European Parliament
2019-2024

Committee on Petitions

30.3.2020

NOTICE TO MEMBERS

Subject: **Petition No 0947/2017 by Julia Baines (British), on behalf of PETA, bearing 109802 signatures, on the REACH refit and the ban of animal testing for REACH**

1. Summary of petition

The petition calls on the European Commission and the European Chemicals Agency to end experiments on animals and to invest in progressive and innovative research to promote alternative methods to animal testing for the implementation of the REACH Regulation. The petitioner claims that although the REACH Regulation provides that experiments on animals must be used only as a last resort, this requirement is often being ignored. She urges the EU institutions to seize the opportunity of the REACH REFIT evaluation to end experiments on animal and prioritize innovative methods for testing chemicals.

2. Admissibility

Declared admissible on 9 January 2018. Information requested from Commission under Rule 216(6), (new Rule 227(6)).

3. **Commission reply**, received on 30 May 2018

Following the submission of this petition to President Juncker in September 2017, the Commission provided a detailed response on 16 October 2017.

In its response, the Commission emphasised that the goal of avoiding unnecessary animal testing and promoting the use of alternative approaches is already firmly rooted in the aim and content REACH Regulation. REACH requires that animal testing is only undertaken as a last resort, and numerous provisions in the Regulation support this principle.

Data requirements under REACH refer to alternative methods where such methods are sufficiently developed to be a standard data source, and those requirements are continuously

updated when new test methods become available. Notably, REACH is the first regulatory framework worldwide introducing a set of newly developed *in vitro* tests for skin sensitisation as the default testing approach. Such well-developed non-animal test systems which can fully replace *in vivo* tests presently exist for only a few of the possible harmful effects of chemicals. However, REACH also allows for the use of other alternative approaches, including new and innovative non-standard methods, as long as they can be shown to provide enough information for the hazard classification and risk assessment of a chemical. Such flexible and far reaching provisions for the use of non-animal data are unique for chemical legislation and put the EU in the global lead for the use of alternative non-animal data in the regulatory assessment of chemicals.

To support REACH registrants in implementing the last resort principle, ECHA provides detailed guidance on different aspects, e.g. on the availability of alternative methods for specific endpoints and their possible uses for REACH registration as stand-alone methods or as supportive information, and on the application of alternative approaches like read-across from related substances which can avoid the need to do additional animal tests for a chemical.

Despite the significant progress that has been made in recent years in the development of new *in vitro* test methods and computerised prediction approaches, it is, however, not yet possible to reliably assess all aspects of the safety of chemicals solely on the basis of such methodologies. This is evidenced e.g. in the report of the recent scientific conference "Non-animal Approaches - The Way Forward"[1], organised by the Commission in December 2016.

The latest issue of the triennial ECHA report on the use of alternatives to testing on animals for the REACH Regulation[2] of May 2017 provides comprehensive information on the data used in the submitted REACH registration dossiers. It shows that the extent of animal testing for the purpose of REACH has remained well below the initial estimations by the Commission and stakeholders[3]. This is due to strict obligations for data sharing, availability of pre-REACH data, and the widespread use of available alternative methodologies and prediction approaches, in particular read-across (i.e. the use of data from related substances to predict toxicity). However, the scientific justifications that registrants provide when applying such alternative assessments of chemicals are often found to be insufficient when ECHA assesses the dossiers in detail, and do not provide sufficient confidence that the conclusions drawn on the properties of the chemical are reliable. This illustrates the importance to strike the balance between the REACH goals to obtain sufficient information to protect human health and the environment and to promote the use of alternative methods.

The ECHA report also shows that for the effects for which alternative test methods exist, these methods are not always used, and that there are still a significant number of recent *in vivo* tests submitted for those endpoints. While there may be valid justifications for still applying *in vivo* tests (e.g. due to certain properties of the substances which interfere with the *in vitro* test), sufficient explanation is not always provided by registrants. ECHA analyses

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[1] http://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/scientific_conference/non_animal_approaches_conference_report.pdf

[2] https://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2017_en.pdf/075c690d-054c-693a-c921-f8cd8acbe9c3

[3] https://echa.europa.eu/documents/10162/13585/pr_09_11_animal_testing_20090828_en.pdf; http://publications.jrc.ec.europa.eu/repository/bitstream/JRC29111/EUR%2021405%20EN.pdf

these cases, and, where non-compliance with the legal obligation to use alternative methods is suspected, refers them to Member State authorities for appropriate enforcement action.

