



“Implication of EU’s REACH legislation for Indian Textile Industry”

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1. INTRODUCTION

REACH is a new European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances. It was in June 2007 that this new law has come into effect. The aim of REACH is to improve the protection of human health and the environment through a better and early identification of the intrinsic properties of chemical substances, making the registration of chemical substances mandatory, and restricting the professional use to only those chemical substances which have been registered, the promotion of alternative test methods, the free circulation of substances on the internal market and enhancing competitiveness and innovation.

REACH ensures that the industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Following the REACH regulation, companies will have the responsibility to provide the physical-chemicals and toxicological data necessary to assess the effect of the substances they would like to produce or utilize on human health and the environment, by means of an integrated system of pre-registration, registration and authorisation.

The new European Chemicals Agency (ECHA) has the role of an evaluator of registration dossiers provided by the manufacturers. Based on this information, they may accept or reject a registration. They are also authorized to define restrictions for the use of specific chemicals. This obligation has also a significant implication on the export to the EU of chemicals (example Apparels, textile, textile polymers, and on articles or article components). The impact of REACH on Indian Apparel, textile and textile chemical exporters to EU depends on the products' positioning in the supply chain and choices of sourcing.

- Ø The Apparel and Apparel chemicals exporters to EU will have to comply with substantial number of obligations under REACH.
- Ø To start with all companies need to register all substances that are used in the production processes or evaluate their products for Substance of Very High Concern as per candidate list released by ECHA.
- Ø This includes substances on their own or in preparation e.g. dyes and pigments used for dyeing and also all substances used for the production of the articles (eg.filaments)

2. SCOPE OF REACH:

2.1. List of Products included:

The regulation is very wide in its scope. It covers all substances whether manufactured, exported to EU or used as intermediates. It goes for substances that are placed on the EU market on their own, in preparations or in articles. The following products are included in the legislation:

- Ø Chemical substances (such as base chemicals, specialty chemicals, metals, natural substances if they are chemically modified);
- Ø Mixtures ('preparations') of chemical substances (such as cleaning products, formulated process chemicals, paints, motor oils);
- Ø Substances or preparations in containers (such as printer cartridges)
- Ø Articles, which contain substances, which are intentionally released during their use (such as fragrance in scented fabrics, substances in textiles, toys and footwear).

Products under REACH?



2.2. List of products exempted from the scope of REACH

The following are the substances exempted from the obligation to register. Which includes?

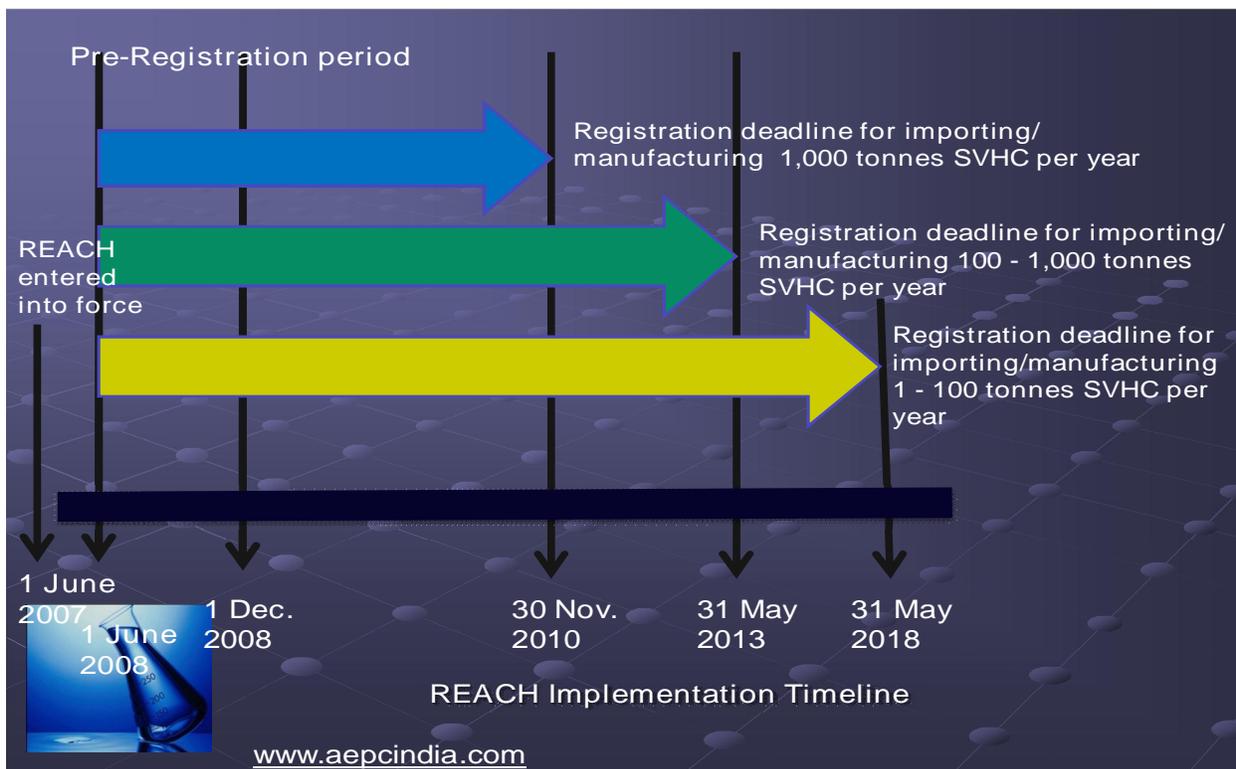
- Ø Radioactive substances, substances in waste.
- Ø Non isolated intermediates, polymers.
- Ø Pharmaceuticals / ingredients of foodstuff.
- Ø Substances in Annex II and III (Natural substances like water, sugar, oil etc.).
- Ø Already registered substance which includes active substances in pesticides and biocides.
- Ø Registered substances according to directive 67/548/EWG
- Ø There are special regulations for research and development and isolated intermediates.

