



REACH

Guideline

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工業貿易署
Trade and Industry Department

Organized by

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香港紡織業聯會



Implementation agents

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CLOTHING INDUSTRY TRAINING AUTHORITY



Contents

1 FOREWORD	2
2 INTRODUCTION	3
3 THE REGULATION	7
3.1 REACH DICTIONARY	7
3.2 ROLES AND TASKS UNDER REACH.....	11
3.3 DEFINITIONS OF RISK TO HUMAN HEALTH	16
3.4 DEFINITIONS OF RISK TO THE ENVIRONMENT	18
3.5 THE CANDIDATE LIST OF SVHC (Substances of very high concern)	19
3.6 REQUIREMENTS FOR SUBSTANCES IN ARTICLES.....	20
4 USE OF CHEMICALS IN THE TEXTILE INDUSTRY	23
4.1 EXAMPLES OF USE OF CHEMICALS IN TEXTILE INDUSTRY	24
4.2 RISKS RELATED TO CHEMICAL SUBSTANCES.....	27
4.3 REACH REALITY: WITHDRAWN PRODUCTS	29
5 IMPLEMENTATION	32
6 REACH IN A NUTSHELL	59
Links for further information.....	61

1. FOREWORD

This guidance document is addressed to textile and garment producers, importers and suppliers of articles located in Hong Kong.

The main objectives of this guidance are to

- assist the REACH actors particularly from the garment and textile industry in deciding whether or not they are manufacturers or importers of substances (on their own or in preparations) or article suppliers.
- support article suppliers (article producers, article importers and/or distributors/retailers of articles in deciding if they have to fulfill registration, notification and/or communication requirements related to substances in their articles
- provide a toolbox for easier implementation of preventive means

An article supplier is a company which produces imports or distributes articles and/or places them on the EU market. Retailers are also article suppliers. Further explanation and the definitions of these roles are included in chapter 3.2 of this guidance.

This guidance mainly describes how a company can check whether it has to fulfil any requirements under article 7 and article 33 of REACH.

1. FOREWORD

Who is the European Union (EU)? In order to answer this question we would like to provide some facts:

- the European Union has 27 independent states;
- 501 million inhabitants;
- \$ 19,000 billion annual gross domestic product;
- world's largest coherent trade area.

The European Union has two means of legislative action:

- a directive needs to be implemented in national law by every single member state;
- a regulation is valid within the complete boundaries of the EU without being incorporated by single states.

REACH being a regulation is valid within the EU. Even if national member states laws are contradictory, the REACH regulation overrules.

2. INTRODUCTION

The European Union chemical regulation REACH Registration, Evaluation, Authorization and Restriction of Chemicals came into force on 1st June 2007. It replaces around 40 existing EU regulations and directives.

The regulation manages all chemicals, about 30.000 at European level, by providing procedures for risk assessment, decision making, communication on the safe use of chemicals and the implementation of measures to adequately control chemical risks.

The implementation of REACH will be a step-by-step process over a period of 11 years.

The current REACH legislative text and Technical Guidance Documents can be found at:

http://echa.europa.eu/legislation/reach_legislation_en.asp

The aims of REACH are

- to improve the protection of human health and the environment from the risks that can be posed by chemicals;
- to enhance the competitiveness of the EU chemicals industry;
- to promote alternative methods for the assessment of hazards of substances;
- to ensure the free circulation of substances on the internal market of the European Union.

2. INTRODUCTION

Regarding the REACH regulation (EG) No. 1907/2006 producers, distributors and importers of substances and mixtures {1} are obliged to register at the European Chemicals Agency (ECHA), if the amount of the produced or imported substance is more than 1 ton per year. Beyond these substances, which are contained at an amount of over 1 ton per year in mixtures or articles and are released in accordance with the law, also have to be registered.

In case there is a duty of registration for a substance, that substance is neither allowed to be produced from 1 ton per year nor to be put in circulation according to article 5 of the REACH regulation. {2}

For the registration a technical dossier has to be established. From a production volume of 10 tons per year producers, distributors and importers have to create an additional Chemical Safety Report (CSR), which informs of the effects to human health and environment. The dossiers are shown at the European Chemicals Agency in Helsinki.

