

How to bring your registration dossier in compliance with REACH – Tips and Hints Part 2

Improving the compliance of registration dossiers - general issues

Hannu Braunschweiler
ECHA

28 January, 2013
11:00 - 14:00 Helsinki Time (GMT +2)

**Key issues in improving
the compliance of
registration dossiers**



Improving dossier quality by targeted compliance checks 1(2)

- Targeted compliance checks complement current compliance check activities
- ECHA will target compliance checks to specific dossier issues (e.g. endpoints) that have immediate impact on safety
- Targeted selection is based on evaluation experience on often occurring non-compliances
 - ECHA applies IT-supported selection of dossiers for targeted compliance checks from the whole registration database

Improving dossier quality by targeted compliance checks 2(2)

- Aimed at having maximum impact on the safe use of chemicals with more efficient use of limited ECHA Evaluation resources
- Poor information on these endpoints affects safety and reliability of the chemical safety assessment
- The chances of low quality dossiers being picked up for compliance check are even higher with the new IT-supported approach

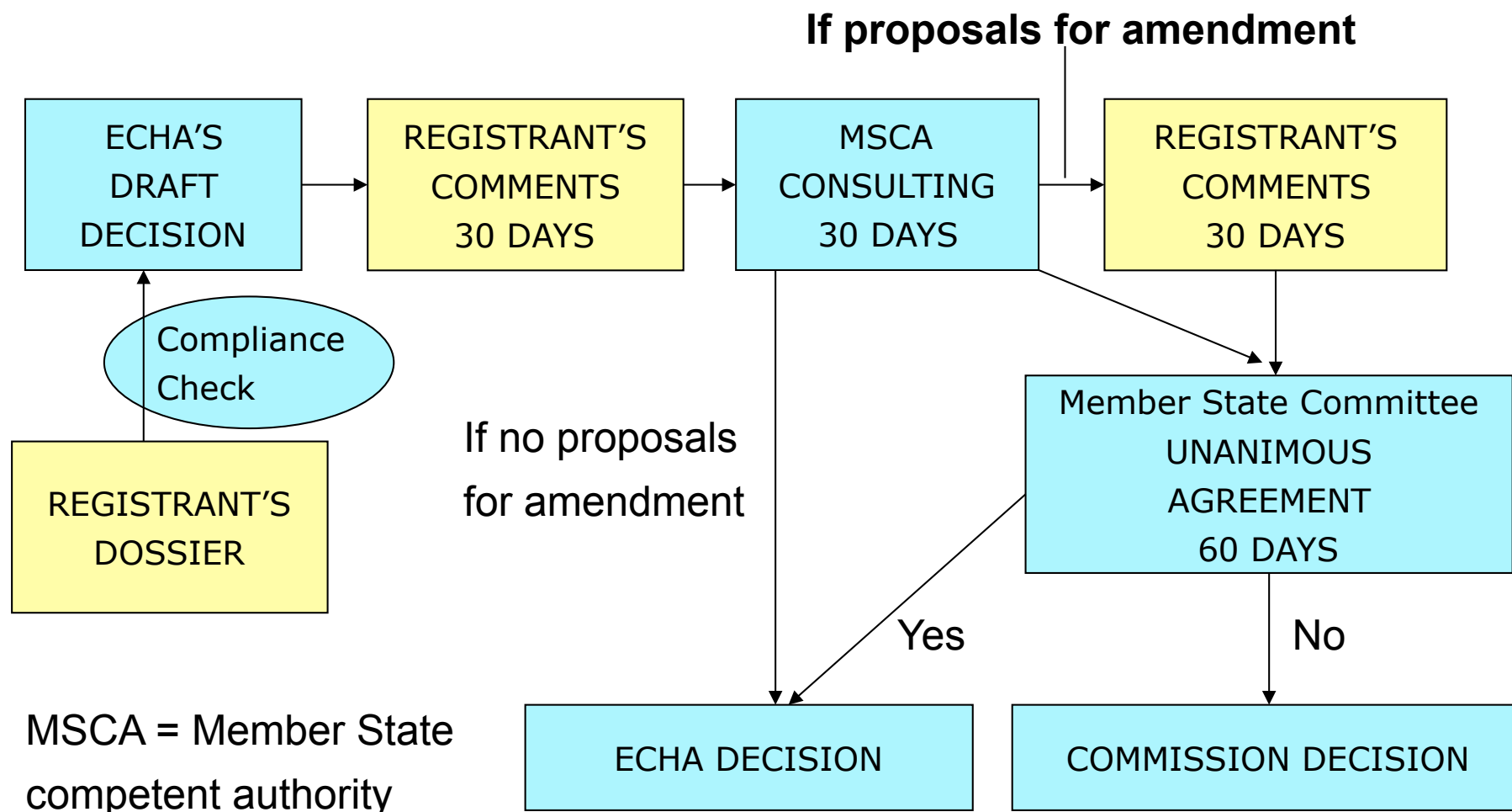
Key points in targeted compliance checks 1(2)

