EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT

The Director-General

Brussels
ENV/B.2/SL

Dear petitioner,

The European Commission confirms its commitment to animal welfare and to the ultimate goal of full replacement of the use of animals in research and testing, when scientifically feasible. These need to be balanced with the commitment to improving public health and protecting the environment.

Therefore, the Commission agrees with the European Parliament Resolution on "Plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education" which acknowledges that animal-based research has contributed significantly to advances in the treatment of many human health conditions and played a role in animal health. Today, non-animal methods are not yet available across all scientific research areas. Animal models are still needed to gain scientific insights in the long search for effective remedies for certain diseases due to the current unavailability of non-animal methods.

Concerning the EU's health research funding, the Commission has been a major supporter of alternatives to animal testing. During the last two decades, more than EUR 800 million have been dedicated to develop a variety of human-relevant non-animal methods and strategies. Some of these tools are currently being accepted and used for regulatory purposes. The further development of alternatives to animal testing will be pursued in the Horizon Europe EU's Framework Programme for research and innovation that runs from 2021 to 2027. Particular attention will also be given to the regulatory aspects.

In relation to animals used in safety and efficacy of testing of drugs for both human and veterinary use, the Pharmaceutical Strategy for Europe[1] recognises the need to promote the ethical use of animals in medicine testing. In this context, the European Medicines Agency (EMA) is promoting activities to replace, reduce and refine animal use (Three Rs principle). Non-clinical models of the effects of medicines, such as improved use of tests based on human cells and organoids and *in silico* modelling for early drug discovery are the subject of much ongoing research and have the potential to benefit medicine development and support early efficacy studies. In the EMA Regulatory Science Strategy

[1] COM(2020) 761 final.

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to 2025[2] the need for encouragement of the use of alternative techniques is highlighted. One of the recommendations is to leverage non-clinical models and Three Rs principle through promoting earlier interaction with developers of new approach methodologies (NAMs), fostering communication with regulatory agencies and relevant EU/international stakeholder platforms, facilitating access to the scientific advice qualification procedure and making use of digital tools and data standards. In September 2021, the EMA announced the opening of the Innovation Task Force as a forum for early dialogue between regulators and developers of medicines to discuss Three R-compliant methods and facilitate their integration into the development and evaluation of medicines[3]. This action will facilitate the development and implementation of NAMs that are in line with the EU legislation on the protection of animals used for scientific purposes. Finally, during the review of the basic pharmaceutical legislation relating to medicines for human use the Commission will consider the need to update the references to the testing of medicine.

Concerning the testing requirements of pesticides and other substances such as biocides, food and feed additives, both the current legislation on pesticides and biocides provide for specific measures aiming at reducing vertebrates testing, like the provision that testing on vertebrates shall be undertaken only as a last resort. This includes requirements for mandatory data sharing by applicants of available tests on vertebrate animals to avoid double testing, or provisions promoting new testing strategies over animal testing. In the field of risk assessment of food additives, EFSA has adopted a "tiered approach" that guides applicants in designing their toxicological testing strategy. Such an approach also aims at reducing the need for animal tests. The alternative methodologies include *in vitro* and *in silico* methods that can be useful for investigating toxicokinetic (what the body does to a chemical) and toxicodynamic processes in humans (what the chemical does to the body), and predict the toxicity of chemicals.

In addition, the legislation on feed additive authorisation pays particular attention to the reduction of animal testing laying down specific provisions to avoid duplication of vertebrates. The legal provisions have been additionally developed and implemented in EFSA guidance for applicants leading to a strong reduction of the use of animals. The revision of that legislation aims specifically to address this matter by the development of additional and more incisive measures.

Finally, with regard to the Chemicals Strategy for Sustainability, even if the testing of chemical substances represents only 10% of all regulatory testing, it includes a strong commitment to promote alternative methods and the use of digital technologies and advanced methods, to move away from unnecessary animal testing in both the EU and beyond. Some use of animals remains necessary due to current lack of alternative approaches.

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2 European Medicines Agency, 2020. EMA Regulatory Science to 2025; EMA/110706/2020.

3 https://www.ema.europa.eu/en/news/ema-implements-new-measures-minimise-animal-testing-during-medicines-development

Actions described in the Strategy that should lead to reducing animal testing include: effective data sharing, making more use of existing academic data, assessing and regulating substances by groups as much as possible, avoiding the most harmful substances upfront (in particular for consumer products). The impact of the planned proposal to revise REACH on the amount of animal testing will be assessed in the Impact Assessment for that legal proposal.

Yours faithfully,

electronically signed

Florika FINK-HOOIJER