Ministry of Infrastructure and the Environment

Substance evaluation

What to do – or not to do

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Outline

- Substance evaluation process
  - Formal process
  - Selection
  - From CoRAP to evaluation
  - After evaluation

- Where is input possible
  - Prior to start of the evaluation
  - During substance evaluation
  - Engagement in decision making

Substance evaluation?

Not a new process!

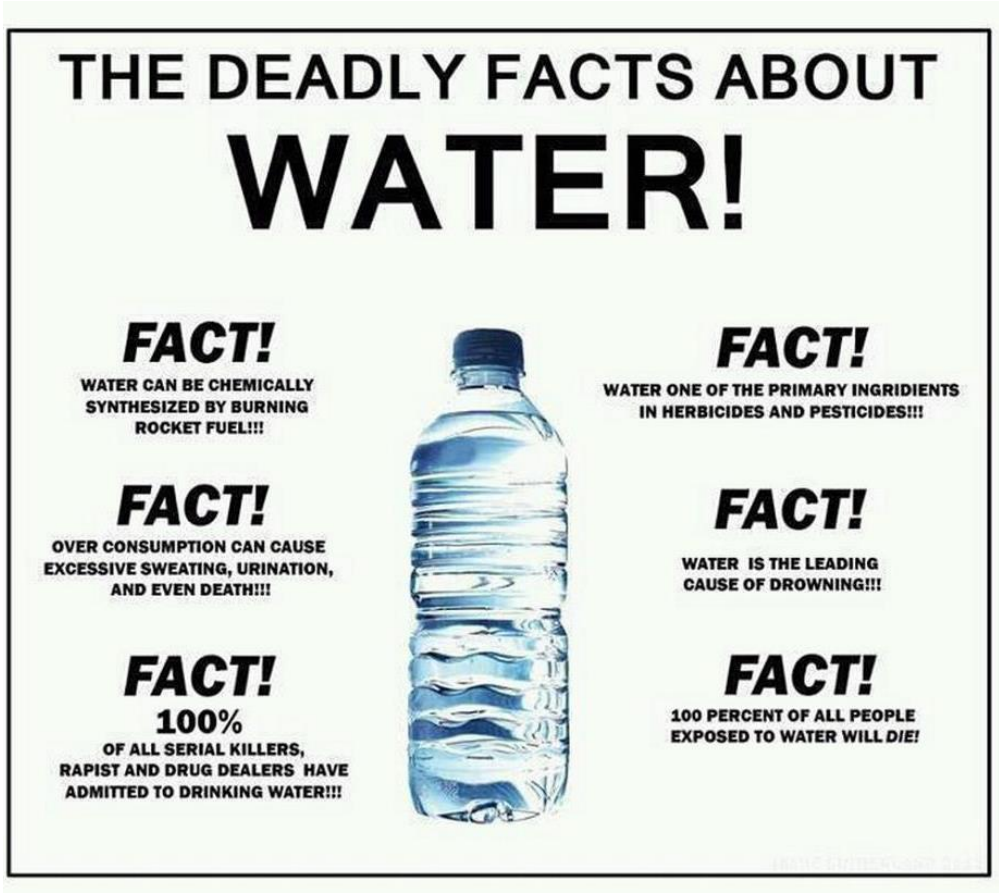
With REACH it is more structured…

…and can result in requests for data

Having a substance selected for SEV does not entail any consequences – yet!

Substance evaluation - selection

- How can your substance be selected for a substance evaluation?
- Is it possible to comment on the selection of a substance?
- If my substance has been evaluated, can it be selected again?



Selection of substances

Article 44(1)

"(...) The criteria shall consider:

(a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;

(b) exposure information;

(c) tonnage, including aggregated tonnage from the registrations submitted by several registrants."

Selection of substances

Article 44(2), second sentence:

"Substances shall be included [in the Community Rolling Action Plan] if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment."

Member States will submit a 'justification document', mentioning the reasons why a substance should be placed on the CoRAP.