- REACH does not limit the number of compliance checks so registrants with a number of incompliances in a dossier may get multiple CCH decisions
- Registrants have an opportunity to make formal comments within 30 days on ECHA's draft decision
 - ECHA may adapt the draft decision
- An opportunity for informal communication with ECHA during the 30-day commenting period is unforeseen 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
 - Registrants should provide the improved adaptations and reasoning in an updated dossier as soon as possible!

Key points in targeted compliance checks 2(2)

- To be able to follow the legally bound Evaluation decision-making procedure ECHA will not take into account dossier updates received after ECHA has sent the draft decision to the Member State competent authorities
 - ECHA will notify the MSCAs without undue delay after the registrant's 30-day commenting period
- Doing a good job from the start is worth the effort and will help you avoid getting one or more draft decisions – improve your dossier quality now and avoid one or more decisions !
 - So far, ECHA has issued about 120 draft decisions under these IT supported targeted compliance checks.
- Further background on ECHA's compliance check strategy can be found in Part 1 of this Webinar series available at:
 - http://echa.europa.eu/view-article/-/journal_content/cda5daf6-7d31-4a07-8d95-c1c820fa802f

Decision making process: Involvement of the Registrant



Tools to improve dossier quality



Technical completeness check

- The technical completeness check (TCC) carried out by ECHA verifies that the registration dossiers address the information requirements set out by REACH Articles 10, 17 and 18
- To support industry in dossier preparation, ECHA has developed the TCC plugin for IUCLID
- By installing the TCC plugin in their IUCLID application and launching the plugin on their dossiers, registrants can verify their dossiers against the TCC requirements prior to submission to ECHA
- The TCC plugin also performs a business rules (BR) check, which assists registrants in detecting and correcting BR failures before submitting their dossiers to the Agency
- The TCC plug-in can be downloaded from the IUCLID website <http://iuclid.eu/>

Dossier quality work

- The compliance checks have revealed several inconsistencies in information provided in registration dossiers
- Frequently occurring inconsistencies were chosen for developing "Quality Checks"
- These checks highlight dossier elements that are likely to be of questionable quality
 - nevertheless, there are circumstances in which the provided information may be acceptable
- The developed Quality Checks are being incorporated into a software to assist registrants with good quality dossier preparation
- This software will be part of the TCC plugin and the outcome of the checks will be displayed on a separate tab, next to the already available TCC and BR rule outcome
- The Quality Checks do not affect the outcome of the technical completeness check carried out by ECHA for the 2013 registration deadline

Dossier quality assistant

- Guiding dossier quality rules – i.e. not directly obligatory for registration as TCC rules
- Substance Identity rules, 29 checks
 - Same set of checks as released for inquiry dossiers in 2011
- General Quality Checks, 25 checks
 - Three main categories:
 - Tonnage: check that appropriate information is provided in IUCLID section 3.2 – Estimated quantities and verify consistency with tonnage bands in dossier header
 - Intermediates: check that intermediate dossiers do not contain incompatible use description in IUCLID section 3.5
 - Endpoint study records: check administrative data section to see that information provided is consistent with approach selected to fulfil the endpoint information requirements

Endpoint study records checks

- In the compliance checks so far, ECHA has frequently observed that registrants choose conflicting options in the administrative part of the endpoint study records
- Registrants are advised to ensure that the approach they have chosen to fulfil the information requirements is clear
 - Key studies should correspond to study summaries of good reliability
 - Study results should not be reported in data waivers
 - All endpoint study records should be correctly identified with regard to the study result they contain
- The Quality Checks will assist registrants to ensure consistent administration for the endpoint study records
- In turn, this will decrease the chances of an otherwise good-quality dossier to be examined, because of reporting studies in an inconsistent way

Thank you