

Use Case Study - Regulators

Supporting efficient and effective development, enforcement and evaluation of regulation

Primary Actor	Regulators (Member State Competent Authorities, enforcement agencies, other policy makers)
Secondary Actors	Researchers, NGOs, consultants
Existing Practice	<p>Regulators use information on substances in articles, products and waste, where available, in several stages of the regulatory process. These include among others:</p> <ol style="list-style-type: none"> 1. Development of legislation: <ol style="list-style-type: none"> a. There are a range of different processes in place to develop regulatory instruments relevant to chemicals, products and waste. These include for instance regulatory risk management option analyses (RMOAs) carried out by Member States or by ECHA; restriction dossiers under Article XV of REACH; impact assessments of legislative proposals as required by EU and/or national laws; or supporting the drafting of permits for waste handlers and recyclers. b. Additionally, there are often calls for data/evidence on the international stage under a variety of treaties and international conventions managed by the UN and OECD, such as work to identify uses of candidate POPs under the Stockholm Convention. c. For all of these processes, information on substances in articles, products or waste are currently collected on an ad-hoc basis, using a variety of sources such as literature, safety data sheets, sampling/monitoring data, stakeholder consultations, REACH registration dossiers, or the Nordic products register SPIN (a database on the use of substances in mixtures in the Nordic Countries), the ICSMS database (European Commission's internet-supported information and communication system for the pan-European market surveillance) and the rapid alert system (RAPEX) for products which pose a serious risk to consumers. 2. Enforcement and monitoring of compliance <ol style="list-style-type: none"> a. Enforcement agencies have suggested that they currently sample individual products (e.g. to monitor compliance with REACH Article 33, or with prior informed consent for transboundary waste movements). They noted that they often find SVHCs that were not reported, partly because manufacturers were not made aware of their presence by their supply chain. b. Enforcement agencies use a range of tools in tests. For example, some agencies reported using an XRF-tool in order to identify elementary substances such as bromine, mercury and lead, based on x-rays. 3. Evaluation of legislation <ol style="list-style-type: none"> a. Similarly to the development of legislation, processes are in place to monitor the performance of existing legislation and evaluate its continued fitness for purpose, such as for example through the European Commission's regulatory fitness and performance (REFIT) programme. b. Where this concerns chemicals, products and waste, it requires information on how the contents of substances in articles, products or waste change over time. As for the development of regulation, this is currently collected on an ad-hoc basis, using a variety of sources.
Challenges related to substances of (very high) concern in waste	There are increasing numbers of candidate list substances and restrictions or authorisation requirements on substances present in articles. These will eventually require changes to handling practices at the waste stage. However, There are relatively few co-ordinated systems for tracking

the presence of SVHCs in different product types and how these change over time, especially for articles.

For instance, stakeholders pointed out that information from REACH registration dossiers is typically not specific enough in terms of the uses of the chemicals in question, making it difficult to link products and substances (e.g. for targeting restrictions).

The SPIN database only covers the Nordic countries. Moreover it only covers substances and mixtures, not articles.

Enforcement and monitoring of compliance with REACH Article 33 and others require costly sampling.

Future Practice with the new database

The database will help regulators to make more informed choices in the three stages outlined above:

1. Data input to inform development of regulatory instruments

- a. Regulators have suggested that the database could be used as valuable data input for restriction proposals, risk criteria / risk assessments, substance evaluation and extending the current capabilities of the ICSMS database and RAPEX, amongst others.
- b. For instance, information from the database can help to determine which substances are present in which materials and product types, and in what quantities or how frequently. It can highlight if substances are used in products with likely consumer/worker exposure and improve coverage of waste stage in substance evaluation. For example, PFAS (some of which are on the candidate list) are used in textiles for their water and oil repelling properties. The database could help to determine which PFAS are used in which textiles, in order to determine how consumers, the environment and textile waste streams will be exposed to which PFAS. This information will help to assess the risk and determine if and how additional regulation (e.g. a REACH restriction) should be developed. It would also facilitate decision-making on re-use or recycling of treated textiles.
- c. The feedback provided by regulators also highlights that aggregated data from the database could support authorities to better draft permits for waste operators within the scope of the national waste legislation. The database could also help to inform policies regarding waste management and treatment by Member States.