The full list of exemptions can be found in Annex IV of Regulation EC.No.1907/2006

3. REACH-TIMELINE

3.1. Pre-Registration

The registration of substances and articles formally started on 1st of June 2008. However “phase in substances”(substances already listed in the European EINECS database, or already placed on the internal market) have been “pre-registered” in the period 1st June 2008 – 1. December 2008 in order to benefit from a delayed registration deadline. For pre-registered substances the following gradual introduction into the registration system is foreseen, depending on the quantities produced or imported:



Potential obligations for article suppliers	Time
Start of obligation to register non-phase-in substances and phase-in substances which have not been pre-registered, if conditions of Article 7.1 are met	From 1 June 2008
Pre-registration of phase-in substances if they need to be registered according to Article 7.1 or according to Article 6 (e.g. substances imported in preparations)	1 June 2008 – 1 December 2008
Participation in SIEF (potential registrants according to Article 6 and 7.1)	1 June 2008, after pre-registration
Communication about substances on the candidate list in articles according to Article 33	After publication of candidate list, first 16 SVHC published on 30 June 2008
Notification of substances in articles according to Article 7.2	6 months after substance is included in candidate list. No notification required before 1 June 2011.
Registration of pre-registered phase-in substances <ul style="list-style-type: none"> • in amounts 1000 tons per year or more, • in amounts 1 t/a if they are known carcinogens, mutagens or reprotoxic substances (category 1 and 2) and • in amounts 100 t/a substances if they are classified with R50/53 	By 30 November 2010
Registration of pre-registered phase-in substances in amounts between 100 and 1000 tons per year	By 31 May 2013
Registration of pre-registration phase-in substances between 1 and 100 tons per year	By May 2018

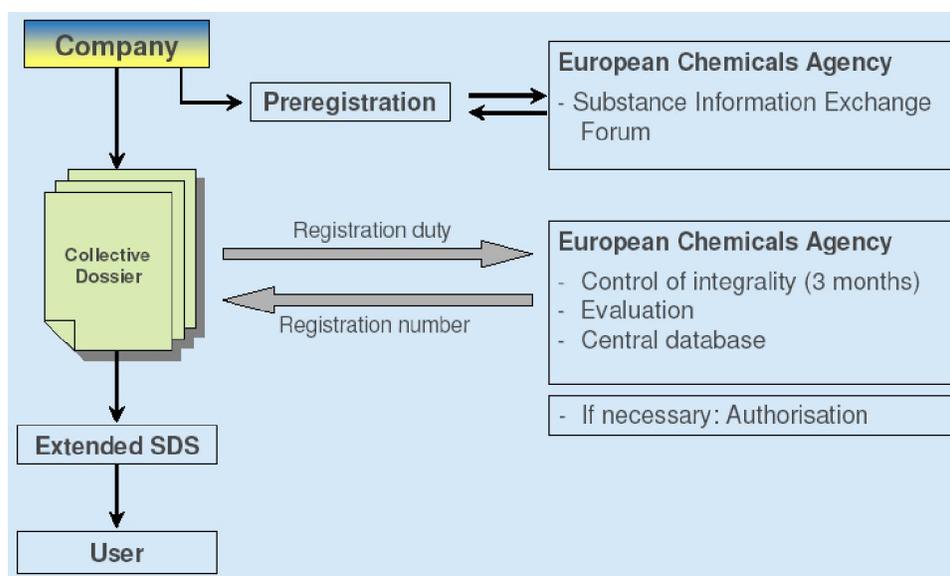
In this phase, 65,655 companies in EU and the Only Representative for Non-EU manufacturers pre-registered their 22,12,129 substances. Pre-registration had provided companies with more time to obtain and compile the information necessary to complete the registration. Also exporters from developing countries were involved. This is because EU importers or their suppliers from Non-EU must fulfill all REACH obligations for imported products to EU. The importers within the EU may emphasize that their suppliers register, pre-register (late pre-registration is possible for first time exporters), themselves.

The last date for Pre-registration was the 1st Dec 2008. After this date the manufacturers in the EU and importers of chemicals will only be allowed entry only if the chemical is appropriately pre-registered. Thus a company which failed to pre-register, will not be allowed to export its chemicals to the EU after 1st December 2008.

3.2. REACH –Registration Process

Each manufacturer or importer of a substance should submit his registration dossier for the substance to the ECHA, accompanied by a fee. The registration dossiers submitted to the Agency

will be handled electronically to facilitate the management of the expected amount of registrations that will be submitted. The Agency assigns a



registration number and a registration date to each registration dossier received and immediately communicates this information to the registrant

3.2.1. Substances on their own or in preparations

There is a general obligation for manufacturers and exporters of substances to EU to submit a registration to the Agency for each substance manufactured or exported in quantities of 1 tonne or above per year. Failure to register means that the substance is not allowed to be exported. However, the registration of polymers may be reviewed later. The Commission will review some of these exemptions, those contained in Annexes IV and V, within 12 months after entry into force of REACH. The Commission will also review the scope of the regulation five years after entry into force.

Manufacturers and importers of substances will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the uses and to ensure that the risks, which the substances may present, are properly managed.

3.2.1.1 Registration documents:

The performance of this duty requires the manufacturers and importers to submit

- Ø A technical dossier, for substances in quantities of 1 tonne or more, and
- Ø A chemical safety report, for substances in quantities of 10 tonnes or more.

Application of Good Laboratory Practice (GLP) is required only for toxicological and ecotoxicological tests and analyses.

For substances in quantities of 1 to 10 tonnes, non-phase-in substances and phase-in substances meeting at least one of the two criteria set out in Annex III: either substances that are potentially CMR category 1 or 2, persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances or substances that are potentially dangerous to health or the environment and are used in dispersive uses are prioritized and must submit a defined set of information (set out in Annex VII) along with any other available information. Other substances at this tonnage level have to submit a set of physicochemical information and any available and relevant (eco) toxicological information.

