How to bring your registration dossier in compliance with REACH

Tips and Hints - Part 5

Biodegradation

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12 February 2014

Tips and Hints on Bio / degradation

Ready Biodegradability

Biodegradation I, Webinar Part 3, 14 May 2013

- Instruction for reporting the TG, results and their interpretation, QSARs, inoculum, adaptation

Biodegradation II, Webinar Part 4, 11 September 2013

- Applicability of the ready biodegradation Test Guidelines (substance properties, study design, validity criteria)

Biodegradation III

Webinar Part 5, 12 February 2014

- Higher tier simulation tests (surface water, sediment, soil)
  - Standard information requirements
  - How to define relevant environmental compartment?
  - Applicability of the Test Guidelines
  - Adaptation from the Standard information requirements

ECHA Guidance - Biodegradation

Endpoint specific guidance for environment (Chapter R7b, Degradation/biodegradation):

Degradation is an important endpoint to fulfil the following *regulatory* needs:

- Persistency assessment
  - To identify whether a chemical has PBT or vPvB properties
- Hazard assessment
  - To determine the potential to cause long-term adverse effects in environmental hazard classification
- Risk assessment
  - To determine the Predicted Environment Concentration (PEC) of a chemical in environmental exposure assessment for use in risk characterisation

REACH Standard Information Requirements

Degradation – simulation tests

Annex IX	COLUMN 1 STANDARD INFORMATION REQUIREMENT	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.2	Degradation	Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.
9.2.1.2	Simulation testing on ultimate degradation in surface water	The study need not be conducted if: — the substances is highly insoluble in water, or — the substance is readily biodegradable.
9.2.1.3	Soil simulation testing (for substances with a high potential for adsorption to soil)	The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of soil is unlikely.
9.2.1.4	Sediment simulation testing (for substances with a high potential for adsorption to sediment)	The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely.
9.2.3	Identification of degradation products	Unless the substance is readily biodegradable

A simulation test might not be required for all environmental compartments. The compartment of highest exposure and risk should be tested first if testing is required for refinement of risk assessment.

Justify the relevance of the studied environmental compartment(s)!

Choosing the appropriate test environment (1)

Intrinsic properties of the substance (e.g)

- **Water solubility** (Annex IX 9.2.1.2 Column 2)
  - Poorly water soluble substances (WS < 0.01 mg/L) → soil or sediment?
- **Adsorption**
  - Strong binding to soil/sediment (log Koc > 4 or log Kow > 5) → soil or sediment?
- **Volatility**
  - Vapour pressure
  - Henry's Law Constant

Choosing the appropriate test environment (2)

<u>Environmental exposure and distribution</u>

(Annex IX 9.2.1.3 and 9.2.1.4 Column 2)

- Partitioning behaviour
- Identifies uses
- Release and/or emission patterns and rates

ECHA Guidance R7.9.2.3

If there is no exposure of the soil/sediment, or the exposure is so low that no refinement of the $PEC_{regional}$ is required, then this test may not be necessary. If the substance is considered a PBT/vPvB candidate, then it may be necessary to consider this test if soil/sediment is environmental compartment of concern.

Test environment

- In simulation test the degradation is studied under environmentally relevant conditions in soil, sediment or surface water
  - Indigenous test environment
  - Typical temperature that represents the particular environment

Note! Test conducted in activated sludge as an inoculum or STP simulation test (e.g. OECD 303 or OECD 314) are not appropriate Test Guidelines to fulfil the Standard information requirement for Annex IX 9.2.12, 9.2.1.3, 9.2.1.4 or 9.2.3.

Appropriate test conditions - Temperature

Testing in relevant environmental conditions:

- "the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions" (REACH Regulation Annex XIII).
- Simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment" (ECHA Guidance R.7b, version 1.2, November 2012).
- **12 °C** (285K) is indicated as the average environmental temperature for the EU to be used in the chemical safety assessment (ECHA Guidance R.16 on Environmental Exposure Estimation., Table R.16-9, version 2.1 October 2012).
- **12 °C** (285K) is considered to be a relevant testing temperature for simulation testing.

Applicability domain of the OECD 307, 308 and 309

Test Guideline		Applicability of test
OECD 307	Aerobic and Anaerobic Transformation in Soil	Chemical substances (non-labelled or radiolabelled) for which an analytical method with sufficient accuracy and sensitivity is available. Slightly volatile, non-volatile, water-soluble or water-insoluble compounds. Not for chemicals which are highly volatile from soil.
OECD 308	Aerobic and Anaerobic Transformation in Aquatic sediment system	Chemical substances (unlabelled or labelled) for which an analytical method with sufficient accuracy and sensitivity is available. Slightly volatile, non-volatile, water-soluble or poorly water-soluble compounds. Not for chemicals which are highly volatile from water. Chemicals in fresh waters and sediments, but in principle can also estuarine/marine systems. Not for simulating conditions in flowing water (e.g. rivers) or the open sea.
OECD 309	Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test	Non-volatile or slightly volatile organic substances tested at low concentrations. Open flasks substances with Henry's Law Constant less than about 1 Pa . m^3/mol. Closed flasks with a head space with Henry's Law Constant < 100 Pa . m^3/mol or < 10^{-3} atm . m^3/mol.