{1} Terms will be defined in point 3.1.

{2} Source: ECHA Guidance on requirements for substances in articles

2. INTRODUCTION

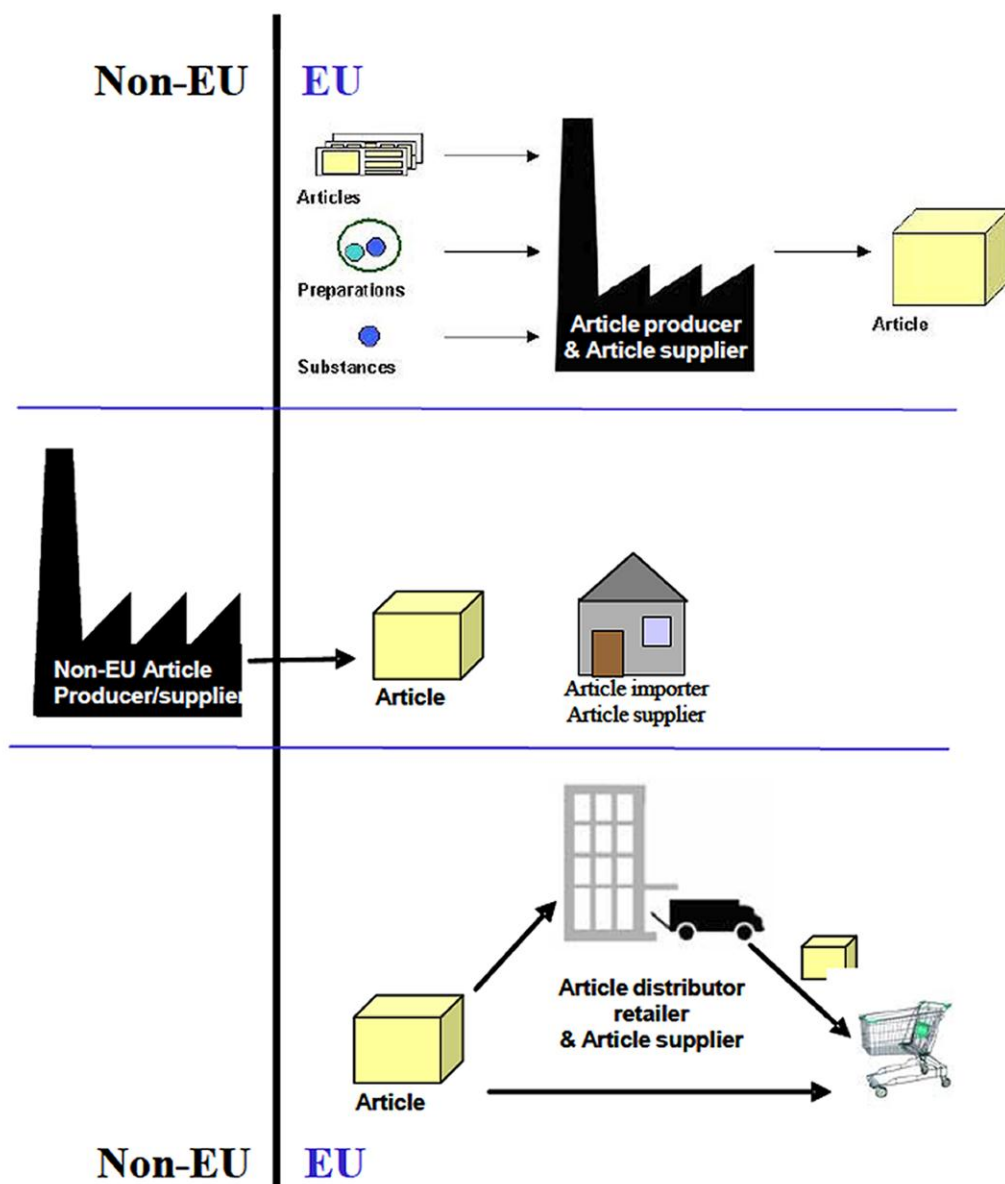


Figure 1 Source: ECHA Guidance on requirements for substances in articles

3. THE REGULATION

3.1 REACH DICTIONARY

Article



is an object which during production is given a specific shape, surface or design, which determines its function to a greater degree than does its chemical composition. e.g. furniture, clothes, toys, electronic equipment.

