How the REFIT process can make chemical legislations stimulate business and protect health and the environment at the same time

In the case of chemical legislation, the REFIT process can have two possible outcomes: either it will iron out any inconsistencies in different chemical frameworks, making it easier for companies to comply, but also reducing protection from hazardous chemicals for the environment and citizens. Or, it will make it easier for businesses to comply *and* heighten the level of protection at the same time.

REFIT goals:

- Identify gaps and overlaps within chemical regulations in the EU
- Eliminate them, and
- Reduce unnecessary burdens on industry

This paper will show you that the latter is the most rational way forward. Not only from the standpoint of citizen health and the environment, but also from an economic perspective.

In short – it is quite possible to make EU chemical regulations more efficient for industry and improve the level of environmental protection and human health at the same time.

1. Make chemical regulation interact more

Did you know that soaps used in healthcare and soaps used in households are covered by different regulations? This is the case, even though the residues of both soaps are flushed down the drain and end up in the same place. Inconsistencies like this are a major obstacle for companies and apply to a large set of products and regulations, making supply chain and consumer communication very complex and burdensome.

These inconsistencies could be overcome by having more interaction between the different pieces of regulation. ChemSec proposes that when a substance is regulated under one framework, a system should alert

Examples

There are many examples of regulation gaps that need to be closed in order to achieve more efficient and protective regulations, and create a level playing field for businesses. Closing gaps would also send clear signals to the market and its supply chain as well as to consumers who at present are often confused about the level of protection.

Triclosan – restricted for use in soaps and shampoos used by medical professionals but allowed to be used in soaps for consumer use. The reason behind the medical restriction is that triclosan has toxic effects on organisms in surface waters, it bioaccumulates in the food chain and it reaches the aquatic environment via wastewater from hospitals. It is however still permitted in soaps and toothpaste for consumers, due to the difference in the EU Biocides regulation and the Cosmetics regulation. The Cosmetics regulation does not consider any environmental aspects even if most cosmetic products end up in the drain eventually.

Biocides – Substances restricted in biocides could be present in finger paints for children since the toys directive does not cover environmental aspects. It is most likely very safe to assume that few parents want hazardous chemicals that are intended to eliminate pests in their children's toys.

all relevant bodies and trigger appropriate action by them. This would ensure less inconsistency, a higher level of protection for human health and the environment, easier communication and more predictability for industry.

In addition to taking care of inconsistencies in regulations, evaluations could be used for more than one regulation, which in turn would make better use of resources. A structural change like this would be very much in line with the ideas of better regulation.

Another problem that arises from poor interaction between regulations is that some regulations are difficult to fulfil due to lack of regulation in other areas. For example the Water Framework directive (WFD) sets limit values for a number of substances in water, but has no power to trigger upstream regulation. For example if the WFD is breached by a certain substance and its source is identified, WFD has no mandate to influence the regulation covering the actual source.

2. Add environmental aspects

Many of the chemical regulations do not include environmental aspects; their focus is on health only. For example EU cosmetics and pharmaceuticals regulations do not cover environmental aspects, which is a clear oversight, since a large proportion of these substances end up in the environment via the drain or the waste bin.

3. Streamline hazard evaluations

At present, various bodies evaluate substances for their hazard properties. Sometimes these bodies come to different results, which leads to frustration and confusion. Moreover, the different pieces of regulation do not necessarily make use of each other's evaluations, leading to unnecessary work and inconsistent levels of protection for human health and the environment. The most logical solution is to have one body, the European Chemicals Agency (ECHA), in charge of all evaluations to avoid unnecessary repetition of work and ensure more consistent results. ECHA has proven to be more transparent in this process and has produced more accurate evaluations than EFSA so far.

4. Harmonise classification

The Classification, Labelling and Packaging (CLP) regulation ensures that chemical hazards are clearly communicated to workers and consumers in the European Union through the classification and labelling of chemicals. The information in CLP is applicable to all kinds of chemical regulations, but at present some information in CLP is not harmonised with other regulations. In order to provide a more efficient regulatory system, harmonised information is key. ChemSec therefore proposes to put more effort and resources into making the CLP process more comprehensive and efficient within the REFIT process.

– Additional endpoints

Even though the CLP has classifications for sensitisation and carcinogenicity, for example, there are still relevant human health and environmental endpoints

missing. Adding further classifications for a number of environmental endpoints (such as Persistence (P), Bioaccumulation (B), PBT, vPvB and EDC) and human health endpoints (EDC, Neurotoxicity, allergenic properties, nanomaterials) would be a logical way forward.

– Shorter evaluation times
The process of harmonising classification is slow and cumbersome. Faster harmonisation of classifications would be very beneficial for the whole regulatory system for chemicals. When no harmonised classification exists, companies should carry out their own classifications of their substances. These self-classifications should then be used as triggers for harmonised classification.

Summary

At the moment there are several different gaps and inconsistencies in a number of chemical frameworks. What applies to a chemical under one regulation does not necessarily apply under another, even though the chemical's use, function and exposure is identical. This makes compliance very burdensome for all involved parties.

To make it more effective, the REFIT process should aim to stimulate more interaction between chemical frameworks, add environmental aspects to regulations where they are missing, have one body conduct all hazard assessments to achieve consistency – instead of several, which is the case today, and finally, harmonise classification to make the data applicable in all chemical regulations.