Decision of the European Ombudsman closing the inquiry into complaint 2186/2012/FOR against the European Chemicals Agency

Decision
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) |

EU law requires companies that produce or import chemicals to collect information on the properties and the uses of these chemicals, and to assess if they constitute a risk to humans or the environment. The companies must submit this information to the European Chemicals Agency (ECHA), which evaluates it. ECHA may require further information from such companies, which may involve further tests being carried out, including tests using animals.

The complainant is an animal welfare campaigner. In 2012, it asked ECHA to give it public access to certain documents relating to the decision-making, within ECHA, on whether certain tests using animals were in fact necessary. ECHA refused. It based its refusal to give access to the documents on the fact that publication of the documents would hinder scientific debate within ECHA.

The Ombudsman inquired into the issue and found that the decision-making process in question had already been concluded. The argument that the process could be hindered by publication of the documents therefore appeared unreasonable. She therefore made a draft recommendation that the documents be released. When ECHA agreed to disclose the requested documents, the Ombudsman closed her inquiry.

The background
1. The European Chemicals Agency (ECHA) deals with the registration, evaluation, authorisation and restriction of chemicals in compliance with the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH Regulation). 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.

2. 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 file is then sent to the Member States' competent authorities (MSCAs), each of which may comment thereon. Eventually, the Final Decision on the testing proposal is taken

by the Member State Committee (MSC) of ECHA. This decision must be adopted unanimously.

3. On 21 June 2012, the complainant, an NGO, asked ECHA to give it public access [1] to certain documents in relation to procedures following testing proposals of three chemical substances.

4. ECHA sent redacted versions of some documents 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.

5. The complainant then sought a review (referred to as a "confirmatory application" in the legislation) of the refusal decision in relation to three categories of documents, namely i) Draft Decision letters, ii) registrant comments and iii) MSCAs proposals for amendments relating to two of the three substances.

6. In its reply, ECHA reiterated its previous position. It further argued that the disclosure would "limit the space to think" of the MSC and that reaching compromise and unanimity would be more difficult if opinions of Member States, which differed from the final decision, were to be disclosed. MSC's members would be subject to external pressure which would undermine the decision-making process. Moreover, ECHA argued 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.

7. The complainant then turned to the Ombudsman [2] .

The inquiry

8. The complainant alleged that ECHA wrongly refused to give public access to documents. It claimed the documents should have been disclosed.

9. In the course of the inquiry, the Ombudsman received the opinion of ECHA on the complaint and, subsequently, the comments of the complainant in response to ECHA's opinion. The Ombudsman also carried out an inspection of ECHA's file on the case. She subsequently issued a draft recommendation to which ECHA replied. The complainant provided further observations on ECHA's reply.

Allegation of failure to give public access to documents

10. In its **complaint** , the complainant argued that further disclosure was likely to throw light on the complete assessment. It added that ECHA should welcome lobbying by citizens who should be able to participate in the decision-making process. It insisted that Member State positions should be identified. As to the issue of overriding public interest, the complainant made detailed arguments regarding a position taken by ECHA in relation to carrying out a particular type of test using animals.

11. In its **opinion** , ECHA argued that because of the pressure from industry and NGOs the decision-makers would restrict themselves in the debate if access was granted. The position 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, thus transforming a scientific debate into a political debate.

12. As to the question of an overriding public interest in the complainant's request, ECHA argued that the requested notification letters contain information of a general nature, which do not emanate from the decision-making process on testing proposals. Moreover, since the notification letters have no binding value, their disclosure would not add substantively to what was already in the public domain. Finally, ECHA noted that the interests of MSC members should be taken into account in order to protect their own safety and privacy. Similarly, the interests of the registrants must be protected.

13. In its **observations** on the ECHA's opinion, the complainant reiterated its previous position. As regards the question of whether there is an overriding public interest served by the disclosure of the requested documents, the complainant argued that transparency itself constitutes an overriding public interest. The complainant however noted that it does not oppose the anonymisation of MSCAs and MSC members' names. Similarly, it did not oppose the redaction of any business information in the documents.

14. More details of the above arguments are set out in the Ombudsman's Draft Recommendation. [3]

The Ombudsman's draft recommendation

15. In her **draft recommendation** , the Ombudsman expressed her disagreement with ECHA's argument that the disclosure of documents would create a misleading picture. The Ombudsman further noted that an EU institution can, when it discloses a document, provide whatever additional explanations are necessary and useful in order to promote the better understanding of that document. This can be especially useful when a misunderstanding results in pressure being placed on the institutions concerned.

16. The Ombudsman acknowledged that an institution's decision-making processes may be undermined, during the period before a decision is taken, if third parties were to, 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. 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.

17. On the basis of the inspection of documents, the Ombudsman confirmed that the information contained therein may indeed be characterised as "opinions for internal use as part of deliberations and preliminary consultations within the institution" since they were

intended to be used, and in fact were used, in the internal decision-making process of ECHA.

