



**COUNCIL OF
THE EUROPEAN UNION**

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NOTE

from: General Secretariat
to: Council (Competitiveness)

Subject: REACH and the Candidate List of Substances of Very High Concern
- Information from the Commission

Delegations will find attached an information note on the subject above prepared by the Commission.

REACH and the Candidate List of Substances of Very High Concern Information Note

CONTEXT

The aims of REACH are to provide a high level of protection for humans and the environment, whilst enhancing competitiveness and innovation. REACH authorisation contributes to achieving this goal by aiming at the substitution of Substances of Very High Concern when technically and economically feasible.

REACH provides for identifying Substances of Very High Concern (SVHCs) meeting the criteria referred to in art 57 of that Regulation¹ and for establishing the so called Candidate List for eventual inclusion into the Authorisation list. Substances are identified on the basis of proposals submitted by Member States or by the European Chemicals Agency (ECHA) on behalf of the Commission. Substances included in the Candidate List are subject to information and notification requirements and can be prioritized and included in Annex XIV of REACH, which lists the substances subject to authorisation.

¹ Substances meeting the criteria for classification as carcinogenic category 1a or 1b; mutagenic category 1a or 1b; toxic for reproduction category 1a or 1b; substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of REACH; substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of REACH; substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the previous criteria - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances meeting the previous criteria and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

In March 2010, Vice-President Tajani and Commissioner Potočnik announced that in line with their ambition of making substitution of SVHCs a reality, the inclusion of new substances in the candidate list should be accelerated. The key point of the agreement was:

- To work with the MS to achieve the objective of including **136** SVHC into the candidate list by the end of 2012 and all relevant currently know SVHCs by the end of 2020;

CURRENT STATUS

The Candidate List currently contains **53** substances and **20** additional substances will be most probably added in January 2012, leaving **63** substances to be added by the end of 2012 to meet the objective set by Vice-President Tajani and Commissioner Potočnik.

ECHA committed to prepare 15 dossiers on behalf of the Commission by the end of 2012. ECHA is on the right track to complete this task.

ACTIVITIES ON-GOING AND NEXT STEPS

Already in 2010, Commission, ECHA and Member States started to work on a common framework to select appropriate substances for identification of SVHC and inclusion in the Candidate list and establish a good coordination between all actors in the area of REACH risk management. In this context, work has been done on substances classified as Carcinogenic, Mutagenic or toxic for Reproduction (CMRs), on PBTs (Persistent, Biaccumulable and Toxic), on vPvB (very Persistent and very Biaccumulable) as well as on development of a common approach to the identification of substances of equivalent concern (namely sensitisers and endocrine disruptors).

These activities created also opportunities for synergies among the Member States via formation of partnerships and knowledge building for all the actors involved.

As a consequence, an important increase in the number of substances included in the Candidate List in 2011 has been observed. The Commission from its side already requested ECHA to prepare dossiers for 10 substances and recently asked ECHA to re-assess its resource availability and, taking into account the other priorities for 2011-2012, eventually identify additional potential to prepare more dossiers than the expected 15. However, there is still a need for more efforts to achieve the target of 136 substances by the end of 2012. Member States are encouraged to contribute more actively to the process of SVHC identification. ECHA and the Commission will continue to contribute by providing assistance, coordination and sharing experiences with the Member States.

Moreover, the Commission has asked ECHA to propose concrete actions with regard to the identification of SVHCs based on the suggestions it had made. This information including actions to be taken by ECHA, Member States and the Commission will be made available to Member States. In the light of further developments we may continue discussions in subsequent Council meetings.
