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EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT

The Director-General

Brussels,
ENV.B2/KS

Dear petitioner,

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

Today, we can observe significant progress in the development of science in non-animal methodologies, to a large part also thanks to EU funding and coordination.

Despite the progress, considerable scientific challenges remain for the more complex effects on organisms when testing for the safety of substances. Where the toxicological mechanisms or physiological processes are not yet sufficiently understood or are very complex, alternative solutions are often not available.

For the purposes of registration under REACH, where information requirements are listed in the Annexes VII – X to the REACH regulation, registrants must not undertake any new studies involving vertebrate animals required by REACH Annex IX or X before submitting a testing proposal to the European Chemicals Agency (ECHA) and only after receiving ECHA's decision requiring the test to be performed, and under which conditions. When they submit their proposal, the registrants must show in their dossier that they have considered alternatives. ECHA organises third party consultations for all testing proposals involving vertebrate animals, for the requirements specified in REACH Annexes IX and X. The aim is to ensure that there is no scientifically valid, existing data that could already address the hazard endpoint covered by the testing proposal. Such information, if it can be used to fill the data gap, may mean that the proposed testing is no longer required and is sent to the registrant together with the draft decision for their consideration. ECHA, in consultation with the Member States, adopts the testing proposal decision based on the registrant's proposal, the information submitted by third parties and any readily available information identified by ECHA. Many comments received from third parties are about potential strategies that the registrant could use, for example, information supporting weight of evidence, references to open literature and, unfortunately seldom, potentially relevant studies. However, the registrant may face challenges to make use of this information. One difficulty is to get reliable and adequate documentation so that the information can be used for classification and risk assessment and to establish that the information has adequate and reliable coverage of the

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key parameters addressed in the corresponding test method. Another challenge is to get access to study reports identified by third parties and compensate the data owner.

Information requirements under REACH at Annex VII and VIII also list some information requirements for which no testing proposal is required:

- The information requirements for skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation have been amended in 2015 to make the non-animal methods the default requirement, and allowing the in vivo method only if the alternative cannot be applied. As shown in ECHA's 4th report on "The use of alternatives to testing on animals for the REACH Regulation", in vitro studies for these endpoints have been clearly taken up since the previous report in 2016. The amendment of the REACH annexes has played an important role in accomplishing this significant change in the use of alternative methods.

- When data are needed for repeated dose toxicity and toxicity to reproduction screening, for which alternative approaches are not yet available, these studies are increasingly performed using the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD 422). This significantly reduces the number of animals and costs.

ECHA uses the findings in the above-mentioned report to promote alternative methods through guidance, web content, webinars and events. With the chemicals knowledgebase as one of the resources, ECHA will use the report's findings to continue to promote non-animal testing methods by developing and maintaining tools, guidance and web content to support registrants.

The European Commission believes that the way forward to replacing animal testing is through the acceleration of the development and validation of non-animal methods. To this end, it continuously seeks out ways to support and facilitate the advancing of non-animal approaches. For example, the Commission organised already two conferences on this topic:

- One in December 2016 "Non-animal approaches – the way forward" (see the conference report and its recommendations) and

- One in February 2021 "Towards replacement of animals for scientific purposes" (see conference report and presentations)

As the European Ombudsman stated, it is the responsibility of the Member States to investigate and sanction non-compliance of the last-resort principle.

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, under REACH as well as for other regulatory and research purposes.

Yours sincerely,

Florika FINK-HOOIJER