

Improving the compliance of registration dossiers

– ECHA's targeted Compliance Check strategy

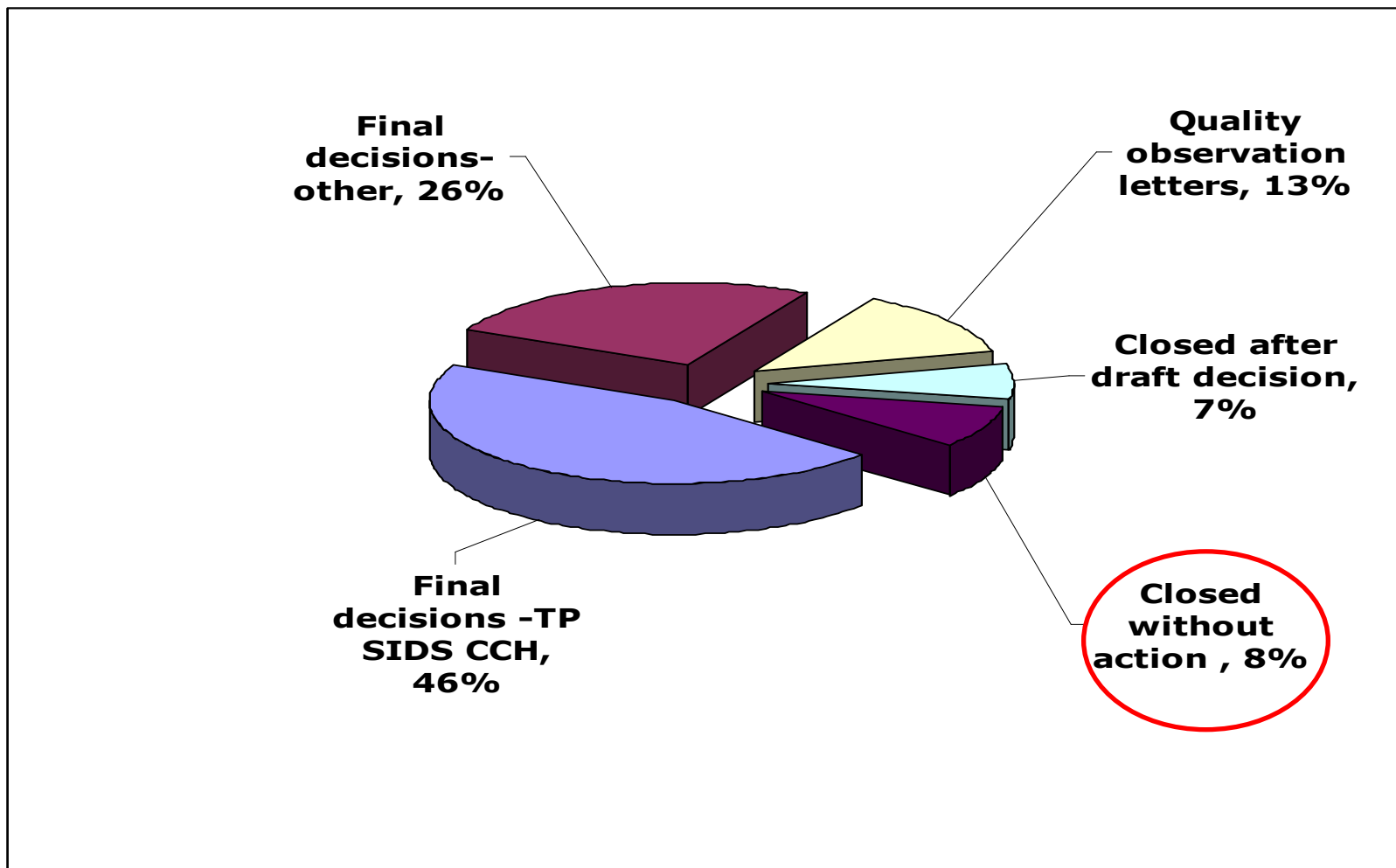
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Dossier quality and compliance

