Role of the registrant

What should every registrant know about Substance Evaluation?

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5 October 2012
Webinar

Substance in the (Draft) CoRAP

Community

Rolling

Action

Plan

Check the substances in the CoRAP

- First CoRAP was published 29 February 2012
- ECHA publishes annually update for the CoRAP
  - **A draft CoRAP** (proposal) will be published every autumn (**October**)
    - With the contact information of the volunteering MS
  - The proposal is published only for information, not for public consultation
  - ECHA Member State Committee will give an opinion on the proposal
  - **The CoRAP update (final)** published in spring next year (**March**) on ECHA website.

Check on ECHA website if your substance is proposed and finally adopted to be included in the CoRAP.

What does it mean if my substance is in the CoRAP? (1)

- Substance in the **first year** of the CoRAP update – the evaluation **starts** at the date of the publication of the CoRAP by the nominated Member State.
- Substance in the **second or third year** of the list - the substance evaluation **is planned** to start later and is subject to the next CoRAP update.
  - e.g. the substances now in the second year will become the substances of the first year. Again, publication of that future CoRAP update determines the date the evaluation starts.
- Listing in the CoRAP does not affect the **current uses** of the substance.

First year substances – time is very limited

Second & third year substances – there is more time to coordinate

Coordination among registrants of the same substance

What to do if my substance is in the CoRAP?(1)

- The Member State cannot interact with all registrants
- Start **coordinating** with other registrants of the substance when the substance is tentatively proposed for the CoRAP (Draft CoRAP update). For the purpose of:
  - Interacting with the evaluating MS
  - Commenting and communicating in the decision making process, if needed (submission of comments on any possible Draft Decision and authorities' proposals for amendments on the Draft Decision, and participation in the Member State Committee)
  - Producing the information subject to request on behalf of all the registrants
- The coordinator can be any of the registrants; please make the entity known to the evaluating MS

Appoint one registrant as the coordinator!

What to do if my substance is in the CoRAP?(2)

- Make contact early with the evaluating MS
  - Especially, if you have questions, please contact the evaluating MS
  - The dialogue can be useful to clarify the initial concern identified
  - Contact information is available in the draft CoRAP and in the final adopted CoRAP
- Usually the evaluating MS will contact the lead registrant and offer the opportunity to meet to discuss technical issues related to Substance Evaluation (in the beginning of the evaluation, in case registrant has not made contact)

Coordinator, have early contacts with the relevant Member State (first year substances!)

