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Policy Brief

Baltic Sea Centre | Stockholm University

Time for smarter and safer chemical management

– grouping and mixture risk assessment in European chemicals legislation

Today's massive flow of chemicals places new demands on risk management. Managing chemicals in groups and introducing mixture risk assessments into all chemicals legislation are two key measures to protect health and the environment.

Organisms in the environment are not exposed to single substances in isolation but to complex mixtures of chemicals from numerous sources over the course of their lives. The science is clear – the risk associated with a chemical mixture exceeds the risk of each individual chemical in the mixture.

Therefore, assessing and managing each chemical in isolation is insufficient. Organising chemicals into well-defined groups helps to reduce the complexity of chemical risk assessment and management. In order to ensure a high level of environmental protection, European legislation must address two crucial aspects of the regulatory system for chemicals control, namely mixtures and grouping of chemicals.

Risks are systematically underestimated

The flow of products and materials in society is also a flow of chemicals. It has been estimated that 95 per cent of all goods are directly linked to chemicals or chemical processes. Chemicals are emitted from all parts of the value chain, from production, through use, to the end-of-life and waste-phase, continuously exposing the environment to complex chemical mixtures that can be toxic and cause adverse effects to environmental species, humans, and ecosystems.

Science no longer deems the single substance assessment approach to be sufficient to assess and control the risks associated with the chemical exposure of the modern world. The current system systematically underestimates risk. But already in 2009, the State of the art report on mixtures toxicity (prepared for the European Commission by Kortenkamp et al.) concluded that "mixture risk assessment (…) is not only necessary, but also feasible". Now – more than ten years later – there is an even larger body of scientific evidence to support this conclusion. However, regulatory risk assessments still focus on one chemical at a time and thus are

Chemical mixtures: any set of chemicals to which an organism may be jointly exposed, and which may potentially cause an adverse effect regardless of sources and exposure routes.

Grouping: the process of identifying, assessing, and managing environmental and health risks involving two or more chemicals based on certain shared aspects.

POLICY RECOMMENDATIONS

- **Establish consistent requirements for mixture risk assessments in all pieces of chemical legislation.** Without such requirements, effective protection against risks from exposure to mixtures will not occur.
- **Establish crosscutting European legislation on chemical pollution with a focus on mixture risks.** Chemical mixtures cannot be fully evaluated and managed by sectorial pieces of legislation.
- **Strengthen the mandate in REACH to manage groups of chemicals to avoid regrettable substitution.** Grouping will also contribute to increase efficiency and to reduce mixture risks.
- **Improve mixture risk assessment and grouping of substances in the context of European water management.** The directive is recipient-oriented and in principle should be able identify and undertake measures against chemical pollution created by chemical mixtures.

