

BETTER SAFETY THROUGH TRANSPARENCY

PROPOSAL FOR A CENTRAL EUROPEAN NAVIGATOR OF CHEMICAL SUBSTANCE REGULATION

Over the past 15 years, the legislations governing substances and products and also the laws relevant to health and environment have evolved enormously – both at European Union level and nationally in the Member States.

The outcome is an extremely complex regulatory framework. This framework covers practically all areas along those value chains which involve chemical substances and their downstream products.

Some examples of existing pieces of regulation and regulated sectors are given in figure 1 below. This listing is far from comprehensive.



In many pieces of regulation, chemical substances are addressed directly and in different ways. For example, there are

- numerous restrictions of the uses of substances, inter alia, under REACH, the RoHS Directive or the Toys Safety Directive;
- rules for the authorisation of products where chemicals are listed as active substances in the Biocides or Pesticides Regulations and used for these applications;
- various substance-specific rules and limit values in occupational health and safety at EU and Member State levels;
- national notification requirements e.g. where substances are listed in export/import regulations;
- substance-specific limit values or indicative values for water/drinking water, air and soil;
- specific transport rules;
- substance-specific national provisions, e.g. in Germany the water hazard classes or assessment values for indoor air

... and many more.

It is also worth noting that comprehensive safety-relevant information and data have been compiled under such existing pieces of regulation. Furthermore, substance-specific results have been obtained in several EU research programmes, e.g. the human biomonitoring projects.

Meanwhile, the above has resulted in an enormously complex regulatory framework with a wealth of different items of information. In consequence, it is today very difficult or near-impossible to find out which rules apply and/or which items of information are available for a given substance.

In fact, the European Chemicals Agency (ECHA) has created a database where information can be retrieved about substances registered under REACH. However, this database is not sufficient, because it covers neither the entire regulatory framework on chemicals in the European Union/Member States nor the results from the European research programmes.

Against this backdrop, it would be necessary to build up a **central European substance-regulation navigator** which provides – after entering e.g. the substance name or CAS no. – answers, inter alia, to the following questions:

- How is the substance regulated?
- What substance-relevant items of information are available at European at national authorities?

Obviously, data protection rules and property rights need to be strictly respected in this proposed initiative.

In more detail, the following particulars could be supplied by a central substance-regulation navigator:

- Properties of the substance*
- Classification and labelling*
- Safe use / disposal*
- Use restrictions*
- Other requirements under specific regulation (e.g. Biocides Regulation, RoHS, Toys)
- Substance-specific occupational health and safety rules (e.g. European and national limit values)
- Substance-specific provisions for various environmental media (e.g. limit values air, water, soil)
- Export-import regulations (PIC)
- Transport rules
- Specific national provisions (e.g. German water hazard classes (WGK), limit values/indicative values for indoor air)

(The items marked with an asterisk* are essentially available in the REACH database or will be covered by the planned ECHA REACH Safety Summaries, where applicable.)

The here discussed central substance-regulation navigator would make an important basis for the following:

- Transparency and harmonisation inside the European Union;
- consolidation and streamlining of existing regulation;
- stronger confidence in existing rules and regulations;
- better safety in the handling of chemicals;
- comprehensive overview of all legal provisions in their entirety for a given substance in the EU;
- assessment of the efficacy of the EU chemicals legislation and of substance-based risk management;
- decisions on the future development of legislation.

The REACH database of ECHA is a good start. But substance-specific information (beyond REACH/CLP), which takes into account all other European and national pieces of regulation, is needed.

From our viewpoint the responsibility to establish the outlined central European navigator for substance-regulation is with the EU Commission.