For substances in quantities of 10 to 100 tonnes, information derived from the application of the relevant testing annexes (VII and VIII) needs to be submitted with the registration as well as all

available and relevant information the registrant has. For substances in quantities of 100 tonnes or more, information derived from the application of Annexes VII and VIII, as well as all other available information the registrant has, needs to be submitted with the registration.

In addition, if the manufacturer or importer does not already possess the required information required by Annexes IX, and for substances at or above 1000 tonnes, Annex X, proposals for testing for the purpose of registration need to be submitted. As those tests might be costly or involve testing on vertebrate animals, the necessity for and the quality of the testing proposal will be checked by the Agency in the evaluation process to save animals' lives and unnecessary costs.

3.2.1.1a Chemical Safety Report (CSR)

The **Chemical Safety Report** (CSR) for substances manufactured or imported in quantities starting at 10 tonnes, documents the hazards and classification of a substance and the assessment as to whether the substance is PBT or vPvB. The CSR also describes exposure scenarios for specific uses of substances that are classified as dangerous or are PBT or vPvB substances. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control, exposures to human and the environment.

3.2.1.1b Exposure scenarios

The **exposure scenarios** must include the appropriate risk management measures and operational conditions that, when properly implemented, it is to be ensured that the risks from the uses of the substance are adequately controlled.

Exposure scenarios need to be developed to cover all “identified uses” which are the manufacturers’ or importers’ own uses, and uses which are made known to the manufacturer or importer

Who	
Where	
How	
How much	
How many times	
How long	
Safety Measures	
External Disposal	

Technical application conditions

Conditions for the application

RMM

by his downstream users and which the manufacturer or importer includes in his assessment. Relevant exposure scenarios will need to be annexed to the safety data sheets that will be supplied to downstream users and distributors.

3.2.2 Intermediate Registration

A “light” registration is required for certain **isolated intermediates** as long as they are being manufactured under strictly controlled conditions. Intermediates are substances that are used in the manufacturing process but are consumed or transformed into another substance and therefore are not present in the final manufactured substance.

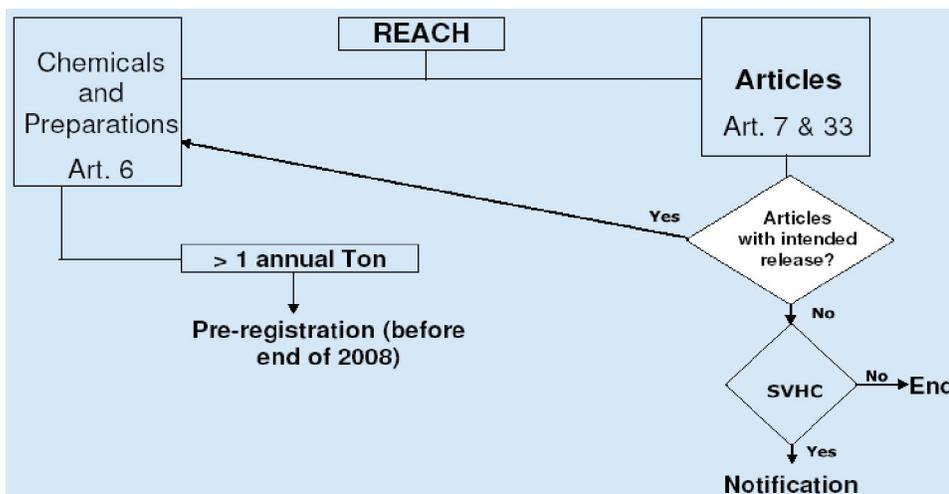
3.2.3. Substances in Articles

Apparels, Textiles and fabrics will be considered as an article under REACH Regulation. An article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. For the registration of substances in articles (e.g. manufactured goods such as textiles, leather and electronic chips), a special regime applies.

REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, including tonnage deadlines and information requirements, if those substances are present in the articles above 1 tonne per year.

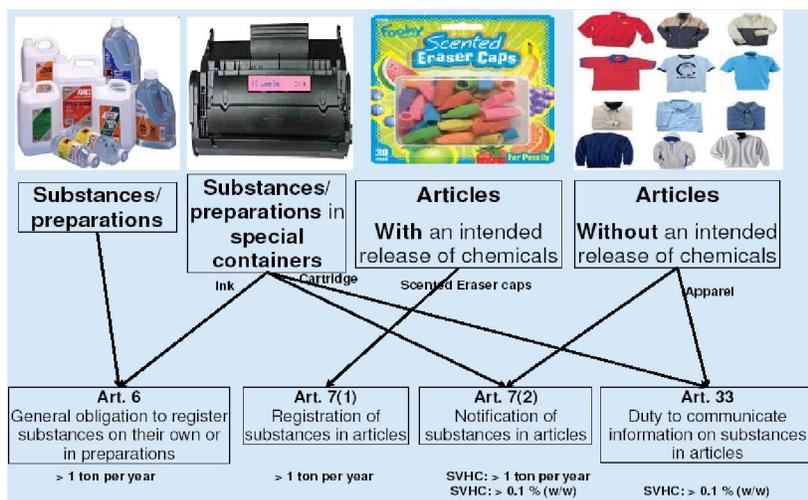
3.2.3a. REACH-Substances of Very High Concern (SVHC) analysis

All substances of very high concern (on a list of candidate substances for authorization that will be produced by the Agency) present in articles above a concentration limit of 0.1% weight by weight and present above 1 tonne per year must be notified to the Agency except where exposure to humans and environment can be excluded during normal conditions of use including disposal. In such case safety instructions should



be provided. Information will also be made available to consumers on request. As a safety net, the Agency can require a registration of a substance in an article at any time when it considers that its release poses a risk to human health or the environment.

3.3. Obligations for exporters to EU



European Chemicals Agency (ECHA) has proposed the first candidate list of 16 substances of very high concern (SVHC) for the authorization process according to the Annex XV of 1907/2006 REACH directive. On 26 May 2009, the Member State

Committee of the European Chemicals Agency (ECHA) and the ECHA Secretariat reached consensus and included seven substances of very high concern (SVHC) in the REACH Authorisation List. Their recommendation has been submitted to the European Commission.

