European Parliament
2019-2024

Committee on Petitions

5.12.2023

NOTICE TO MEMBERS

Subject: **Petition No 1379/2015 by Gisela Urban and Gabriele Menzel (German) on behalf of several animal welfare organisations, supported by 4.680 co-signatories, on the protection of humans and animals against toxins and pesticides**

1. Summary of petition

Petitioners call upon the EU to see to it that Member States meet their obligations to protect the health of humans and animals. It is their opinion that up to now this has not been the case and that legislation is being violated and priority is given to the interests of the chemical industry. Petitioners call upon the Commission to ban without exception chemical substances that are cause for serious concern. In addition, petitioners call upon the Commission to see to it that institutions, which because of their opinions and advice have great influence on the legislation on the protection of the health of humans and animals, be independent bodies, not under the influence of sectorial lobbies and the chemical industry. The petitioners demand the adjustment of research methods for chemical substances to the latest developments in science and to move to alternative intelligent testing methods instead of continuing to rely on the results of animal testing.

2. Admissibility

Declared admissible on 10 May 2016. Information requested from Commission under Rule 216(6) (current Rule 227(6)).

3. **Commission reply**, received on 31 August 2016

A similar petition was submitted by the same petitioners in 2013 (petition 1833/2013) and the petitioners are referred to the Commission's reply to that petition as background which is still relevant.

The reply to petition 1833/2013 highlights all features of REACH that are designed to protect the health of humans and the environment. The enforcement of the provisions, however, is a competence of the Member States. The Commission continuously monitors how Member States live up to their legal obligations, and REACH also obliges both the Commission and the Member States to act if unacceptable risks occur or could occur.

In relation to substances of high concern, the Member States are working together with the European Chemicals Agency (ECHA) to evaluate and risk-manage these efficiently based on the REACH principles. The 2016 ECHA Report on the Operation of REACH and of the Classification, Labelling and Packaging of substances and mixtures legislation (CLP) shows that since the previous report in 2011, the operations of REACH and CLP have effectively steered companies towards manufacturing, formulating, importing and using industrial chemicals more safely.

Regarding the independence of the bodies providing scientific advice to the Commission, the relevant agency committees and working groups and the Commission scientific committees have procedures in place to ensure the independence of the experts.

The test methods for regulatory testing of chemicals are regularly modernised and amended. Alternative methods are fit for use to fulfil REACH obligations as soon as they have reached OECD validated status, and all such validated methods are regularly being added to the EU Test Method Regulation. Further, several amendments of REACH Annexes have already been published which mandate the use of non-animal approaches instead of animal testing.

The Commission closely monitors the functioning of these provisions. Reports on the use of alternatives to testing on animals under the REACH Regulation are issued by ECHA every three years, and the next report will be published in early 2017.

While working towards the ultimate goal of full replacement of animals, Directive 2010/63/EU on the protection of animals used for scientific purposes[1] is an indispensable tool at EU level to protect those animals still required for testing.

Directive 2010/63/EU implements the 3 Rs (Replacement, Reduction and Refinement) and the Commission underlines the importance of continued efforts by all actors involved, from Member States to the research community, to achieve these goals.

At the same time, Directive 2010/63/EU is the catalyst for the development and uptake of alternative approaches. Fully recognising the need to further advance scientific understanding before alternatives can be developed for all areas where testing still occurs, the Commission will continue to promote the development and implementation of alternative approaches, encourage cooperation and knowledge sharing across sectors, validate new methods and facilitate their regulatory approval. In addition, the Commission actively monitors compliance with Directive 2010/63/EU, in particular the 3 Rs principle. The Commission will stay in close dialogue with the scientific community at EU and international level to identify alternative test methods. It will also organise a conference by the end of 2016 on how to advance towards the goal of phasing out animal experiments.

[1] OJ L 276, 20.10.2010, p. 33

4. Commission reply (REV), received on 27 April 2018

The Commissions observations in its communication of 31 August 2016 are still relevant.

Since then, the Commission published its General Report on the operation of REACH and the review of certain elements - the second REACH review. The report provides a detailed assessment about the achievements of REACH so far in protecting human health and the environment, about the use of alternative methods to animal testing, as well as about effects on the internal market for chemicals and on the competitiveness and innovation. The second REACH review concludes that REACH has significantly increased the protection of human health and the environment, promoted alternatives to animal testing and ensures the free movement of chemicals on the EU single market. The review also identifies room for improvement and proposes 16 concrete actions in order to further improve the implementation of the Regulation. Among others, addressing data gaps in registration dossiers and reinforcing of Member State activities have been identified as priority areas for immediate action.

