

## **Background document to the decision of the Executive Director of ECHA, ED/32/2011**

### **Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria)**

#### **1. Introduction**

Substances subject to substance evaluation are substances registered under the REACH Regulation<sup>1</sup>. The prioritised substances for evaluation will be placed on the so called Community Rolling Action Plan (CoRAP). Prioritisation of substances shall be risk based. This paper lays down the first set of CoRAP selection criteria used for establishing the CoRAP. The selection criteria will be further refined along with the experience gained from the substance evaluation process.

#### **2. The criteria laid down in the REACH Regulation and their further development in co-operation with the Member States**

Article 44(1) of the REACH Regulation provides the general criteria for substances to be selected for substance evaluation. Furthermore, the legal text defines that prioritisation shall be on a risk-based approach.

*Article 44(1) reads:*

*“(...) The criteria shall consider:*

*(a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;*

*(b) exposure information;*

*(c) tonnage, including aggregated tonnage from the registrations submitted by several registrants.”*

The above-mentioned general selection criteria in the legal text cover both hazard (intrinsic properties) and exposure aspects and the general risk-based approach suggests that both elements should be taken into consideration when selecting substances for substance

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<sup>1</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

evaluation. It is expected that over time on the basis of experience, the criteria will be further developed and refined, with the possibility of a shift towards a different emphasis on certain groups of substances, hazard properties or exposure patterns. This is also foreseen by Article 44(1) as a task of ECHA in cooperation with the Member States. For this first set of the criteria ECHA has consulted the Member States in two workshops organised by ECHA, in ECHA Member State Committee meetings and by a written procedure.

### **3. The refined “2011 CoRAP selection criteria”**

In setting up the selection criteria for substance evaluation, it is necessary to take into account legal, regulatory and practical aspects.

While developing CoRAP criteria, ECHA took into account the following principles:

- Refinement of the three general criteria; i.e. hazard and exposure characteristics,
- Ability to detect the substances of greatest concern,
- Ability to search of specific criteria in registration dossiers and
- The expected outcome of substance evaluation i.e. a decision to request further information that can cover but also go beyond standard information requirement of Annexes VII to X to the REACH Regulation and the relevance to other REACH or Community level processes.

Thus, the following pragmatic approach is established to select candidate substances for the CoRAP. The criteria set are not an exhaustive list of all possible risks that chemicals can cause. By nature, priority criteria, as also in this case, cover to a reasonable extent the most important risk-based concerns that should be clarified through substance evaluation in the first instance. The overall ranking and prioritisation of candidate CoRAP substances will be based on the severity of the risk and the willingness of Member States to select the substance for evaluation.

Hazard or exposure related criteria should not be used in isolation for prioritisation of substances, but in combination with each other. These criteria do not predefine the combination to be used. For example in case when hazard of a substance is known and well established, more information on exposure may be necessary if the use pattern is such that the population may be widely exposed. In general, a suspected property is considered by default to be more important criterion than a known property, as it is more obvious that some further information is needed to confirm the existence of the property in case of suspicion.

#### Hazard related selection criteria:

- Suspected Persistent, Bioaccumulative and Toxic substances (PBTs), Very Persistent and very Bioaccumulative substances (vPvBs) and PBT-like substances (e.g. close to meet REACH Annex XIII-criteria and/or based on structural similarities)
- Known PBTs/vPvBs<sup>2</sup>
- Suspected endocrine disruptors (e.g. based on reproductive effects and/or on structural similarities)<sup>3</sup>

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<sup>2</sup> “Known PBT/vPvB” can refer to a) substances agreed by the ECHA Member State Committee and included in the candidate list (SVHC), substances agreed by authorities, e.g. by the previous ECB PBT Working Group, and b) substances concluded to fulfil the criteria by the REACH registrants. In many cases when the PBT-property is known, substance evaluation is no needed, if other risk management measures can be directly taken. However, if still some data gaps exist for a PBT-substance, it can be included in the CoRAP for substance evaluation.

<sup>3</sup> Currently there is no legal definition for the term “substances having endocrine disrupting properties”. For example, Article 57(f) of the REACH Regulation does not provide any criteria for endocrine disrupting properties nor does it constrict the interpretation to specific types of modes of action.

- Suspected Carcinogenic, Mutagenic and Reprotoxic substances (CMRs) (e.g. based on structural similarities)
- Known CMRs<sup>4</sup> (Category 1A , 1B and 2 according to CLP)
- Suspected sensitizers (e.g. based on structural similarities)
- Known sensitizers (skin and especially respiratory sensitizers)

Exposure related selection criteria:

- Wide dispersive use<sup>5</sup>
  - The number of sites of use
  - Pattern and amount of releases/exposure
  - The number and type of reported uses and exposure scenarios from different registrants
  - The substance is incorporated into mixtures or articles used by the public (e.g. consumers)
  - The potential size of the exposed population
- Number of using sites if emission due to industrial use
- Consumer use and exposure of sensitive subpopulations such as children
- Aggregated tonnage

Risk related selection criteria:

- The risk assessment in the chemical safety report shows that risk characterisation ratio is not well below to 1 (for human and/or environmental exposure)
- Cumulative exposure from structurally related substances with critical hazardous properties (e.g similar endocrine disrupting property like antiandrogenic or estrogen-like effect).

#### **4. From the refined criteria to the CoRAP**

These criteria are the initial step in the identification of substances with potential concerns. Also it needs to be considered whether there is the possibility of clarifying the concern by

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<sup>4</sup> "Known CMR" can refer to a) CMR substances already classified and included in CLP, Annex VI, b) substances identified as CMRs by authorities (e.g. IARC, TC C&L) but not (yet) included in Annex VI, and c) substances identified as CMRs by REACH registrants (self-classification). However, by the available tools it is easiest to filter cases under a) and b).

<sup>5</sup> The term 'wide-dispersive use' is explained in Chapter R.16.2.1.6 of the Guidance on Information Requirements and Chemical Safety Assessment as follows: '*Wide-dispersive use refers to many small point sources or diffuse release by for instance the public at large or sources like traffic. ... Wide-dispersive use can relate to both indoor and outdoor use*'. Wide-dispersive uses are characterised by use(s) of a substance on its own, in a preparation or in an article at many places (sites) that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers, general public) and/or the environment. This means that uses taking place at many places, which however do not result in significant releases of a substance, may be considered only as 'widespread' but not as 'wide-dispersive'.

requesting further information under substance evaluation process. Thus meeting the risk-based criteria alone does not automatically mean an inclusion of the substance in the CoRAP. Therefore ranking is needed after the initial selection of candidate CoRAP substances is performed.

Another practical criterion is that a Member State must express an interest to perform an evaluation on a substance.