



REACH

Registration, Evaluation, Authorization & restriction of Chemicals - Obligation for Textile and Apparel Industry

October 13th 2011, TAG 2011, Mumbai



Quality



Health & Safety



Hygiene



Environment



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■ REACH – The aim of the new chemical regulation

- Ensuring a high level of protection of human health and the environment,
- Identifying and minimizing of risks of EINECS-listed substances
- Ensuring a free circulation of substances on the internal European market while enhancing competitiveness and innovation (Establishment of a integrative single European market)
- Transparency of the properties of chemical substances in the public
 - « The well informed consumer »

Registration

Evaluation

Authorisation of

Chemicals



**REGULATION (EC) No 1907/2006
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
was passed on 18th December 2006**



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 **TÜVRheinland**[®]
Precisely Right.

■ REACH – The new European chemical legislation – Actions

Registration

Evaluation

Authorisation of

Chemicals

- According to REACH all manufacturers, importers and users have to register their substances on their own or in preparations from an amount of 1 t/yr.
- REACH affects each company which wants to bring substances into the European Market ("**No data, no market**")
- For hazardous substances (SVHC) there is only a restricted Authorisation.
- At least 30,000 „old“ substances (EINECS *), which are in Europe on the market, will be affected.
- REACH entered into force from June 2007.



* „European inventory of existing commercial chemical substances“

** „European list of notified chemical substances“

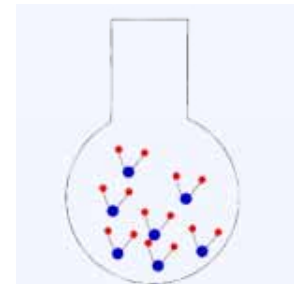
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■ REACH – Basic definitions

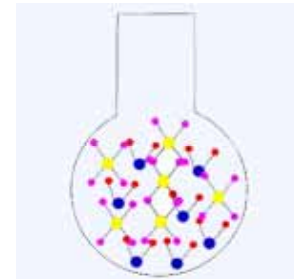
Substance:

means a chemical element and its compound in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.



Preparation

means a mixture or solution composed of two or more substances.



Only the substances have to be registered, not the preparations!!



■ REACH – Basic definitions

- **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;
- **Intended release**: A release of substances from articles is intended if the intended releases are deliberately planned and have a specific function for the article, which is frequently not the main but an accessory function of the object

