DISCUSSION PAPER

27 MAY 2020

Chemicals Strategy for Sustainability

This paper was developed in the context of a stakeholder dialogue that followed our submission to the EU Commission's Roadmap consultation on the future Chemicals Strategy for Sustainability. It is meant to trigger an exchange of policy ideas or suggestions to inform the dialogue but does not constitute the agreed position of Cefic or its Members.

Simplification of EU Chemicals Legislation

Issue

- Today, more than forty pieces of EU legislation are in place to manage chemicals. We have REACH and CLP Regulations as overarching frameworks focusing on substances and mixtures, but are also faced with other Regulations and Directives like the Restriction on Hazardous Substances in Electrical and Electronic Equipment (RoHS), Toys, Cosmetics, Biocidal Products, Plant Protection Products, etc. Those tend to be product/article or application specific. As such, they complement the horizontal assessment achieved with REACH and CLP.
- The different pieces of legislation have been built over decades, often in silos (by different DGs) and at different times, with different protection goals. Different decision-making processes are in place (involving EU agencies ECHA or EFSA, or EU Scientific Committees SCHER or SCCS), with different expertise involved e.g. Member States Committees. There are historical and well-founded reasons for such complexity, founded in the intrinsic needs of the uses that are being regulated. The specifics of these uses are often not addressed by Regulations with broader scope like REACH.
- The Fitness Check on Chemical Legislation Excluding REACH[1] found it to be a "*comprehensive and generally well-functioning framework*", that is *"fit for purpose in terms of meeting the core policy objectives of ensuring a high level of protection of human health and the environment, ensuring the efficient functioning of the internal market while enhancing competitiveness and innovation"*. However, it would be desirable to simplify the regulatory framework, e.g. to reduce the number of measures/regulatory processes/legislations to the extent possible while preserving core principles: science, robustness, effectiveness. Any changes or merges would need to carefully consider the implications. Impact assessment should be carried out to ensure potential consequences are properly considered.

Approach proposed

- A wholescale consolidation of chemical substance regulation into one single legal text (e.g. REACH) would be a major undertaking. A pros and cons assessment may be worthwhile. It deserves a **multi-stakeholder process**, like CAFÉ (Clean Air For Europe) in the past for air pollution. Such process should involve experts from the Commission, Member States and stakeholders to deliberate and 'co-design' the reform.
- We need to build on the conclusions of the Fitness check of Chemical Legislation (except REACH) to move forward. The 'One Substance, One (hazard) Assessment' approach is worth exploring.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1566802607995&uri=CELEX:52019SC0199R(01)

European Chemical Industry Council - Cefic aisbl
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.93.00 mail@cefic.be www.cefic.org
EU Transparency Register n° 64879142323-90

More cooperation from the EU Agencies in the evaluation of chemicals would be a step in that direction too. The interaction of the different processes needs to be carefully examined and new governance established.

- To optimise efficiency and predictability for chemical operators, there needs to be a common understanding of which legislation applies to which case. We need to put in place a systematic process to select the most appropriate measures from the full available pallet to address a concern (so called regulatory management option analysis). Doing this is a win-win for authorities and industry, it allows to find the optimum between benefits, impacts and practical workability.
- To ensure a properly functioning European Single Market, it would be beneficial to have **only Regulations instead of Directives** for all legislation dealing with production, handling, use or disposal products, when legislatively fit and possible (e.g. RoHS, WEEE, Toys, Single Use Plastics …).
- Simplification cannot be at the expense of transparency and involvement of stakeholders in decision-making. Simplification does not mean 'automatic bans' or 'generic risk assessment' applied everywhere (which in effect is generic risk management) and substances systematically addressed in groups. Where specific data exist, they should be given precedence.

Cases/evidence/examples

- Some of the best practices already carried out as a result of the Fitness Check are the coordination between ECHA and EFSA regarding Plant Protection Products. It clearly benefited all actors by having agreements on the steps followed for product evaluations. Another example is the joint ECHA-EFSA guidance on endocrine disruptors (for biocides and plant protection products).
- Another example of good synergies is the use of CLP across legislations; however, it needs to be acknowledged that CLP is a hazard-based regulation, while exposure is a key element to take into consideration in real life applications. For example, inhalation of dust like particles, e.g. flour, is not recommended but if bound into a matrix, like a dough, the hazard disappears.
- For that reason, when considering simplifying the chemicals legislation, we must ensure that all the relevant factors are accounted for: hazard, use, exposure and options to control risks if needed.

