

Guidance on REACH/CLP inspection within the framework of ECHA Forum activities

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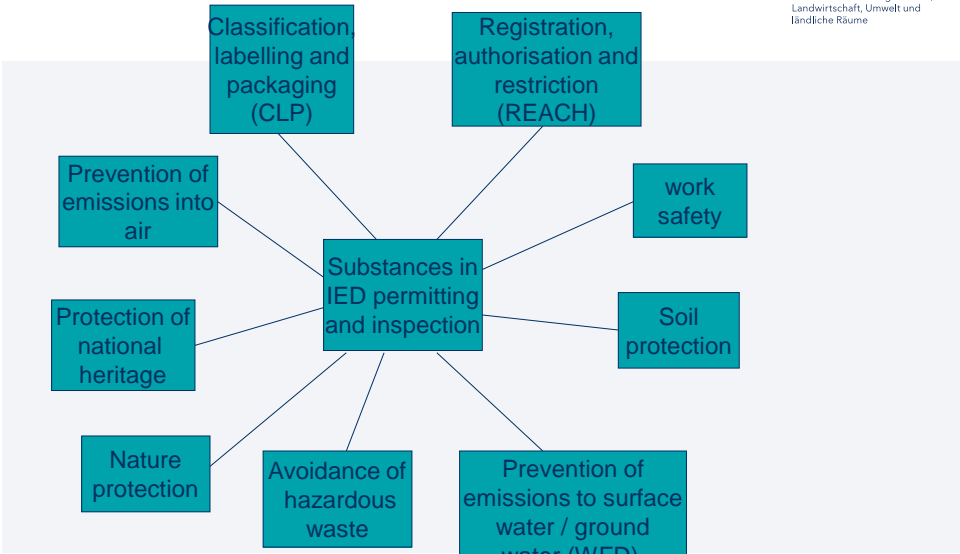
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Substances in IED permitting and inspection



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IED and REACH / CLP inspection - Guidance



| IED inspections | REACH / CLP inspections |
|---|---|
| IPPC Directive 1996 | REACH Regulation (EC) 1907/2006 |
| Recommendation of minimum criteria for Environmental inspections (2001) | Minimum Criteria for REACH inspections (2009, updated 2011) |
| Directive on industrial emissions (IED) 2010 | |
| Parts of RMCEI became binding | MCRI not binding |
| <ul style="list-style-type: none">- Highest risk annually- Lowest risk every third year- Determination based on risk assessment | Risk analysis |
| Plan, programme, inspections, follow-up, reporting | Organisation, plan, inspections, follow-up, reporting |

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Forum – role and responsibilities

The **Forum for Exchange of Information on Enforcement (Forum)**, according to Regulation (EC) 1907/2006, coordinates a network of Member State authorities responsible for enforcement.

The Forum is **composed of**:

- Members appointed by the Member States (one member per MS – EU MS plus EEA-EFTA States Iceland, Liechtenstein and Norway).
- Up to five co-opted members chosen on the basis of their specific competence.
- Stakeholders may be invited to attend meetings as observers.

Forum – tasks

- **Spread good practice** and highlight problems at Community level
- **Propose, coordinate and evaluate harmonised enforcement projects** and joint inspections
- Identify **enforcement strategies**, as well as best practice in enforcement
- Develop **working methods and tools** of use to local inspectors
- Liaise with industry,
- Examine proposals for restrictions with a view to advising on enforceability (Art.77(4))

Guidance on REACH / CLP inspections

❖ Strategies for Enforcement of REACH and CLP (March 2011)

❖ Minimum Criteria for REACH and CLP Inspections (March 2011)

- REACH and CLP inspection activities should be carried out in Member States **following minimum criteria** to be applied in the effective organisation, planning, implementation, carrying out and review of such tasks
- Comprehensive **risk analysis** should be used to ensure that enforcing authorities concentrate their resources on the areas that need them the most.
- **Enforcement Strategy**
- For a structured and transparent approach to REACH and CLP enforcement, an appropriate enforcement strategy or strategies should be developed.

Guidance

- **Organisation:**
- Appropriate provisions should be made to **ensure that enforcing authorities cooperate and exchange information.**
- **Planning:**
- MS should have at all times **an inspection plan** or plans, collectively taking into account all the territory of the MS and of the known target groups
- **Carrying out REACH and/or CLP inspections**
- criteria in respect of all REACH and/or CLP inspection:
 - a) that the role of the dutyholder is correctly identified
 - b) that an appropriate check is made of compliance with the REACH and/or CLP requirements

Minimum Criteria for REACH / CLP Inspections

- c) that if **site visits** are to be carried out **by more than one enforcing authority**, then as far as possible they **exchange information** on each others' activities and coordinate site visits and other REACH and/or CLP inspection work;
- d) that the **findings of the inspections** are contained **in reports**
- i) that **serious accidents or incidents are investigated** without undue delay after these come to the notice of the relevant enforcing authorities,
- k) that, **if hazards are identified** related to any product, the enforcing authorities shall take **measures** to alert users by using the appropriate procedures as required by Article 19(2) of the AMS Regulation;

Minimum Criteria for REACH / CLP Inspections

- **Action following REACH and / or CLP inspections**
- Enforcing authorities should ensure that after every inspection **reports** are produced and stored. **Content:**
 - basic data on the inspection
 - the significant findings of the REACH and/or CLP inspection
 - steps of evaluation
 - ...
 - the **measures taken** pursuant to the REACH and/or CLP inspection, by the enforcing authority and/or by the dutyholder.