Concerning the substances of very high concern (SVHCs), the second REACH review concludes that the work under the SVHC Roadmap is progressing beyond expectations. Most of the substances with confirmed SVHC properties have now been assessed, for example those which are persistent, bioaccumulative and toxic (PBTs) and carcinogenic, mutagenic and toxic for reproduction (CMRs), allowing decisions on appropriate risk management measures. Addressing data gaps from registration and improving substance evaluation will enable identification of new SVHCs. At the same time, applying assessment of groups of similar substances could further speed up the process. ECHA in cooperation with the Member States regularly updates the SVHC candidate list. The last update stems from January 2018 and the list now contains 181 substances. The second REACH review also acknowledges that the number of new restrictions has so far not met the original expectations, identifying the need for further improvement in particular to identify relevant candidates for restriction and to increase Member State involvement. The review encourages Member States to enhance their involvement in the preparation of new restrictions.

In its third report under Article 117(3) of the REACH Regulation published in June 2017, ECHA reported on the use of alternatives to testing on animals for the REACH Regulation. It describes in detail how the instruments in REACH to avoid unnecessary animal testing are working until now and what ECHA does to promote the use of alternative methods.

In December 2016, the Commission organised a big stakeholder conference on the topic “Non-animal approaches - The Way forward”. All conference materials have been published, as well as a detailed report which contains a number of follow-up actions for all players in the field to advance the use of alternative approaches.

A review of Directive 2010/63/EU on the protection of animals used for scientific purposes (based on Article 58 of the Directive) was concluded in November 2017. The key conclusion is that the Directive's framework is generally considered a sound foundation for the use of animals for scientific purposes. There are indications that the impact of the Directive varies among Member States. The Commission continues to work with the Member States to facilitate efficient application of the Directive provisions. Some aspects of the Directive are developing and working well, for example Animal Welfare Bodies which are already contributing positively to animal use and care practices.

In relation to the independence of opinions and advice that have influence on the legislation on protection of the human and animal health, the Commission and its agencies have launched a broader discussion on the EU approach on transparency, quality and independence of data on which risk assessment and risk management decisions are based .

Conclusion

The Commission and the EU agencies are working towards the same goals as the petitioners, via the legislative provisions and activities detailed above.

5. **Commission reply (REV. II)**, received on 16 April 2021

The Commission's observations

The Commission's observations in its replies of 31 August 2016 and 27 April 2018 are still relevant.

Since then, the Commission published several documents that should further support the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[2] regulation goals of protecting human health and the environment.

In October 2020, the new Chemicals Strategy for Sustainability[3] was published**,** which aims to further increase the protection of health and environment, while it recognises REACH as one of the most comprehensive and protective regulatory frameworks for chemicals globally. Nevertheless, the strategy sets out that innovation for the green transition of the chemical industry and its value chains must be stepped up and the existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals. This includes ensuring that all chemicals are used more safely and sustainably, promoting that chemicals having a chronic effect for human health and the environment - substances of concern – are minimised and substituted as far as possible, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products.

The strategy is strongly committed to promoting alternative methods and the use of digital technologies and advanced methods, to move away from unnecessary animal testing in both the EU and outside. Notably it calls for innovation of safety testing and chemical risk assessment in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments. One of the strategy's actions is "to foster multidisciplinary research and digital innovations for advanced tools, methods and models, and data analysis capacities to move away from animal testing". In addition, further actions will allow to reduce unnecessary animal testing. These include effective data sharing, making more use of existing academic data, assessing and regulating substances by group where possible, and avoiding

[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, *OJ L 396, 30.12.2006, p. 1–850.*

[3] Chemicals strategy (europa.eu)

the most harmful substances from entering the EU market.

Also in October 2020, the Commission published an Implementing Regulation on REACH dossier updates[4], which sets specific timeframes within which companies have to update their registration dossiers with new or changed information. This should ensure that the European Chemicals Agency (ECHA) can evaluate dossiers and substances in an efficient manner and that advice on safe use of substances and products is based on up-to-date and reliable data.

In order to increase the speed at which REACH dossiers are evaluated, i.e. checked for compliance with the requirements to guarantee protection of health and the environment, the Commission and ECHA agreed in 2019 on a Joint Evaluation action Plan[5]. This action plan sets out how ECHA and the Commission will step up their efforts to address the substances, which are of priority for data generation, via compliance check or substance evaluation.

Since the last Commission reply, ECHA published its fourth report under Article 117(3)[6] of the REACH Regulation in June 2020, reporting on the use of Alternatives to testing on animals for the REACH Regulation. It gives an update on the use of alternatives and concludes that the instruments in REACH to avoid unnecessary animal testing are working generally well. In addition, it explains how ECHA is benefitting from its big database under REACH for the purpose of promoting non-animal testing methods by developing and maintaining tools and guidance to support registrants.

