EUROPEAN COMMISSION

Directorate-General for Environment
Circular Economy and Green Growth
Sustainable Chemicals

Directorate-General for Internal Market, Industry, Entrepreneurship and SME's
Ecosystems I: Chemicals, food, retail
REACH
Bioeconomy, chemicals, cosmetics

Brussels, 26/01/2022
Doc. CA/08/2022

Ad-hoc Meeting of Competent Authorities for REACH and CLP (CARACAL)

27 January 2022

Online

Concerns:	**Discussion on potential options for amendments of the REACH Regulation in order to reform REACH evaluation process**
Agenda Point:	**3.4 (Open session)**
Action Requested:	**Competent Authorities and observers are invited to comment on the document and the discussion points put forward. Written comments should be sent by 24 February 2022 to:** **GROW-CARACAL@ec.europa.eu** **ENV-CARACAL@ec.europa.eu** **GROW-ENV-REACH-REVISION@ec.europa.eu**

Introduction

CSS does not elaborate on REACH Evaluation as one of the tools requiring radical reform, but it does describe several objectives to which Evaluation process is contributing as it aims at a 'zero tolerance for non-compliance by a.o. "***strengthening the principles of 'no data, no market' and the 'polluter-pays'*** *under REACH, in particular by requiring compliance of all registration dossiers and revoking the registration numbers in case of non-compliance*".

Evaluation would contribute also when it comes to objectives to coordinate and simplify actions across EU chemical legislations, in particular within the **one substance-one assessment** and its instruments as the coordination tool and testing by authorities. Evaluation processes are also expected to effectively respond **to changed needs due to other actions under CSS** as they may reflect/impact it, in particular changes in registration: scope and information requirements, working on groups, methodologies for risk assessment, support to protection against most harmful chemicals etc. Ensuring adequate information is available regarding the hazards of chemicals goes in parallel with the strong objective to exploit better (and move towards) use of non-animal methods; evaluation processes, capacity and resources behind should reflect this change.

REACH review has identified (while acknowledging Evaluation works rather well and noting a number of improvements in the recent past) specific weaknesses in the evaluation processes and opportunities to **further increase their efficiency**. Some MS had expressed ambition to support some changes to the compliance check and substance evaluation setup, and/or to reconsider decision-making processes including role of MSC.

Current Joint REACH Evaluation Action Plan should meet its objectives by 2027, close to the time when implementation of REACH revision would start to kick in. The **future role of REACH evaluation and its eventual targets** should be considered now.

Possible improvements

The Commission is reflecting upon a set of possible measures under Evaluation and closely related tasks (technical completeness check, registration, testing by authorities).

Considered issues/potential measures are grouped in themes. Note that only the measures for which changes to the enacting terms is likely required, are presented. Improvements to the evaluation processes instituted by ECHA through own processes, by further implementing regulation or implicitly through changes to the technical annexes of REACH, are not listed. Many of these have been already implemented in the past as part of the Joint REACH Evaluation Action Plan.

Measure **(heading of group of measures in bold)**	**Short description -** As measures are not fully developed, these descriptions are for information purpose. They should convey the objective but may not adequately represent the eventual measure (or measures) under each item. If chosen, this would be subject to legal scrutiny, effectiveness/efficiency assessment etc.	**Comment**
Registration and Technical Completeness Check (TCC)		
Maintain compliant dossier; dossier 'expiration date'	Legal changes to strengthen the common expectation of dossiers 'compliant at all times', not perhaps only at time of compliance check as perceived by some actors. Data is expected to reflect, in compliant manner, declared circumstances under which access to market is granted, and is kept updated as required (Article 22, evaluation decisions, changes to information requirements…).	Exact legal options still to be determined.
Strengthen TCC, clarifying that completeness check may include determination of compliance with information requirements	Not meant as linking or merging TCC and CCH that remain separate mechanisms, but rather to address assessment of dossier before it is considered complete, likely also with modification of Article 20(2) on TCC, in particular last sentence "…shall not include quality or the adequacy of any data or justification provided". ECHA should be empowered to consider a dossier to be incomplete, not only because it is formally missing required information but also because the information in the dossier is manifestly inappropriate/non-compliant.	Definition of 'manifestly inappropriate/non-compliant information' needs to be developed.
Revocation of registration number	Discussed as an important support to effective enforcement across the EU (removing access to EU market), to be applied for persistent failure to comply.	Legal instrument under development.
Information requirements: application of waivers	Application and consequent assessment of waivers under Evaluation have important impact on effectiveness and efficiency of data generation. Having at least some specific waivers (e.g. exposure based) subject to validation/authorisation prior to their use may improve data availability and efficiency of evaluation procedures	Selection and mechanism under development.
Dossier Evaluation		
Testing proposal (TP): - Restrict use or - expand (for animal testing)	Making changes to the legal provisions that determine when a testing proposal must be issued before proceeding with the testing, which may go in two directions: - Raise expectation that (all) data is available when registering, also by generally reducing requirement to first prepare test proposals and subject them to examination, e.g. for higher tier in ecotox - Extend TP to effectively all animal/vertebrate testing to use the process to help ensure animal testing is only done where strictly necessary - Combination: limit TP to animal/vertebrate testing	
Compliance Check (CCH) Strategy after 2027 – percentage, prioritization	Changes to compliance check provisions in Art. 41. A mixed bag and may be separated in submeasures: a) Ambition: CCH after 2027 when current evaluation action plan expires b) Prioritisation of CCH cases	Discussion ongoing whether it does even need any reference or should be left outside legal text for ECHA to optimize, e.g. as presently linked to ECHA integrated regulatory strategyscreening and grouping processes
Scope of CCH and CCH decisions	c) Scope: CCH addressing also self-classification & DNEL; CSR/exposure d) Grouping: setting legal frame that would maximise effectiveness to jointly check compliance for all substances	Still open question whether changes are really required.

