Frequently asked questions and answers

1) (Manual) screening process and timelines

Q: Does ECHA manually check the results of the IT screening?

A: ECHA validates and quality checks the IT algorithms but does not examine all individual findings one by one. The IT results for a selected substance are checked and validated by MSCAs during the manual verification phase.

Q: What is the timeline for manual screening?

A: ECHA released the shortlist of substances of potential concern in late January and Member States have until 11th March to select substances for manual verification. The manual verification can take from a few days to several weeks, depending on the complexity of the case. There are two deadlines for the Member States to finish their screening. If they wish to place the substance on the draft CoRAP list for next year, they need to submit their screening results by 31 May 2016. For all other substances, they need to submit their screening results by 31 July 2016. For more information on the screening process and timelines, please see the Common Screening Approach document (http://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf)

Q: Do MSCAs select substances from the shortlist or are they allocated? Can we know which MSCAs manually verify our substances?

A: MSCAs select their own substances from the shortlist and not all substances will be selected. We don't publish the outcome of the screening or the evaluating MSCA but whenever a regulatory activity is initiated on a substance, the Member State or Authority initiating the activity is published on our website, along with their contact details.

Q: Does ECHA consider other on-going REACH/CLP processes before shortlisting a substance for manual screening? Are substances with ongoing processes removed from the shortlist?

A: We check to see whether there are any ongoing activities with the substances before shortlisting. Depending on the nature of the process and the concern examined in these ongoing processes, we may exclude the substance from the shortlisting or inform the evaluating MSCA of the ongoing process.

Q: What is the difference between the shortlist for manual screening of substances of potential concern and the list of substances for potential compliance check (CCH)?

A: The shortlist for manual screening is only released once a year and aims at identifying candidates for several REACH and CLP processes such as substance evaluation (SEv), Authorisation and Harmonised Classification and Labelling (CLH). Member State Competent Authorities perform the screening. Compliance check can also be an outcome of manual screening. The list of potential candidates for CCH is updated several times a year and aims at identifying candidates with specific data gaps that can be addressed with CCH. ECHA performs the screening and it is ongoing throughout the year.

Q: We have sent a question to the ECHA helpdesk regarding a shortlisted substance. How long will it take to receive a reply?

A: ECHA aims to reply to all received helpdesk questions within 15 working days. We will try to reply to all received questions as soon as possible but depending on the number of questions received and the complexity of the reply, some questions may be delayed.

Q: There are additional explanations provided in the CSR, which are not noted in IUCLID. Will the CSR be carefully reviewed during the manual verification?

A: Yes, the CSR will be examined during the manual verification of the IT-screening.

Q: How is the outcome of the manual screening communicated to registrants? Will the registrant be informed in case of no action? How do Member States decide on the follow up actions?

A: the manual screening can result in the following outcome options:

- Candidate for substance evaluation (CoRAP Substance): in October each year the draft CoRAP is published on ECHA website (http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan). If the outcome of the manual screening was candidate for substance evaluation then the substance would appear in the draft CoRAP.
- Candidate for Further Regulatory Risk Management:
    - Risk Management Option Analysis (RMOA): if the outcome of the manual screening was RMOA then the substance will appear on the Public Activities Coordination Tool (PACT) available at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact
    - Proposal for Harmonised Classification and Labelling (CLH) at EU level: if the outcome was CLH proposal then once the Member States is ready to prepare the dossier the intention to do so will be available at http://echa.europa.eu/web/guest/registry-current-classification-and-labelling-intentions
    - Need for further assessment before the SVHC properties are confirmed and further regulatory risk management can be decided (e.g. the substance needs to be further assessed and discussed by the PBT or ED Expert Groups): if the outcome is further assessment and the need is to investigate PBT/ED properties then this information will be available on http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact
- Candidate for the compliance check (CCH) – Standard Information requirements are not fulfilled: if the outcome is CCH and the substance is considered of priority to ECHA then the substance would appear in the list of substances potentially subject to CCH (http://echa.europa.eu/regulations/reach/evaluation/compliance-checks)
- Need for other action (e.g. enforcement or action under other regulations)
- No need for further action.

In case the outcome of the manual screening would be no action the substance would not appear in any follow up action however this information is not made publicly available and is not communicated to registrants.

Please note that this is up to the Member States to decide on the outcome of the manual screening. In general if there is enough information to conclude that there is a concern then the immediate follow up would be RMOA or CLH. if there is a need first to generate additional information then either substance evaluation or compliance check would be selected by Member States.

We would recommend monitoring the ECHA dissemination on a regular basis to see if some further actions have been started on your substance (http://echa.europa.eu/information-on-chemicals).

