Afgørelse i sag 1568/2012/AN - Unødvendige dyreforsøg udført af registranter af kemiske stoffer

Afgørelse
Sag 1568/2012/AN - **Indledt den** 19/09/2012 - **Afgørelse af** 11/12/2014 - **Den vedrørte institution** Det Europæiske Kemikalieagentur (Løst af institutionen) |

Sagen, som blev anlagt af PETA, omhandlede omfanget af Det Europæiske Kemikalieagenturs (ECHA's) beføjelser og pligter i henhold til REACH-forordningen. Klageren mente ikke, at ECHA gør nok for at sikre, at registranter af kemiske stoffer undlader at udføre unødvendige dyreforsøg for at påvise, at deres stoffer er sikre.

Ombudsmanden undersøgte sagen og konstaterede, at ECHA's fortolkning af sine forpligtelser faktisk var meget restriktiv. Ombudsmanden fremsatte derfor et forslag til en mindelig løsning over for ECHA vedrørende agenturets rolle samt det samarbejde, det burde iværksætte med medlemsstaternes myndigheder. Ombudsmanden var tilfreds med ECHA's svar og lukkede sagen.

The background
1. The complainant is an animal protection charity. ECHA is the EU specialised agency in charge of the registration, evaluation, authorisation and restriction of chemicals under Regulation 1907/2006 (REACH) [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 enforce the principle that animal testing should not be performed where it can be avoided (the 'last resort principle').

2. In June 2011, following the publication of an ECHA report concerning animal testing, the complainant identified a series of animal tests which might not comply with the last resort principle. The complainant had an extensive exchange of correspondence and several meetings with ECHA in that regard. The complainant's position was that ECHA should ensure follow-up of the relevant cases in order to check compliance with the REACH Regulation. ECHA believed that the tests in question were not necessarily performed in violation of the REACH requirements. ECHA explained that it was evaluating a number of those cases and, if it concluded that new tests should not have been performed, it would send a request for clarification to the registrants. ECHA had also completed checks in a number of dossiers which did not show any non-compliance. ECHA, however, could not assure the complainant that it would check all the relevant cases, as this depended mainly on resources and prioritisation of cases.

3. The complainant turned to the European Ombudsman with the following allegations and claims:

Allegations:

(i) When conducting detailed evaluations of selected dossiers, ECHA fails to evaluate properly whether the " *last resort* " principle has been applied.

(ii) ECHA allows and even rewards the use of illegal animal tests, by accepting data resulting from animal tests which are potentially non-compliant with the REACH Regulation.

(iii) ECHA does not apply correctly the provisions of the REACH Regulation (and potentially Directive 2010/63/EU) concerning animal testing requirements and it thereby fails to fulfil some of its specific responsibilities under EU law.

Claims:

(i) The compliance check should include an evaluation of compliance with the requirements of Articles 13 and 25 and Annexes VI and XI to the REACH Regulation.

(ii) ECHA should reject dossiers containing avoidable animal tests on the ground that they infringe EU law. Effective evaluation would require ECHA to develop clear and regularly updated guidance for registrants and its own staff about what would constitute a breach of the requirements of Articles 13 and 25 for any given information requirement. In the event that any non-compliance is identified, competent Member State enforcement authorities must be informed.

(iii) Wherever IT tools identify evidence of possible breaches of Articles 13 and 25 of the REACH Regulation (for instance, when the test study dates are subsequent to the validation of alternative methods and when testing is conducted without prior testing proposals where these are required), steps should be taken to investigate the reasons for non-compliance. If evidence of non-compliance is found, competent Member State enforcement authorities must be informed.