3.3.1 SVHC chemicals generally used in textile industry included in the Candidate List

S.NO.	Substance Name	EC No./CAS No.	Application Areas
1	Dibutyl phthalate	201-557-4/ 84-74-2	Clothes of coated textile, dresses, jerseys, pullovers, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets, work & protection clothes for Men.
2	Bis (2-ethyl (hexyl) phthalate) (DEHP)	204-211-0/117-81-7	Softener in Polymers and Synthetical resin
3	Hexabromocyclododecane (HBCDD)	247-148-4/ 25637-99-4	Clothes of coated textile, dresses, jerseys, pullovers, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets, work & protection clothes for men
4	Alkanes, C10-13, chloro (short chain chlorinated Paraffins)	287-476-5/ 85535-84-8	Fire retarding substances in textiles

5	Bis(tributyltin)oxide	200-268-0/ 56-35-9	Biocide in anti-mould colours
6	Benzyl butyl phthalate	201-622-7/ 85-68-7	Softner in polymers and synthetic resin
7	Sodium dichromate, dehydrated (CMR)	234-190-3/ 10588-01-9	Clothes of coated textile, dresses, jerseys, pullovers, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets, work & protection clothes for men
8	Anthracene	204-371-1/ 120-12-7	Textile mordant
9	Cobalt dichloride	231-589-4/ 7646-79-9	Mordant dye
10	Diars pentaoxide	215-116-9/ 1303-28-2	Colouring industry, preserver.
11	Potassium dichromate	231-906-0/ 7778-50-9	Clothes of coated textile, dresses, pullover, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets, work & protection clothes for men
12	Tris(2-chloroethyl) phosphate	204-118-5/ 115-96-8	Clothes of coated textile, dresses, jerseys, pullovers, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets
13	Lead Sulfochromate yellow (C.I. Pigment Red 104)	215-693-7/ 1344-37-2	Clothes of coated textile, dresses, jerseys, pullovers, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets
14	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9/ 12656-85-8	Clothes of coated textile, dresses, jerseys, pullovers, vests etc., overcoats & jackets, ski suits, socks & stockings of knitwear, track suits, t-shirts & singlets, work & protection clothes for men
15	4,4'-Diaminodiphenylmethane	202-974-4/ 101-77-9	Raw Material for the production of "Methylenediphenyl diisocyanat" for PUR (main application) Epoxy resin, adhesives

As a manufacturer, importer or retailer for EU markets, it is of great importance that the manufacturer makes sure that their products are free of the 15 SVHCs listed under EU REACH legislation and avoid using any SVHCs

All the article exporters to EU have to provide information to consumers about SVHC in articles without an intended release within 45 days upon request. The inclusion of a substance in the Candidate List is solely based on the specific intrinsic hazardous properties of the substance (as described by Article 57 of REACH).

3.3.2. ECHA updates the REACH Candidate List

Seven new substances have been added to the Candidate List of Substances of Very High Concern (SVHC) for authorisation. Companies manufacturing or importing these substances, or articles containing the substances, need to check their potential obligations that result from the listing.

<u>Substance name</u>	<u>EC No.*</u>	<u>CAS No.*</u>	<u>Reason for inclusion</u>
1,2,3-Trichloropropane	202-486-1	96-18-4	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	Toxic for reproduction (article 57c)
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	Toxic for reproduction (article 57c)
1-Methyl-2-pyrrolidone	212-828-1	872-50-4	Toxic for reproduction (article 57c)
2,4-Dinitrotoluene	204-450-0	121-14-2	Carcinogenic (article 57a)
2-Ethoxyethanol	203-804-1	110-80-5	Toxic for reproduction (article 57c)
2-Ethoxyethyl acetate	203-839-2	111-15-9	Toxic for reproduction (article 57c)
2-Methoxyethanol	203-713-7	109-86-4	Toxic for reproduction (article 57c)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	Carcinogenic (article 57a)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	81-15-2	vPvB (article 57e)
Acrylamide	201-173-7	79-06-1	Carcinogenic and mutagenic (articles 57 a and 57 b)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	85535-84-8	PBT and vPvB (articles 57 d and 57 e)
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	-	Extracted from Index no.: 650-017-00-8	Carcinogenic (article 57a)

following conditions:			
a) Al ₂ O ₃ and SiO ₂ are present within the following concentration ranges:			
Al ₂ O ₃ : 43.5 – 47 % w/w, and SiO ₂ : 49.5 – 53.5 % w/w,			
Or			
Al ₂ O 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).			
Ammonium dichromate	232-143-1	9/5/7789	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Anthracene	204-371-1	120-12-7	PBT (article 57d)
Anthracene oil	292-602-7	90640-80-5	Carcinogenic ¹ , PBT and vPvB (articles 57a, 57d and 57e)
Anthracene oil, anthracene paste	292-603-2	90640-81-6	Carcinogenic ² , mutagenic ³ , PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	91995-15-2	Carcinogenic ² , mutagenic ³ , PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene paste, distn. lights	295-278-5	91995-17-4	Carcinogenic ² , mutagenic ³ , PBT and vPvB (articles 57a, 57b, 57d and 57e)
Anthracene oil, anthracene-low	292-604-8	90640-82-7	Carcinogenic ² , mutagenic ³ , PBT and vPvB (articles 57a, 57b, 57d and 57e)
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Toxic for reproduction (article 57c)
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	117-81-7	Toxic for reproduction (article 57c)
Bis(tributyltin)oxide (TBTO)	200-268-0	56-35-9	PBT (article 57d)
Boric acid	233-139-2 / 234-343-4	10043-35-3 / 11113-50-1	Toxic for reproduction (article 57 c)
Chromic acid,	231-801-5	7738-94-5	
Oligomers of chromic acid and	-	-	Carcinogenic (article 57a)

