Quality of dossiers

Feedback from ECHA including read-across, substance evaluation and nanomaterials

07/12/12/Ofelia Bercaru

REACH Implementation Workshop XII, Brussels

Outline

- Findings from Dossier Evaluation (TPE, CCH)
- Recommendations
- Substance evaluation
- Nanomaterials

Evaluation under REACH

ECHA
EUROPEAN CHEMICALS AGENCY

MSCAs
Member State Competent Authority

Dossier evaluation

Substance evaluation

Examination of Testing Proposals

Compliance Check

Examine any information on a substance

ECHA Decision requesting information

Dossier evaluation

- Good quality dossiers are needed to ensure the safe use of chemicals
- Evaluation supports registrants to provide adequate information on registered substances
- The main findings of the evaluation processes are reported annually in ECHA's Evaluation Progress Reports

Evaluation of testing proposals

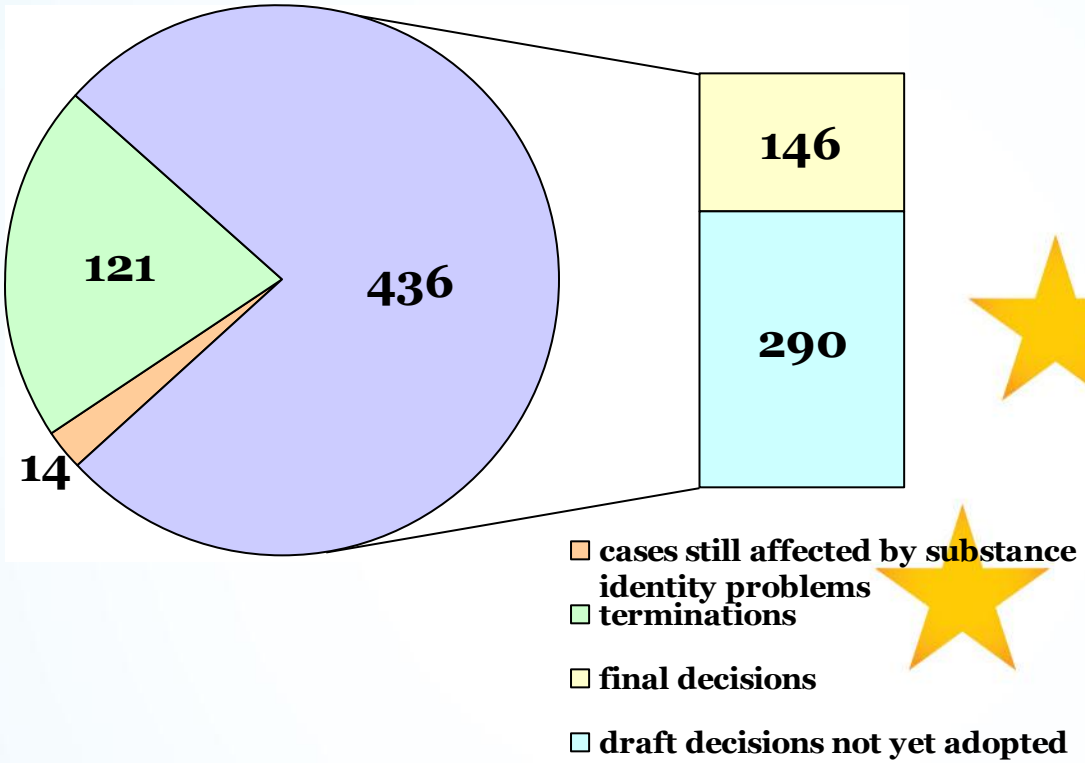
Phase-in testing proposals

- ECHA had to evaluate all dossiers containing testing proposals submitted by the 2010 registration deadline by 1 December 2012

- All testing proposals evaluated by the deadline

    - 571 dossiers with testing proposals motivated by the 2012 evaluation deadline received
        - 1 184 individual testing proposals
    - 557 dossiers concluded
    - 14 dossiers – ECHA was not able to conclude the testing proposals due to severe SID issues in the dossiers

Findings from examination of TP



24 draft decisions (partial or full) - referred to the Commission

- **All refer to reproductive toxicity**
- **MSC did not reach agreement on the issue**

Challenges in evaluating dossiers with TP

- Ambiguous substance identity
- Read-across and category approach with insufficient supporting evidence
- Update of dossiers – withdrawal/addition of testing proposals

Ambiguous substance identity

128 dossiers with TP - subject to targeted compliance check on substance identity prior to evaluation of TP

- 59 cases – ECHA was able to conclude on the related TP based on the information provided as a response to the ECHA decision
- 55 cases - draft decision on the testing proposal was sent in parallel to a draft or final decision on compliance check targeted to substance identity
- 14 cases – it was not possible to conclude on SID – TP examination suspended