Carcinogenic

causing cancer

CAS

Chemical Abstract Service

CMR

Carcinogenic, mutagenic and toxic for reproduction

Effect

is the damage a chemical can cause; the contact time with the chemical product as well as the amount of chemical product can influence the severity of the effect; a short time exposure with high amount of chemicals is called an acute effect; a long time exposure with small amount of chemicals is called a chronic effect.

3. THE REGULATION

3.1 REACH DICTIONARY

Intermediate

means a substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance...



non-isolated intermediate means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.



on-site isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one more legal entities.



transported isolated intermediate means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

Hazard

is the potential of a chemical product to cause an adverse effect; chemical hazards are invisible and dangerous properties.



Mixture

is composed of two or more substances which do not react. e.g. paint, detergent, glue.

Mutagenic

causing genetic damage

3. THE REGULATION

3.1 REACH DICTIONARY

Polymer

means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. e.g. a plastic

Phase-in substance

means a substance which, over 15 years preceding the entry into force of this Regulation, meets at least one of the following criteria:

- It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).
- It was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this.
- It was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this.



3. THE REGULATION

3.1 REACH DICTIONARY

Reprotoxic

causing infertility or health effects to human embryo

Substance

is a chemical element and its compounds, in the natural state or obtained by any manufacturing process. e.g. formaldehyde, phthalate DEHP, cadmium, chromium, pentachlorophenol.



Substances of Very High Concern

A Substance of Very High Concern (SVHC) is a chemical substance (or part of a group of chemical substances) for which it has been proposed that the use within the European Union is subject to authorisation under the REACH Regulation.

Listing of a substance SVHC by the European Chemicals Agency (ECHA) is the first step in the procedure for authorisation and restriction of the use of chemicals.



3. THE REGULATION

3.2 ROLES AND TASKS UNDER REACH

The following activities related to chemical substances are covered through the REACH regulation:

- manufacturing of substances inside the European Union. Manufacturing is defined as extraction or production of substances in its natural state;
- import of substances into the European Union regardless of their form. Which might be substances, mixtures or articles;
- different uses in which chemicals are applied. This means any processing, formulation, consumption, storage keeping treatment, filling into containers, production of an article or any other utilisation.

Several actors are concerned by REACH:

- European Commission
- European Chemicals Agency
- National authorities
- Substance manufacturers and importers
- Downstream Users
- Producers or importers of articles
- Distributors and traders

3. THE REGULATION

3.2 ROLES AND TASKS UNDER REACH

Manufacturers of substances:

means any natural or legal person established within the EU who manufactures a substance in one or more Member States.

Producers of articles:

means any natural or legal person established within the EU who manufactures a substance in one or more Member States.

Importers of substance and/or articles:

means any natural or legal person established within the community who is responsible for import. Importing means the physical introduction into the customs territory of the European Union.

Downstream users:

any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oils or lubricants in other industrial processes or producers of manufactured articles such as electronic components. Most participants of the REACH Pilot Project are Downstream Users.



3. THE REGULATION

3.2 ROLES AND TASKS UNDER REACH

Under REACH the supply chain actors have to identify the conditions for safe use through:

- intensive communication up the supply chain to receive information of the current use of their substances.
- how and to what purposes the substances are used.
- based on this information, the substance producer will define the assessment and conditions for safe use.
- communication of safe use will be given in form of a Safety Data Sheet and an Exposure Scenario down the supply chain.
- Exposure Scenario describes how the substance can be used safely by all actors in the supply chain.
- Different Exposure Scenarios are established for different uses.
- example: instructions for mixing the paint and instructions for save spray application.