Q: Can a substance enter one regulatory process (e.g. CoRAP, SVHC) without being screened (e.g. substance already with a harmonised classification and labelling, SVHC substance)?

A: At the level of manual screening not only consideration on hazard are looked at but also exposure and uses consideration should be taken into account in order to decide whether there is a need to initiate further regulatory action and which regulatory action needs to be initiated. However Member States can initiate regulatory action on any substance at any time so it is possible for a substance not to go via screening and go straight through RMOA (PACT listing) or regulatory risk management. Note though that there is a general agreement among member States to have first a RMOA done before proposing a substance for being identified as SVHC or to go through the restriction process.

Q: Can registrants propose to delete one substance from the short list?
A: It is not up to the registrant to decide whether one substance should be deleted or not from the short list. For a substance considered as not being hazardous and/or for which there is no need to go for further action based on uses and exposure information the outcome of the manual screening done by the Member States will most probably be no need for further action for the time being.

2) Use of in silico methods for the screening

Q: Which predictive tools are used for screening?
A: We use a variety of commercial and public predictive tools, such as the public tools OECD QSAR Toolbox (http://www.qsartoolbox.org/) and EPISUITE (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface). The tools are of various kinds, including classical QSAR models and predictive methods based on structural alerts. ECHA is not in position to publish the full set of tools used for screening, especially if they are commercial. We try to cover all major REACH endpoints, often with more than one tool, so that the tools can be used in combination in order to assess the consistency of the predictions. For certain endpoints, the model predictions are only used as supporting information to other hazard evidence, such as the listing of the substance in priority lists of non-governmental organisations.

Q: Is the quality of the predictions used in screening assessed?
A: The algorithms use applicability domain considerations when appropriate. Moreover, multiple models are often used in combination to be able to check their consistency. For models where the expected error may be larger, predictions are only used as supporting information to other findings, such as week/inconclusive evidence of hazard in experimental studies reported in the registration dossiers. The validity and relevance of all findings, including the model predictions are assessed by Member States during manual screening.

Q: Does ECHA carry out its own predictions or are you using the QSAR estimations in registration dossiers?
A: ECHA is independently running a suite of predictive tools but is also using the model results found in registration dossiers. The screening algorithms utilise all endpoint study records in the registration dossiers, but they give different weights depending on the reliability of the information provided. This is to ensure that good quality experimental studies have more weight compared with predicted results, although contradicting results are also identified for further investigation.

Q: Which structures does ECHA use to run predictions on?
A: Common screening uses an extended set of tools to generate molecular structures from the identifiers provided in registration dossiers and C&L notifications. The algorithms consider all registrations/notifications, all compositions and all reference substances in ECHA's databases. For each reference substance we utilise all identifiers provided, such as the CAS number, CAS name, IUPAC name, SMILES, InChI and synonyms. In this way, we can ensure that the algorithms are run on the broadest possible set of chemical structures associated with the registered substance. This means that the algorithms also generate predictions for minor constituents, impurities and additives, but their concentration and frequency of occurrence in the joint submission are used as criteria for short listing. ECHA is currently expanding its algorithms to better structurally represent UVCB substances. During manual screening, Member States examine the validity of the predictions, that on some occasions may be compromised due to the generation of erroneous structural information, e.g. when a registrant provides a synonyms that points to a molecular structure other than the constituent, impurity or additive indented to be included in the registration.

3) Screening for endocrine disruptors

Q: What are the criteria for endocrine disrupters? Considering that the criteria are under development now, why not wait for the final criteria?

A: Although there are no formal criteria for identification of EDs at the moment, under REACH EDs are identified case by case based on the WHO/IPCS definition. According to the recommendation of the EU Commission's Endocrine Disruptor Expert Advisory Group (ED EAG), factors such as severity, irreversibility, lead toxicity and potency can be considered to characterise the hazard potential of an endocrine disrupting substance, e.g. when assessing the relevance of a substance for consideration in regulatory terms.

Therefore, on the basis of the WHO/IPCS definition, it is possible to search for indications that a substance may be endocrine active and/or elicit adverse effects that are (potentially) mediated by endocrine modes of action and the lack of formal criteria is not a reason to postpone screening activities. For the purposes of screening it is sufficient if algorithms identify endocrine active substances although some scenarios provide suspicion of adverse effects potentially caused due to an ED mode of action. The substances will then be manually screened and any ED activity and/or adverse effects will be scrutinised. The common screening algorithms will be updated once the final criteria are available.

Please refer to the screening definition document for more details on our current approach in identifying potential ED substances in common screening algorithms.

