RAPID REMOVAL FROM THE WATER COLUMN

2nd Workshop on the Applicability of the Rapid Removal concept for environmental hazard classification

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A G E N D A

Re-cap of the issue

The concept of environmental hazard classification as applied to

- *Organics (concept of degradability)*
- *Metals and inorganic metal compounds*

Brief history

- *Rapid Removal – from 2011 to date*

Environmental hazard classification for organics (1)

Chronic aquatic hazards

- Basic elements are chronic aquatic toxicity data, degradation and bioaccumulation data (the latter in absence of adequate chronic toxicity data)
- The actual chronic hazard category is depending on the information on rapid degradation of the substance:
  - **Non-rapidly degradable** substances are classified in categories 1 (≤ 0.1 mg/L) or 2 (≤ 1 mg/L); and
  - **Rapidly degradable** substances are classified in categories 1 (≤ 0.01 mg/L), 2 (≤ 0.1 mg/L) or 3 (≤ 1 mg/L) depending on their toxicity

Rapid degradability does not necessarily lead to no classification.

Environmental hazard classification for organics (2)

The classification system recognises that:

- Substances that do not rapidly degrade have a higher potential for longer term exposures and therefore should be classified in a more severe category than substances which are rapidly degradable.

A substance not meeting the criteria for rapid degradation is likely to be persistent in the environment.

When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable.

CLP, Annex I.4.1.2.9.1

Substances that rapidly degrade can be quickly removed from the environment. While effects of such substances can occur, […], they are localised and of short duration. In the absence of rapid degradation in the environment a substance in the water has the potential to exert toxicity over a wide temporal and spatial scale.

The concept of degradability

CLP, Annex I.4.1.1.1

'Degradation' *means the decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts.*

The degree of degradation depends on:

- the intrinsic degradability of the molecule; and
- the actual conditions in the receiving environmental compartment (redox potential, pH, temperature, presence of suitable microorganisms, concentration of the substance and occurrence and concentration of other substrates).

CLP, Annex I.4.1.2.9.2

Demonstrating rapid degradation:

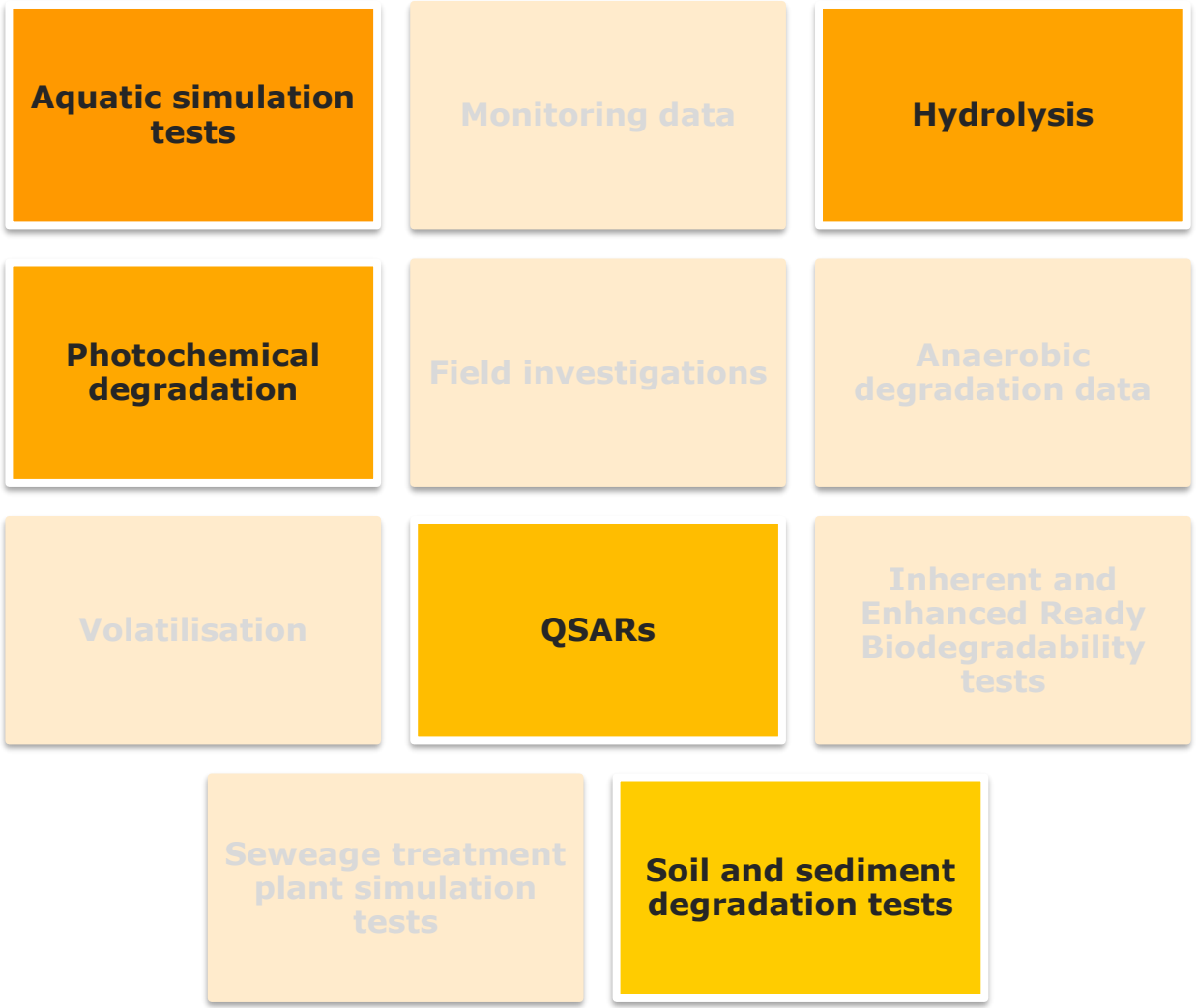
- Biodegradation **screening tests**; or
- **BOD/COD** ratio; or
- **Other convincing evidence** that the substance can be degraded biotically or abiotically in the aquatic environment to a level of >70% within a 28-day period.

