

AmCham event 24 February

The future of risk management in EU chemicals policy

Kristin Schreiber, DG GROW

MS have unanimously supported the ambition of the strategy - they are also very much behind the calls for strengthening the generic approach to risk management, the introduction of a mixture assessment factor and limiting the use of endocrine disruptors and persistent substances to essential uses.

CSS – it is much more relevant how those elements will be implemented. This is currently being assessed in the impact assessments on the planned legislative revisions, including REACH and CLP.

Extension of the generic or hazard-based approach to risk management – the essence of the precautionary principle as enshrined in the EU Treaty. Reasoning behind the generic approach to risk management - carcinogenic, mutagenic and reprotoxic substances are banned by default in cosmetics, toys, plant protection products and biocides, but also in REACH for any consumer uses as substances on their own or in mixtures.

Thus, the question is not whether to apply the generic approach to risk management, but for what hazard classes and for which uses.

Additional hazard classes - substances cause serious and mostly irreversible effects that EU citizens are very concerned about.

Identifying risks for those substances – procedures must be simplified.

Our plan is not a blanket ban for all substances in all concerned hazard classes – we will introduce generic restrictions in a step by step way, according to a work plan. The way to do this is currently being assessed in the impact assessment for the REACH revision.

There will be exemptions for essential uses.

Main challenge - make the procedures for granting such derogations clear and lean.

Reform of authorisation and restriction procedures -> allow broader and generally applicable derogations, without the need for separate authorisations per applicant or groups of applicants. This should in particular help SMEs, which have difficulties to put together all the necessary information for authorisation applications.

Important - define clear and simple procedures for assessing essentiality, in particular for clearly essential or clearly non-essential uses. For all other cases, there will still be a need for a detailed scientific and technical assessment.

Invited stakeholders to participate in our public consultation on the REACH revision, which is open until 15 April. Workshops - on essential uses on 3 March and two more on REACH authorisation and restrictions, on 21 March and tentatively on 7 June.

BfR (German Institute for Risk Assessment)

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Scientific Foundation of Chemicals Regulation

Fundamental paradigm of toxicology by Paracelsus (1493/94 - 1541)

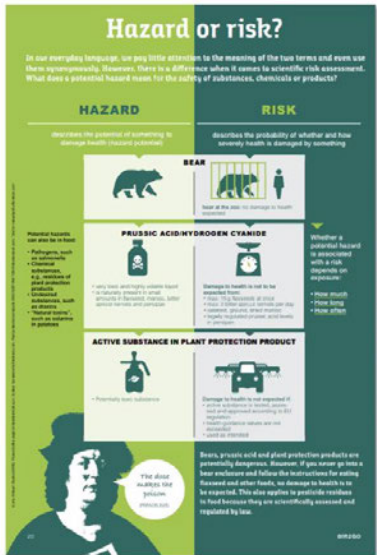
"What is there that is not poison? All things are poison and nothing is without poison. Solely the dose determines that a thing is not a poison"

For a **dangerous** chemical to become **harmful** to people/the environment, exposure must exceed a critical level.

Dangerous substances are **present** in a virtually endless list of **products**, where they can be used **safely**, provided that people/the environment are **protected from harmful levels of exposure**.

To claim **scientific legitimization** in terms of health protection, chemicals regulation needs to focus on risk, not hazard.

The determination of risk also is a **pre-requisite for determining the proportionality of action** and for **cost/risk-benefit analysis**, as required by the precautionary principle (COM, 2000).



Hazard or risk?

In our everyday language, we pay little attention to the meaning of the two terms and even use them synonymously. However, there is a difference when it comes to scientific risk assessment. What does a potential hazard mean for the safety of substances, chemicals or products?

