


Presentation of Ms. Ninja Reineke



Data requirements for chemicals and the animal testing issue

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Some myths about animal testing and REACH

REACH will kill x millions of animals

- too many tests for too many chemicals
- old safety tests are not accepted
- the retesting of chemicals is required
- data produced for other regulatory systems are not accepted



Too little information on chemicals

ca. 30,000 chemicals >1t/a on EU market


even for 2750 chemicals > 1000 t/a

- only 14% enough data for basic safety assessment
- 21% no available data at all

Since 1993:

- 141 high volume chemicals identified for a risk assessment
- meanwhile only 27 have completed the process


Therefore:
Not possible to identify risk to health and environment and to take risk reduction measures



Registration requirements in REACH

1-10 t/a	Generally in vitro information (Annex V)	17,500*
10-100 t/a	Chemical safety report (hazard, exposure and safe uses) and info Annex V and VI	4,977*
100-1000t/a	As above + testing proposal for Annex VII	2,641*
>1000t/a	As above + testing proposal for Annex VII and VIII	2,704*


* Estimate by Commissions Joint research centre, September 2003



REACH elements to reduce animal testing

- Existing test data**
can (+should) be used for registration dossier (Title 2: Registration)
- Data sharing** is required for vertebrate tests and a pre-registration and communication forum will enable **consortia forming** (Title 3: data sharing and consortia)
- testing plans will be checked** to see if these tests are necessary in dossier evaluation by member state Authorities with regard to Annexes VII and VIII (Title 6: Evaluation)

New: One substance, one registration (OSOR)
Council: suggestions by UK/Hungary, approved by legal advice



More development of alternatives needed

Non- animal test data are accepted under REACH (Art. 12)

- tests with cell lines, tissue, (in vitro tests)
- Computer modelling and analogies of chemical structures
- Quantitative structure activity relationship (QSARs)

NGOs support all efforts to develop alternatives to animal tests

- more funds for research and development
- Enhanced validation and regulatory acceptance
- This can benefit other areas where animal tests are used (drug development, medical devices)



Precautionary approach

Rather **phase out and reduce chemicals of concern** instead of investigating many different toxicological properties in all kinds of tests

Some chemical properties can be investigated with computer models quite easily (persistence, biodegradation), but **some tests will still be necessary** to determine the toxicological properties

Global experiment that currently takes place threatens animals and humans by interfering with their reproduction, immune system and even their behaviour



Data requirements for low tonnage chemicals: Currently not sufficient!

Chemicals produced or imported in 1-10 t/a only need very basic information in the current proposal (Annex V)

Physical chemical properties (14):

Melting/freezing point, boiling point, water solubility

Toxicity tests (5):

Skin irritation (non animal test)

Eye irritation (non animal test)

Skin sensitisation (animal test!)

Mutagenicity (in vitro test with bacteria)

Aquatic toxicity (using water fleas *Daphnia*)



3 more (non animal) tests needed for Chemicals between 1-10 t/a

- 1-10t/a Chemicals are the majority of chemicals under REACH
- No sufficient info for identifying priorities for the authorisation
- No classification or labelling possible

NGO demand:

Re-instate the 3 non animal tests that were removed after the internet consultation in October 2003

Mutagenicity (in vitro test with mammalian cells)
Chronic toxicity in aquatic environment with algae
Biodegradation (does the chemical break down?)



Summary I

REACH requires industry to compile existing data, accepts old valid data and new tests are only necessary where data not available so far

REACH encourages data sharing between companies, and in the evaluation procedure testing plans are checked to avoid duplication

NGO demand: More should be done to develop and validate alternative methods

OSOR will further reduce amount of tests (and their costs)



Summary II

Many of the required data industry should already have, especially for the 20,000 chemicals between 1-10 t/a

Replacing hazardous chemicals with safer alternatives applying the precautionary principle will avoid unnecessary testing

The current data requirement for these low tonnage chemicals is not sufficient to evaluate the risk, therefore 3 more non-animal tests and a safety report are needed