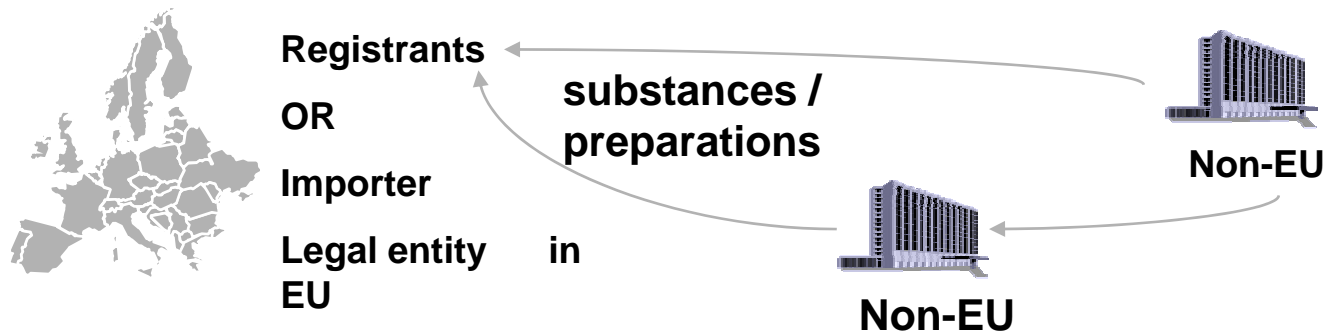


■ Who can register / Notify a substance

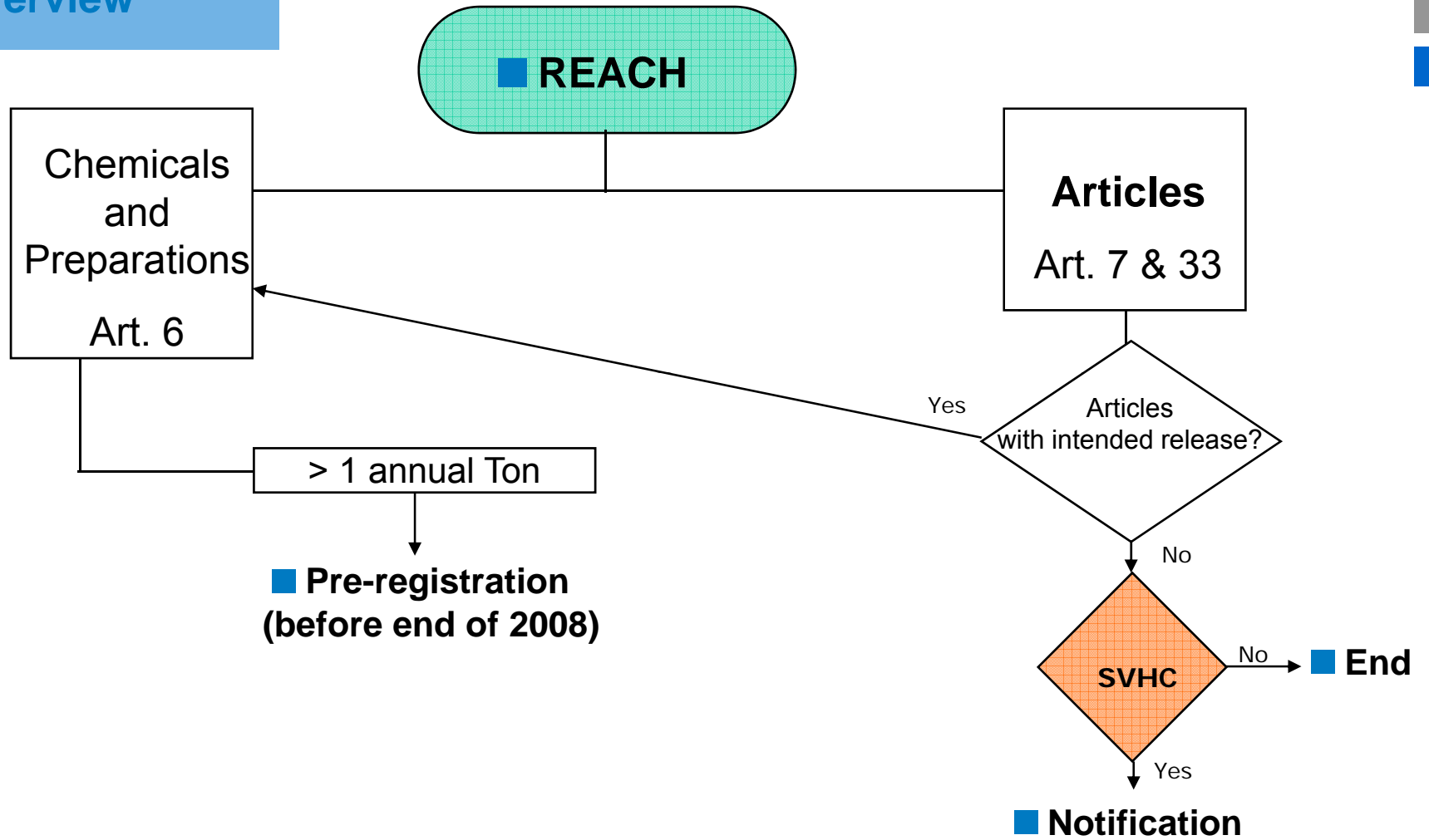
Registrants

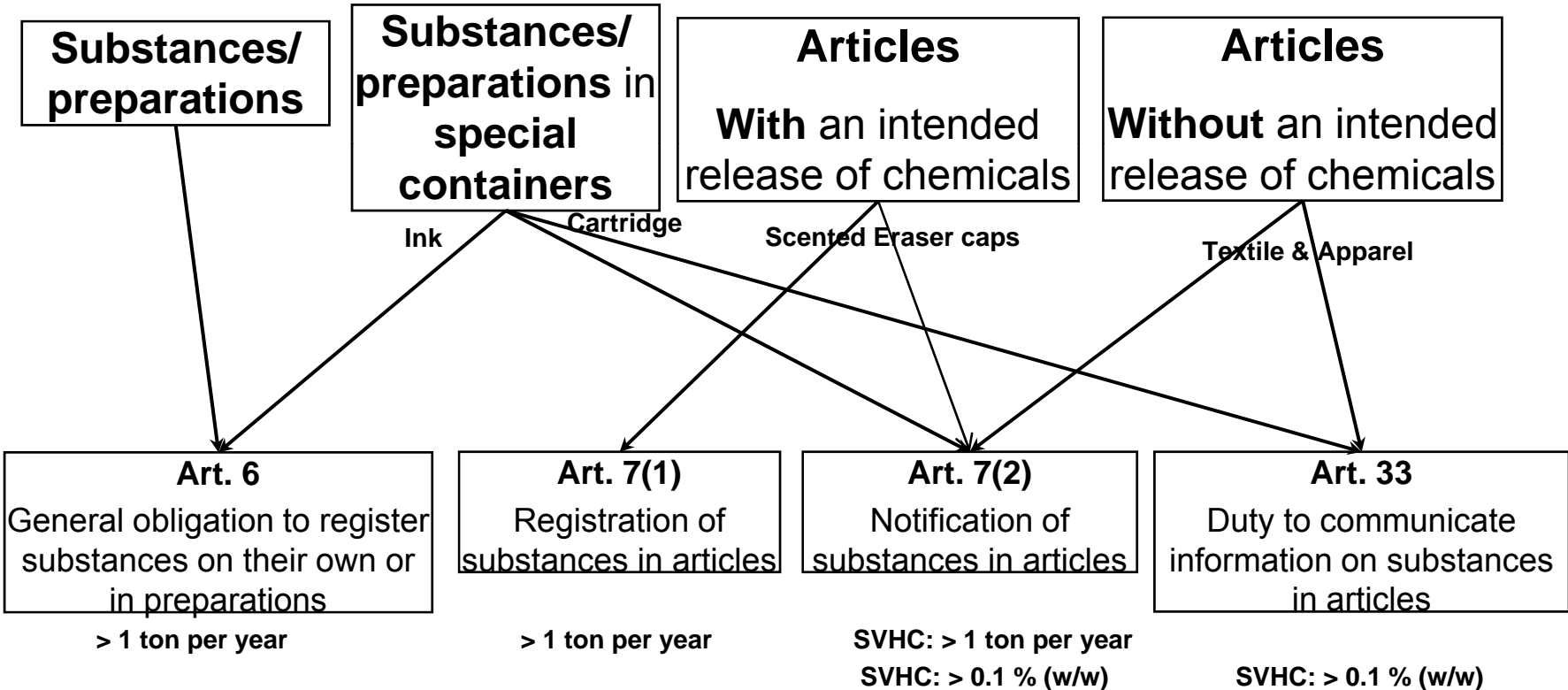
- **EU manufacturers** of substances on their own or in preparations.
- **Importers** of substances on their own or in preparations.
- **Only representatives of non-EU manufacturers**

only a natural or legal person established in the European Union can be a registrant



• Overview





■ Time schedule for the registration of substances

ECHA

Registration of Non-Phase-In-Substances > 1 t/a

June 1st 2007

Entry into force of REACH

Pre-registration
June 1st 2008 until
December 1st 2008

for subs > 1 t/a

**Phase-In until
December 1st 2010**

CMR 1+2 > 1 t/a
R50/53 > 100 t/a
and subs > 1000 t/a

**Phase-In until
June 1st 2013**

subs > 100 t/a

**Phase-In until
June 1st 2018**

subs > 1 t/a

2007

1.5 years

3.5 years

6 years

11 years

Precondition to ensure the transitional time is the pre-registration!



- REACH – Deadlines for article suppliers



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 \geq 1000 tons per year or more, • in amounts \geq 1 t/a if they are known carcinogens, mutagens or reprotoxic substances (category 1 and 2) and • in amounts \geq 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



■ REACH – Which substances have to be registered?

Substances, which will be produced or imported in amounts greater than 1 ton / year

- As a single substance – Textile chemical , eg. Dyes & Pigment
- As part of a preparation – eg. Colourant Mixtures

Substances of very high concern, which are contained in articles , if

- the substance is intended to be released (eg. Scented fabrics) and / or
- the substance is present in quantities > 1 t per year and
- the substance is present in concentration > 0.1% by weight in the article

Unregistered substances will not be allowed on the European market!!

**Substances of very high concern has to be authorized
by the European member states!**



■ REACH – Which substances in article have to be notified?

■ Notification required if

- Substance is on candidate list for authorisation
 - Substance is present in quantities >1 t
 - Substance is present in concentration >0.1% by weight
- (except where there is no exposure)

at the earliest 42 months after entry into force, or 6 months of identification of substance on candidate list)



■ REACH – Which substances will be exempted from REACH?

