

ANNEX - QUESTIONS TO THE COMMISSION

- ▶ Question no 51 by Caroline Lucas ([H-0182/05](#))

Subject: Validity of animal testing

[H-0182/05](#)

What is the Commission's opinion on the many challenges to the validity of animal testing, and what does it intend to do in order to speed up the development and use of alternative methods?

(EN) In response to the honourable Member's question about the validity of animal testing, the Commission would like first to express its strong conviction that animal testing should be minimised as far as possible, and that all efforts should be put into development of alternative methods.

Now, to address the question put forward by the honourable Member, it is often argued that results of animal tests are not valid in order to predict effects on humans. For that reason – and to try to give an answer to these concerns –, the Commission requested its Scientific Committee for Toxicity, Eco-toxicity and Environment (CSTEE) to assess the validity of animal testing.

In its opinion of 8 January 2004, the Scientific Committee for Toxicity, Eco-toxicity and Environment stated that scientific literature is full of examples demonstrating that animal models are good predictors for chemically-induced disorders in humans.

Certainly, there may be differences in responses between animals and humans, but they are most often of a quantitative, rather than a qualitative, nature.

Finally, the Scientific Committee for Toxicity, Eco-toxicity and Environment notes that there are exceptions to this rule: there are some chemicals that induce toxic effects in humans that are not seen in animals, and vice versa: some chemically-induced diseases in humans have not been modelled in animals. However, according to the Scientific Committee, these are the exceptions rather than the rule.

Development of alternative methods and assessment of the validity of test methods fall within the competence of my colleague Commissioner Potocnik, and I will respond to this part of the question on his behalf.

Before new test guidelines can be accepted into Community legislation, their scientific validity has to be established. This is done by national co-ordinators from the Member States through meetings steered by the European Chemicals Bureau (ECB), as part of the Commission's Joint Research Centre.

The development, validation and use of alternative methods have been a priority

for the Commission for quite some time. Specifically, there have been four main strands of activity.

Firstly, the development of in vitro tests as alternatives to animal experiments has been a priority for the various European Community research programmes since 1985.

The Commission is funding development of novel alternative, non-animal testing methods through two specific parts of the current 'Sixth Framework Programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006)'⁽¹⁾

So far, € 39 million has been allocated for projects in this area, and additional calls for proposals will be published in the forthcoming months. In the 7th Framework Programme, the development of alternative test methods will be further pursued under two priorities, Priority 1, 'Health', and Priority 6, 'Environment'.

Secondly, the Commission supports validation of alternative methods through Directorate General JR⁽²⁾ European Centre for the Validation of Alternative Methods (ECVAM). ECVAM ensures the necessary information flow on supported projects and transfer of results obtained.

Thirdly, to speed up the use of alternative methods, the Commission proposes their inclusion as a matter of priority in the relevant Community legislation as appropriate.

Finally, to promote alternative methods to animal tests on the international level, the European Centre for the Validation of Alternative Methods is working closely with the Organisation for Economic Cooperation and Development (OECD) in the validation, acceptance and promotion of alternative methods. It is a major success that, in 2004, the OECD adopted, for the first time, alternative methods that are aiming at replacing animal tests (they are in particular used for skin absorption, skin corrosion, photo-toxicity).

The Commission takes also a leading role in the international regulatory dialogues with authorities in the United States and Japan. This is very important to facilitate mutual recognition, acceptance and implementation of scientifically validated testing methods.

In addition, in order to speed up the use of alternative methods, the 7th Amendment of the Cosmetics Directive 76/768/EEC established in 2003 new provisions related to non-animal testing of cosmetic finished products and ingredients. The amendments will gradually introduce an animal testing ban for cosmetics, and a marketing ban for cosmetic products which were tested on animals.

Finally, the Commission has set up an Ad Hoc Group with representatives from industry, academia, animal welfare groups and governmental bodies to monitor

the progress in this field.

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- (1 These are Development of new in vitro tests to replace animal experimentation
) (Thematic Priority 1 - Life Sciences, Genomics and Biotechnology for Health)
and Development of alternative in vitro testing methods and strategies for
chemical substances (Specific activities covering a wider field of research -
Policy support and anticipating scientific and technological needs).
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