How to do it concretely (which legislation/article etc.)

Concrete measures to benefit simplification are difficult to list exhaustively. Below we provide examples of what could be done to help simplify the legislation of chemical products in Europe.

- Start by ensuring the simplification findings from the second REACH Review.
- To ensure a properly functioning European Single Market, it would be beneficial to have **only Regulations instead of Directives** for all legislation dealing with production, handling, use or disposal products when legislative fit and possible (c.f. Articles 26 and 114 of the Treaty on the Functioning of the EU). In that way, we would limit uneven implementation across Europe, facilitate free movement of goods with the same standards, ensure all EU citizens are protected in the same way (e.g. RoHS, WEEE, Toys, Single Use Plastics, …). It also means that individual member states should avoid implementing over-regulations at national levels.
- **Holistic Regulatory Management Option Analysis (RMOA) should be conducted based on a common guidanc**e. Classification should only be one half of the assessment, if the risk is appropriately managed resulting in no harm for human health or the environment, the substance should be allowed on the market. RMOA increases predictability and predictability reduces complexity. It also helps align initiatives from different Member States (e.g. REACH processes initiated by MS).

- A **systematic process** needs to be designed to perform an RMOA:
    - Make an RMOA mandatory under REACH (e.g. a new annex or amendment of REACH Annex XV)
    - Define content of the RMOA or at least some minimal principles
    - Consult stakeholders on technicalities, scientific inputs and socioeconomics
    - Ensure cooperation between agencies in the context of RMOA
    - Set guidelines on how to finally select the best regulatory option.
- Next to RMOA, an overall Commission Communication summarising the different pieces of EU Chemicals Legislation, their scope and how they interact/relate to each other could be developed (beyond current EUCLEF which is substance-based). It would help companies understand which pieces of legislation they have to comply with. An extension of EUCLEF could be an option as well, as long as it clarifies interlinkages and avoids inconsistencies between different pieces of legislation obvious
- Consistency between legislation could be improved by ensuring **systematic consideration of REACH conclusions/findings/measures in product/use-specific legislation**, e.g. the RoHS starting point should be the REACH restriction. We note some progress has been made in relation to REACH and OSH (OELs/DNELs) and in the area of water (REACH and EQS).
- In relation to REACH, some simplification could be achieved in relation to extended Safety Data Sheets and applications for Authorisation, as highlighted by the second REACH Review.
- Another option could be to focus simplification on **uses seen as a priority under the Green Deal** (construction, electronics, renewable energy, etc.), assessing if and how sector legislation in these areas could be better aligned with horizontal schemes like REACH.
- **Decision-making on hazardous properties of chemicals**, including via the Committees, needs to be re-examined to achieve more harmonisation to avoid situations where different experts may give different advice in different committees for the same hazardous properties of a substance. For decision-making involving specific scientific complexity and emerging issues, ECHA Committee members should better reflect all relevant disciplines (toxicology, industrial hygienists and occupational health experts). Moreover, they should leverage on external practitioners' expertise, e.g. academia and industry, so that decisions reflect state-of-the-art science (e.g. on the model of the Scientific Advisory Mechanism) but also better take into account the proportionality, practicability and enforceability of the measure. Risk assessment should remain use- and sector-specific and may require specific expertise.
- How REACH deals with the waste needs to be re-examined in the context of circular economy, recycling needs and waste management. We need '**waste-back-to-the-product-regime'** solutions.
- **Predictability and stability** of the regulatory requirements is essential to complexity management (particularly REACH):
    - Registrations: Stability of data requirements, extension of test requirements only where scientifically justified, where there is added value, and if validated test methods exist.
    - More clarity and certainty on the application of the data waiving provisions of REACH, particularly on how to establish robust justification for 'read-across" (both for positive and negative extrapolation) which is essential for grouping purposes, and on exposure-based waiving; and increased acceptance of the use of alternative methods to avoid animal testing.
    - Stabilise IT tools (IUCLID) as IT changes complicate dossier update
    - Authorisation procedure: Improve and simplify based on experience gained
    - More harmonised, digitised and effective communication of safe use information in supply chains via clear and easy-to-use extended Safety Data Sheets, in line with the REACH Review conclusions and on-going CARACAL discussions.
- More coherence between REACH and occupational health and safety legislation.