Soil risk assessment in the regulatory context - *REACH perspective*

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- → Biocides Regulatory Framework
- → REACH standard information requirements for terrestrial toxicity
- → Integrating Testing Strategy (ITS) for effects on terrestrial organisms

ECHA and REACH in a nutshell

ECHA key facts

- Started on 1 June 2007
- Over 570 staff from 25 countries

- **REACH**
  → *entry into force: June 2008*
- **CLP**
  → *entry into force: January 2009*
- **Biocides**
  → *entry into operation: September 2013*
- **PIC** (Prior Informed Consent)
  → *entry into force: August 2012*
  → *entry into operation: March 2014*

REACH and CLP - key players and operations

- Pre-registration
- Data sharing
- **R**egistration
- Self classification

Facilitated by ECHA, industry gathers information and ensures management of risks

ECHA
EUROPEAN CHEMICALS AGENCY

MSs

- **E**valuation
  - Dossier evaluation
  - Substance evaluation

ECHA and MSCAs control and request for further info

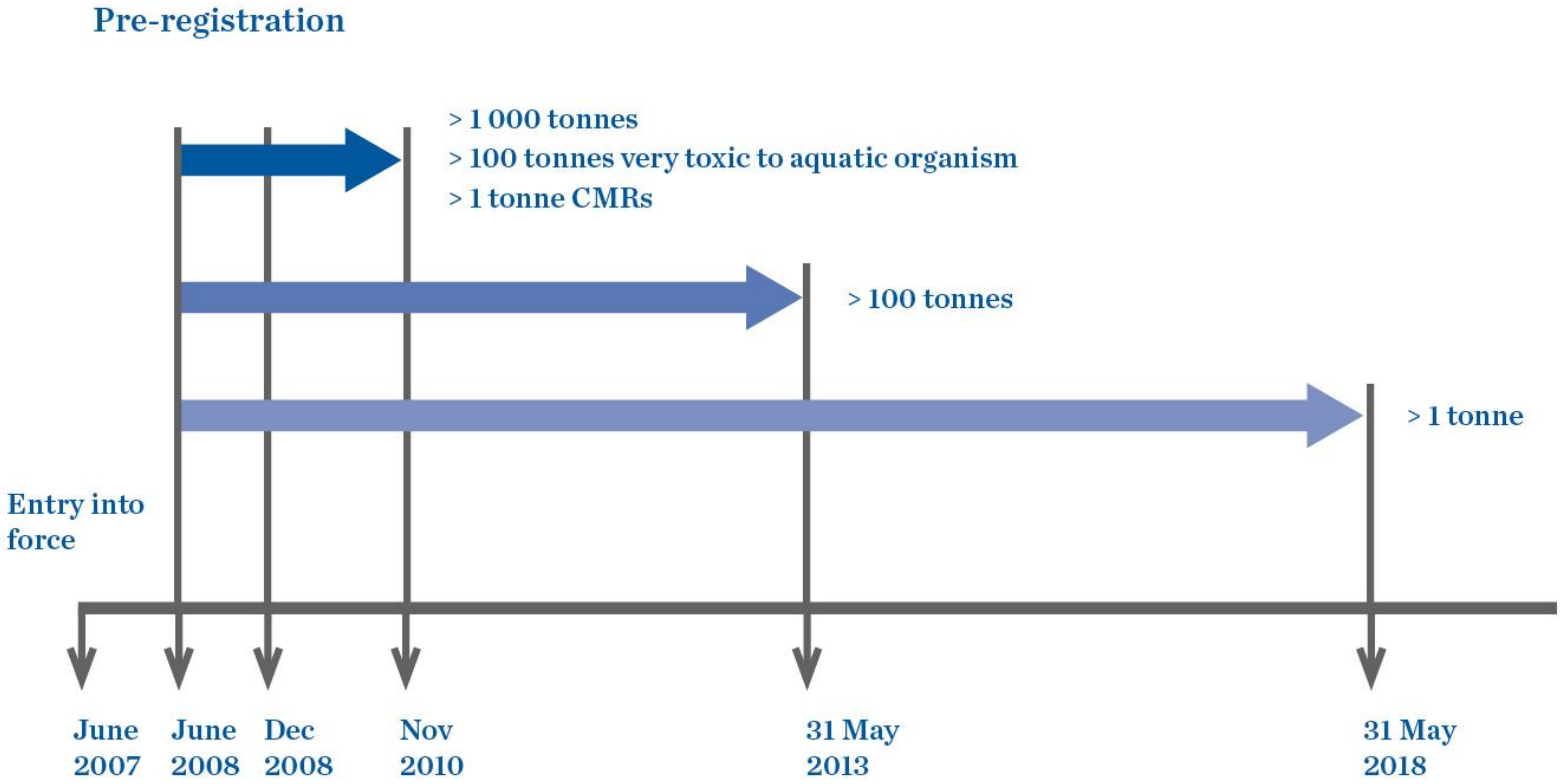
- **A**uthorisation
- Restriction of **Ch**emicals
- Harmonised C&L

