2017 shortlisting letter campaign to industry: scope and expected outcome

ECHA Webinar - How are substances screened and shortlisted?

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ECHA, 14 February 2017

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Letter campaign on shortlisted substances

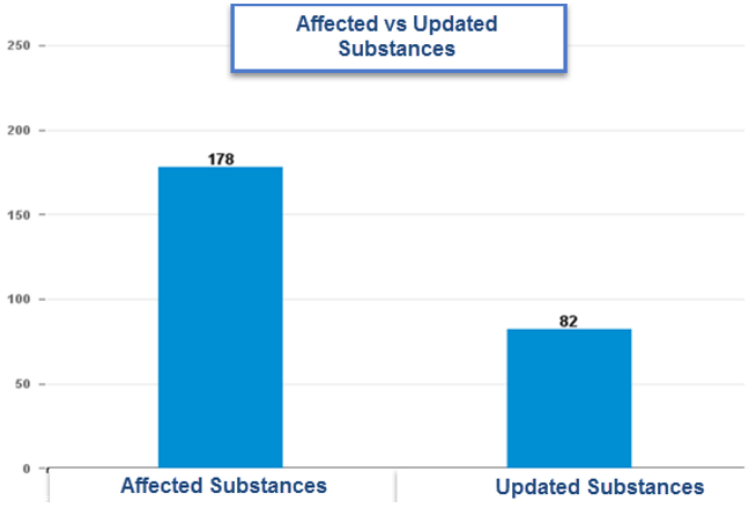
Aim of letter campaign

- Inform Registrants of shortlisting, i.e. substances are under authorities' scrutiny

- Invite Registrants to review the registration dossiers and update them before manual screening starts

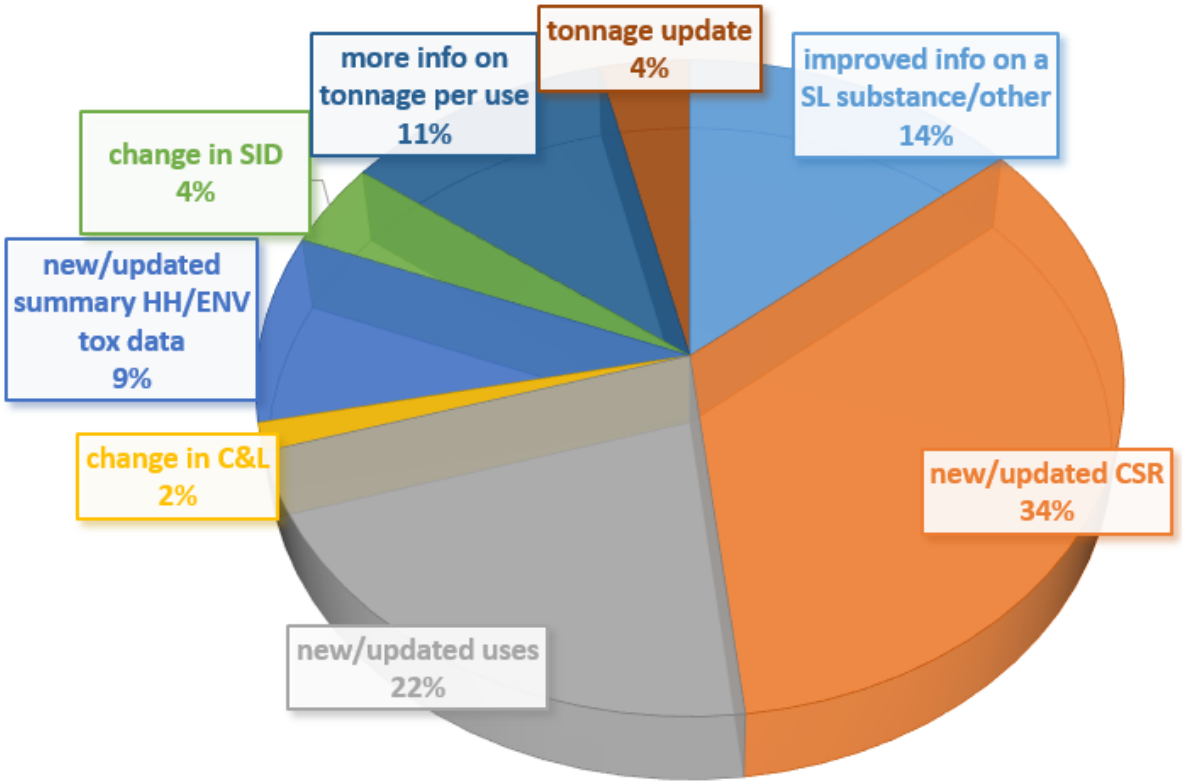
Statistics and overview of updates/1

- Dossiers updated for approximately 50% of substances within ~6 months
- A report monitoring the updates is shared with the MSCAs monthly
- Updates not received in time for manual screening will be valuable if/when further regulatory action starts