2. Prioritisation of enforcement and targeted monitoring of compliance

- a. The database can be used to prioritise enforcement efforts (e.g. of Articles 32-33 of REACH and of control and management of transboundary waste movements) and therefore make enforcement more effective and cost-efficient.
- b. Enforcement agencies have explained that they could focus their resources for targeted monitoring of compliance based on which substances are present in which materials and product types. For instance, if one company claims to use a specific SVHC in an article then enforcement agencies will know that market surveillance may be useful for this type of article category.
- c. They could also allow focusing of their resources through more targeted monitoring based on individual product-level data. For instance, checks can focus on suppliers that have not notified the use of SVHCs in articles/products, where other suppliers of similar articles/products have.

3. Monitor the effect of regulation

- a. The database can also be used to monitor how regulatory action affects products over time, e.g. by monitoring the numbers of new articles being notified to the database containing specific SVHCs that are subject to regulation. It could also help to detect regrettable substitution, for instance if a restricted SVHC is replaced with another SVHC in the same (type of) article.
- b. The database can help regulators to provide useful information for their reporting obligations, such as those on POPs in articles, imports and exports under the Stockholm Convention.

Some stakeholders have noted that it would be useful if the database would also cover other substances than candidate list substances (e.g. all POPs used in articles) in the future.

Potential benefits of this use

The main benefits of the uses described above include:

- Better informed regulation, leading to a higher level of protection of human health and the environment whilst minimising costs to the economy.
- More effective and targeted enforcement of chemicals regulation
- Savings from reduced, more focused sampling for monitoring of compliance.

Incentives and barriers for this use

Regulators have highlighted that it is important not to discourage detailed notifications by using the submitted information against them. As an incentive, regulators could target the majority of enforcement scrutiny away from suppliers that provide information to the database. Instead the focus should be to find suppliers that have SVHC in their products but which do not comply with the notification requirements for the database.

One concern raised by stakeholders was a potential lack of information in the database on quantities of substances used. This would limit some of the uses described above to numbers of new articles containing a certain substance, for example.

Presentation of information in the database to support his use

The consultation suggested that, in order to support this use, the database would need to categorise and aggregate information according to the types of products and material categories (i.e. all similar articles/products would need to be linked via a common identifier). One stakeholder suggested that the aggregation of uses/types of products should go beyond the level of detail used in Article 7 of REACH (e.g. more detailed than "construction products" or "cars"). Stakeholders noted that a high level of granularity is required to enable broad and varying data extraction. There is also a need to know very specific information about where and how a substance is used in order to estimate real-life exposure.

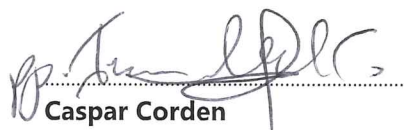
For the use to focus targeted monitoring of compliance, disaggregated product-level data is needed.

This use case is an extract of a report that has been prepared under contract ECHA/2018/338. Further background is provided in the full report.

Issued by


Julius Kreißig

Approved by


Caspar Corden

Copyright and non-disclosure notice

The contents and layout of this report are subject to copyright owned by Wood (© Wood Environment & Infrastructure Solutions UK Limited 2019) save to the extent that copyright has been legally assigned by us to another party or is used by Wood under licence. To the extent that we own the copyright in this report, it may not be copied or used without our prior written agreement for any purpose other than the purpose indicated in this report. The methodology (if any) contained in this report is provided to you in confidence and must not be disclosed or copied to third parties without the prior written agreement of Wood. Disclosure of that information may constitute an actionable breach of confidence or may otherwise prejudice our commercial interests. Any third party who obtains access to this report by any means will, in any event, be subject to the Third Party Disclaimer set out below.

Third party disclaimer

Any disclosure of this report to a third party is subject to this disclaimer. The report was prepared by Wood at the instruction of, and for use by, our client named on the front of the report. It does not in any way constitute advice to any third party who is able to access it by any means. Wood excludes to the fullest extent lawfully permitted all liability whatsoever for any loss or damage howsoever arising from reliance on the contents of this report. We do not however exclude our liability (if any) for personal injury or death resulting from our negligence, for fraud or any other matter in relation to which we cannot legally exclude liability.



Management systems

This document has been produced by Wood Environment & Infrastructure Solutions UK Limited in full compliance with our management systems, which have been certified to ISO 9001, ISO 14001 and OHSAS 18001 by LRQA.

