NL non-paper on the REACH Revision

The Netherlands welcomes the upcoming revision of the REACH Regulation. This revision should improve the efficacy and efficiency of REACH in realising its goals. The goals of REACH are protecting human health and the environment, the promotion of alternatives to animal testing, enhancing innovation and free trade of substances within the EU.

This paper summarises the views of the Netherlands on the upcoming revision of REACH ahead of the publication of a proposal by the European Commission (proposal pending).

General approach

Our industry is important for Europe's open strategic autonomy and provides a significant contribution to its welfare. The European industry suffers from competitive disadvantages due to higher energy prices and unfair competition. In addition, lengthy procedures as well as administrative costs in general do lead to uncertainty for the sector and hamper innovation and investments. The Netherlands therefore invites the Commission to quickly and to the full extent implement the Chemical Industry Action Plan. The objective of the Netherlands is that the REACH revision provides clarity by accelerating procedures and reducing administrative burdens, while maintaining a high level of protection for health and environment. Comprehensive policies are needed to ensure the best protection of health and environment, rapid replacement of animal testing and free trade of substances within the EU, while facilitating innovation. This includes good alignment of the different legal instruments addressing chemicals.

In this light, the Netherlands proposes several changes that should be included in the upcoming revision of REACH ahead of the publication of a proposal by the Commission.

1) The Authorisation and Restriction processes should be optimised in order to maximise its strengths.

The instrument of authorisation serves to regulate the use of *Substances of Very High Concern* (SVHCs). Valuable information on specific uses, exposure and emissions is generated as part of this process. At present SVHCs are placed on the Candidate List for authorisation. As part of One Substance, One Assessment, the Netherlands believes that the Candidate List could be added as an annex to REACH to better enable the use of this list. This will increase clarity for competent authorities and businesses.

The Netherlands believes that Member States should be committed to provide clarity to stakeholders on which risk management options they regard most appropriate. These management options include use of the *Classification, Labelling and Packaging Regulation* (CLP) or the *Occupational Safety and Health Regulation*. Currently, it is possible to first assess the most appropriate risk management option by using a so-called *Regulatory Management Option Analysis* (RMOA). This is an important instrument that can prevent the choice of a legislative instrument that leads to high administrative costs for companies and authorities or might fail to properly address the identified risk. Therefore, the Netherlands proposes the authorities will always execute a RMOA during which, stakeholders may choose to voluntarily provide data on uses, exposure and alternatives. This serves to ensure that the most appropriate measures for all stakeholders can be realised so it can reduce high costs at a later stage. This would improve transparency and speed up the process. Sometimes different approaches could be applied to consumer products and industrial uses. A hazardous substance could be banned in consumer products whereas industrial uses might continue using risk mitigating measures which equally guarantee safety of workers, health and environment.

The Netherlands finds that the authorisation process – which applies to the production and use of substances in the EU – should be directly linked to the restriction process. In that way, not only the use of a certain chemical is regulated, but at the same time (imported) products containing this chemical. This way, also the risks during use or at the waste stage are addressed and it contributes to a level playing field as EU producers will no longer be in the disadvantaged situation they are not allowed to use the particular chemical whereas the foreign competition can.

Often, a chemical that is banned is replaced by a similar chemical. That might work well but also, over time it might become clear the new chemical is in fact as hazardous as the original, which then leads to again the need for industry to find an alternative. To prevent this regrettable substitution, group assessments can provide clarity and predictability to the industry on which alternatives are a long term solution. Off course, the grouping of chemicals should be based on scientifically just measures.

2) Introduction of a targeted Mixture Allocation Factor (MAF) to address combined exposure.

Already in 2012, the Commission determined that because at present the safety of chemicals is assessed individually, the EU legislation does not provide sufficient protection to health and environment as people and environment are exposed to several chemicals over time[1]. In its 2020 Chemicals Strategy for Sustainability[2], the Commission proposed to introduce a targeted *mixture allocation factor* (MAF) in the safety assessment. The Netherlands supports this approach and the introduction of such factor within REACH but only if applied to relevant chemicals, for instance those which qualify as Substances of Very High Concern or chemicals close to the individual safety limits. The final choice how to apply this factor will also depend on the Commission's legislative proposal and their impact assessment. The Netherlands is in favour of introducing a MAF, conditional on its proven effectiveness, as it is necessary to guarantee safe use of chemicals, in a way that prevents unnecessary burden provided its effectiveness is supported by the Impact Assessment.