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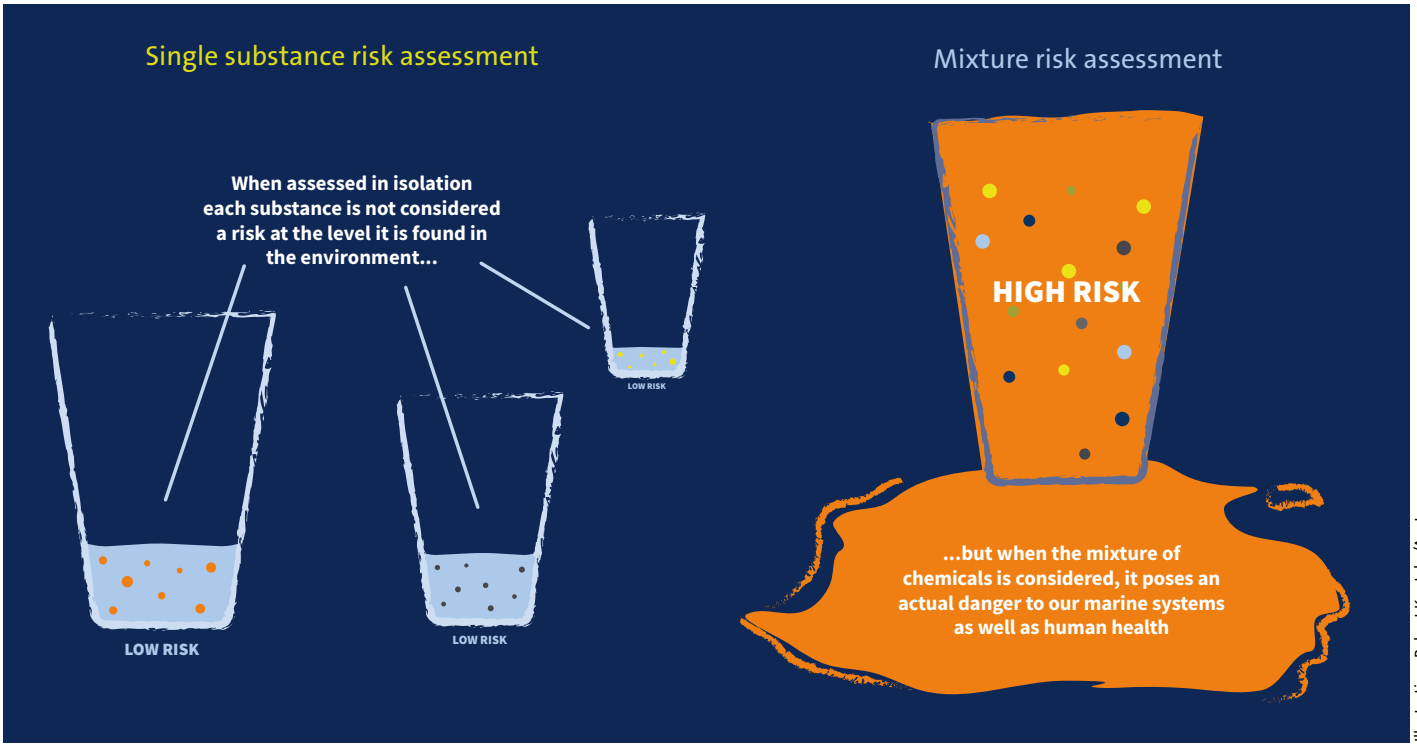

Illustration: Robert Kautsky/Azote

based on a gross oversimplification of reality that does not take the complexity of exposures into account.

Furthermore, the legal requirements for risk assessment of chemicals still differ depending on the chemicals' intended uses. The level of requirements is not the same for chemicals used in, for example, food packaging, electronic equipment, or pharmaceuticals.

In practice, these two shortcomings – a single substance approach and fragmented, usage-oriented legal requirements – mean that the regulatory system systematically underestimates significant risks connected to chemical exposure. To address this, important aspects of the regulatory system for chemicals control need to be strengthened.

Introduce mixture risk assessment in chemical legislation

Much of the concern about mixture risks has been triggered by research on endocrine disrupting chemicals (EDCs). These alter the functioning of the endocrine system and negatively affect the health of humans and animals. Using this as a starting point is positive, but not enough. The risks associated with mixtures also include other types of chemicals and a variety of other adverse effects. To reach a high level of protection of human health and the environment, requirements for mixture risk assessment should cover all kinds of adverse effects, not only endocrine disruption.

Windows of opportunity for including requirements for mixture risk assessments in EU legislation may open whenever a piece of legislation becomes subject to regular or occasional revision. When this is the case, a general rule is needed that is clear and comprehensible and that can be inserted into different legislations. As a tentative generic phrasing, the following sentence could be introduced in all relevant EU legislations:

The environmental and health risk assessments performed under this legislation shall take mixture effects into account, which may result from combined exposures to multiple chemicals from the same or from different sources.

However, this individual legislation approach is only a first step, and it must be followed by initiatives to establish a crosscutting European policy framework on chemical pollution.

Control is scattered across laws and agencies

Even though the EU REACH Regulation in 2006 combined more than 30 different pieces of chemicals legislation, the regulatory system for chemicals control is still scattered across different laws and agencies and between EU and national levels. This has led to a situation where there are inconsistencies between the different regulatory frameworks, with only little exchange of information between them and no overarching or systematic attempts to harmonise across.

