



Janez Potočnik
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European Commission
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18 July 2011

Dear Mr Potočnik,

The People for the Ethical Treatment of Animals Foundation (PETA UK), PETA US and the Physicians Committee for Responsible Medicine are animal protection organisations based in the European Union and the US. These groups, which are collectively supported by more than 2 million individuals around the world, take a close interest in regulatory toxicology and have been active on the animal testing implications of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation since it was first announced.

We wrote to you in 2009 regarding the implementation of REACH, and you replied in June 2010. However, the European Chemicals Agency's (ECHA) recently published report *The Use of Alternatives to Testing on Animals for the REACH Regulation 2011* has provided documentation that underscores our long-standing concerns on this issue. These concerns require immediate action from both the European Commission and ECHA.

It is clear from the report that the administration of REACH is failing to fulfil its legal obligation to allow animal testing only as a last resort (Article 25). Apparently, and as detailed below, more than a quarter of the 200,000* animals already consumed by testing for REACH were killed in breach of this obligation (including 58,000* in tests that were performed rather than proposed for review). Further, there is strong evidence that ECHA is not fulfilling its mandated role of ensuring that registrations are compliant with the last-resort obligation. Finally, there appears to be no designated authority or authorities responsible for enforcing this legal requirement. The Commission must immediately take action to investigate the reasons why violations of the last-resort requirement have taken place and to prevent additional violations from occurring.

After significant efforts by campaigners and legislators, mechanisms designed to minimise animal testing were introduced into the REACH Regulation, including data-sharing, specific

* European Coalition to End Animal Experiments

waivers for tests in Annexes VII to X and general mechanisms that registrants can employ under Annex XI, in particular the use of weight-of-evidence. However, the report indicates a number of instances in which it convincingly appears that the current approach taken by ECHA has failed to ensure that animal testing is genuinely used only a last resort. These include the following:

- 135 *in vivo* skin irritation tests were conducted after 2009, and assumed by ECHA to be for the purpose of compliance with REACH. These were conducted despite the fact that *in vitro* methods for skin irritation were validated and adopted in the Test Methods Regulation in 2009.
- 188 rabbit eye irritation tests were conducted after 2009, again despite validated *in vitro* methods being available and included in the Test Methods Regulation.
- 107 tests, consuming an estimated 58,000 animals, were conducted for Annex IX and X endpoints for which testing proposals should have been submitted, rather than testing being performed.
- More than 250 short term fish toxicity studies were conducted even though effective QSARs are available for this endpoint. Uptake of QSARs and weight-of-evidence approaches was very low (2.1% and 14.1% respectively).
- Registrants correctly omitted a 28-day study in 55 dossiers because they made a testing proposal for a 90-day study but no information is provided on how many registrants performed the 28-day study despite also proposing the 90-day study.
- Registrants correctly omitted a reproductive/developmental screening study in 236 dossiers because they proposed reproductive or developmental tests but no information is given on how many performed the screening study despite also proposing the longer studies.
- Despite acceptance of the Extended One Generation Reproductive Toxicity Study by the Organisation for Economic Cooperation and Development last year (awaiting the formality of full ratification), ECHA has given no indication to registrants that it will accept the study under Annex XI rules. It has been estimated that up to 90% of the animals killed for REACH will be used in reproductive tests; the EOGRTS protocol has the potential to save up to 50-75% of those animals.

According to Article 41.1(a) of the REACH Regulation, the compliance check that ECHA performs should ensure that information "complies with the requirements of Articles 10, 12 and 13", and Article 13 states that "information shall be generated *whenever possible* by means other than vertebrate animal tests" (emphasis added). It appears, however, both from this report and from other ECHA communications that the agency is applying its responsibility regarding compliance checks selectively. In a letter to our organisations and others dated 22 July 2010, ECHA stated that it would evaluate "whether or not the specific adaptations registrants have used to fulfil information requirements comply with REACH regulation". In other words, ECHA is apparently only checking whether the alternatives to animal testing used are appropriate – it is not evaluating whether animal testing is compliant. However, as described above, the legislation clearly indicates that ECHA should be using the compliance check to evaluate whether any new animal testing conducted to fulfil REACH data requirements could have been replaced by an alternative approach. This rigorous approach must also be taken in the evaluation of test proposals.

In light of this evidence that companies are not fulfilling their last-resort requirements and that ECHA is failing to meet its obligations to enforce them, we urgently request that the Commission:

1. Take immediate steps to ensure that ECHA is fulfilling its legal requirement at compliance check to assess whether animal testing could have been avoided. Testing proposals must also be scrutinised with equal rigour.
2. Take immediate steps to ensure that suitable penalties for breaches of the Article 13 and 25.1 obligations regarding animal testing are implemented by member states and that companies are made aware of the consequences of violations.
3. Set up a process, in collaboration with ECHA if appropriate, to investigate the reasons for low uptake of alternative mechanisms such as QSARs and ensure that they are used to the fullest possible extent under the law going forward.
4. Ensure full public disclosure of information explaining why breaches of last-resort requirements have occurred.

Thank you in advance for your immediate attention to these important issues. As you know, registrants are already preparing and submitting dossiers in preparation for the next REACH deadline for phase-in substances, in addition to dossiers for non-phase-in substances. It is therefore imperative that urgent and timely action be taken to limit the massive number of animals consumed in this programme.

We would also be happy to meet with you in Brussels at your earliest convenience to discuss these issues and we look forward to your earliest possible reply. Correspondence may be sent to Alistair Currie, PETA, PO Box 36678, London, SE1 1YE, UK or to the email addresses below.

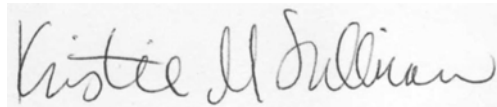
Yours sincerely,



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