

Interlinkage REACH and IED outcomes of IMPEL activities

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Interactions of REACH / CLP and IED ...

- IED and REACH - relation between them? = substances
 - **Aim of REACH:** to ensure a high level of protection of human health and the environment as a whole from the risks that can be posed by chemicals.
 - **Aim of IED:** to prevent pollution and where that is not practicable to reduce emissions from industrial activities into air, water and land in order to achieve a high level of protection of the environment as a whole.
- IED covers a subgroup of chemicals under REACH
- IED directly refers to REACH and CLP

Interactions REACH / CLP and IED

- IMPEL projects on the item assessed relevant REACH processes and their relevance for the interactions between IED and REACH
- Link between IED and REACH = substances and their properties / characteristics
- examples for explanation of relevance of interactions between REACH / CLP and IED
- Example 1: baseline report and waste
- Example 2: new classification of formaldehyde and consequences
- Example 3: use of trace element mixtures for biogas plants

Example 1 baseline report

Article 22 IED (site closure and remediation)

- Baseline report required, where the activity involves the use, production or release of relevant hazardous substances and having regard to the possibility of soil and groundwater contamination
- Baseline report has to be prepared before starting operation of an installation or before a permit is updated
- COM published guidance on the baseline report in 2014 (2014/C 136/03)

Example 1 baseline report

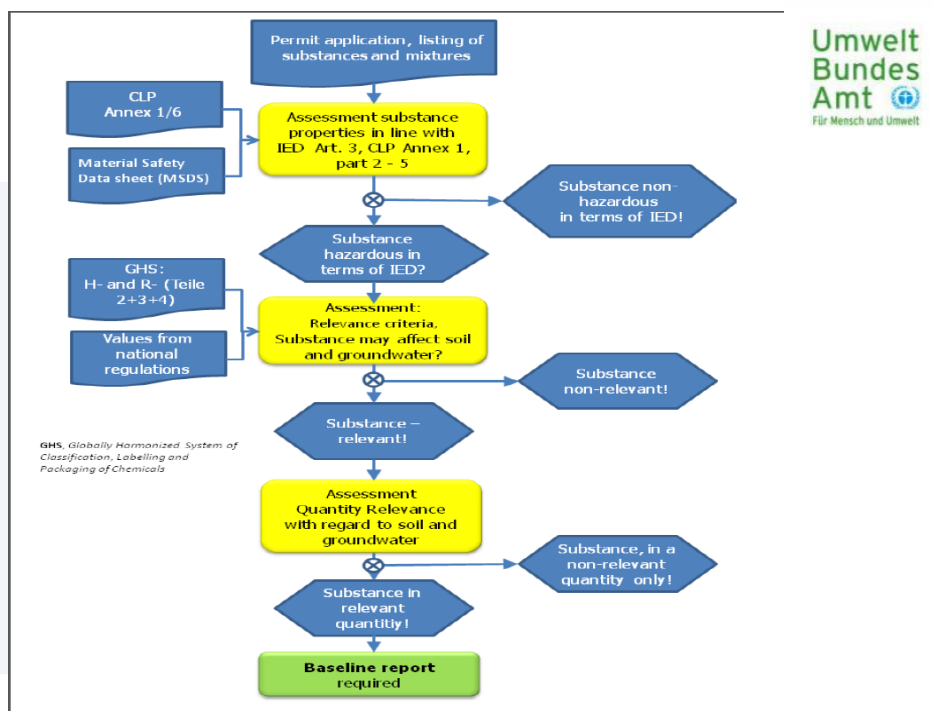
Article 22 subpar. 3 IED → no-deterioration approach

- After definitive cessation of the activity, the operator has to assess the state of soil and groundwater contamination by relevant hazardous substances
- The operator compares the results of the final assessment and the initial baseline report
- Where the comparison indicates contamination, the operator must take measures to return the site to the initial state established in the baseline report
 the technical feasibility of such measures may be taken into account.

Example 1 baseline report

- Guidance in Germany:

- Guidance on the baseline report for soil and groundwater (2013)
workshop in September 2016, explore the need for an update
- Guidance on remediation (the procedure to be carried out after
definitive cessation (not yet published)



Example 1 baseline report – waste

- The baseline report on soil and groundwater contamination is a new instrument - there was a need for guidance on its content and for criteria concerning “the relevant hazardous substances” and “the relevant amounts”.
- Baseline report - IED only refers to relevant hazardous substances or mixtures as defined in Article 3 of CLP Regulation → hazardous waste is not covered. Hazardous waste can contaminate soil and groundwater in the same way. Here seems to be a gap.

