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BETER
LEEF VOOR DE TOEKOMST
MILIEU


Corporate
Europe
Observatory

To: Executive Vice President Timmermans and Commissioners Breton, Sinkevičius, Kyriakides
CC: Heads of Cabinets Samson, Moutarlier, Šatūnas, Rossides

Re: Need to update the REACH information requirements

Brussels, 27 February 2023

Joint NGO letter

Dear Executive Vice President, Dear Commissioners

We, the undersigned NGOs, warmly welcome your initiative to reform the EU flagship regulations REACH and CLP as part of the commitments made under the EU Chemicals Strategy for Sustainability (CSS). When it comes to the revision of the chemicals legislation the priority is to ensure a higher level of protection and minimise the rampant exposure of people and the environment to harmful chemicals.

The reforms of the REACH and CLP regulatory systems are a crucial opportunity to address the current, undeniable data gaps[1] and the need to speed up regulatory action on harmful chemicals[2] . With this letter, we would like to express our serious concerns about these data gaps, which hamper an effective identification and risk management of the chemicals of most concern such as chemicals causing cancer, infertility, or disruption of our hormonal systems. In the absence of such data, regulatory decisions are not taken, and potentially harmful chemicals unnecessarily remain on the market, exposing billions of people and the environment for years to come.

Therefore, the undersigned NGOs call on the EU authorities to:

1. **Update the REACH information requirements to ensure the necessary information is available to protect people and the environment in line with the commitments of the CSS.**

The current information requirements under REACH are not sufficient for the identification of serious, long-term hazards for human health and wildlife. An update of the information requirements under REACH is urgently needed to enable an effective identification of all carcinogenic, reprotoxic and endocrine disrupting chemicals. While we support and share the efforts to reduce and limit tests on laboratory animals to the minimum, unfortunately for the moment, regulatory accepted new approach methods (NAMs) are not available to fully replace animal tests for the regulatory identification of the most serious hazards such as carcinogenicity and endocrine disrupting properties. Therefore, these are still needed when prioritising protection of citizens and wildlife.

2. **Work towards a gradual transition to hazard identification based on NAMs in the future, as a foundation for the regulatory control of harmful chemicals**

As more reliable and regulatory accepted NAMs become available, a gradual transition towards NAM-based hazard identification can be made possible in the future. However, currently a full replacement of animal tests by NAMs is not yet possible given the too limited development of regulatory accepted NAMs covering all relevant hazards.

[1] *The unknown territory of chemical risks — European Environment Agency*

[2] *The Need For Speed - Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protection - European Environmental Bureau*

Therefore, we call for the introduction of legal provisions in the regulatory framework that allow the use of NAMs, when they are considered acceptable by regulatory authorities. In this way, they can effectively be used to serve the identification and regulatory control of the most hazardous chemicals. This will improve the level of protection, while gradually replacing animal testing.

3. **Implement the precautionary approach[3] to increase health and environment protection and reduce animal testing**

The precautionary approach is the most cost-efficient way to enhance protection of health and the environment, while reducing the need for animal testing. In the event that hazardous properties are identified for a substance, based on evidence from structurally related chemicals, NAMs, academic data and other existing information, this evidence should directly lead to a precautionary decision by authorities. Additional animal tests should not be required to prove the evident harm and there is no need to put people and wildlife at further risk. Ensuring better use of existing data for hazard identification and taking precautionary action to phase-out the most harmful chemicals from consumer products, will decrease the burden of evidence, while effectively reducing the need for animal tests.

We have attached a position paper that elaborates on these proposals in more detail. We urge you to take action on these proposals to protect human health and the environment from hazardous chemicals and we would greatly appreciate the opportunity to further discuss our concerns and proposals in a meeting with you.

Sincerely,

Patrick ten Brink
Secretary General, European Environmental Bureau (EEB)

Michael Warhurst
Executive Director, CHEM Trust

Genon K. Jensen
Executive Director, Health and Environment Alliance (HEAL)

Frida Hök
Deputy Director, ChemSec

Luis Hernández
Toxics Area Coordinator
Ecologistas en Acción, Spain

Véronique Moreira,
Présidente, WECF France,

Éger Ákos
ügyvezető elnök - executive president
Magyar Természetvédők Szövetsége - Friends of the Earth Hungary

Francesco Romizi,
Public Affairs, ISDE (International society of Doctors for Environment Italy)

[3] As stated in this EC communication. *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*

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Director
Bond Beter Leefmilieu

Vicky Cann, Campaigner
Corporate Europe Observatory (CEO)

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Position paper

Recommendations for working towards human health and environmental protection, while gradually replacing animal testing

Context

The REACH and CLP regulations are complementary to each other and aim to improve the protection of citizens and the environment against the threats from hazardous chemicals. Revision of both regulations is required to achieve the goals of the CSS. The foreseen revision of the CLP would be a major step forward with the inclusion of the new hazard classes for endocrine disrupting chemicals and persistent chemicals that either bioaccumulate in organisms or are mobile in water and pollute our drinking water. However, revision of the REACH Annexes is also needed to ensure that the information to identify these serious hazard properties becomes available, to enable companies to fulfil their obligations regarding safe use, and authorities to identify the substances of most concern such as chemicals causing cancer, infertility, or disruption of our hormonal systems. This information can then be used for increased risk management under REACH, as well as for other sectoral legislation.

