Decision in case 1606/2013/AN on how the European Chemicals Agency applies rules concerning animal testing

Decision
Case 1606/2013/AN - **Opened on** 20/11/2013 - **Decision on** 11/09/2015 - **Institution concerned** European Chemicals Agency (Friendly solution) |

The complaint, made by the European Coalition to End Animal Experiments, concerns the position of the European Chemicals Agency (ECHA) regarding the limiting of animal testing. The complainant disagreed with ECHA's position that it could not reject testing proposals involving animals on the grounds that the data could be generated by an alternative method not involving animal tests. These proposals are submitted to ECHA in the context of the procedure leading to the authorisation of chemical substances to be marketed in the EU in accordance with the REACH Regulation.

The Ombudsman's inquiry concluded that ECHA's interpretation of its role was too strict and did not take into account the fact that the avoidance of animal testing was, together with the protection of human health and the environment, one of the guiding principles of the Regulation. The Ombudsman thus proposed to ECHA (i) that it require all registrants to show that they have tried to avoid animal testing and (ii) that it provide registrants with all the information at its disposal which could allow them to avoid animal testing.

ECHA accepted both proposals. It also stated, however, that it needed to hold further discussions with the European Commission and the competent authorities of the Member States as regards the practical consequences of its acceptance of the first proposal. The complainant expressed doubts in this context. The Ombudsman considered that ECHA had settled the matter but asked it to report on how it had implemented her proposals within six months of the date of this decision. The Ombudsman also invited the complainant to monitor the outcome of this case.

The background
1. The European Chemicals Agency (ECHA) is the EU's specialised agency in charge of the registration, evaluation, authorisation and restriction of chemicals under Regulation 1907/2006 (the 'REACH Regulation') [1] , which aims at ensuring " *a high level of protection of human health and the environment as well as the free movement of substances ...* [and] *also* [at] *promot* [ing] *the development of alternative methods for the assessment of hazards of substances* " [2] . Moreover, the REACH Regulation provides for safeguards intended to minimise new animal testing and to give practical effect to the principle that animal testing should not be performed where it can be avoided, known as the last resort principle.

2. ECHA is responsible for ensuring that registrants have supplied the information required by the REACH Regulation relating to the safety of chemical substances they introduce on the EU market. The information to be supplied depends on the tonnage of the substance that will be placed on the market and is detailed in the annexes to the REACH Regulation. The annexes contain standard requirements as regards the information to be provided through specific tests. However, in some cases, there may be alternatives to the standard information requirements, that is, adaptations which are also listed in the relevant Annex. In addition to these specific rules, a registrant may adapt the standard information requirements according to the general rules provided by the REACH Regulation.

3. Where the data required by the relevant Annexes are not available when the application for registration is made, the registrant needs to submit testing proposals to generate the missing data and thus fill this information gap. ECHA is in charge of evaluating these testing proposals [3] .

4. This decision concerns the results of the Ombudsman's inquiry into (i) the complainant's allegation that ECHA misinterprets its powers under the REACH Regulation by considering that it cannot validly reject an animal testing proposal on the grounds that the data could be generated by an alternative, more animal friendly method; and (ii) its claim that ECHA should align its practice in relation to the issue of animal tests with its published guidance [4] .

5. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.
Alleged wrong position of ECHA concerning the rejection of animal testing proposals

The Ombudsman's proposal for a solution

6. The Ombudsman noted that the REACH Regulation has two main aims, namely, to ensure a high level of substance safety and the avoidance of unnecessary animal testing. It is for the registrants to prove that their substances are safe. In this context, the Ombudsman agreed that it is not ECHA's role to put forward adaptation arguments on behalf of the registrants or identify, in every case, the most appropriate alternative testing method.

7. However, the Ombudsman considered that when ECHA is aware, or can very easily become aware, of the existence of alternative means of generating the missing information without animal testing, ECHA should share any relevant information concerning the potential availability of non-animal testing methods for the substance in question with the registrant. Moreover, ECHA also needs to make sure that registrants have made a genuine effort to put those methods into practice, or to obtain scientifically valid information allowing them to avoid animal testing.

8. The Ombudsman concluded that ECHA's excessively restrictive interpretation of its obligations in the context of evaluating testing proposals was not compliant with the REACH Regulation. She therefore proposed to ECHA that it adopt the following practice:

(i) to systematically require registrants to show that they have considered alternative testing methods [5] **to generate the missing information and have found that the information gap cannot reasonably be filled through such methods; and**

(ii) to share with the registrant any relevant information concerning the potential availability of alternative testing methods for the registered substance. If a registrant does not adopt the non-animal testing method in question, ECHA should require it to explain to ECHA's satisfaction why it does not consider it useful or possible to do so.