Exceptions to the registration

- Radioactive substances, substances in waste
- Non isolated intermediates, polymers
- Pharmaceuticals / ingredients of foodstuff
- Substances in Annex II and III (natural substances like Natural Rubber, water, sugar, oil as well as coal, crude oil etc.)

Already registered:

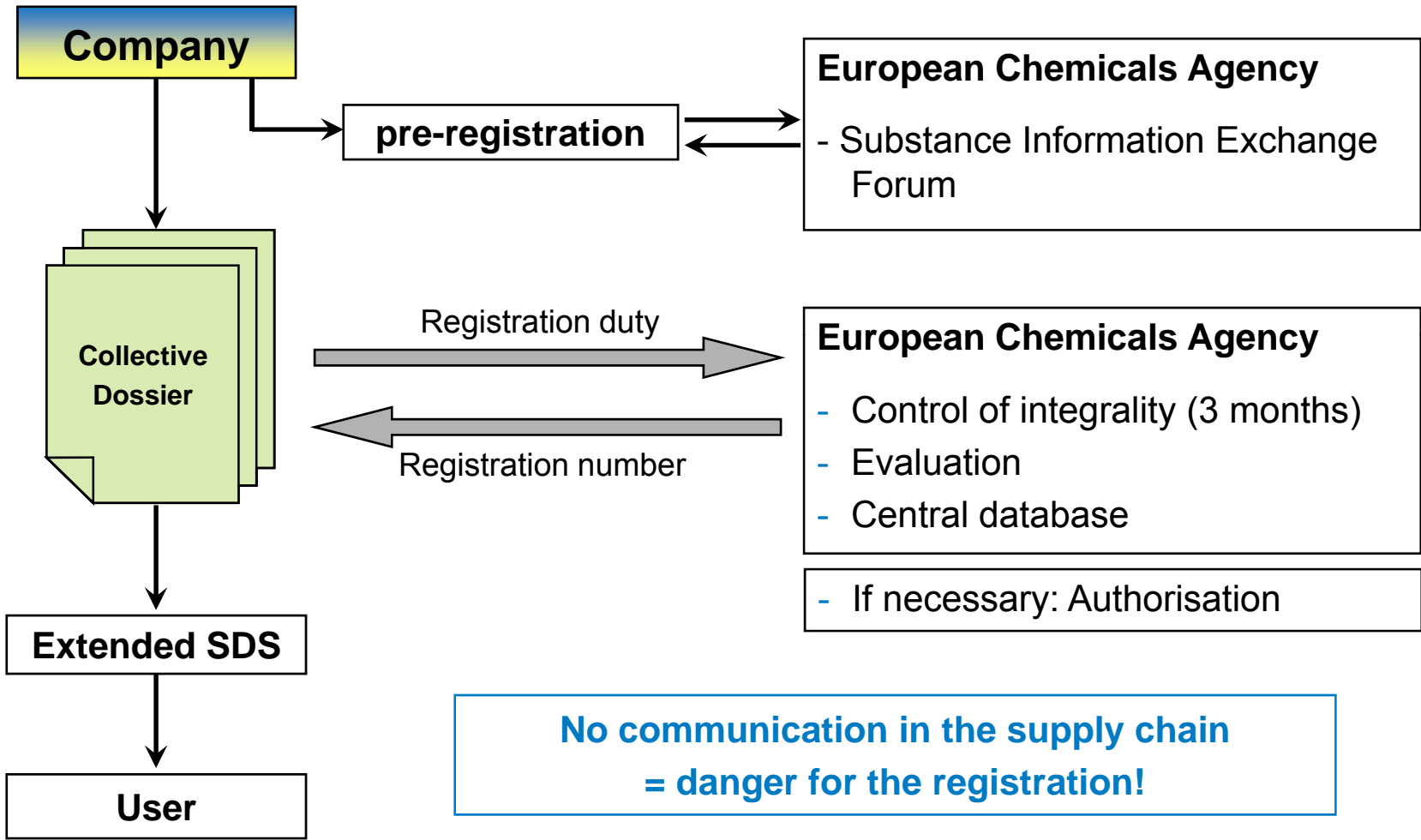
- Active substances in pesticides and biocides
- Registered substances according to directive 67/548/EWG

There are special regulations

- for research and development
- isolated intermediates



REACH –Obligation for substances and preparation manufacturer





■ REACH – Reminder about the pre-registration

■ Pre-registration = 1st June – 1st December 2008

Purpose: identification of all future registrants of a same substance to build up a SIEF

Which information do you need for the pre-registration?

- Chemical name according to IUPAC
- EC and CAS number
- Anticipated registration deadline
- Substances, which are applicable for analogy conclusions (for the chemical and toxicological properties)

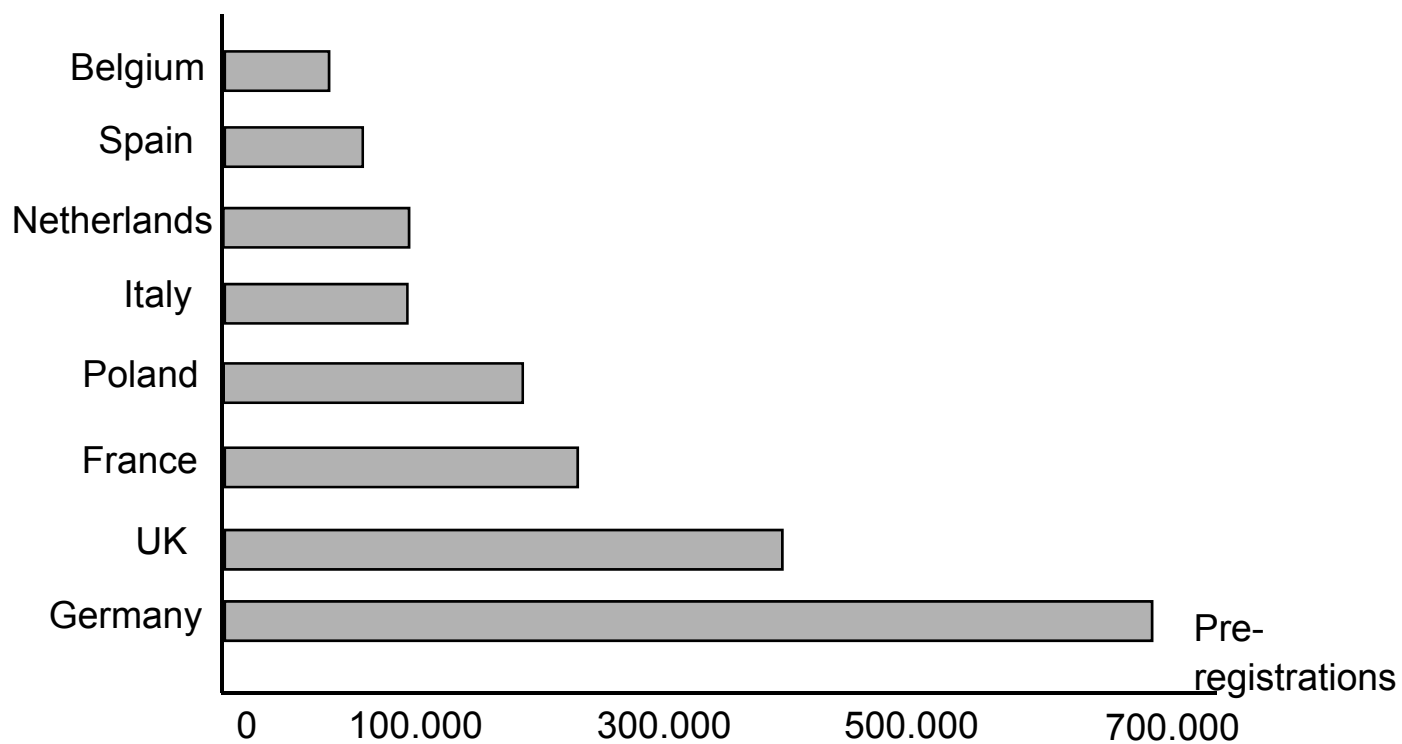
A pre-registration did not generate automatically a registration!!