Compliance check request prior to SEv

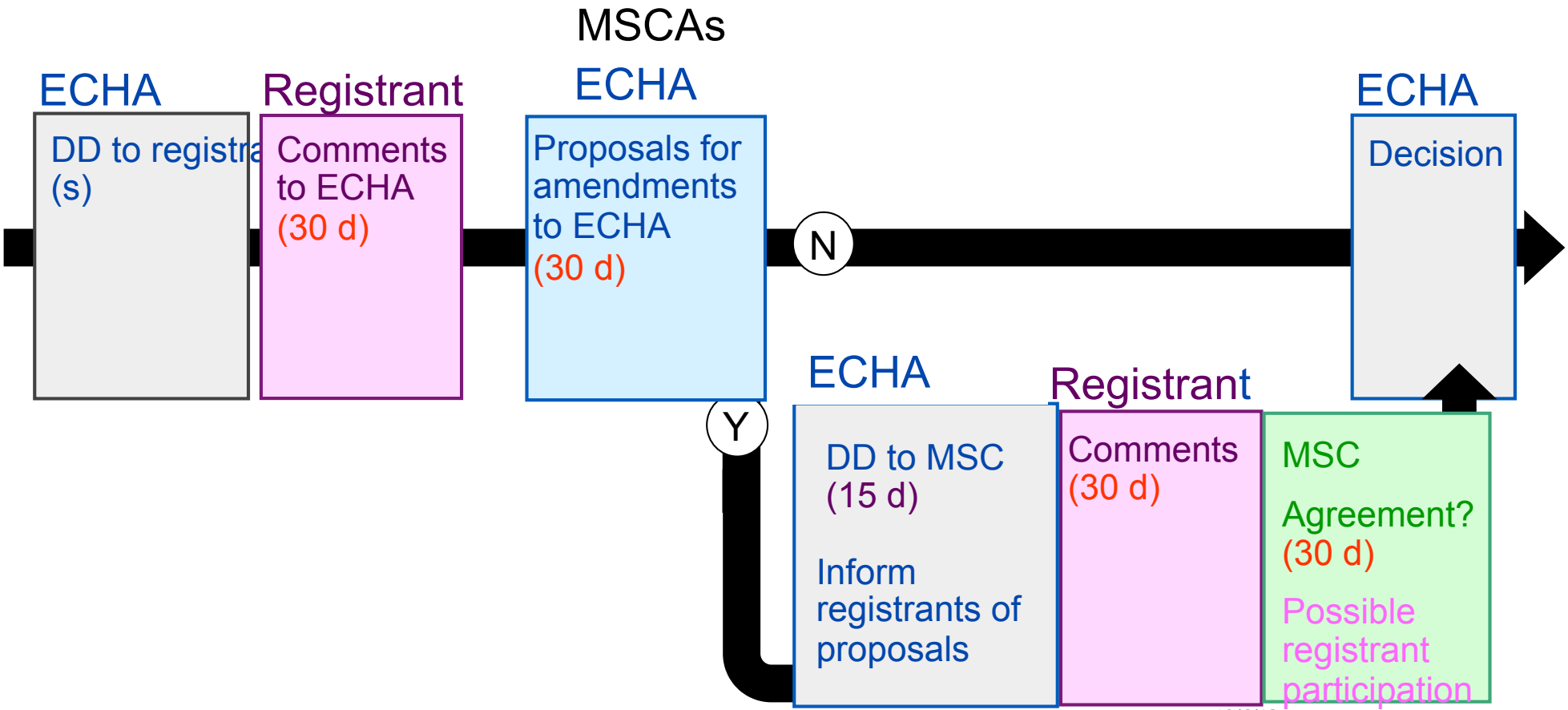
- ECHA has started a number of compliance checks on substances in the first CoRAP (years 2013 -2014)
  - Mostly on lead registration dossiers and opt-outs
- If clear data gaps are noticed, ECHA issues a CC draft decision
  - Substance identity
  - The evaluating MS is informed and consulted to avoid duplication of work
- The idea is to have the necessary information available when substance evaluation starts

You may first receive a compliance check decision on your CoRAP substance. Then submit the data asap.

Key steps in the prodecure if data are requested

Decision-making scheme

In case of disagreement in the MSC, the Commission takes the decision.



When can the first results of the evaluation be expected?

- The evaluating MS has to issue a Draft Decision (DD) within **12 months** from the start of the evaluation i.e. from the publication date of the CoRAP update.
- The MS sends the DD first to ECHA
- ECHA in turn, without undue delay (normally within four weeks), sends the DD for registrants' comments
- The same DD is normally addressed to all registrants
- In some cases, only some registrants are concerned, e.g. information on specific uses
- If confidentiality business information is involved, different DDs may need to be addressed to each registrant

Formal decision making in case of a Draft Decision (1)

- ECHA sends any Draft Decision via REACH-IT to **all relevant registrants** of the same substance for their comments
- Also, if other MSs or ECHA proposes **amendments** to the DD, all the registrants are notified of this and they can make comments on the proposed amendments
- **Speak with one voice**: Coordinate your views and submit one set of comments, if possible
  - Instructions for submission of comments will be in the notification letter
- All commenting periods last 30 days

Formal decision making in case of a Draft Decision - MSC (2)

- ECHA's Member State Committee (MSC) is only involved if **proposals for amendments** on the DD are made
- MSC will discuss only those aspects subject to proposals from the authorities
- There may be an opportunity to send a representative to the MSC meeting upon MSC secretariat's invitation
- For organisational reasons the number of participants is limited; normally ECHA would invite the coordinator who has submitted the comments

Speak with one voice, if possible.

Submission of new information

Final decision

- Final decision has a **deadline** by which the information must be submitted.
- ECHA sends the final decision to **all relevant registrants.**
- Registrants must decide **who performs the studies** on behalf of others within **90 days** of the date of the decision and inform ECHA of this.
  - Otherwise ECHA will designate one of the registrants to take this responsibility.
- Agree on cost- and data sharing. All registrants should have a copy of the full study report.

Agree who performs the tests.

Dossier updates – at the end of the process

- **All** registrants must update their dossiers **with the requested information by the deadline** which is mentioned in the final decision

- Evaluating MSs never update dossiers for you, dossier update remains the responsibility of the registrant
  - MSs submit their own SEv-IUCLID-dossier to ECHA

Dossier updates – during evaluation?

