European Ombudsman

Proposal of the European Ombudsman for a friendly solution in the inquiry into complaint 1606/2013/(FOR)AN against the European Chemicals Agency (ECHA)

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

Made in accordance with Article 3(5) of the Statute of the European Ombudsman [1]

The background to the complaint

1. The complainant, a group of NGOs, complained against the European Chemicals Agency (ECHA). ECHA is the EU specialised agency in charge of the registration, evaluation, authorisation and restriction of chemicals under Regulation 1907/2006 (the 'REACH Regulation') [2] , 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* " [3] . 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 [4] have supplied the information required by the REACH Regulation relating to the safety of chemical substances which are produced in or imported into (in other words, marketed in) the EU. 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 [5] . The default position is that (i) the tests listed in the first column of the relevant Annex, which contains the standard information requirements, need to be carried out in order to demonstrate that the substance is safe. However, in some cases, there may be alternatives to the standard information requirements ('adaptations'): a registrant may (ii) rely, where appropriate, on the adaptations listed in the second column of the relevant Annex, which contains specific rules allowing for the required standard information to be omitted, replaced by other information, provided at a different stage or adapted in another way. In addition to these specific rules, a registrant may (iii) adapt the standard information requirements according to the general rules in Annex XI.

3. Where the data required by Annexes IX and X [6] are not available at the time that the application for registration is made, the registrant needs to submit in its registration dossier testing proposals to generate the missing data and thus fill this information gap. The REACH Regulation entrusts ECHA with the evaluation of such testing proposals [7] .

4. This complaint concerns the complainant's and ECHA's divergent interpretations of ECHA's obligations in assessing testing proposals.

The inquiry

Allegations and claim

5. On 20 November 2013, the Ombudsman opened an inquiry into the complaint and identified two allegations, namely, that (i) ECHA's practice in approving or rejecting animal testing proposals does not follow its published guidance, and (ii) 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. The inquiry also focused on the claim that ECHA should align its practice in relation to the issue of animal tests with its published guidance.

Admissibility issues

6. ECHA questioned the admissibility of the complaint. It argued that the complaint did not concern ECHA's behaviour, but a conscious choice of the EU legislator, which decided to place the burden of proof in registration procedures on applicants in order to " *better allocate authorities' resources and ... to hold manufacturers and importers responsible for the chemical substances* ". The complainant wishes ECHA to interpret its powers in dossier evaluation procedures " *in a way that would undo the reversal of the burden of proof* ".

7. Based on the definition approved by the European Parliament, maladministration occurs when a public body fails to act in accordance with a rule or principle binding upon it. The Ombudsman understands the complaint to concern ECHA's interpretation of its own competences under the REACH Regulation, which is a concrete rule binding upon the Agency. Based on this understanding, which nothing in the file contradicts, the Ombudsman considers that the complaint is clearly admissible.

Scope of the Ombudsman's assessment

8. During the inquiry, ECHA withdrew its 2007 Guidance on Dossier and Substance Evaluation, to which the first allegation and the claim referred. The Ombudsman, therefore, will no longer

take a position on that allegation and claim as such, since they have become devoid of purpose. However, the underlying issue concerning the approach ECHA should adopt in assessing the applicants' animal testing proposals will, in any event, be addressed in relation to the complainant's second allegation.

9. The Ombudsman's friendly solution proposal follows the submission of ECHA's opinion on the complaint and the complainant's observations in response to ECHA's opinion. It takes into account the arguments and opinions put forward by the parties during the inquiry.

Legal framework—the REACH Regulation

The relevant provisions of the Reach Regulation are the following.

Article 1 *Aim and scope*

" *1. 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...* "

Article 5 *No data, no market*

" *substances ... shall not be manufactured in the* [EU] *or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required* ."

Article 6 *General obligation to register substances...*

" *1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance ... in quantities of one tonne or more per year shall submit a registration to* [ECHA]".

Article 10 *Information to be submitted for general registration purposes*

" *A registration ... shall include all the following information:*

(a) a technical dossier including: (i) the identity of the manufacturer(s) or importer(s) ...; (ii) the identity of the substance ...; (iii) information on the manufacture and use(s) of the substance ...; (iv) the classification and labelling of the substance ...; (v) guidance on safe use of the substance ...; (vi) study summaries ...; (vii) robust study summaries ...; [...] *(ix) proposals for testing where listed in Annexes IX and X;* [...]