Criteria recognise: Ultimate degradation – biotic or abiotic – consideration of classifiable degradation/hydrolysis products

Other convincing scientific evidence

- Aquatic simulation tests
- Monitoring data
- Hydrolysis
- Photochemical degradation
- Field investigations
- Anaerobic degradation data
- Volatilisation
- QSARs
- Inherent and Enhanced Ready Biodegradability tests
- Seweage treatment plant simulation tests
- Soil and sediment degradation tests

Other convincing scientific evidence



Are difficult or not considered under the criterion of „other convincing scientific evidence", because:

- Difficult to interpret the results – Is the removal a result of degradation or other processes? Can formation of non-degradable intermediates be excluded?
- Optimised test conditions stimulating the adaptation of microorganisms
- Dependent of environmental conditions (water depth, gas exchange coefficients, stratification)

Metals and inorganic compounds

CLP, Annex I.4.1.2.10

For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather, such substances may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species.

Poorly soluble inorganic compounds and metals may be acutely or chronically toxic in the aquatic environment depending on the intrinsic toxicity of the bioavailable inorganic species and the rate and amount of this species which enter solution. All evidence must be weighed in a classification decision. This would be especially true for metals showing borderline results in the Transformation/ Dissolution Protocol.

Environmental hazard classification for metals and inorganic metal compounds (1)

Assessment of solubility:

- All metal compounds which in a 24 hours T/D screening test at a loading of 100 mg/L achieve a metal ion concentration ≥ EC_{50} of the metal ion are regarded as soluble metal compounds, and are **considered in the same way as organic substances under CLP**.
- Metal compounds that do not fulfil this criterion are regarded as sparingly soluble and are **classified according to the strategy for metals**.

Environmental hazard classification for metals and inorganic metal compounds (2)

Chronic aquatic hazards (based on chronic data)

- Classification depends on the chronic ERV (EC_{10} or NOEC) for the metal ions of concern and concentrations measured at different loading rates:
  - If chronic ERV **> 1 mg/L ➔ No classification**
  - If chronic ERV **≤ 1 mg/L ➔** then 28 days T/Dp testing should preferably be performed:

    - **No classification**, if the dissolved metal ion concentration at 1 mg/L loading < chronic ERV
    - **Chronic 1**, if the dissolved metal ion concentration at 0.1 mg/L loading ≥ chronic ERV; OR
    - **Chronic 2**, if the dissolved metal ion concentration at 1 mg/L loading ≥ chronic ERV

If there is evidence of rapid environmental transformation, lower loading rates define the hazard category.

In absence of 28 days T/Dp data the surrogate approach should be applied.