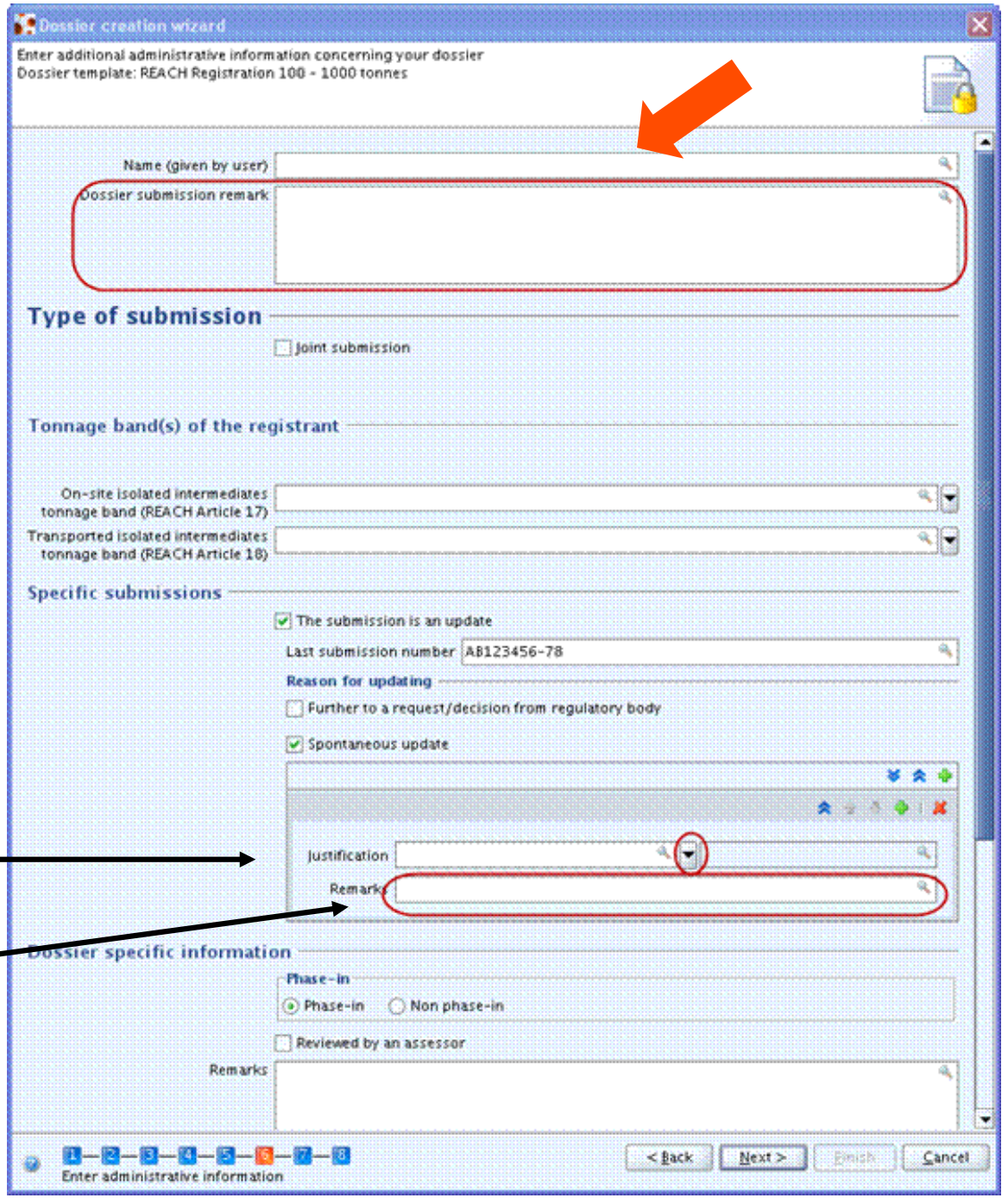
- Inclusion of a substance in the CoRAP, should not alone induce a need for a dossier update
  - If you need to make an update, do it **before the evaluation starts**!
  - MSs may have difficulties to take into account late dossier updates; if during the evaluation you need to make an update, **discuss** this with the MS to gain common understanding of whether the MS is able to consider this new information in its assessment
- Discuss any planned testing with the evaluating MS especially concerning **first** year substances.
- The evaluating MS will identify any further information needs and prepare SEv DD so that there should not be a need for submission of a testing proposal. (Assumption is that dossiers are compliant and a TP would have already been submitted if considered necessary by the registrant)

Instruction to flag dossier update

Two places where to flag the type of submission; at least the lower one should be used.

