2016 SHORTLISTING LETTER CAMPAIGN TO INDUSTRY: SCOPE AND EXPECTED OUTCOME

ECHA Webinar - How are substances screened and shortlisted?

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  - Reasons for shortlisting
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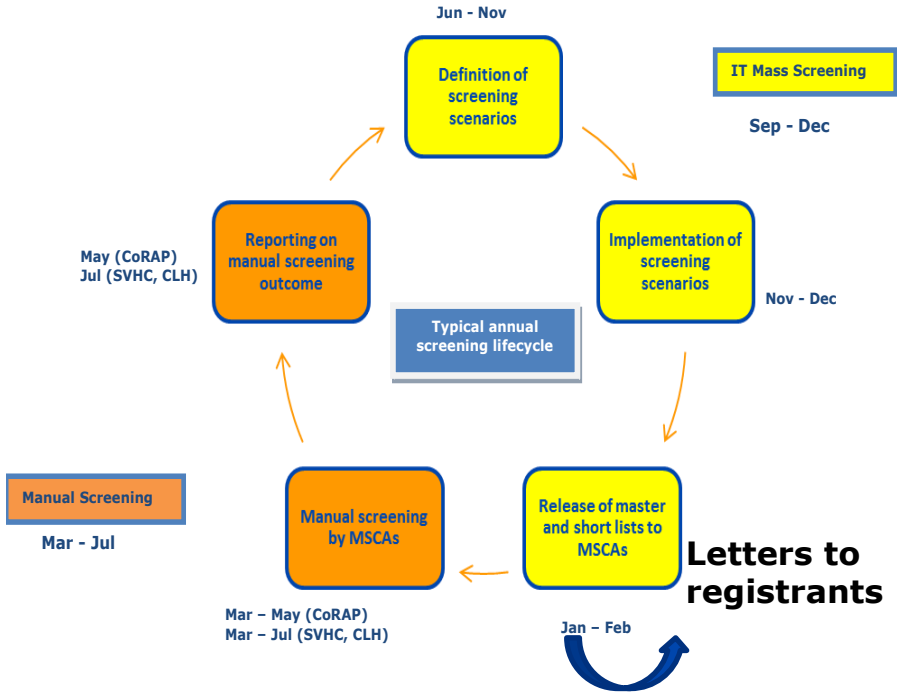
Shortlisting and aim of letter campaign

Shortlisting and letter campaigns

- **Round 1** → 2014 Shortlist
- **Round 2** → 2015 Shortlist → 1st Letter campaign (June 2015)
- **Round 3** → 2016 Shortlist → New letter campaign (January 2016)



Aim of letter campaign on shortlisted substances

- 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

2015 letter campaign: lessons learnt

Overview of 2015 letter campaign on shortlisted substances

- First letter campaign on shortlisted substances was launched last June for substances shortlisted last year

- Round 2 short listing letters covered the following:
  - Inform about shortlisting and invite to update
  - Provide only general information on reasons for shortlisting and uses/exposure
  - Provide general recommendation on Substance Identity and Read-Across

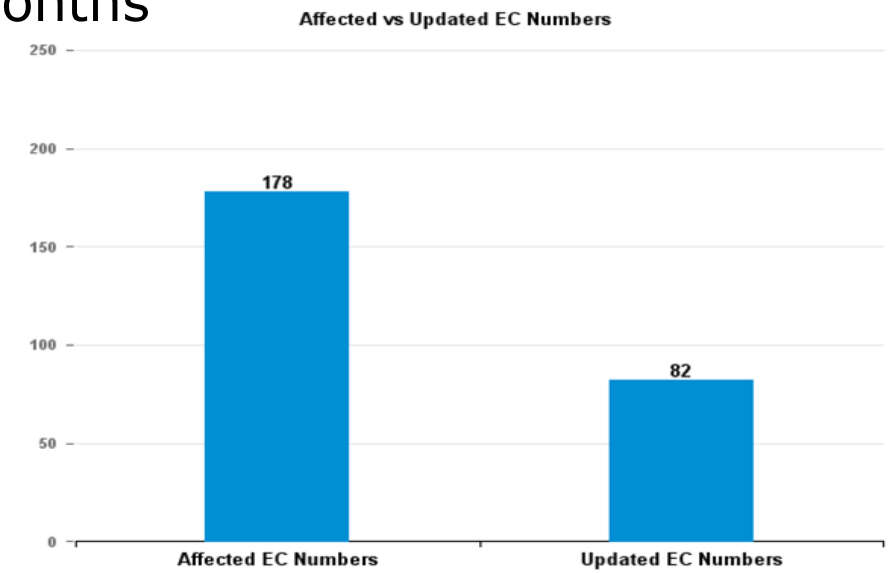
Industry feedback on 2015 letter campaign

