11 January 2019

Screening Definition Document

Methodology for identifying (groups of) potential substances of concern for (further) regulatory action

Round 6 of common screening

Contents

1 Integrated Regulatory Strategy: addressing groups of substances via common screening

ECHA has developed an integrated regulatory strategy based on the experience gained so far in implementing REACH and CLP regulatory processes. This strategy brings all the processes together to achieve the aims of these Regulations, as well as contributing to meeting the 2020 goals of the World Summit on Sustainable Development (WSSD).

In that context, ECHA has agreed, together with Member States and the Commission, to have a sufficient understanding of all substances registered above 100 tonnes by 2020. ECHA's ambition by 2020 is to have mapped the 'universe of registered substances' above 100 tonnes through a number of actions. The aim is to conclude for all these substances whether there is a need for specific action (i.e. data generation or regulatory risk management) or whether the substances are currently of low priority for further regulatory work. The decision to consider a substance as being of low priority for further regulatory work will be regularly reassessed, in particular when new information on the substance (e.g. on uses or hazards) becomes available.

One important element of this strategy is the common screening. Since 2013, together with the Member States, ECHA has developed a common screening process, which identifies (groups of) substances that have the greatest potential for adverse impacts on human health and the environment.

The common screening allows a conclusion to be reached on which substances need further data generation under compliance check and/or substance evaluation and which substances can be directly earmarked for EU level risk management measures.

Screening has evolved from identifying single substances to identification of groups of related substances. The concept of "grouping" similar substances is as such not new in the regulatory world. Grouping of similar substances can:

- enhance coherence of authorities' work through all steps from identification of substances of potential concern (screening), via further information generation (CCH, SEV, other means including direct contacts with industry) to regulatory risk management (CLH, SVHC identification and authorisation, restriction, but possibly also actions under other legislation),
- maximise the use of the available resources by avoiding overlaps/gaps of activities while providing transparency towards industry and supporting them to avoid regrettable substitution.

Working with groups of substances is for instance important to identify those substances, for which there is clearly less information available (e.g. only registration with intermediates uses or C&L notifications) but which could be potential substitutes to substances already identified for regulatory action (so called supplementary activities in the SVHC Roadmap Implementation Plan). The same applies for substances that are currently not on the EU market as such or in mixtures but may be imported in articles. Without a grouping approach those substances may not be identified early enough to avoid regrettable substitution.

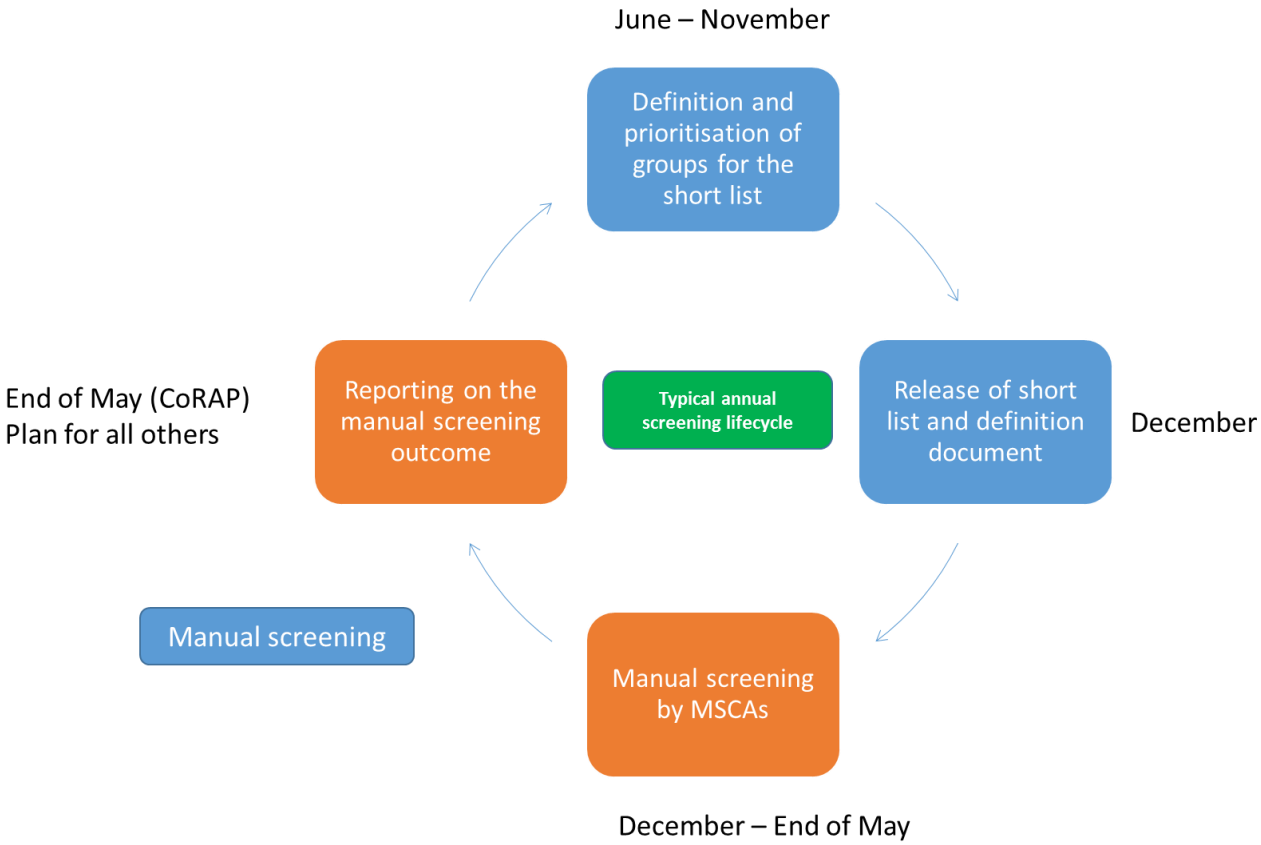
2 Manual screening of (groups of) substances and screening timelines