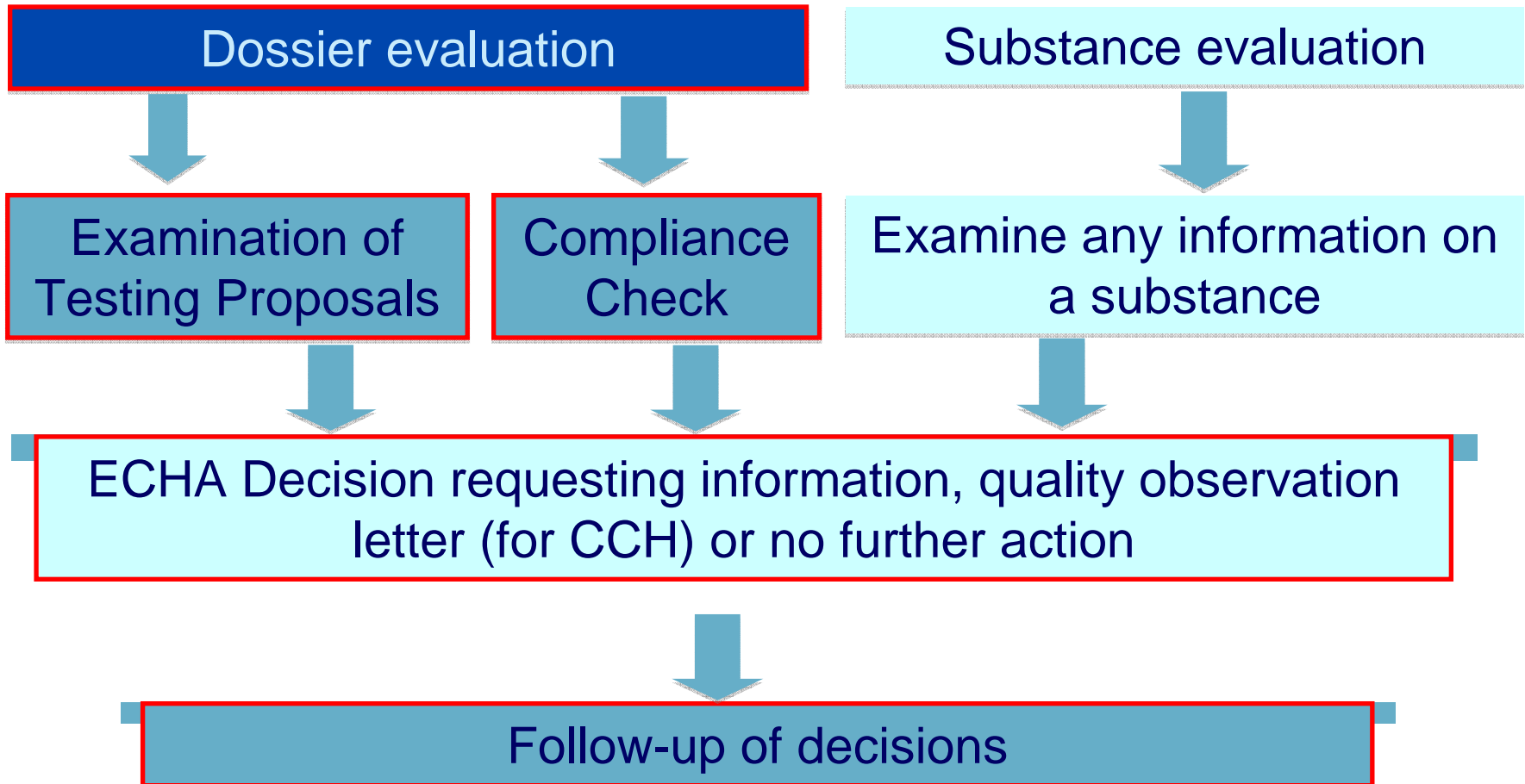
- Good quality information in registration dossiers is needed to ensure the safe use of chemicals
- REACH places the responsibility on companies to ensure safe use of their substances and compliance
- Evaluation (the “E” in REACH) is there to support registrants in their obligation to provide adequate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

Dossier quality - Compliance checks 2011



ECHA's strategic approach for Compliance Checks (CCH)

- ECHA's observations on the quality of registration dossiers: significant part have important quality deficiencies
- ECHA's strategic aim: *"improve the quality of data submitted by industry and disseminated by ECHA to enable the safe manufacture and use of chemicals"*
- Improved IT tools for Evaluation are crucial for Dossier Evaluation throughput
 - Supporting consistency and efficiency
 - IT-supported selection and pre-assessment essential