REACH – Outcome of the pre-registration



Germany carried out most of the pre-registration



Quelle: Echa Press Release, www.echa.europa.eu, December 2008

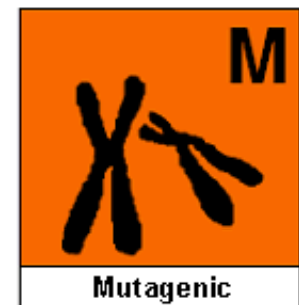
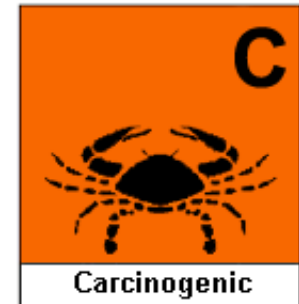


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• REACH Terminology II

- **SVHC (Substances of very high concern)**: 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





■ Notification of SVHC by ECHA

- The notification should be performed by each importer or by the non-European company (via an European legal entity or an Only Representative)
- The submission is only possible on the ECHA Internet Portal (REACH-IT). The notification dossier should be performed with IUCLID 5 (dedicated REACH software)
- Information to be notified:
 - Identity and contact details of the importer
 - Registration numbers for the substances if available
 - Identity and classification of substance
 - Brief description of use of the substance in the article
 - Tonnage range of the substance contained in the article

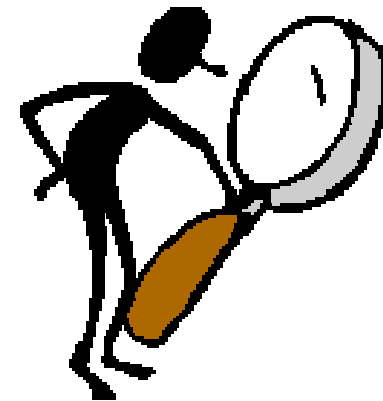




■ >> European Regulation regarding SVHC

- Candidate List :
 - List of substances identified as SVHC by ECHA (European Chemicals Agency)
 - Substances will be added in Annex XIV of the regulation, it means that they will be subjected to the authorization
 - The Candidate list contains currently 53 substances
 - The list is updated regularly : 6 updates in ~ 2,5 years

**Companies should also check
their compliance after each update!!**



■ >> European Regulation regarding SVHC

Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion
2-Ethoxyethyl acetate	203-839-2	111-15-9	20.06.2011	Toxic for reproduction (article 57c)
Strontium chromate	232-142-6	02.06.7789	20.06.2011	Carcinogenic (article 57a)
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	20.06.2011	Toxic for reproduction (article 57c)
Hydrazine	206-114-9	302-01-2 / 7803-57-8	20.06.2011	Carcinogenic (article 57a)
1-Methyl-2-pyrrolidone	212-828-1	872-50-4	20.06.2011	Toxic for reproduction (article 57c)
1,2,3-Trichloropropane	202-486-1	96-18-4	20.06.2011	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	20.06.2011	Toxic for reproduction (article 57c)
Trichloroethylene	201-167-4	79-01-6	18.06.2010	Carcinogenic (article 57 a)
Boric acid	233-139-2 / 234-343-4	10043-35-3 / 11113-50-1	18.06.2010	Toxic for reproduction (article 57 c)
Disodium tetraborate, anhydrous	215-540-4	1303-96-4/ 1330-43-4/ 12179-04-3	18.06.2010	Toxic for reproduction (article 57 c)
Tetraboron disodium heptaoxide, hydrate	235-541-3	12267-73-1	18.06.2010	Toxic for reproduction (article 57 c)
Potassium dichromate	231-906-6	7778-50-9	18.06.2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Ammonium dichromate	232-143-1	05.09.7789	18.06.2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
Potassium chromate	232-140-5	7789-00-6	18.06.2010	Carcinogenic and mutagenic (articles 57 a and 57 b).
Sodium chromate	231-889-5	03.11.7775	18.06.2010	Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c)
2,4-Dinitrotoluene	204-450-0	121-14-2	13.01.2010	Carcinogenic (article 57a)
Acrylamide	201-173-7	79-06-1	30.03.2010	Carcinogenic and mutagenic (articles 57 a and 57 b)





