



Technical Note

Obligations for the Substances of very high concern (SVHC) included in the Candidate List

Procedure for Identification of SVHC substance, some of which may go for Authorization

Substances that are of high concern, meaning that they are carcinogenic, mutagenic & toxic to reproduction CMR category 1 & 2 and persistent, bio-accumulative and toxic (PBT) cat. 1 & 2 are proposed as candidate SVHC (Pl. refer Section C of this Technical note); based upon the consultation (for a period of about 45 days) the list is then finalized of the SVHC substances. Once finalized for SVHC, based upon the consultation with the member states, the authorization list is finalized (Pl. refer Section B of this Technical note) from these SVHC substances (Pl. refer Section A of this Technical note).

Applicable sections of REACH Regulation:

REACH Articles (pl. refer the REACH legal text for details)	Summary
Article 56: General provisions	<p>SUBSTANCES SUBJECT TO AUTHORISATION (listed in Annex XIV – Reach reg.) – conditions when these substances can be placed into EU market – authorization, or exemptions</p> <p>Further, following uses of substances are exempted from requirements of Article 56 :</p> <ul style="list-style-type: none"> (a) Uses in plant protection products within the scope of Directive 91/414/EEC; (b) Uses in biocidal products within the scope of Directive 98/8/EC; (c) Use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (1); (d) Uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
Article 57: Substances to be included in Annex XIV	<p>Condition for inclusion of a particular substance in Annex XIV (Authorization list):</p> <ul style="list-style-type: none"> - in accordance with Directive 67/548/EEC substances meeting the criteria of CMR cat. 1 & 2; - Substances in accordance with Annex XIII of Reach Regulation categorized as PBT cat. 1 & 2; - vPvB substances may also be included;
Article 58: Inclusion of substances in Annex XIV	<p>Procedure and timeline that would be adopted by ECHA to include a particular substance in to Annex XIV; prioritization of substances to be included for Annex XIV</p>
Article 59: Identification of substances referred to in Article 57	<p>Procedure for identification of candidate list as mentioned within Article 57</p>

Article 60: Granting of authorizations	Criteria for Granting of Authorization to be followed by ECHA / Commission
Article 61: Review of authorizations	Authorizations may be reviewed at any time if: (a) The circumstances of the original authorization have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or (b) New information on possible substitutes becomes available. The Commission shall set a reasonable deadline by which the holder(s) of the authorization may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 64.
Article 62: Applications for authorizations	Application Procedure and details necessary to be included in the Authorization application to the Agency
Article 63: Subsequent applications for authorization	Other applicants that may want to use the existing application – procedures for the same; the later applicant can use the submitted application provided he has permission from the previous applicant.
Article 64: Procedure for authorization decisions	
Article 65: Obligation of holders of authorizations	General obligations of the holder of the Authorization
Article 66: Downstream users	Inventory of Down-stream users with the Agency, need to inform by Down Stream users on the use of such substances

Explanation:

Introduction

Substances that are present in the Candidate List have been identified as Substances of Very High Concern (SVHC) and the criteria for inclusion of these substances in the candidate list 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)

Under REACH regulation, SVHC may have very serious and often irreversible effects on humans and the environment and so such hazardous substance needs to be controlled. The SVHC may be inadvertently introduced in various consumer products due to the complexities of both supply chain and manufacturing process. To secure their sustainable competitive advantage, EU-based companies have started requesting their suppliers to justify the presence of SVHC in their products.

Nearly thousand substances have been recognized as SVHC by the agency. The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is a continuous process and so the list is updated periodically by the Agency.

[Section A] Obligation for the 29 SVHC substances present in Candidate list

The SVHC substances are added to the Candidate List by ECHA. The inclusion of a substance in the List may have legal obligations on companies. These **obligations are as listed below.**

For article producers:

- The first step applicable for the supplier of the article (to 27 EU countries) is to check if the substances given in Table 1 are present in the articles in quantities totalling over 1 tonne per producer and are above a concentration of 0.1% (w/w).
- The producers of articles have to notify to the agency (ECHA) if their article contains a substance from the Candidate List.
- For substances included in the Candidate List before 1 December 2010, the notifications have to be **submitted not later than 1 June 2011**.
- For substances included in the Candidate List on or after 1 December 2010, the notifications have to be submitted no later than 6 months after the inclusion.
- A notification is not required were the manufacturer can exclude exposure of humans and environment or substance has already been registered for that use.
- From the date of inclusion the manufacturers of substances on the Candidate List have to provide their customers with a safety data sheet.
- The manufacturer has to provide sufficient information to allow safe use of the article to their customers or upon request, to a consumer within 45 days of the receipt of the request.