(b) a chemical safety report ...".

Article 12 *Information to be submitted depending on tonnage*

"1. *The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that*

provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant, and as a minimum the following: [...]

(d) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;

(e) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer ."

Article 13 *General requirements for generation of information on intrinsic properties of substances*

" *1. Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods ... Testing in accordance with ... Annex IX and Annex X may be omitted where justified by information ... as specified in Annex XI, section 3.* "

Article 25 *Objectives and general rules*

" *1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort ...*"

Article 40 **Examination of testing proposals**

" *1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance.*

2. Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit ... scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with paragraph 3.

3. On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions...:

(a) a decision requiring the registrants ... to carry out the proposed test ...;

(b) a decision in accordance with point (a), but modifying the conditions under which the test is

to be carried out;

(c) a decision in accordance with points (a), (b) or (d) but requiring registrant(s) ... to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;

(d) a decision rejecting the testing proposal; ...

4. The registrant or downstream user shall submit the information required to the Agency by the deadline set. "

Alleged wrong position of ECHA concerning the rejection of animal testing proposals

Arguments presented to the Ombudsman

10. The complainant takes the view that ECHA should reject animal testing proposals when other data about the safety of the substance are available and can be used ("read-across"), or when data could be generated by an alternative 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). The complainant strongly disagrees with ECHA's position that it can reject testing proposals only when the exact information is already available or that information is not required for the tonnage of substance that will be marketed.

11. The complainant emphasised that avoiding animal testing is a key principle of the REACH Regulation, clearly enshrined in its Articles 13(1) [8] and 25(1) [9] . In its view, ECHA's restrictive interpretation of its powers following an animal testing proposal is wrong and contradicts both these Articles and the spirit of the REACH Regulation. In accordance with Article 40(3)(a) of the Regulation, when ECHA agrees with a testing proposal, it must require the registrants to perform the relevant tests. This means that, unless ECHA uses its powers carefully, it might end up requiring registrants to perform animal tests which are banned by the REACH Regulation. Such tests might also be contrary to the Directive on animal experiments [10] .

12. The starting point of ECHA's view is that, in adopting the REACH Regulation, the legislator intended to reverse the burden of proof for demonstrating the safety of substances and place it on the registrants. In accordance with Annex VI of the REACH Regulation [11] , before submitting a registration application, the registrants need to have: (1) gathered and shared existing information; (2) considered information needs; and (3) identified information gaps. Steps 2 and 3 require the registrants to identify alternatives to carrying out new tests. If no alternative is identified, they need to (4) submit a testing proposal, which will be assessed by the ECHA.

13. ECHA will verify whether the information that would be generated through the proposed tests is needed, and will also assess the appropriate conditions of testing. But it cannot take over the responsibility of registrants to adapt standard information requirements. The introductory paragraph of Annex XI to the REACH Regulation clearly provides that "[...] *a registrant may adapt the standard testing regime ... the Agency may assess these adaptations to the standard testing regime* ." Otherwise, contrary to the legislator's intentions, the burden of proof that has been placed on the registrants would be on ECHA. ECHA stated that its Board of Appeals and the European Commission support its view.

14. ECHA added that the fact that it is not required to perform a full assessment on behalf of the registrants is also illustrated by Article 40(2) of the REACH Regulation, which provides that third parties may submit scientifically valid information and studies addressing the relevant information gaps. If this is done, ECHA will take the third-party information into account. However, the party submitting such information might not have granted permission for the registrant to use it, or might not have submitted all the information ECHA needs to ascertain whether the information is sufficient to fill the information gap. In such cases, ECHA can inform the registrant of the information received, but it is up to the registrant to see whether it can gain access to the full information and/or whether it is sufficient.

15. Finally, ECHA acknowledged that registrants may not always fulfil their obligations to identify an adaptation before making a testing proposal. This, however, does not mean that ECHA should take over their responsibility to identify an adaptation. In any event, even after ECHA has issued a decision allowing for a test to be performed, the registrant can, although belatedly, identify a possible adaptation and submit it to ECHA for consideration. ECHA will consider this deviation acceptable.