■ >> European Regulation regarding SVHC

Workflow for substances identified in an article

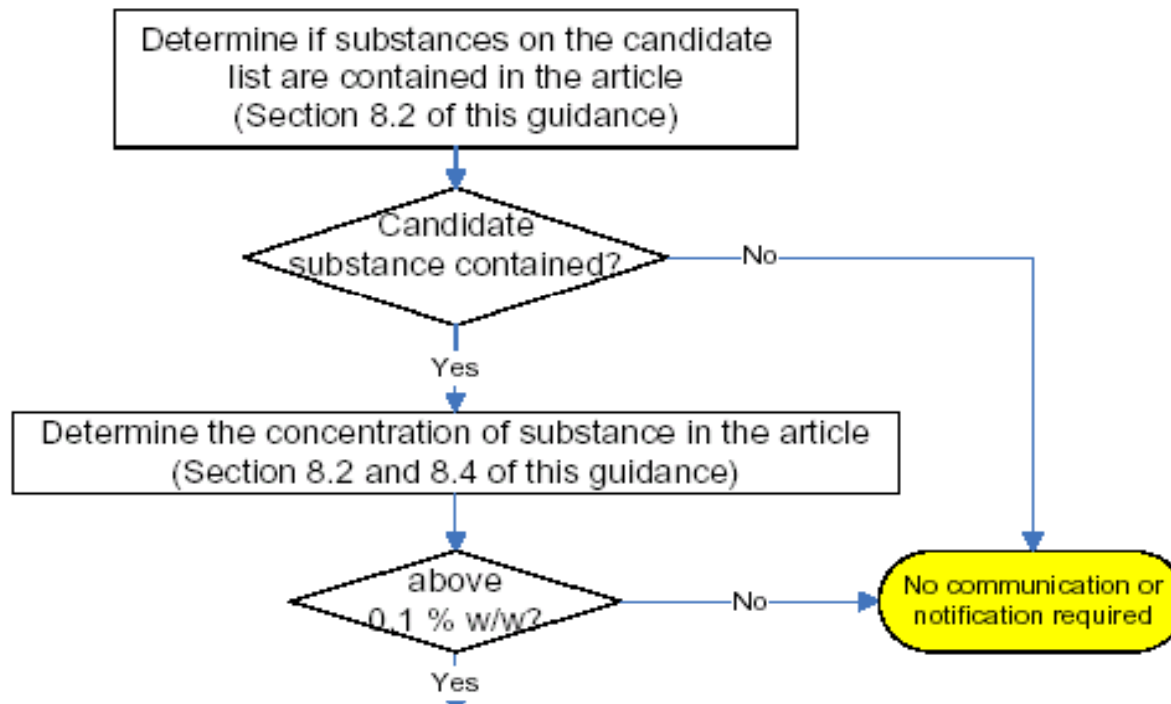
1. Determine the concentration of the substance in the article
 - ✓ Below 0.1 % → no communication, no notification
 - ✓ Above 0.1 % → communication to the customers

2. Check if the substance is registered for that use
 - ✓ If yes → no notification but communication

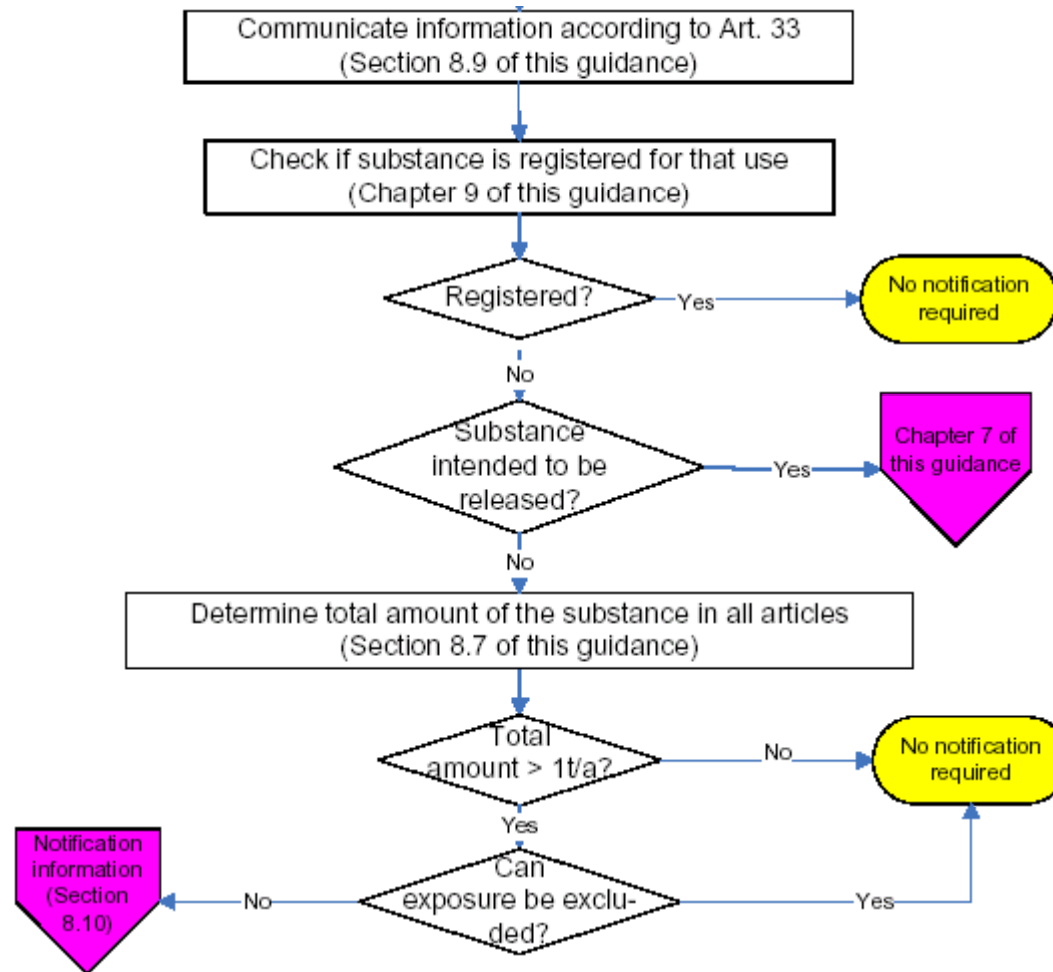
3. If not, determine total amount of substance in all articles
 - ✓ Amount < 1 t/y → no notification
 - ✓ Amount > 1t/y → exposure can be excluded??
 - Exposure can be excluded → no notification
 - Exposure possible → notification



REACH – Workflow for the Notification of substances in articles



REACH – Workflow for the Notification of substances in articles



■ REACH – Articles in REACH- Information in the supply chain on SVHC's in articles



Item	Example
Substance name	Diarsenic trioxide
CAS Number	1327-53-3
Registration number (if provided by supplier)	01-1234567-49-00
Classification and SVHC properties	Carc. Cat. 1; R45; May cause cancer T+; R28; Very toxic is swallowed C; R34; Causes burns N; R50/53; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Concentration in the article ³¹	1% w/w
Information on safe handling including safe disposal if relevant	Prevent from heating above 60 °C Keep article out of reach of children This article should be disposed of as hazardous waste. Do not dispose of via normal household waste