4. On 19 June 2014, the Ombudsman made a friendly solution proposal to ECHA [3] . ECHA replied on 30 September 2014, and the complainant sent its observations on ECHA's reply on 31 October 2014. The Ombudsman's decision takes into account all the elements submitted by the parties during the inquiry into this case.
The Ombudsman's friendly solution proposal and the parties' reaction

First allegation and claim: Scope of compliance checks

5. Article 41 of the REACH Regulation mandates ECHA to perform compliance checks of registrations in order to verify that dossiers comply, among others, with Article 13 of the same Regulation. Article 13 requires in imperative terms that " *for human toxicity, information* shall *be generated whenever possible* by means other than vertebrate animal tests, through

the use of alternative methods ." (emphasis added)

6. The Ombudsman considered that the inclusion of Article 13 of the REACH Regulation in the parameters for compliance checks under Article 41(1)(a) shows that such compliance checks are meant to verify whether the information submitted by registrants was generated in full compliance with the last resort principle, as laid down in Article 13 of the REACH Regulation. This verification takes place in two steps: first, ECHA needs to establish whether the information provided by a registrant was obtained through animal tests. If it was, ECHA needs to ascertain whether there was another means of obtaining the information that was generated through animal tests.

7. The Ombudsman further considered that it is for the registrants to demonstrate to ECHA, upon request, that the data obtained though animal testing could not reasonably have been obtained though alternative methods. Moreover, Article 41(3) of the REACH Regulation provides for a clear procedure through which ECHA can require registrants to clarify if their information is compliant and, if necessary, complete their registrations with compliant data.

8. Consequently, the Ombudsman's friendly solution proposal encouraged ECHA to acknowledge that:

" **1. ...** *under Article 41 of the REACH Regulation compliance checks are meant to verify whether the information submitted by registrants was generated in compliance with Article 13 of the REACH Regulation, which requires the information to be generated whenever possible by means other than vertebrate animal tests, through the use of alternative method;*

2. ... pursuant to Article 41(3) of the REACH Regulation, ECHA can require registrants to (a) clarify whether the information they submitted complies with all the necessary requirements and (b) if necessary, complete their registrations with compliant data within the deadline set by ECHA; "

9. In its reply, ECHA fully accepted point (2) of the above friendly solution proposal. The complainant, in its observations, made no specific reference to this.

10. As regards point (1), ECHA suggested that it could be amended as to read "under *Article 41 of the REACH Regulation compliance checks* **can be used to** *verify whether...*" This is in order to avoid an interpretation to the effect that the compliance check in Article 41 of the REACH Regulation is the only or most effective way for ECHA to investigate potential breaches of Article 13. This is not necessarily the case for a number of reasons: the length and complexity of the compliance check decision-making process, which takes more than two years and involves multiple actors; or the requirement in Article 41(3) of the REACH Regulation that ECHA should actually demonstrate non-compliance before requesting additional information.

11. In fact, ECHA would like to use an alternative approach to tackling possible breaches of Article 13 of the REACH Regulation, namely, through direct contacts with the registrants concerned and direct cooperation with the relevant enforcement authorities of the Member States. The advantages of such an approach are that it is a quicker and more cost-effective

process than compliance checks; it does not require ECHA to demonstrate any non-compliance with the REACH Regulation's information requirements in order to ask registrants for information on how they have complied with Article 13 of the REACH Regulation; and ECHA can still request Member States to investigate these cases further and where necessary take action, including where a registrant has failed to provide the requested information or ECHA considers that there has been a breach of Article 13(1) of the REACH Regulation.

12. In its observations, the complainant considered that ECHA's suggested modification amounts to a fundamental change of the Ombudsman's friendly solution proposal. The Ombudsman's proposal rests on the premise that ECHA has a duty, when conducting an Article 41 compliance check, to verify compliance with Article 13 of the REACH Regulation. This duty turns into discretion if one were to accept ECHA's version.

13. The complainant thus suggested that the Ombudsman should maintain the initial wording of her friendly solution proposal that " *compliance checks are meant to verify whether the information submitted by registrants was generated in compliance with Article 13 of the REACH Regulation"* , whilst adding *" unless such compliance with Article 13 of the REACH Regulation has been otherwise verified by ECHA ."* This would accommodate ECHA's legitimate observations as to the different methods to ensure compliance.