The Ombudsman's preliminary assessment leading to the friendly solution proposal

16. It is undisputed that the REACH Regulation has two main aims: the first is to ensure a high level of substance safety, while the second is to reduce unnecessary animal testing. The second aim is clear from the Preamble to the Regulation, and even clearer from Articles 13(1) and 25(1). In particular, Article 25(1) states that testing on vertebrate animals for the purposes of the REACH Regulation is to be undertaken only as a last resort. It follows from the generic wording of this Article that the legislator intended to make animal testing in any context governed by the Regulation, including testing proposals, subject to the last resort principle.

17. It is also undisputed that the REACH Regulation significantly changed the previous system of registration of chemical substances, by placing on the registrants the burden of proving that their substances are safe, instead of requiring public authorities to justify that they may not be. Consequently, ECHA does not have to, and should not, take the place of the registrant in assessing what information is needed to demonstrate the safety of substances and how such information can be best obtained.

18. The Ombudsman, however, does not share ECHA's view that, since the burden of proof has been placed on the registrants, ECHA should not verify whether testing proposals comply with the last resort principle. Although the two issues are related, the procedural requirement concerning the burden of proof of the safety of substances is a different issue from that of the obligation to avoid animal testing. A registrant may very well prove that its substance is safe, thus discharging its burden of proof, while completely disregarding the last resort principle. Such a course of action, while compliant with the procedural requirements of the REACH Regulation, would blatantly contradict its aims. If, as it contends, ECHA had no role to play in assessing whether testing proposals submitted by registrants respect the last resort principle, the second aim of the REACH Regulation would be little more than a dead letter. This conclusion is not altered by the fact that national authorities are, as argued by ECHA, entrusted with imposing penalties for breaches of the REACH Regulation [12] : it is highly unlikely that any national authority would ever consider that a test not only approved, but also requested by ECHA, is not in accordance with the Regulation.

19. In her friendly solution proposal on 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 last resort principle enshrined in Article 13(1). As regards the evaluation of testing proposals, the Ombudsman notes that 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 as a parameter of evaluation.

20. Nevertheless, the Ombudsman considers that ECHA's obligations as regards respecting the last resort principle are the same when it evaluates testing proposals. In fact, this principle applies to the entire REACH system.

21. On the one hand, Article 40(3)(c) of the REACH Regulation allows ECHA to reject a testing proposal that does not comply with Annexes IX, X and XI, while requesting the registrant to perform additional tests. Annexes IX, X and XI contain not only the standard information requirements, but also the possible adaptations to them, as well as the general conditions which need to be fulfilled for the standard information requirements to be adapted. This means that a testing proposal might not comply with those Annexes in two ways: the first, if the registrant proposes an alternative testing method that does not fulfil the conditions in the Annexes allowing the standard requirements to be departed from; or the second, if the registrant ignores the possibility of demonstrating the safety of a substance by alternative means (adaptations), even though this would be possible in the given case. In both situations, Article 40(3)(c) enables ECHA to reject the non-compliant proposal and to request that another proposal be submitted; one which, it goes without saying, complies with the relevant Annex.

22. On the other hand, registrants that intend to market a substance in quantities of 100 tonnes or more per year need to make testing proposals only if they identify an information gap which needs to be filled. However, in some cases there may be no gap, and thus registrants will be able to submit a complete dossier to ECHA from the very beginning. Such a dossier will not be subject to the evaluation of testing proposals, but instead be subject to compliance checks

under Article 41 of the REACH Regulation. In complaint 1568/2012/(FOR)AN, the Ombudsman has already stated that, in that context, ECHA must verify whether the information submitted fulfils the last resort principle. The Ombudsman sees no logical or practical reason for some registrants to be exempted from ECHA's scrutiny as regards compliance with that principle, while others are not exempted, bearing in mind that the obligation enshrined in Article 25(1) of the Regulation applies to everyone without exception.

