REACH: update on Compliance Checks

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Aktualisierung und Fehlerminimierung in Registrierungsdossiers

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Objective of the presentation

- Compliance check (CCH)
  - Previous and new CCH strategies
  - New CCH decisions addressing all concerned members
  - Other changes
- Important failures observed in CCH
  - Quality of data, documentation, justifications
  - Substance identity
  - Read-across adaptation

Compliance Checks (CCH)

Compliance Check until 2018

- ECHA Compliance Checks (2009 – 2018)[1)]
  - CCH on 2140/66728 dossiers; 1118/16866 substances
  - ≥1000 tpa 6.8% dossiers; 24% substances
  - 100 – 1000 tpa 4.1% dossiers; 12% substances
- BfR "REACH Compliance Project" (2014-2018)[2)]
  - ≥1000 tpa 12-61% of the examined endpoints "*non-compliant* "
  - 1000-1000 tpa 2-44% of the examined endpoints "*non-compliant* "
- REACH review by Commission (2017)[3)]
  - "*REACH is effective but not efficient*"
  - "*Significantly improve evaluation procedures*"
- Media and stakeholder attention

[1)] *Source:* https://echa.europa.eu/progress-in-dossier-evaluation
[2)] *Source:* https://www.bfr.bund.de/cm/349/data-quality-of-environmental-endpoints-in-registrations.pdf
[3)] *Source:* http://ec.europa.eu/growth/sectors/chemicals/reach/

Joint action plan from ECHA and the European Commission[1)]

1 (7)

ECHA EUROPEAN CHEMICALS AGENCY

European Commission

REACH Evaluation Joint Action Plan

Ensuring compliance of REACH registrations

1. Why This Action Plan?

The 'R' in REACH[1] ('Registration') sets out legal obligations on industry to demonstrate that the substances they manufacture or import are used safely. Industry thereby must meet tonnage dependent minimum information requirements on the hazards of their substances, and also inform on their volumes, uses and exposure.

The 'E' in REACH ('Evaluation') provides that ECHA and the Member States can evaluate the information submitted by companies. Under dossier evaluation, ECHA, in cooperation with the Member States, checks if industry meets their registration obligations. If the information submitted is insufficient, industry is required to fill the gap. Under substance evaluation, Member States evaluate substances to clarify a potential concern. Industry may be required to submit further information or perform a test if additional information is needed going beyond the standard information requirements. Therefore, both dossier and substance evaluation contribute to the generation of relevant data which can then be used to identify if risk management measures by industry or at EU level are necessary.

[1)]Source: https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17

Joint Action Plan: Areas

Area	Actors
1. Address all substances	Commission, ECHA
2. Improve clarity of certain legal provisions	Commission, ECHA, Member States
3. Accelerate the compliance check decision making	ECHA, Member States
4. Keeping dossiers compliant, improving follow-up and enforcement of ECHA evaluation decisions	ECHA, ECHA Forum and National Enforcement Authorities, Commission
5. Industry takes on the compliance challenge	ECHA, Industry associations

[1)]Source: https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17

Joint Action Plan: actions related to compliance checks

❑ Proposed amendment of REACH (Area 2)

- Commission proposes to amend REACH CCH target from 5% to 20% of dossiers in each tonnage band; on 19.09.2019 Member States agreed to this proposal[1)]

❑ ECHA‘s committment (Areas 1 & 3)