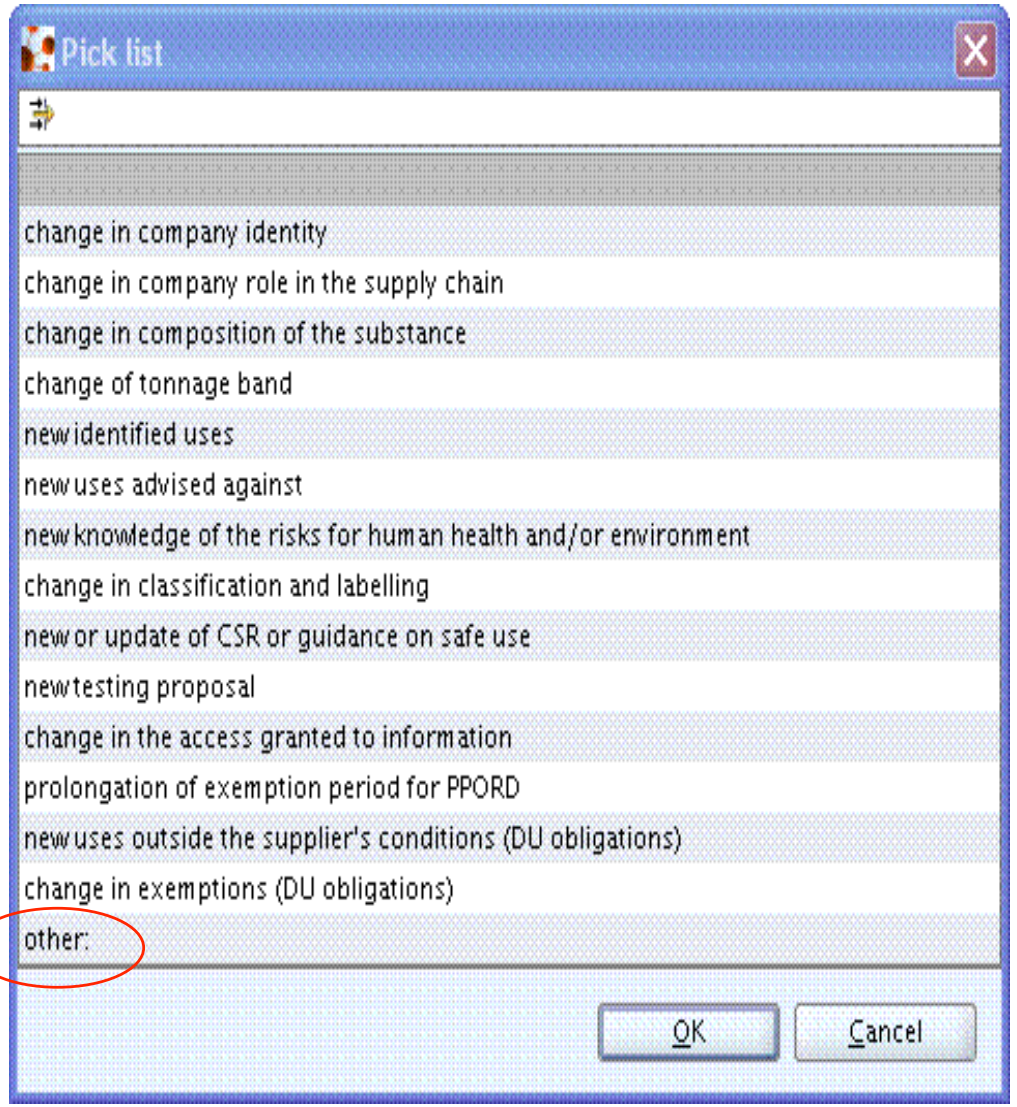
See the pick list next slide

”relevant for on-going Substance Evaluation”



Instruction to flag dossier update

Include an explanation in the adjacent field + enter text under 'remarks'