Environmental hazard classification for metals and inorganic metal compounds (3)

"Surrogate" chronic

- Used in absence of appropriate chronic toxicity reference data
  - If the acute ERV of the ion **> 100 mg/L ➔ No classification**
  - If the acute ERV of the ion **≤ 100 mg/L ➔** then 7 days T/Dp testing should preferably be performed:

- **Chronic 1**, if the dissolved metal ion concentration at 1 mg/L loading ≥ acute ERV; OR
- **Chronic 2**, if the dissolved metal ion concentration at 10 mg/L loading ≥ acute ERV; OR
- **Chronic 3**, if the dissolved metal ion concentration at 100 mg/L loading ≥ acute ERV
- **Chronic 4**, if the dissolved metal ion concentration at 100 mg/L loading < acute ERV

If there is evidence of rapid environmental transformation, do not classify for chronic hazards.
Apply safety net classification in absence of T/Dp test data.

Environmental transformation

Has an **impact on the chronic environmental classification category**:

- It defines the ERV cut-off and hence the potential classification outcome for chronic environmental hazards.

Classification category	No rapid environmental transformation	Rapid environmental transformation
Aquatic Chronic 1	≤ 0.1 mg/L	≤ 0.01 mg/L
Aquatic Chronic 2	≤ 1 mg/L	≤ 0.1 mg/L
Aquatic Chronic 3		≤ 1 mg/L

Rapid Removal – brief history from 2011 to date

2011

- CLP Guidance development launched to implement the **2nd ATP to CLP**

2012

- **Rapid Removal WS** on the applicability of the concept for environmental hazard classification

2013-2018

- Several **CLH proposals** for environmental classification raised the need for guidance
- Development of the **extended T/Dp**

2019

- Re-opening of the debate at EU-level triggered by **MISA**
  - Focus on **"Group 3 metals"**

2012 - Rapid Removal WS conclusions (1)

Workshop on the validity of the use of the concept of "rapid removal"

8 February 2012

ECHA Conference Centre
Annankatu 18, Helsinki, Finland

Final Agenda

- Distinction between **3 groups of metal(s) (compounds)** in respect of the assessment of the degradability principle, those that:

Group 1: Metals that methylate
- like Hg for example

Group 2: Metals that hydrolyse and form different species that precipitate in the water column.
- such as Fe, Sb, Mo, Al, Sn, Cr and others

Group 3: Metals for which the key question is "irreversibility" (i.e. binding to a non-bioavailable form under a range of environmental conditions), which needs to be demonstrated.
- such as Cu, Zn, Ni, Co, Pb and others.

2012 - Rapid Removal WS conclusions (2)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- No overall consensus on **whether and how the concept should be used** in the environmental hazard classification of metals and metal compounds
- Broad agreement is, however, evident on **certain ‚rapid removal' mechanisms** for **certain types** of metals
- An expert group should be established to further discuss the concepts and **relevant information requirements**
- If in future industry wishes to justify the application of the concept of Rapid Removal **for certain types of metals**, they should aim to provide further arguments supported by examples

2019 - CLP Guidance

IV.3 Assessment of environmental transformation

Environmental transformation of one species of a metal to another species of the same metal does not constitute 'degradation' as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. In addition naturally occurring geochemical processes can partition metal ions from the water column while also other processes may remove metal ions from the water column (e.g. by precipitation and speciation). Data on water column residence time, the processes involved at the water – sediment interface (i.e. deposition and re-mobilisation) are fairly extensive for some metals. Using the principles and assumptions discussed above in Section IV.1 of this document, it may therefore be possible to incorporate this approach into the classification.

Such assessments are difficult to give guidance for and will normally be addressed on a case-by-case approach. However, the following may be taken into account:

a. Changes in speciation if they are to non-available forms, however, the potential for the reverse change to occur must also be considered;

b. Changes to a metal compound which is considerably less soluble than that of the metal compound being considered.

Some caution is recommended; see Section IV.1 of this document, the 5th and 6th paragraph.

⚠ Comment by ECHA: Please note that in the light of a lack of scientific consensus and continuing discussions on the interpretation of rapid removal from the water column in the context of classification, it has been decided to remove certain parts from the Annex IV for the time being until agreement on the validity of use of the concept of rapid removal for classification purposes has been reached.

More information at

https://echa.europa.eu/-/echa-and-eurometaux-agree-on-framework-for-cooperation

https://www.reach-metals.eu/reach/metals-and-inorganics-sectoral-approach-misa

https://echa.europa.eu/-/workshop-on-the-validity-of-the-use-of-the-rapid-removal-concept

Thank you!

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