Geert Dancet
Executive Director
European Chemicals Agency
Annankatu 18, P.O. Box 400
FI-00121 Helsinki
Finland

13 August 2009

Re: Urgent action required by ECHA to minimise animal testing for the Annex IX and X (2010-2013) Registration deadlines and to improve the utility of third party scrutiny procedures for test proposals

Dear Mr Dancet,

We are writing today to alert you to the risk of duplicative animal testing being conducted to meet REACH information requirements, to make recommendations for action and to seek your assurance that ECHA will take positive steps to ensure that, in the words of the Regulation, animal testing is conducted only as a last resort.

Our concerns relate to two areas: first, "pre-emptive" animal testing conducted by companies before options are even assessed; second, the conduct of testing to meet mandatory information requirements which could be rendered redundant by later tests.

We would also like to take this opportunity to raise our concerns over the mechanism of the public comment period for testing proposals, in light of the first proposal published this week.

1. Pre-emptive testing to meet the Annex X (2010 deadline)

In the case of "pre-emptive testing", we are informed by contacts in the global chemical industry that companies registering Annex X chemicals believe that they may not be able to obtain results from animal tests stipulated in Annex VII and VIII in time for the December 2010 deadline unless they perform them as soon as possible. As a result, they are booking and, potentially, undertaking testing now, rather than waiting to see if the standard test regimes can be adapted by using the mechanisms established in Annex XI or as a result of existing data being brought forward in SIEFs.

Their concern arises partly as a result of limited laboratory capacity worldwide which means that there may be a delay in commencing studies and results may not be obtained before the registration deadline of December 2010 for the relevant chemicals. There appears to be a genuine belief that it will not be possible to meet this deadline if information about existing data is too slow in emerging from the SIEF process. In these cases, companies risk being unable to contract the work and receive the necessary data before the registration deadline and so feel compelled to conduct the required animal tests without waiting for these processes to be completed.

Such activity prior to SIEF formation would be in clear breach of the requirements of Article 25 that animal testing shall be a last resort and Article 26's requirement that studies on vertebrate animals shall not be repeated. This is of particular concern because it is more clearly understood that pre-emptive testing after SIEF formation would be in breach of a registrants' obligation under Article 30 to make enquiries within their SIEFs before conducting testing.

However, not only may these facts not be widely known to companies but there has been an acknowledged slow start to the SIEF formation process, exacerbating the time pressures for companies and raising the risk that companies may be acting outside of SIEFs. **It is therefore necessary that the Agency advises companies as soon as possible that such testing is in breach of the Regulation.**

2. Redundant tests within Annex VIII

The second issue we wish to draw to your attention arises from the requirement for registrants of Annex IX and X chemicals to provide animal data under Annex VIII that could be made redundant by subsequent tests required to meet Annex IX or X requirements.

Specifically, this concern relates to the situation where there is insufficient data to derive a DNEL for either a screening test for reproductive/developmental toxicity (Annex VIII) or a prenatal developmental toxicity study or a two-generation reproductive toxicity study (Annex IX). The SIEF may, as a result, commission a screening study and, subsequent to the acceptance of the testing proposal, then commission a prenatal developmental study or a two-generation reproductive toxicity study.

This situation represents duplicative/redundant animal testing that can be avoided, since in the scenario described above it is highly likely that the Annex IX studies will be required by the Agency. This is especially pertinent given the Amendment of 16 February 2009 to Annex XI of the Regulation which has already made it clear that DNELs from the shorter-term/less comprehensive studies will not be considered appropriate to waive the longer term/more comprehensive studies.

This does not, however, prevent the reverse situation being acceptable; i.e. it is accepted that a DNEL from a prenatal developmental or two-generation reproductive toxicity study would render a screening study redundant. Indeed this 'waiving' of the lower/less comprehensive test if data from the higher/more comprehensive tests exists is written into the Sections 8.6 and 8.7 of Annex VIII for such scenarios.

Within Annex IX account is made under 8.6.1 that a 28-day study does not need to be conducted if a 90-day (8.6.2) study is to be proposed:

8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VIII requirements ***or if tests according to Section 8.6.2 of this Annex is proposed****. In this case, Section 3 of Annex XI shall not apply.*

This is specifically stipulated to avoid the clearly duplicative nature of this testing. However, there exists no similar language within 8.7 regarding the screening study and reproductive toxicity endpoints.

There is, in the absence of clarity on this issue, a very real danger that over the relatively short time frame of REACH registration duplicative/redundant testing will occur. Each reproductive/developmental toxicity screening study consumes at least 675 animals at a cost more than €65,000. Thus, assuming previous Commission estimates are correct that approximately 6,000 substances will be subject to Annex VIII plus Annex IX and X information requirements, redundant testing for this endpoint could equate to avoidable suffering and death for more than 4 million animals, and an unnecessary financial burden of the order of €390 million.

It is imperative that, if the Regulation's aim that animal testing is a last resort is to be maintained, the Agency **advise companies that for substances manufactured or imported in sufficient tonnage to qualify for Annex IX or X information requirements, new vertebrate testing to satisfy Annex VIII information requirements for repeated dose and reproductive/developmental toxicity *is not to be carried out.***

3. Improving the utility of Agency third party scrutiny procedure for test proposals

On 10 August, ECHA published its first request for information from third parties regarding testing proposals involving vertebrate animals. We recognise the Agency's adherence to the letter of Article 40(2) by listing "the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required", but do not believe that this information alone is sufficient to permit a meaningful and efficient contribution by third parties.

Without providing public access to the testing proposal itself—including a robust summary of all existing data and other relevant information regarding a substance—it will not be possible for a third party reviewer to understand the context in which a test has been proposed, including data that have already been considered, the basis for their rejection (if applicable), the findings from earlier or related studies, human or environmental exposure considerations, etc. The current example of the "hydrogenated oligomerisation product, including dimers and trimers, of tetradec-1-ene and alkene" provides an excellent case in point. Does the SIEF/company propose to test each of these substances individually, or are they regarded as a category to which a read-across strategy may be applied? At what tonnage level are these substances produced/imported and what are the relevant exposure considerations?

Failure to provide the necessary background information to answer these and other basic questions could at best lead to much unnecessary duplication of effort, with third parties taking on the responsibilities of a SIEF and coming forward with data that have already been identified (or rejected). At worst, the above scenario could deter external experts from contributing at all to this important process. We therefore urge the Agency to **make testing proposals publicly**

available to facilitate a value-added contribution by third parties. Additionally, we encourage ECHA to **modify its response matrix to include a non-word-limited open field to enable submissions of 'scientifically valid information' other than quantitative test data, e.g. suggestions for read-across to other substances, endpoint-combining, and other ITS approaches.**

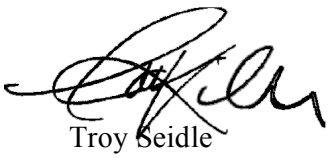
On behalf of the parties to this submission and our more than 30 million members and supporters throughout the EU and North America, we thank you for your urgent attention to these matters and look forward to your earliest possible reply to katy.taylor@buav.org.

We would also like to request a meeting with you to discuss these and other issues associated with ensuring animal testing is a last resort.

Yours sincerely,

Dr Kirsty Reid
Policy Officer
Eurogroup for Animals

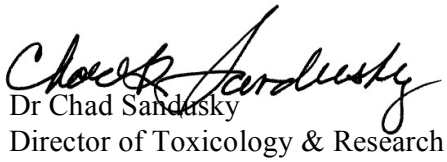
Dr Katy Taylor
Scientific Co-ordinator
European Coalition to End Animal Experiments



Troy Seidle
Director of Research & Toxicology
Humane Society International-Europe

Alistair Currie
Policy Adviser
PETA Europe Ltd.

Dr Kate Willett
Science Policy Advisor
People for the Ethical Treatment of Animals



Dr Chad Sandusky
Director of Toxicology & Research
Physicians Committee for Responsible Medicine

cc:
Commissioner Verheugen, DG Enterprise
Commissioner Dimas, DG Environment
Prof Jerzy Buzek, President of the European Parliament
REACH Competent Authorities
European Chemicals Industry Council
European Partnership on Alternative Approaches to Animal Testing
American Chemistry Council