■ >> SVHC in Textile

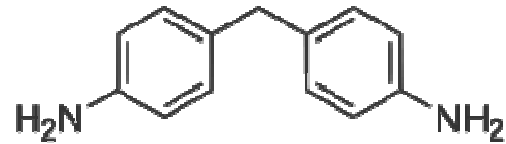
- At least 8 substances or substances groups could be present in textile products
- **4,4'-diaminodiphenylmethan (MDA)**
- **Chlorinated paraffins, C₁₀₋₁₃**
- **Chromate**
- **Sodium dichromate**
- **Anthracene & anthracene oils**
- **Dibutyl phthalate (DBP)**
- **Hexabromocyclododecane (HBCDD)**
- **Phthalates**





■ >> SVHC in Textile - 4,4'-diaminodiphenylmethan (MDA)

- General information:



CAS 101-77-9 / EINECS 202-974-4

- Hazard: Carcinogenic category 2
- Application:
 - Technical impurities in azo-dyes
 - Impurities in paint formulations, acrylic paints and inks
 - This substance could also be present as impurities in textile



■ >> SVHC in Textile - Chlorinated paraffins, C₁₀₋₁₃

- General information:

CAS 85535-84-8 / EINECS 287-476-5

- Hazard: N, R50-53 : Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
- The substance is also classified as carcinogenic cat. 3 → the classification could change in the next years because of the REACH regulation ...
- Application:
 - Application as flame retardant in textile
 - This substance is also used for its flame retardant properties for paints and adhesives



■ >> SVHC in Textile - Chromate

- General information: Lead chromate, Lead chromate molybdate sulfate (pigment red 104), lead sulfochromate (pigment yellow 34)

New SVHC from 06.2011: Sodium chromate (231-889-5), Potassium chromate (232-140-5), Ammonium dichromate (232-143-1) & Potassium dichromate (231-906-6)

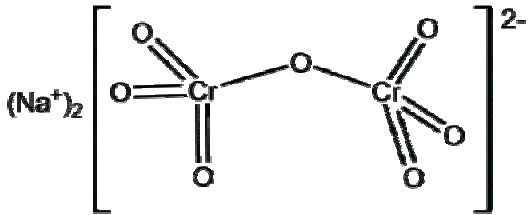
- Hazard: Carcinogenic, mutagenic and/or toxic for the reproduction
- Application:
 - The 3 first substances are used as pigment (mainly orange, red and yellow) for paints and as printing inks for textiles
 - The newly proposed chromates are also used for textile dyeing and generally by their manufacture





■ >> SVHC in Textile – Sodium dichromate

- General information:



CAS 7789-12-0
EINECS 234-190-3



- Hazard: Carcinogenic, mutagenic **and** toxic for the reproduction
- Application:
 - Corrosion inhibitor for dyes production
 - Mordant for dyeing
- Other SVHC generally used for dyes production: 2,4-dinitrotoluene (CAS 121-14-2), Cobalt-II-sulphate (10124-43-3), Cobalt-II-dinitrate (10141-05-6), Cobalt-II-carbonat (513-79-1)



■ >> SVHC in Textile – Anthracene & Anthracene oils

- General information: Anthracene (204-371-1)
+ 5 anthracene oils
(292-602-7, 292-604-8, 292-603-2, 295- 275-9,
295-278-5)
- Hazard: Anthracene = PBT substance
292-602-7 = carcinogenic, PBT and vPvB
Other = carcinogenic, mutagenic, PBT and vPvB
- Application:
 - Anthracene oils are used in the manufacture of Anthraquinone which is an important intermediate of many synthetic dyestuffs
 - Anthracene is used in the artificial production of the red dye alizarin



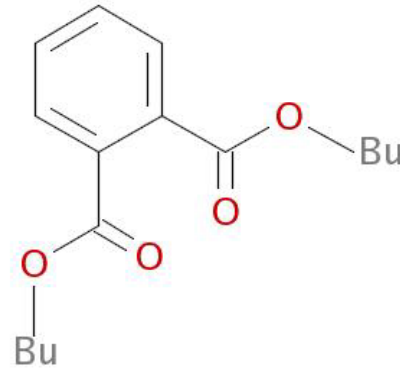


■ >> SVHC in Textile – Dibutyl phthalate (DBP)

- General information:

CAS 84-74-2

EINECS 201-557-4

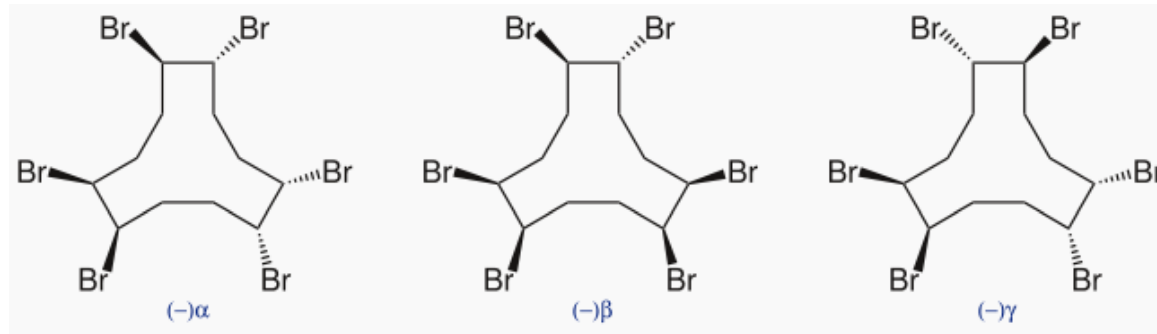


- Hazard: Toxic for the reproduction : may cause harm to the unborn child and possible risk of impaired fertility
- Application:
 - Insect repellents for textiles



■ >> SVHC in Textile – Hexabromocyclododecane (HBCDD)

- General information: HBCDD & all major diastereoisomers identified
 - HBCDD = CAS 25637-99-4 & 3194-55-6
EINECS 247-148-4 & 221-695-9
 - Diastereoisomers = CAS 13423751-7, 134237-50-6 & 134237-52-8



- Hazard: Persistent, Bioaccumulative and Toxic (PBT)
- Application:
 - Flame retardant for textiles



■ >> SVHC in Textile – Phthalates

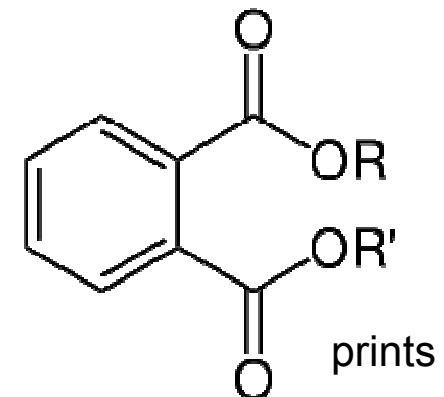


- General information:
 - Bis (2-ethyl(hexyl)phthalat) (DEHP) 117-81-7,
 - Benzyl butyl phthalat 85-68-7,
 - Diisobutylphthalat (DIBP) 84-69-5
 - 1,2-Benzenedicarboxylic acid, di-C7-11 -branched and linear alkyl esters (DHNUP) 68515-42-4
 - 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP), 71888-89-6