Grouping and read-across

- No or insufficient justification for the read-across provided
  - the registrant just claims that read-across is possible because of structural similarity
- Read-across hypothesis e.g. chemical similarity, trends, mechanisms
  - not scientifically robust or inconsistent
  - not supported by data (either experimental or model-based)
- Category cases
  - insufficient data for the endpoint to be read-across
  - it is not explained (in sufficient detail) why membership of a category goes with a certain property

Other findings from Evaluation of TP

Third party consultations – vertebrate testing

- Comments received too generic or concentrated only on alternative testing strategies
- Supporting studies submitted did not provide sufficient detail

Misplaced data remain hidden

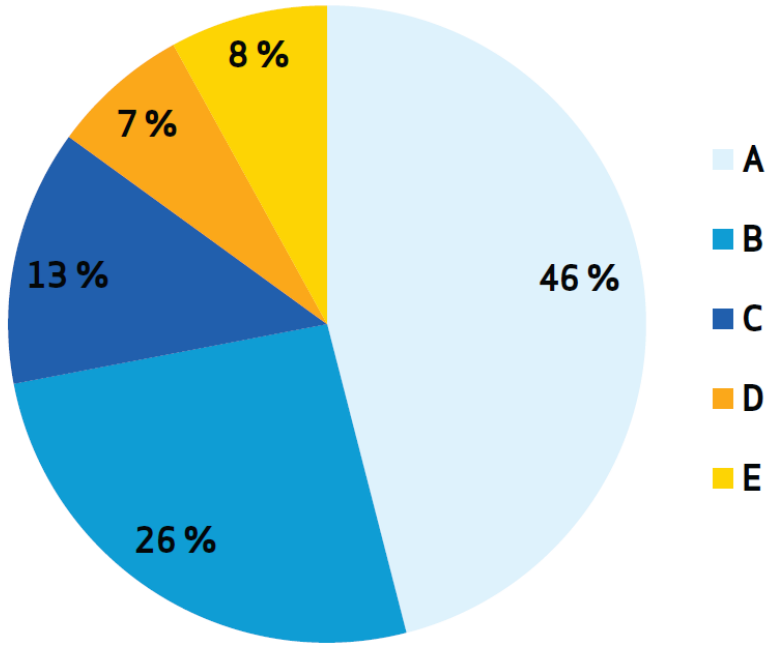
- "Testing proposals" in CSR

Annex IX and X endpoints

- Animal testing done after 1 June 2008? – no testing proposal had been submitted

Compliance checks

Compliance checks 2011



COMPLIANCE CHECKS

A	Final decision - substance identity checked for a dossier with a testing proposal;
B	Final decision - a dossier without testing proposal;
C	Quality observation letter;
D	Closed - upon dossier update after draft decision;
E	Closed - no regulatory action

- The majority of dossiers checked had room for improvement: ECHA took action to notify these registrants

- Almost half of the compliance checks were on **substance identity "roadblocks"** in the course of testing proposal examination

Findings from compliance checks

Mostly similar to the ones from evaluation of testing proposals

- Substance Identity often unclear
- Read Across used lightly
- Chemical Safety Assessment deviating from default without reason
- No information on (Q)SAR models used

Improving dossier compliance by targeted compliance checks

- Complements compliance check activities
- Aims at having maximum impact on safe use of chemicals
- ECHA targets compliance checks to specific dossier issues (endpoints)
- The chances of poor quality dossiers being picked up for compliance check are higher

How does it work?

- Identify "Areas of Concern" – ECHA in agreement with MSCAs
- Screen all available dossiers by means of IT tools
  - Criteria for selection may be e.g.
    - Individual registrations outside of a joint submission
    - Not justified adaptation/waiving statement
- Evaluation of the specific endpoints in selected dossiers under a formal CCH
- If non-compliant, the registrant receives a compliance check decision from ECHA
- Registrants may receive multiple decisions for the same dossier

N.B. Issuing a compliance check draft decision for a specific endpoint does not mean that ECHA has checked the entire dossier. Companies have to keep all the information in their registration dossiers up-to-date.

Recommendations to registrants

Recommendation - SID

- Define your substance precisely and unambiguously
- Ensure that the description of your substance represents the substance actually manufactured (per individual registration)
- Ensure that the test material represents the variability of the substance for all members

Recommendation

Grouping of substances and read across

- Needs adequate and reliable documentation
- The approach should be based on scientifically sound arguments
- Support with (experimental) data the assumptions made

Recommendation

Testing proposals within a category approach

- One/few testing proposals may not be sufficient to cover the whole category for that specific endpoint
- Provide supportive evidence from related lower tier studies (e.g. *in vitro* data, 28 day studies) demonstrating trends
- Provide a testing strategy
    - it may include tests which do not require testing proposals, e.g. toxicokinetics, tests on lower tier endpoints, etc.
    - Never rely on structural similarity alone! E.g. *Provide in silico* investigations to support the approach
- If tiered testing is foreseen: provide a full testing plan including all relevant steps ahead that you anticipate (expect no interim decisions from ECHA during tiered testing)

