Information requirements for co-formulants under REACH

Technical workshop on assessment of plant protection products

21 June 2023

Sampo Karkola
Head of unit – Hazard assessment
European Chemicals Agency

Outline

- → Principles of REACH information requirements
- → Compliance check
- → Testing proposals and substance evaluation
- → Data requests and level of compliance
- → Further information

Principles of REACH information requirements

- → Accumulative depending on the tonnage band (see last slides)
- → Annexes VI-X list the *minimum* information requirements
  - Obligation to provide *other available and relevant* information (Annex VII-X preamble)
  - Vertebrate animal testing as the last resort (Art 25(1) of REACH)
- → Column 1 of each Annex describes the standard information requirements
  - Test Method Regulation (Art 13(3) of REACH), ECHA Guidance
  - Good laboratory practice (GLP) for toxicological and ecotoxicological endpoints (Art 13(4) of REACH)
- → Column 2 of each Annex describes endpoint-specific adaptation possibilities and/or triggers for further studies
- → Annex XI describes requirements for general adaptation possibilities

Compliance check (Art 41 of REACH) (1)

→ Substance identity check prior to compliance check

→ Evaluation focuses on key endpoints
- Genotoxicity
- Repeated-dose toxicity
- Reproductive and Pre-natal developmental toxicity
- Carcinogenicity
- PBT properties: Degradation, Bioaccumulation, Long-term (aquatic) toxicity
- Endocrine disruptors (human health and environment)
- (Related endpoints in Annexes VII-VIII)

→ What is checked in a compliance check?
- Compliance with test guidelines and GLP, adaptation requirements, and possible triggers for further studies

Compliance check (Art 41 of REACH) (2)

- → Either full or targeted compliance check (lead registrant dossier and opt-outs)
- → If information is not compliant, ECHA may request an experimental study with the registered substance according to REACH Annexes VII-X and ECHA Guidance
  - ECHA cannot develop adaptations (e.g. read-across) for the registrants
  - In case data is requested, ECHA must request a study according to column 1
- → The purpose is to achieve compliance with REACH and ensure sufficient hazard information for possible further regulatory processes, e.g.
  - Harmonised classification and labelling
  - Substance of very high concern (SVHC) identification
  - Restriction
  - Authorisation
- → Focus in 2023 is on substances registered above 100 tonnes per year

Testing proposals and substance evaluation as data generation mechanisms

→ Testing proposal (Art 40 of REACH) is registrant-initiated data generation
- Applicable to Annex IX and X endpoints
- If a data gap is identified by registrants and no alternatives are available, a testing proposal must be submitted to ECHA in the IUCLID dossier
- Third party consultation for proposed vertebrate studies
- To ensure that data generation meets real information needs
- To avoid unnecessary animal testing (alternative considerations)

→ Substance evaluation (Art 44 of REACH) is concern-based evaluation by Member States competent authorities
- Concern=risk, i.e. (potential) hazard and exposure must be demonstrated
- Data generation must have a high chance to lead to improved risk management measures
- Information outside Annexes VI-X can be requested if it can be justified

Data requests and level of compliance in DEV

→ Adaptations for higher tier endpoints are widely used (read-across and categories, weight-of-evidence)
- Often not compliant (scientifically not robust or missing required elements)

→ Top 5 endpoints requested in 2022 compliance checks
- Long-term aquatic toxicity
- Genotoxicity
- Biodegradation
- Pre-natal developmental toxicity
- Reproductive toxicity

→ In 2022, 421 decisions (CCH and TPE) were adopted with almost 2000 study requests

Links to further information

- → ECHA grouping and screening of substances: https://echa.europa.eu/working-with-groups
- → Public activities coordination tool (PACT): https://echa.europa.eu/pact
  - ARN reports
  - Evaluation status (dossier and substance evaluation)
  - Regulatory risk management processes
- → ECHA dissemination website (frozen until Dec 2023): https://echa.europa.eu/information-on-chemicals/registered-substances
  - Information on co-formulants
- → Progress in evaluation: https://echa.europa.eu/overall-progress-in-evaluation
- → Alternatives to animal testing (2020): https://echa.europa.eu/documents/10162/0/alternatives_test_animals_2020_en.pdf/

Thank you

name.surname@echa.europa.eu

echa.europa.eu/subscribe

Connect with us

echa.europa.eu/podcasts

European Chemicals Agency

@one_healthenv_eu

@EU_ECHA

@EUECHA

EUchemicals

Annex VI and Annex VII information requirements – high level, non-exhaustive

→ Annex VI; all registrations: Registrant info, substance identification, manufacture and use, classification and labelling, guidance on safe use

→ Annex VII; 1-10 tonnes per year:

- Physchem information
- Screening for mutagenicity (*in vitro*)
- Skin/eye corrosion/irritation
- Skin sensitisation
- Acute toxicity (oral)
- Short-term for aquatic toxicity (algae and invertebrates)
- Screening for degradation

Annex VIII information requirements – high level, non-exhaustive; 10-100 tonnes per year

- → Skin/eye corrosion/irritation *in vivo* (if triggered)
- → Further screening for genotoxicity (*in vitro*)
- → Acute toxicity (dermal and inhalation if appropriate)
- → Short-term repeated dose toxicity (28-day)
- → Screening for reproductive/developmental toxicity
- → Toxicokinetics (no test; available information)
- → Short-term toxicity to fish
- → Activated sludge respiration inhibition
- → Abiotic degradation (hydrolysis)
- → Adsorption/desorption

Annex IX information requirements – high level, non-exhaustive; 100-1000 tonnes per year

- → Genotoxicity *in vivo*
- → Sub-chronic toxicity (90-day)
- → Pre-natal developmental toxicity 1st species
- → Extended one-generation reproductive toxicity (if triggered)
- → Long-term toxicity to invertebrates
- → Long-term toxicity to fish
- → Biotic degradation; simulation studies
- → Identification of degradation products
- → Bioaccumulation in aquatic species (fish)
- → Toxicity to terrestrial organisms (invertebrates, soil microorganisms, plants)

Annex X information requirements – high level, non-exhaustive; more than 1000 tonnes per year

- → 2nd genotoxicity *in vivo*
- → Pre-natal developmental toxicity 2nd species
- → Extended one-generation reproductive toxicity
- → Carcinogenicity
- → Further degradation studies
- → Further information on environmental fate
- → Terrestrial toxicity (long-term invertebrates, plants, sediment organisms, birds)

Annex XI general adaptation possibilities – high level, non-exhaustive

→ Testing not scientifically necessary
- Use of existing data (i.e. data generated before 1 June 2008)
- Weight of evidence
- Qualitative or quantitative structure-activity relationship (QSAR)
- *In vitro* methods
- Grouping of substances and read-across

→ Testing is technically not possible

→ Substance-tailored exposure-driven testing