- Hazard: Toxic for the reproduction

- Application:

- Commonly used as plasticizers
- Application also for paints, coatings, adhesives, and coatings on textiles



■ REACH – Articles in REACH- Information in the supply chain on SVHC's in articles



Item	Example
Substance name	Diarsenic trioxide
CAS Number	1327-53-3
Registration number (if provided by supplier)	01-1234567-49-00
Classification and SVHC properties	Carc. Cat. 1; R45; May cause cancer T+; R28; Very toxic is swallowed C; R34; Causes burns N; R50/53; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Concentration in the article ³¹	1% w/w
Information on safe handling including safe disposal if relevant	Prevent from heating above 60 °C Keep article out of reach of children This article should be disposed of as hazardous waste. Do not dispose of via normal household waste



■ REACH – Penalties

EU member states	Penalties
Belgium	Fines: €52 to €4,000,000 Imprisonment: 8 days to 3 years
Czech Republic	Fines: CZK 500,000 to CZK 5,000,000
Denmark	Chemical substances and products Act no. 1755 Imprisonment up to two years
Germany	Less severe infringement: fines up to €50,000 or imprisonment up to 1 year More severe infringement: fines up to €100,000 or imprisonment up to 5 years
Finland	Chemical Act No. 774/1989 and Penal Code of Finland No. 39/1889 Fines or imprisonment up to 2 years
Hungary	Government decree on chemical load penalty HUF 50,000 to 20,000,000
Ireland	Chemical Act 2008 (S.I. No. 273 of 2008) On summary conviction, a fine not exceeding €5,000 or imprisonment for a term not exceeding 6 months or both, or On conviction on indictment, to a fine not exceeding €3,000,000 or imprisonment for a term not exceeding 2 years or both.
Malta	Fines: €466 to €23,294 Imprisonment: < 6 months to 4 years
Netherlands	Economic Offences Act Fines up to 670,000 or imprisonment up to six years
Latvia	Fines: 300 to 1000 lats
Lithuania	Fines: 500 to 300,000 litas
Romania	Fines: Lei 6,500 to 50,000
Sweden	Environmental Code (Chapter 29) Fines or imprisonment up to 2 years
United Kingdom	REACH Enforcement Regulations 2008 No. 2852: Up to £5,000 fine and/or up to 3 months imprisonment following summary conviction An unlimited fine and/or up to two years imprisonment following conviction on indictment



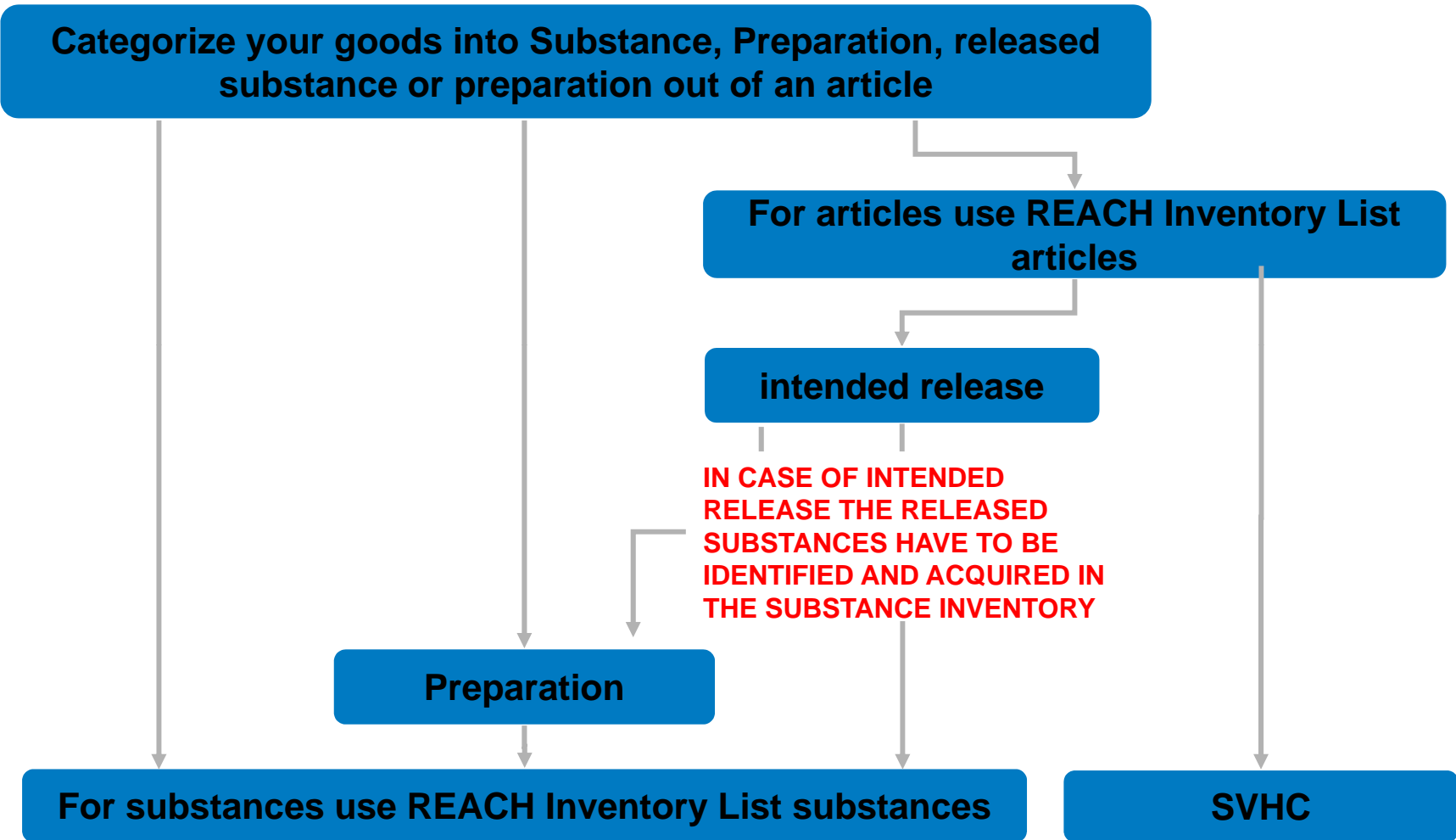


■ >> Recommendations

- There are also at least **27 substances** from the 53 identified SVHC which could occur in textile...
- ... and the candidate list will be updated regularly !
- A quality management should also been se in your company in order to follow up the presence of SVHC
- Set up a transparent communication with yc customers. Many European importers are a asking for a „SVHC-free“ certification !!