We call on the EU authorities to:

1. Update the standard registration requirements under REACH to enable an effective identification and regulation of hazardous chemicals in line with the commitments of the CSS
2. Work towards a gradual transition to hazard identification based on NAMs in the future, as a foundation for the regulatory control of harmful chemicals
3. Implement the precautionary approach[4] to increase health and environment protection and reduce animal testing

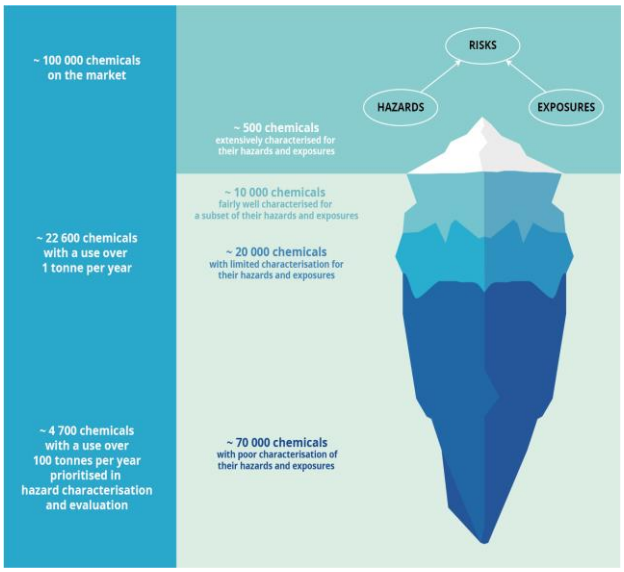
In this position paper, the NGO recommendations for improving protection of health and the environment, while gradually replacing animal testing are further elaborated.

1. Standard information requirements under REACH should allow for effective identification and regulation of hazardous chemicals as committed in the CSS

The **standard information requirements under REACH should allow for a swift identification of the hazardous properties of all harmful chemicals.** However, the current information requirements under REACH are not sufficient for the identification of serious, long-term hazards. For example, they do not enable the identification of all carcinogens or chemicals that affect our hormonal systems. The European Environment Agency (EEA) reported in their 2020 outlook[5] on the European environment about the unknown territory of chemical risks in Europe. Over 22.000 chemicals were registered under REACH and placed on the EU market. Only 500 of these chemicals were well characterised with respect to their hazards and exposure.

[4] As stated in this EC communication. "*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*".

[5] *The European environment - state and outlook 2020 - European Environment Agency*



The unknown territory of chemicals risks - EEA, 2020[6]

These data gaps hamper an effective identification and risk management of the chemicals of most concern such as chemicals causing cancer, infertility, or disruption of our hormonal systems. In the absence of such data, regulatory decisions are not taken and potentially harmful chemicals unnecessarily remain on the market, exposing billions of people and the environment for years to come.

The reforms of the REACH and CLP regulatory systems are a crucial opportunity to address the current, undeniable data gaps and the need to speed up regulatory action on harmful chemicals[7]. Therefore, an update of the standard information requirements in the REACH Annexes is urgently needed, to enable an effective identification of all carcinogenic, reprotoxic and endocrine disrupting chemicals by companies and authorities.

While we support and share the need to reduce tests on animals, as already promoted by the REACH regulation, we note that it is currently not possible to fully eliminate animal testing. This is because the availability of non-animal methods that are both relevant for the purpose of identifying a certain hazard property, and that have also been validated and regulatory accepted, is still quite limited, especially with regards to the capacity to predict complex, adverse effects in intact organisms and effects in multiple generations. For example, NAMs do not enable the identification of certain types of carcinogens or chemicals that affect our hormonal systems. New types of endocrine effects or immunotoxic effects are still discovered through animal studies. Furthermore, it is currently not possible to predict certain transgenerational effects with the non-animal testing procedures available today, such as learning disabilities and behavioural disorders.

As long as regulatory accepted NAMs are not available to fully replace animal tests for the identification of serious hazards, animal tests will still play a role when giving priority to the protection of billions of citizens, livestock, pets and wildlife over the protection of test animals. The future solution therefore has to establish a regulatory system which allows earlier action based on different kinds of evidence (see point 3).

2. Working towards NAM-based hazard identification and regulatory control of the most harmful chemicals

New assessment methods, new approach methods, or non-animal methods (NAMs) are widely used under REACH by many chemical companies in their registration dossiers to facilitate their market access and to demonstrate that their chemicals are safe. However, on the contrary, companies hardly use NAMs in their chemical safety assessments to identify hazardous properties of the chemicals they put on the EU market. Also, when it comes to the regulatory risk management of hazardous chemicals, the legislation often requires animal data for the identification of a hazardous property and NAMs are barely accepted by authorities to identify and regulate harmful chemicals. This is because the purpose is to not overlook harmful properties as long as only a few NAMs are validated and accepted as suitable for regulatory purposes.