23. Nevertheless, the Ombudsman agrees 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. This is neither feasible in terms of the available resources and the deadlines under the REACH Regulation, nor respectful of the regulation's intentions to free public authorities from the excessive burden they bore in the past. As the complainant put it in its observations, " *in no case... would* [ECHA] *be expected to conduct its own research to see whether an adaptation could be created, still less to create a read-across.* [ECHA] *'s role is a reviewing one* **."**

24. As mentioned in the Ombudsman's friendly solution proposal in complaint 1568/2012/(FOR)AN, which ECHA accepted on 30 September 2014, ascertaining whether there is an alternative method to obtain the relevant information is a complex task which requires extensive technical, scientific and even market knowledge. Despite its immense expertise in the chemicals industry, ECHA's specific knowledge of a particular substance and of the tests that could be performed in order to prove its safety, is necessarily less than that of the registrant, which has been, or has direct access to the entity having been, involved in its development. **It is for the registrants to show to ECHA, upon request, that before proposing animal testing, they have considered other methods to generate the missing information and have found that the gap cannot reasonably be filled through such methods.**

25. While it is true that no specific REACH provision requires registrants to provide this sort of information, it is also true that nothing prevents them from doing so. A diligent registrant that has fulfilled its obligations under REACH, including the obligation to undertake animal testing only as a last resort for the purposes of the REACH Regulation, will necessarily be able to show why it believes that no adaptation argument satisfactorily fills the information gap.

26. It may be that, in some cases, ECHA is aware, or can very easily become aware, of the existence of alternative means of generating the missing information which would not require animal testing. This might be the case when third parties, either with their own registration applications or following the publication by ECHA of the testing proposal under evaluation, submit to ECHA information showing that there is a validated alternative testing method to the animal test proposed, or that a read-across has been accepted for the substance in question. **ECHA should share any relevant information concerning the potential availability of non-animal testing methods for the substance in question with the registrant, which should take a position on whether it intends to adopt the non-animal testing method in question or explain, to ECHA's satisfaction, why it does not consider it useful or possible to do so.**

27. The Ombudsman notes that ECHA already takes steps in this regard at present, by conveying to registrants the information which it has received from third parties and which might suggest that animal testing may not be justified. ECHA might build on this constructive practice in order to implement the above suggestions, at the very least by verifying the follow-up that registrants have given to the information. It is not sufficient to inform a registrant that other testing methods might be available for the substance in question. 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. Otherwise, it would be pointless to inform registrants of other testing methods in the first place.

28. The above suggestions do not require ECHA to " *take over the responsibility from registrants to adapt standard information requirements* ", but allow it to verify that registrants have exercised their responsibility in a reasonable way and have complied with their obligations under the REACH Regulation.

29. The Ombudsman thus makes the preliminary finding that ECHA's excessively restrictive interpretation of its obligations in the context of evaluating testing proposals may not be compliant with the REACH Regulation. This might constitute maladministration, and the Ombudsman will make a friendly solution proposal below, in accordance with Article 3(5) of the Statute of the European Ombudsman.

The proposal for a friendly solution

Taking into account the above findings, the Ombudsman proposes that ECHA adopt the following practice:

(i) to systematically require registrants to show that they have considered alternative testing methods [13] 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.

Emily O'Reilly European Ombudsman Strasbourg, 08/10/2014

[1] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

[2] 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.

[3] Recital 1 of the REACH Regulation.

[4] A registrant is the person submitting a registration for a substance with ECHA (Article 3, definition 7 of the REACH Regulation).

[5] The tonnage will determine which of Annexes VII to X to the REACH Regulation will apply.

[6] Substances marketed in quantities of at least 100 tonnes and 1 000 tonnes per year, respectively. There is no need to submit testing proposals for substances governed by Annexes VIII and VIII.

[7] Article 40(1) REACH: " *The Agency shall examine any testing proposal set out in a registration* ..."

[8] " *Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods...* "

[9] " *In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort* ..."

[10] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

[11] Annex VI: " *Guidance Note on fulfilling the requirements of Annexes VI to XI* ".

[12] Under Article 125, Member States shall maintain a system of official controls. In accordance with Article 126, they shall lay down the provisions on penalties applicable for infringement of the provisions of the REACH Regulation.

[13] 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).