18. Following this conclusion, it had to be examined if the release of the documents, after the ECHA decision making process has ended, would seriously undermine that decision-making process. The Ombudsman acknowledged that ECHA must, in order to properly 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. She also agreed it was reasonably foreseeable, since the issue of animal testing is particularly sensitive, that civil society actors may seek to put pressure on the ECHA decision-making process. Similarly, 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.

19. However, the Ombudsman pointed out that the 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. She also noted that all pressure from third parties, who seek to engage with ECHA on issues of science alone, is entirely legitimate and useful pressure since it can identify alternative options that were overlooked, and even errors that may have occurred, in the ECHA decision-making process.

20. As regards the specific case at hand, a careful examination of the various MSCA documents inspected by the Ombudsman led her to the conclusion that the Member States concerned might have no objections to its MSCA's proposals for amendments being released. ECHA hadnot, moreover, produced any evidence that it has consulted with the Member States to determine if they did in fact have concerns as regards the disclosure of the documents [4] .

21. As regards the comments of registrants, they 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 a useful one. Indeed, such pressure can seek to improve the decision-making of ECHA by identifying errors that may have occurred and alternative options that were overlooked.

22. As regards the non-disclosure of the Draft Decisions, the Ombudsman concluded there was no reason why ECHA could not release these documents.

23. She also underlined that disclosure of such Draft Decisions was vital to the understanding of ECHA's decision-making process, since they reveal the starting point for ECHA's deliberations and concluded that the very same points can be made as regards registrant comments.

24. The Ombudsman therefore made the following draft recommendation [5] to ECHA:

ECHA should disclose the requested Draft Decisions.

ECHA should disclose the registrant comments.

ECHA should disclose the MSCA proposals for amendments.

25. In its **reply** , ECHA informed the Ombudsman that it had decided to grant access to the requested documents. It had, however, redacted personal data and commercially sensitive data. It also noted that the complainant did not object to these redactions. It added that prior to its decision, it consulted the relevant MSCAs in order to safeguard their rights as a third party author pursuant to Article 4(4) of Regulation 1049/2001. ECHA also consulted the registrants as to their data from the Draft Decisions and the registrants' comments.

26. ECHA also expressed its commitment to the principle of transparency and granting the widest-possible access to its documents. It will therefore undertake third party consultations where necessary. It noted however that due to the sensitivity of its tasks, it must, before any disclosure, and especially in relation to on-going decision-making processes, carry out a careful assessment. It therefore endorsed the Ombudsman's recognition that it must, in order to carry out its complex technical role, take all necessary measures to obtain full and frank scientific views.

27. In conclusion, ECHA agreed that the threshold to refuse access to documents in cases where a procedure had been concluded was higher than in cases where the procedure was still on-going. It consequently argued that it remains entitled to invoke the exemption for the protection of the institution's decision-making process but only under exceptional circumstances.

28. In its **observations** , the complainant agreed that each case has to be approached on its merits. It noted that it was never disputed that access to documents can in some cases be refused even after a decision-making process is concluded. The question in this case, however, was whether the disclosure would seriously undermine the procedure. The complainant further welcomed ECHA's acceptance of the draft recommendation and expressed its agreement on the remarks the Ombudsman made in the draft recommendation.

29. The complainant concluded by expressing its hope that ECHA will continue to act in accordance with the spirit of the draft recommendation in future cases where access to documents has been requested after the decision-making was concluded.

The Ombudsman's assessment after the draft recommendation

30. The Ombudsman thanks ECHA for accepting her draft recommendation to disclose the requested documents.

31. The Ombudsman notes that ECHA has redacted limited information from those

documents. However, she also notes that the complainant does not object to these limited redactions.

32. The Ombudsman acknowledges that in carrying out its important tasks, the monitoring of the safety of chemical substances, ECHA needs independent and high quality scientific advice. However, she insists that scientific advice can only be reliable if it is open to scientific review by others, including academics and specialised third parties, such as NGOs. The disclosure of the documents can therefore be nothing but beneficial to ECHA.

33. The Ombudsman also stresses that the issue of animal testing is highly sensitive. The public must therefore be given the opportunity of assessing, through an appropriate disclosure of documents, whether a fair balance has indeed been struck between guaranteeing the safety of chemicals and protecting the welfare of the animals used for testing.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion:

The European Chemicals Agency has accepted the Ombudsman's draft resolution and taken steps to implement it.

The complainant and the European Chemicals Agency will be informed of this decision.

Emily O'Reilly

Strasbourg, 16/06/2015

[1] The request for access to documents was made under Regulation 1049/2001 on public access to documents (see OJ L 145, 31.5.2011, p. 43–48) 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] For further information on the background to the complaint, the parties' arguments and the Ombudsman's inquiry, please refer to the full text of the Ombudsman's draft recommendation available at: http://www.ombudsman.europa.eu/en/cases/draftrecommendation.faces/en/58553/html.bookmark

[3] See footnote 2.

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

[5] A copy of the Draft Recommendation is available at: