



Communication about SVHCs in the supply chain

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VLARIP- event REACH and CLP for everybody

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Outline presentation

- **Introduction**
- **Candidate list of SVHCs**
- **Next steps in the authorisation procedure**
- **Direct impact of the listing**
- **Notification of substances in Articles**
- **Use exemption**
- **Communication**
- **Articles and authorisation**
- **Articles and restrictions**
- **Conclusions and challenges**

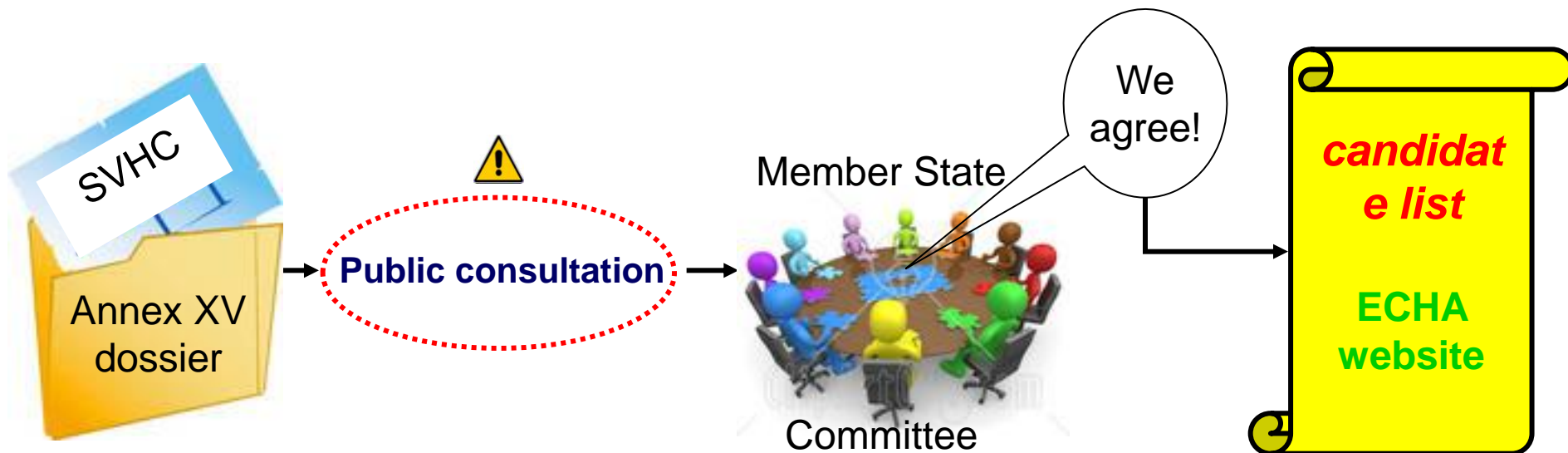
- Substances of Very High Concern are:
 - PBT substances
 - vPvB substances
 - CMR category 1, 2 substances
 - Substances of equivalent concern (Article 57f)
- Identified via the procedure of Article 59
- http://echa.europa.eu/chem_data/candidate_list_en.asp

Authorisation procedure = a two-step approach

- Step 1: **subjecting substances** to authorisation
 - Step 1A: SVHCs identification → the « Candidate List »
 - Step 1B: prioritising substances for authorisation requirement → Annex XIV
- Step 2: **granting** (or refusing) authorisations

Candidate list of SVHCs

Step 1A – The Candidate List

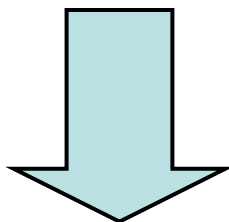


Candidate list of SVHCs

Today **46 substances** are included in the
Candidate list of Substances of Very High Concern
(**SVHCs**)

(18 December 2010)
















http://echa.europa.eu/chem_data/candidate_list_en.asp



6 of the 7 prioritised SVHCs will be included in Annex XIV
based on a recommendation made to the European Commission
in June 2009

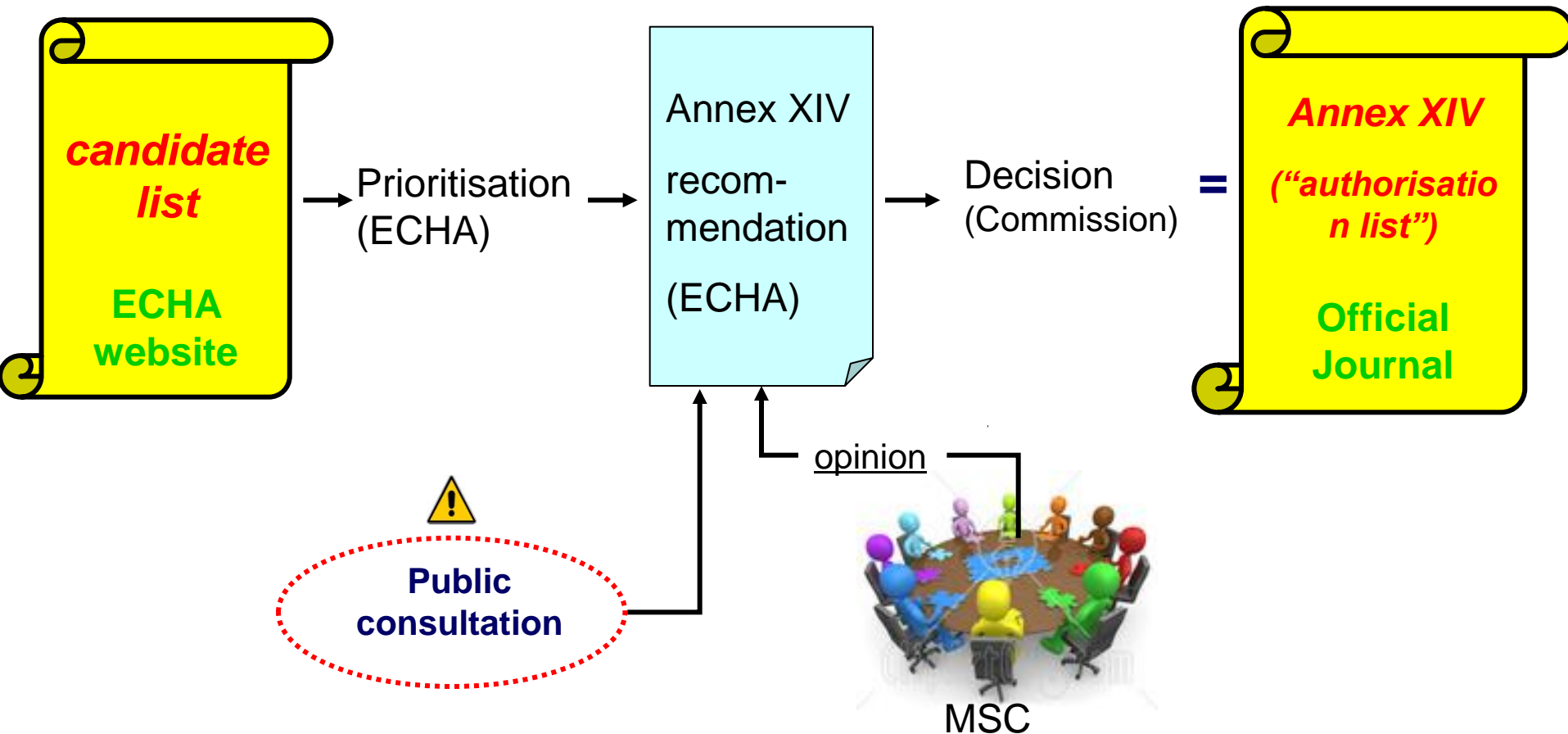
A second recommendation on 8 SVHCs sent to the European
Commission on 18 December 2010