Compliance check

- ECHA uses compliance checks to see if information from registrants fulfills the legal requirements
- At least 5% of all registration dossiers received within each tonnage band to be checked
- ECHA can decide which dossiers to check
- Dossier selection is either random or based on concern-driven criteria
- Mix of approaches allows different aspects of poor compliance to be addressed (e.g. all or specific aspects of a selected dossier)

Types of Compliance Check

Full Compliance Check (mostly random)

1. Substance ID CCH
2. Technical dossier
3. Chemical Safety Report
- CSR

Targeted Compliance Check (concern based)

- General concern (“Very poor content”)

- **Area of Concern (AoC)**
 1. **Selected (combination of) endpoints**
 2. **Including “Special AoCs”**
 - **SID CCH** (Testing proposals, Categories, Read Across)
 - **Substance Evaluation** (Concern for CoRAP)
 - **Individual submission** (Violation of “joint submission principle”)

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 (e.g. endpoints) that have immediate impact on safety
- 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 dossier issues, e.g. endpoints, of highest concern
- IT tools screen **all** submitted registration dossiers to identify suspicious dossiers with respect to the specific concern
- 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) Dossiers submitted individually outside an existing joint submission;
 - ii) Dossiers with incomplete essential elements of Chemical Safety Report
- If non-compliant, the registrant receives a compliance check decision from ECHA

Effects of the targeted CCH strategy 1(2)

- REACH does not limit the number of compliance checks so registrants with a number of incompliances in a dossier may get multiple CCH decisions
- Registrant has an opportunity to make formal comments
- ECHA does not foresee an opportunity for informal communication with ECHA during the 30-day commenting period due to the reduced complexity of the cases and the high numbers of such targeted CCH draft decisions
 - This series of Webinars is provided instead
- When receiving a draft decision requesting testing, registrants have the opportunity to check if the adaptations used could be improved in order to avoid testing

Therefore:

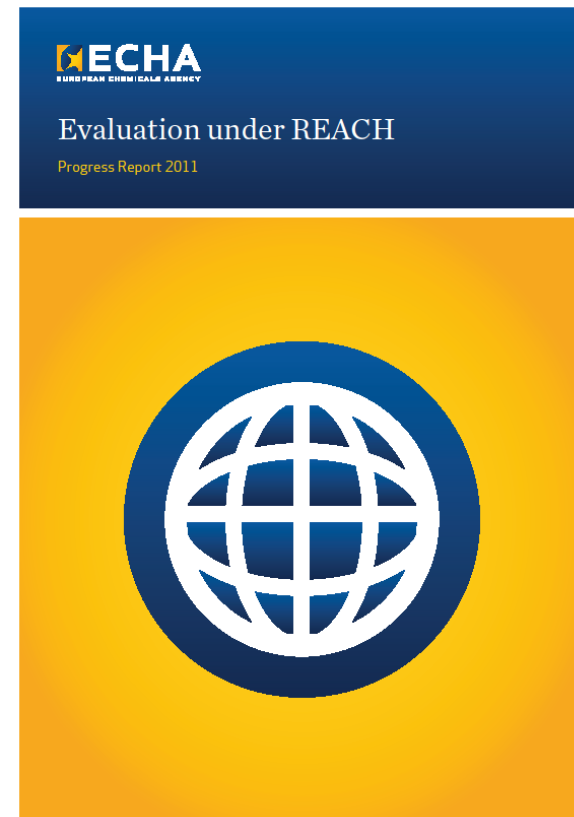
- Registrants are encouraged to proactively update their dossiers to avoid multiple decisions
- Doing a good job from the start is worth the effort and will help you avoid getting one or more draft decisions

Effects of the targeted CCH strategy 2(2)

- Rewards companies that do a good job by addressing poorly performing companies effectively
- The chances of poor quality dossiers being picked up for compliance check are even higher with the new approach
- Companies have the last chance to update their dossiers before they are picked up for evaluation – **improve your dossier quality now!**
- Joint registration is not an option, it is a legal obligation
- To be able to follow the legally bound Evaluation decision-making procedure ECHA will not take into account dossier updates received after when ECHA has sent the draft decision to Member State Competent Authorities
 - ECHA will notify the Member State Competent Authorities without undue delay after the Registrant's 30-day commenting period
- Monitoring and follow-up of compliance with the ECHA decisions is an integral part of Evaluation

Evaluation Progress Report 2011

- Annual Report
- On ECHA website, 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
- Progress Report 2012 – will be published in February 2013
- <http://echa.europa.eu/regulations/reach/evaluation>



Thank you

Evaluation Directorate
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