

Llistat de substàncies proposades a requerir autorització .

First list of substances candidate to authorisation

As far as the authorisation process concern, which will involve substances so-called SVHC (Substance of Very High Concern), the European Commission has required to Competent Authorities of Member States and to the ECHA to prepare dossiers for the identification of these substances. The aim of the procedure is the preparation of the candidate substances list to authorisation.

At the end of June 2008 the Competent Authorities of Germany, UK, Austria, France, Sweden, and Norway have issued 16 dossiers that identify SVHC substances. Some of them are marked as PBT (Persistent , Bioaccumulable, and Toxic) others as CMR (Cancerogenous, Mutagenic, and Toxic for Reproduction) and a only case of substance defined as vPvB (very Persistent and very bioaccumulable).

In the following table, details on the substances, object of dossiers, can be found, with related EINECS and CAS numbers. The table has been published on ECHA website, with the aim of obtaining other useful safety information (exposure, risks, alternatives) or other identifying data from companies interested in marketing these substances. This action could give the possibility to gather other important information, to complete the knowledge of these substance and to elaborate then a better evaluation of hazards by the Competent Authorities.

Extra information were to be given 45 days after the publication of the list, in a confidential and/or public way.

En el moment de publicació del reglament REACH, l'annex XIV In the framework of the authorisation process, Member States Competent Authorities or the European Chemicals Agency (ECHA), on a request by the Commission, may prepare Annex XV dossiers for the identification of substances of very high concern (SVHC). Substances of very high concern are defined in Article 57 of Regulation (EC) No 1907/2006 ("the REACH Regulation") and include substances which are:





- Carcinogenic, Mutagenic or toxic to Reproduction (CMR), meeting the criteria for classification in category 1 or 2 in accordance with Directive 67/548/EEC,
- 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 human health or the environment of an equivalent level of concern as those above (e.g. endocrine disrupters)

The Annex XV report prepared by a Member State or the Agency is available in the table below in order to inform interested parties. The interested parties have 45 days from this publication to give scientific comments on the identification of the substance as SVHC as well as further information related to exposures, alternatives substances and risks and send their comments to the Agency. It would facilitate the evaluation process of comments to receive them in English.

The interested party is requested to provide a non-confidential version of the information which ECHA may make available to the public. There is an opportunity to submit confidential details to support the non-confidential information (see detailed instructions below). A justification must be given by the submitting party to explain why the information is confidential. Such confidential information will only be used by ECHA, including its Committees.

In case you want to submit comments, please use the link to the submission form given in the table before the indicated deadline.

Substance identification			Authority	Reason for proposing	Date of publication	Deadline for commenting	Link to the Annex XV report	Link to commenting form
Substance name	CAS number	EC number						
Anthracene	120-12-7	204-371-1	Germany	PBT	30/06/08	14/08/08		Anthracene
4,4'-Diaminodiphenylmethane	101-77-9	202-974-4	Germany	CMR	30/06/08	14/08/08		4,4'-Diaminodiphenylmethane
Dibutyl phthalate	84-74-2	201-557-4	Austria	CMR	30/06/08	14/08/08		Dibutyl phthalate
Cyclododecane	294-62-2	206-33-9	France	PBT	30/06/08	14/08/08		Cyclododecane

Cobalt dichloride	7646-79-9	231-589-4	France	CMR	30/06/08	14/08/08		<u>Cobalt dichloride</u>
Diarsenic pentaoxide	1303-28-2	215-116-9	France	CMR	30/06/08	14/08/08		<u>Diarsenic pentaoxide</u>
Diarsenic trioxide	1327-53-3	215-481-4	France	CMR	30/06/08	14/08/08		<u>Diarsenic trioxide</u>
Sodium dichromate, dihydrate	7789-12-0		France	CMR	30/06/08	14/08/08		<u>Sodium dichromate, dihydrate</u>
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4	Netherlands	vPvB	30/06/08	14/08/08		<u>5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)</u>
Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0	Sweden	CMR	30/06/08	14/08/08		<u>Bis (2-ethyl(hexyl)phthalate) (DEHP)</u>
Hexabromocyclododecane (HBCDD)	25637-99-4	247-148-4	Sweden	PBT	30/06/08	14/08/08		<u>Hexabromocyclododecane (HBCDD)</u>
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5	United Kingdom	PBT	30/06/08	14/08/08		<u>Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)</u>
Bis(tributyltin)oxide	56-35-9	200-268-0	Norway	PBT	30/06/08	14/08/08		<u>Bis(tributyltin)oxide</u>
Lead hydrogen arsenate	7784-40-9	232-064-2	Norway	CMR	30/06/08	14/08/08		<u>Lead hydrogen arsenate</u>
Triethyl arsenate	15606-95-8	427-700-2	Norway	CMR	30/06/08	14/08/08		<u>Triethyl arsenate</u>
Benzyl butyl phthalate	85-68-7	201-622-7	Austria	CMR	30/06/08	14/08/08		<u>Benzyl butyl phthalate</u>