European Commission

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By email only

Dear Members of the European Parliament,

Thank you for your letter of 30 January 2017 on Directive 2010/63/EU on the protection of animals used for scientific purposes (here below referred to as "the Directive") and its review obligations.

As required by the Directive, the European Commission will be carrying out a review and a feasibility study by 10 November 2017.

The review will focus on the early impacts of the Directive based on preliminary findings in selected target areas. This is due to the partly delayed transposition into Member State national legislations and hence still limited experience as regards implementation of the Directive. It is unlikely that the Directive's projected benefits, especially in terms of improved welfare and science, will have fully materialised already this year. However, the Commission has planned another, more comprehensive evaluation for 2019, in line with the Commission Better Regulation programme.

In the meantime, extensive stakeholder consultations were held between 27 May and 31 August 2016 inviting the user community (those who breed, supply or use animals), Member State authorities, other EU-level stakeholder organisations and animal welfare organisations at national and at EU level to participate. The responses to these consultations are currently being analysed. Further stakeholder input is possible before the Commission review report is finalised at a stakeholder meeting planned to take place before April 2017.

Furthermore, the Commission requested an update from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) of its predecessor's opinion "The need for non-human primates in biomedical research, production and testing of products and devices". The draft SCHEER Opinion is open for public consultation between 10 February and 26 March 2017 and a public hearing will be held on 14 March 2017 in Luxembourg.

The feasibility study under Article 10 of the Directive follows a similar process, but with a much more defined scope. Its objective is to assess the availability of non-human primates that are the offspring of an animal which has been bred in captivity, or that are sourced from self-sustaining colonies, within the timelines as set out in Annex II of the Directive. The responses to the targeted stakeholder consultations are being analysed and the summary findings will be presented at a consultation meeting scheduled to take place by the end of March 2017 in Brussels.

With regard to figures on implementation, please note that Member State implementation reports will be submitted to the Commission in 2018, as provided by Article 54(1) of the Directive. Attentive to the correct and complete transposition of this Directive into national legislation, the Commission has launched pre-infringement enquiries for all the Member States (25 enquiries were already sent, the remaining 3 are in process).

Regarding figures on the evolution of animal testing, please note that the new Directive revised the statistical reporting substantially, so that new data will not be comparable to the previous reports. 2014 was the first year in which the Member States collected data using the new reporting requirements. The Commission has set up a webpage showing Member State data as they become available[1].

The first EU report is foreseen for 2019. Information on how Member States are promoting alternatives towards full replacement of animals or guidance for correct application of the Directive can be found on the corresponding Commission website[2].

Finally, I would like to draw your attention to a forthcoming report from a scientific conference organised by the Commission on 6 and 7 December 2016. It gathered scientists, researchers, animal welfare organisations and policy makers to take stock of the current advances in science and to discuss how to advance faster towards the ultimate goal of replacing animals in science, research and regulatory testing. The report is expected to be published later this month on the Commission's website[2].

Yours sincerely,

Karmenu Vella

[1] http://ec.europa.eu/environment/chemicals/lab_animals/member_states_stats_reports_en.htm
[2] http://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm