



Questions for chemical companies:

- Has your company provided data and reference chemicals to assist in validation studies, and data for development of QSARs? (This is for confidential use by validating authorities, not sharing with other companies.)
- Would your company object to validating authorities making (confidential) use of data held by regulatory bodies?
- Do you see any possibility for allowing public use of non-animal tests developed by your company 'in house'?
- Do you have evidence to demonstrate the extent of your contribution?

International Perspectives and the 'global portal'

REACH has the potential to contribute to the elimination of animal toxicity testing worldwide, not only through development of non-animal tests, but also through the establishment of a publicly accessible chemicals database. Both of these areas are of enormous significance to the animal welfare movement and citizens worldwide.

- The EU and its member states must continue to participate pro-actively in OECD processes, so that there is no delay between adoption of a test at EU level and acceptance by the OECD.

Part of the EU's commitment under REACH is to help devise and launch an international chemicals database, the 'global portal'. This will be accessible through the OECD website, and should become the main repository of information on chemicals worldwide.

- Animal test data obtained through REACH must be made available to third country regulators and companies to help to stamp out duplicate animal testing worldwide.

How long to full replacement?

Estimates of the time needed to replace each animal test vary. What is becoming clear is that estimates change over time and, unbelievably, instead of seeing the replacement of animal tests getting nearer, failure to provide sufficient resources leads to the deadlines frequently disappearing over the horizon.

Many animal welfare experts believe that the Commission's current timetables for replacement of animal tests are laughably conservative, and should be challenged.

Advocates of animal testing can even claim that it will 'never' be possible to replace some tests, and in some instances have already been proved wrong. For example, in July 1994, DG Research published a document titled 'An assessment of current scientific developments in the field of non-animal testing for cosmetics products'. COLIPA, the European Cosmetic, Toiletry and Perfumery Association, contributed through compiling answers from its member companies to a set of questions from the Commission.

In answer to the question: 'for finished product testing of cosmetics and toiletries generally, do you think that animal tests can be replaced entirely by non-animal methods?', 19% said yes, 14% said no and 67% gave no answer. Today, animal testing for finished cosmetics products has been entirely replaced in the EU (although testing of individual ingredients continues). Those industry experts who claimed in 1994 that this could never happen were wrong.

The chart overleaf sets out the agenda for replacement of animal tests, endpoint by endpoint. Please join us in campaigning for change.

References

- 1 Pedersen F. et al. 2003. 'Assessment of Additional Testing Needs Under REACH: Effects of QSARs, risk based testing, and voluntary industry initiatives'. Technical Report 2063, September 2003.
- 2 According to the UK's Royal Commission on Environmental Pollution, in its report 'Chemicals in Products: Safeguarding the environment and human health', 2001, Cm. 5827, para. 4.62.
- 3 BUAV/ECEAE. 'Animal Toxicity Testing - A Regulatory Smokescreen?' 2004.
- 4 The European Centre for the Validation of Alternative Methods.
- 5 See 'Acute toxicity testing without animals: more scientific and less of a gamble'. Dr. Gill Langley for the ECEAE/BUAV 2005.

REACH – Amending the Commission's proposal

Data sharing

REACH will require companies to submit test data for around 30 000 so called 'existing substances' (those first marketed before 1981). The data requirements and deadlines for submission of test data vary depending on production volume.

Considerable data for these 'phase in' substances is highly likely to exist, both within companies and on publicly accessible databases. Use of existing data is essential in preventing duplicate animal testing, but the Commission's proposal fails to make data sharing mandatory, and does not introduce sufficient penalties for failure to share data. There is no obligation for companies or competent authorities to search public databases for additional data, a practice that has proved in the US to help prevent duplicate animal testing.

- REACH must ensure that companies are required to share vertebrate animal test data and any other data that could help to prevent additional animal testing. Companies failing to share data should not be allowed to register.

- A single early deadline must be set for 'pre-registration' so that companies planning to register are able to participate in data/cost sharing arrangements at the earliest opportunity.

- Companies holding vertebrate animal data on substances they do not intend to register must also share that data to prevent duplicate animal testing. These companies should be allowed to recuperate the costs of testing from other companies using test data.

- All proposals for vertebrate animal testing must be open to scrutiny by stakeholders for a period of 90 days to ensure that all publicly available data is brought forward.

The One Substance One Registration (OSOR) proposal, whilst introducing some measures that will encourage data sharing, does not currently include early pre-registration for all chemicals. This is vital if full data sharing is to take place.

Use of non-animal testing strategies (application of Annexes I – IX)

Although 'promotion of non-animal testing' is an objective of REACH, and many of the measures proposed in Annexes I – IX include opportunities to use non-animal data, there is nothing in the proposal to create and implement a strategy for the replacement of animal tests, nor is adequate consideration given to choosing and utilising non-animal techniques during dossier- and substance-evaluation.

As well as increasing efforts to develop and validate new tests (see 'The Agency', below), existing non-animal tests should be used to full advantage, with ECVAM* and animal welfare experts involved at every stage.

