

The European Commission proposed a new EU regulatory framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) on 29 October 2003. The objectives of the legislation were to improve the protection of human health and the environment through the better and earlier identification of the properties of chemical substances, while at the same time aiming to maintain and enhance the competitiveness of the European chemical industry, increase transparency, and promote non-animal testing.

The original Commission paper on REACH would have resulted in the use of millions of animals in testing. It failed to prevent duplicate testing by adequately ensuring that all existing animal data is made available and shared, as well as other relevant data that would prevent animal testing. Furthermore, the Commission proposal as it stood was likely to result in a large programme of testing chemicals on animals that would not necessarily generate information that is relevant for the protection of human health and the environment. It failed to introduce a flexible system with step-by-step testing strategies aimed at identifying and adapting the information needs for a given substance, and collecting appropriate data with non-animal test methods.

During the plenary vote on REACH (First reading), 17<sup>th</sup> November 2005, the European Parliament adopted a large number of amendments which will significantly reduce the number of animals used for the safety evaluation of chemicals. MEPs supported a requirement which in principle obliges industry to share all information from animal tests and a single early pre-registration. The Parliament also adopted a provision for the new Chemicals Agency to work on alternative test methods; more funding for the development of alternatives through the registration fee; and the submission of testing proposals before any animal tests can be carried out, which will be evaluated by experts in the field of alternatives before being approved. Regrettably, three unvalidated non-animal testing strategies for lower tonnage substances were not adopted and an acute toxicity test was included.

### 1. The obligation to make available and share existing data

#### Commission

Eurogroup supported that the Commissions Proposal included the obligation to make available and share existing animal data, with strict requirements and implementation and enforcement. The Commission claimed that the sharing of animal data is mandatory in their proposal. But although the Explanatory Memorandum states that '*data sharing will be obligatory*' with respect to animal testing, it was not included anywhere in the text of the Regulation. In addition, the proposal failed to set strict requirements or implementation and enforcement measures that would ensure that all existing data is shared without exception. Eurogroup also supported a single deadline for the submission of data for pre-registration, as it will help ensure that data from animal tests can be shared regardless of when substances have to be registered under REACH.

#### Parliament

At the plenary vote, MEPs supported a requirement which in principle obliges industry to share all information from animal tests, to prevent duplication of tests involving animals. Companies (owners, downstream users, manufacturers, importers etc) will be unable to register a chemical when animal test data or other information to prevent animal testing is not shared or when the share of the cost of animal test data or other information to prevent animal testing is not paid. All

registration dossiers must include all information regarding which tests on vertebrate animals have been carried out and the number of animals used. Companies must submit animal testing proposals for evaluation for Annexes V and VI in addition to VII and VIII, to ensure that generation of data is tailored to real information needs. It will be the task of the Agency to ensure data sharing and prevent superfluous experiments from being carried out. During the evaluation process, animal studies will only be made available by evaluating competent authorities to other registrants on receipt of proof of payment of their share of the costs. In addition, all information from animal tests must be forwarded to the Agency within 18 months of the regulation coming into force to avoid duplication of animal tests, also in circumstances where substances are no longer produced.

## **2. Development, validation and acceptance of non-animal test methods**

### **Commission**

Although the promotion of non-animal testing is one of the objectives of the Regulation, the Commission Proposal did not include any measures or incentives for the development of non-animal test methods. Without these, it was unlikely that industry would make any substantial investments in research and development of new non-animal tests. There would continue to be insufficient resources and commitment to ensure that alternative tests are available as soon as possible in order to meet the information requirements under REACH. Significantly increased resources and efforts from industry, the Commission and Member States are necessary to speed up the development, validation and acceptance of non-animal test methods.

### **Parliament**

The Parliament adopted a provision for a new Chemicals Agency to work on alternative test methods to ensure their development and use during the implementation of REACH, with more funding for the development of alternatives through the registration fee. The communities, Commission, Member States and industry are requested to allocate more resources to the development, validation and acceptance of non-animal tests. If ECVAM (European Centre for the Validation of Alternative Methods) declares an alternative test method valid, the Agency shall submit a decision to amend the relevant Annex(es) with the view to replacing the animal test method with the alternative.

## **3. Evaluation of testing proposals involving animal tests for Annexes V and VI**

### **Commission**

In the Commission's Proposal it is not required to submit testing proposals before performing the animal tests in Annexes V and VI. Eurogroup believes that testing proposals involving animal tests that may be required by Annexes V and VI must also be submitted for evaluation.

### **Parliament**

MEP's agreed to the evaluation of animal testing proposals for Annexes V and VI in addition to VII and VIII, to ensure that generation of data is tailored to real information needs.

