

## **Explanatory Note – The authorisation process and the candidate list**

### **REACH and Annex XIV**

REACH has been described as the world's most far-reaching regulation on chemicals. It is a European regulation which impacts all companies which manufacture or import substances into the Member States of the European Union. One of its major aims is to communicate appropriate information about a chemical and to ensure the safe use of those chemicals classified as dangerous.

One aspect of REACH, the so-called Annex XIV, will list the Substances of Very High Concern (SVHC) that will be subjected to the authorisation procedure. These SVHC can belong to different categories:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR) classified category 1 or 2 according to the criteria described in the Dangerous Substance Directive; or
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation; and/or
- Identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to humans (such as endocrine disruptors) or the environment of an equivalent level of concern as those above.

Once included in Annex XIV, a substance cannot be placed on the market or used after a date to be specified in Annex XIV (the so-called "sunset date") unless the company is granted an authorisation for its use.

**If a substance is included in Annex XIV, it follows that the use of the substance needs to be authorised. It does not mean that it is to be banned entirely from the market.**

### **The authorisation process**

Member States or the Agency, at the request of the Commission, can propose substances for the candidate list by preparing a dossier in accordance with the procedures outlined in Annex XV of REACH.

The substances for which such a dossier has been introduced will be published on June 30, 2008 to enable scientific comments from stakeholders.

**The draft list of substances published on 30 June is NOT the candidate list. It is the Agency's notice that dossiers have been introduced by Member States and the Agency.  
This draft list is open for scientific comments and can be seen as a "pre-candidate" list (although not a REACH term)**

The Member State Committee will then identify from this list of Annex XV dossier- substances, those which form the List of Candidates for possible Annex XIV inclusion. The candidate list is

expected to be published in October 2008.

**Being on the Candidate List does not mean that a substance will automatically need authorisation or is going to be banned.**

The substances on the Candidate List will be prioritised by 1 June 2009 to determine which ones should finally be subject to authorisation. At the end of this prioritisation process, the following decisions will be taken:

- which uses of the included substances will not need authorisation (because there are already sufficient controls established by other legislation);
- the “sunset date” by when a substance can only be used when authorised.

**The prioritisation of the candidate list brings a substance into Annex XIV, hence requiring an authorisation for non-exempted uses.**

At this stage a company can then apply for authorisation for specific uses of a substance by submitting an authorisation dossier. It has to provide

- a chemical safety report (including hazard assessment, and where appropriate, exposure assessment and risk characterisation, if not done yet under registration) to assess risks arising from the use of a substance to demonstrate that they are adequately controlled;
- an analysis of possible alternative substances or technologies (including, where appropriate, information on research and development);
- a substitution plan if a suitable alternative substance is identified.

Authorisations are to be granted if it can be demonstrated that the risk from the use of the substance is adequately controlled. Even if a chemical has hazardous properties – meaning an in-built ability to cause an adverse effect - any risk to human health and the environment might be extremely low if the chemical is handled safely under controlled conditions.

Substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties will be considered as not adequately controllable. However, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

**Downstream users may only employ such substances for uses which have been authorised.**

Annex XIV is a living documents. Note that substances might be added to it or they also may be deleted from the Annex if new information becomes available that proves that the substances no longer meets the criteria for substances of very high concern.

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