

How to bring your registration dossier in compliance with REACH

Tips and Hints - Part 5

Communication during decision making

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11:00 - 14:00 Helsinki Time (UTC +2)

Outline

- Evaluation processes of REACH
- Decision making
- Communication

Evaluation Overview

Dossier evaluation

Substance evaluation

Examination of
Testing Proposals

Compliance
Check

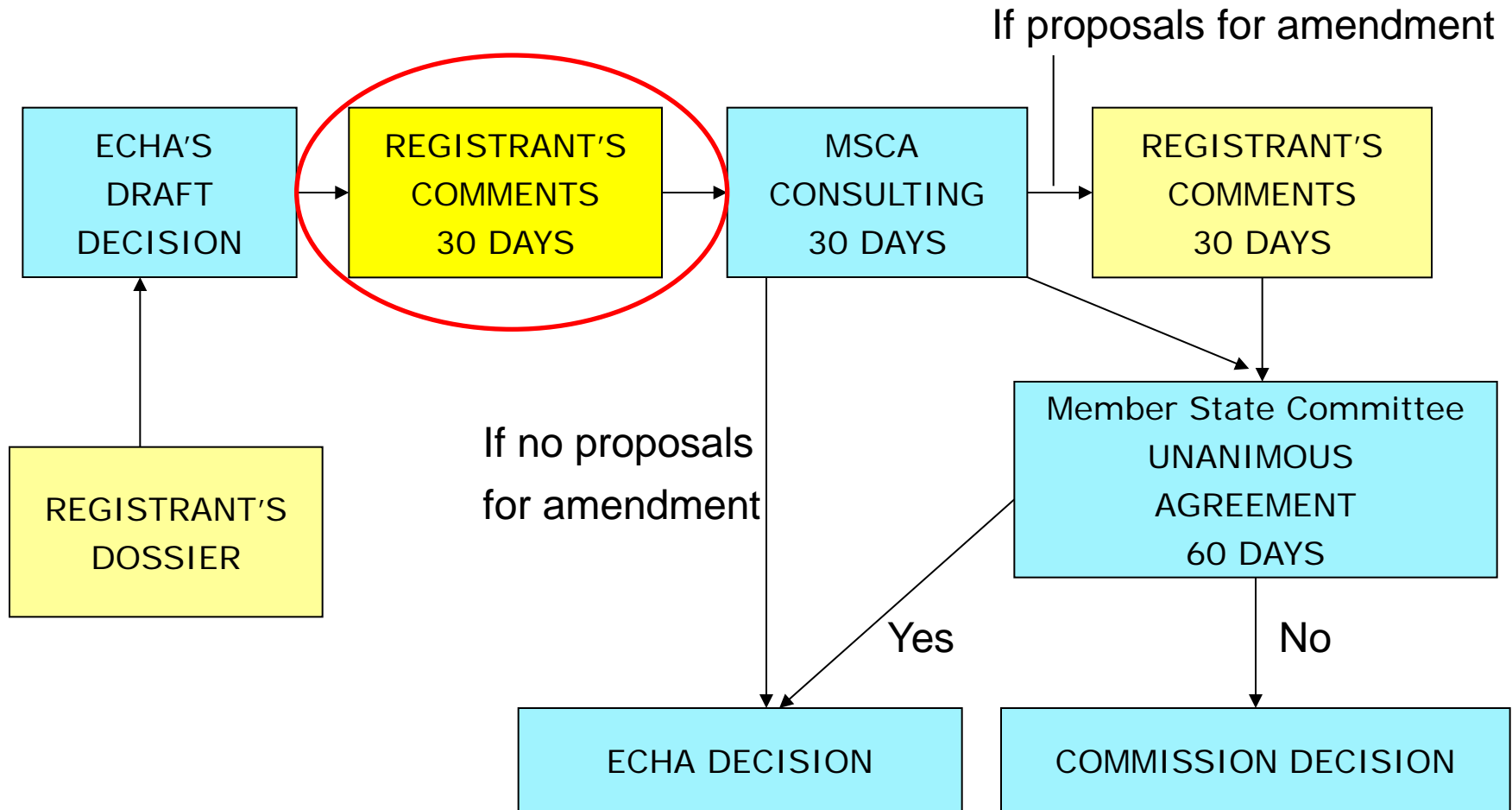
Examine any information on
a substance

ECHA Decision requesting further information

Follow-up

MSCA = Member State Competent Authority

Registrant participation in decision making



MSCA = Member State
Competent Authorities

Submit comments in 30 days upon receipt

Following the procedure set out in Article 50(1) of the REACH Regulation you are hereby notified of the draft decision. You have 30 days to send any comments you may have to ECHA. In order to submit your comments please use the webform available at the following link:

<https://comments.echa.europa.eu/comments/draftdecisioncomments.aspx>

General comments on draft decision/ proposals for amendments by MS-CAs



Endpoint specific comments

Endpoint

- select -

Comments



add comment for another endpoint

Test ongoing:

Dossier update with the data latest on 3 February 2014.
[If this concerns Annex IX or X requirements, please add a reason, why (e.g. "to cover regulatory requirements of country-x")]