Commission, with the support of ECHA and MSCAs, applies Community-wide risk management measures

Principles of REACH

- **High level of protection** of human health and the environment
- Enhance **competitiveness and innovation**
- **Industry responsible** for safe manufacture and use
- Get adequate information on hazards while **minimising animal testing**
- Enforcement at national level

Registration deadlines



BPR: main objectives

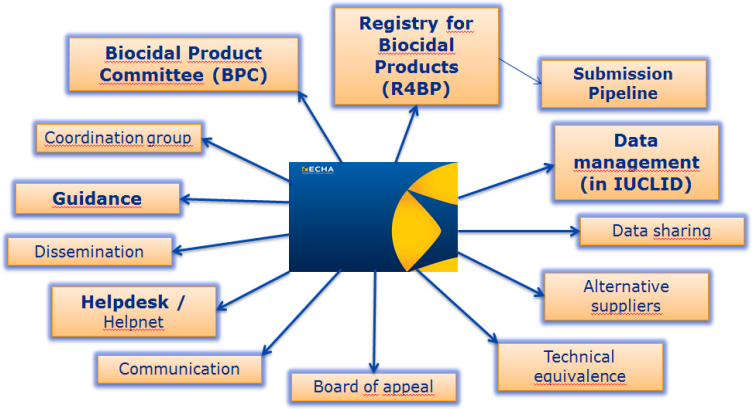
- Improve the functioning of the internal market
- Ensure a high level of safety for health and environment
- Encourage innovation of products with a better profile
- Ensure safety of articles treated with biocides
- Ensure effective and harmonised implementation and enforcement

Key elements of the biocides regulatory framework

- Biocidal products can only be placed on the market and used if they have an authorisation, given only if their use does not present unacceptable risks and they are efficient.

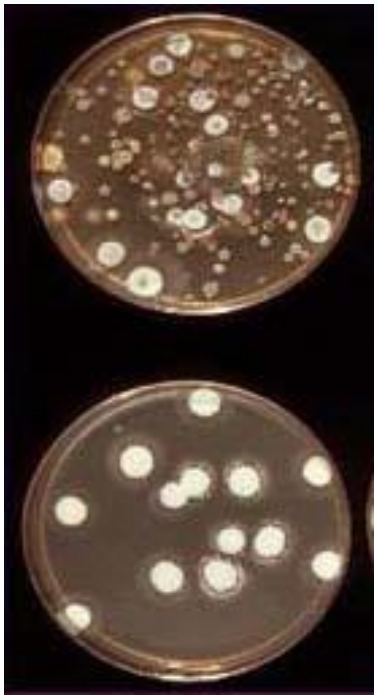
- Two-step system:
  - First: establishment of a *list of active substances approved at EU level*, that can be used in biocidal products
  - Secondly: *authorisation of biocidal products* containing these actives substances
  - Authorisations can be given either at national level by Member States (in a mutual recognition process, where requested by the applicant) or at the Union level by the EU Commission

ECHA's role in biocides



- Centralised IT system
  - Register for Biocidal Products - R4BP 3
  - IUCLID 5.5 including biocides functionalities
- Biocidal Products Committee, working groups, coordination group
  - Central bodies for an EU-wide approach
  - Scientific and administrative support to members
  - Assure quality, consistency and transparency
- Support to applicants and Member States
  - Provide guidance and an ECHA Helpdesk/Helpnet
  - Promote a consistent approach between Member States
- Data sharing, dissemination, technical equivalence and chemical similarity
  - Benefit from REACH experience
- Communication
  - Awareness raising with key actors and stakeholders

REACH standard information requirements for terrestrial toxicity



REACH Annex IX (>100 tpa)

9.4 Effects on terrestrial organisms

Short-term studies on **three** trophic levels:

- ***Invertebrates***
- ***Microorganisms***
- ***Plants***

- The choice of the appropriate tests depends on the outcome of the chemical safety assessment
- Long-term studies should be preferred to short-term tests for substances that are persistent or that display a high affinity to organic matter
- Rules for adaptation of this information requirement are provided:
  - ✓ *Column 2 and Annex XI*
  - ✓ *e.g. no (in)direct exposure to soil*

REACH Annex X (>1000 tpa)

9.4 Effects on terrestrial organisms

Long-term terrestrial toxicity testing for **plants** and **invertebrates**.