Concerning the question of translation of results from preclinical studies in animals used in the early phases of safety testing of pharmaceuticals to the effects in humans which are then further studied in clinical trials, more and more tools based on human cells, such as organ-on-chip models built from human embryonic stem cells are being employed in pharmaceutical research. However, some animal models continue to be necessary and useful in pharmaceutical research and safety testing while more alternatives are being developed.

Finally, in February 2020, the Commission adopted the first implementation report on Directive 2010/63/EU[7] on the protection of animals used for scientific purposes. It concludes that most Member States are clearly making determined efforts to comply with the Directive. Furthermore, regular inspections take place and include on average 40% unannounced inspections. The Commission assertively follows up on issues of conformity of the transposition of the Directive into national legislation, including with formal infringements, where appropriate.

Conclusion

Further measures are being taken to protect human health and the environment from negative impacts of chemicals. There are a lot of developments on the path to move to alternative, non-animal testing methods. For the remaining testing in animals that is not yet possible to be replaced,

[4] Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ L 331, 12.10.2020, p. 24–29.*

[5] Company name (europa.eu)

[6] (version for corrections) Final draft: Fourth report under Article 117(3) of the REACH Regulation (2020) (europa.eu)

[7] COM(2020) 15 final.

the compliance with the provisions of DIR 2010/63/EU[8] has significantly increased.

6. **Further reply from the Commission (REV. III)**, received on 5 December 2023

The Commission's observations on REACH-strategy towards non-animal testing – endocrine disrupter testing

The Commission has responded to the ECI 'Stop cruelty free cosmetics' on 25 July 2023 and announced in its reply a Roadmap to Transform EU chemicals legislation: The Commission will work together with all relevant parties on a roadmap towards chemical safety assessments that are free from animal testing. The roadmap will serve as a guiding framework for future actions and initiatives aimed at reducing and ultimately eliminating animal testing in the context of chemicals legislation within the European Union.

In parallel, the Commission is preparing a proposal for a revision of the REACH regulation. The introduction of in vitro mechanistic assays for the identification of endocrine disruptors is in principle foreseen. However, the information obtained via in vitro testing that a substance may potentially have endocrine disrupting properties is not sufficient to conclude on classification under the Regulation on Classification and Labelling of products, CLP. For example, classification as Category 1 or 2 endocrine disrupting chemical can only be made where evidence of both endocrine activity and adversity is generated which currently still requires completion of higher-level in vivo tests (according to the OECD guidance document on evaluating chemicals for endocrine disruption)[9].

The Commission's observations on the renewal of glyphosate approval

The Commission recalls that authorisation of plant protection products (PPPs) in the European Union is a two-step process. At the first step, the Commissions approves (or renews the approval) of an active substance for use in PPPs, only if it has been demonstrated after a comprehensive scientific assessment that it fulfils the approval criteria as set in the legislation (Regulation (EC) No 1107/2009 and that at least one use of a product containing it is safe for human health and environment in at least one Member States under realistic conditions of use. In the case of glyphosate, the risk assessment conducted in the context of the renewal process and summarised in the EFSA Conclusion[10] is based on an unprecedented amount of scientific information including both regulatory studies, peer-reviewed publications and other relevant data sources, among them the IARC Monograph. The European Chemicals Agency (ECHA) has confirmed in 2022 that glyphosate is not to be classified as carcinogenic, mutagenic, or toxic to reproduction[11]. EFSA has not identified any critical areas of concern that would preclude the renewal of the approval of glyphosate for use in plant protection. However, several outstanding issues and data gaps were identified as is also the case for the vast majority of other active substances. To address those gaps and issues, the Commission has proposed that the renewal of approval is subject to certain conditions and risk mitigation measures.

In a second step, the Member States authorise individual PPP for use in their territory. When they evaluate applications for authorisation of products containing glyphosate, they are obliged to respect the condition and restrictions set out in the approval. This is a precondition before any such products can be placed on the market and used.

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8 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.

9 https://www.oecd.org/chemicalsafety/testing/oecdworkrelatedtoendocrinedisrupters.htm

10 https://www.efsa.europa.eu/en/efsajournal/pub/8164

11 https://echa.europa.eu/fr/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e185e41a77

Conclusion

The Commission is still committed to pursue the protection goals set out in the Chemicals Strategy for Sustainability while a concrete roadmap is being developed to set out requirements as to how this can be achieved without the need for animal testing in the future.