



13 JUN 2017

Brussels,
ENV.B2/SL/Ares(2017)

Dear petitioners,

The European Commission is fully committed to animal welfare, as well as to protecting health and the environment. These are the obligations laid down in the Treaty for the functioning of the European Union. At the same time, specific EU legislation obliges the Commission to ensure the safety and efficacy of new pharmaceutical products and the safety of chemical substances for people, animals and the environment. Achieving these obligations involves careful consideration.

Today, significant progress in the development of science in non-animal methodologies can be observed, in part also thanks to EU funding and coordination.

Despite the progress, considerable scientific challenges remain for the more complex endpoints in basic and applied research, pharmaceutical product development and safety testing of substances. Where the toxicological mechanisms or physiological processes are not yet sufficiently understood or are very complex, alternative solutions are often not available. I can assure you that also in these cases, all available methods are being used, including computer based technologies, *in vitro*, as well as those based on animal procedures. A complete moratorium on animal studies is currently not compatible with the obligations to ensure a high level of protection of human and animal health and the environment.

The Commission Communication in response to the Citizens' Initiative "Stop Vivisection" explains this in more detail. The European Commission believes that the way forward is through the acceleration of the development and validation of non-animal methods.

The European Commission acknowledges the value of systematic reviews and meta-analyses of animal studies, especially with clearly defined scientific questions, and therefore encourages all those involved with research, including funding bodies at national level, to do more systematic reviews. Systematic reviews, for example in the guidance on Project Evaluation and Education and Training under the Directive for the protection of animals used in science (2010/63/EU) are also actively promoted. Systematic reviews can provide valuable information for the purposes of harm-benefit assessments. However, the methodology may not be appropriate for all types of projects.

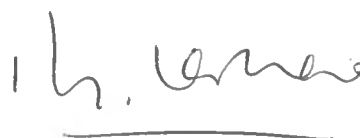
In addition, Directive 2010/63/EU is still in its first years of being implemented, and it will take time until all benefits of the systematic project evaluation mandated by the Directive will emerge. For now, one can already observe that there is much more focus on the proper scientific justification before projects using live animals are authorised in the EU.

With regard to research funding, in the period 2006 – 2016, the EU spent more than €400 million on more than 100 projects about animal-free testing and research methods. However, national and private funding bodies also play a key role in keeping the balance of support for specific research areas – EU funding complements national and private research funding.

Finally, the European Commission continuously seeks out ways to support and facilitate the advancing of non-animal approaches. For example, the two-day conference last December "Non-animal approaches – the way forward" brought together a wide range of high level scientists from the different disciplines of research using animal and non-animal methods, and set off an expert debate. (See [the conference report and its recommendations](#)).

I appreciate your concern, and remain committed to working towards the ultimate goal of replacing the use of animals for scientific purposes.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D. Calleja', written over a horizontal line.

Daniel Calleja