- Non-animal test strategies must be adopted, and the scientific weaknesses of animal tests analysed, endpoint by endpoint (see REACH amendments at www.reachnonanimaltests.org)

- Evaluation of test proposals where vertebrate animal tests are required by Annexes VII and VIII must be extended to cover proposals for all vertebrate animal testing (including animal tests required by Annexes V and VI).

- ECVAM and animal welfare experts must be involved in decisions relating to data requirements and evaluation of testing proposals.

The Agency – an important role in replacing animal tests

The proposed Chemicals Agency must have a mandate to promote the use of non-animal tests; ensure data-sharing requirements are enforced, and formulate a strategy to eliminate animal testing. To this end, animal welfare policy and scientific experts must be involved in strategic decisions relating to animal welfare and funding must be made available within the Agency for this vital work.

- Part of the registration fee paid by companies to the Agency should be allocated to fund the development and validation of non-animal tests.

- A Committee should be established within the Agency, with ECVAM and animal welfare stakeholder involvement, to allocate funding obtained through the registration fee and formulate a strategy to replace animal tests.

Cosmetics and REACH

The animal test and marketing bans established through the 7th Amendment to the Cosmetics Directive must not be affected by implementation of REACH, and sharing of data on chemicals used in cosmetics (and held by cosmetics companies) must be mandatory.

Acute toxicity testing and REACH

Acute toxicity data is used for establishing guidelines for classification and labelling and setting doses for longer term studies. The tests are crude and extremely cruel, often causing death by poisoning through inhalation, skin penetration and/or oral dosing¹.

The Commission's proposal does not require acute toxicity data for low volume substances. However, if ECVAM confirms that non-animal methods can be used to inform classification and labelling decisions, adding the acute toxicity endpoint to Annex V using non-animal methods is acceptable, and could hasten the end of acute toxicity testing on animals worldwide. The Commission must be pressed to establish guidelines for testing substances for acute toxicity *in vitro* in time for implementation of REACH.



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Replacing animal based toxicity tests – REACH and beyond

The Commission's proposal for a new EU chemicals policy (REACH) rightly seeks to address concerns over the safety of chemicals.

But a new and improved regulatory system for chemicals must not rely on outdated and cruel animal tests.



REACH provides Europe with an opportunity to lead the world in the adoption and use of non-animal tests, publication and sharing of existing test data, and effective regulation of chemicals.

The measures outlined in this briefing apply

specifically to REACH, as well as the broader campaign to end animal toxicity testing worldwide.

The animal tests and non-animal replacements described overleaf demonstrate the urgency of the need for change, and set an agenda for action. Please join us in creating that change.

The European Coalition to End Animal Experiments

The European Coalition to End Animal Experiments is the only EU-wide organisation campaigning solely to end animal experiments. With members in 14 European countries and close links to partner organisations in the US and Japan, the ECEAE has been at the forefront of the campaign to end animal testing since 1993. As a member of ICAPO (the International Coalition for Animal Protection at OECD), the ECEAE is actively engaged in pressing for change globally.

Saving animal lives and saving costs – use of non-animal tests

The Commission has estimated that as much as €1.2bn¹, and 2 million animal lives, could be saved if certain non-animal techniques are brought into use in time for implementation of REACH. However, evidence that sufficient progress is being made in relation to *in vitro* and QSAR (computer) methods is sparse.

- The Commission should report regularly to member states and the European Parliament on progress in this area, including giving information on whether chemical companies have assisted by providing data for developing QSARs and conducting validation studies.

Why non-animal?

Animal tests have never been validated to modern standards. Extrapolating test results from small animals with short life spans to real-life human exposure is fraught with difficulties. Animal tests analyse the effects of single substances, whereas human beings and wildlife are typically exposed to mixtures. The science of animal testing is outdated.

In vitro tests can assess chemical toxicity and underlying mechanisms, for single chemicals and mixtures, rapidly and cost effectively. Using human cells, receptors and enzymes will eliminate problems of species differences. These tests must be better resourced through the Commission, member states and the industry.

QSARs (Quantitative Structure Activity Relationships) are computer models that allow assessment of chemicals based on knowledge of their molecular structure. These systems can produce results at the press of a button and will prove invaluable in any modern regulatory framework.

Further new technologies are also significant and must be exploited early on. Toxicogenomics, allowing rapid analysis of toxicity-related gene activity *in vitro*, has the potential to revolutionise toxicity testing. Combining toxicogenomics with bio-informatics can increase the predictive power of safety assessments².

Animal suffering

During animal toxicity testing, animals are often force-fed using tubes, have toxic substances applied to their skin or eyes, and can be restrained in sealed containers and forced to breath chemical fumes. REACH, unless substantially modified, will allow this cruelty to continue, and cause a massive increase in animal testing.

Regulatory smokescreen

Animal tests frequently produce confusing or misleading information. The effects of poisoning often differ from one species to another, or even between different strains of the same species. It is common for control of chemicals to be delayed because animal tests cannot provide 'proof' of particular hazards. Rather than take action where hazards are indicated, regulators frequently call for 'further testing'³.