3. THE REGULATION

3.2 ROLES AND TASKS UNDER REACH

TASKS FOR MANUFACTURERS AND IMPORTERS

They carry the vast majority of obligations under REACH. The manufacturers and importers have two core obligations.

1st Obligation to ECHA

- Submission of a registration dossier for each substance one produces in amounts above 1 ton a year;
- Production over 10 tons per year needs a Chemical Safety Report (CSR);
- Dangerous substances need Chemical Safety Assessment and definition of the condition of safe use with Exposure Scenarios.

2nd Obligation to customers

- Communicate information on safe use for all dangerous substances via Safety Data Sheets and Exposure Scenarios.

3. THE REGULATION

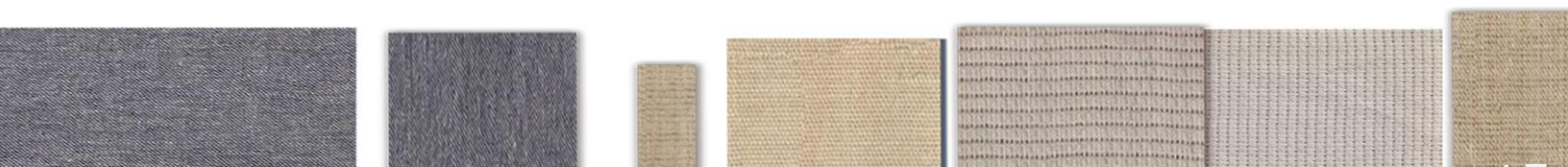
3.2 ROLES AND TASKS UNDER REACH

TASKS FOR DOWNSTREAM USERS

- implement the conditions of safe use of chemicals which are communicated to them in a Safety Data Sheet and if required in an Exposure Scenario;
- communicate upstream on new information of substance hazards and different risk management measures;
- communicate downstream on new measures to supply chain.

TASKS FOR DISTRIBUTORS

- forward information they receive from the chemical they trade down the supply chain to their customers in form of Safety Data Sheets and Exposure Scenarios
- supply information upstream from their customers to their suppliers on substance hazards, use and exposure; or risk management measures.



3. THE REGULATION

3.2 ROLES AND TASKS UNDER REACH

The Information Cycle



3. THE REGULATION

3.3 DEFINITIONS OF RISK TO HUMAN HEALTH

In order to prevent damage to human health, information is given on dangerous properties by GHS (Global Harmonized System) symbols like:



The risk of being harmed by a chemical product is dependant on the level of exposure. The threshold of save level of exposure also depends also on the degree of chemical hazard. A chemical risk is a combination of exposure and hazard. It defines if a certain adverse effect happens in a specific situation.

There are thee types of exposure in which humans can come into contact with chemicals:

- Dermal exposure (ex. cleaning acid on hands)
- Inhalant exposure (ex. evaporation of solvents)
- Oral exposure (ex. food ingestion)
- Injection exposure (ex. bites and needles)

3. THE REGULATION

3.4 DEFINITIONS OF RISK TO THE ENVIRONMENT

There are three main ways in which chemicals enter in the environment: by air, by water or by soil. Chemical substances interact with the compartments. That is called partitioning. e.g. evaporation, sedimentation, deposition.

Chemicals are destroyed in the environment through biodegradation and a biotic destruction by sunlight and water. They can persist in the environment. The level of environmental exposure is defined by emission pathway, partitioning, degree of destruction or animal uptake.

The level of environmental exposure is defined as substance concentration in the air, water, soil, plants and animals. Two definitions of exposure are defined:

- Short term chemical exposure = acute environmental effect
- Prolonged chemical exposure = chronic environmental effect

There are a few chemical substances that have properties that can cause chronic toxic effects. Two groups are of particular concern:

- PBT chemicals (Persist, Bioaccumulate and Toxic for the environment or humans)
- vPvB chemicals (very Persistent and very Bioaccumulative, but not toxic)

3. THE REGULATION

3.5 THE CANDIDATE LIST OF SVHC (Substances of very high concern)

A **Substance of Very High Concern (SVHC)** is a chemical substance (or part of a group of chemical substances) for which it has been proposed that the use within the European Union is subject to authorisation under the **REACH** regulation. Listing of a substance **SVHC** by the European Chemicals Agency (ECHA) is the first step in the procedure for **authorisation** and **restriction** of the use of chemicals.

A substance may be proposed as a **SVHC** if it meets one or more of the following criteria:

- it is carcinogenic;
- it is mutagenic;
- it is toxic for reproduction;
- it is persistent, bioaccumulative and toxic according to the criteria set out in Annex XIII to the REACH regulation (PBT substances);
- it is very persistent and very bioaccumulative according to the criteria set out in Annex XIII to the REACH regulation (vPvB substances);
- there is "scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern"; such substances are identified on a case-by-case basis

In October 2008 the first candidate list of Substances of Very High Concern (SVHC) was published by European Chemical Agency (ECHA). This candidate list of SVHC is continually extended and updated. Therefore, the below ECHA website must be concerned for the SVHC releases and the candidate list updates.

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

3. THE REGULATION

3.6 REQUIREMENTS FOR SUBSTANCES IN ARTICLES

Four types of requirements exist for producers, importers and other suppliers of articles:

- to register (1)
- to notify (2) substances contained in articles to the Chemicals Agency
- to communicate specific information related to the content of some specific substances to the customers (3)
- to comply with any community wide restriction (4). These obligations only apply under certain conditions, which are specified in article 7, 33 and the entries in Annex XVII of REACH.

Article suppliers, which are only supplying (i.e. not themselves producing or importing the articles), only have to comply with article 33.

The following parts of **REACH** are of particular relevance for producers, importers and other suppliers of articles:



Article 3: Article definition



Article 7: Registration and notification of substances in articles

(Defines under which circumstances article producers and importers are to register or notify)



Article 23, 28-30: Deadlines for pre-registration and registration of phase-in substances and participation in Substance Information Exchange Forum (SIEF)

(Article producers and importers who have to register substances intended to be released should make a pre-registration to benefit from the transitional provisions for phase-in substances)

3. THE REGULATION

3.6 REQUIREMENTS FOR SUBSTANCES IN ARTICLES



Article 57 and 59

Criteria for substances of Very High Concern (SVHC) and procedure for how they are placed on the candidate list.



Article 33 Duty to communicate information on substances in articles

Producers, importers and other suppliers of articles containing substances on the candidate list may have to forward required information available to them down the supply chain (article 33(1)) and to consumers on request (article 33(2)).



Substances intended to be released from articles under normal or reasonably foreseeable conditions of use are to be registered under Article 7(1) by the same deadlines that apply to substances as such or in mixtures to be registered under Article 6. Also the same distinction between phase-in substances and non-phase-in substances applies.



Annex XVII

listing the conditions of restrictions, which may pertain to certain substances in produced and imported articles.

3. THE REGULATION

3.6 REQUIREMENTS FOR SUBSTANCES IN ARTICLES

Substances being (an integral) part of imported articles cannot be subject to authorisation.

Details on the authorisation procedure, notifying the use of authorised substances etc. can be found in the ECHA guidance for Downstream Users (Chapter 12 on authorization), guidance on Annex XIV inclusion (substances subject to authorization) and the guidance on authorization application.

As already noted, producers of articles using substances/preparations may also have other importer and/or downstream users obligations under REACH.

In general, it may be helpful for article producers/importers/suppliers to understand more of the overall legislative system, e.g. to understand the possibilities of obtaining information in the supply chain and to get a full overview of their REACH obligations. Please refer to the web-site of the ECHA.

http://echa.europa.eu/home_en.asp

4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

The textile industry is a significant contributor to many national economies, encompassing both small and large-scale operations worldwide. In terms of production and employment it is one of the largest industries in the world.

The textile industry has a huge environmental impact and processes are characterised by the large volume of water consumption and a variety of chemicals used from the fibre to the final garment.

Textile processing generates many waste streams in different forms

- Liquid waste
- Gaseous waste
- Solid waste
- Hazardous waste

The main environmental problems and dangers to human health associated with the textile industry are

- Water pollution by the discharge of untreated effluents
- Air emission of Volatile Organic Compounds (VOC)
- Noise
- Odour

4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

There are several legally restricted substances for protection of human health and the environment like banned azo dyes, toxic chemicals etc.

Additionally there are private Restricted Substances Lists like the ones from PUMA, Nike, Marks & Spencer, Levi's etc.

Furthermore there are governmental organisations (environmental agency, RAPEX) and NGOs monitoring consumer protection.

RAPEX is the European rapid alert system for dangerous consumer products — with the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms. It facilitates the rapid exchange of information between member states and the commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.

Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are reported by RAPEX.

The manufacturer and importer of textile articles is a Downstream User and has to...

- be aware if the textile articles that fall under REACH.
- assure that they do not contain more than 0,1 % (weight by weight) of a Substance of Very High Concern.
- be aware of his duty to communicate along the supply chain.
- be able to define risky processes in the company and assess them.

4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.1 EXAMPLES OF USE OF CHEMICALS IN TEXTILE INDUSTRY

During the process of manufacturing, a textile article has to go through a long process of chemical and non-chemical treatments.

Certain textile chemical products are highly specialised chemicals such as biocides, flame retardants, water repellents, dyestuffs, auxiliaries, printing inks, etc. Others are relatively simple chemicals or mixtures such as emulsified oils and greases, starch, sulfonated oils, waxes and some surfactants.

A great number of chemicals that can be applied in the production of textiles and clothes show hazardous properties.

Dyeing, printing, spinning, weaving, knitting and other processing mills have to receive information from their suppliers if the raw materials, dyestuffs, auxiliaries or substances contain SVHC. If yes, it is necessary to give detailed information about the concentration (weight by weight) and about the safe handling.

The same requirements apply to the suppliers of trimmings and accessories as well as to the suppliers of packaging materials, who have to receive information on potential SVHC in the raw materials, dyestuffs, auxiliaries and chemicals. As well the concentration is the determining factor again.



4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.1 EXAMPLES OF USE OF CHEMICALS IN TEXTILE INDUSTRY

EXCEPTION:

From the point of view of the REACH regulation, naturally occurring substances are exempted from the registration process:

This would be

- Cotton
- Silk
- Wool

Furthermore POLYMERS are generally exempted from the registration process generally.

Man-made are treated as articles under REACH.
Those are:

- Viscose
- Polyester
- Nylon
- Polypropylen etc.

4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.1 EXAMPLES OF USE OF CHEMICALS IN TEXTILE INDUSTRY

In the following, some examples of chemical substances or mixtures, which may be applied in textile processing are stated.

CROP PRODUCTION/FARMING:

pesticides (such as insecticides, fungicides, etc.)

SPINNING:

lubricants, additives, emulsifiers, wetting agents, anti-static agents, biocides, oils ...

FABRIC PRODUCTION:

sizes, preserving agents, biocides, PCP (Pentachlorophenol) ...

BLEACHING:

chlorine containing agents, textile auxiliaries, stabiliser ...

DYEING:

dyestuffs (restricted aromatic amines in colorants, allergenic/carcinogenic dyestuffs) PCP (Pentachlorophenol), chelating agents ...

PRINTING:

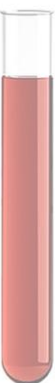
pigments, dyestuffs (restricted aromatic amines in colorants) PVC (Polyvinyl chloride), phthalates, formaldehyde ...

FINISHING:

formaldehyde containing agents, phthalate based softeners ...

STORAGE/TRANSPORTATION:

PCP (Pentachlorophenol), TeCP ...



4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.2 RISKS RELATED TO CHEMICAL SUBSTANCES

At the production site, several critical aspects should be recognised and, if possible, be cleared. For instance the lack of knowledge of the stored chemicals as well as a missing inventory list can increase the risk of not being in compliance with REACH. The workers are at high risk too as they are possibly exposed to hazardous substances. Additionally, mixing chemicals can provoke accidents that might also be harmful to the environment.

One first step

to avoid accidents or harmful situations would be a proper storage and good and detailed knowledge of what is stored in the company.

Furthermore chemicals might contaminate the water through the waste water as well as the air through deflagration. Contamination can also occur through the supply of chemicals into the watery system of a water drinking area, which would pose a risk to not only to the workers but all people in the area.

A second step

would be to have a proper functioning effluent treatment plant in the factory to avoid the contamination of drinking water in the area. It is not only the question of what is used but also how much of a substance is used. The quantities of chemicals used in products and processes are unknown and thus pose a risk of non-compliance with the REACH regulation. Further failures in dyeing recipes can influence the quality of a product in a negative way. As a consequence of the insufficient management of chemicals the exposure limits are not controlled in the different processes.



4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.2 RISKS RELATED TO CHEMICAL SUBSTANCES

As a third step

is the need of a proper management of the different substances as well as regular updates on the inventory and provided information is needed.

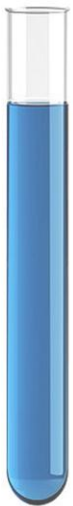
A constant control on what is done and how it is done helps to avoid risks.

But it is not only the chemicals a producer has in a company but also the raw materials and accessories that are bought and stored might contain any unknown substance. If the producer and the supplier of accessories or trimmings are unknown this creates even a bigger risk.

A fourth step

is the risk reduction when the accessories, trimmings and other supplied products are properly controlled and the relationship along the supply chain is reliable.

Through an insufficient or nonexistent control of the chemicals in use as well as their ingredients, a high risk for the workers, the environment and the company itself results. The non-compliance with REACH regulation and an insufficient handling of the SVHC might provoke problems within the customer-supplier relationship. If offences to the REACH regulation occur product recalls might be the consequence. This should be avoided!



4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.3 REACH REALITY WITHDRAWN PRODUCTS

Baby Goovy Cotton bib with teether stopped to sell and the stock destructed - Spain

In December 2009, Baby Goovy Cotton bib with teether was stopped to sell and the stock was destructed by the importer in Spain. The product poses a chemical risk to children because the teether contains di-"isononyl" phthalate (DINP-Diisononylphthalate) in a concentration exceeding 10% by weight. According to REACH regulation, phthalates DEHP (Bis(2-ethylhexyl)phthalate), DBP (Dibutylphthalates), and BBP (Benzylbutylphthalates) are prohibited in childcare articles, while phthalates DINP, DIDP (Diisodecyl phthalates) and DNOP (dioctylphthalates) are prohibited when the childcare article can be placed in the mouth by children. The product was manufactured in China.

Red textile scarf with black decoration and fringes withdrawn from the market

The product poses a chemical risk because it contains banned azo-colourants. It releases 196 mg/kg (ppm) benzidine in the red textile which is a known human carcinogenic which can easily be absorbed through the skin. The product does not comply with the REACH regulation. Results of checks were voluntary withdrawal from the market and destruction of stocks. The country of origin was India.