Q: ECHA's letter indicates that the registered substance (or an impurity in it) may be an endocrine disrupter. How should this endpoint be addressed in the dossier, as it is not one of the standard endpoints?

A: Endocrine disruption may manifest itself in toxicological and ecotoxicological standard (in REACH Annexes) tests. As explained above, and in more detail in our definition document, common screening is looking for such evidence. Therefore, if there is a concern for ED properties based on the dossier, or external data, registrants might perform or propose further specialised in vitro or in vivo ED tests as necessary. The OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters lists the OECD Test Guidelines and standardized test methods available, under development or proposed that can be used to evaluate substances for endocrine disruption and could provide a guide to the tests for endocrine disrupters' assessment.

4) Use and relevance of lists, external sources and C&L Inventory for screening purposes

Q: Which sources of information is ECHA using in addition to the data in the registration dossiers?
A: The primary input to the common screening algorithms come from REACH registration dossiers. With regard to submitted data, common screening is also using the data in the C&L inventory, although more weight is given to classifications that are underpinned by test data in the registration dossiers. In addition to the submitted data in REACH dossiers and C&L notifications, the algorithms use external tools and databases to derive molecular structures from the chemical names and numerical identifiers, such as the CAS number and the EC number, when a structure cannot be directly derived from the SMILES and InChI information provided in the registration dossier. These structures are used to run predictions for fate and (eco) toxicological properties using models. Finally, the algorithms use external lists, such as the SIN list (http://chemsec.org/what-we-do/sin-list), and the assessments from other regulatory regimes, such as the IMAP programme (http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments) in Australia.

The different sources of information and how these are used are described in the definition document that is updated annually at http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening.

Q: Is ECHA examining all external sources of information for their validity and regulatory relevance?
A: The external sources used are carefully selected based on the available information, which includes discussion with the data providers, e.g. other regulatory authorities and non-governmental organisations. Nevertheless, ECHA is not in position to assess every individual entry in the external lists. ECHA provides to Member States all algorithm results that enables the Member State experts to verify the relevance of all findings before deciding on any required regulatory actions. If ECHA is in possession of additional information, such as toxicological assessment accompanying non-governmental substance priority lists, this information is provided to Member States.

Q: Are the external lists used in common screening referenced in the communication letters sent to industry?
A: ECHA is making every effort to provide as much information as possible in the communication letters. The letters sent in round 3 of common screening have been more customised compared to the letters in round 2. However, due to the high number of letters

and complexity, ECHA was not in position to list in the communication letters all technical information that led to short listing, such as the entry in the particular external list that was matched against a constituent, impurity or additive in the registration dossier. However, the external sources are listed in the definition document that can be consulted for more information.

Q : Why is the C&L Inventory used as part of the selection criteria in the IT screening when it is filled with unverified classification data?
A: The C&L Inventory is one of the sources used in identification of substances of potential concern as it represents an overview of how the substance is classified on the EU market. We take into account the number of notifiers behind each classification and the consistency of the notifications. Diverging classifications in the C&L Inventory can reveal disagreements among manufacturers and importers as to how to classify the substance, which might require regulatory action such as harmonised classification and labelling. The IT screening findings are manually checked by MSCAs during manual verification.

5) Use and Exposure related screening criteria

Q: Questions on clarification on the information used in the common screening when it comes to prioritisation based on uses and exposure information

A: the detailed description of the uses and exposure related screening criteria used to prioritise substances having a high tonnage in uses considered as being wide dispersive is available in the screening definition document available at http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf.

Note that IUCLID6 has been further enhanced from a use and exposure perspective also taking into account the needs from the screening by authorities. Registration information is the main source of information for screening and it is therefore important that this information is up to date. We are also using external sources of information as listed in the screening definition document to support registration information.

The aim of the screening is to prioritise those substances that matter and for which the need for regulatory action is expected in order to best use the resources of both authorities and industry. For instance a substance registered at 100 t/y for which 99t goes to intermediate uses and only 1t would go to wide dispersive uses would be of lower priority compared to a substance with same tonnage but for which 99t would go to wide dispersive uses. This highlights the fact that the following information are needed in order to best assign priorities to substances:

- Information on the scope of the regulatory status of the uses (e.g. intermediate use, biocide)
- Tonnage per use
- Level of containment to decide whether the substance has wide dispersive use or not.

Authorities are interested in those substances where the uses can be regulated by REACH. For each REACH process exemptions are available and documented both in the REACH regulation but also in the screening definition document.

