

Commissioners Dimas and Verheugen
European Commission
Rue de la Loi, 200
Bruxelles 1049

11 July 2005

Dear Commissioners Dimas and Verheugen,

I am writing with regard to animal toxicity testing, particularly in the context of the current REACH discussions. As a member of the European Parliament's Committee on the Environment, Public Health and Food Safety, the success of REACH is of the utmost importance to me.

You may be aware that I have tabled a set of amendments to Annexes V – VIII of the proposal, aimed at replacing all animal tests with non-animal alternatives. I now wish to outline my reasons for taking this radical step, and to ask whether the Commission intends to take any specific action towards seeking the replacement of animal toxicity testing.

In addition to the powerful ethical arguments against using animals to test chemicals, it has become increasingly apparent that many scientists and regulators believe that animal tests are simply not able to provide the high level of protection expected from a modern regulatory system.

Evidence that animal tests are inherently poor predictors of human health effects appears to be mounting, and yet these tests – which have never been validated to the high standards set for new non-animal tests – are in use throughout the world. It seems that their continued use is, at least in part, due only to the fact they have always been used. But I believe that their replacement, as demonstrated by the huge interest in in-vitro techniques, QSARs, and new toxicogenomic testing, must now be seen a matter of 'when' rather than 'if'.

My amendments can now be viewed in full at a designated website: www.reachnonanimaltests.org. You will see that as well as setting out alternative test strategies, I have included references to scientific literature providing evidence of the weaknesses of animal tests. I fully appreciate that far more work is needed to perfect many non-animal test strategies, but I do want to set the non-animal methods already available alongside the non-validated animal tests which I believe should be replaced as a matter of urgency. I believe the direct comparison is worthy of further attention, especially in those areas where animal tests are particularly weak.

As well as being concerned about the performance of individual animal tests, I also wish to raise awareness of the fact that animal testing frequently produces misleading or uncertain results that can hinder effective regulation.

The extrapolation of test data from animals to human beings and from laboratory doses to real life exposure is fraught with problems. The UK's Royal Commission on Environmental Pollution's 2003 report: 'Chemicals in Products', presented detailed analysis of the problems associated with identifying and controlling chemicals of concern. After examining the consequences of reliance on animal test data, the RCEP concluded that: 'The limitations arising from the need to use surrogate species, the consequent use of safety or application factors, the inadequate characterisation of long term effects, and the use of tests based on single substances, all introduce a significant degree of uncertainty into hazard characterisation.' They go on to state that Animal testing 'seems at present to be the best approach to answering some questions about toxicity, but it also seems to stand in the way of reasonable progress.'

I believe that if we are to seek a better approach, we must act now. It is unacceptable for the EU's flagship new chemicals policy to rely on outdated and cruel animal tests, and I believe we must not let the opportunity presented by REACH, and the formation of the European Chemicals Agency, slip by.

Actions already taken in relation to implementation of the 7th amendment to the Cosmetics Directive must be extended through REACH and the work of the Agency to ensure that all non-animal tests available are brought into use immediately. Strategies to replace animal testing must be devised and implemented, and where further work is needed, funding must be increased. And where animal tests are simply not up to the job of accurately predicting human health effects, their use must simply stop. (In those cases, a precautionary approach, together with substitution of hazardous chemicals with safer alternatives, is far more valuable than data gathering.)

In closing, I wish to seek two things. Firstly, I would be very grateful if you could give me an indication of whether the Commission intends to take further action in accelerating the development, validation and regulatory acceptance of non-animal tests. Secondly, I would be interested to hear your response to points made above, and most especially to seek your views on the conclusions reached by the UK's Royal Commission on Environmental Pollution regarding the use of animal tests.

Thank you in advance for your consideration.

Yours sincerely,

Caroline Lucas MEP