European Parliament
2019-2024

Committee on Petitions

8.6.2020

NOTICE TO MEMBERS

Subject: **Petition No 1125/2019 by Julia Baines (British), on behalf of PETA UK, PETA France, PETA Germany and PETA Netherlands, on a moratorium on animal experimentation**

Petition No 0058/2020 by S.S. (German) on animal testing

1. Summary of petition 1125/2019

The petitioner asks for a Europe-wide moratorium on the use of animals in scientific research while the value of such experiments is being assessed and recognised. She argues that research shows that animal experimentation has contributed very little to current knowledge regarding infectious diseases, neurodegenerative disorders, strokes, cancer, and many other human illnesses. According to the petitioner, the future of science lies in cutting-edge, non-animal methodologies such as organs-on-chips, 3-dimensional human skin cultures, micro-models of the brain, and computer models that can accurately predict what happens in humans.

Summary of petition 0058/2020

The petitioner calls for immediate ban on animal testing. He explains that there are alternatives testing methods and gives the example of the Netherlands.

2. Admissibility

Petition 1125/2019 declared admissible on 6 March 2020.
Petition 0058/2020 declared admissible on 30 April 2020.

Information requested from Commission under Rule 227(6).

3. **Commission reply**, received on 8 June 2020

Introduction

The European Commission is fully committed to animal welfare and to the ultimate goal of full replacement of animal testing. This is also reflected clearly in Directive 2010/63/EU on the protection of animals used for scientific purposes[1]. At the same time, to protect people, animals and the environment, EU legislation obliges us to ensure the safety and efficacy of new pharmaceutical products; the safety of chemicals (including plant protection products and biocides); as well as food and feed safety. Fulfilling these obligations involves careful consideration.

Contrary to the petitioners' assertion that animal research is of limited value, it is a fact that animal studies have contributed significantly to improved health and quality of life as well as to longer life expectancy. Effective treatments exist today for many infectious diseases, some forms of cancer, and several chronic diseases such as diabetes. These advancements would have been impossible without the insights gained through animal studies. Such studies are also required by Union legislation to authorise human clinical trials, and to protect health and the environment.

Strengths and weaknesses of animal models

The Commission recognises that animal models, like all research tools, have their strengths and limitations, depending on the question to be addressed. For instance, zebra fish have provided an excellent model to study developmental processes of higher organisms. Mice are a highly informative model for many human genetic diseases, e.g. for hearing, vision or bone disorders - but of limited value for studying Ebola, or acquired immune deficiency syndrome (AIDS), for example.

Technological advances have revolutionised biomedical research, bringing new possibilities to improve our knowledge, such as the capacity to sequence the genome of organisms, computational tools to analyse biological processes and to simulate the complex mechanisms involved in health and disease. Innovative tools include human 3D-tissues and reconstituted mini organs. These major breakthroughs allow the development of alternatives based mainly on cell or tissue cultures, as well as computational methods, thus replacing, reducing and refining animal use, where possible.

These and other tools are discussed in the report from a scientific conference organised by the Commission in December 2016 to engage the scientific community and relevant stakeholders in a debate on how to exploit cutting edge advances in biomedical and other research in the development of scientifically valid non-animal approaches[2].

The Commission is currently organising another conference, postponed to the end of 2020 due to the corona crisis, aiming at promoting the use of non-animal models to a targeted audience of academia, researchers, educators, industry, authorities and non-governmental organisations

[1] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes Text with EEA relevance, *OJ L 276, 20.10.2010, p. 33–79.*

[2] https://ec.europa.eu/environment/chemicals/lab_animals/3r/scientific_conference_non_animal_approaches_en.htm

(NGOs).

Implementation of Directive 2010/63/EU

Directive 2010/63/EU requires the use of alternative approaches whenever a scientifically satisfactory method or testing strategy is possible instead of a procedure using animals. The Directive furthermore establishes mechanisms to speed up the development, validation and uptake of alternative approaches. The Commission is committed to ensuring full implementation of the Directive across the EU. Since several instances of incorrect transposition issues were identified, the Commission entered into dialogue with all Member States. Some discussions have led to good results and others have been followed up by a formal infringement procedure. If the national laws transposing the Directive are identified as non-compliant, more infringement procedures may follow where appropriate.

Progress in development of alternative approaches and EU funding

Despite significant progress in the development of alternative approaches, 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 or physiological processes and mechanisms are complex or not sufficiently understood, often alternative solutions are not yet available. Thus, the complete replacement of animal studies is currently not possible as we need to ensure a high level of protection of human and animal health and the environment. Also in these areas all available methods are being used, including computer based technologies, in vitro and others, in order to minimise the use of animal procedures as much as possible.

The Commission considers that the ultimate goal of full replacement of all use of animals for scientific purposes is most efficiently progressed through focused and targeted efforts. The Directive provides for a strategy that is a legally binding step-wise approach as soon as scientifically satisfactory methods become available. The statistical reporting under the Directive was revised in support of this same objective. The new, more comprehensive and detailed data, including on animal suffering, will facilitate the identification of animal use areas on which efforts by the Commission, Member States and other stakeholders for the development and validation of alternative approaches will have the widest impact in progressing towards the ultimate goal.

On that basis, the Commission has been supporting research into alternative approaches and continues to do so. Over the last two decades, the Commission has funded more than 200 projects with over EUR 700 million.

A variety of in vitro and computer tools have been developed and used to acquire new knowledge relevant to human physiology, pathology and toxicology. They are increasingly applied in the replacement of animal tests for some key endpoints for safety assessment, such as skin sensitization and irritation, and are being refined further to gain knowledge of more complex toxicological pathways.

Two further opportunities for significant funding in 2020 are currently open in the last calls of Horizon 2020. They include a call of EUR 60 million for the advancement of safety assessment of chemicals without the use of animal testing and a call of EUR 18 million for the next generation organs-on-chip. The new Programme for Research and Innovation (Horizon Europe:

2021-2027) is expected to continue developing improved alternative methods to animal testing.

Furthermore, the Commission is pursuing actively the development, validation and practical implementation of new, non-animal methods through the European Partnership for Alternatives to Animal Testing (EPAA) that brings together regulators, academia and practitioners from laboratories and industry to foster the acceptance and uptake of alternatives.

Conclusion

The Commission's ultimate goal is to replace all animals in research, as stated in Directive 2010/63/EU for the protection of animals used in science, and the Commission is actively working towards this goal, *inter alia*, by monitoring the correct implementation of the legislation, by funding research in non-animal models and by facilitating dissemination and exchange on latest scientific developments in the field of alternatives through, for example, organising scientific conferences. A Europe-wide moratorium on the use of animals in science is, however, not yet possible.