Feedback from evaluation

CEFIC REACH Implementation Workshop Brussels, 18-19 June 2012

Watze de Wolf,
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Outline presentation

- Introduction
- Dossier Evaluation
  - Learnings Evaluation Progress Report (e.g. Art 54 report)
  - Targeted Compliance Checks
  - Nanomaterials
- Substance Evaluation
- Concluding remarks

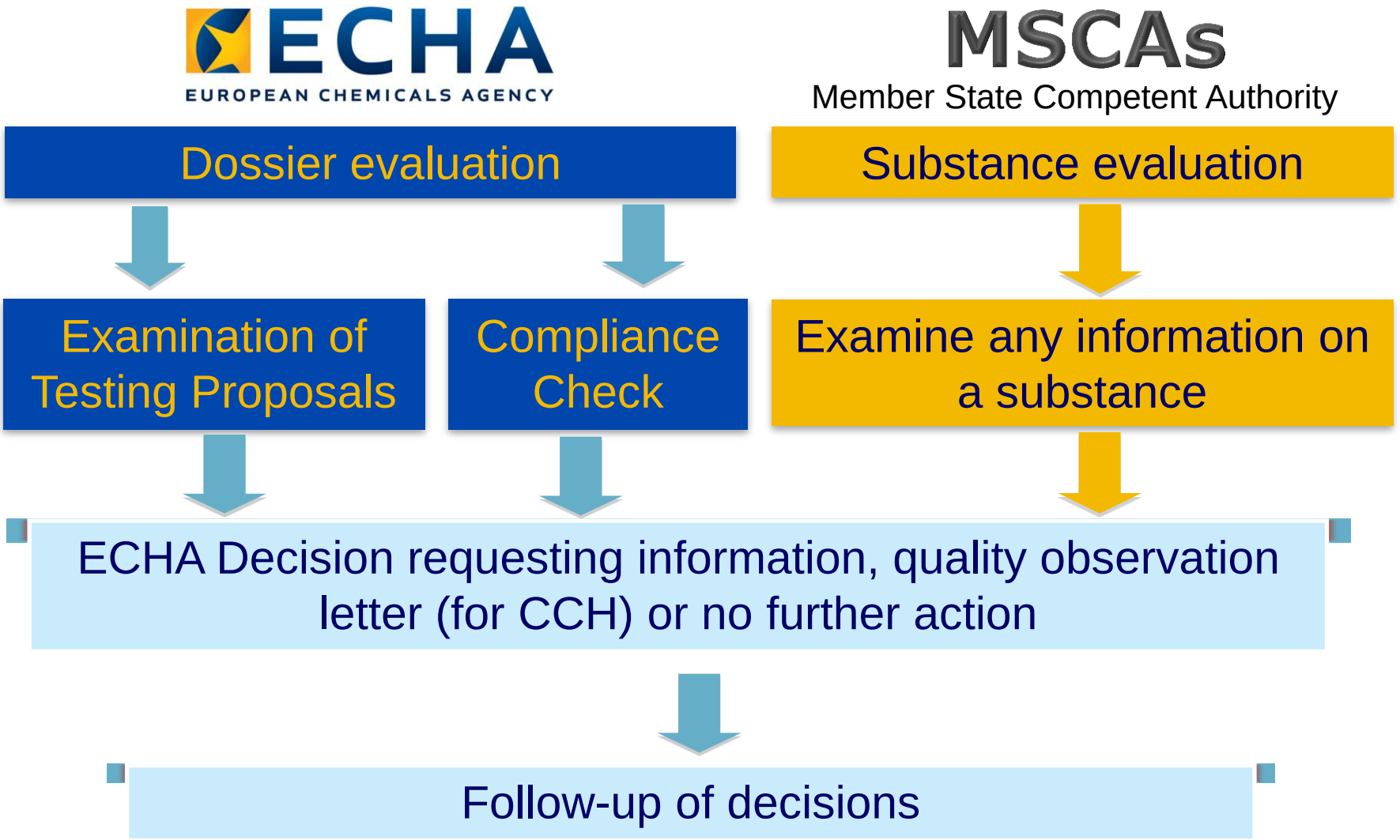
REACH: Evaluation

- Dossier evaluation
  - Examination of testing proposals
  - Compliance check
  - To instil confidence that companies meet their legal obligations
- Substance evaluation
  - To clarify risk with a view to using regulatory instruments, i.e. 'added value'