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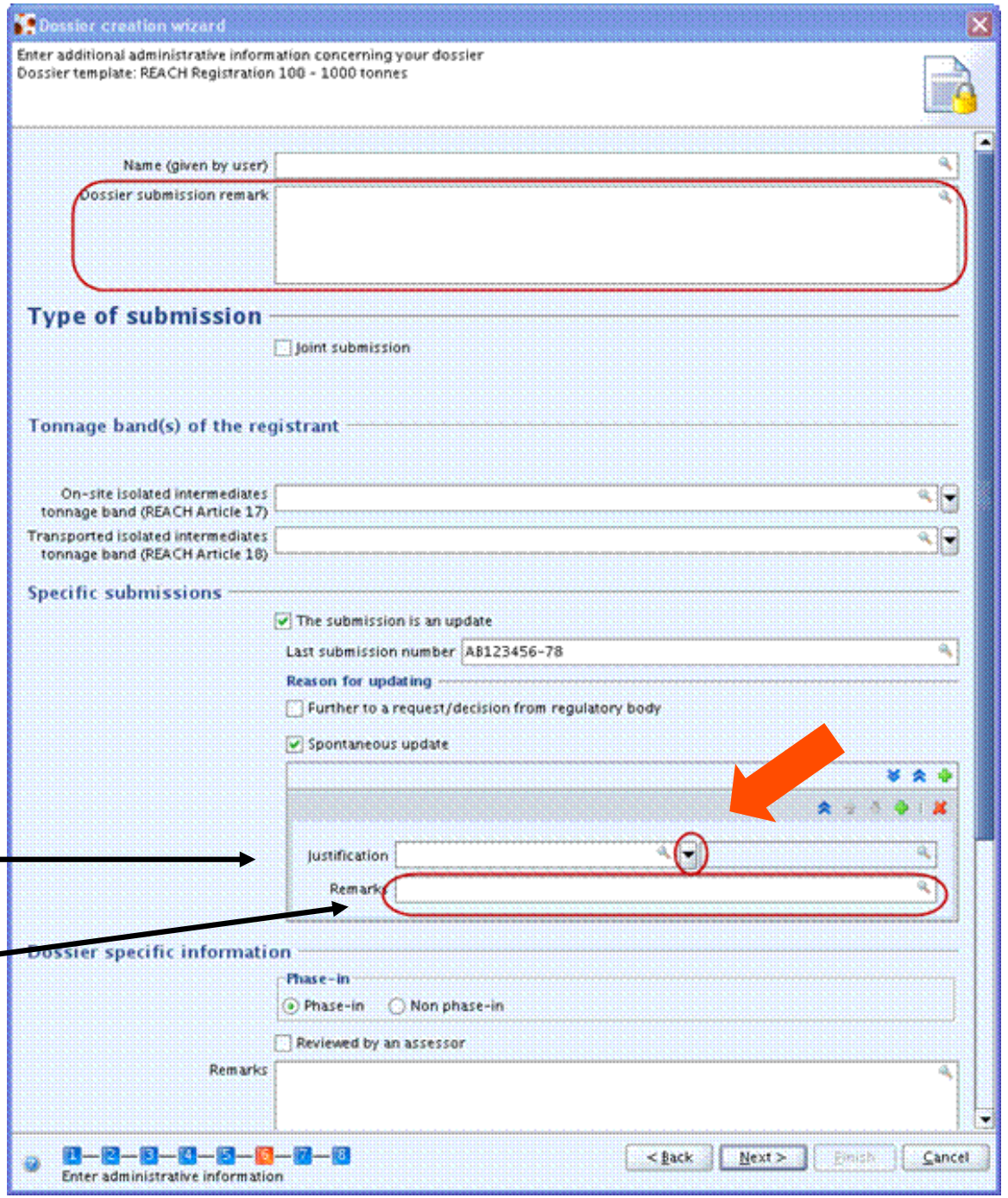