- Rules for adapting this information requirement are provided e.g.:
  - ✓ no (in)direct exposure to soil
  - ✓ weight of evidence
  - ✓ QSAR
  - ✓ technically not feasible
  - ✓ (Column 2 and Annex XI)

What is the goal?

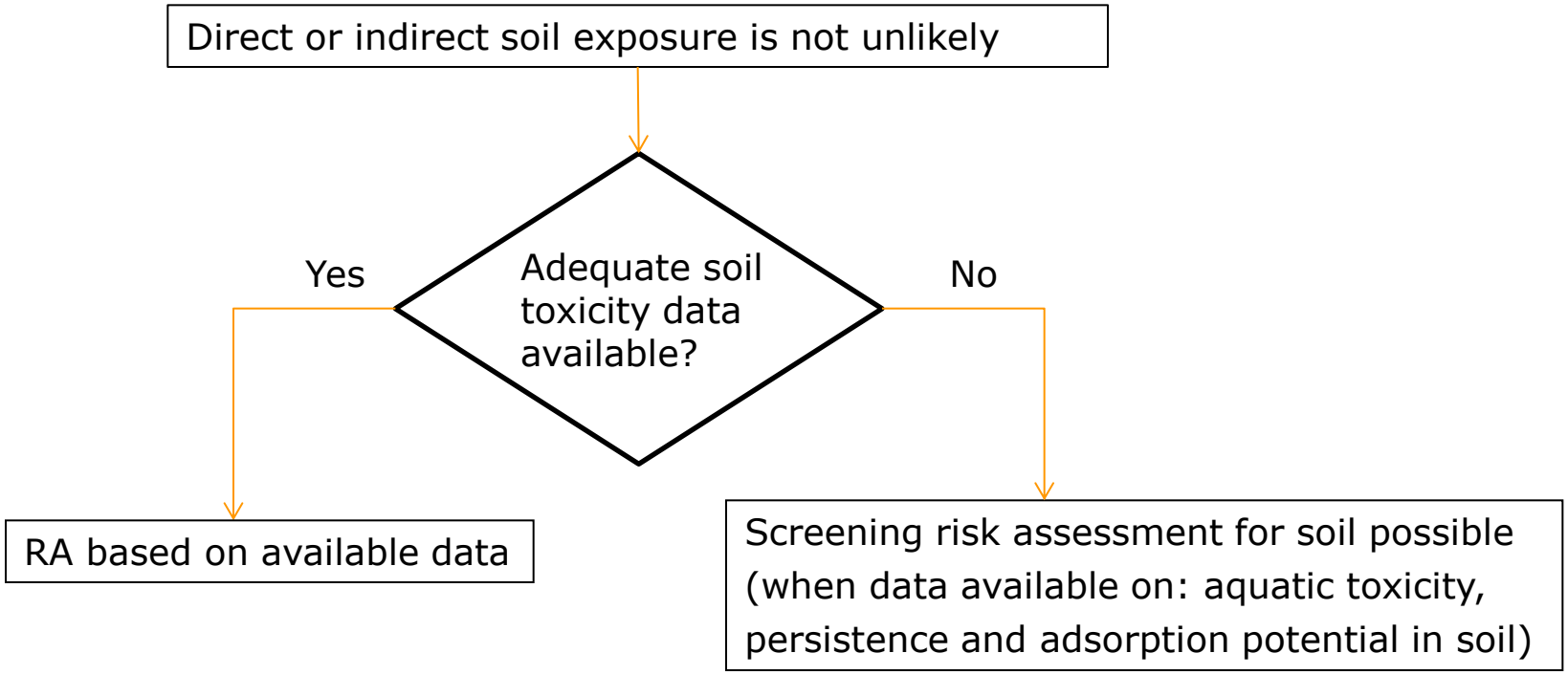
ECHA Guidance (R7c) http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf

Organism group	Ecological process
Terrestrial plants	✓ Primary production
Soil dwelling invertebrates	✓ Breakdown of organic matter ✓ Formation of soil structure
Soil microorganisms	✓ Transformation and breakdown of organic matter ✓ Recycling of nutrients

PNECsoil → Used for risk assessment

Protection of soil organisms to maintain soil functions

Soil risk assessment



Screening RA for soil: Integrating Testing Strategy (ITS) for effects on terrestrial organisms

Integrating Testing Strategy (ITS) for effects on soil organisms

- Application of ITS for terrestrial toxicity:
  - ✓ When indication of high adsorption (log Kow >5 or an ionisable substance)

    OR
  - ✓ high persistence (18 DT50 > 180 days (default setting, unless classified as readily biodegradable))

    AND/OR
  - ✓ Substance very toxic to aquatic organisms

	Hazard Cat. 1	Hazard Cat. 2	Hazard Cat. 3	Hazard Cat. 4
Is there an indication for high adsorption or high persistence of the subst. in soil?	NO	NO	YES	YES
Is there an indication that the substance is very toxic to aquatic organisms?	NO	YES	NO	YES

ITS for effects on soil org.

	Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4
Approach for screening assessment	PEC/ $PNEC_{screen}$ (based on EPM)	PEC/ $PNEC_{screen}$ (based on EPM) AND conduct a confirmatory **short-term** soil toxicity testing (e.g. one limit test with the most sensitive organism group as indicated from aquatic toxicity data) + tox to microorg. test	PEC × 10/$PNEC_{screen}$ (based on EPM) AND conduct a confirmatory **long-term** soil toxicity testing (e.g. one limit test with the most sensitive organism group as indicated from aquatic toxicity data) + tox to microorg. test	Screening assessment based on EPM not recommended, intrinsic properties indicate a high hazard potential to soil organisms
Consequences from screening assessment Toxicity testing with soil organisms and derivation $PNEC_{soil}$ Choose lowest value for derivation $PNEC_{soil}$	If PEC /$PNEC_{screen}$>1 *Conduct short-term toxicity tests according to Annex IX (invertebrates, microorg. and plants)*	If PEC /$PNEC_{screen}$>1 or indication of risk from confirmatory short-term soil tox. test: *Conduct short-term toxicity tests according to Annex IX (invertebrates, micro-organisms and plants)*	If PEC /$PNEC_{screen}$>1 or indication of risk from confirmatory long-term soil tox. test: *Conduct long-term toxicity tests according to Annex X (invertebrates and plants) AND conduct tox to microorg. Test according to Annex IX*	*Conduct long-term toxicity tests according to Annex X (invertebrates and plants) AND conduct tox to microorg. Test according to Annex IX*
	If PEC_{soil} /$PNEC_{soil}$>1 Conduct additional long-term or higher tier test on soil organisms and/or consider refinement of PEC_{soil}	If PEC_{soil} /$PNEC_{soil}$>1 Conduct additional long-term or higher tier test on soil organisms and/or consider refinement of PEC_{soil}	If PEC_{soil} /$PNEC_{soil}$>1 Conduct additional long-term or higher tier test on soil organisms and/or consider refinement of PEC_{soil}	If PEC_{soil} /$PNEC_{soil}$>1 Conduct additional long-term or higher tier test on soil organisms and/or consider refinement of PEC_{soil}

in the case of risk...

Authorisation and restrictions of REACH

- The aim of authorisation (Title VII of REACH) is to ensure that risks of substances of very high concern (SVHCs) are properly controlled and that these substances are progressively substituted, where this is technically and economically viable.
- Restriction (Title VIII of REACH) is a safety net to address unacceptable risks to human health or to the environment arising from the manufacture, use or placing on the market of substances which need to be addressed on a Community-wide basis.

Relevant presentations and posters:

Presentation *by Romanas Cesnaitis*:

- Compilation of (REACH) case studies with challenges in regulatory soil risk assessment

ECHA posters:

- Integrated testing strategy for effects on terrestrial organisms under REACH
- Analysis of experimental terrestrial toxicity studies submitted in the framework of the REACH Regulation
- Making use of publicly available studies within the REACH Regulation: An overview of submitted terrestrial toxicity data

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