Minimum Criteria for REACH / CLP Inspections

- The **reports should be communicated to dutyholders** promptly with clear explanations of what action they are required to take.
- The enforcing authorities should **ascertain that the required action has been taken**, and as soon as possible after the expiry of any deadline given to the dutyholder.

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Minimum Criteria for REACH / CLP Inspections

- **Checking and review:** Enforcing authorities should regularly check and review the success of their arrangements for REACH and CLP inspections, including the elements of organisation, planning and carrying out, using appropriate performance indicators.
- **Reporting:** Enforcing authorities should ensure that appropriate systems are in place to facilitate the collection and collation of relevant information on REACH and CLP inspection activities (reporting under Article 117(1) of REACH (with reference to Article 127) and under Article 46 of CLP).

Guidance in the Member States

– IMPEL project 2014 (in cooperation with Forum) showed:

- Most countries have general guidance for carrying out REACH inspections in place
 - several countries use the manual / checklists of the FORUM-Enforcement projects,
 - others have own checklists for REACH in inspections.

Forum task no. 2:

Propose, coordinate and evaluate harmonised enforcement projects and joint inspections

Forum Enforcement Projects

- **REACH-EN-FORCE 1**
 - Project on pre-registration/registration of phase in substances and SDS
 - **REACH-EN-FORCE 2**
 - Enforcement of obligations of downstream users – formulators of mixtures
 - **REACH-EN-FORCE 3**
 - Inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs
 - **REACH-EN-FORCE 4** preparatory phase 2015, operational phase 2016
 - Enforcement of classification and labelling of mixtures
- + pilot projects and projects on special items

Forum Enforcement Projects – objectives

- Building the instutional capacity of enforcement authorities
- Training of inspectors
- Improvement of institutional cooperation of national authorities in enforcement of chemical legislation
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- Contribution to coordination and harmonisation of REACH enforcement in the MS's of the EU and EEA-EFTA states,
- Harmonisation of reporting carried out by the MS

REACH-EN-Force projects

- **Preparatory phase:**
 - Based on a proposal the Forum decides on the project.
 - A working group is established. In each MS a national coordinator is appointed.
 Tasks: elaboration of a **manual**, developing the reporting tools and regulating the tasks of writing a final report
- **Training phase**
 - Forum carries out a training phase – train the trainers of the MS
 - Trainers inform the colleagues in their countries in workshops and supervise the project
- **Operational phase**
 - authorities carry out inspections and report the results
- **Project report**

project manuals

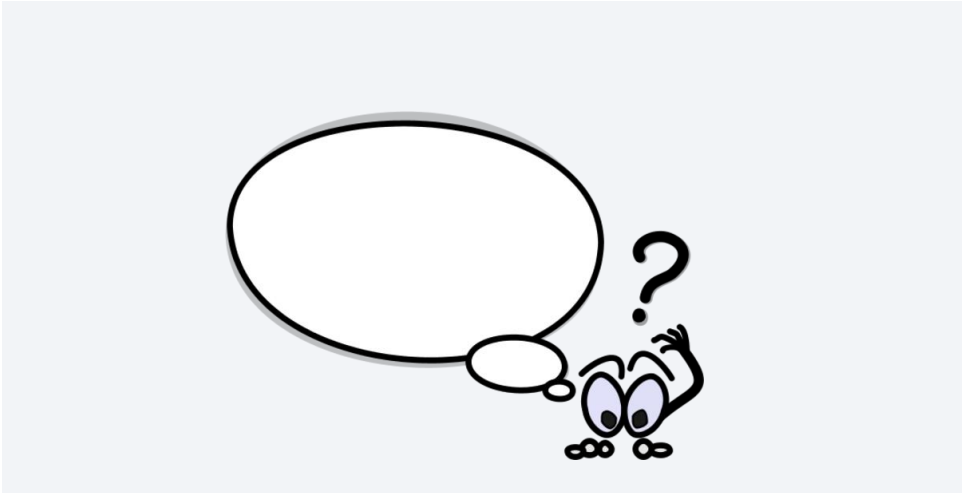
- The project manuals provide good information on:
- **Description of work methods** with advice for the inspector what to do in case of non-compliance (general advice – details may be in national legislation)
- A **questionnaire**
- **Report templates**
- REACH / CLP provisions to be inspected and
- the common understanding of the legal terms

- **Manuals** are **translated** into the languages of the participating Member States
- Member States are free to add further information,

- Development of a guidance document on inspections based on experience

Future?

- Development of a guidance document on REACH and / or CLP inspections based on experience from Forum Enforcement projects ??



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