It is also important to note that this information is used to set priorities among substances. The screening has so far considered as high priority those substances having wide dispersive uses (i.e professional, consumer and/or article service with potential for exposure to human or release to the environment). However industrial uses can also be considered wide dispersive and may be prioritised later on as described in the screening definition document.

Q: How to gather the information on uses and tonnages in the supply chain? What are the duties of registrants and downstream users?

A: The screening is done at the level of the substance and therefore considers information on uses coming from all registration dossiers for that substance.
As a consequence it is in the interest of all registrants to have up to date uses reflected in the registration dossier.
We are aware that it may be difficult to gather information on uses and tonnages per uses from downstream users in the supply chain. However, it should be clear to all that if some uses are relevant for further regulatory action the Member State will consider the substance for further action even though it may only be present in one member dossier.
It may be difficult and time consuming at the level of the manual screening to gather such information but it should be kept in mind that if the substance is moved to further action then there will be more time and more possibilities for exchange with the Member States and this information can still influence the outcome of the action envisaged for that substance.

In case of difficulty of communication with your downstream users we would encourage you to try to explain those considerations. In case of confidentiality it will potentially be easier for the downstream user to provide such information directly to the Member State in charge for instance of substance evaluation or RMOA. However it should be kept in mind that providing clarification on the uses as early as possible is in the interest of registrants, downstream users (DU) and authorities.

In addition, in ECHA's view a DU would not disclose confidential business information (CBI) if he breaks down the tonnage received from his supplier into generic type of use (possibly making reference to the cumulative tonnage fields in IUCLID 6:
- consumer uses
- widespread professional workers
- industrial use
- service life

Both lead registrants and co-registrants are responsible for updating the information in their registration dossiers.

6) Update of registration dossiers

Q: How does ECHA decide whether to inform a registrant of the shortlisting of a substance they registered? As a recipient of the letter informing of the shortlisting of my substance, should I update my registration?

A: For transparency, ECHA informs all the registrants of the shortlisting of a substance they registered. No differentiation is made between lead registrants, member registrants or individual registrants. No differentiation is also made between registrants at the level of the information they submitted separately.
You are not formally required to update your registration. However, if you consider that the information related to the reason for the shortlisting of the substance in your own registration is not up-to-date, ECHA recommends updating your dossier by the deadline specified in the letter you received. If the information to be updated is submitted jointly, the Lead registrant can update the registration he submitted on behalf of the co-registrants. The updated information will be taken into account during the manual screening carried out by the MSCAs or during any potential follow up regulatory action.

Q: The time between receipt of the letter and the date to update the dossier is quite short (1.5 months). This time is too short to understand why the substance has been selected (especially if it comes from external sources), review the full dossier and define the update to do with experts and co-registrants, particularly if more than one substance is implicated. Next time can the period between letter and update deadline be increased?

A; ECHA is aware of the short time between the receipt of the letters (26-28 January 2016) and the start of the manual screening work by the MSCAs (11 March 2016). For this reason the letters give two options regarding the possibility to update the registration's dossier:
(i) to update it by 11 March, i.e. the date when manual screening by the MSCAs will start or
(ii) to submit an update plan if this update will require longer time, e.g. because of the complexity of the update or the need for further discussion within a SIEF.

On a monthly basis, ECHA provides the MSCAs with a report with all the updates and update plans submitted. Therefore, if a substance is selected for manual screening, MSCAs will be informed about dossier updates or update plans as communicated by the Registrants. Please note that dossier updates not considered during the manual screening will be anyway valuable if the substance is selected for further regulatory processes as a result of this manual verification.

ECHA sent these information letters much earlier this year based on the feedback received for the first letters' campaign. Unfortunately, we cannot send the letters earlier than January because this is when the short list is finalised.

Q: What is the process that is followed when ECHA receives a dossier update plan?

A: On a monthly basis ECHA is sharing with the MSCAs a report with all the updates and update plans submitted for the shortlisted substances. Therefore, if a substance is selected for manual screening, MSCAs will be informed about dossier updates or updates plans as communicated by the Registrants.

Q: If a company submits an update timeline plan will this influence the timeline for the manual screening outcome and will there be direct communication with the company to advice if the update plan will be taken into account?

A: If the substance is selected for further scrutiny, the manual screening cannot be postponed and will be performed starting from 11 March 2016. However, MSCAs are informed on a monthly basis about the updates and update plans submitted for the shortlisted substances. Please note that dossier updates not considered during the manual screening will be anyway valuable if the substance is selected for further regulatory processes as a result of this manual verification. Unfortunately, no direct communication between the MSCAs and industry is foreseen for the screening process.