The manual screening of the (groups of) substances performed by Member States and ECHA can result in the following outcome:

- Compliance check under **Dossier Evaluation (CCH);**
- Community Rolling Action Plan (CoRAP) under **Substance Evaluation (SEv)**;
- **CLH – Harmonised classification and labelling** at EU level
- **RMOA – Regulatory Management Option Analysis** which may lead to the substances being proposed for further regulatory risk management measures under the REACH and CLP Regulations i.e.:
    - **Authorisation - Identification of Substances of Very High Concern (SVHC);**
    - **Restriction.**
- **Further assessment** – in particular for substances with potential PBT/vPvB and/or ED properties for which further discussion may be needed at the PBT and ED expert groups
- **Other action** – An action other than the ones listed above (outside REACH/CLP processes and activities) is needed (e.g. enforcement)
- **No action** – The substance is of low priority and there is no need for further action for the time being based on currently available information.
- **Pending action** – It is not possible to conclude on the (groups of) substances as some generation of data or assessment is ongoing and needs to be finalised before a conclusion can be reached.

Different members of the group can have different outcomes from screening. Member States will perform the manual screening of groups of substances where the focus is on those substances of potential concern for further regulatory risk management action. ECHA will focus on those substances where the outcome is expected to be compliance check.

The following figure provides the indicative timelines that are followed in a screening round.



3 Starting pool of substances

The starting pool of substances for all common screening activities comprises the approximately 130 000 substances in the C&L inventory[1] and, additionally, substances that have been notified under the Dangerous Substances Directive, but for which ECHA has not yet received an updated registration dossier or C&L notification[2].

The registrations and notifications that are screened fall under one of the categories described in Table 1.

Table 1: Categorisation of registrations/notifications

Group	Definition
REACH registrations	Registrations that are not associated with a prior notification under the Dangerous Substances Directive
Tonnage upgraded NONs	For these registrations ECHA has received a REACH dossier that contains higher information requirements compared

[1] Please note that all registrations are also included in the C&L inventory.
[2] In principle manufacturers or importers of such notified substances should have submitted a registration dossier with the GHS classification, but the algorithm does not rely on this and explicitly includes notified substances in the starting pool.

registrations	with the original notification due to a tonnage upgrade (detected using a conservative implementation with emphasis on the information requirements)
Updated NONs registrations	For these registrations ECHA has received a REACH dossier that has not increased the information requirements compared with what was needed under the Dangerous Substances Directive
Non-updated NONs registrations	For these registrations ECHA has not yet received a REACH dossier
Notifications in the C&L inventory	These are notifications in the C&L inventory submitted according to Article 39 of the CLP Regulation, that are not due to registrations (every registration is also a notification, but such registrations belong to one of the categories above)

4 Substance grouping

The grouping methodology used in priority setting is based on two broad methods, namely (i) structural similarity that uses the substance identity information in registration dossiers and C&L notifications and (ii) read-across/categories that uses the test material and category information in registration dossiers and category/read-across information in external sources. The two methods can be seen as complementary. It is expected that typically read-across/category arguments are built around substance pairs/groups that share common structural features, but do not necessarily include all substances that are structurally related and are known to Authorities because they are present in a registration or C&L notification. Both methods do not constitute validated read-across/category information because structural similarity alone may not be sufficient and because read-across/category arguments in registration dossiers are often not sufficiently robust. Nevertheless, they are both useful screening tools for grouping substances that will be subject to manual investigation at a later stage with the understanding that part of the manual investigation will also examine the reliability and relevance of the proposed substance grouping before this grouping is further utilised in subsequent regulatory processes.

4.1 Grouping based on structural similarity

The first step before grouping based on structural similarity is the generation of molecular structures by using all the identifiers, such as IUPAC name and CAS names, provided by the registrants in the IUCLID dossiers. The generated molecular structures form the basis for all similarity considerations in common screening. The way to achieve this is to generate the structural fingerprints of all molecular structures and then use these fingerprints to identify the structures that are closer to a given target structure by calculating the structural distance. The result of the similarity analysis is to identify EC number pairs that are structurally related.