	that are members of groups and address data gaps with testing strategy	
Information requirement and scope of CCH decision: improving adaptations by registrants	E.g. modifying the CCH provisions to support registrants ensuring compliance by providing quality adaptations, where warranted	
Substance Evaluation		
Link to TP **examination (TPE)**/CCH	Through changes of the legal text allow for efficient application of both mechanisms, if appropriate concurrently.	Still open question whether any legal changes are really required.
ECHA to be also able to perform SEv	Extend ability to perform SEv from evaluating MS competent authorities also to ECHA.	
Extension of SEv requirements from risk-based concerns to hazard-based concerns	Changes to Art.44, Art 46 to ensure the tool is used effectively for hazard data generation.	
Replace CORAP with lightweight and dynamic registry		
SEv as assessment	Extensive SEv exercise serves as data generation tool using mechanisms at EU level but has also safety assessment dimension that stays at MS level (SEv Conclusion document). Should this aspect be modified?	Open question whether the issue requires to be addressed.
Changes to evaluation decision making procedures and conditions for registrants		
Specify conditions and consequences of cease manufacture	Clarify legal text (Art 50(3)), making clear what are consequences to the decision-making process as well as to the obligation of the registrant declaring cease manufacture at specific points in time during CCH procedure. In particular relevant to clarify following BoA-9-2020.	Under development.
Limit specific CCH process to assessment of the dossier and associated ECHA draft assessments	In particular relevant to clarify following BoA-6-2020. Registrant is accountable for the compliant data submitted and kept updated in the dossier in exchange for having market access ('licence') Potential consequences during CCH decision-making process: 1) The registrant cannot modify the scope of the information requirements (e.g. through declared tonnage, intermediate use) 2) The registrant can only comment on the assessment of ECHA of the information in the dossier at the time (e.g. no new adaptation can be proposed) Whilst the concept of right to be heard and need to assess all relevant information are maintained.	Under development.
Removing & modifying	These are resource efficiency/timing improvement considerations. Addressing Art 51 deadlines should allow for more efficient/smooth workflow submitting and assessing draft	

procedural steps, provisions (e.g. Art 51 deadlines) involving registrants with commenting, authorities & ECHA, role of MSC	decisions. Under consideration are also questions: - can CCH/TPE decisions be taken by ECHA alone? - should required unanimous vote in MSC be replaced by qualified majority?	
Testing by authorities	New tool that should work in conjunction with other EU chemicals legislation (commitment under CSS), enabling authorities to do (or better: order using Contract Research Organization) tests under specific circumstances. The tool shares data generation dimension with DEv and SEv but may not necessarily even be part of Evaluation. Different options to be assessed under IA: - Link to DEv/SEv processes andto REACH reversal of burden of proof - Who decides, orders and accepts results, data hosting, funding	Options under development
Coupling fees to actions causing ECHA workload (e.g. dossier updates, comments on draft evaluation decisions, new adaptations, etc.)	Under consideration/development within ECHA funding regulation discussions	

Discussions points (at the meeting):

- Clarification of individual items and link to other activities (e.g. registration-related measures)
- Comprehensiveness (identification of additional opportunities)
- Under each theme or individual measure: perception of relevance, assessment of impact (and role of impact assessment), different options to be considered

For written comments:

- Identification of potential other measures regarding Evaluation process or in close relation to it
- For the measures in the list presented: perception of relevance, assessment of impact (and role of impact assessment) with information that could contribute to it, identification of different options, including legal aspects, to be considered; relation with other actions, changes planned
- Testing by authorities: consideration of specific questions presented at the meeting