3) The *Generic Approach to Risk Management* will ensure that consumers and the environment are more consistently protected and should be effective and proportionate.

In the 2020 strategy referred to above, the Commission also proposes to extend the *Generic Approach to Risk Management* (GRA). This concept implies the possibility to take risk management measures or to restrict the use of chemicals in (consumer) products. This reduces the administrative burden for authorities and industry and leads to fast implementation of a restriction. However, this might also involve chemicals with widespread use, not posing any risk at the use phase. The option to provide case-by-case derogations in such case would lead to a huge administrative burden. Therefore, the Netherlands supports only the extension of the GRA to other categories of most hazardous substances limited to consumer products.[3] However, due to the potentially large impact on the market, the Netherlands is of the opinion that the Commission should be the only actor to propose such measures, in close consultation with stakeholders, including the industry. The GRA should only be applied in case the Commission has identified a risk during use that justifies its use, including likely exposure to hazardous substances. This way procedures will be faster and simpler when necessary, and administrative burden is avoided if this is not the case.

4) Performing *Safe and Sustainable by Design* needs to be facilitated for companies. A network of expert centres could provide such support by combining local knowledge with accessing a common data platform and exchanging learning experiences.

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[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52012DC0252

[2] https://environment.ec.europa.eu/strategy/chemicals-strategy_en

[3] For other target groups other regulation is in place e.g. occupational safety regulation for work force

Substitution of SVHCs is a priority for REACH. *Safe and Sustainable by Design* (SSbD) can boost substitution with safer and more sustainable solutions. It is a voluntary approach to guide the innovation process for chemicals and materials. A framework has been developed to assist companies along the value chains to steer the innovation process towards clean and sustainable options. Further support is needed for companies. National or regional expert centres should be developed that are easily accessible to industry and have local and technical knowledge. These centres should cooperate with a centralised hub which manages a common data base. We consider the initiative from the Commission to set up a network of substitution centers as announced in the *Chemicals Industry Action Plan* a positive development. The effectiveness of these centres would benefit from also facilitating SSbD. The Netherlands proposes that these centres can also give policy advice to improve policies in support of SSbD and provide counsel on including SSbD in the curricula of relevant education and training programmes.

Transition from a linear to a circular economy means that more products will need to be reused and recycled. The REACH revision should support this.

5) An EU Strategy *Test Method Development & Validation* will help the intended development and validation of methods that are fit for regulatory purposes, for new types of effect, for both new and existing materials, while minimising animal testing.

The pace at which new substances and materials are developed, which are necessary for transitions, is higher than the development and validation of test methods. Furthermore, new tests are required for upcoming challenges such as endocrine disruptors and advanced materials without the use of laboratory animals. To accelerate the availability of regulatory accepted test methods and further improve the risk assessment of chemicals, the Commission should implement a strategy on the development and validation of test methods. This Strategy ensures that developed tests are validated so they can subsequently be approved by the OECD. The resulting test guidelines are globally accepted and so eliminate trade barriers. This will also help to realise the Commission's *Roadmap towards phasing out animal testing*.

6) Call for consistency and uniformity in enforcement by introducing audits on control and enforcement systems.

The Netherlands advocates further clarification of the Safety Data Sheets information in order to improve its understanding, accessibility and relevance for everyone in the workplace.
More generally, improvement of ICT-support for companies and competent authorities to fulfil their information requirements and reporting obligations should be pursued vigorously as this will contribute to reduction of the administrative burden. Also the information requirements on the presence of hazardous chemicals in products are important but should focus on information necessary for safe use.

Member States are responsible for the compliance and enforcement of REACH. A network of national enforcement authorities promotes the exchange of knowledge and expertise, to harmonise enforcement and ensure consistent interpretation of the legislation. Still, effective enforcement remains a challenge and additional actions including intensifying collaboration of enforcement and spread of best practices, might help to further improve the level of enforcement and to ensure that companies are treated equally. Special attention should be paid to dumping practices and the rising import of products from third countries and direct online purchases by consumers, which often do not meet EU standards on safety and thus pose a risk to human health and the environment. This contributes to a level playing field and will improve the competitiveness of European industry. The introduction of a lean European Audit Capacity that coordinates audits on control and enforcement systems in Member States or measures with similar effect - such as peer review - are supported.