An explanation on selection criteria can also be found on ECHA's site.

Selection of substances

ECHA, after an opinion of the Member States Committee (MSC), decides on the update of the CoRAP. There is no formal public consultation on this update.

The Community Rolling Action Plan (CoRAP) is a public document, outlining the substances to be evaluated in the three upcoming years, including the justification for this evaluation.

Year	Member State	EC Number	CAS Number	Substance Public Name	Initial grounds for concern (*)	Source	Member State contact details
2017	the Netherlands	219-006-1	2312-35-8	propargite	suspected PBT/vPvB, potential endocrine disruptor	new entry	Ministry of Infrastructure and the Environment; CA.REACH.NL(at)MINIENM.NL, bureau-reach(at)rivm.nl. Correspondence related to Substance evaluations should contain in the subject field the following string: "SUBSTANCE EVALUATION"

http://www.echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

From CoRAP to evaluation

After publication of the CoRAP (march/april) evaluation for substances listed for that year starts immediately.

Evaluation planned for future years can be postponed – or speeded up, depending on many factors (dossier updates, new input, evaluation capacity)

Once started, the evaluating member state(s) has 1 year to carry out the substance evaluation

Cooperation with the evaluating member state

- Ideally, contact is established **prior** to the start of the evaluation
  - In some cases the concern can be clarified upfront
  - A dossier update might be pending
  - Facilitates contacts during the evaluation phase
  - In principle 1 point of contact for all registrants

- After the evaluation commences, contact can be **useful**
  - To understand the process
  - To discuss a possible outcome (testing?)
  - To inform on dossier updates

Any contact should be informal and not binding for a party

Things to avoid

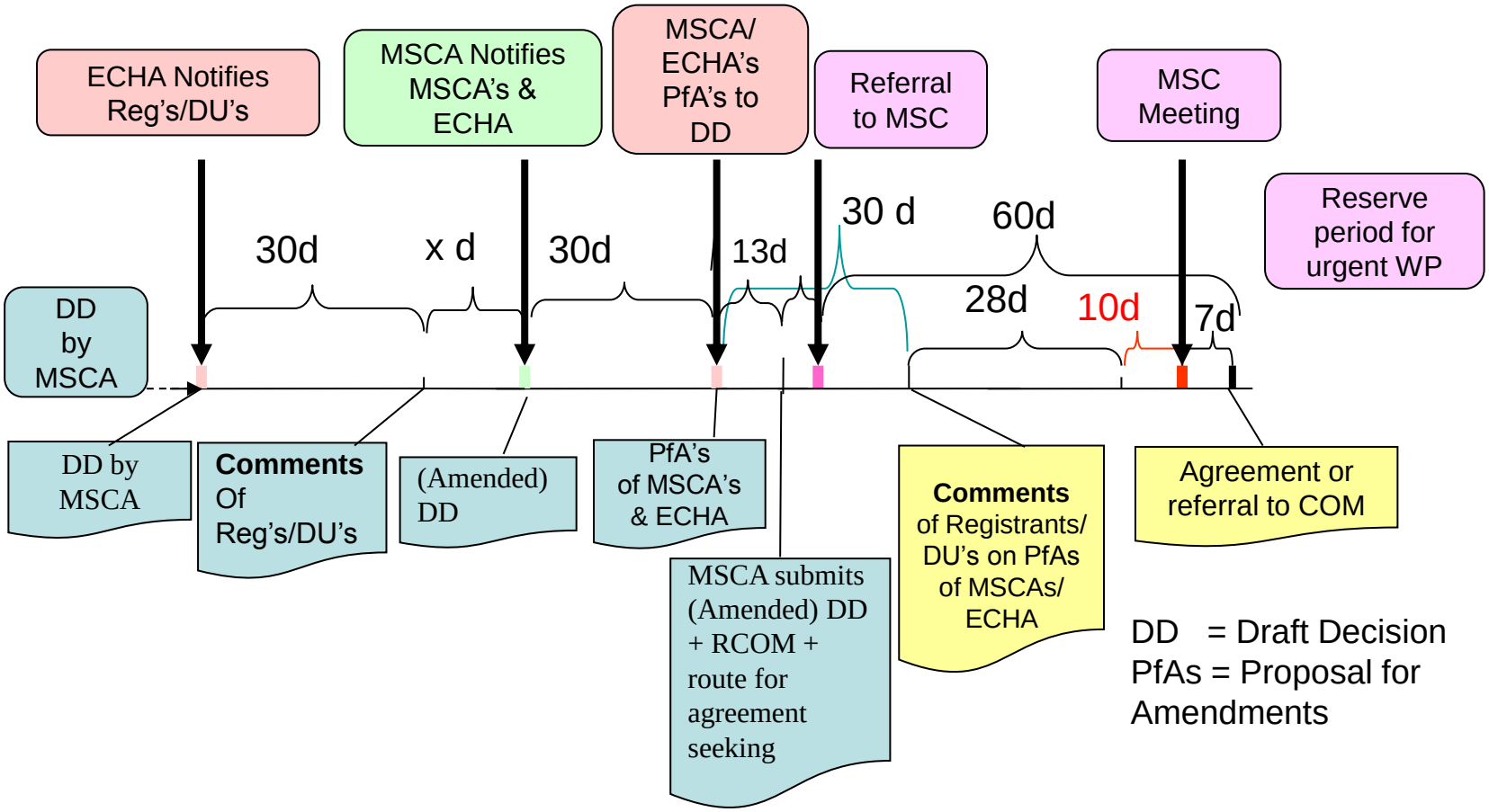
- Writing formal letters (e.g. to ministries)
- Starting court cases during the evaluation
- Approach other Member States on the evaluation
- No coordination (if there are multiple registrants)
- Update the registration dossier without prior communication with and (if possible) agreement of the MS