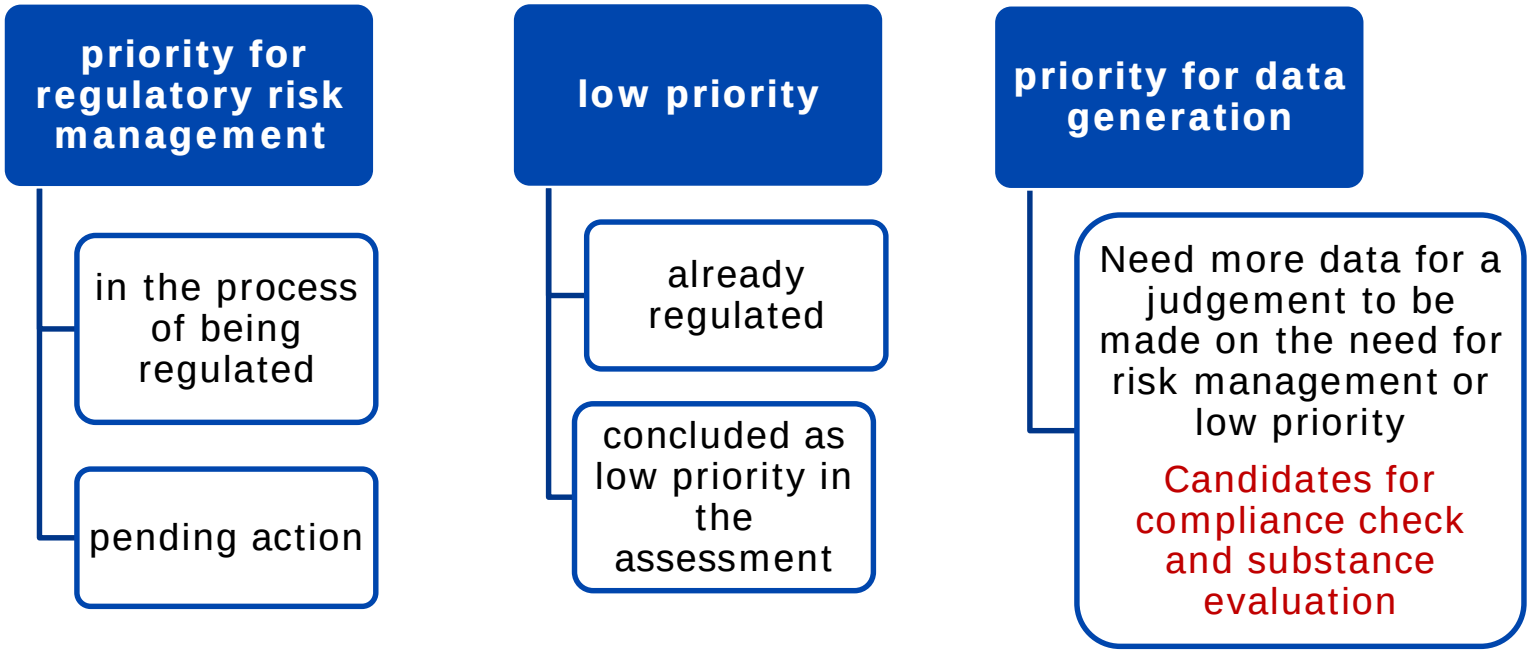
- By 2023 to screen all dossiers >100 tpa
- By 2027 to screen all dossiers 1-100 tpa
- CCH ~30% of substances where more information is needed
- Simplification of CCH decisions

1) *https://ec.europa.eu/growth/content/commission-proposes-improve-compliance-chemical-registration-dossiers-eu-law_en*

Strategy to address all substances

IT screening → Grouping → Regulatory pools

- Put all substances above 100 tonnes in regulatory pools by end of 2020
- Develop a plan to enable similar conclusions for lower tonnage bands



Decisions to all non-compliant members

- Since January 2019, all members of a joint registration started to receive dossier evaluation decisions[1)]
  - check of compliance of all relevant dossiers for a given substance
    - focus still on the 8 “super-endpoints”
    - ensure that lower tonnages are compliant
  - decisions sent to all non-compliant registrants, and having obligations to comply with respective testing or required information
    - Not necessarily only the lead
    - Not necessarily all registrants of a joint submission
    - Can be a registrant with opt-out, for one or more endpoints
    - Can be a registrant at any tonnage

[1)] Source: https://echa.europa.eu/-/member-registrants-will-start-receiving-dossier-evaluation-decisions-in-2019

New structure of decisions

- Requests listed by increasing Annexes (VII to X)
- Appendix on general considerations that are common to several requests
  - eg. read-across
- Appendices with reasoning for the requests (separate Appendix for each Annex with requests)
  - More standardised text
  - Justifications for a request shorter and focussed on the main information that is not compliant
- Example (fictive!) next slide

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***exact date*** –24 ***months*** *from the date of the decision*.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD series on Testing and Assessment Number 29 - Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media) with the Substance;

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203) with the Substance;

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

D. Requirements applicable to all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rat), oral route with the Substance.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, with the Substance, specified as follows:

   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation and
   - Cohorts 2A and 2B (Developmental neurotoxicity).