- Report if and how volatility has been taken into account!
- Report modification in the test design e.g. due to the substance properties!

Identification of the degradation products

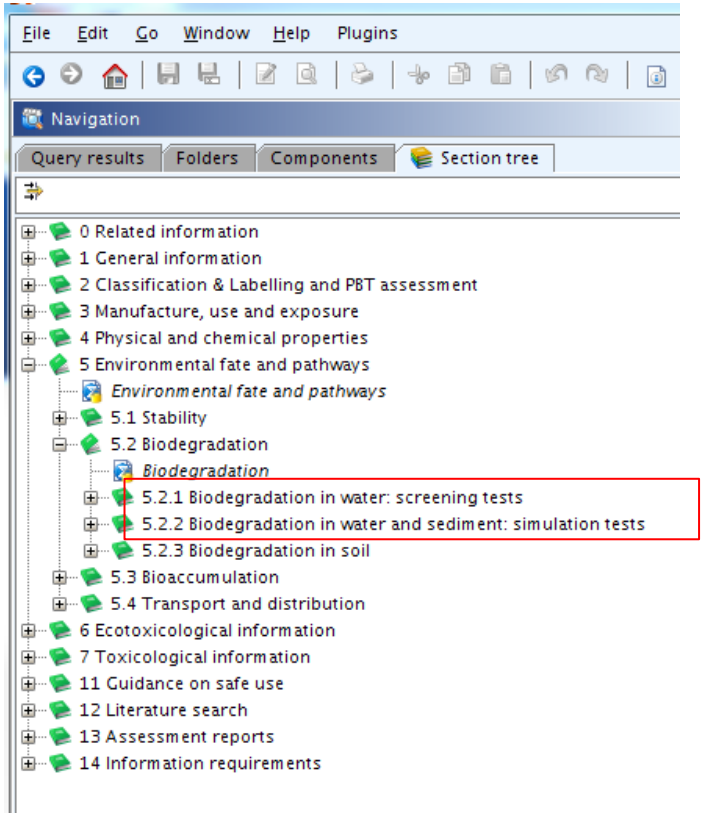
- Annex IX 9.2.3 standard information requirement when CSA triggers the need for further testing and substance is not readily biodegradable
- Identification of the major degradation/transformation products and proposed pathway of transformation
- Bound residues and incorporation into biomass to be recorded
- Substance specific methods
- Information for environmental assessment for classification, PBT/vPvB and potential exposure
- Assessment of potential persistent metabolites is needed when information on the degradation products following primary degradation is required to complete the CSA

Additional tips and hints on Column 2 adaptation from information requirements (1)

- Column 2 Adaptation criteria for surface water simulation ≠ sediment

  → Single adaptation argument may not cover both water and sediment compartments

  - Rapid degradation in one of the ENV compartments may not be valid adaptation argument for other EVN compartment
  - Degradation in Sewage Treatment Plant environment ≠ Degradation in the environment



Additional tips and hints on Column 2 adaptation from information requirements (2)

Column 2 adaptation may be possible when direct and indirect exposure of the ENV compartment is unlikely. And the criteria of Annex XI section 3 are fulfilled i.e.;

- Adequate justification and documentation is provided
- The justification is based on a thorough and rigorous exposure assessment

Annex XI

GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES VII TO X

1. Testing does not appear scientifically necessary
   - 1.1 Use of existing data
   - 1.2 Weight of evidence
   - 1.3 Qualitative or Quantitative structure-activity relationship (Q(SAR))
   - 1.5 Grouping of substances and read-across approach
2. Testing is technically not possible
3. Substance-tailored exposure-driven testing

Please find more on general rules for adaptations from e.g.
How to bring your registration dossier in compliance with REACH – Tips and Hints Part 5
“Dissociation constant” and “Adsorption/desorption”

Tips and hints for reporting the results and test setup

- Consider applicability of the Test Guideline regarding the test substance e.g. how volatility has been taken into account.
- Report results in detail (e.g. degradation rate, half-life, degradation%, mineralisation%, mass balance, identification of the degradation products/metabolites).
- Consider potential role of abiotic degradation.
- Include information on validity of test (if validity criteria are met, provide details, info on reference materials etc.).
- Conclude clearly your findings on degradation.

Links to relevant Guidance documents

- Guidance on information requirements and chemical safety assessment
  - Chapter R.7b: Endpoint specific guidance / R.7.9 Degradation/biodegradation
    http://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf
  - Chapter R.11: PBT and vPvB Assessment - draft
    http://echa.europa.eu/documents/10162/13643/inforeq_csa_r11_draft_for_peg_201305_en.pdf

- Practical Guides
  - How to report weight of evidence, data waiving, (Q)SARs…
    http://echa.europa.eu/practical-guides

Questions?

To the Q&A panel (between 11:00 and 13:30, Helsinki time), or

To the ECHA helpdesk (any time): http://echa.europa.eu/contact/helpdesk-contact-form