dichromic acid,			
Dichromic acid	236-881-5	13530-68-2	
Chromium trioxide	215-607-8	1333-82-0	Carcinogenic and mutagenic (articles 57 a and 57 b)
Cobalt dichloride	231-589-4	7646-79-9	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Cobalt(II) carbonate	208-169-4	513-79-1	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Cobalt(II) diacetate	200-755-8	71-48-7	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Cobalt(II) dinitrate	233-402-1	10141-05-6	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Cobalt(II) sulphate	233-334-2	10124-43-3	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Diarsenic pentaoxide	215-116-9	1303-28-2	Carcinogenic (article 57a)
Diarsenic trioxide	215-481-4	1327-53-3	Carcinogenic (article 57a)
Dibutyl phthalate (DBP)	201-557-4	84-74-2	Toxic for reproduction (article 57c)
Diisobutyl phthalate	201-553-2	84-69-5	Toxic for reproduction (article 57c)
Disodium tetraborate, anhydrous	215-540-4	1303-96-4/ 1330-43-4/ 12179-04-3	Toxic for reproduction (article 57 c)
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	247-148-4 and	25637-99-4	
	221-695-9	3194-55-6	
Alpha-hexabromocyclododecane		(134237-50-6)	
Beta-hexabromocyclododecane		(134237-51-7)	
Gamma-hexabromocyclododecane		(134237-52-8)	
			PBT (article 57d)
Hydrazine	206-114-9	302-01-2 /	Carcinogenic (article 57a)

		7803-57-8	
Lead chromate	231-846-0	7758-97-6	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead hydrogen arsenate	232-064-2	7784-40-9	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	Carcinogenic and toxic for reproduction (articles 57 a and 57 c)
Pitch, coal tar, high temp.	266-028-2	65996-93-2	Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e)
Potassium chromate	232-140-5	7789-00-6	Carcinogenic and mutagenic (articles 57 a and 57 b).
Potassium dichromate	231-906-6	7778-50-9	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Sodium chromate	231-889-5	11/3/7775	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Sodium dichromate	234-190-3	7789-12-0/ 10588-01-9	Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c)
Strontium chromate	232-142-6	6/2/7789	Carcinogenic (article 57a)
Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	Toxic for reproduction (article 57 c)
Trichloroethylene	201-167-4	79-01-6	Carcinogenic (article 57 a)
Triethyl arsenate	427-700-2	15606-95-8	Carcinogenic (article 57a)
Tris(2-chloroethyl)phosphate	204-118-5	115-96-8	Toxic for reproduction (article 57c)
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	-	Extracted from Index no. 650-017-00-8	Carcinogenic (article 57a)

following conditions:			
a) Al ₂ O ₃ , SiO ₂ and ZrO ₂ are present within the following concentration ranges:			
Al ₂ O 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).			

3.3.3. SVHC-Impact of the Listing

Companies may have legal obligations resulting from the inclusion of the substances in the Candidate List from the date of inclusion. These obligations are linked to the listed substances on their own, in preparations and in articles.

3.3.4. SVHC -Obligation for substance

It is now obligatory, effective 28 Oct 2008, for EU & EEA suppliers of a substance to provide a safety data sheet to their customers when the substance is on the Candidate List.

3.3.5. SVHC -Obligation for preparation

EU and EEA suppliers of a preparation not classified as dangerous according to Directive 1999/45/EC have to provide the recipients, at their request, with a safety data sheet if the preparation contains at least one substance on the Candidate List and its individual concentration is at least 0.1% (w/w) for non gaseous preparations and at least 0.2% by volume for gaseous preparations⁴. This is now made mandatory.

3.3.6. SVHC-Obligation for articles (Read as Apparels, Textiles, Home textiles, Packaging material etc...)

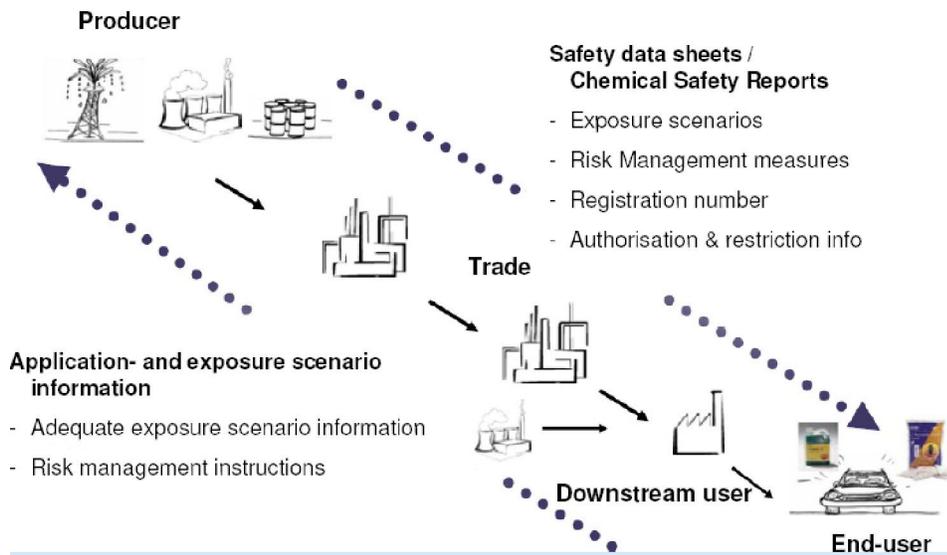
From 1st December 2011, EU and EEA producers or exporters of articles to EU have to notify ECHA if their article contains a substance on the Candidate List. This obligation applies if the substance is present above 0.1% (w/w) and its quantities in the produced/imported articles are above 1 ton in total per year per company (As per Article 7(2) of Regulation EC No.1907/2006) and must provide sufficient information, available to them, to their customers and on request to consumers within 45 days of the receipt of this request (As per Article 33 of Regulation EC No.1907/2006). This information must ensure safe use of the article and, as a minimum, include the name of the substance.