Other important changes

- ECHA has the expectation that a dossier is up-to-date, when starting a compliance check
- No change of tonnage band or status taken into account after draft decision sent to registrants!
- Cease of manufacturing (no longer registered)
  - Before final decision is taken: no more request
  - After finals decision is taken: need to comply with the request(s)
- Help to Registrants to increase transparency
  - ECHA publishes all CCH and TPE opened
  - How to find the status of your substance:
    - go to ECHA homepage
    - search your substance
    - ECHA Regulations / REACH / Dossier evaluation status

Frequent shortcomings observed in compliance checks

Quality of data: HH and ENV

❑ Old data (i.e. data available before REACH)

- Registrant to provide detailed evaluation and justification as to why an old study can or can not be used (itself or within weight of evidence) to address an information requirement:
  - adequate for classification and labelling
  - adequate and reliable coverage of key parameters of the study that is required to fulfill the information requirement
  - exposure duration is appropriate
- ECHA evaluates the provided information and justifications
- ECHA may request new testing if needed

Documentation / Justification

❑ Not a robust study summary

- Sufficient level of detail in robust study summaries required to allow for an independent assessment

❑ Insufficient justification of an adaptation

- Use correct legal adaptation (relevant for the Annex)
- The justification must addressed the wording of the legal text
- Sufficient justification of the adaptation

Substance identity (SID)

- Clarification SID of the registered substance
  - ECHA SID team clarifies the identity of the registered substance before further evaluation continues
- SID of UVCB and multiconstituent substances
  - More detailed information is needed on substance identity and composition of the registered substance and - in case of read-across – also the source substance(s)
  - More detailed information is needed on identity and composition of the substances actually tested in the provided and requested studies
  - Information needs to be appropriate to assess the properties of the substance registered within the joint submission (i.e. boundary composition)

Read-Across – REACH Legislation

REACH Annex XI 1.5 covers aspects such as:

- Grouping and read-across used to predict properties
  - From source (analogue) substance(s) whose physiochemical, toxicological and ecotoxicological properties are likely to be similar to the target (registered) substance
- Structural similarity is a prerequisite
- Scientific justification and supporting evidence required
- Read-across may be based on, e.g.,
  - common functional group
  - common precursors and/or the likelihood of common break-down products
  - A constant pattern in the changing of the potency of the properties across the category
- Adequate for risk assessment and classification

Read-across – Guidance[1)]

- General guidance for developing and reporting adaptations:
  - ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.6 QSAR and grouping of chemicals
  - ECHA Practical Guide on "*How to use alternatives to animal testing to fulfil your information requirements for REACH Registration*", Chapter 4.4
  - Illustrative example on grouping of substances
- Read-Across Assessment Framework (RAAF)
  - Tool developed by ECHA which structures and codifies regulatory assessments of read-across
  - Registrants can use of the RAAF to check the robustness of the read-across adaptation and use it to improve the read-across adaptations

1) https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Read-across – Principles (1)

- Read-across must be based on structural similarity
- Read-across hypothesis must explain why properties of structurally similar substances can be predicted despite their structural differences
- Target and source substance(s) must be sufficiently characterised
  - For MCS and UVCBs: Characterisation of source and target substances: must allow to verify the extent of the structural similarities and differences
- Sufficient supporting evidence required
  - Adequate and reliable data of sufficient quality required for target substance and source substance(s)

Read-across – Principles (2)

- All the results of a study are read across to the target substance
- Type and amount of information needed depends on the read-across hypothesis and the information requirement to be read across.
- The RAAF defines two general read-across hypothesis:
  1. (Bio)transformation into a common compound
     - Toxicokinetic information may support the approach
  2. Different compounds have the same type of effects
     - Toxicodynamic information may support the approach