Recommendation

Chemical Safety Assessment

- use harmonised C&L
- use default assessment factors
- assess the exposure of all identified hazards
- use substance specific exposure scenarios
- ***use solid science to justify deviations***

Recommendation – general

- Be prepared to react on ECHA decisions (make use of the interaction at the draft decision stage)
- Keep your dossiers up-to-date
- Join or follow our events
  - Expert meeting/workshop on read-accross
  - Webinar on targetted compliance checks

Part 1 – How to bring your registration dossier in compliance with REACH – Tips and Hints - 27 September 2012

Evaluation Progress Report 2011

- Annual report
- On ECHA website, now available in 22 languages
- Progress in our activities
- Information on common pitfalls
- **Recommendations**
- All (existing and future) registrants are strongly advised to read this report
- 2012 report – February 2013

Substance evaluation

Community Rolling Action Plan (CoRAP)

- First CoRAP published on 29 February 2012
  - Contains 90 substances for evaluation in 2012, 2013, 2015
  - Member States astarted evaluation
  - Co-operation with the registrants in foreseen during the proccess

- CoRAP update to be published in March 2013

What to do if my substance is in the CoRAP?

- Appoint one registrant as coordinator
  - When the substance is listed on the Draft CoRAP update
    - Interact with the evaluating MS
    - Communicate during the decision making process
    - Produce the information subject to request on behalf of all the registrants

- Contact the evaluating MS
  - Discuss technical issues related to Substance Evaluation

Dossier updates during substance evaluation

- Inclusion of a substance in CoRAP does not trigger automatically a need for dossier update
- If update is needed it shall be done **before the evaluation starts**!
- Discuss any planned testing (e.g. testing proposals) with the evaluating MS
- The evaluating MS will identify any further information needs and prepare a draft decision

Substance evaluation - recommendation

- Coordinate your actions towards the evaluating Member State & ECHA – nominate a representative
- Relevant dossier updates should be submitted before the substance evaluation starts officially
- Speak with one voice while providing the formal comments
- Respect the deadlines

Nanomaterials under REACH – ECHA activities

Where do nanomaterials fit under REACH?

- No explicit reference to nanomaterials in REACH
  - Considered as covered by the substance definition under REACH
  - Commission 2nd regulatory review on nanomaterials
- Nanomaterials (NM) can be either
  - Substances on their own and thus registered as such substances
  - Nanoforms of a substance and included in the dossier of the corresponding bulk substance
- Registrant needs to demonstrate the safe use of its substance, whatever the form

Characterisation of nanomaterials

The characterisation of nanoforms of a registered substance is a prerequisite to the proper determination of hazards and risks of the substance

ECHA is thus concentrating on this characterisation:

- when elements in a dossier indicate that the substance (may) fall under the definition of a nanomaterial
- when there is sufficient indication that the substance may be a nanomaterial in spite of the absence of reference in the dossier

Article 36 Decisions

- Article 36 decision (166 decisions sent):
  - Request information that the registrant should have in order to carry out his duties under REACH
  - Does not require generation of new data that could be obtained under a CCH
  - No information in the dossier showing the substance is a nanomaterial
- Required registrants to provide:
  - Information on all size grades placed on the market
  - Information on surface treatment
- ECHA is currently assessing the updates

Dossier evaluation

- Limited number of dossiers with testing proposals
  - One dossier triggered by the 1 Dec deadline evaluated and DD sent

- Compliance check
  - Tiered approach – ECHA sent a number of draft decisions requesting further information on granulometry

Nanomaterials on CoRAP

2012: silicon dioxide (NL), initial grounds for concern: Substance characterization - Nanoparticles, toxicity of different forms of the substance

2014: silver (NL) Substance characterization - Nanoparticles, toxicity of different forms of the substance

2014: titanium dioxide (FR) HH: suspected respiratory sensitizer, CMR; ENV: suspected vPvB; Exposure: Wide dispersive use, consumer use, high exposure for workers and environment

Advice to registrants on nanomaterials

- Guidance development for NMs
  - Guidance on information requirements were updated with nano specific appendices (Summer 2012)
- ECHA webpage on nanomaterials
- GAARN best practices
- Webinar series
  - first one on 30 October 2012
  - will continue in 2013

Nanomaterials – key messages

- Provide all available information on the nanomaterials that you have
- Document as a minimum:
  - Shape
  - Particle size
    - Primary/constituent particle
    - Number based
  - Specific surface area
- ECHA will continue addressing nanomaterials under REACH (Art 36, CCH, TPE)

Thank you.

Questions?

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What registrants may expect from ECHA during December 2012?

1. Proposals for amendments received from MSCAs to the registrants - 5 December ECHA
   - commenting deadline of 04.01.2013
2. Draft decisions on targetted compliance checks
   - 30 days commenting period – extension possible upon request
   - No informal interaction possible
3. Draft decisions on non phase-in testing proposals
4. Input on publication of final decisions on ECHA website
   - Message via REACH-IT, feedback to be provided within 5-10 days
   - Deadline for comments before Christmas