Dossier Quality

- Good quality information in registration dossiers is needed to ensure the safe use of chemicals
- REACH places the responsibility on companies to ensure safe use of their substances and compliance
- Evaluation (the “E” in REACH) is there to support registrants in their obligation to provide adequate information on registered substances
- The main findings of the evaluation processes are reported each year in Evaluation reports (since 2008)

Evaluation – Overview



Findings from Evaluation

Evaluation Progress Report 2011

- Annual Report
- Progress in our activities
- Informs on common pitfalls
- Recommendations
- All (existing and future) registrants are strongly advised to read this report
- Available in 22 languages on the ECHA website:

http://echa.europa.eu/web/guest/regulations/reach/evaluation

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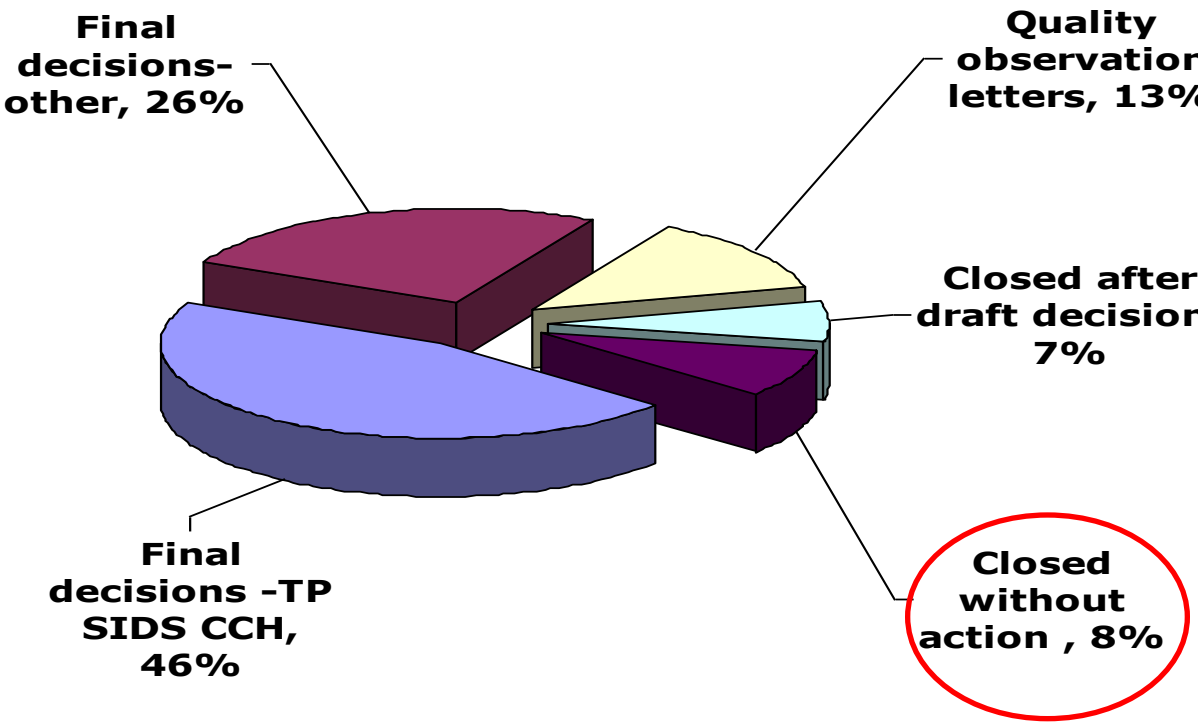
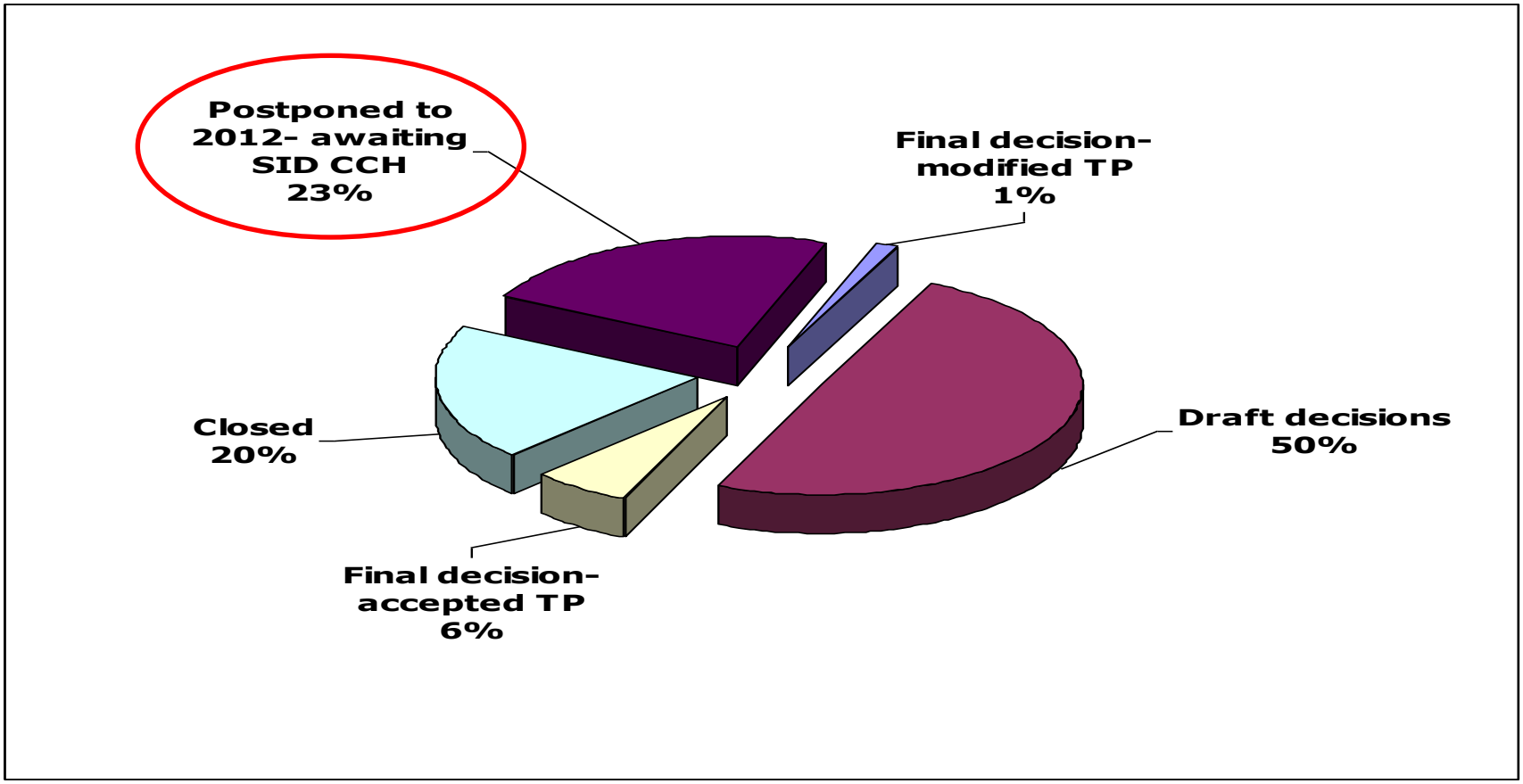
Dossier quality - Compliance checks 2011