Candidate list of SVHCs

Substance identification		Substance composition	Date of inclusion	Reason for inclusion	Supporting documentation	Decision number
Substance name	EC (CAS No.)	Impurities (where relevant for C&L, PBT/vPvB)				
Triethyl arsenate	427-700-2	-	28.10.08	Carcinogenic (article 57 a)	 (annex XV rep.)	ED/67/2008
Anthracene	204-371-1	-		PBT (article 57 d)	 (support doc.)	ED/67/2008
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	-	28.10.08	Carcinogenic (article 57 a)	 (support doc.)	ED/67/2008
Dibutyl phthalate (DBP)	201-557-4	-	28.10.08	Toxic for reproduction (article 57 c)	 (support doc.)	ED/67/2008
Cobalt dichloride	231-589-4	-	28.10.08	Carcinogenic (article 57 a)	 (support doc.)	ED/67/2008
Diarsenic pentaoxide	215-116-9	-	28.10.08	Carcinogenic (article 57 a)	 (support doc.)	ED/67/2008
Diarsenic trioxide	215-481-4	-	28.10.08	Carcinogenic (article 57 a)	 (support doc.)	ED/67/2008
Sodium dichromate	234-190-3 (7789-12-0 and 10588-01-9)	-	28.10.08	Carcinogenic, mutagenic and toxic to reproduction (articles 57 a, 57 b and 57 c)	 (support doc.)	ED/67/2008
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	-	28.10.08	vPvB (article 57 e)	 (support doc.)	ED/67/2008
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	-	28.10.08	Toxic to reproduction (article 57 c)	 (support doc.)	ED/67/2008
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	247-148-4 and 221-695-9	-	28.10.08	PBT (article 57 d)	 (support doc.)	ED/67/2008
Alpha-hexabromocyclododecane	(134237-50-6)					
Beta-hexabromocyclododecane	(134237-51-7)					
Gamma-hexabromocyclododecane	(134237-52-8)					
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	-	28.10.08	PBT and vPvB (article 57 d - e)	 (support doc.)	ED/67/2008
Bis(tributyltin)oxide (TBTO)	200-268-0	-	28.10.08	PBT (article 57 d)	 (support doc.)	ED/67/2008
Lead hydrogen arsenate	232-064-2	-	28.10.08	Carcinogenic and Toxic to reproduction (articles 57 a and c)	 (support doc.)	ED/67/2008
Benzyl butyl phthalate (BBP)	201-622-7	-	28.10.08	Toxic to reproduction (article 57 c)	 (support doc.)	ED/67/2008

Next steps in the authorisation procedure

Step 1B – Prioritising substances for authorisation



Next steps in the authorisation procedure

- **Priority setting and preparation of the Annex XIV proposals**
- **MSC consultation**
- **Public consultation**
- **Review of comments**
- **MSC consultation**
- **Recommendation to COM**

Approximately 7 months

Direct impact of the listing

**Companies
may have legal
obligations**

Substances

EU and EEA suppliers have to provide a safety data sheet to their customers

Mixtures

EU and EEA suppliers of a mixture not classified according to Directive 1999/45/EC (from 1 June 2015 CLP Regulation) have to provide the recipients, at their request with safety data sheet

Articles

EU and EEA producer or importers have to notify ECHA if the substance is present >0.1% (w/w) and in quantities >1 tonne per y/c

EU and EEA suppliers have to provide information to allow safe use of the article to customers or upon request, to consumers

REACH Articles 7(2),7(3) and 7(4)

- SVHC in articles shall be notified if:
 - The substance is included in the candidate list and
 - The substance is present in the articles at a total of > 1 tonne per producer/importer per year and
 - The substance is present in those articles at a concentration > 0.1% (w/w)
 - If the producer/importer cannot exclude exposure of humans or environment during normal and reasonably foreseeable conditions of use including disposal
- Information to be provided in a notification is limited and specified in Article 7(4)