HAZARD	RISK
<p>Increases the potential of something to damage health (hazard potential)</p> <p>BEAR</p> <p>Increases the potential of something to damage health (hazard potential)</p>	<p>Describes the probability of whether and how severely health is damaged by something</p> <p>BEAR</p> <p>Describes the probability of whether and how severely health is damaged by something</p>
<p>Prussic acid-hydrogen cyanide</p> <p>Increases the potential of something to damage health (hazard potential)</p>	<p>Prussic acid-hydrogen cyanide</p> <p>Describes the probability of whether and how severely health is damaged by something</p>
<p>Active substance in plant protection product</p> <p>Increases the potential of something to damage health (hazard potential)</p>	<p>Active substance in plant protection product</p> <p>Describes the probability of whether and how severely health is damaged by something</p>

The dose makes the poison

Bees, prussic acid and plant protection products are potentially dangerous. However, if you never get into a bear enclosure and follow the instructions for using fava beans and other foods, no damage to health is to be expected. This also applies to pesticides residues in food because they are scientifically assessed and regulated by law.

https://mobil.bfr.bund.de/cm/429/07_hazard_or_risk.pdf

Mathias Hübner, AnChem 688 conference, 2022.03.24

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Combination Effects/Mixtures

Current regulation focuses on substance-by-substance assessment; chemicals may give rise to combination effects of additional regulatory concern, if

- substances have **properties of high concern (CMR, potentially others)**;
- they share the **same mode of action (MoA) or otherwise interlinked MoAs**;
- people are exposed at levels **below** those triggering single substance regulation, but **high enough** to be adverse in concert, and
- co-exposure needs to occur long enough** to cause the effect of concern.

COM wants to introduce a Generic Mixture Assessment Factor (generic MAF)

- MAF will allow **only partial exhaustion of** single-substance **DNEL**, e.g. MAF = 10 → risk is assumed if exposure exceeds DNEL/10, **regardless of relevant co-exposure**.
- Ignores **tiered approach to Chemical Safety Assessment (CSA)** under REACH.
- Could lead to a **massive need for reopening of REACH dossiers**.

Concern scientifically justified in general, but only weak evidence for major health issue needing urgent action

- Several **COM-funded research projects** (e.g. PANORAMIX with BfR participation, upcoming PARC partnership) explore this.
- However, COM does not want to wait for further results → **implementation already planned for 2022**.

GRA and Essential Use Concept (EUC)

EUC concept is integral part of the "Generic Risk Management Approach (GRA)" for consumer products

- Ban on "most harmful" chemicals in consumer products (i.e. including articles) unless "essential to society".
- "Most harmful" suggests **risk**. But in fact, all "dispensable" chemicals with certain **dangerous properties** will be **banned**
- **All non-essential uses are considered dispensable**, without (mandatory) risk characterisation or SEA.
- REACH Committee decides which products consumers can do without → **practicalities and legal implications?**
- **Products may be removed** from the market even though they may **not pose a risk** to consumers.
- COM plans extension to **professional uses, other dangerous properties**

Examples of consumer products that could be affected because they contain dangerous substances

- All electronic products (rare earths, heavy metals, lithium ions (!), organic flame retardants etc.) ... lighters, varnishes and paints, adhesives (neurotoxic substances) ... wall paints (titanium dioxide!) ... musical instruments (heavy metals, nickel) ... all stainless steel items (Cr, Ni, Mo, Ti, Nb, W, V, Co etc...) ... aluminum foil ... most plastic products, packaging made of (recycled) cardboard ... glazed ceramic products, div. DIY and construction materials ...



Conclusions

The intention of the CSS to improve the **efficiency** of European chemicals legislation is **strongly supported**.

However, the general **equation of dangerous chemicals with hazardous chemicals is not backed up by science**.

A number of proposals under the CSS **need further discussion and more thorough analysis**, in particular with respect to their **consequences**.

There is **limited evidence of urgency** to improve what is **already one of the most protective regulatory systems** for chemicals in the world.

The immense **time pressure and simultaneousness** of developments also are **not helpful** for finding the best and most practical solutions.

Discussion

Question to KS

- *How is the Commission planning to ensure the CSS is conducive to a competitive, innovative and resilient EU industry?*

Kristin Schreiber

The challenge to policy makers is to make the regulatory framework as strong but also as lean and practical as possible and to work together with industry on ways to overcome barriers in that transition.

Focus our resources where they are most needed (as ██████ said).

Make sure that the tools will be clear and strong but also simple, so that we can achieve more with less resources in authorities and companies, and to make sure that those tools also work for SMEs.

Make sure that the future regulatory framework will be conducive to innovation – called for ideas from stakeholders. We want innovation to take place in Europe.

Work on transition pathways to the implementation of all three C's, climate neutrality, circular economy and chemicals safety. The work on the transition pathway for the Chemicals industry has been launched at the industry days on 7 February. We expect to present a first draft of the transition pathway at the 18 May High Level Roundtable.