For substance producers:

- Producers of the substances will have to check if their substances figure in the Candidate List
- From the date of inclusion the manufacturers of substances on the Candidate List have to provide their customers with a safety data sheet.

Table No. 1: Total number of substances in the 'Candidate list'

Sr. No.	EC No.	Chemical Name	Reason for inclusion
1	204-450-0	2,4-Dinitrotoluene	Carcinogenic
2	202-974-4	4,4'- Diaminodiphenylmethane (MDA)	Carcinogenic
3	201-329-4	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	vPvB
4	287-476-5	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	PBT and vPvB
5		Aluminosilicate Refractory Ceramic Fibres <i>are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions:</i> a) Al_2O_3 and SiO_2 are present within the following concentration ranges: Al_2O_3 : 43.5 – 47 % w/w, and SiO_2 : 49.5 – 53.5 % w/w, or Al_2O_3 : 45.5 – 50.5 % w/w, and SiO_2 : 48.5 – 54 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm).	Carcinogenic
6	204-371-1	Anthracene	PBT
7	292-602-7	Anthracene oil	Carcinogenic, PBT and vPvB
8	292-603-2	Anthracene oil, anthracene paste	Carcinogenic, mutagenic, PBT and vPvB
9	295-275-9	Anthracene oil, anthracene paste, anthracene fraction	Carcinogenic, mutagenic, PBT and

			vPvB
10	295-278-5	Anthracene oil, anthracene paste, distn. lights	Carcinogenic, mutagenic, PBT and vPvB
11	292-604-8	Anthracene oil, anthracene-low	Carcinogenic, mutagenic, PBT and vPvB
12	201-622-7	Benzyl butyl phthalate (BBP)	Toxic for reproduction
13	204-211-0	Bis (2-ethylhexyl)phthalate (DEHP)	Toxic for reproduction
14	200-268-0	Bis(tributyltin)oxide (TBTO)	PBT
15	231-589-4	Cobalt dichloride	Carcinogenic
16	215-116-9	Diarsenic pentaoxide	Carcinogenic
17	215-481-4	Diarsenic trioxide	Carcinogenic
18	201-557-4	Dibutyl phthalate (DBP)	Toxic for reproduction
19	201-553-2	Diisobutyl phthalate	Toxic for reproduction
20	247-148-4 and 221-695-9 (134237-50-6) (134237-51-7) (134237-52-8)	Hexabromocyclododecane (HBCDD) and all major diastereoisomers Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	PBT
21	231-846-0	Lead chromate	Carcinogenic and toxic for reproduction
22	235-759-9	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	Carcinogenic and toxic for reproduction
23	232-064-2	Lead hydrogen arsenate	Carcinogenic and toxic for reproduction
24	215-693-7	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Carcinogenic and toxic for reproduction
25	266-028-2	Pitch, coal tar, high temp.	Carcinogenic, PBT and vPvB
26	234-190-3 (7789-12-0 and 10588-01-9)	Sodium dichromate	Carcinogenic, mutagenic and toxic for reproduction
27	427-700-2	Triethyl arsenate	Carcinogenic
28	204-118-5	Tris(2-chloroethyl)phosphate	Toxic for reproduction
29	-	Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al_2O_3 , SiO_2 and ZrO_2 are present within the following concentration ranges: <ul style="list-style-type: none"> • Al_2O_3: 35 – 36 % w/w, and • SiO_2: 47.5 – 50 % w/w, and • ZrO_2: 15 - 17 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm).	Carcinogenic

[Section B] Obligation for the 7 substances included in the Authorisation list

Substances of very high concern will be gradually included in the Authorisation list of the REACH Regulation. Once included in that list, they cannot be placed on the market or used after a date to be set (the so-called “sunset date”) unless the company is granted an authorisation. The obligations for the substances incorporated in the authorisation list are as given below.