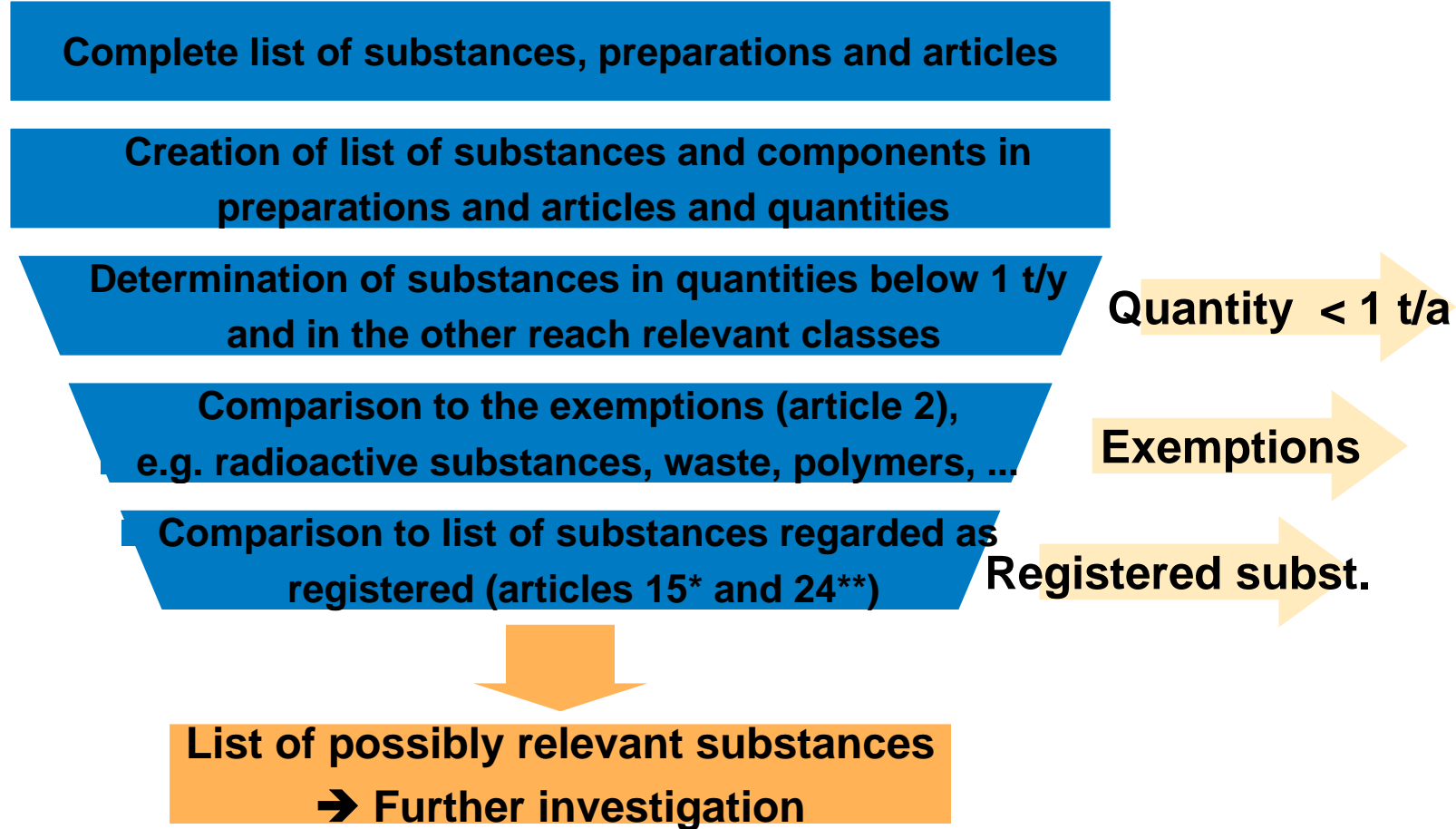


■ Steps involved in REACH Compliance





■ **Filtering of data: stepwise approach – decreasing number of substances**



* Article 15 → plant protection substances and biocides
** Article 24 → notified substances according to directive 67/548/EEC
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Our Services to Textile & Apparel Industries



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Tests for Textile and Apparel Industries

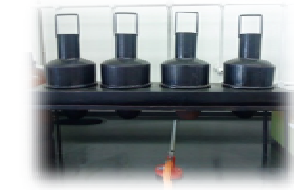
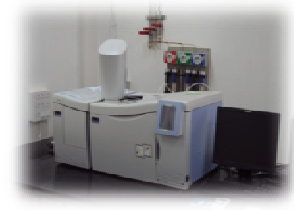
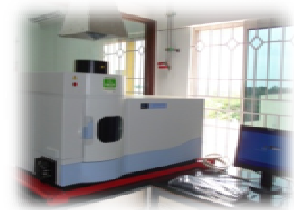
- REACH SVHC testing
- REACH Consultancy & Notification services
- REACH Only Representative services
- RSL testing
- Textile physical testing
- Antimicrobial function test
- European Union Directive Compliance



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■ Facility available at TÜV Rheinland India

- Inductively Coupled Plasma Optical Emission Spectrophotometer (ICP-OES)
- Gas Chromatograph with Mass Spectrometer (GC-MS)
- Ultraviolet Visible Spectrophotometer (UV-VIS)
- FTIR
- Cyclic Corrosion Chamber
- Dry Heat, Humidity and Sub Zero Chambers
- Petroleum product testing equipments etc.



■ TÜVRheinland (I) Pvt.Ltd – We'll do REACH for you



We would like to undertake the whole REACH compliance for you

Please contact :

Shanmuga Sundaram

Country Head - Material Testing Laboratory

Laboratory :

TUV Rheinland India Pvt.Limited

Plot 17B, Electronic City Industrial Area, IInd Phase,

Hosur Road,Bengaluru – 560 100,Karnataka, India

Mob:+91-9620288836, Tel.Direct: +91-80-39235311

Email: ps.sundaram@ind.tuv.com

VOIP: 9614008

Internet: <http://www.ind.tuv.com>



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Thank You!



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