European Ombudsman

Decision in case 23/2018/SRS on how the European Commission updates EU rules on chemical testing when alternative test methods are identified

Decision
Case 23/2018/SRS - **Opened on** 23/04/2018 - **Decision on** 30/01/2019 - **Institution concerned** European Commission (No maladministration found) |

This case concerned how the European Commission deals with updates of the Test Method Regulation (TMR), which defines the approved methods for chemical testing in the EU. The Commission is obliged to update the regulation when it identifies a potential alternative test method to current testing on animals.

The complainant is of the view that the TMR can be updated without the need for the test method to be verified by the Organisation for Economic Co-operation and Development (OECD), which is the practice followed by the Commission. The complainant also believes that, even if OECD input is necessary, the process for updating the TMR still takes too long.

The Ombudsman found that the Commission was justified in involving the OECD. While she recognised that the process for updating the TMR is lengthy, she found no maladministration on this aspect of the case.

The Ombudsman, however, made two suggestions to the Commission to seek to accelerate the process in the future.

Background to the complaint

1. The complaint was submitted by a UK organisation that campaigns for the abolition of all animal experiments. It concerns how the European Commission deals with updates of the Test Method Regulation (TMR), which defines the approved methods for the testing of chemicals in the EU, to take account of new alternatives to animal testing.

2. The EU's rules on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [1] allow for chemicals to be tested on animals *"as a last resort"* [2] . Testing is regulated by the Test Methods Regulation (TMR) [3] . In line with the TMR and the REACH Regulation, the EU is committed to promoting alternative test methods in accordance with the

‘Three Rs Principle’: avoiding the use of animals in testing as far as possible (‘replacement’), using fewer animals (‘reduction’), and causing less suffering to animals (‘refinement’) [4] . Thus, alternative test methods include not only those methods that avoid the use of animals, but also those that reduce both the number of animals used and their suffering.

3. When it needs to update the TMR, the Commission cooperates closely with the Organisation for Economic Co-operation and Development (OECD) which prepares guidelines on chemical testing [5] (see annex for details). Once the OECD adopts its guidelines, the Commission presents a proposal to update the TMR under the so-called ‘regulatory procedure with scrutiny’ [6] . According to this procedure, the Commission first submits the proposal to the REACH Committee [7] for an opinion, and then to the European Parliament and Council, which can veto the proposal. If it believes that there is *“undue delay”* within the OECD, the Commission may proceed without waiting for the adoption of test guidelines by the OECD [8] .

4. In correspondence with the Commission in 2009 and 2010, the complainant expressed concerns about the time taken by the Commission to update the TMR to take account of alternative test methods that do not require animal testing. In response, the Commission reassured the complainant that the introduction of new alternative methods was not being unduly delayed.

5. In June 2017, the complainant again contacted the Commission to express concern about the time taken to update the TMR and the involvement of the OECD in this process. In its reply of July 2017, the Commission stated that the procedure for updating the TMR was balanced, and did not lead to undue delay in approving new test methods.

6. Dissatisfied with the Commission’s reply, the complainant turned to the Ombudsman on 22 December 2017.

The inquiry

7. The Ombudsman opened an inquiry into the complainant’s concerns that (i) the Commission should not ask the OECD to verify alternative test methods before proposing to update the TMR, and (ii) the Commission takes too long to update the TMR.

8. In the course of the inquiry, the Ombudsman’s inquiry team met with the Commission to clarify the complainant’s concerns and inspected the Commission’s file on this case. The Ombudsman then received the reply of the Commission and, subsequently, the comments of the complainant in response to the Commission's reply.

Involvement of the OECD

Arguments presented to the Ombudsman

9. The complainant considered that, by involving the OECD, the Commission had introduced an additional and unnecessary stage in the process of updating the TMR, which was not compatible with the applicable rules [9] . The Commission should amend the TMR, when new test methods are identified that would advance the Three Rs principle and the principle embodied in REACH that animal testing should take place only as a last resort.

10. The Commission emphasised that, in order to ensure a high level of protection for human health and the environment, REACH requires test methods to be **valid** and **adequate** and **sufficient** for the regulatory process. The body that deals with scientific validation is the European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM), which is part of the Commission's Joint Research Centre. Consulting the OECD enables additional expert verification by a broader group and provides guidance on the possible end uses of these methods in the EU regulatory context.

