VIRGINIJUS SINKEVIČIUS
Commissioner for Environment,
Oceans and Fisheries

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Dear Dr Taylor, dear Mr Mensink, Honourable Members,

Thank you for your letter of 22 November 2021 to Executive Vice President Timmermans, Commissioners Breton, Gabriel and me, expressing your concern about excessive additional animal testing that could be triggered by the Chemicals Strategy for Sustainability. Please allow me to respond, also on behalf of my colleagues.

The Commission welcomed the European Parliament's resolution aiming at accelerating a transition to innovation without the use of animals in research, regulatory testing and education, which you referred to as this also being our common goal, laid down in the EU Directive 2010/63/EU on the protection of animals used for scientific purposes.

Besides the ambition of ensuring the highest levels of protection of human health and the environment, the Chemicals Strategy for Sustainability (COM(2020) 667) also announced that safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing, but also to improve the quality, efficiency and speed of chemical hazard and risk assessments. In the Strategy, the Commission has committed to foster multidisciplinary research and digital innovations for advanced tools, methods and models, and for data analysis capacities to move away from animal testing.

As regards a clear action plan to implement our ambition to replace animal testing,we would like to point out that although the science behind alternatives is progressing fast, it is not possible to predict when scientifically valid methods will become available that can replace particular animal procedures. The EU supports the transition to innovation without the use of animals through providing maximum transparency in animal use for scientific purposes via open access data mining

tools to support all concerned stakeholders in their efforts to identify appropriate new strategic initiatives.

It is worth noting that animal use in science is very heterogeneous, therefore non-animal alternatives are most efficiently developed in clearly defined contexts of use. However, drawing knowledge across sectors can help to address scientific challenges hindering the progress towards non-animal methodologies.

Against this background, the Commission considers that a transition to innovation without the use of animals is best supported by focusing on and intensifying current efforts, reinforcing existing structures and networks, and by identifying potential areas where new actions could be undertaken within the Commission's remit.

Concerning the on-going revision of REACH information requirements in order to implement the ambition of the Chemicals Strategy, the Commission is indeed investigating how chemical safety assessment can be modernised without compromising the expected high level of protection. A project team lead by colleagues from the JRC and comprising experts from other services as well as ECHA is working to propose different options on how this could be done. The options will consist of different degrees of modifications of the information requirements in REACH Annexes VII – X and adaptation possibilities in Annex XI. The modifications will also cover different ways of relying on New Approach Methodologies (NAMs).

In order to include all latest knowledge as well as practical experience already existing in industry or elsewhere with using NAMs, the JRC has conducted a targeted survey in order to capitalise on this experience and to learn about NAM-based strategies that have the potential to fulfil one or more of the regulatory needs under REACH. In addition, the project team has also consulted with experts from the EU-funded research projects developing alternatives to animal testing EU-ToxRisk, PrecisionTox, Risk-Hunt3R and Ontox.

The different options for revised REACH information requirements will feed into the impact assessment that will be conducted during 2022 for the targeted REACH revision following the Chemicals Strategy. Impacts of the options on animal use will be assessed as part of this work.

Another action initiated under the Chemicals Strategy, the 'one substance, one assessment' approach, aims to ensure that assessment methodologies are made as coherent and harmonised as possible. This should help to avoid or reduce any duplicate testing. It strives to remove any technical or administrative obstacles to data access, according to the principles that data should be easily findable, interoperable, secure, shared and reused by default. Data will be made available in appropriate formats and tools – e.g., via IUCLID and IPCHEM - to ensure interoperability.

The Commission will continue its strong financial support of the development of alternatives to animal testing, as was the case over the past two decades, during which the Commission has provided more than EUR 800 million to more than 230 projects in this field. Under Horizon 2020, 7 new projects calling on animal-free alternative method have started in 2021 for a total funding of EUR 84 million. The further development of alternatives to animal testing will be pursued in Horizon Europe, with a funding foreseen to be at least in the same range as that of Horizon 2020.

At the same time, the Commission as well as ECHA will continue to be active partners in OECD programmes developing and/or validating alternative approaches. The Commission also actively contributes to the work on alternatives by GHS (the United Nations sub-committee on Globally Harmonised System of Classification and Labelling of Chemicals), APCRA (Accelerating the Pace of Chemical Risk Assessment), ICATM (the International Cooperation on Alternative Test Methods), ICCR (International Cooperation on Cosmetics Regulation) and ICH/VICH initiatives. I trust that you are familiar with these initiatives.

Finally, the Commission has also invested significant time and effort to develop various e-learning modules with the financial support of two European Parliament Pilot projects. These e-modules cover different Three R's aspects for professionals still working with animals as well as training on how to identify available alternative methods and how to design new alternative in vitro methods for regulatory use.

I hope to have addressed your concerns for the time being. More information on how all the goals of the Chemicals Strategy will be reached should become available during 2022.

Yours sincerely,

Virginijus Sinkevičius

Cc: Ms Tilly Metz MEP
Ms Jutta Paulus MEP
Ms Sirpa Pietikainen MEP
Ms Maria Spyraki MEP