4.2 Grouping based on read-across and categories

This method uses two major families of information sources:

- the test material identifiers in endpoint study records (one-to-one read across) and category objects in registration dossiers (registrant information)
- read-across and categories proposed by other regulatory Authorities, such as NICNAS[5], OECD[6] and HPVIS[7]

The method essentially collects "substance pair" information from all these sources. Category information in IUCLID dossiers is converted to substance pairs by enumerating all possible combinations. The directionality of read-across is not considered, i.e. the two substances are entered into the substance pair in random order regardless of which is the source and which is the target substance[8]. The information from the different sources is harmonised so that regardless of the original format it is converted to an internally consistent format suitable for further considerations. The framework is sufficiently generic to allow the utilisation of additional external category information as this becomes available. Two substances in registration dossiers or C&L notifications are then linked if they are the two members in one or more substance pair. The method allows to limit the substance pairs that are considered, e.g. to only consider certain information sources such as only one-to-one read across arguments in registration dossiers or even only consider read-across argument only for certain endpoints. We can argue that substance grouping based on read-across or category information has more significance than structural similarity alone because the grouping is normally accompanied by argumentation to demonstrate that any differences in structure are not (eco)toxicologically important. The method is not concerned with the validity of this argumentation, which is examined during manual screening.

5 Short listing criteria for Round 6 of manual screening

The section below describes the short listing criteria used to create the shortlist for Round 6. Please note that from Round 4 onwards, ECHA applies a grouping approach to identify substances to be manually screened. In this approach so called group seeds are identified around which groups of similar substances are formed. Group seeds substances may be for instance substances under CoRAP, under Substance Evaluation, in the candidate list, classified as CMR under CLP, substances identified by external bodies and non-EU Authorities and substances proposed by national prioritisation projects. In order to provide as wide an overview as possible for any group, all members of the group are included on the shortlist for authorities to consider them in their assessment. This includes not only those group members with widespread uses potentially leading to exposure to human health and/or releases to the environment but also those registered as intermediates or those only notified to the C&L Inventory. However, there is always at least one substance in each group which has widespread uses based on the automatic IT screening.

[5] http://www.nicnas.gov.au/chemical-information/imap-assessments
[6] http://webnet.oecd.org/HPV/UI/ChemGroup.aspx
[7] http://www.epa.gov/hpvis/
[8] Identifying such directionality based e.g. on worst case would require endpoint-specific algorithms that are of unjustifiable complexity given the acceptable level of uncertainty at the screening stage.

The following seeds have been used in the Round 6 of manual screening:

1. Substances short listed in previous rounds but not assessed

Substances shortlisted in previous rounds but not assessed by authorities were used as groups seeds for the grouping approach. Those substances have potential hazardous properties and widespread uses.

2. Substances identified in national priority programmes

ECHA invites Member State Competent Authorities to propose their own candidates for manual screening. Those candidates are usually based on national priorities and reasoning behind their selection varies. Those substances are used as seeds and groups of substances formed around.

3. Substances with a recent harmonised classification as CMR1A/B and 2 or STOT RE

Substances with a recent harmonised classification as CMR1A/B and 2 or STOT RE have been used as groups seeds for the grouping approach. By definition, those substances and the groups created around them have suspected hazardous properties and may be potential alternatives to those recently classified.

4. Substances from the pool of substances not yet addressed by regulatory action

ECHA has considered the following substances for which there was no previous regulatory action before as group seeds:

- Substances self-classified by registrants potential hazard properties and relevant uses using the algorithms developed in past common screening rounds.
- Substances with potential hazard properties and expected high release potential determined in the context of the work done between ECHA and industry sectors in the Plastic Additives Initiative (see project description in Annex 1). The outcome of the PLASI project was a relative release potential ranking from plastic materials of substances that were confirmed to be used as plastic additives. Those substances ranking high in the PLASI project were used as group seeds due to their potential for exposure.

Annex 1 Plastic additives initiative

In late 2016, ECHA and over 20 industry sector organisations started a joint initiative for characterising the uses of plastic additives and the corresponding potential for release from articles. The project aimed to generate an overview of substances used as additives (stabilisers (UV, heat, other), plasticisers, antioxidants and –statics, pigments, nucleating agents, flame retardants) in plastics in high volumes (registered above 100 t/a) in the EU and to demonstrate how use and exposure information for plastic additives can be used to focus authorities' regulatory work. It also aimed to demonstrate that improved communication in the supply chain is needed for making such information available.

The initiative produced 1) an overview of over 400 substances confirmed by industry to be used as additives in plastic together with information on their properties, function and usual concentration, as well as the polymers and article types in which they are usually used; 2) a method for comparing the release potential of additives from plastic matrices (developed with expert input from industry, academia and authorities); and 3) an indicator value for relative release potential for substances which have not been regulated / under regulatory scrutiny.