Example 1 baseline report - waste

Guidance concerning baseline reports under Art. 22(2) IED

Definition „hazardous substance“ - reference to CLP Regulation (EC) No. 1272/2008

Reference to: 4.3 Landfill Directive: point 3 Annex
 requirements concerning the protection of soil and groundwater

Main **stages** (8) of preparing the baseline report:

- Stage 1: identifying hazardous substances used, produced or released at the installation - produce a list of all hazardous substances dealt with inside the installation boundary (raw materials, products, intermediates, by-products, emissions or **waste**)

Example 1 baseline report - waste

- Stage 2: identifying the relevant hazardous substances – determine the potential pollution risk of each hazardous substance
- Stage 3: assessment of site-specific pollution possibility – quantity, single emission or accumulation from multiple emissions
- Stage 4: site history – i.a. What changes or improvements were made to the process, chemicals handled, storage locations, **disposal methods** and why? E.g to reduce waste.
- Stage 5: environmental setting: 1 – 4 past and future emissions identified. Now determination of the fate of any such emissions.
- Stage 6: site characterisation
- Stage 7: site investigation → checklist in the annex
- Stage 8: Production of baseline report (checklist in the annex)

Example 2: new classification of formaldehyde and consequences

- Example 2: new classification of formaldehyde,
 EC number: 200-001-8, CAS number: 50-00-0

Sept. 2011	proposal submitted by France to ECHA,
Nov. 2012	Committee for Risk Assessment (RAC) adopted opinion on the proposal for harmonised classification and labelling of formaldehyde (mutagenicity and carcinogenicity)
2014	adoption by COM, then proposal for Adaptation to Tech. Progress
2015	Regulation (EU) 2015/491: new classification entered into force 1 January 2016

Example 2: new classification of formaldehyde and consequences



	CLP	DSD
former entry in AnnexVI to Regulation (EC) No 1272/2008	Carc. 2 – H351	Carc. Cat. 3; R40
Proposal by submitter consideration by RAC	Muta. 2 – H341 Carc. 1A – H350	Muta. Cat. 3; R68 Carc. Cat. 1; R45
Opinion of the RAC	Carc. 1B – H350 Muta. 2 – H341	Carc. Cat. 2; R45 Muta. Cat. 3; R68

- classification in category 1B, “presumed to have carcinogenic potential for humans, classification is largely based on animal evidence” (instead of suspected human carcinogen)

Example 2: new classification of formaldehyde - consequences



- 1. emission limit values for a number of industrial activities have to be adjusted, e.g.:
 - organic fine chemicals industry
 - pulp and paper industry
 - ceramic manufacturing industry
 - food, drink and milk industries (e.g. coffee roasting: main contaminants in exhaust air: CO₂, dust and formaldehyde)
 - textile industry
- **European level:** review of BREF documents and conclusions necessary

Example 2: new classification of formaldehyde – consequences in DE



- national level, e.g. consequences in Germany for industrial installations:
- approach of TA Luft:
 - ❖ now general emission limit value (ELV) for organic substances class I in exhaust air: 20 mg/m³ or 0,1 kg/h plus specific ELVs for different types of installations
 - ❖ with new classification: change to carceogenic substance class III
→ general ELV **would be** 1 mg/m³ or 2,5 g/h
- expert discussions showed that it is difficult to find technologies that could comply with that
- July 2014: start of a project to determine new emission limit values (general ELV and sector specific ELVs – based on criteria for determining BAT)

Example 2: new classification of formaldehyde - consequences



Results: (proposal for a guidance – not yet adopted by Conference of Ministers for the Environment)

- General ELV: 5 mg/m³ or 12,5 g/h (not Class III because of threshold)

Sector / installation	Current ELV	proposal
Combustion engines (gas and oil)	60 mg/m³	20 mg/m²
Manufacture of glass	20 mg/m³ *	10 mg/m³
Melting of mineral substances	20 mg/m³	10 mg/m³
Production of synthetic resins (with formaldehyde)	20 mg/m³	10 mg/m³ or 25 g/h
Production of paper and card board (depending of type of dryer)	20 mg/m³	5 (indirect, IR), 15 Flotation dryer

Example 2: new classification of formaldehyde - consequences



Activity	Current ELV	Proposal
Installations for coating, waterproofing, laminating, painting or impregnation of glass and mineral fibres – impregnating and drying	30 mg/m³	5 – 10 mg/m³
Production of chip boards, wood fibre or wood fibre mats: depending on drying technology	TOC → cannot be compared	10 – 20 mg/m³
Production of synthetic rubbers	20 mg/m³	10 mg/m³
Smoke installations for meat and fish products	20 mg/m³	10 mg/m³
Coffee roasting	20 mg/m³	15 mg/m³
Textile industry: depending on process step	TOC and other criteria → not comparable	5 – 20 mg/m³

Example 2: new classification of formaldehyde - consequences



2. work safety requirements have to be adjusted

Discussion about the measures in Germany started
→ occupational exposure limit value (OEL), identification of alternatives

Example 3: use of trace element mixtures for biogas plants



Case of an occupational disease with nickel intoxication and high concentration of other heavy metals

