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The Director-General

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People for the Ethical Treatment of Animals
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Dear Petitioners,

The Commission shares the goal of promoting non-animal test methods and supports the use of alternative approaches for chemical safety assessment wherever possible. This goal has been integrated in the REACH Regulation, which, under the objective of protecting human health and the environment, states that the promotion of alternative methods for the hazard assessment of substances is one of its aims.

The data requirements under REACH refer to alternative test methods where such methods are sufficiently developed to be a standard data source. In addition, REACH allows the use of other, including non-standard, alternative approaches if they provide sufficient information for the purpose of the Regulation. Such far-reaching and flexible provisions for the use of non-animal data are unique for chemical legislation and put the EU in the global lead for regulatory use of alternative non-animal data.

REACH information requirements are being continuously updated to adapt to developments in science and the increasing availability alternative test methods that can reduce or replace animal testing, e.g. for reproductive toxicity and skin sensitisation. Furthermore, ECHA provides ample guidance to registrants, giving comprehensive information on available alternative test methods and approaches and their use in REACH registration dossiers. However, despite the significant progress in recent years in the development of new *in vitro* test methods and computerised prediction approaches, it is not yet possible to reliably assess all aspects of the safety of chemicals solely on the basis of such methods. This is evidenced, for example, in the report of the recent scientific conference "Non-animal Approaches – The Way Forward"[1], organised by the European Commission in December 2016.

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

The latest ECHA report on the use of alternatives to testing on animals for the REACH Regulation[2] provides comprehensive information on the data used in the submitted REACH registration dossiers. It clearly 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 the strict rules for data sharing, the availability of pre-REACH data, and to the widespread use of available alternative test methods and prediction approaches, in particular read-across (the use of data from related substances to predict toxicity). However, it is of concern that the scientific justifications used in alternative assessments of chemicals are often found to be insufficient when the dossiers are scrutinised in detail. This illustrates the importance of striking the right balance between the REACH goals to obtain sufficient information to protect human health and the environment and to promote the use of alternative methods.

It is important to point out that, beyond following and implementing the progress in the area of alternatives, the European Commission is also 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. 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 the 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.

The Commission will continue its efforts to drive the development of alternative approaches fit for regulatory applications, and to promote their use under EU legislation wherever the resulting information is adequate for the safety assessment of chemicals.

Yours faithfully,

Daniel Calleja
Director General

[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