3.3.7. Obligation for Non EU Manufacturer

Downstream users will need to ascertain that the substances they use have been registered by their suppliers. Moreover, for each substance used in the production process, the "Safety Data Sheets" will have to comply with the new REACH provisions; basically, the "Safety Data Sheets" must be updated with the Only REACH registered substances will be allowed to enter the European market or to be used in European factories. This will result in a significant impact on manufacturers, in term of supply chain organisations, revision of import/export strategies, internal and external communication on the technical and environmental features of substances, etc

3.3.8. Downstream users' obligation and supplier communication strategies

A "downstream user" is any natural or legal person established within the EU who uses a substance in the course of its industrial or professional activities. A downstream user may be for instance a factory using a polymeric fibre for producing textile articles.



For the downstream users in the textile industry, beyond the formal REACH requirements, one of the key issues is the verification of the available information from the suppliers, in order to ensure that

all the substances and raw materials used in the production process have been registered and are suitable with the specific use.

It is clear that, for the suppliers, providing their clients with all this information – the updated safety data sheet, the inclusion of exposure scenarios in the registration dossiers – will be a key issue.

4. CONCLUSION

In practice, anyone producing in non EU countries, although not subjected to the obligations foreseen by the REACH regulation as “downstream users”, must in any case register the substances and (in some cases) the articles he wants to export to Europe. Summarizing, in order to export into EU, textile factories must meet the following requirements:

- 1) Chemical substances, preparations and, in some cases, articles produced in non EU countries, and exported to Europe, will have to be registered.
- 2) The presence in articles of certain hazardous substances, or of substances subject to Restrictions if exceeding a certain thresholds of use or concentration in articles, must be notified.
- 3) Beyond the formal obligations imposed by the REACH regulation, it will be essential, for non-European industries to understand how REACH will affect their own business. In particular, suppliers must have the capability to provide their customers with all the information required by the REACH regulation concerning the substances or preparations sold to them. Firms unable to comply with this need may experience a reduction in their market share.

5. FREQUENTLY ASKED QUESTION (FAQ)

5.1 REACH general

Q1. What is the overall goals of the new chemicals regulation?

The two most important goals are to improve the protection of human health and the environment from the hazards of chemicals and to enhance the competitiveness of the EU chemicals industry. Enterprises that manufacture or import more than one tonne of a chemical substance per year will be required to register the chemical in a central database.

Q2. How does REACH provide for punishments / penalties / fines / imprisonment? Are they country-specific punishments or EU-wide punishments?

Penalties are country-specific and Member States will impose a penalty for non-compliance, which will be effective, proportionate and dissuasive.

Q3. How will ECHA monitor REACH implementation?

ECHA will request reports about REACH implementation from member states. The national authorities will perform the implementation checks.

Q4. ELINCS substances are regarded as registered” per Article 24. Clearly, registration is not required from the person who notified the substance under Directive 67 / 548/EEC. Must others who use the ELINCS substance register it, or is it regarded as registered for them also?

ELINCS substances are regarded as registered only for companies who submitted the required information under Directive 67/548/EEC. The Agency will assign a registration number by 1 Dec. 2008 Source: Article 24(2) says, “If the quantity of a notified substance...reaches the next tonnage

threshold...additional required information... shall be submitted." The concept of next tonnage threshold is only meaningful for those who submitted information for a particular tonnage threshold under Directive 67/548/EEC.

Q5. Are there different requirements to be introduced for Small and Medium Enterprises (SME)?

Small and medium-sized enterprises (SME) are a vital part of the EU chemicals industry; for that reason the Regulation has been made workable also for them (e.g. a lower registration fee). Since safety is a key concern regardless of company size, the REACH information requirements relate to production volumes, uses and properties of the chemicals, and not to turnover or the number of employees of the companies.

Q6.SME will face more difficulties in compliance with REACH administration than large-scale enterprises. How did the EC balance the different interests between the large-scale enterprises and SME?

For the most part, SME are more likely than other companies to be registering at the 1-10 t/y level. They will therefore benefit from the longest transition period and a lower registration fee will be required. The information requirements for these volumes are also light compared to the higher tonnages and no CSR needs to be developed.

Q7. What information network has been built for supply chains in Europe?

It is responsibility of the Industry to determine how to handle this.

5.2 Pre-registration and Registration

Q8. Is there a legal requirement to pre-register all substances?

There is no legal obligation for it, but pre- registration is strongly encouraged to gain the benefit of the extended registration deadlines.

Q9. What are the substances within articles that have to be registered?

Pursuant to Article 7(1) all substances in imported articles that meet the following two conditions must be registered under REACH:

1. the substance is present in the imported articles in quantities above 1 tonne per importer per year, and
2. the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Q10. What happens if we, as a DU, find out after preregistration has ended that our substance has not been pre-registered?

You can ask the ECHA to publish your name and substance on its website, which will enable potential registrants to contact you (REACH Article 28.5). The new potential supplier can pre-register it by sending the information described in REACH Article 28.1 within 6 months of first manufacture/ import or use (REACH Article 28.6). Also, this information must be sent at least 12 months before the phase-in deadline. If the supplier is not manufacturing/importing it for the first time, they cannot benefit from the phase-in dates and must register it immediately in order to continue supplying it.

Q11. Which substances are exempt from registration?

Some substances are exempted from REACH altogether and so will not be subject to Registration, for example: radioactive substances, non-isolated intermediates, wastes, substances under customs supervision, and, if Member States so choose, substances necessary for the interests of defense. In the REACH regulation you will find a more comprehensive list of general exemptions within Article 2 and Annex V and more specific substance exemptions within Annex IV. Substances manufactured or imported in quantities less than 1 tonne per year do not need to be registered.

Q12. Is there an obligation to register steel or other alloys?

Alloys (including steel) are Preparations under REACH, albeit special ones where the properties of the Preparation do not always simply match the properties of the components. As Preparations, alloys do not have to be registered but their component metals must be registered if manufactured/imported in quantities greater than 1 tonne per year.

Q13. One of the registration requirements is “(a) the substance is present in those articles, in quantities totaling over 1 tonne per producer or importer per year.” We understand that this 1 tonne is for each individual producer or importer. Is our understanding correct?

Yes, it is per producer or importer (legal entity).