## **4. Consultation on evaluation of testing proposals involving animal tests**

### **Commission**

Eurogroup believes all testing proposals involving animal tests must be open for commenting by stakeholders to ensure the use of all available alternative test methods in intelligent risk assessments. Comments received must be taken into account by the competent authorities, and any decision must be made in consultation with experts in the field of alternative methods, in particular with ECVAM.

## **Parliament**

The Parliament adopted amendments whereby testing proposals must be submitted before any animal tests can be carried out. These proposals will be open for comment by interested parties and evaluated by experts in the field of alternatives, including consultation with ECVAM, before being approved. During the evaluation process, stakeholders are given a 90 day period to comment on testing proposals. Priority shall be given to *in vitro* methods and (Q)SARs (Quantitative Structure Activity Relationships), whereby a list of all tests will be made available to companies.

## **5. Agency Mandate and fee**

### **Commission**

The objective of this Regulation to promote non-animal testing should be included in the mandate and work of the Agency to ensure its effective implementation. The development, validation, legal acceptance and use of alternative test methods are often hampered by a lack of strategic planning and coordination. Therefore the Agency should have a Committee consisting of experts in the field of alternative test methods with the mandate to develop and implement such strategic planning and to ensure that alternative test methods are used in intelligent, flexible risk assessment wherever possible to prevent animal testing and save costs. The Committee should also allocate funding for alternative test methods and produce a yearly report on the progress made to ensure transparency.

### **Parliament**

Also adopted was an Agency mandate on alternatives to ensure integration of the development and use of alternatives to prevent animal testing and save costs. A committee for Alternative Test Methods will be established, consisting of experts from ECVAM, animal welfare organisations and other relevant stakeholders, to ensure relevant up-to-date scientific and technical expertise. Part of the registration fee shall be allocated to the development of non-animal test methods.

## **6. Recognition of animal welfare organisations as stakeholders**

### **Commission**

Article 105 states that the Management Board of the Agency shall develop contacts between the Agency and representatives of listed interested parties. Animal welfare organisations are not included among the stakeholders mentioned. As the involvement of stakeholders is relevant in relation to many areas under the Regulation, exclusion of animal welfare organisations is unacceptable.

### **Parliament**

Animal welfare organisations are to be included as stakeholders.

## **7. Exemption of cosmetic ingredients**

### **Commission**

When REACH was proposed, the Commission stated that it was designed to complement and not overlap with other EU legislation. However, the Commission has failed to include cosmetic ingredients among the substances exempt from REACH. Cosmetic ingredients are covered by the Cosmetics Directive, where the current testing requirements are stricter than those under REACH. The Directive, which was amended in 2003, prohibits animal testing of cosmetic ingredients in the EU after March 2009 and phases in a ban on the sale of animal-tested cosmetics. If cosmetic ingredients are not exempt from REACH, this legislation would become void. The Directive provides for the possibility of a derogation from the animal testing ban in circumstances where

serious concerns arise about the safety of an existing ingredient. Cosmetic companies should share data from animal tests for (pre-)registration of ingredients that are used for other purposes as well.

#### **Parliament**

MEPs agreed on the exemption of animal tests for cosmetic ingredients in line with the 7<sup>th</sup> Amendment of the Cosmetics Directive.

### **8. Inclusion of Flexible step-by-step non-animal testing strategies**

#### **Commission**

The information requirements in the Annexes consist of tonnage-related, standard testing regimes that are not necessarily linked to use, exposure or risk management. This approach fails to ensure that only information that is necessary to ensure safe use is collected and would likely result in large numbers of tests on animals, to generate data irrelevant for the protection of human health and the environment if left unchanged. Eurogroup believes that a flexible step-by-step strategy should be adopted, in which the data collected are evaluated after each step, and decisions on remaining information needs are made based on the results of previous steps.

Presently, the Annexes are mainly based on animal tests and do not include all validated non-animal tests currently available.

#### **Parliament**

Eurogroup believes that as a minimum the base set of standard information requirements for Annex V (1 –10 tons) and the additional information requirements for Annex VI (10-100 tons), data should be collected with non-animal *in vitro* tests, as was foreseen by the amendments adopted by the Environmental Committee of the European Parliament in their vote on October 4, 2005.

Regrettably, at the plenary, the Parliament failed to include a flexible step-by-step strategy. Additionally, while the Parliament has included exposure and use categories into the REACH system, it does not adequately link them to the testing strategies as such, and it also failed to include all available non-animal test methods or to ensure a sensible toxicological approach.

