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EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Circular Economy and Green Growth
Director

Brussels,
ENV.B.2/KS/ARES(2020)

Dear petitioner,

The president of the European Commission has asked me to reply to your letter on her behalf.

The European Commission is fully committed to animal welfare and to the ultimate goal of full replacement of animal testing. This is clearly reflected in the European legislation, Directive 2010/63/EU on the protection of animals used for scientific purposes.

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 pesticides and biocides); as well as food and feed safety.

Achieving these obligations involves careful consideration.

Contrary to what you claim, animal studies have contributed significantly to improved health and quality of life as well as 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 in animal studies. Such studies are also required by legislation to authorise human clinical trials, and to protect health and the environment.

We recognise that animal models, like all research tools, have their strengths and limitations, depending on the question to be addressed. For instance, zebra fish have been 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 e.g. Ebola or AIDS.

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, when sufficiently mature, allow the development of alternatives based mainly on cell or tissue cultures, as well as computational methods, thus reducing animal use.

These and other tools are discussed in the report from a scientific conference organised by the European 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:

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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. 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 not sufficiently understood or are very complex, alternative solutions are often not available yet, despite of technological advances. Thus, the complete replacement of animal studies is currently not possible while needing to ensure a high level of protection of human and animal health and the environment. We can assure you that 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 European Commission also supports research into alternative approaches. Over the last two decades, the European Commission has funded more than 200 projects with over € 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 € 60 million for the advancement of safety assessment of chemicals without the use of animal testing and a call of € 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.

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

Yours faithfully

Kęstutis Sadauskas