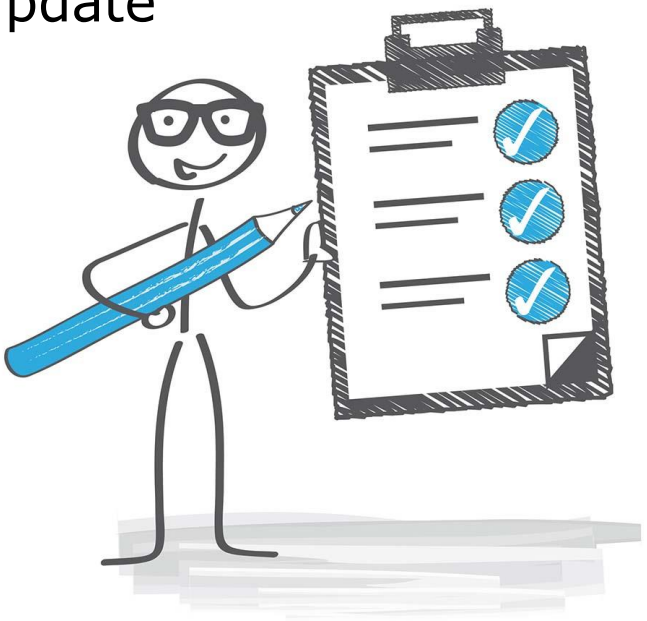
Statistics and overview of updates/2

2016 letter campaign: main reasons for updating



Industry's feedback

- Several Registrants appreciated ECHA's transparency, the campaign and submitted a dossier update



- First letter campaign (2015):
  - timing of letters-sending not optimal
  - content of letters 'too generic'
  - not clear deadline for updating

- Second letter campaign (2016):
  - timelines for dossier updating too tight
  - need to better understand the reasons for shortlisting

Letter campaign – main improvements

- ***Earlier letters-sending*** - same week shortlist is released to Member States
- ***More targeted letters*** - more information on the reasons for shortlisting is provided in the letters
  - Definition Document to be consulted for further information
- ***Timeline for updating*** - Tight deadline, however…
  - a report monitoring the updates is shared with the MSCAs monthly
  - updates not received in time for manual screening will be valuable if/when further regulatory action starts

Reasons for shortlisting and how you can influence the outcome of 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 shortlisting 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 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)

Current (mass) screening approach

- At present, no use-specific tonnage information available
- Potentially relatively high number of false positives and negatives
- E.g. two substances with similar overall tonnage

Substance A:

- Several intermediate uses, high tonnage
- One wide dispersive use, small tonnage

Substance B:

- One intermediate use, low tonnage
- Several wide dispersive uses, high tonnage

→ **Same priority** as no specific information on tonnage

Reasons for shortlisting: Definition document

- More information on the criteria applied could be found in a Definition Document uploaded on ECHA website. LINK:

  http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf

- Please consult this document if you have questions with the reasons why your substance was shortlisted!

Review of your dossier: hazard information

- Updated information on potential hazard(s) could influence the manual screening/further processes

- **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

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

Review of your dossier: uses information

to summarise

Report and/or update information in your registration dossier on tonnage, use and exposure information, in particular

- For substances (potentially) hazardous to human health (e.g. CMR, S, ED) and with most uses
  - exempted from REACH and CLP processes (e.g. intermediates) and/or
  - taking place under strictly controlled conditions and/or
  - taking place in a limited number of industrial sites
- For substances (potentially) hazardous to the environment (PBT, ED) and with most uses
  - exempted from REACH and CLP processes (e.g. intermediates) and/or
  - taking place under strictly controlled conditions