The use of NAMs for the prediction of intrinsic hazardous properties can speed up the identification of highly hazardous chemicals. A successful example of such transition under REACH was the shift from *in-vivo* animal tests to *in-vitro* tests for the assessment of eye and skin irritation and skin sensitisation, making the OECD validated *in-vitro* tests the default requirement under REACH since 2016.

[6] *The unknown territory of chemical risks — European Environment Agency*
[7] *The Need For Speed - Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protection - European Environmental Bureau*

Future developments in *in-vitro* methods, *in-silico* methods, and omics will contribute to improved prediction of other intrinsic substance properties. Increased acceptance of NAMs for the identification and regulatory control of harmful chemicals will contribute to a higher level of protection and accelerate regulatory action. Therefore, we call for the introduction of legal provisions in the regulatory framework that allow the use of NAMs that are considered acceptable by regulatory authorities to serve the identification and regulatory control of the most hazardous chemicals, thereby improving the level of protection, while gradually reducing animal testing. **A gradual transition towards a NAM-based hazard identification can be made possible in the future as more reliable and regulatory accepted NAMs become available.**

Promoting the use of group assessments is needed as a basis for regulatory actions such as classification, SVHC identification and restrictions. The current approach of regulating chemicals one-by-one takes a long time and has resulted in regrettable substitution, as seen for example with halogenated flame retardants, phthalates, bisphenols and PFAS. Therefore, authorities should stop regulating chemicals one-by-one and move towards the use of group approaches, using read-across to structurally related chemicals, in order to speed-up regulatory action on hazardous chemicals, while reducing animal testing.

3. Implement the precautionary approach[8] to increase health and environment protection and reduce animal testing

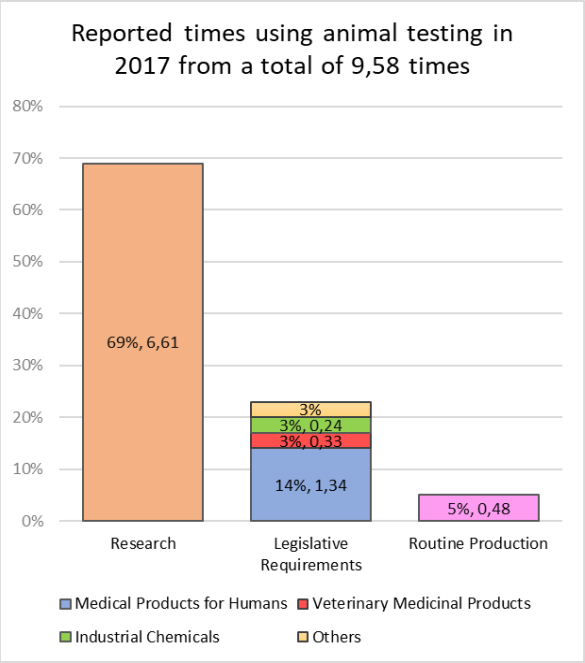
Regulators should work towards **reducing the burden of proof for authorities to identify, classify, and regulate hazardous chemicals**, with the aim to speed up the phase-out of the most hazardous chemicals to the benefit of people's health and the environment as committed in the CSS and, at the same time, replacing animal testing.

A precautionary use of all available evidence (including information from structurally related chemicals, academic data or NAMs) to identify substances' hazardous properties could play an essential role in achieving these goals. If evidence indicates potential harmful properties of a substance, there is no need to sacrifice additional animals and there is no need to put people and wildlife at further risk. We advocate for the reduction of animal testing as much as possible by **ensuring a better use of existing information**. Therefore, we promote the use of all available data for hazard identification and regulatory action, including academic data, and promote re-use and sharing of all existing data across sectors. Authorities should be allowed to use all available evidence for the identification of harmful chemicals and take a **precautionary approach to risk management** without delay. To increase the confidence in the regulatory use of NAMs, we recommend a comparative study on NAM-based hazard identification and experimental data-based hazard identification of substances as a starting point. The precautionary approach is the most cost-efficient way to enhance protection of health and the environment, while reducing the need for animal testing.

[8]As stated in this EC communication. "*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*".

Final note on animal testing - Looking at the source of the problem

Animals are used in laboratory experiments for various purposes. According to the latest EU statistics[9], the large majority of animals are used for research purposes, while only 1.5% of the animals were used for the purpose of REACH. This is a further decrease of the share of animals used under the REACH regulation since 2017 (see figure)[10].



[9] Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2019 (Commission Staff Working Document, 2022)

[10] In 2017 the use of animals for scientific purposes was mainly reported for research (69 %), followed by regulatory use to satisfy legislative requirements (23 %) and routine production (5 %); whereas among the testing carried out for regulatory purposes, the majority involved medical products for humans (61 %), followed by veterinary medicinal products (15 %) and industrial chemicals (11 %) (EP resolution - 2021/2784(RSP)).