11. Moreover, during the development of the OECD guidelines, OECD expert groups may draft accompanying guidance documents on alternative test methods. These guidance documents are not only useful for those doing the testing, but also help inform how to introduce the new test method under the EU's regulatory framework.

12. According to the Commission, if it did not consult the OECD, then **the same discussions would take place at EU level** , taking just as long and requiring an equivalent structure to be set up for the EU. Failing to involve the OECD could also lead to the EU **diverging from international test methods** and, consequently, in repeated testing, with chemicals having to meet different standards under different test methods. To avoid this, the OECD introduced the Mutual Acceptance of Data (MAD) system, a multilateral agreement. According to this system, test data generated in any member country in accordance with OECD guidelines should be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment. This allows operators to use the same test data in different jurisdictions.

13. In the course of the inquiry, the complainant argued that, if it is necessary to involve the OECD, this should be done in parallel to the other steps that need to be taken for updating the TMR to include alternative test methods.

The Ombudsman's assessment

14. Under REACH, test methods that involve animals must be regularly reviewed and improved with a view to replacing, reducing or refining animal testing (see point 2). Where alternative test methods are identified, the Commission is expected, if appropriate, to make a proposal to amend the TMR "as soon as possible" [10] .

15. At the same time, REACH aims to ensure a high level of protection of human health and the environment, including by promoting alternative methods for assessing hazards, and is

underpinned by the ‘precautionary principle’ [11] . In the context of a previous inquiry, the Ombudsman has said that the precautionary principle is a principle of good administration. [12]

16. While the EU has committed to the Three Rs principle and to using animal testing as a last resort, these provisions must be interpreted in the light of the precautionary principle and the need to ensure that human health and the environment are not adversely affected [13] .

17. It is clear that scientific verification procedures and regulatory validation procedures are justified and important in how REACH is implemented. Therefore, it is reasonable for the Commission to consider that consulting the OECD and taking into account its test guidelines contribute to the legitimate objective of protecting human health and the environment.

18. The Ombudsman finds particularly convincing the Commission’s explanation that, if it did not consult the OECD, a similar structure would have to be set up for the EU, and the verification of test methods would take just as much time.

19. Moreover, as the Commission stressed, failing to consult the OECD would risk causing divergences with international testing standards, and possibly result in duplicated testing. In this regard, a test method used before being adopted by the OECD could risk being different to OECD test guidelines adopted at a later stage, and the test results not being accepted for regulatory purposes in other OECD member countries under the MAD agreement. This would occur in cases where alternative test methods do not result in the replacement of the use of animals, but rather in the reduction of the number of animals used or in their level of suffering.

20. The Commission has stated that it can and does proceed with the other steps necessary for updating the TMR, in parallel with the OECD verification, in some cases. The Commission also said that, when there are undue delays with the OECD verification, it can proceed with updating the TMR.

21. In the light of the above, the Ombudsman finds no maladministration as regards the Commission’s practice of consulting the OECD when updating the TMR.

22. However, as noted by the complainant, the Commission should, where possible, carry out the other steps necessary for updating the TMR in parallel with the OECD verification. The Ombudsman will make a suggestion to this effect below.

Time taken to update the TMR

Arguments presented to the Ombudsman

23. The complainant argued that, even after an alternative test method has been approved by the OECD, there are still unexplained delays of several years [14] . For the complainant, the time required to update the TMR after the OECD verification stage should be much shorter [15] .

In particular, the complainant criticised the Commission's practice of translating legislation like the TMR, when it is clear that this delays the process and despite English being " *the universal language used in regulatory toxicology".* The complainant contended that *"the Commission relegates animal welfare below other considerations and therefore fails to honour the REACH imperative that animals should only be used as a last resort"* .

24. The Commission stated that the time taken to update the TMR is due to the many preparatory stages required to ensure that an alternative method complies with REACH's provisions. Once the OECD guidelines are available, they are adapted to the EU legal framework and subject to internal consultation in the Commission, before the draft proposal is submitted to the regulatory decision-making procedure (see point 3). Moreover, draft amendments have to be translated in all EU languages. The Commission stated that it is exploring possibilities to simplify and speed up the process [16] .

25. The Commission stated that it is continuously working to introduce new and updated methods to the TMR: there have been seven amendments to the TMR since 2008, which resulted in 75 new test methods being introduced. However, simply updating the TMR to include new test methods does not necessarily mean they are used in practice. This is because there are other conditions that may be necessary for test methods to be used (such as amendments to the REACH Regulation or guidelines from the European Chemicals Agency, ECHA) [17] .