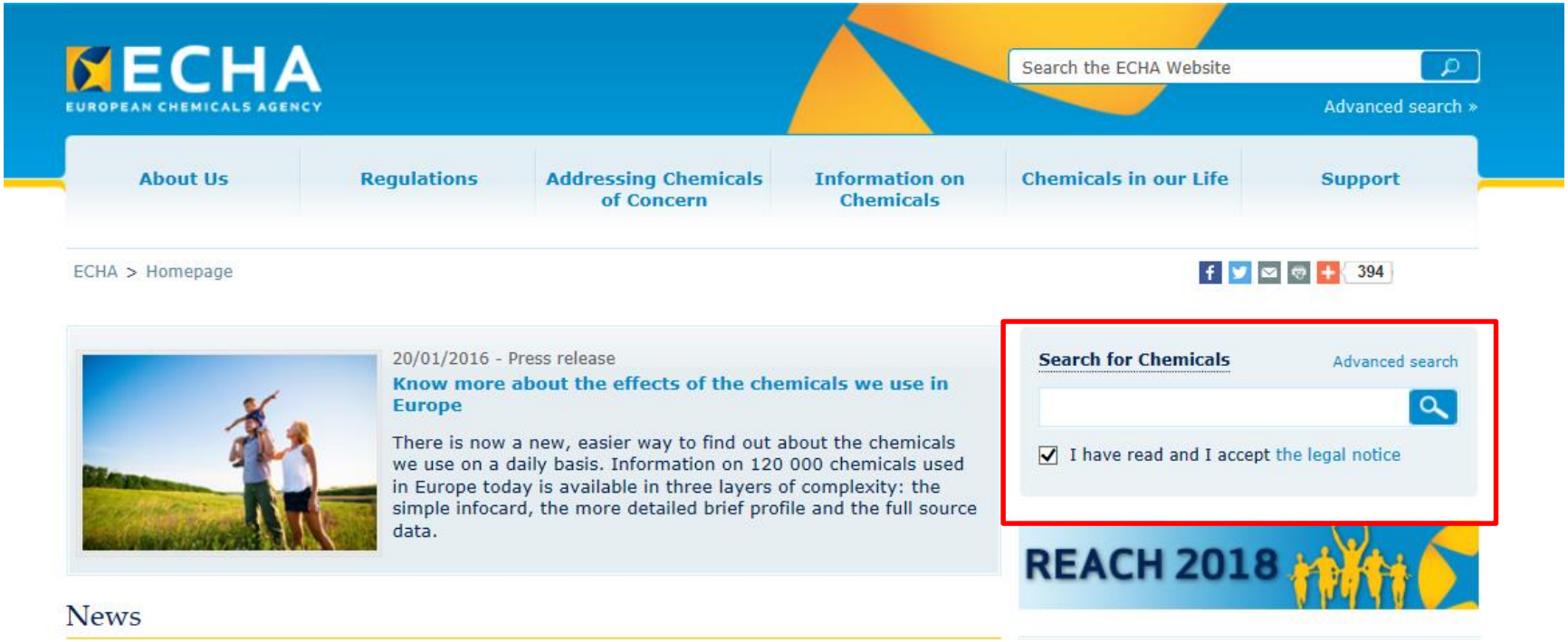
Expected outcome and next steps

Expected outcome and next steps/1

- Shortlist opened for booking on 27 January 2017 and manual screening to start 17 March 2017
- Up-to-date information will help the Member State authorities better assess whether the concern indicated by the screening is confirmed, and whether regulatory action is still needed
- Consider updating your dossier by 17 March 2017

Expected outcome and next steps/2

- Results of the manual screening is not communicated directly to industry
- Companies can check the status of their substance through the ***Search for chemicals*** available on ECHA's homepage.



Additional information

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

- ECHA common screening webpage

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

- Updated definition document to support common screening

http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf

- 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-screened-and-shortliste-1

- Links provided in the annexes to the letters

Conclusions

- Letter campaign gives you the possibility to clarify the potential hazard and use profile of your substances
- Up to date and complete information might influence the MSCAs manual screening or any further process
- Review your dossier and consider updating it **by 17 March**

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Webinar agenda

How are substances screened and shortlisted?

10:40 – 11:00 2017 shortlisting letter campaign to industry: scope and expected outcome

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- Aim of letter campaign, changes from previous campaign
- How registrants can influence the screening outcome by updating their dossiers

11:00 Q&A session – *All*

- Questions and answers in writing
- Please send your questions until 11:45 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