  Supporting information important

Read-across – Shortcomings (1)

- ❑ Missing/incomplete read-across hypothesis
- ❑ Insufficient characterization of the source substance

For MCS and UVCBs:

- Structural similarity of the multiple constituents of the source and target substances to be considered
- Detailed compositional information required to understand the structural similarity and extent of the differences
- More detailed information needed for read-across approaches than required for registration purposes

Read-across – Shortcomings (2)

❑ Insufficient justification

- No explanation provided as to why it is possible to read across from substance X to substance Y
- No considerations on the impact of structural differences

❑ Data quality issues

- Insufficient data quality (e.g. test guideline only partially followed)
- Source study not relevant for the information requirement (e.g. Daphnia study provided fish study required)
- Source study duration not adequate (90-day study required 28-day study provided)
- Source substance is classified then classification must be read across as well

Read-across – Shortcomings (3)

❑ Differences in toxicity

- Available information show differences in toxicity between source and target substances which contradict the hypothesis

❑ Missing supporting information: e.g. hydrolysis

- Missing substance specific data on rate and extent of (e.g., enzymatic) hydrolysis where the prediction relies on the claim of rapid hydrolysis

Read-across – Shortcomings (4)

❑ Missing supporting information for HH endpoints

- No information available that allows for a side-by-side comparison of the toxicity profiles of the source and target substances
- Bridging studies can sometimes be used to overcome the shortcomings provided that the results are consistent with the read-across hypothesis AND that the study provides information relevant for the information requirement

  Example for read-across between structurally different substances: Findings from 28 day study/studies, used to bridge between 90-day studies, may show whether the read across hypothesis is supported or not (need to take into account qualitative and quantitative nature of the results, e.g. similarity and differences in observed toxicities and potencies)

Read-across – Shortcomings (5)

- Missing supporting information for ENV fate and ecotoxicity (1)

- Hypothesis not adequately justified and supported
  - Environmental compartment specific aspects not considered (aquatic, soil, sediment)
  - Species specific aspects not considered (e.g. biotransformation, uptake mechanisms)
  - Substance specific aspects not considered; e.g.
    - for surfactants uptake/bioaccumulation not necessarily dependent on logKow
    - for substances that are „difficult to test“ for environmental properties (e.g. poorly soluble) analytical monitoring should be performed to establish the composition in the test solution

Read-across – Shortcomings (6)

- Missing supporting information for ENV fate and ecotoxicity (2)

- Missing/unreliable supporting information:
  - Supporting information on physicochemical and fate properties to support similar behavior of the substances in the compartment in question missing
  - *Relevant* supporting information to compare the predicted property of the substance missing (relevant = considers the endpoint, species and compartment)

Read-across – Shortcomings (7)

- Further shortcomings observed for Categories
  - Applicability domain of a category
    - Absence of clear inclusion and exclusion criteria to define the category
  - Category members
    - Failure to address all substances with available data meeting the applicability domain (no substance selection bias!)
  - Substance composition
    - Failure to consider boundary composition of category members *especially* important in case of UVCB and multi-constituent substances

Conclusion:

Registrants should be proactive

- Increasing number of CCH = increased chance to receive a CCH decision
  - As all substances will be addressed
- Consider regular updates
  - Update is a legal obligation but also the proof for safe use of chemicals
  - The Commission is preparing an implementing regulation to further specify by which timelines the updates should be made[1)]
- Consider submitting testing proposals
  - Testing strategy can only be based on relevant data on your substance, not merely hypothetical considerations
- Get organised if you need to generate further studies/data

1) *https://ec.europa.eu/growth/content/commission-proposes-improve-compliance-chemical-registration-dossiers-eu-law_en*

Useful Links

- REACH registration statistics: https://echa.europa.eu/registration-statistics
- Recommendations to registrants: https://echa.europa.eu/recommendations-to-registrants
- Documents on grouping of substances and read-across: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

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