REACH Article 7(6) use exemption



- Pre-registration alone is not sufficient to comply with this provision
- A registered use =
 - Information provided as part of the registration dossier (REACH Annex VI, Section 3.5: brief description of use)
- Approaches to determining whether a use has been registered:
 - SDS
 - Exposure Scenarios
 - Company website
 - Supply chain communication (SIEFs, trade associations, make your use known to your supplier)

Communication: Article 33

- Only if article contains SVHC on the candidate list
- Exemption
 - There is no exemption from this obligation merely via registration under Article 7(6) for the same use
- Similarly
 - There is no exemption from this obligation via Article 7(3) concerning the absence of exposure under reasonably foreseeable conditions of use
- No tonnage limit → also applies < 1 tonne/year

Communication: Article 33

Item	Obligatory	Example
Substance name	Yes	Diarsenic trioxide
CAS Number	No	1327-53-3
Reg. No (if provided)	No	01-1234567890-49-0000
Classification	No	Carc. Cat. 1; R45; T+; R28; C; R34 ; N; R50/53 May cause cancer
Conc. in article[1]	No	1% w/w
Safe handling	(Yes) [2]	S53, S45, S60, S61
Safe disposal	No	This article should be disposed of as hazardous waste. Please do not put it in your normal household waste

[1] Concentration ranges could be considered in order to preserve confidential business information

[2] If the information is necessary to ensure safe handling by the user of the article, it is obligatory to forward.

Articles and authorisation

- Substances in articles **are not** subject to authorisation
- The process of incorporation of substances into articles may be subject to authorisation
 - Only relevant for EU article producers

Misunderstanding by many article producers is that substances in articles can be subject to authorisation.

Articles and restrictions

- Substances in articles may be subject to restrictions
- Also the process of incorporating a substance into an article may be subject to a restriction
 - Only relevant for EU article producers

Conclusions and challenges

- Study the relevant chapters and examples of the Guidance on requirements for substances in articles on how to determine whether an object is an article!
- Make an inventory of substances in articles supplied into the EU
- Ensure that you know whether:
 - There is a substance in your article which is intentionally released when the article is used
 - Your article contains a substance of very high concern

Conclusions and challenges

- Provide information to recipients/consumers where appropriate
- Ensure appropriate communication in the supply chain to overcome difficulties (certificates?)
- Balance the use of safer alternatives where technically and economically viable versus potential business risks arising from continued use of the SVHCs

Further information



- CV** Evropská agentura pro chemické látky
- DA** Det Europæiske Kemikalieagentur
- DE** Europäisches Amt für chemische Stoffe
- ET** Euroopa Kemikaalide Amet
- EL** Ευρωπαϊκός Οργανισμός Χημικών Προϊόντων
- EN** European Chemicals Agency
- ES** Agencia Europea de Sustancias y Preparados Químicos
- FI** Euroopan kemikaalivirasto
- FR** Agence européenne des produits chimiques
- IT** Agenzia europea delle sostanze chimiche
- LT** Europos cheminių medžiagų agentūra
- LV** Eiropas ķīmisko vielu aģentūra
- HU** Vegyi Anyagokkal Foglalkozó Európai Ügynökség
- MT** L-Aġenzija Ewropea tal-Kimika
- NL** Europees Chemicaliënagentschap
- PL** Europejska Agencja ds. Substancji Chemicznych
- PT** Agência Europeia dos Produtos Químicos
- SK** Európska agentúra pre chemické látky
- SL** Evropska agencija za kemikalije

European Chemicals Agency

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Further information



<http://echa.europa.eu>

http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf

http://guidance.echa.europa.eu/docs/guidance_document/dissenting_en.pdf

http://guidance.echa.europa.eu/docs/fact_sheets/articles_en.pdf

http://guidance.echa.europa.eu/docs/guidance_document/nutshell_guidance_articles2_en.pdf

http://guidance.echa.europa.eu/guidance4_en.htm

<http://echa.europa.eu>

Questions