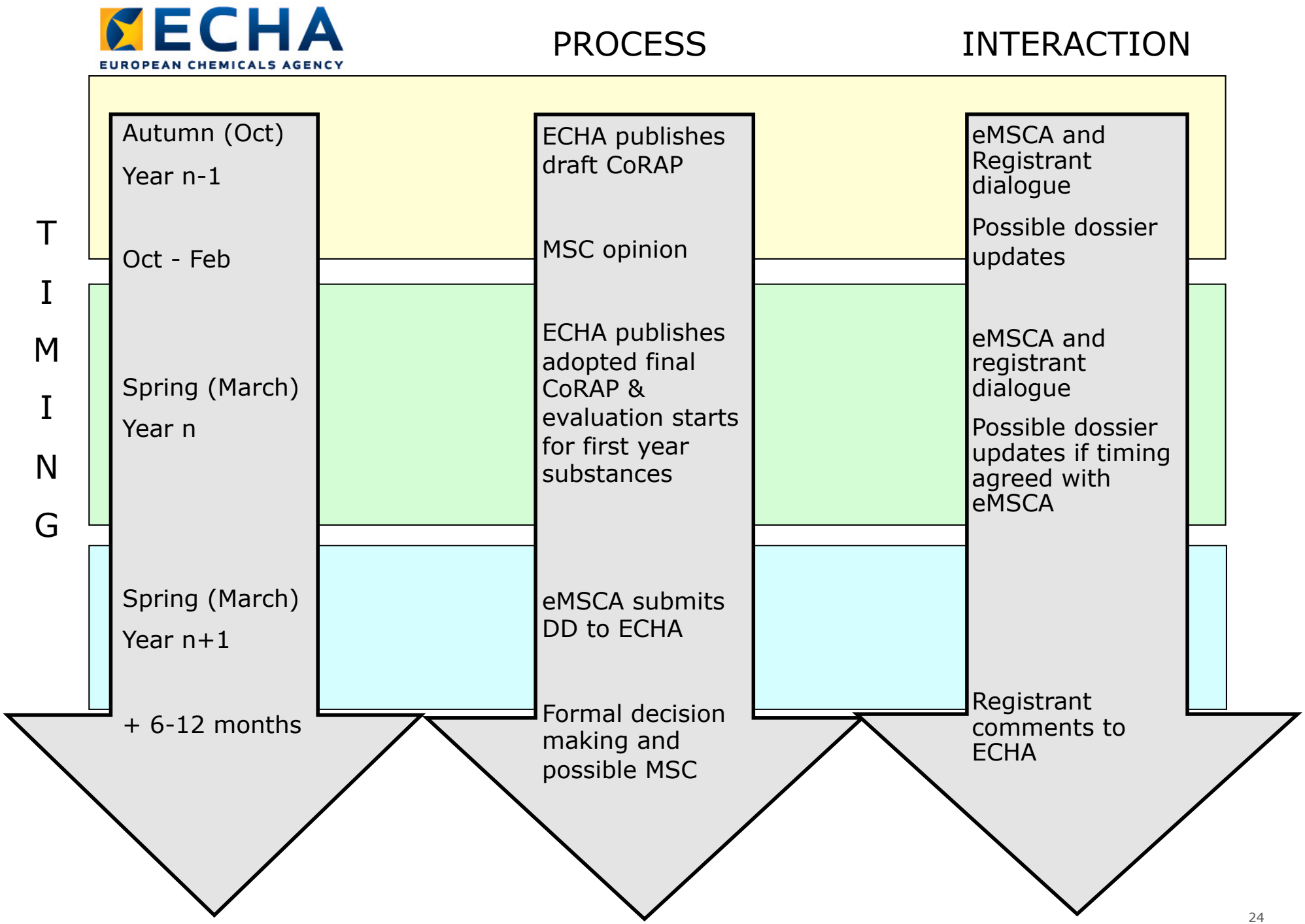
What else should the registrants be aware of?

Other SEv outcomes

- Unconfidential part of the decision will be published on ECHA's website.
- Once the evaluation is finished the evaluating MS will finalise a substance evaluation report and conclude on the basis of all available information if any further, separate, actions are needed such as:
  - Proposals for harmonised classification and labelling
  - Proposals for restrictions or identification as an SVHC
- ECHA will inform the registrants, other MSs and Commission of the overall conclusions. The SEv report will also be published on ECHA's website.

Registrants should take note of the finalised report and reflect it in their registration dossiers.

Summary


ECHA
EUROPEAN CHEMICALS AGENCY
PROCESS
INTERACTION
TIMING
Autumn (Oct)
Year n-1
Oct - Feb
Spring (March)
Year n
Spring (March)
Year n+1
+ 6-12 months
ECHA publishes draft CoRAP
MSC opinion
ECHA publishes adopted final CoRAP & evaluation starts for first year substances
eMSCA submits DD to ECHA
Formal decision making and possible MSC
eMSCA and Registrant dialogue
Possible dossier updates
eMSCA and registrant dialogue
Possible dossier updates if timing agreed with eMSCA
Registrant comments to ECHA

Conclusion

- Coordinate your actions towards the evaluating Member State & ECHA – nominate a representative
- Speak with one voice while providing the formal comments
- Time for relevant dossier updates is before the evaluation of your substance officially starts
- Respect the deadlines
- A leaflet about these tips will soon be published on ECHA's website

Thank you

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