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

- Helpdesk questions arrived to ECHA indicated
  - Time of 2015 letter campaign (June) not optimal
  - Letter 'too generic'
    - *General recommendation not very helpful*
    - *Reason for shortlisting too vague*
  - Timing for dossier update not specified
  - Influence of these informative letters with other on-going processes (e.g. CCH) unclear

Dossier monitoring for 2015 campaign

- 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 started
- Dossiers for approximately 50% of substances updated within 6 months



2016 letter campaign

2016 letter campaign: main changes

Based on the feedback received on the 2015 campaign ECHA improved the campaign by:

- Having the campaign earlier (same week shortlist was released to Member States)
- Having letters more targeted and with more information on the reasons for shortlisting, avoiding generic statements on potential hazard
- Indicating a timeline for dossier update with possibility to
  - update before the manual screening work starts
  - submit an update plan for updates requiring longer time
- Clarifying the interlinks of these informative letters with other processes (e.g. CCH)

Letters outline

- Company and Substance related information
- **Reason for shortlisting**
- General information on screening (useful links in Annex I)
- **Dossier updates and their timing**
- Invitation to review uses and tonnage per use and hazardous properties (useful info/links in Annex II)
- Clarification of interlinks of these informative letters with other processes

Reasons for shortlisting

Reasons for shortlisting/1

- Substances are shortlisted for further scrutiny by the Member State competent authorities because of their **potential hazards** and **use profile**
- ECHA has developed several scenarios to support this automated IT screening
- These scenarios include information in the dossiers as well as external sources, e.g. external lists, other regulatory programmes, QSAR predictions
- Single scenario are often not used in isolation but a combination of scenarios is often used to trigger shortlisting depending on the scenario reliability
  - e.g. scenarios based on external sources are combined with other evidence to trigger shortlisting

Reasons for shortlisting/2

- 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!

Examples of criteria triggering shortlisting

Reason for shortlisting: suspected ED

There is evidence in a registration indicating endocrine disruption effects in (eco)toxicological studies and the substance or a constituent is listed as (suspected) endocrine disruptor in external list(s)

- **ED effects**: ECHA used text search functionality for indications of potential ED related (adverse) effects in (eco)toxicological studies in the dossier

  AND

- **ED External lists**: Commission, WHO, TEDX, SIN list

This evidence is considered sufficient to trigger shortlisting as 'suspected ED'

- *initiating manual screening only requires an indication of potential risk and not absolute certainty!*
- *manual verification by MSCAs verifies the findings and increases confidence, if the concern is confirmed*

Reason for shortlisting: suspected sensitiser

The substance is classified as a respiratory sensitiser by at least one REACH registrant and does not have a harmonised classification for that hazard class

- This is considered enough to trigger shortlisting as 'suspected sensitiser' and a potential CLH candidate
- MSCAs will assess whether the classification is justified and whether it is due to the registered substance or e.g. due to an impurity or a minor constituent
  - If due to the composition, the variation of the composition across the JS will be assessed to determine whether the substance needs further regulatory actions or the concern arises from a minority of registrations that may need to be followed up separately

Dossier updates and their timing

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

- Updated info on uses could influence the manual screening/further processes

- **Uses.** ECHA advises you to ensure that:
  - review if the uses are still up to date
  - provide, to the extent possible, the tonnage per use
  - uses are described using a sufficiently informative use name
  - the whole life-cycle of the substance is covered
  - the uses described are assigned to the appropriate life-cycle stage
  - the uses can be linked to the relevant exposure scenario


same substance


same information

One Substance One Registration (OSOR) principle

Implications for dossier updates

- The implementation of the OSOR principle (one substance one registration) is on-going in REACH-IT
- You may be affected by this when you update your dossier
  - if you are a lead or a member in an existing joint submission you will be able to submit an update
    - …but remember that eventually there will be one JS for one substance and registration type → act proactively!
  - if you are an individual you are not allowed to update your dossier if there is a joint submission (of the same type, i.e. full vs. intermediate) → you need to join the JS
  - if you are an individual you are not allowed to update your dossier if you change your dossier type and there is another individual of the same type → you need to submit jointly
- For more information please see http://echa.europa.eu/view-article/-/journal_content/title/reach-it-is-back-up-echa-clarifies-criteria-for-one-substance-one-registration