Findings from Evaluation

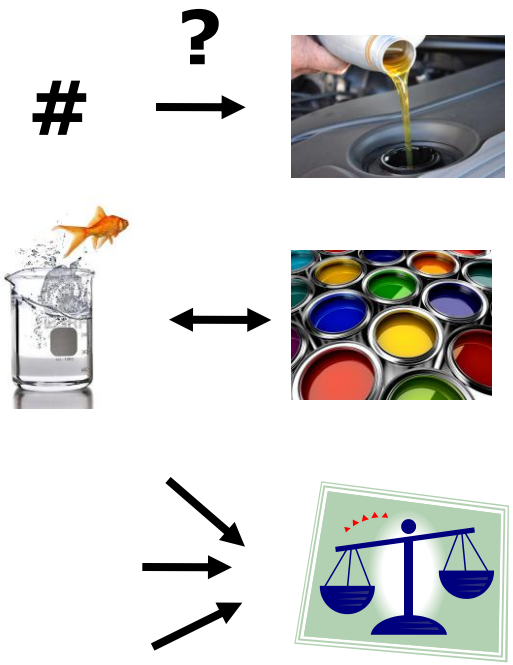
Examination of Testing Proposals



Findings from Evaluation

The SID:

- Defines the scope of your registration
- Link hazard data with the substance registered
- Required for a sound chemical safety assessment



Recommendation

- Ensure that the description of your substance represents the substance actually manufactured
- Demonstrate that the test material used in studies are representative for the registered substance
- Deliver appropriate analytical information on the substance as manufactured.

Findings from Evaluation

- Substance Identity *often unclear*
- Read Across *used lightly*
- Chemical Safety Assessment
  deviating from default without reason

Example administrative issue - Testing proposals not made correctly

- Higher tier information gaps (Annexes IX and X) require the submission of a TP
  - Under the relevant IUCLID endpoint in the section "study result type" select "experimental study planned" from the drop-down menu
- TPs have not been submitted correctly
  - TP provided only in the Chemical Safety Report
- TPs have been omitted
  - TP omitted awaiting the outcome of planned/ongoing lower tier test

Therefore,

- Learn from the Evaluation Progress reports
- Urgently update your dossier with testing proposals where necessary.

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Improving dossier quality by targeted Compliance Checks

- Complements current compliance check activities
- Aimed at having maximum impact on safe use of chemicals
- More efficient use of limited ECHA Evaluation resources
- ECHA will target compliance checks to specific dossier issues (endpoints)
- Poor information on these endpoints affects safety and reliability of the chemical safety assessment

And how will it work?

- ECHA and Member State Competent Authorities identify Areas of Concern (AoC) = dossier issues (endpoints) where safety matters
- IT tools screen **all** submitted registration dossiers to identify suspicious dossiers with respect to the AoC
- The specific endpoints in selected dossiers are then evaluated manually under a REACH compliance check
- Criteria for automatic selection for checking will include, *inter alia*:
  i) Individual registrations outside of a joint registration;
  ii) Dossiers where the Chemical Safety Report is missing
- If incompliant, the registrant receives a compliance check decision from ECHA

Effects of the new CCH strategy 1(2)

- Multiple incompliances in a dossier may lead to multiple decisions
- Opportunity to make formal comments during the 30-day commenting period
- No informal communication foreseen due to the high numbers of targeted CCH draft decisions

Therefore:

- Do a good job from the start
  - It is worth the effort and will help you avoid getting one or more draft decisions
- Proactively update your dossiers now to avoid multiple decisions

Effects of the new CCH strategy 2(2)

- Rewards companies that do a good job by addressing poorly performing companies more effectively
- Increases chances of poor quality dossiers being picked up for compliance check
- Monitoring and follow-up of compliance with the ECHA decisions is an integral part of Evaluation

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Workshop on Nanomaterials, 30-31 May Conclusion (1)