9. ECHA replied to the Ombudsman's proposals after consulting the European Commission.

10. As regards the first proposal , ECHA agreed that the REACH Regulation requires registrants to consider alternative methods prior to requesting an animal test. It added that, as a matter of fact, a large proportion of the registration dossiers address the relevant information requirements through other means than vertebrate testing. Although the REACH Regulation does not require registrants to demonstrate that they have considered alternative methods, ECHA agreed that nothing in the Regulation prevents it from requesting registrants to provide this information. It believed that this will further remind registrants of their obligations in this regard.

11. Consequently, ECHA undertook to systematically ask for this information for all new testing proposals involving vertebrate animals submitted after the Ombudsman's decision in this case. ECHA also stated that it intends to publish the information so received on its website when it invites third parties to submit scientifically valid data addressing the substance and risks addressed by the testing proposal.

12. Nevertheless, ECHA warned that, as the Ombudsman acknowledged in her proposal for a solution, it is not its role to put forward adaptation arguments on behalf of the registrants. As such, ECHA is not in a position to assess whether a registrant has adequately considered all viable alternative methods. In addition, ECHA will not be in a position to reject a testing proposal for a standard REACH information requirement on the ground that the registrant has not considered alternative methods. In such cases, the main purpose of the REACH Regulation, which is to safeguard human health and the environment from risks posed by chemical substances, has to prevail.

13. Finally, this new approach should not push registrants to provide invalid adaptations which ECHA can verify only by means of a compliance check [6] .

14. ECHA thus concluded that it needs to hold discussions with the Commission and Member States' authorities with regard to the practical consequences of ECHA's acceptance of the Ombudsman's first proposal. It did not rule out that further measures will need to be implemented, also bearing in mind that the industry needs guidance on the additional information it is required to provide and on how it should do so. ECHA also conveyed the Commission's message that the latter will assess whether this implies changes to the annexes of the REACH Regulation.

15. As regards the second proposal , ECHA stated that it already fully implements it, by sharing all relevant existing information with registrants and providing them with the opportunity to comment on it. If registrants do not take into account scientifically valid information which fully addresses the information gap and do not explain why they believe a test is nevertheless needed, ECHA rejects the testing proposal involving vertebrates. In fact, ECHA stated, it has already rejected such tests on this ground. It has, moreover, made extensive efforts to guide and assist registrants in identifying alternative testing methods, including through an information toolkit available on its website. In any event, registrants can at any time submit a valid adaptation to address the information gap, even after ECHA has validated the testing proposal.

16. The **complainant** rejected ECHA´s reply and considered that, in fact, it amounted to a false acceptance of the Ombudsman's proposal.

17. With regard to the first proposal , the complainant considered that ECHA placed unjustified barriers in the path of its effective implementation. The complainant argued that ECHA needs to reject a testing proposal if the registrant has not considered alternative methods. ECHA is also in a position to assess whether the registrant has considered all viable alternative methods. Moreover, the need to fill a data gap in order to demonstrate substance safety cannot entitle a registrant to submit a non-compliant testing proposal and does not entitle a registrant to perform animal tests without approval in order to submit a complete dossier to ECHA. Finally, the complainant argued that neither discussions with Member States and the Commission, nor changes to the annexes of the REACH Regulation by the latter are needed in order to implement the Ombudsman's proposal for a solution.

18. With regard to the second proposal , the complainant believed that the acceptance was insufficient as it referred to existing information filling the data gap in question, instead of the " *potential availability of alternative testing methods* ", as the Ombudsman required.

19. The complainant thus requested the Ombudsman clearly to " *set out what would, and what would not, constitute implementation of the solutions* ".

The Ombudsman's assessment after the proposal for a solution

20. The Ombudsman's proposal for a solution was the result of a thorough assessment of the legal context in which ECHA and registrants operate under the REACH Regulation. That assessment is clearly and fully laid down in the Ombudsman's proposal document.

21. Concerning the second proposal , the Ombudsman understands that the actions which ECHA listed as examples of how it is already implementing that proposal are indeed merely examples. There is nothing to suggest that ECHA intends to limit its information obligations towards registrants to existing information which fully fills in the identified data gap, and to ignore the Ombudsman's proposal that it share with registrants " *any relevant information concerning the* **potential availability** *of alternative testing methods* ."