Consequently, the risk assessment of chemicals is largely carried out in regulatory silos – dictated by how and in which sector the individual chemicals are used, rather than by their exposure patterns and interactions with other chemicals in real-life scenarios.

A telling example of this is how the risk of exposure to chemical mixtures in food is assessed. Animals that are raised for human consumption are exposed to a variety of chemicals during their lifetime – directly, via veterinary drugs and biocides, and indirectly, via contaminants in the air and water and pesticide residues in their feed.

In addition, food additives are added to the meat and chemicals from food-contact materials are unintentionally included before the meat eventually ends up on the plate. From a chemical and risk assessment perspective, this chain involves at least three different authorities:

- European Food Safety Authority (EFSA) – assesses pesticides, food additives, and food contact materials.
- European Chemicals Agency (ECHA) – handles industrial chemicals and biocides.
- European Medicines Agency (EMA) – deals with human and veterinary medicines.

Moreover, each of these authorities interacts with the corresponding regulatory authorities in the individual EU member states. This organisational division, and the ensuing complexity of the European system for regulating chemicals, results in inconsistent and insufficient assessment frameworks.

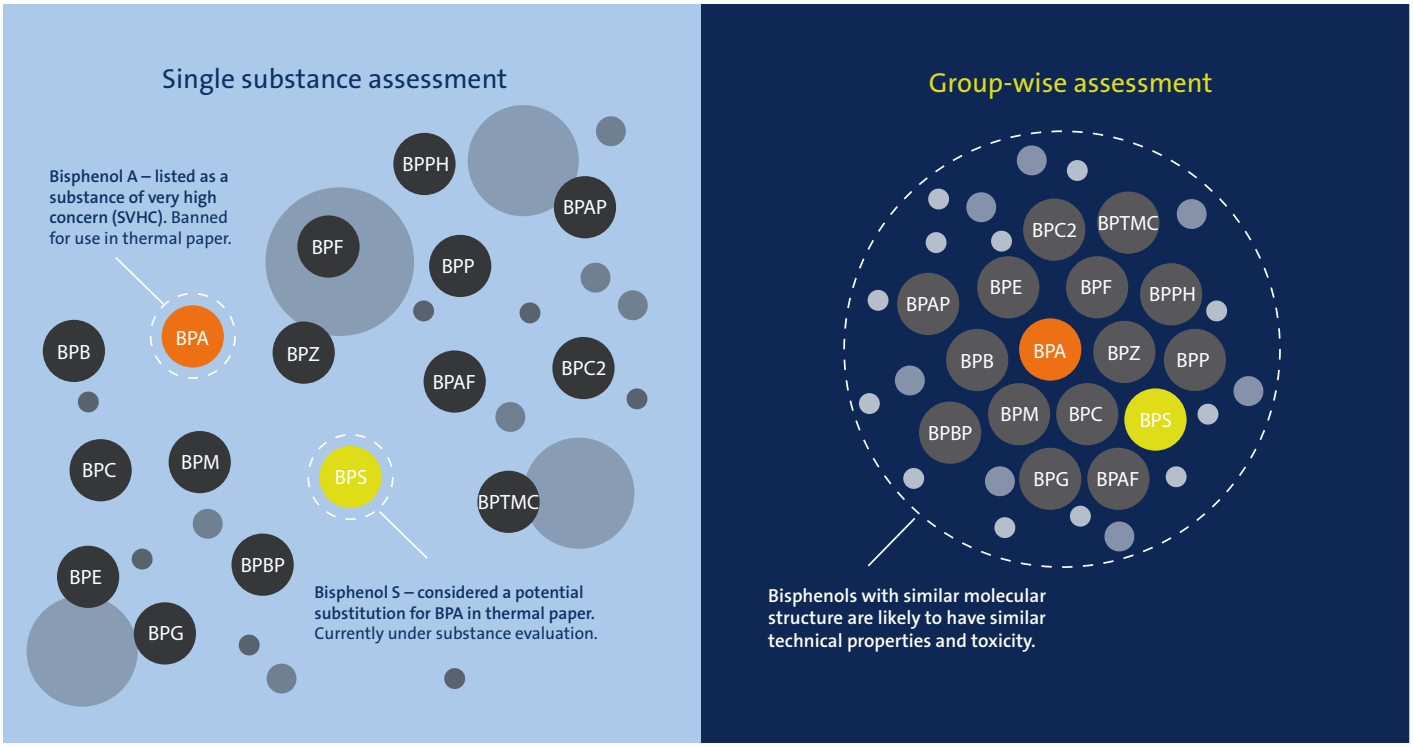

Illustration: Robert Kautsky/Azote

Introduce crosscutting legislation

To address these inconsistencies (see above), a crosscutting European policy framework for dealing with mixtures of chemicals falling under different legislations is needed.

Establishing a dedicated European framework on chemical pollution that cuts across regulatory silos will have the benefits of:

- data compilation that facilitates exposure assessments across legislations
- common definitions, assessment principles, goals and targets, and suitable policy options to act on the fact that typical exposures are characterised by complex chemical mixtures.

Opportunities for introducing a crosscutting policy framework include, for example, the 8th European Environmental Action Programme and the forthcoming chemical strategy for sustainability, where mixture considerations can be taken into account in order to consider all groups of hazardous chemicals, not just EDCs, and to provide specific provisions for environmental protection.

Biodiversity protection is important to include as a specific protection goal – considering that biodiversity currently is declining EU-wide and globally and that chemical pollution has been highlighted as a major underlying cause.

Manage chemicals in groups

Managing chemicals in groups has been identified as a key approach for preventing regrettable substitution and for making regulatory risk assessment and management less fragmented and more efficient and transparent.

