

Upstream meeting RSB – DG ENV, DG GROW
Impact Assessment for the targeted review of the Regulation on REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)

The purpose of RSB upstream meetings is for report authors and Board members to discuss informally questions concerning how to prepare the best possible report on the issue at hand. Board members give their advice in a personal capacity and advice is not binding for the subsequent Board meeting.

22 April 2022

List of participants:

RSB: Rytis MARTIKONIS, Bernard NAUDTS, Dorota DENNING, Antonio NICITA, James MORRISON

ENV: Patrick CHILD, [REDACTED]

GROW: Kristin SCHREIBER, [REDACTED]

JRC: [REDACTED]

SG: [REDACTED]

DGs ENV and GROW introduced the REACH Regulation on registration, evaluation, authorisation and restriction of chemicals, including its main objectives and the actors involved. Links with other horizontal and sectoral chemical legislation was structured under information on chemicals, identification of hazards and managing risks. The DGs presented the link with the Chemicals Strategy for Sustainability and the sources of available evidence (evaluations, fitness checks, ECHA reports, supporting studies and stakeholder consultations). They described the problems and their drivers, the objectives of the REACH revision and the measures currently considered for addressing the problems. [REDACTED]

Points raised in the discussion

- Board members highlighted the need for clear evidence of the problems and an explanation of the rationale for intervention. The report should clearly present the problems and their scale. [REDACTED]
- [REDACTED]
- Regarding the problem of insufficient enforcement, Board members asked to be clear if this is due to the regulatory design or because of a lack of enforcement *per se*. Measures related to a basic lack of enforcement could be included in the dynamic baseline. It would also be useful to analyse if the measures for enforcement in the current Regulation are sufficient and if a lack of enforcement originates from a lack of monitoring. The impact of the proposed policy options on enforcement should be analysed.
- [REDACTED]
- Board members underlined the need for a coherent, logical and consistent analysis, particularly given the rich evidence base presented. The information from the support studies should be presented in a comparable way.
- Both positive and negative impacts should be presented and quantified (to the extent possible). This should include a clear identification and quantification of the administrative burdens and savings in scope of the 'one in, one out' approach.
- Board members stressed that a monitoring and evaluation framework (or at least its basis) needs to be presented in the impact assessment, e.g. the definitions of indicators.

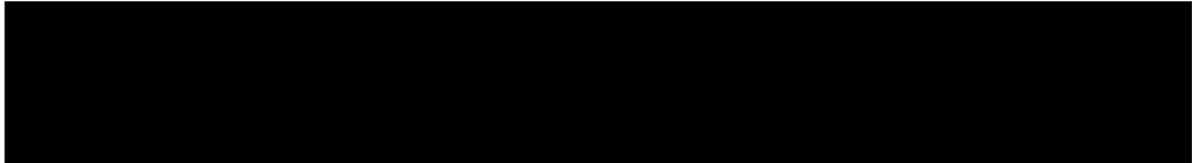
JRC comments on RSB upstream meeting with DG ENV, DG GROW on REACH (Registration, Evaluation, Authorisation and restriction of Chemicals), 22 April 2022

JRC.I1.CC-ME stated that possibly other parts of the JRC are already supporting this file, and made the following comments in view of future related monitoring and evaluation.

1. How to measure success. [REDACTED]

It would be important to define indicators or measures of success for each of the stated overall objectives and specific problem areas. This is relevant both to compare merits of options in the impact assessment, as well as for the planning of future monitoring and evaluation.

2.

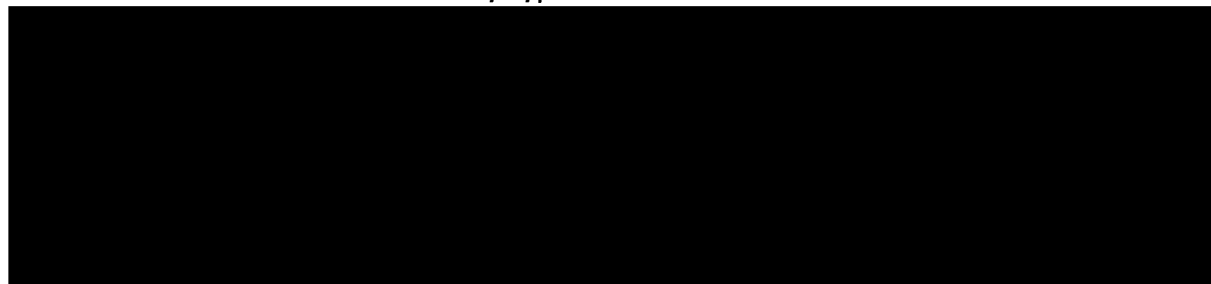


Does this mean that data will be

collected ex-ante on specific identified risks and the related risk-management measures? Will this data be paired with ex-post results related to them, such as materialized risks (or not) incidence of diseases that are related to exposures to some substance, etc.? Is there a plan to re-use health data at granular level (in time and space) already collected at Member States (such as on occupational diseases), so as to make this data collection cost-efficient?

- The monitoring and evaluation of this initiative could have synergies with other initiatives under the Commission Chemical Strategy also on data collection. The administrative cost for a joint monitoring and evaluation plan with some of these other initiatives may imply synergies and cost-savings. Enough information should however be collected to distinguish the specific contribution of the present initiative. A side effect of a joint monitoring and evaluation plan would be to see how different related initiatives are working, reinforcing each other or otherwise.
- This joint approach could allow to investigate the combined effects of several chemicals jointly, addressing 'combination' effects (mixture assessment factors). Is this foreseen?
- Is the European Injuries Data Base (IDB) going to be used for some of these outcomes? Is there a plan to update this data source? Who will have ownership of the IDB, in view of its update? Is the collection of this data going to be covered by some other interoperability initiatives in sharing data from Member States, so as to reduce the cost of survey-type data collection?

3.



- Information on innovation expenditure in firms could be associated with patent data; is this foreseen?
- An example of analysis in this context for the toys safety directive is Dumangane et al (2021).

4.



- Could data from the European Rapid Alert System for dangerous non-food products be used to monitor compliance with the revised REACH?
- How is compliance of online sales going to be monitored?

- What are success indicators for the improved enforcement of REACH requirements (larger number of compliant dossiers, etc)? Are the specific rules for customs and OLAF foreseen going to include provisions that will automatically allow to collect data for the monitoring and evaluation of the improved enforcement?
- Are there specific indicators of success for improvement of the REACH revision on the functioning of the single market?

JRC.I1.CC-ME would be happy to discuss and give further input if useful.

It also shared the following piece of information, in case modelling is used in this IA:

Models used in support to Commission Impact Assessments (IA) should be made available in MIDAS, the Modelling Inventory of the Commission, at the time of publication of the IA report. If there is a plan to use simulation models, please contact the Competence Centre on Modelling at EU-MIDAS@ec.europa.eu to insert in MIDAS the description of the model as well as of its contribution to the IA. Models already used on behalf of the Commission are already included in the system; in this case, the information can be easily retrieved and updated if needed. Please note that the model descriptions included in MIDAS allow to easily generate the information required for Annex 4 of the IA report.

Reference

Dumangane, M., Elia, L., Guthmuller, S. and Yoon, M., Evaluation of the benefits and the costs generated by the Toy Safety Directive: a supply side analysis (2021), EU 30695 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-37537-1, doi:[10.2760/97203](https://doi.org/10.2760/97203), JRC118635.