



REACHING A SAFER FUTURE

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EU REACH Regulation
(EC) No 1907/2006

SVHC in consumer products
– Legal obligations of
products suppliers

What is REACH?

- **REACH** - Registration, Evaluation, Authorization and Restriction of Chemicals
- **Regulation (EC) No 1907/2006**
- Entered into force in June 2007, main provisions started from June 2008
- A legislative tool to achieve sound chemical management - monitor chemicals on the market over 1 tonne per year
- Create ONE single system to manage all chemicals within the Community
- Cover chemicals, mixture of chemicals and **finished products**

Substance of Very High Concern

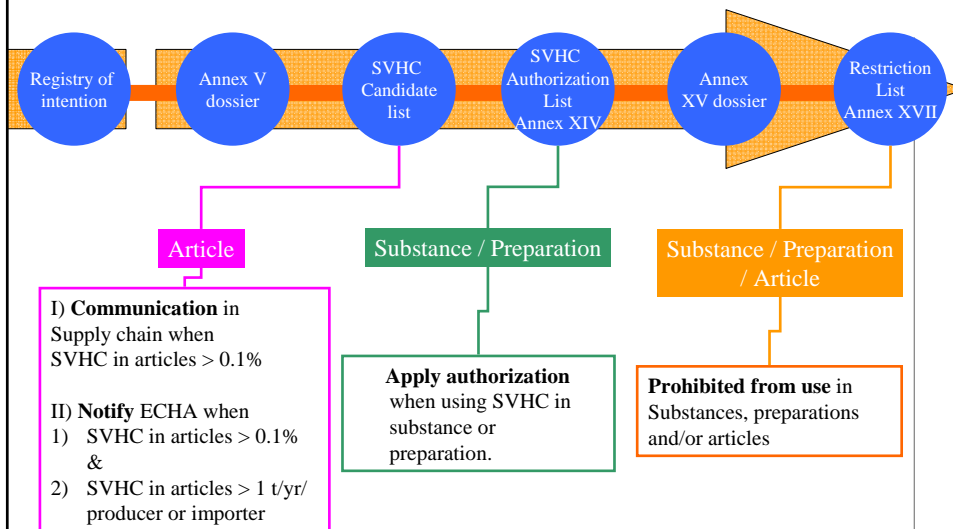
Article 57 of REACH Regulation:

- Cat 1 & 2 Carcinogen
- Cat 1 & 2 Mutagen
- Cat 1 & 2 Toxic for reproduction
- Persistent Bioaccumulative Toxic (PBT)
- Very persistent, very Bioaccumulative substance (vPvB)
- Substance of equivalent concern (endocrine disruptor)

SVHC

Substance to be included in authorization

Obligations of EU manufacturers or importers



Responsibility of
EU manufacturers /
EU importers / EU suppliers
of articles

Article 33

Duty to communicate information on substances in articles

→ SVHC concentration in articles > 0.1% w/w

- Mandatory provide to recipient of article (industrial, professional users and distributors)
- Provide information to consumer upon request within 45 days

Information required for communication:

- Name of SVHC (minimum)
- Safe use information



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- One of the Key provisions of REACH is that companies are legally required to respond to requests from customers on whether a certain customer product contains **substances of very high concern**
- Aim:
 - Substances of very high concern (SVHC) are properly controlled.
 - Progressively replaced by suitable alternatives.
- Substances of very high concern (SVHC) have been included in Annex XIV of the REACH Regulation
 - Article 58 (3) "The Agency shall make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV."
- Authorization will be granted
 - if the applicant demonstrate the risk from the use of the substance is **adequately controlled**
 - **socioeconomic benefits** out weigh the risks in the absence of suitable alternative

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Responsibility of
EU manufacturers /
EU importers / EU downstream
users of substances

Objective of this title is to ensure SVHC is under control and progressively replaced by suitable alternative substance or technologies

SVHC included in Annex XIV can not be used, unless

- The use of substance is authorized
- Has been exempted
- Not reaching the sunset date

Eligible applicants

- EU manufacturers
- EU importers
- EU downstream users

Authorization related to substance, Substance in preparation and the incorporation of substance in article
→ **Not applicable to imported articles**