Types of Compliance Check (CCH)

Overall* Compliance Check

1. Substance ID CCH
2. Hazard Information
3. Properties and fate
4. Chemical Safety Report

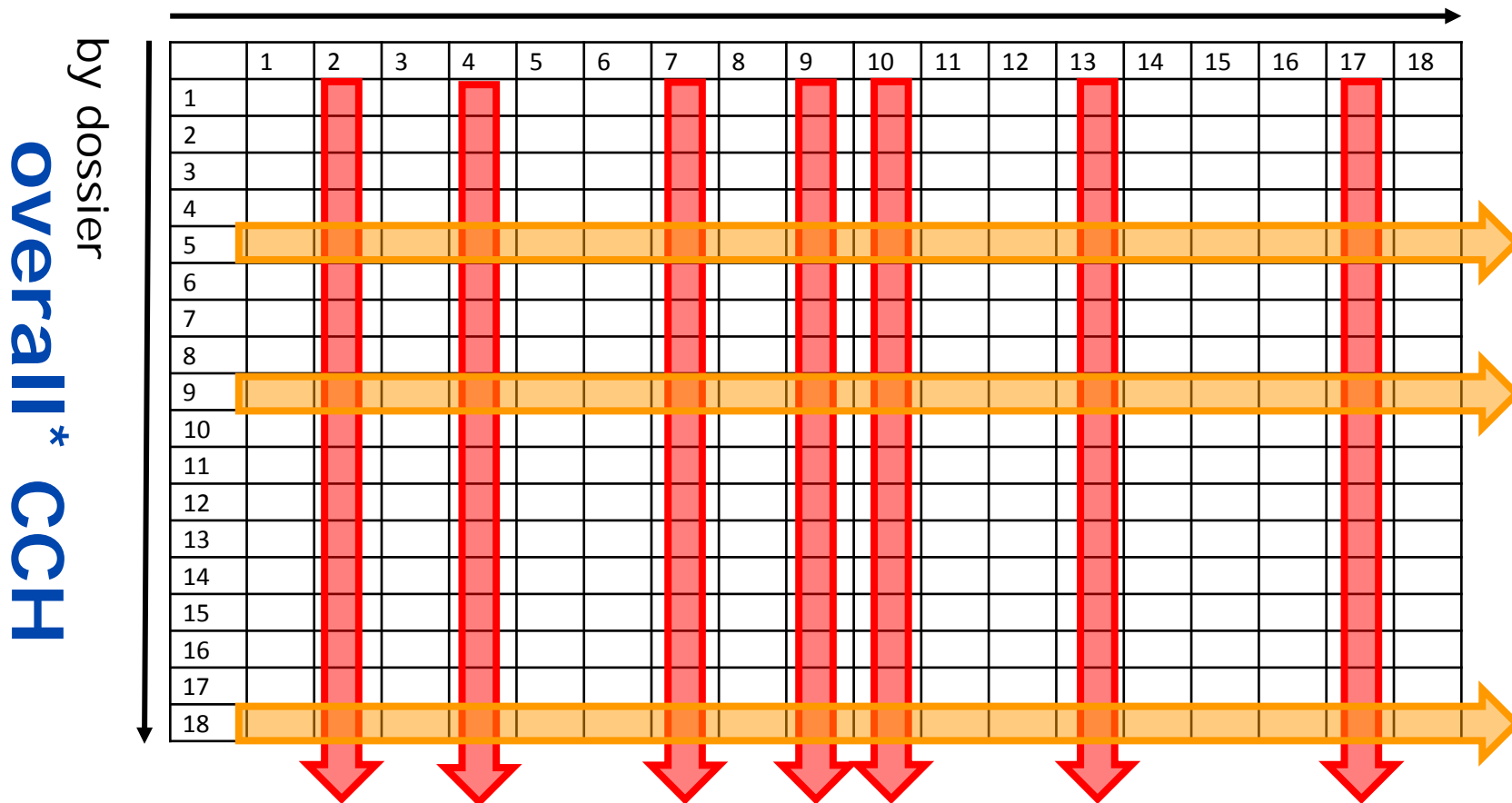
Targeted Compliance Check (tCCH)

1. Concern driven
2. Typical shortcomings
3. Prioritised endpoints
 - Substance identity
 - PBT related properties
 - Information for selected hazards
 - Classification and labelling

*corrected from "full"

targeted CCH

by information requirement



*corrected from "full"

Important details of CCH decision-making

- For targeted compliance check cases these webinars offered instead of informal communication with ECHA for full compliance check cases
 - **Because:** The targeted compliance check draft decision is less complex than for a full compliance check
- Dossier gets only compliant when the new information has been submitted in an updated dossier
 - **Because:** A comment with the required information is not sufficient to get the dossier into compliance
- Dossier updates can be taken into account until referring the draft decision to MSCAs
 - **Because:** The decision making process involves parties in 28 Member States across the EU

Questions?

To the Q&A panel (between 11:00 and 13:30, Helsinki time), or

To the ECHA helpdesk (any time):

<http://echa.europa.eu/contact/helpdesk-contact-form>