MAROŠ ŠEFČOVIČ
VICE-PRESIDENT OF THE EUROPEAN COMMISSION

B-1049 BRUSSELS

Brussels, 21/05/2010
C/2010/3242

Dear Lord Roper,

The European Commission would like to thank the European Union Committee of the House of Lords for having examined the proposal for a Directive on the protection of animals used for scientific purposes, revising Directive 86/609/EEC {COM(2008)543}, and for having provided its opinion on the proposal. This Report constitutes valuable input to the procedure leading to the adoption of the new directive.

In line with the Commission's decision to encourage National Parliaments to react to its proposals in order to improve the process of policy formulation, we welcome this opportunity to respond to your comments. I enclose the Commission's reply and hope you will find this a valuable contribution to your own deliberations.

I look forward to developing our policy dialogue further in the future.

Yours sincerely,

Maroš Šefčovič

P.S. Thanks for your kind words in Stockholm.

Lord Roper
Chairman of the European Union Select Committee
House of Lords
Palace of Westminster
UK-London SW1A OPW

EUROPEAN COMMISSION

COMMENTS OF THE EUROPEAN COMMISSION ON THE REPORT OF THE HOUSE OF LORDS ON THE COMMISSION PROPOSAL FOR A DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES ***{COM(2008) 543}***

The general support expressed by the European Union Committee in its Report towards the measures proposed in the Commission's proposal is highly appreciated. With respect to the comments made by the Committee, the European Commission has taken note, in particular, of concerns raised in relation to the following issues: The scope of the proposal, inclusion of severity classifications in the proposal and establishment of an upper pain threshold, the re-use of animals and inspections of establishments, the introduction of new care and accommodation standards in establishments, the specific attention to the use of non-human primates whilst allowing them to be used should no other animal be suitable, systematic ethical evaluation and promotion of the '3Rs'.

In reference to inclusion/exclusion of invertebrate species from the scope, it is important to note that comitology procedures can only be applied when modifying non-essential elements of a legal instrument. However, the scope of a Directive is a fundamental element and thus cannot be changed through comitology.

With regard to severity classification and the inclusion of an upper threshold in the Directive, as you may be aware, the Commission organised an expert working group in July last year which was tasked with establishing definitions for severity categories to be included in the proposal during the co-decision procedure. The work was completed swiftly and resulted in the definitions of four categories: non-recovery, mild, moderate and severe; as well as in the definitions of the lower threshold and a clear upper threshold of pain, suffering and distress. The Report of the Working Group was published on our website[1] and the Swedish Presidency used the findings in the compromise text. Linked to this, during the co-decision negotiations it was agreed that re-use of animals could be permitted following procedures classified as moderate, rather than only mild, as was originally proposed by the Commission.

Enforcement was one of the key elements of the Commission proposal, and as you are aware, the Commission proposal called for two annual inspections, one of which was to be unannounced. During the lengthy discussions with the EP and the Council other elements were brought to our attention having an influence on the efficacy and frequency of

[1] http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

inspections. It was concluded that annual inspections should be performed on one third of establishments, a proportion of which should be unannounced. The Commission would be responsible for controlling the inspection systems of national authorities should the need arise.

Extensive and thorough discussion on these pertinent issues and others took place during the co-decision procedure, with the aim of achieving a compromise text acceptable to all parties and providing the best improvements possible in animal welfare standards. During these discussions, the Commission defended its original proposal. In this context it is important to note that three central elements - systematic ethical evaluation, the authorisation of projects and the promotion of the 'Three Rs' - were supported by the vast majority of negotiators throughout the discussions and these have been reflected accordingly in the final outcome.

The Commission would like to thank the Committee for its generally supportive view of the Commission's proposal. In particular the Commission would like to thank the Committee for supporting the following elements: the concept of an ethical review process for all projects involving animals; restrictions placed on the use of non-human primates in scientific procedures linked to debilitating and life-threatening conditions having a substantial impact on patients' day-to-day functioning; full authorisation for all projects; a minimum frequency of inspections of one per year for all relevant sites; and finally endorsing the aspiration of limiting the supply of non-human primates to second-generation purpose-bred animals in the future.

Regarding the adoption procedure, the Swedish Presidency managed to obtain a political agreement on the substance of the text of the proposal shortly before the end of 2009. Issues related to comitology remained unresolved in light of the entry into force of the Treaty of the Functioning of the EU (Lisbon Treaty). However, these were finally settled under the Spanish Presidency during a trilogue on 7 April between the Parliament, the Council and involving the Commission. Final adoption of the directive is likely to take place early autumn.

The European Commission would be happy to respond to any further questions the Committee may have on the new legislation in the future.