Q14. Will each company that registers a substance receive a different registration number for it?

Yes, each company receives an individual registration number.

Q15. Is it right to think that the mechanism for registration and restriction of new chemicals is almost the same as the existing one?

Yes, substances put on the market after 1981 and compliant with the existing regime are seen as “REACH compliant”.

5.3 Authorisation / Notification and SVHC

Q16. Can the industry predict which substances may be subject to an authorisation? Are the criteria clear enough?

The identification of the different groups of substances that may be subjected to authorisation is clearly defined. For CMR category 1 and 2 substances, the criteria have long been established in the present legislation (Directive 67/548), for PBT and vPvB substances the criteria are included in REACH Annex XIII. For any other substance there must be scientific evidence of probable serious effects to humans or the environment, which give rise to an equivalent level of concern as CMRs category 1 and 2, PBTs or vPvBs. To provide more certainty for industry, substances will be identified through an open process and the decision to include the substance in REACH Annex XIV will finally be taken by the Commission in accordance with the Comitology procedure. The process for such decisions is as follows:

Dossiers to identify a substance for the authorisation procedure will be prepared either by a Member State or by the Agency if requested by the Commission. All dossiers will be published and will be open for comments by interested parties. Substances identified as having any of the listed properties of very high concern will be included on a candidate list published by the Agency, within which the Agency indicates the substances that are on its work programme. The Agency then recommends substances to the Commission for inclusion in REACH Annex XIV. Priority will normally be given to substances with PBT or vPvB properties, with wide dispersive use or in high volumes. These priority substances may then finally be included in REACH Annex XIV.

Q17. Can applications for authorisation be submitted together?

Grouping of applications for authorisation is possible in REACH. Groups can be of: manufacturers, importers and DUs; substances; uses; or any combination of these groups. This is to enable costs to be minimised and the system to process applications rapidly

Q18. Which are the substances within articles that require agency notification?

Pursuant to Article 7(2), SVHC listed on the candidate list for Annex XIV that meet the following two conditions must be notified under REACH: 1. the substance is present in the imported articles in quantities above 1 tonne per importer per year, and 2. the substance is present in the imported quantities above a concentration 0.1 % weight by weight.

Q19. How will notification work for DUs of substances under the product & process oriented research and development (PPORD) exemption?

The PPORD exemption from registration (Article 9) is for manufacturers and importers doing research, either by themselves or with listed customers. The substances for these uses do not require registration (and DU requirements do not apply because the supplier is not required to prepare a Chemical Safety Report) and would not be supplied to others in the supply chain for commercial purposes or to the general public at any time. However if the substance is used in quantities greater than 1 tonne per use per year, the DU must notify the Agency.

Q20. If a product contains more than 0.1% weight by weight (w/w) of SVHC, a manufacturer is liable to submit notification. Should 0.1% be calculated in terms of vehicle weight or component weight?

Always use the weight of the article manufactured in or imported into EU.

Q21. Could you be more specific about the expression “the substance is present in those articles above a concentration of 0.1% weight by weight?” Because a general automobile weights about 1,500 kg, 0.1 wt% of an automobile is 1.5 kg. It

follows that substances used in an automobile should be controlled if the weight exceeds 1.5 kg. Is this understanding correct?

Yes, if a car is imported (the article in this case), this is correct for SVHC.

Q22. Manufacturers of final products are required to confirm that the use of SVHC contained in Articles (such as materials, parts, and subassemblies) has been authorized for a certain purpose. Suppose that substance X is a SVHC.

(Case 1) When a final product contains 2% (w/w) of substance X:

The article manufacturer/importer notifies the agency.

(Case 2) When a final product contains 0.05% (w/w) of SVHC substance X:

0.1% (w/w) is the threshold. If X is below 0.1% this obligation does not apply.

Q23. How is chemical control in REACH linked to waste control?

For all substances above 10 tonnes / year, a Chemical Safety Report (CSR) and a Chemical Safety Assessment (CSA) assessment have to be prepared. This risk assessment has to take into account

all ways (including waste streams) in which the substance could contaminate the environment.
“Waste” by itself is exempt from REACH and need not be registered.

Q24. We understand that REACH assumes that the European Chemicals Agency is responsible for the registration and assessment of chemicals. In which organizations are mechanisms for conveying information on substances contained in articles discussed?

The ECHA is the only agency registering substances. The agency will deliver IT tools for all registration and notification obligations.

Q25. What kind of SVHC do we need to take care of?

Substances that are one of the following:

- carcinogenic, mutagenic or toxic to reproduction (CMRs)
- persistent, bio-accumulative and toxic (PBTs)
- very persistent and bio-accumulative (vPvBs)
- seriously and / or irreversibly damaging the environment or human health, as substances damaging the hormone system

The general aim of REACH is to replace these potentially very hazardous substances by safer alternatives whenever possible.

If this is not possible, in exceptional cases hazardous substances can be authorised if the registrant can prove that

- an adequate risk control is guaranteed
- the benefits for the society or the economy are estimated higher than the potential risk
- no alternative substances are existent according to research results

Every such authorisation is however limited in time in order to encourage research for an alternative substance. If the potentially hazardous substances are used for R&D purposes, exemptions can be granted.

Q26. Considering that supply chains spread beyond national boundaries, the implementation of REACH requires the cooperation of different countries. Does the EU have a plan to promote activities to raise awareness of REACH?

Each Member State has established "National help desks, these help desks will network together. Raising awareness is a task for industry and its associations. The responsibility for complying with REACH lies with the industry.

Q27. The "use" is the key to REACH. Some metals may serve as a catalysts when reduced to a fine powder but do not have oxidizing properties when used for decoration or plating. In this case, is it right to think that the metal must be registered as a "catalyst?"

The substance must be registered for the appropriate "Use and Exposure Category" depending if it is used as a catalyst or alternatively for decoration or plating. RIPs will clarify this.

Q28. Is there a mechanism for conveying information on "use" to upstream suppliers? Shouldn't textile industries in different countries share the recognition of "use?"