### **FUTURE ACTION**

Eurogroup recommends the EU Member States to support the position of the European Parliament regarding adopted animal welfare issues. The Council of Ministers will be voting on the 13<sup>th</sup> December 2005 for a political agreement. A letter has been sent to ministers and member organisations highlighting the animal welfare concerns we wish they support. In the letter the following points were highlighted: data sharing; pre-registration; registration and evaluation; the Agency; development, validation and acceptance of non-animal test methods; exemption of cosmetic ingredients, and access to information.

#### **1. Data Sharing**

It is essential that animal test data is shared to prevent duplicate animal testing.

- We support the OSOR proposal, whereby it is obligatory to share data. We favour sharing of both animal and non-animal data, as there are many cases in which non-animal data, when considered as part of a general assessment of data needs, can be used to indicate whether or not further animal testing is required.
- The proposed opt-out to single registration outlined in Article 10 of the Presidency compromise (October 25, 2005) allows for separate registration on grounds of cost; commercial sensitivity or disagreement on selection of information. While we oppose any opt-out, if an opt-out should be included, for non-animal data it must be made clear that no such opportunity exists for companies to avoid sharing animal test data.

- We strongly object to any changes that would prevent free access to data for substances registered 10 years previously as outlined in Article 23.

## **2. Pre-Registration**

We support the establishment of a single pre-registration phase for all chemicals outlined in both the Presidency's October compromise text and the European Parliament Report. However, we strongly oppose deletion of Article 26 paragraph 1 (d) as this removes the obligation for companies to signal the presence of animal test data when pre-registering. We therefore ask that paragraph 26(1) d is re-instated. The European Parliament Report addresses this issue to some extent through inclusion of Article 26, Paragraph 1 A (new).

## **3. Registration and Evaluation**

We wish you to support the following aspects of the European Parliament Report. All registration dossiers must include all information regarding which tests on vertebrate animals have been carried out and the number of animals used. Companies must submit proposals for all animal tests to be conducted in order to fulfil information requirements in Annexes V and VI in addition to VII and VIII, to ensure that generation of data is tailored to real information needs. It will be the task of the Agency to ensure data sharing and prevent superfluous experiments from being carried out.

## **4. The Agency**

The European Parliament text establishes an Agency mandate to develop strategies to reduce and replace animal testing and to ensure integration of the development and use of alternative test methods. A committee for Alternative Test Methods would be established, consisting of experts from ECVAM, animal welfare organisations and other relevant stakeholders including industry, to ensure up-to-date scientific and technical expertise. Part of the registration fee shall be allocated to the development of non-animal test methods (Article 72.1d(new)). We strongly urge Member States to make changes to Article 72 of the Presidency compromise text to reflect the European Parliament Report.

## **5. Development, validation and acceptance of non-animal test methods**

We ask the Council to support the development, validation and acceptance of non-animal test methods as adopted by the European Parliament. The European Parliament amendment includes provision for part of the REACH registration fee to be allocated to the development and validation of non-animal test methods. In addition, the Parliament text provides that as soon as ECVAM (European Centre for the Validation of Alternative Methods) declares an alternative test method valid, the Agency shall submit a decision to amend the relevant Annexes with the view to replacing the animal test method with the alternative.

## **6. Exemption of cosmetic ingredients**

When REACH was proposed, the Commission stated that it was designed to complement and not overlap with other EU legislation. However, the Commission has failed to include cosmetic ingredients among the substances exempt from REACH. We support the Presidency Compromise for the exemption of cosmetic ingredients (Articles 2, 13, 29, 53, 64). The European Parliament also supports the exemption of animal tests for cosmetic ingredients in line with the 7<sup>th</sup> Amendment to the Cosmetics Directive.

## **7. Access to information**

Article 116 of the Commission's REACH proposal allows for publication of the 'results' of toxicological and ecotoxicological studies on a publicly accessible database. The Presidency compromise text allows for publication of study summaries and robust study summaries. This provision must not be weakened, as any weakening will result in duplication of animal tests, possibly in third countries and as a result of data requirements set out by third country regulations.

## **8. Flexible step by step non-animal testing strategies**

We ask the Council to support the inclusion of a flexible step-by-step strategy in the Annexes, in which the data collected are evaluated after each step, and decisions on remaining information needs are made based on the results of previous steps. For this purpose, the part 1 of Annex IV and Annex IX should be revised and combined to precede the Annexes V to VIII so that it will be considered before any new testing is done or proposed. This would ensure a sensible toxicological approach based on chemical safety assessment, including full use of all existing data (including human data), weight of evidence, (Q)SARs, grouping of substances and read across, and all available *in vitro* and other non-animal test methods. Further available non-animal test methods must be included in Annexes V to VIII to replace animal tests where possible. In particular, Annex V should include further *in vitro* test methods such as for basal cytotoxicity, to allow for a more comprehensive hazard assessment at the first level of testing.