2018 shortlisting letter campaign to industry: scope and expected outcome

Webinar: how are substances shortlisted and manually screened?

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Letter campaign on shortlisted substances

Main objectives of the letters campaign on short-listed substances

- **Increase ECHA's transparency** and inform REGs of shortlisting, i.e. substances are under authorities' scrutiny

- Give registrants the possibility to clarify in particular the suspected hazard(s) and use profile of their substances when necessary

- Invite REGs to update and improve the quality of dossiers early enough before substances are selected for REACH/CLP processes

Statistics and overview of updates

- From experience in previous rounds, dossiers are updated for approximately 40% of substances within ~4 months (towards the end of manual screening)

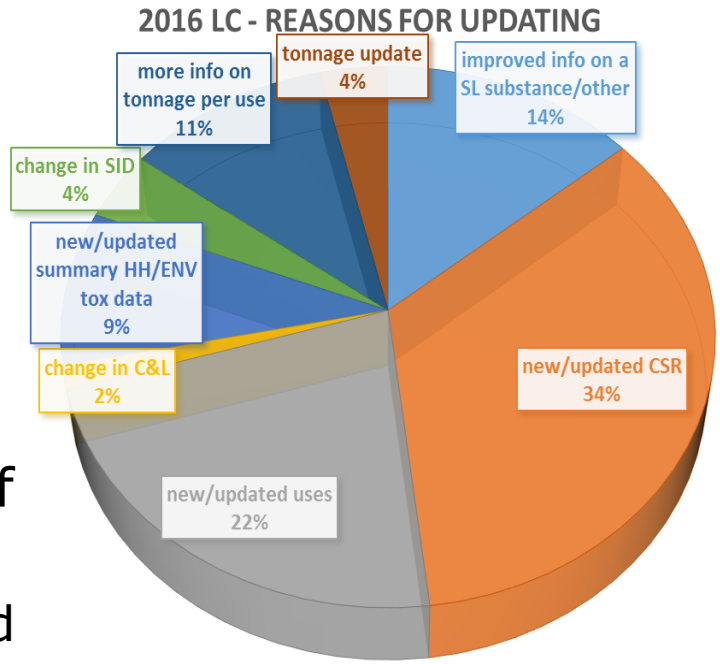
- A report monitoring the updates is shared with the MSCAs monthly
  - Even if the update is done after the end of manual screening MSCAs will take this information into account in the follow up processes

- Updates received after the end of the manual screening will be valuable if/when further regulatory action starts

Main reasons for updating

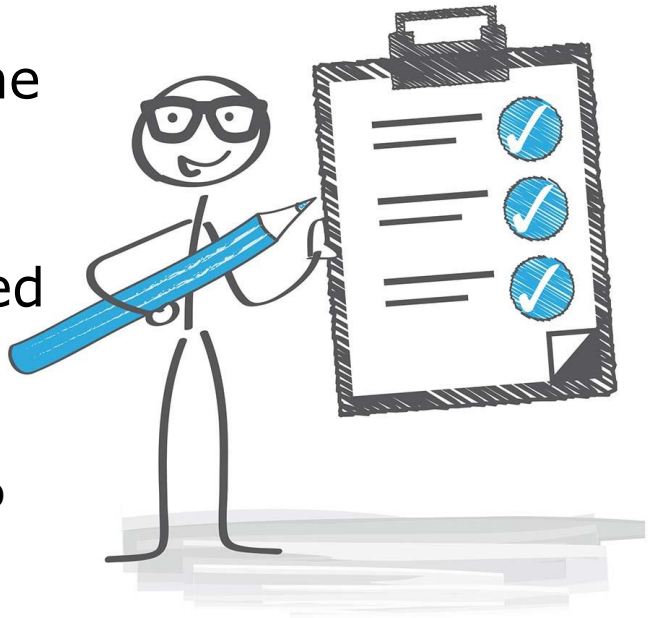
- Majority of updates seem to be related to improved info on uses/exposure
  - Lower number of updates based on improved info on hazards

- Most substances go for generation of further data (SEv, CCH)
  - Very few testing proposals submitted
  - ➢ If you identify the need to generate data you can act now to clarify the hazards and improve your dossier (e.g. Testing proposal)



Industry's feedback

- Registrants have appreciated ECHA's transparency and the campaign
- Many registrants have considered the need to clarify and improve their dossiers
- Dossier updates have been submitted however:
  - timing of letters-sending not optimal
  - content of letters 'too generic', difficult to link the concern identified to the substance
  - not clear deadline for updating or too tight deadlines



Letter campaign 2018 – main improvements

- ***More targeted letters*** – even more information on the reasons for shortlisting and grouping is provided
  - Group members are all listed in an annex to the letter
- ***Increased predictability and transparency this year*** –
  - All shortlisted substances have been addressed (individual substances, groups' seeds and members).
    - This includes those being already on Candidate List, CoRAP for transparency
  - Letters have been sent to all REGs (Lead and members in JS and individual REGs)
- ***Timeline for updating*** - Tight deadline, however…
  - a report monitoring the updates is shared with the MSCAs monthly
  - updates received after the manual screening will still be valuable if/when further regulatory action starts

How can you influence the outcome of manual screening?