The Ombudsman's assessment

26. According to the REACH Regulation, the Commission should regularly review alternative test methods, with a view to reducing testing on animals and the number of animals involved. Where it identifies an alternative test method, the Commission must consult the relevant stakeholders and, if appropriate, make a proposal *as soon as possible* to amend the TMR [18] .

27. Given REACH provides for the timely review and update of the TMR to promote alternative test methods, it is not good administration for there to be any significant delays in how the Commission deals with such updates **without a very good objective reason** .

28. Although complying with all the required preparatory steps means that the process of updating the TMR is lengthy in certain cases, the complainant has not shown that these steps are unnecessary or manifestly inappropriate to fulfil the objectives pursued by REACH. The complainant's argument that technical legislation like the TMR should not be translated into all languages, as this prolongs further the whole review process, cannot be accepted given the legal obligation to translate EU legislation in all official EU languages. [19]

29. The Ombudsman has not identified anything that would indicate that this process is inherently flawed or involves unnecessary delays. She therefore finds no maladministration on this aspect of the case.

30. At the same time, the Commission itself has acknowledged that the process for updating the

TMR is lengthy, and has stated that it is currently exploring possibilities to simplify and speed up this process. Given that its obligation is to seek to amend the TMR *as soon as possible* , if appropriate, the Commission should step up its efforts to this end. The Ombudsman will make another suggestion to this effect below.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion :

There was no maladministration by the European Commission.

The complainant and the Commission will be informed of this decision **.**

Suggestions for improvement

The Commission should intensify its efforts to simplify and speed up the process for introducing new alternative test methods under the TMR.

The Commission should ensure, where feasible, that it carries out the other steps necessary for updating the TMR in parallel with the OECD's verification process.

Emily O'Reilly

European Ombudsman

Strasbourg, 30/01/2019

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32006R1907R(01) [Link].

[2] Article 25(1) of REACH

[3] Council Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0440&from=EN [Link] .

[4] Recital 47 of the TMR Regulation reflects the Three Rs principle.

[5] The Test Guidelines Programme, more information available at: http://www.oecd.org/chemicalsafety/testing/oecd-guidelines-testing-chemicals-related-documents.htm [Link].

[6] The regulatory procedure with scrutiny is no longer to be used in new legislation but **continues to apply** to existing laws until they are formally amended. This procedure empowers the European Parliament and EU Council **to block a measure proposed by the Commission.** For more information, see http://ec.europa.eu/transparency/regcomitology/index.cfm?do=implementing.home [Link].

[7] A 'comitology' committee consisting of EU Member State representatives, which assists the Commission in taking decisions under REACH, such as a decision on including a testing proposal under the TMR.

[8] Although this appears to have occurred only once.

[9] The complainant referred to Articles 13(2), 133(4) and 131 of REACH.

[10] Article 13(2) REACH.

[11] The precautionary principle is a form of preventative decision-making, which essentially implies that a decision should not be taken where there is a potential risk. For more information, see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al32042 [Link].

[12] Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides), para 10, available at https://www.ombudsman.europa.eu/en/decision/en/64069 [Link].

[13] Article 1(3) REACH.

[14] The complainant cites the examples of the in vitro membrane barrier test, the alternatives to skin sensitisation in mice and to the rabbit eye irritation test.

[15] According to the complainant, the total time taken to update the TMR can take up to four years. Without consulting the OECD, it could take from 14 to 17 months. The complainant considers that the REACH Committee should vote on its opinion within three months of the OECD verification.

[16] The Commission referred to the Commission Staff Working Document accompanying the General Report on the Operation of REACH, which outlines a number of possibilities for speeding up the process. These would have to be first discussed with Member State governments (http://eur-lex.europa.eu/resource.html?uri=cellar:2834985c-2083-11e8-ac73- [Link]

01aa75ed71a1.0001.02/DOC_1&format=PDF [Link]).

[17] The Commission provided the example of skin sensitizers. In its comments, the complainant contended that this was a rare occurrence.

[18] Article 13(2) REACH

[19] Article 4 of Regulation 1/1958 determining the languages to be used by the European Economic Community, available at:

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31958R0001:EN:HTML [Link]. See also Article 3(3) Treaty on European Union, Articles 21 and 22 of the EU Charter of Fundamental Rights, and Rule 106 of the European Parliament's Rules of Procedure, available at:
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+RULES-EP+20180731+RULE-106+DOC+XM
[Link].