Communication within the supply chain is key for REACH compliance. The textile and textile chemical Industries along with others, is building up networks.

Q29. What does it cost to use the Reach-IT system (including IUCLID5)?

IUCLID 5 can be downloaded free of charge from the ECHA homepage, see Guideline 12.

Q30. Approximately how many substances are treated as SVHC?

The first candidate released by ECHA in the month of October 2008 covers 16 substances. A rough estimate is 1000-2000 substances will be added in the list. From 2011 the REACH Annex XIV priority list will be updated at least every 2 years.

Q31. Will all SVHC substances be disclosed at one time?

Priority list for inclusion of the substances within REACH Annex XIV will be established and published for comments, so not all will be included at one time. It will be an ongoing process for years to come. At the moment only 16 SVHCs identified and added in the candidate list

Q32. If a supply chain extends into more than one country, it may be difficult to collect sufficient information on the content of SVHC.

In light of this difficulty, sufficient time should be allowed for data collection. Start collecting the information you need now.

5.4 Response to REACH

Q33. We understand that chemical manufacturers are basically responsible for the registration of new and existing chemical compounds, and automobile manufacturers need only be concerned with preparations “intended to be released.” What does the TF-REACH think about this point?

You must identify your roles and responsibilities under REACH.

Use the AIG and / or consult the REACH Navigator under: http://reach.jrc.it/navigator_en.htm

Q34. We think that preparations “intended to be released” include brake pads (preparation) and windscreen washer fluid (preparation) in RIP 3.8. What is the TF-REACH opinion about this point?

This AIG makes it clear. We and the brake pad supplier organizations have the same opinion: brake pads are articles with no “intended releases”. The guideline includes the intended AI releases, see Chapter 5.7: Guideline 7 and RIP 3.8

Q35. What do you think about legal compliance with REACH? Of course textile manufacturers should respond in good faith. However, how do you check the contents of SVHC contained in articles that are difficult to check by data or by other means?

“Legal Compliance” is a need for each company in the supply chain. Your supplier has to inform you about SVHC in the products he delivers to you. You are obliged to deliver information about SVHC to your customer after you have received it from your supplier.

Q36. How about parts purchased from outside the EU? How will you direct the suppliers to respond to REACH?

The obligations for importers are described in REACH and this AIG.

Q37. After the raw materials to be used in pigment ,dyes etc. are shipped by the chemical industry, suppliers might add more substances. How strictly should textile manufacturer control these materials?

In general, all substances have to be registered, independent of when or who has added it to a product.

Q38. Shouldn't textile industries in different countries share the recognition of exposure scenarios of substances "intended to be released?"

Yes, it is possible.

Q39. Is there a plan to ask suppliers to pre-register their substances/preparations? If so, could you please tell us the expected period of preregistration?

The pre registration period is over.1st of June 2008-1st of December 2008. Proposals for an awareness letter and a declaration of intent are in this guide.

Q40. What are the obligations of a distributor?

A distributor has the obligation “not to interrupt” the information flow within the supply chain. He has to pass the information needed for REACH compliance up and down the supply chain. (REACH article 34)

Q41. Is it necessary to inform your supplier if you are a DU and using a substance at less than 1 tonne per year?

Yes, because your supplier must note your usage on the SDS regardless of the tonnage.

5.5 Import of substances to the EU – Only Representative (OR)

Q42. What are the responsibilities of a non- EU company who has nominated an Only Representative?

Non-EU companies have no obligation under REACH. Compliance with REACH must be ensured by their EU-based importers (i.e. they have to register the substance, provide safety data sheets where necessary, etc.). In order to allow importers to fulfill their obligations, non-EU companies will however have to provide the necessary information on the substance to the importer. If a non-EU company does not wish the importer to be responsible for obligations under REACH (e.g. if the non-EU company does not wish to disclose confidential information), it may appoint an Only Representative. In this case, the Only Representative takes over all obligations of the importers under REACH. (See also ECHA website and article 8 of REACH regulation.)

Q43. Are EFTA member states included in the scope of REACH?

Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Agreement (EFTA). The EFTA Convention established a free trade area among its Member States

in 1960. Iceland, Liechtenstein and Norway entered into the Agreement on the European Economic Area (EEA) in 1992, which entered into force in 1994. Therefore, the EEA is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States. As soon as REACH is implemented by the EEA EFTA-States (which means EFTA States covered by EEA agreement), imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH. EFTA is preparing a proposal for an EEA Joint

Committee Decision, incorporating the Regulation and establishing the conditions for the EEA EFTA participation in the EU Chemicals Agency. EFTA is targeting to have the Regulation incorporated by 1 June 2008. Therefore, an importer of a substance from an EEA country would not be required to register the substance under REACH and would simply be regarded as a DU. However, his supplier in the EEA/EFTA States will have to register the substance as a manufacturer under REACH with all associated obligations like any other manufacturer within the EU. Importers of a substance from Switzerland (a non EU country belonging to EFTA but not to EEA) will have the same obligations under REACH as any other importer. Examples: A formulator purchasing his substances in Germany or Iceland will be considered as a DU. A formulator purchasing his substances in Switzerland or Japan will be considered as an Importer.

Q44. When will Norway, Iceland and Liechtenstein bring REACH into force?

1 June 2008

Q45. What are “Appropriate Instructions” and how are they to be provided? Is it possible to include the information in the pre-existing systems?

Yes, but other solutions are possible as well.

Q46. Does the candidate list exist already?

Yes, the first list with 16 SVHCs available

Q47. How will the new legislation ensure confidentiality of information with a public list of chemical substances?

The first list of substances that the Agency publishes will be the list of pre-registered substances. This list will be comprised of only the names of the substances and not the names of any company manufacturing or importing it. The purpose of this list is to give an overview of the substances that will be phased into REACH.

6. REFERENCES:

1. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18th December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
2. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances
3. DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of dangerous preparations

4. European Chemical Agency, Helsinki, press release Ref: ECHA/PR/08/34 Dt: 9th October 2008

method (ISO 17353:2004)
