with the registrant comments and the MSCA proposals for amendments, are eventually submitted to the MSC, which is a committee of ECHA in which Member State representatives take part. The MSC deliberates, on the basis of the views expressed in these documents, for the purposes of taking a position on the testing proposals. If the MSC reaches an unanimous decision, ECHA shall take a final decision on the testing proposal (if no unanimous decision is reached, the issue is referred to the European Commission for decision-making under the Comitology procedure).

[6] Neither has ECHA produced any evidence that it has consulted with the registrants concerned to take their views on this issue.