Hazard and risk in EU chemicals legislation

Hazard and risk are two central concepts in EU chemicals legislation. However, to provide strong protection against the most harmful substances, it is important to give hazard centre stage. This is best done with the generic risk approach (GRA).

The concept of hazard and risk provides the entire foundation for regulating chemicals: only after the hazardous properties of a chemical are known can risk management measures be taken.

Even though they are interlinked, in the debate around the EU's main chemicals legislation REACH, hazard and risk are often juxtaposed.

The generic risk approach, on the one hand, seeks to regulate the most harmful chemicals based on their intrinsic hazards combined with the likelihood of exposure. In doing so, it effectively eliminates the exposure risks.

The specific risk assessments, on the other hand, rely on detailed calculations for specific uses and seek to regulate hazardous chemicals only when the estimated exposure would lead to assumed "safe levels" being exceeded.

Generic risk approach

This approach considers exposure to the most harmful chemicals in a generic, pre-determined way.
These are substances that are, for example, cancer-causing, hormone-disrupting, toxic to reproductive or neurological systems, or persistent in the environment. Due to such hazardous properties, risks can be assumed as a default for widely used products. No resource-intensive specific risk assessment is required. By eliminating the hazard, you effectively eliminate the exposure and thus eliminate the risk. This is, for example, suitable for chemicals where the level of exposure is difficult or impossible to assess or control.

Specific risk assessment

This approach depends on specific probability calculations for risks that are based on estimated exposure levels compared to safe exposure levels. However, in many cases, it is not possible to scientifically establish safe exposure levels. This approach might be useful in a sealed-off environment where all the exposure routes are known but it must account for uncertainties, including mixture effects, in order to be protective enough.

Calculation is not more scientific

Advocates of the specific risk assessment approach argue that this method is the correct way to handle hazardous chemicals since it is thorough and specific to the use in question. However, the sealed-off and perfectly managed environment necessary for this method is often unachievable. In reality, it is extremely challenging to accurately estimate the exposures to a chemical throughout its lifecycle; from workers involved in production, consumers exposed to a product throughout its lifetime, all the way through to waste and recycling.

Moreover, persistent chemicals such as PFAS make things even more difficult since they easily spread in waterways, building up in the environment and the food chain. Generally, information on exposures to chemicals is scarce. In fact, we don't even know where all hazardous chemicals are used. This makes exposure estimates impossible.

Even if it were possible to estimate the exact exposure to a chemical, for many of the most harmful substances, there is no safe level of exposure. Cancer-causing substances can, for example, cause harm at any level, while hormone-disruptive chemicals can have the most severe effects at low concentrations.

On top of this, we are constantly exposed to multiple substances, causing a combined toxic effect where the combination of chemicals poses a larger risk. This is often called the "cocktail effect" and is not considered in legislation today.

In short, specific risk assessments:

❌ Are very complex and require a huge amount of data, which is rarely available
❌ Require significant resources from the authorities
❌ Have difficulties in estimating exposures from widespread uses
❌ Cannot establish scientifically safe levels of exposure for many hazardous chemicals

This makes specific risk assessments obsolete. They are not an effective regulatory approach to ensuring a high level of protection for people and the planet — not from the most harmful substances and especially not for those with widespread uses.

A safer and more effective approach

A generic risk approach, on the other hand, does a better job of effectively protecting human health and the environment. It is a simpler and much more cost-efficient regulatory approach, which is why the EU's Chemicals Strategy for Sustainability (CSS) suggested that the use of the generic risk approach be extended to all most harmful substances.

The generic risk approach relies on well-established scientific reasoning, as well as a number of historical examples of damage caused by environmental toxins.

This approach is already used by responsible companies when evaluating substitution priorities as a way to future-proof their business. Such straightforward identification of substances and uses to phase out is a very efficient driver of innovation toward new and safer chemicals and products because anticipation of regulation creates a demand for safer alternatives that producers are eager to meet.

The call for extending the use of the generic risk approach in regulation is partly based on recent years' lessons, which have clearly shown that it is not possible to scientifically define safe levels for many of the most harmful chemicals. Hormone-disrupting substances are one example of such “non-threshold chemicals,” which have no safe level of exposure at which they do not have a harmful effect.

Yet, authorities still treat these chemicals as if it is possible to manage their risks with safe levels (see example below), one substance at a time.

In summary, the generic risk approach:

✅ Protects human health and the environment more effectively
✅ Is simpler and much more cost-efficient
✅ Drives innovation toward safer chemicals and products more effectively
✅ Is already used by responsible companies when evaluating substitution priorities

Example: Bisphenol A (BPA)

The estimation of how much BPA humans can tolerate has been lowered by a factor of 250.000 (!) over the last twenty years:

In 2006, the European Food Safety Authority (EFSA) established a Tolerable Daily Intake (TDI) of 50 micrograms/kg body weight per day. EFSA reviewed new scientific information on BPA in 2008, 2009, 2010, and 2011 and concluded on each occasion that they could not identify any new evidence that would lead them to revise the TDI.

In 2015, however, EFSA temporarily updated the limit to 4 micrograms/kg body weight — more than 10 times lower. This decision was based on 800 new studies, but still highlighted the need for additional data.

In 2023, EFSA lowered the limit for BPA again. This time by a factor of 20,000 to 0.2 nanograms (0.2 billionths of a gram) per kilogram of body weight per day. The reason was “potential harmful effects on the immune system” with EFSA experts concluding that current exposure levels to BPA posed a risk to consumers of all ages.

Another obvious example of “too little, too late” is the global PFAS crisis we are facing as a consequence of insufficient regulatory action.

In contrast, there is not one single example of the European Union acting too early or too forcefully on harmful chemicals.

The demand for detailed risk assessments — even for the most harmful substances — has contributed to severe under-regulation of chemicals.

Policymakers must act when there is scientific suspicion of risk and apply the generic risk approach to avoid similar mistakes in the future. This is the only way to effectively prevent pollution at source.