Organising chemicals with similar molecular structure, hazard, risk, or function into well-defined groups helps to reduce the complexity of chemical risk assessment and management. In particular, a systematic group-wise assessment would facilitate a more effective application of the substitution principle and reduce the risk of regrettable substitutions, i.e., replacing a hazardous chemical by a structurally and toxicologically similar chemical, for instance, replacing bisphenol A (BPA) with bisphenol S (BPS) in thermal paper.

Photo: Bengt Olsson/Mostphotos

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Grouping starts with REACH

Options for grouping depend on data requirements, which differ largely between legislations. Therefore, the work could start by focusing on the REACH regulation, which covers the greatest number of chemicals on the European market with the lowest test data requirements.

Group-wise handling of chemicals is possible within REACH, and ECHA and member states have started working with groups of chemicals. One example is the recent restriction proposals for PFAS, a group of highly persistent fluorinated compounds widely found in the environment. However, the extent of group-wise management is still not systematic, suffers from resource constraints, and is highly dependent on the engagement and resources available from member states' competent authorities.

To improve the situation and make group-wise management the first-hand choice, legal provisions must be strengthened and clear tasks need to be assigned to ECHA and member states' competent authorities.

Beyond initiatives that can be taken under the current version of REACH when the regulation is next up for revision, an amendment could introduce a legal requirement to consider groups of similar chemicals as the default in all assessment and management processes under REACH.

Instrumental for good water quality

To achieve and maintain good chemical status of water bodies under the Water Framework Directive (WFD), which in addition to freshwater covers the coastal zone, a number of environmental quality standards have been laid down for 45 individual substances. There is also a short watch list with substances that have to be monitored in the environment.

The focus on a limited number of priority chemical substances is insufficient to deal with the present situation, where hundreds of different organic chemicals can be found in water samples. With no obligation to perform mixture risk assessments – combined with the fact that there is no clear mandate in the directive to group substances when developing quality standards – there is room for improvement. This was also acknowledged in the 2019 review of the WFD.

Whether facing a future revision or an action plan for improved implementation, this area deserves devoted attention.

This policy brief is based on the findings and analyses made in the report *Future chemical risk management – Accounting for combination effects and assessing chemicals in groups* (SOU 2019:45) to the Swedish Minister for Environment and Climate.

Photo: Niklas Virsén/ Azote

TO BRIDGE THE GAP BETWEEN SCIENCE AND POLICY

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