22. Consequently, the Ombudsman considers that ECHA has accepted her second proposal and thus settled the matter.

23. Concerning the first proposal , as summarised in paragraphs 6 and 7 above, the Ombudsman's approach was based on the finding that the REACH Regulation has two objectives, namely, the protection of human health and the avoidance of animal testing. While it is undoubted that the first objective is the most important one, this does not mean that the second one can arbitrarily be disregarded. On the contrary: as the REACH Regulation stands, ECHA needs to ensure that no animal testing takes place if the protection of human health can be demonstrated without it. This means that ECHA must request registrants to show that they have tried to achieve both aims, and could not **reasonably** do so; it also means that if an applicant does not show that it considered alternative methods to generate the missing data, ECHA must reject the application.

24. ECHA stated, in its reply, that it is " *prepared to accept both... proposals... with the understanding that the first point... may subsequently involve the possible stepwise implementation of further measures* ." The Ombudsman understands that ECHA's intention was to accept her first proposal for a solution in a meaningful way. ECHA must be aware that requesting the relevant information from the registrants, without drawing any conclusions if it is not provided is a useless exercise [7] . Similarly, it would be absurd for ECHA to grant prior authorisation for the performance of an animal test under Article 40 of the REACH Regulation (which does not explicitly oblige ECHA to verify whether the information submitted by registrants fulfils the requirements of the last resort principle), when it would not subsequently validate such a test in the context of Article 41 [8] (which explicitly obliges ECHA to verify compliance with the last resort principle).

25. Normally, the Ombudsman would continue her inquiry into this case by requesting ECHA to clarify whether it endorses the above considerations. However, in the spirit of good cooperation which ECHA has shown throughout this and other recent inquiries, the Ombudsman is willing to provisionally accept that it has endorsed them. This will also avoid delays in the implementation of the proposals, which ECHA stated would begin as soon as the Ombudsman has taken a decision on this case.

26. The Ombudsman therefore considers that ECHA has accepted both her proposals. However, in order to implement the first proposal, further measures may need to be adopted and the Ombudsman trusts that ECHA will take all the necessary steps to do. The Ombudsman therefore closes the case but invites ECHA to inform her, within six months of the date of this decision, of its position on the matter in order to enable her to review the progress made. The Ombudsman also invites the complainant to monitor ECHA's implementation of its commitments in this case. In light of the feedback received, the Ombudsman will consider whether it is appropriate to open a new inquiry.

Conclusion

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

ECHA has accepted the Ombudsman's proposals for a solution. However, in order to implement the first proposal, further measures may need to be adopted and the Ombudsman trusts that ECHA will take all the necessary steps to do so. The Ombudsman therefore invites ECHA to inform her, within six months of the date of this decision, of its position on the matter in order to enable her to review the progress made.

The complainant and ECHA will be informed of this decision.

Emily O'Reilly Strasbourg, 11/09/2015

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 L 396, p. 1.

[2] Recital 1 of the REACH Regulation.

[3] 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 friendly solution proposal/draft recommendation available at: http://www.ombudsman.europa.eu/cases/correspondence.faces/en/60890/html.bookmark

[4] The complainant's other allegation, according to which ECHA's practice in approving or rejecting animal testing proposals does not follow its published guidance, was dismissed at an earlier stage of the inquiry, following ECHA's withdrawal of its 2007 Guidance on Dossier and Substance Evaluation, to which the first allegation and the claim referred.

[5] That is, read-across or any other method which takes into account the " *3R principle* "— namely, it does not use animals (replacement), uses fewer animals than proposed (reduction), or causes them less suffering (refinement).

[6] See Article 41 of the REACH Regulation.

[7] This does not require ECHA to create adaptation arguments on behalf of registrants, but to use the knowledge already in its possession, if any, and the information provided by the registrant, to decide whether the latter has fulfilled its obligations to consider alternative methods.

[8] See ECHA's undertakings in case 1568/2012/AN, referred to in paragraph 19 of the

Ombudsman's proposal for a solution. In her proposal for a solution concerning complaint 1568/2012/(FOR)AN, the Ombudsman found that, in the context of compliance checks of registration applications — the other main category of checks that ECHA performs — Article 41(1) of the REACH Regulation explicitly obliges ECHA to verify whether the information submitted by the registrants fulfils the requirements of the last resort principle enshrined in Article 13(1). As regards the evaluation of testing proposals, Article 40 of the REACH Regulation is not as explicit, as it does not specifically refer to either Article 13(1) or 25(1) of the Regulation (which both refer to the last resort principle) as a parameter of evaluation.