- The first step is to identify the presence of the substance from the Authorisation list given below (Table 2).
- The next step is to identify use of the substance seeking authorisation.
- Applications for authorisation need to be made within the set deadlines for each use that is not exempted from the authorisation requirement.
- The application should include the chemical safety report covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties.
- Start with the analysis for alternatives, considering their risks and the technical and economic feasibility of substitution.
- Appropriate information about any relevant research and development activities by the applicant is also to be provided in the application.
- Where the analysis shows that suitable alternatives are available, a substitution plan including a timetable for proposed actions by the applicant is required.
- When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.
- The decision of granting an authorisation shall be taken after considering the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise the substance.
- Update the safety data sheet without delay once an authorisation has been granted or refused.

Table No. 2: List of Substances Subject to Authorization

Sr. No.	Substance	EC No.	CAS No.	Intrinsic Properties	Transitional arrangements	
					Latest Application date	Sunset date
1.	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2	vPvB	Date of inclusion in Annex XIV + 24 months (June 2011)	Date of inclusion in Annex XIV + 42 months
2.	4,4'-Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	Carcinogenic category 2	Date of inclusion in Annex XIV + 24 months (June 2011)	Date of inclusion in Annex XIV + 42 months
3.	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)	287-476-5	85535-84-8	PBT and vPvB	Date of inclusion in Annex XIV + 27 months (Sep. 2011)	Date of inclusion in Annex XIV + 45 months
4.	Hexa bromo cyclo dodecane (HBCDD), and all major diastereo isomers identified, i.e.: alpha-, beta- gamma- hexabromocyclodode	247-148-4 221-695-9	25637-99-4 3194-55-6 134237-50-6 134237-51-7 134237-52-8	PBT	Date of inclusion in Annex XIV + 27 months (Sep. 2011)	Date of inclusion in Annex XIV + 45 months

	cane					
5.	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Toxic to reproduction - category 2	Date of inclusion in Annex XIV + 30 months (Dec. 2011)	Date of inclusion in Annex XIV + 48 months
6.	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Toxic to reproduction - category 2	Date of inclusion in Annex XIV + 30 months (Dec. 2011)	Date of inclusion in Annex XIV + 48 months
7.	Dibutyl phthalate (DBP)	201-557-4	84-74-2	Toxic to reproduction - category 2	Date of inclusion in Annex XIV + 30 months (Dec. 2011)	Date of inclusion in Annex XIV + 48 months

[Section C] Obligation for the 8 new SVHC substances under consideration

The European Chemicals Agency (ECHA) has recently published a proposal to identify fresh substances as Substances of Very High Concern (SVHC) and possible candidates for authorisation.

All eight substances are proposed because of their potentially serious effects on human health. They are carcinogenic, mutagenic and/or toxic for reproduction. The names of the substances, the reasons for their proposal as SVHC and their potential uses are provided in the table below (Table 3).

Once these substances are included in the candidate list (after complete consultation) then the obligation of the manufacturers will be same as in section [A].

Table 3: Proposed list of Additional SVHC

Sr. No.	CAS No.	EC No.	Substance name	Proposed SVHC property
1.	201-167-4	79-01-6	Trichloroethylene	Carcinogenic category 2
2.	233-139-2 / 234-343-4	10043-35-3 / 11113-50-1	Boric acid	Toxic for reproduction category 2
3.	215-540-4	1330-43-4 12179-04-3 1303-96-4	Disodium tetra borate, anhydrous	Toxic for reproduction category 2
4.	235-541-3	12267-73-1	Tetra boron disodium heptaoxide, hydrate	Toxic for reproduction category 2
5.	231-889-5	7775-11-3	Sodium chromate	Carcinogenic category 2; mutagenic category 2; toxic for reproduction category 2
6.	232-140-5	7789-00-6	Potassium chromate	Carcinogenic category 2; mutagenic category 2
7.	232-143-1	7789-09-5	Ammonium dichromate	Carcinogenic category 2; mutagenic category 2; toxic for reproduction category 2
8.	231-906-6	7778-50-9	Potassium dichromate	Carcinogenic category 2; mutagenic category 2; toxic for reproduction category 2