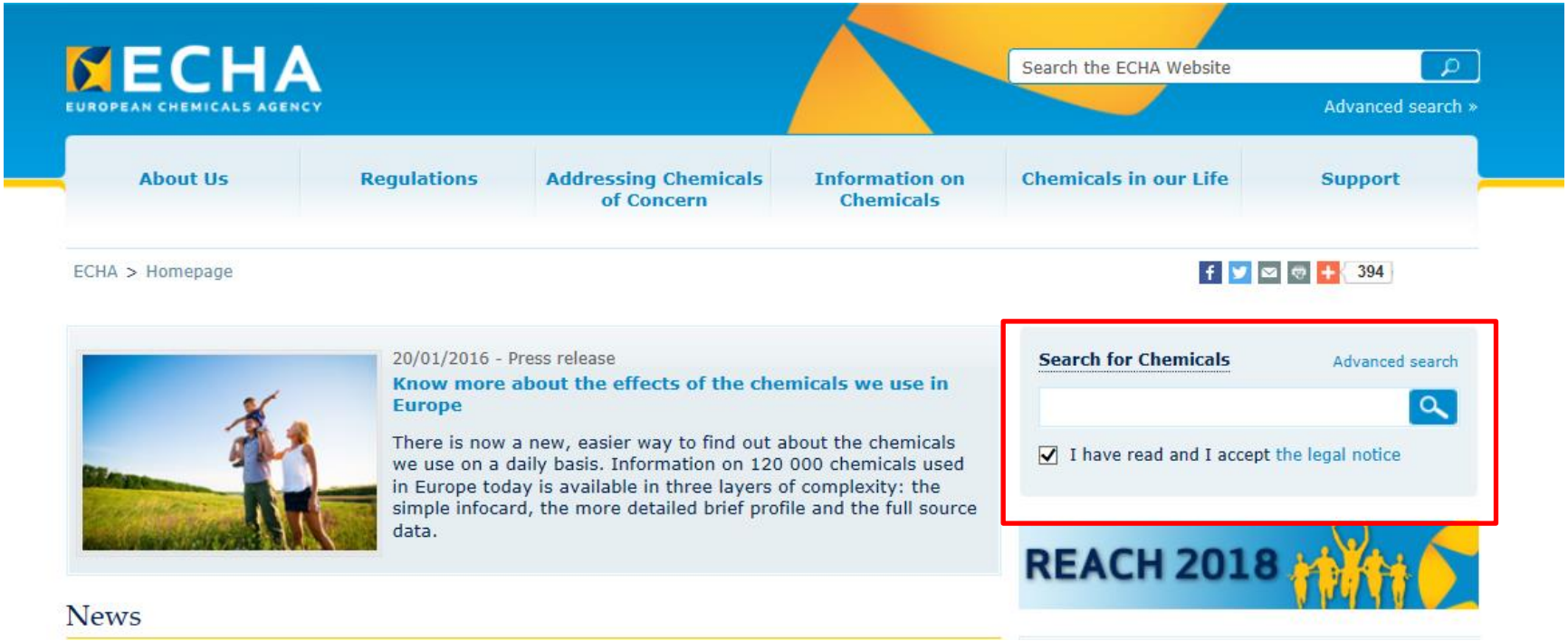
Expected outcome and next steps

Expected outcome and next steps/1

- Shortlist opened for booking on 25 January 2016 and manual screening to start 11 March 2016
- 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 11 March 2016 or submitting an update plan to ECHA (as indicated in the letter)

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.



Expected outcome and next steps/3

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

- The ECHA common screening webpage

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

- the new and updated definition document to support Round 3 of common screening

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

- Links reported in the annexes to the letter (repeated in the last two slides), this webinar material and the Q&A document ECHA will soon prepare

http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/how-are-substances-screened-and-shortlisted-

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 11 March**, or submit an update plan

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Additional info - useful links/1

- Substances of potential concern:

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

- Common screening approach

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

- Information on planned regulatory actions from the Public Activities Coordination Tool (PACT)

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

- Information on the Community Rolling Action Plan (CoRAP) list

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

- List of substances potentially subject to Compliance Check

https://echa.europa.eu/documents/10162/13628/substances_compliance_checks_en.pdf

Additional info - useful links/2

- Guidance on information requirements and chemical safety assessment, chapter R.12 on use description

http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

- Generic exemptions from the authorisation requirement

http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf

- Practical guide 16. How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID

http://echa.europa.eu/documents/10162/13655/pg16_intermediate_registration_en.pdf

- Non suitable use descriptors in the technical dossier of intermediates registered under Article 17 or 18 of the REACH Regulation. Annex II to the following document:

http://echa.europa.eu/documents/10162/13583/intermediate_status_scc_background_note_en.pdf