- Background: work at a biogas plant,
- Task inter alia: regular (daily) addition of a trace element mixture (in powder form) to the substrate in the fermenter
- Characteristics: no protective measures → without respiratory protection, measures for avoidance of skin contact (protective gloves)
- Findings: Operators optimise the fermentation biology through addition of trace element mixtures. (biomass biogas plants without use of manure)
- Germany: ca. 30 companies offering such mixtures

Example 3: Components of trace element mixtures (metal salts of):



cobalt	<u>carciogenic</u> , <u>mutagenic</u> , <u>reproduction toxic</u> , <u>toxic</u> , <u>sensitising</u> , <u>dangerous for the environment</u>
copper	<u>harmful to human health and to the environment</u>
iron	<u>harmful to human health</u>
manganese	<u>harmful to human health and to the environment</u>
molybdenum	<u>harmful to human health</u>
nickel	<u>carciogenic</u> , <u>mutagenic</u> , <u>reproduction toxic</u> , <u>toxic</u> , <u>sensitising</u> , <u>specific organ toxicity</u> , <u>dangerous for the environment</u>
selenium	<u>toxic</u> , <u>specific organ toxicity</u> , <u>sensitising</u> , <u>dangerous for the environment</u>
tungsten	<u>harmful to human health</u>
zinc	<u>Hazardous to the environment</u>

Example 3: use of trace element mixtures for biogas plants - consequences



Inspections manufacturers / distributors

- Check of labelling: low concentrations of Co and Ni compounds (e.g. 0,1 %) may lead to a labelling as carcinogenic resp. toxic
- Check of safety data sheets (in several cases poor quality)
- control of compliance with provisions on storage and provisions on sales
- control of compliance with occupational safety regulations
- Communication in the supply chain

Recent developments:

- Change to liquid trace element mixtures
- change to solid trace element mixtures in biodegradable packages

Example 3: use of trace element mixtures for biogas plants - questions



Permit application(s):

Why no information about the mixtures ?

Why no notification to the authority(ies) about the use of additives ?

Permit should contain obligations on

- Regular analysis of the substrate
- Regular analysis of the fermentation residues
- Requirements concerning work safety

→ Lack of cooperation between permit writers and REACH colleagues

interactions REACH / CLP and IED

Conclusions

- Clear statements needed in guidance documents (example baseline report – guidance document has no clear position concerning waste)
- Developments in legislation on chemical substances influence the work of permit authorities to a good deal (example formaldehyde)
- Up to now in many MS permit authorities and operators are not aware of the role of requirements concerning chemicals (example biogas plants)

➤ **Exchange between IED and REACH regulating bodies needed on national and on European level (including procedures for the development of BREF documents)**

Development of BREF documents

Step 1: European IPPC Bureau sets up a **Technical Working Group (TWG)**
 (40 – 100 experts)

EIPPCB as neutral and technically competent body – organises the process and writes the BREF document

Representatives of MS from authorities (air, water, soil waste, and energy / climate), industry and NGOs plus COM

(REACH / CLP experts not involved)

Step 2: Data collection

- quantitative data (emission concentrations, consumption quantities, plant operating parameters)

- qualitative data (techniques, process routes, material types, output...)

Development of BREF documents

Step 3: Data validation by IPPCB and **data analysis**

Step 4: TWG consultation and IPPCB drafts **first draft**

Step 5: Consultation concerning first draft

Step 6: Development of **second draft**

Step 7: Final discussion in TWG

Step 8: Adoption through comitology procedure

- Stakeholders have to do a good job ! If not, problems occur later!
- BAT conclusions are binding for MS

Recommendations IMPEL project 2014

- Proposals for integration of REACH aspects into the procedure for the development of BREF documents
- Cooperation between IPPC Bureau and ECHA in the development of BREF documents
- General chapter on chemicals should be in the BREF documents and in the BAT conclusions, to the extent that is relevant.
- „The use of substance x for process y is not BAT“ could be an acceptable approach for making operators substitute substance x.
- In BREF documents appropriate alternatives for substances regulated by the REACH candidate list, Annex XIV and XVII should be mentioned.
- BREF documents should take into account phasing out obligations under the Water Framework Directive and offer alternatives.

Recommendations IMPEL project 2014

- For a separate guidance document on REACH and IED a stepwise approach might be successful: To begin with, a webpage (IMPEL?) with links and best practice examples. Guidance from different countries could provide valuable information. Translations are necessary.
- REACH national competent authorities together with ECHA should raise awareness of the Chemical Safety Reports (CSR) and their value to IED authorities.

Substitution of hazardous chemicals

- OECD Synthesis report on alternatives assessment and substitution of harmful chemicals (January 2016)
- Driving forces: legislation, incentives, market, consumers
- Analysis of supporting material, tools and further needs
- Further IMPEL activities?