- ECHA used and will use the EU Commission recommendation for nanomaterial (NM) definition
- ECHA shared experiences in evaluation registration dossiers containing nanomaterials
  - Scope of the registration is often unclear (i.e. whether and how many nano-forms are included)
  - There is significant room for improvement regarding the level of nano-specific information provided (e.g. substance characterisation, hazards, exposure and risks)
- Clear support for ECHA to continue assessment of NM in dossier evaluation
- ECHA's approaches on how to use the current legal tools in REACH to cover NM registration was supported (tiered approach considering case by case basis)
  - Decisions under article 36 (only available information is requested under Art. 36)
  - Compliance check
  - Substance Evaluation

Workshop on Nanomaterials, 30-31 May, Conclusion (2)

- Registrants are invited to proactively characterise their substances in light of the EU Commission recommendation on the definition of a nanomaterial
- The first aim is to provide clarity on the physico-chemical characteristics (including sample preparation and dosimetry)
- In a later stage, priority will move to hazard and risk considerations
- This gradual approach combined with a collaborative and constructive interaction with registrants should be the first step towards future safety assessments of nanomaterials under REACH

Workshop on Nanomaterials, 30-31 May, Conclusion (3)

- ECHA will set up a **Nanomaterial Working Group** (NMWG)
  - Provide advice on scientific and technical principles related to nanomaterials under REACH
- Supported by Commission and Member States.
- Mandate will be further adapted taking into account comments received
- Balancing the composition of the NMWG
  - Continuity: 1 representative from each MSCA and
  - Expertise: invitation of additional scientific experts (from an agreed "pool" of expert?) depending on the issues discussed
- Avoid overlap with scope of CASG-Nano.
- Primary focus of NMWG: supporting (not interfering with) ECHA's Evaluation process.

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  - 2-Generation Reproductive Toxicity Information Requirement
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Substance Evaluation – state of play

- ECHA published the first Community Rolling Action Plan ('CoRAP') 29 February 2012
  - ➢ list of 90 substances
  - ➢ Member State Competent Authorities and ECHA can identify candidates among the registered substances based on a agreed criteria
  - ➢ CoRAP 'rolling' 3-year list; the 1st one covers years 2012 to 2014

- Substance evaluation – first evaluations ongoing

http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Substance Evaluation

- Substances on the CoRAP
  - Not proposed for restriction or to be banned
  - Purpose of the evaluation is to clarify whether their use poses a risk to human health or the environment

- Evaluation outcomes
  - Risks are sufficiently under control with measures already in place
  - A request for further information from the registrants of the substance to verify the suspected concern
  - A separate proposal on EU-wide risk management measures

sshttp://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

Workshop on Substance Evaluation, 4-5 June Conclusions (1)

- **Member State to initiate informal interaction with the registrants**
  - As soon as it is evident the MS will be the evaluating MS
  - One registrant to coordinate the views and handling the contacts with the evaluating MS
  - Focus on technical information on the substance
  - Dossier updates before the Substance Evaluation has started

- **Submission of one set of comments during formal commenting steps in the decision making process**

Workshop on Substance Evaluation, 4-5 June Conclusions (2)

- **No immediate need to revise the prioritisation criteria for the selection of CoRAP substances**
- **Draft CoRAP update planned to be published by the end of October 2012**
- **Publication adopted CoRAP foreseen for end of March 2013**

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Take-home messages

- Keep yourself up-to-date with Evaluation Progress Reports and act to avoid common pitfalls
- Keep your dossiers up-to-date
- Join or follow our events
- Joint registration is not an option, it is a legal obligation
- Do not wait for a draft decision – **improve your dossier quality now**!

ECHA's strategic aims for the next years

1. Maximise the availability of high quality data to enable safe manufacture and use of chemicals

2. Tackle the right chemicals of concern and focus on the best regulatory action

3. Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints

4. Address the scientific challenges by serving as a hub for scientific and regulatory capacity building of Member States, European institutions and other actors

Conclusion

To ensure safe use of substances

- REACH places the responsibility on companies
- High quality information is required
- Evaluation is there to support registrants
- The main findings of the evaluation processes are reported each year in Evaluation reports (since 2008)

Thank you

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