Common screening approach

- to identify substances of concern

- Selection of substances based on a combination of **(potential) hazard** information and **use/exposure information**

- **Priority** for regulatory action is given to those substances having:

  *A high tonnage for **wide dispersive uses** within the scope of regulatory action (Substance Evaluation, Classification and Labelling, authorisation, restriction)*

- What does that mean?

Definition of wide dispersive use

- **Wide dispersive:**
  - ***widespread*** (used at many sites, by many users) and
  - ***potential for release to environment*** and/or ***potential for human exposure***

- See also R12 Guidance and Screening Definition Document

What does it mean for screening?

- A substance (potentially) hazardous with high tonnage for wide dispersive uses within the scope of regulatory action will be **prioritised** for further regulatory work

- But also that the following (potentially) hazardous substances will be parked for the time being (**low priority**):
  - Substances with no wide dispersive uses
  - Substances with no uses in the scope of regulatory action (Substance Evaluation, Classification and Labelling, authorisation, restriction)

Review of your dossier: hazard information and read across/category justification

- Updated information on potential hazard(s) could influence the manual screening and further regulatory actions

- **Hazard**. Look critically into your data and the potential hazard(s) indicated in the letter
  - Is there a risk uncovered?
  - Is your data robust enough (validity of study/WoE/RA) to clarify this potential risk?
  - Strengthen your reasoning or make a Testing Proposal

- **Read across and category justification**
  - A rough grouping of substances is done at the level of screening
  - Improved information will help to clarify whether the group holds

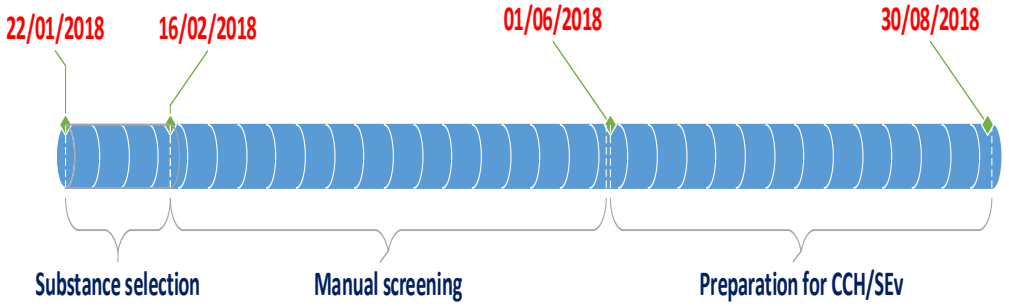
Review of your dossier: uses information

- **Uses.** ECHA advises you to:
  - review if the uses are still up to date
  - provide, to the extent possible, the tonnage per use
  - ensure uses are described using a sufficiently informative use name
  - cover the whole life-cycle of the substance

- Updated info on uses could influence the manual screening outcome and also the follow up processes
  - Resources from both authorities and industry should focus on those substances that matter for which uses are of relevance from a regulatory risk management perspective

Next steps

Next steps



- Shortlist opened for booking now and manual screening to start 16 February 2018
- Up-to-date information will help the Member State authorities to better assess whether the concern indicated by the screening is confirmed, and whether regulatory action is still needed
- Consider updating your dossier:
  - Preferably by the end of May (e,.g. on uses and exposure information) to ensure prioritisation of substances is done on the right substances for both selection of substances for the next CoRAP and for compliance check
  - Consider updating your dossier in any case to ensure the right information is available also later on for follow up processes

Additional information

In case of further questions with the common screening and the letter campaign, please consult:

- ECHA common screening webpage

https://echa.europa.eu/screening

- Updated definition document to support common screening

https://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf/e588a9f8-c55e-4412-a760-49ddbf7ac687

- FAQ on screening and shortlisting

https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Screening+of+substances+of+potential+concern

- This webinar material

https://echa.europa.eu/-/how-are-substances-shortlisted-and-manually-screened-

- Links provided in the annexes to the letters

Key messages

- Letter campaign informs you that your substance will be under scrutiny by Authorities
- Letter campaign gives you the possibility to clarify the potential hazard and use profile of your substances and also to best support Member states in understanding whether or not the group built in the context of screening can hold.
- Up to date and complete information might influence the MSCAs manual screening or any further process
- Review your dossier and consider updating it as soon as possible

Webinar agenda

How are substances screened and shortlisted?

11:00 – 12:00 Q&A session – *All*

- Questions and answers in writing
- Please send your questions until **11:30** at the latest
- Recurring issues will be addressed in the Q&A published on the ECHA website
- Link to the Q&A: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Screening+of+substances+of+potential+concern

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