



ecopa Workshop

**REALity CHECK: Proposals, Amendments and Conclusions
– from the alternative point of view**

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The Alternative Point of View

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1



REACH Timetable 2006

UK Presidency July – December 2005

Council of Ministers reached Political Agreement on 13 December 2005.

Austrian and Finnish Presidencies

Adoption of Common Position

- Firstly, working groups will meet in to discuss recitals. Then the text will be translated (February 2006).
- An 'A' point (Official adoption within the Council) is expected in May.

REACH Timetable 2006

Second Reading

- The Council is expected to formally hand over the text to Parliament in **September**.
- The EP is allocated maximum three months for second reading, however, it is expected the Parliament will vote in **Nov/Dec**.
- The Council is then expected to make a decision **one week** later.
- If the Council does not approve the EP position they will convene a conciliation committee (**six weeks**).

It is likely that in Spring 2007 the Regulation will enter into force and by Spring 2008 the Agency will become operational.



Eurogroup's Position

The **original Commission Paper** would have resulted in the use of millions of animals in testing.

WHY?.....

It **failed to prevent duplicate testing** by adequately ensuring that all existing animal data is made available and shared.

It was likely to result in a large programme of **testing chemicals on animals** that would not necessarily generate relevant information 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**.

Eurogroup's Objectives

1. The obligation to make available and share existing data;
2. Development, validation and acceptance of non-animal test methods;
3. Evaluation of testing proposals involving animal tests for Annexes V and VI;
4. Consultation on evaluation of testing proposals involving animal tests by ECVAM, experts and stakeholders;
5. Agency Mandate and fee;
6. Recognition of animal welfare organisations as stakeholders;
7. Exemption of cosmetic ingredients; and
8. Inclusion of a flexible step-by-step non-animal testing strategies.



European Parliament

The European Parliament adopted a large number of amendments which would significantly reduce the number of animals used.

They supported....

- A requirement which **obliges** industry to **share all information** from animal tests
- A single early **pre-registration**.
- A provision for the new Chemicals **Agency** to work on **alternative test methods**.
- Development of alternatives through the registration **fee**.
- The **submission of testing proposals** before animal tests are carried out, and **evaluation by experts** before being approved.
- Exemption of **cosmetics**.

Regrettably... three unvalidated non-animal testing strategies for lower tonnage substances were not adopted and an acute toxicity test was included.



Council Common Position

The Common Position is an improvement from the Commission's original proposal for REACH

However...

Most of what was achieved for animal welfare through the European Parliament has been excluded from the Council's Common Position Document

Data Sharing

We support the OSOR proposal, whereby it is **obligatory** to share data. It is essential that animal test data be shared to prevent duplicate animal testing.

Council Common Position

Sharing of animal test data and other data remains mandatory, however, companies may **opt-out** of submitting joint information

Action: We oppose any opt-out of animal test data, therefore, for it must be made clear that no such opportunity exists for companies to avoid sharing animal test data.

Data Sharing

We support the EP text which states a company **MUST** share data otherwise it will not be allowed to register a substance.

Council's Common Position

Only Article 28 (3) states that if an owner of a study involving testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to another participants, he shall **not** be allowed to proceed with registration until he provides the information to the other participants.

Action: It is important all EP amendments which support the requirement obliging industry to share all information from animal tests, are resubmitted.

(Articles

Pre-Registration

We support the adoption of a single preregistration phase

Council Common Position

- Single pre-registration phase.
- 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.

Action: An amendment must be put forward during 2nd Reading to the European Parliament (EP) to either reinstate Article 26 1(d) or to include the adopted EP plenary amendment.

There is confusion in the text as to whether downstream users may be possible participants in a SIEF (substance information exchange forum).

Action: Companies must be obliged to indicate the presence of animal test data at pre-registration and must be able to share data through SIEFs.

(Article 27 (1) and Article 26 (6))

The Agency and Fee

It is important for the chemicals Agency to have a **mandate to promote the development, use and validation of alternatives**

Action: Amendments need to be resubmitted from the EP text whereby establishing an Agency mandate to ensure the development and use of alternative test methods. A committee for Alternative Test Methods would be established, consisting of experts from ECVAM and animal welfare organisations.

It is important that part of the **fee** is allocated to the development of alternatives to animal tests

Action: Resubmission of the EP amendment whereby part of the registration fee is allocated to the development of non-animal test methods.



Development, validation and acceptance of non-animal test methods

We ask for the support of the development, validation and acceptance of non-animal test methods.

Council Common Position

Article 12 (2) states that in order to refine, reduce and replace animal testing, where tests on substances are required to generate information, the Commission must set up an appropriate Committee to agree to adaptations to the set of test methods approved for use to allow new tests to be brought into regulatory use when ready

Action: We need to ensure resubmission of the EP amendment providing that as soon as ECVAM (European Centre for the Validation of Alternative Methods) declares an alternative test method valid, the relevant Annexes shall be amended.

Access to Information

Council Common Position

The results of each toxicological and ecotoxicological study will be available free-of-charge over the Internet except where a justification is submitted requesting information to be kept private.

Article 116



Consultation on evaluation of testing proposals

Council Common Position

Examination of testing proposals if several registrants of the same substance have submitted proposals for the same tests, then the registrants will be given the opportunity to agree who will perform the tests (90 days).

(Article 39 d)

Action: Eurogroup believes all testing proposals involving animal tests must be open for commenting by stakeholders (including ECVAM) for 90 days to ensure the use of all available alternative test methods in intelligent risk assessments.



Evaluation of testing proposals involving animal tests for Annexes V and VI

Eurogroup believes that testing proposals involving animal tests that may be required by lower tonnage must also be submitted for evaluation in addition to those for higher tonnages.

Action: It is important that we resubmit all amendments adopted in plenary where the EP agreed to the submission and evaluation of animal testing proposals for lower tonnages.



Exemption of cosmetic ingredients

Commission Report

Commission failed to include cosmetic ingredients among the substances exempt from REACH.

European Parliament Text

The EP text exempts cosmetics from the entire scope of REACH, but only exempts chemical ingredients exclusively used in cosmetics (Article 2).

Council's Common Position

Cosmetic ingredients are exempted from the scope only partially. Cosmetics are exempted from Title IV – Information in the supply chain, this section focuses on safety data sheets (SDS) and be relating to restrictions for substances also covered by the cosmetics directive. In the original text, Article 53, prevents an overlap between 76/768/EEC and REACH over human health assessment and authorisation.

Exemption of cosmetic ingredients

Therefore...

Apart from being exempt from providing SDS down the supply line, **cosmetics companies will be covered by REACH and will have to participate in the registrations, evaluation and authorisation process.** Cosmetics will be exempt from providing information already covered by directive 76/768/EEC, but will need to provide other information such as environment assessments. Unlike the EP first reading, this will apply to all cosmetic ingredients including those exclusively used in cosmetics

In the Annexes

Council Common Position

Animal test for acute toxicity testing (low volume chemicals)

Action: An alternative cell based test, which is presently being validated by ECVAM and ICCVAM, is expected to be validated in time for implementation of REACH. It is important the acute toxicity test is substituted by the alternative.

The ability to waive certain tests in Annex VI is strengthened to minimize the burden for testing at a higher tonnage bands.