After the evaluation

- Evaluating authority needs **more information** to conclude on the concern – or on any other concern identified during the evaluation
  - You will be notified of the draft decision by ECHA and can comment on it, in several stages

- If **no additional information** is needed: the evaluating authority will submit an evaluation report/conclusions to ECHA.
  - No other authority can propose a draft decision. However, a substance can be re-selected (if new information arises)

Everything explained in one graph…



A decision may…

…contain information requests that are non-standard

(tests not required at your tonnage level, tests according to non-EU guidelines, with specific adaptations, for degradation products or specific uses, etc.)

…contain information requests specific to your use

(multiple decisions, directed at individual registrants, usually in the case of CBI)

…have a specific time schedule or test order

Follow-up phase

- After issuance of the decision, the information should be delivered within the specified period
- Contact ECHA or the evaluating Member State if you have any questions
- After the final delivery, the eMSCA has 12 months to assess the data
- In some cases, a 2nd (3rd, …) decision can be proposed, other regulatory action or termination of the evaluation.

Selected again?

Yes, substances can be evaluated multiple times, if there is new information.

Previous evaluations under chemical substance legislation or evaluations under other schemes (EFSA, EMEA, UN, US, OECD…) do not prohibit a re-evaluation.

Things to take into account

- Substance evaluation is a process to clarify a possible concern. It is does not have any direct regulatory risk management consequences.
- Evaluating authorities are usually engaged in other activities – the time available for contacts is limited.
- A registration dossier should always be up to date. If you plan to make an update during the evaluation, please inform the authority
- If a concern can be lifted through an update, and this has been agreed, update the dossier within the agreed timeframe. Otherwise a decision will be drafted.

Additional information

ECHA's website contains a lot of information:
http://www.echa.europa.eu/web/guest/regulations/reach/evaluation/substance-evaluation

If your substance is to be evaluated:
Contact details of the Member State can be found in the CoRAP

Alternatively, ECHA's helpdesk or your national helpdesk can also assist:
http://echa.europa.eu/contact/helpdesk-contact-form

Thank you for your attention

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