██████ SME United

Authorisation system has been especially difficult for SMEs. Good we are exploring alternatives.

GRA and professional users – should they be treated as individual users eventually?

A key issue – the short DDL. There are about 80 actions in the CSS to be implemented until 2024, looking into very important elements of chemicals legislation. This is a very short time. Limited resources for input. If the Commission expects quality input, more time would be needed to assess the proposals.

Ex: SCIP system – it has been implemented quickly without much planning, we should not repeat this mistake with chemicals legislation.

██████

Essential uses: We are filtering cases that are political. On some cases, there is no need to get a scientific opinion. But, there are also cases where we'd like to have faster decisions in favour of essential uses, without going through the lengthy scientific assessment.

██████ SME United

There is inconsistency between the political will and what we can resource and finance as MS/authorities.

ECHA is getting additional work, but so are the enforcement authorities in MS. Some MS only have 2-3 chemicals experts. We need to raise the level of protection for consumers, professional and industrial users, and we are not going sufficiently into this. Good that the HLRT picked up on this topic. If we go into too rigid system, instead of reducing the work of authorities, it will be counter-productive. Risk option management analysis process is, therefore, important.

We should not just talk about chemicals, we should talk about uses of chemicals.

BfR are not against essential uses, he's only worried if this is turned into a negative goal – over-regulate all substances that are not deemed as essential.

Comments & Questions from the Audience

Covestro - The essential use concept can only be used for broad restrictions covering all uses. REACH Restrictions are not only "bans" and can be other options for risk management (e.g. training requirements), and also targeted Restrictions. What will be the future of targeted Restrictions for DG GROW? Moving to broad Restrictions only could be a de facto reversal of the burden of proof in drafting Restrictions from authorities to companies having to prove safe use/essentiality.

Kreab: We are already witnessing the implementation of the generic risk assessment to restrict articles for hazard classes not mentioned in the CSS, as it is the case of the skin sensitizers restriction in textile and leather articles. An interesting element of this restriction is the dynamic link, which goes one step further in the application of the generic risk assessment by proposing to automatically ban/restrict substances that will be added to CLP in the future, even if they don't present a risk for consumers. How could the essential use concept be used in this regard, if we're talking about colouring/treatment of clothes and footwear? Shouldn't there be a possibility to request derogations for safe use?

[REDACTED]: While using hazard assessment as the basis of CSS is clearly a mistaken approach, as has been presented by **[REDACTED]** and argued by the regulatory community in general, there is even a major bias when assessing the perceived hazards of substances on the basis of scientific studies published in the scientific literature. Scientific journals historically only accept publications with positive results of toxic studies, hence the "body of evidence" available to assess the hazard of substances is a priori skewed. Has the Commission worked with the scientific community and major academic institutions and scientific journals to address this basic bias and launch a new strategy that journals also publish toxicological studies with negative outcome?

[REDACTED] ExxonMobil Europe: Almost any substance can be determined to be a CMR/ED - depending on the dose, the type of study and increasingly the interpretation of the data - and not taking into account the robustness and quality of studies - this is a fundamental issue. Essential use should be left to the market - otherwise we will see many unintended consequences. Having a committee decide on essential use is ideology in action and spells the end of the market economy - which has brought so many benefits. This is in effect anti democratic i.e. we the regulators know better than the market economy and public on detailed uses of substances- and we see literally today where this thinking can take us.

[REDACTED] (German Steel Association)

The presence of a hazardous substance in a product should not be the focus of restrictions. The real risk occurring shall be regarded. How the planned revisions of REACH and other regulations will implement this issue (focussing currently only on substances and not the expected emission/ release of the regarded substance) ?

[REDACTED]
Professional users – it is important to distinguish between different types of generic users. However, we should also be aware that certain groups of professional users are not necessarily better trained.

There will be a debate on this during the two workshops in March and June.

There is a clear will in Europe to enhance protection.

Recap from AmCham:

- Opportunity to simplify processes (Schreiber's message).
- Make better use of scientific advice and evidence.
- CSS will be implemented as it is – no point in challenging it, we need to work on the details – focusing on the "how".
- Much debate on the "safe use" concept.