Second and third allegation and related claims: consequences of non-compliance with the last resort principle and exhaustive investigation of possible breaches

14. As regards the **second allegation** , the Ombudsman agreed with ECHA's opinion that, under the current wording of the REACH Regulation, ECHA would have no legal basis to reject a registration based on an animal test performed in violation of the Regulation. Therefore, if a registrant refuses to complete its application with compliant information following a request from ECHA, the latter must rely on Member States to investigate and sanction the non-compliance, but it cannot sanction the registrant itself, since the legislator has not provided for this possibility.

15. The Ombudsman therefore proposed to ECHA to:

" 3 **. ...** *systematically inform Member States of any registrant's refusal to supply compliant data following ECHA's finding, in the context of a compliance check, that the last resort principle has been violated.* "

16. With regard to the **third allegation** , the Ombudsman was of the view that the REACH Regulation has not entrusted ECHA with the general competence to investigate compliance with its provisions. This responsibility was explicitly granted to Member States. However, ECHA could play an important role in supporting Member States' efforts and prerogatives.

Therefore, the Ombudsman made a friendly solution proposal that:

" **4** . *...pursuant to the principle of sincere cooperation enshrined in Article 4(3) TEU,* **[ECHA]** *considers informing Member States not only of proven violations of the REACH Regulation, but also of possible instances of non-compliance with it, in order to facilitate their enforcement tasks.* **"**

17. ECHA accepted without any reservations points (3) and (4) of the Ombudsman's friendly solution proposal. The complainant made no specific comment in this regard.
The Ombudsman's assessment after the proposal for a friendly solution
18. The Ombudsman applauds ECHA's full and unconditional acceptance of points 2, 3 and 4 of her friendly solution proposal.

19. As regards point 1, prior to the Ombudsman's friendly solution proposal, ECHA's view had been that when carrying out compliance checks under Article 41(1)(a), ECHA cannot assess compliance with the obligation set out in Article 13(1). The Ombudsman is pleased to note that ECHA no longer maintains that position in its reply to the friendly solution proposal. This is a positive and long awaited outcome which the Ombudsman warmly welcomes.

20. The Ombudsman remains firmly convinced that, for the reasons laid down in the assessment leading to her friendly solution proposal, compliance checks under Article 41 of the REACH Regulation were meant to be a way to verify compliance with the last resort principle, among other things. However, this does not mean that ECHA cannot achieve the same goal through other means, particularly if those are quicker, more cost-effective or in any other way more effective than compliance checks.

21. From this perspective, the Ombudsman is happy to accept the modification to her friendly solution proposal suggested by ECHA, provided that its sole aim is, as ECHA stated, " *to avoid an interpretation that the compliance check is the only or most effective way for ECHA to investigate potential breaches of Article 13* ." ECHA's suggested drafting should in no way affect its obligation to verify that data submitted to it is in line with the last resort principle, as required by Article 13 and 41 of the REACH Regulation, or render such verifications discretionary, as the complainant fears.

22. Bearing this in mind, the Ombudsman believes that the respective wordings suggested by ECHA and the complainant are in fact equivalent and fully in line with the purpose that the Ombudsman pursued when putting forward her proposal for a friendly solution. She therefore concludes that this part of her friendly solution proposal has also been accepted.
The Ombudsman thanks ECHA for its exemplary cooperation in the present case. She also thanks the complainant for having raised this issue with her and for having given her the possibility to clarify matters.
Conclusion
On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion:

The Ombudsman is satisfied with the way in which ECHA has accepted her friendly

solution proposal and thus settled the case.

The complainant and ECHA will be informed of this decision.

Emily O'Reilly

Done in Strasbourg on 11 December 2014

[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.

[2] Article 1(1) REACH.

[3] The full text of the Ombudsman's friendly solution proposal is available at: http://www.ombudsman.europa.eu/cases/correspondence.faces/en/58545/html.bookmark