Concerning the REACH evaluation the petitioner refers to, the Commission General Report on the operation of REACH and review of certain elements[1] was adopted on 5 March 2018. The Staff Working Document to this report[2] analyses in detail the situation related to data sharing, test methods and the avoidance of unnecessary animal testing, including the aspects addressed above, as well as the numerous activities of the Commission to promote the development and validation of new alternative methods. The conclusion of such analysis is that the mechanisms in REACH to minimise animal testing are generally working well, and that REACH is one of the main drivers for the development and use of alternative methods in the EU.

In this context, it is important to point out that, far from only following and implementing the progress in the area of alternatives, the European Commission is taking a very active role in improving the availability of non-animal approaches for regulatory testing. The Commission makes significant investments in the development of new methodologies by financing research projects through its research programmes, amounting to EUR 350 million of EU funding for the period 2012-2016. Furthermore, it invests significant resources in activities that promote the regulatory acceptance of alternative data.

Differing regulatory requirements in non-EU countries illustrate the urgent need to improve acceptance of alternative methods not only in the EU but across different regulatory regions. Fully recognising this, the Commission's Joint Research Centre (JRC) is leading global efforts for the validation of *in vitro* test methods and the development of OECD test guidelines for validated methods. Moreover, the JRC is a major player in the ongoing projects under the auspices of OECD to advance the understanding of toxicological mechanisms and their description in the form of Adverse Outcome Pathways. These form the basis for the development of novel and innovative non-animal testing and assessment strategies, with the potential of ultimately replacing the use of animals. Moreover, the Commission also makes significant financial contributions to support the OECD test guideline programme, a major instrument for the international harmonisation of test methods.

Conclusion

The REACH Regulation includes far reaching provisions to ensure safety of chemicals by means other than animal testing, making it one of the most innovative legislations in this respect. The Commission's second REACH review highlights the achievements, but also some shortcomings in the practical implementation of the REACH provisions aiming to minimise animal testing. The evaluation report forms a good basis to direct the continued efforts by the Commission, together with ECHA, to promote the use of alternative test methods and assessment approaches under REACH wherever the resulting information is adequate for the safety assessment of chemicals, and to drive the development of alternative approaches fit for regulatory applications.

4. Commission reply (REV.), received on 30 March 2020

[1] https://ec.europa.eu/docsroom/documents/28201
[2] https://ec.europa.eu/docsroom/documents/28202

The Commission's observations

On 5 February 2020, the Commission adopted two reports under Directive 2010/63/EU on the protection of animals used for scientific purposes[1]: the first report on the implementation of Directive 2010/63/EU in the Member States[2], and the report on the statistics on the use of animals for scientific purposes by the Member States[3] covering data from 3 years, 2015-2017.

For the first time at EU level, full datasets are available for each use of an animal, allowing for much more precise reporting. The new reports also include aspects of animal use, which have not previously been available, for example, on the genetic status of animals and the actual severity experienced by the animals during their use in procedures. It also contains information on regulatory uses of animals to satisfy regulatory data requirements for producing, placing and maintaining products and substances on the market.

In 2017, there were a total of 9,581,741 uses (first and any subsequent reuse) of animals for the purposes of research and testing. Toxicity and other safety testing covers testing carried out to fulfil data requirements contained in different pieces of legislation, including for industrial chemical legislation. Between 2015-2017, there was an increase of 17.5% of animal uses for the purposes of industrial chemical legislation[4]. In 2017, there were approximately 230,000 uses of animals to satisfy data requirements under industrial chemical legislation, which represents 2.4% of all uses of animals in the EU, and 11% of uses to address regulatory requirements.

The new reports allow analysing animal use by specific toxicity end-points, the level of suffering experienced by the animals as a result of these tests, and the legislation requiring such testing. The more comprehensive and detailed data facilitates the identification of animal use areas on which the development and validation of alternative approaches will have the widest impact both in terms of numbers and animal suffering, and progressing towards the ultimate goal of the Directive, the full replacement of all use of animals for scientific purposes.

Conclusion

A report on the review of the testing requirements of Section 8.7 of Annex VIII of REACH[5] regarding the reproductive screening study, as well as the fourth report of the European Chemicals Agency on the use of alternatives to testing on animals for the REACH Regulation will be published in the course of 2020.

[1] 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 Text with EEA relevance, *OJ L 276, 20.10.2010, p. 33–79.*
[2] https://ec.europa.eu/environment/chemicals/lab_animals/other_reports_en.htm
[3] https://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm
[4] 2015: 195,950 uses; 2016: 214,772 uses; 2017: 230,177 uses.
[5] 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 L 396, 30.12.2006, p. 1–850.*