1st ECHA recommendation list of SVHC for Authorization

Chemical Name	EC number	CAS number	Possible route of authorization	Latest application date*	Sunset date*	Exemption of uses (categories)
Musk xylene	201-329-4	81-15-2	socio-economic route	24 months	42 months	not recommend
4,4'-Diaminodiphenyl methane (MDA)	202-974-4	101-77-9	socio-economic route	24 months	42 months	not recommend (need to check consistency with Annex XVII for artist paint)
Alkanes, C10-13 (SCCP)	287-476-5	85535-84-8	socio-economic route	27 months	45 months	≤1% by weight where the preparation is intended for a use in metalworking or fat liquoring of leather
Hexabromocyclododecane and all major diastereoisomers identified	221-695-9, 247-148-4	3194-55-6, 25637-99-4	socio-economic route	27 months	45 months	not recommend
Bis(2-ethylhexyl)phthalate (DEHP)	204-211-0	117-81-7	adequate control route or socio-economic route	30 months	48 months	not recommend
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	adequate control route or socio-economic route	30 months	48 months	not recommend
Dibutyl phthalate (DBP)	201-557-4	84-74-2	adequate control route or socio-economic route	30 months	48 months	not recommend

* Count from the entry into force of the Decision to include the substance in Annex XIV

Article 33 request catches Europeans importers and manufactures unawares



Retailer and supplier unaware of Candidate List phthalates in shoes (Sep 09)

- There were many cases among the EU importers and manufacturers related to unawareness of candidate list substances, presence of substances which are on the candidate list resulting in embarrassment, recall of products from the market, insufficient information to allow the article to be used safely

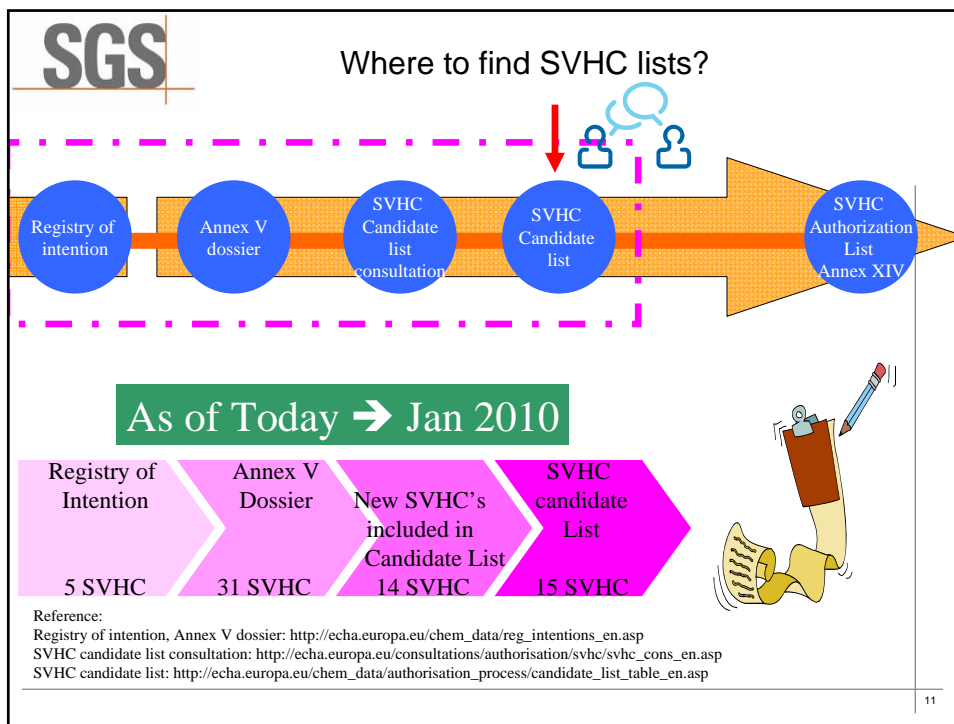
SVHC for Article 33 (communication in supply chain)



http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Substances	CAS No.
Cobalt dichloride	7646-79-9
Sodium dichromate	10588-01-9
Diarsenic pentaoxide	1303-28-2
Diarsenic trioxide	1327-53-3
Lead hydrogen arsenate	7784-40-9
Triethyl arsenate	15606-95-8
Dibutyl phthalate (DBP)	84-74-2
Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7
Benzyl butyl phthalate (BBP)	85-68-7
Anthracene	120-12-7
Bis(tributyltin) oxide	56-35-9
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2
Hexabromocyclododecane (HBCDD)	25637-99-4
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8
4,4'-Diaminodiphenylmethane	101-77-9

15 SVHC_Candidate list



- SGS** Updated Candidate list
- **REACH Candidate List of Substances of Very High Concern for Authorisation Grows**
 - **Today, the European Chemicals Agency has added 14 more chemical substances to the Candidate List of Substances of Very High Concern (SVHC) for authorisation.**
 - **Companies manufacturing or importing these substances need to check their potential obligations that result from the listing.**
 - The substances which ECHA added on the Candidate List are listed below. Decisions on whether the substances need to be subject to authorization will be taken later.
 - Companies may have legal obligations resulting from the inclusion of substances in the List.
 - These obligations can apply to the listed substances on their own as well as in mixtures and in articles.
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15 updated SVHC

No.	Chemical name	EC No.	Possible occurrence
1-5	Anthracene oil and related compounds	292-602-7; 295-278-5; 295-275-9; 292-604-8; 292-603-2	- Wooden products - Paints - Rubbery products - Plastic products
6	Diisobutyl phthalate (DIBP)	201-553-2	- Plastic products - Printing inks
7	2,4-Dinitrotoluene	204-450-0	- Shoe sole - Lingerie - Mattress
8	Coal tar pitch, high temperature	266-028-2	- Active carbon fibres - Paints and coatings
9	Tris(2-chloroethyl)phosphate	204-118-5	- Upholstered furniture - Textile coatings
10	Aluminosilicate (RCF)	Index no. 650-017-00-8	- Fire protection for buildings and industrial process - Products with insulating functions
11	Zirconia Aluminosilicate (RCF)		
12	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	- Paints, varnishes & coatings - Printing inks - Textile printing, - Leather products
13	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	235-759-9	
14	Lead chromate	231-846-0	
15	Acrylamide (removed)	201-173-7	- Coatings & paints - Textile processing

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5 SVHC in intention list

No.	IUPAC name (Chemical name)	EC No.	Possible occurrence
1	Arsenic acid and its salts	Index no. 033-005-001	- Textile products - Wood products - Electrical & electronic products
2- 5	Coal tar distillates	295-507-9; 292-607-4; 295-304-5; 295-313-4	- Wood products - Skin care medications

May Available for consultation in Feb 2010

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Arsenic acid and its salts (Registry of Intention for SVHC candidate list inclusion)

http://edexim.jrc.it/index.php?id_left=152&id=383&annex=92&part_limit=1&rank=0

EC#	CAS#	Chemical
310-019-9	102110-21-4	Arsenic acid (H3AsO4), magnesium salt, manganese-doped
236-841-7	13510-44-6	trisilver arsenate
233-970-0	10476-82-1	strychnine arsenate
231-547-5	7631-89-2	arsenic acid, sodium salt
231-904-5	7778-44-1	calcium arsenate
232-096-7	7786-36-9	pentahydroxyarsorane
232-062-1	7784-37-4	mercury hydrogenarsenate
232-063-7	7784-38-5	manganese hydrogenarsenate
308-917-0	99035-51-5	vanadium(4+) diarsenate (1:1)
233-275-2	10102-50-8	iron bis(arsenate)
232-065-8	7784-41-0	potassium dihydrogenarsenate
232-067-9	7784-44-3	diammonium hydrogenarsenate
233-274-7	10102-49-5	iron arsenate
233-285-7	10103-50-1	arsenic acid, magnesium salt
233-286-2	10103-61-4	arsenic acid, copper salt
233-287-8	10103-62-5	arsenic acid, calcium salt
236-762-8	13477-04-8	tribarium diarsenate
236-682-3	13464-38-5	trisodium arsenate
236-683-9	13464-44-3	zinc arsenate
236-684-4	13464-68-1	tristrontium diarsenate
236-771-7	13477-70-8	trinickel bis(arsenate)
236-773-8	13478-14-3	trilithium arsenate
251-151-6	32680-29-8	ammonium copper arsenate
222-979-5	3687-31-8	trilead diarsenate
246-428-3	24719-13-9	triammonium arsenate
249-916-4	29871-13-4	arsenic acid, copper(2+) salt
246-429-9	24719-19-5	tricobalt diarsenate
236-667-1	13462-93-6	ammonium dihydrogenarsenate
231-901-9	7778-39-4	arsenic acid
231-902-4	7778-43-0	disodium hydrogenarsenate

Arsenic acid
and its salts

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SVHC for Article 33 (important remarks)

- ★ **Packaging** is always consider as **separate article**. SVHC in packaging material has to communicate
- ★ **The substance concentration threshold of 0.1% (w/w) applies to the article as supplied**. It does not relate to the homogeneous materials or parts of an article, but to the article as such



6 Member States do not agreed with this interpretation, there is still an on going discussion regarding this issue

- ★ The obligation also applies to articles which were produced or imported before the substance was included in the candidate list and are supplied after the inclusion. Thus, the **date of supply** of the article is the relevant date here

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Application Standard fees (Article 62)

Base fee	€ 50 000
Additional fee per substance	€ 10 000
Additional fee per use	€ 10 000
Additional fee per applicant	€ 37 500 (non SME applicant)

Authorization review Standard charges (Article 61)

Base Charge	€ 50 000
Additional charge per use	€ 10 000
Additional charge per substance	€ 10 000
Additional charge per applicant	€ 37 500 (non-SME applicant)

A set of reduced fees for micro, small and medium size enterprises

Article producer or importer has to notify ECHA when all of below conditions are met:

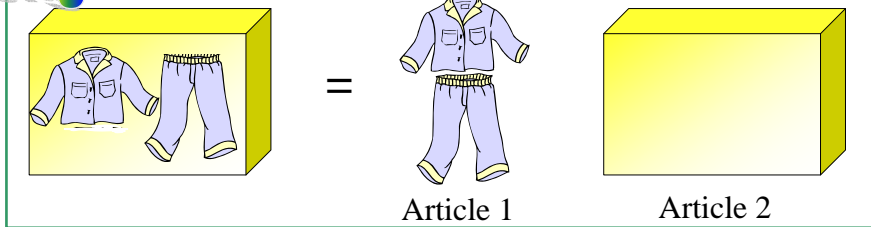
- SVHC in candidate list
http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp
- SVHC in articles > 0.1% w/w (Complex articles, packaging considers as separate article)
- SVHC in all articles > 1 tonne/year/producer or importer

Responsibility of
EU manufacturers /
EU importers of articles

Notification (2)

- The substance concentration threshold of 0.1% (w/w) **applies to the article as produced or imported**. It does not relate to the homogeneous materials or parts of an article, as it may in some other legislation, but relates to the article as such (i.e. as produced or imported).

e.g.



- A notification of substances in articles shall be made at the latest 6 months after it has been included on the candidate list of substances for authorisation, but only starting from 1 June 2011.

Notification is not required (3)

- The producer/importer can **exclude exposure** of the substances **to humans or the environment** during normal or reasonably foreseeable conditions of use including disposal (i.e. it can be demonstrated that no exposure occurs at all life-cycle stages of the substance).
- The substance has already been registered for that use (i.e. the use by which the substance is included in the article) by another company.
- ★ The articles have only been **produced and/or imported** by the producer/importer **before the substance was included in the candidate list** of substances for authorisation.



(Previously regulated by 76/769/EEC, Currently under Title VIII of REACH)

Article 67(1)

- A **substance** on its own, in a **preparation** or in an **article**, for which Annex XVII contains a restriction **shall not be manufactured, placed on the market or used** unless it complies with the conditions of that restriction.

Article 67(3)

- **Until 1 June 2013**, a Member State may **maintain any existing and more stringent restrictions** in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty.

Related to
EU manufacturers /
EU importers of substance,
preparation and articles



Until 2013, Member states can maintain its existing and more stringent requirements regarding restrictions.

General restrictions under Annex XVII

Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
42. Alkanes, C ₁₀ -C ₁₃ , chloro (short-chain chlorinated paraffins) (SCCPs) EINECS No 287-476-5	Shall not be placed on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 %: — in metalworking, — for fat liquoring of leather.



More stringent national restrictions (Netherlands)

Designation of the substance, of the group of substances or of the mixture in Annex XVII of REACH	More stringent national provisions	Authorized by the Commission
42. Alkanes, C ₁₀ -C ₁₃ , chloro (short-chain chlorinated paraffins) (SCCPs) EC No 287-476-5 CAS No 85535-84-8	Restriction on the use of short-chain chlorinated paraffins: — as flame retardants in rubber, plastic or textiles; — as plasticisers in paints, coatings or sealants (?).	Commission Decision 2007/395/EC (*)


COMMISSION REGULATION (EC) No 552/2009

of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards **Annex XVII**

- PFOS
- 2-(2-methoxyethoxy)ethanol (DEGME)
- 2-(2-butoxyethoxy)ethanol (DEGBE)
- Methylenebisphenyl diisocyanate (MDI)
- Cyclohexane
- Ammonium nitrate



EU RAPEX (2)
Legal basis for recall – REACH

No. Ref.	Notifying country	Product (Click on the photo to enlarge)	Danger	Measures adopted by notifying country	Products were found and measures were taken also in: (*)
25 0918/09	Slovakia	<p>Category: Toys Product: Doll - Fairies Magically</p> <p>Brand: Meibaoer Type/number of model: No. M6900. EAN 5907784427281 on the pack; G277737 LALKA on the sticker</p> <p>Description: A doll made from softened PVC, dressed in long clothing from textile material, with a necklace and diadem. Packed in a coloured cardboard box with transparent front. Accessories - shoes, handbag and hair clips.</p> <p>Country of origin: China</p> 	<p>Chemical</p> <p>The product poses a chemical risk since the plastic material from which the toy is made contains 13.40% by weight of bis (2-ethylhexyl) phthalate (DEHP) and 0.11% by weight of di-"isononyl" phthalate (DINP).</p> <p>The product does not comply with the REACH regulation.</p>	Sales ban, withdrawal from the market and recall from consumers ordered by the authorities.	

Phthalates

Proposal for restriction



- **Proposals for restrictions** will be prepared by **Member States** or by the **Agency** on request of the Commission in the form of an Annex XV dossier.
- The Annex XV dossier should demonstrate that there is a **risk to human health or the environment** that needs to be addressed at Community level and should identify the most appropriate set of risk reduction measures.
- **Interested parties** will have an **opportunity to comment** and the Agency will provide opinions on any proposed restriction.

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp



Current Intention For restriction Proposal June 22, 2009

Dossier by	Substance			Relevant impurities for CLH, SVHC or restriction		Notification of intention	Expected date of submission	Scope and other remarks
	IUPAC name (chemical name)	EC number (CAS number)	Purity range	IUPAC name (chemical name)	EC number (CAS number)			
Current Intentions for Restriction proposals								
Norway	phenylmercuric octanoate	(13864-38-5)				22/06/2009	15/06/2010	use of the substance in polyurethane elastomers and placing on the market of articles containing the substance
Norway	phenylmercury acetate	200-532-5				22/06/2009	15/06/2010	use of the substance in polyurethane elastomers and placing on the market of articles containing the substance
Norway	phenylmercury neodecanoate	247-783-7				22/06/2009	15/06/2010	use of the substance in polyurethane elastomers and placing on the market of articles containing the substance
Norway	phenylmercury propionate	203-094-3				22/06/2009	15/06/2010	use of the substance in polyurethane elastomers and placing on the market of articles containing the substance
→ France	dimethylfumarate	210-849-0				22/06/2009	15/04/2010	dimethylfumarate in treated articles
→ France	lead and its compounds					22/06/2009	15/04/2010	lead and its compounds in jewellery