Q: is there a limit period to submit an updated plan?

A: There is no limit period to submit an updated plan. Of course the earlier the better since the MSCAs are informed on all updates and update plans during the manual screening (March to July 2016). Nonetheless, late updates/update plans are anyway valuable if the substance is selected for further regulatory processes as a result of this manual verification.

Q: If a registrant or group of registrants come to the conclusion that the dossiers are up-to-date and the concerned raised is sufficiently disproved, shall they still update

the dossier or communicate with ECHA? Is it possible to send a clarification letter with document (i.e. peer reviewed papers)?

A: The aim of the letter campaign for shortlisted substances is to inform Registrants of shortlisting and to invite them to review the related registration dossiers and consider to update them in particular for information on uses and tonnage per use and possibly on the potential hazard properties, as indicated in the letters, before the manual screening starts. However, if the Registrants are confident that the information in the dossiers is up-to-date then no action is needed. Registrants can also attach a clarification document/peer reviewed papers in an updated dossier if they wish so.

Q: The lead registrant updates the dossier for all registrants of the substance and indicates that he confirms the data of the dossier. In this case should this confirmation be filled in a remark field of the IUCLID dossier? Or each registrant should update its own dossier? Or each registrant answers to ECHA's letter?

A: Registration updates are only relevant if new/revised information is to be included. If the information in your registration is correct, you do not need to update your dossier or respond to the letter you received.

In case relevant new/revised information is to be included in a dossier submitted jointly, an update by the Lead Registrant is sufficient if this new/revised information is valid for all Registrants. However, if the new/revised information to be included in a dossier updated is members' specific (e.g. information on substance composition or on specific uses) than it could be that only certain members need to update their dossiers.

Q: What provision is made for problems with ECHA's IT systems hindering meeting a deadline outlined in a letter? I ask this because of recent problems with REACH-IT and other ECHA sites.

A: The deadline set in the letter for the 2016 shortlisted substances is the date when MSCAs may start the manual screening. It is important to clarify that these are informative letters, so there is no legal obligation to update registration dossiers. However, it is in the Registrants own interest to review their dossiers and ensure that information on potential hazard properties and uses is up-to-date. REACH-IT is not foreseen to be non-operational over a significant period of time until 11 March 2016, so please consider updating your dossier, if relevant, as soon as possible.

Q: Why is the timing for updating the dossiers in relation to Common Screening almost identical with the timing for updating the dossiers for potential CCH? This is causing resources constraints at registrants

A: To use resources efficiently candidates for potential CCH are screened continuously during the year but shortlisting is done only once per year in late January/early February. Therefore, only the current batch of potential CCH candidates overlaps with the shortlisted substances. Future batches of potential CCH candidates will be published later in the year and will not overlap with the shortlisted substances.

Q: It was recommended to wait with updating dossiers until the new IUCLID, why now requesting updating the dossiers?

A: The manual screening for round 3 will begin on 11 March 2016. It is advisable that dossiers for short listed substances are updated before this date in order to ensure that MSCAs have all

necessary information to carry out their manual assessment. Later updates will also be considered, but will not influence anymore the outcome of the manual screening by MSCAs.

7) General issues

Q: Where can I find an explanation for all the abbreviations used in substance screening?

A: An "ECHA-term" page is available from the front page of the ECHA website. Acronyms mentioned during the webinar presentation may not all be found there. We recommend you consult first the document entitled "a common screening approach for REACH and CLP processes". The document can be found at www.echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf-

Q: If in a given group of registrants, there are two very similar substances (same tonnage band, same hazard profile and the same registered uses). One of them was shortlisted and the other one was not. What could be the reason for that?

A: There are either minor differences (please see chapter 8 of the definition document) or only one substance was shortlisted due to MSCA resource constraints and the other one may be shortlisted next year. Also it could be that the other one has been or is currently already under scrutiny for the same or similar concern. We are looking into identifying similar substances and inform MSCAs to enhance efficiency in future rounds

Q: Will the webinar slides be available afterwards?

A: The presentations were published before the webinar and a video recording will be published together with this Q&A document with at http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/how-are-substances-screened-and-shortlisted-- However, this Q&A document does not contain all Q&As as some of the were case specific.

Q: In the letters the reason for shortlisting is quite wide. Could ECHA give more detailed information to the registrant why the substance was selected for the short list (e.g. QSAR tool used, which external list etc.)

A: The external sources or QSARs are provided in detail in the definition document http://echa.europa.eu/documents/10162/19126370/screening_definition_document_en.pdf It is advisable to consult this document if you have received a letter pointing to an external source or QSARs.