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REACH revision - establishment of a European Audit Capacity

6 April 2022.

DG ENV. Unit B2

Chemicals Strategy for Sustainability (CSS)

Zero tolerance approach to non-compliance

- The CSS includes an action to:

“propose to entrust the Commission with the duty to carry out **audits in Member States**, where relevant, to **ensure compliance and enforcement** of chemicals legislation, in particular REACH” (Section 2.3.2. *A zero tolerance approach to non-compliance*)
- The Action Plan laid down in the Annex to the CSS specifies among its measures:

“Proposal to amend REACH to introduce a European Audit Capacity”

Objective of this action:

- Improving compliance and enforcement of chemical legislation by **strengthening the effectiveness** of national **control systems** throughout the **EU**
- **Audits** to verify the functioning of MSs official controls **systems**:
 - identifying potential weaknesses
 - their possible causes
 - so that corrective action is taken

Intended role is mainly 'control of controller', i.e.: to verify effectiveness of MSs control systems for the purpose of REACH, not to directly control specific operators

- Standards for uniform assessment

Study by Milieu ongoing

to assist the Commission:

- in identifying possible options for establishing a European Audit Capacity
- in identifying criteria/standards relevant for the effectiveness of Member States control systems that could be evaluated by that Audit Capacity
- The study shall also assess the possible extension of the above actions for the purpose of the CLP, POPs and PIC Regulations.

Consultations

- **Experts from Member States:**
 - FORUM
 - CARACAL, PIC DNAs and POPs competent authorities
- **Experts from the Commission**
- **Public consultation** within the Study for the Impact Assessment **ONGOING**
- In parallel, the European Audit Capacity is also part of the follow up discussions (at sherpa level) on the High Level Roundtable's joint report on enforcement (adopted in Nov 2021)

Preliminary results of the study

Options for designing EAC

This is a modular system and elements in different options can be combined

Option	Short description
Option 1: Comprehensive audit capacity system	Combination of general and specific programmed audits and ad-hoc audits, additional activities like fact-finding missions; EC lead; Auditors: EC auditors, with MS experts and ECHA if relevant; Conclusions and actions for follow-up; Audit criteria are laid down in legislation
Option 2: An audit capacity system	Combination of specific programmed audits and ad-hoc audits; EC lead; Auditors: EC auditors; Conclusion and actions for follow-up; Audit criteria are laid down in legislation
Option 3: A minimal control capacity system	Combination of EC ad-hoc controls and MS peer reviews; Controllers from EC for ad-hoc controls, from MSs for peer reviews; Control report; Control criteria are laid down in guidance
All options	A form of report discussed at Forum



Preliminary results of the study

What this would mean for ECHA, Forum and MSs?

- ▶ Audited MS: MS authorities to cooperate and provide information to auditors (all options)
- ▶ Other MS: in some cases, MS to provide experts for audits (option 1) or peer reviews (option 3)
- ▶ Audited MS: actions can be taken to address the shortcomings identified during the audit (options 1 and 2 and 3)
- ▶ Forum: to provide feedback on audit programme (options 1 and 2), discuss findings of audits (all options)
- ▶ ECHA: to provide auditors and technical expertise where necessary (options 1 and 2)

Preliminary results of the study

List of criteria relevant for MSs control systems

Takes into account those existing in other areas of legislation, including Market Surveillance Regulation and guidance from Forum

Criteria concerning:

- the competent authorities (e.g. designation, lack of conflict of interest or coordination)
- organisation of controls (e.g. risk based planning)
- Implementation of controls (e.g. following documented procedures, reporting, follow up)
- evaluation of the control system (e.g. control verification procedures, internal evaluation, horizontal analysis)

Options: to lay down criteria as binding in the legislation or as guidance

REACH revision

Results of the study should inform the Overall Impact Assessment for the Revision of the REACH Regulation

Thank you



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Slides 6 and 7: source: Milieu consulting