Product recall for DMF in articles

2009 - 24	24 0834/09	Spain	<p>Category: Clothing, textiles and fashion items Product: Children's shoes Brand: Tokitos Type/number of model: Ref: 62077</p> <p>Description: Children's leather shoes with Velcro fasteners, packaged in a cardboard box.</p> <p>Country of origin: China</p> 	<p>Chemical</p> <p>The product poses a chemical risk due to the presence of dimethylfumarate (DMF) in the footwear and in the sachet included in the packaging.</p> <p>Dimethylfumarate is a substance which has to be considered harmful, irritating and sensitising on contact with the skin, and its use as a biocide is not authorised.</p> <p>One incident has been reported.</p>	<p>Withdrawal from the market ordered by the authorities.</p>
2009 - 22	13 0747/09	Finland	<p>Category: Furniture Product: Recliner chair</p> <p>Brand: Buffalo / Rento Type/number of model: Unknown</p> <p>Description: Recliner chairs for single use, different colours, both fabric and leather chairs.</p> <p>Country of origin: China</p> 	<p>Chemical</p> <p>The product poses a chemical risk because of the presence of dimethylfumarate (DMF), substance used as an anti-mould agent. Dimethylfumarate is a substance which is considered harmful, irritating and sensitising on contact with the skin, and its use as a biocide is not authorised.</p>	<p>Voluntary withdrawal from the market.</p>

Product recall for lead in Jewellery

2009 - 13	20 0478/09	Denmark	<p>Category: Jewellery Product: Jewellery</p> <p>Brand: KARVANY</p> <p>Type/number of model: - 334: necklace - 340: necklace - 346: bracelet - 352: necklace - 350: bracelet - 337: necklace</p> <p>Description: - 334: Black textile necklace with silver coloured metal pendant, embossed, approx. 3.5 cm in diameter. - 340: Necklace with 8 circular pendants of embossed metal. - 346: Large metal bracelet with three shiny charms, between 2 and 3 cm in diameter. - 352: Long thin necklace, with crystal like light red, green and light blue pendants. Three droplet shaped pendants.</p> 	<p>Chemical</p> <p>The products pose a chemical risk because the items release lead.</p>	<p>Sales ban and withdrawal from the market ordered by the authorities.</p>
2009 - 13	18 0476/09	Denmark	<p>Category: Jewellery Product: Earrings</p> <p>Brand: Monsoon Accessories Type/number of model: 381 721 08 00</p> <p>Description: Silver coloured metal earrings, approximately 5 cm in diameter.</p> <p>Country of origin: Unknown</p> 	<p>Chemical</p> <p>The product poses a chemical risk because it releases lead.</p>	<p>Sales ban and withdrawal from the market ordered by the authorities.</p>

Provisions Comparison Table

		Communication of SVHC in articles	Notification of SVHC in articles	Authorization
Legal basis in REACH		Article 33	Article 7(2)	Article 55
Actors concerned		EU Article suppliers	-EU Article producers and importers	EU substance/ preparation manufacturers, importers and downstream users; EU article producers
Substance concerned		SVHC in candidate list	SVHC in candidate list	SVHC in Annex XIV
SVHC concentration threshold		0.1% w/w	0.1% w/w	Case by case (refer to slide 12)
Tonnage threshold		-	1 tonne per year	-
Exemption from obligation	Substance already registered for that use	No	Yes	-
	Exposure can be excluded	No	Yes	-

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HIGHLIGHT OF THE DAY

“ Its never too late to set your goals therefore set your goals to give you a balanced and successful life I use balanced before successful

Balanced means ensuring your health , relationships , mental peace are all in good order

There is no fun in driving a car if your back hurts shopping is not enjoyable if your mind is full of tensions

Life is one of those races in the nursery school where you have to run with a marble in a spoon kept in your mouth. If the marble falls there is no point coming first . Same is with life where health & relationships are like marble. Your striving is only worth it if there is harmony in your life. Else you may achieve the success , but this spark , this feeling of being excited and alive will start to die

‘Don’t be serious Be Sincere’

Chetan Bhagat of Symbiosis

“Live and let live in healthy and safe environment”

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SGS

THANK YOU