4. USE OF CHEMICALS IN THE TEXTILE INDUSTRY

4.3 REACH REALITY WITHDRAWN PRODUCTS

Girls Shirt stopped to sell because of softeners and intended release

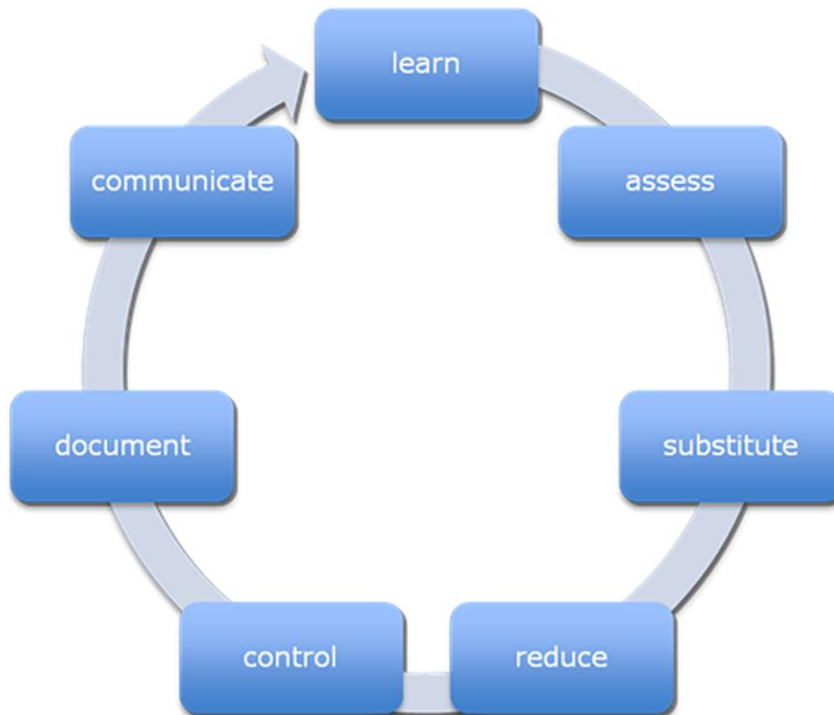
The product poses a chemical risk because the print contains 0.68% by weight of Di-"isononyl" phthalate (DINP) and 2.7% by weight of Bis (2-ethylhexyl) phthalate (DEHP).

According to REACH regulation, phthalates DEHP, DBP and BBP are prohibited in childcare articles, while phthalates DINP, DIDP and DNOP are prohibited when the childcare article can be placed in the mouth by children. The t-shirt does also releases a strawberry-fragrance out of xylene. This may be topic of REACH in the future. It was manufactured in Bangladesh.



5. IMPLEMENTATION

The basic principles for a system to enable REACH implementation is based on



The approach of knowledge management and continuous improvement enables the user to achieve a better practice without any interference in their core business activities.

The REACH program introduced in this guideline is follows an integrated concept of sustainable performance management and monitoring.

5. IMPLEMENTATION

The conformity with REACH is achieved through knowledge of used ingredients, avoidance or controlled use of substances, which are classified as potentially harmful to humans or the environment.

The program is concerned about the implementation of a

- supply chain traceability system
- data record system on chemicals and components
- documentation on risks
- installation of risk management system and alert functions
- communication procedures

LEARN

Knowledge is the key to success to establish a system which enables REACH conformity.

There are three pillars of a solid knowledge base to be established in an organization.

5. IMPLEMENTATION



STEP 1

Learn and keep updated on the REACH regulation and its amendments. It is recommended to define a responsible person or team for that duty. The maintenance of a REACH management system is guaranteed only if an organization has the knowledge in-house.

How to learn about REACH?

- **fix a date** (for example the first working day in a month) to gather new information on REACH such as add-ons of Substances of Very High Concern, new security measures for workers and environment, etc.
- **subscribe to the ECHA newsletter** at the Press Office of the European Chemicals Agency. Now you automatically receive all Press releases, news alerts, news items and background memos and general-purpose information. To subscribe to the newsletter, send your e-mail address to info@echa.europa.eu
- **contact the ECHA helpdesk**
http://echa.europa.eu/help/echahelp_en.asp

5. IMPLEMENTATION



STEP 2

Learn and keep updated on your own processes and the set up of your organisation to identify possible risks and establish means in a second step to manage these risks.

How to do that:

Learn About

- products produced
- processes applied
- materials used
- material flow

- Identify REACH relevant processes
- Assess which processes bear risks
- Define **REACH CRITICAL CONTROL POINTS**



5. IMPLEMENTATION

Start with a REACH Risk Mapping

- Mapping is a tool to help identify and record aspects and impacts;
- Inventory of practices and problems;
- Systematic method of conducting an on-site initial review;
- Collection of information which shows the current situation using drawings, symbols and pictures;
- Working and awareness-raising tool;
- Do-it-yourself tool for companies;
- Tool which allows employees' involvement and participation

Take a pencil and a notebook or clipboard with you and draw a floor plan of the company. You can also take a copy of an existing plan such an evacuation plan. Take this plan and walk through the facilities to make an REACH assessment.

5. IMPLEMENTATION

Mark all places where you identify a potential risk related to REACH. For help you can use symbols such as:

Points with potential hazards are e.g.

places where:



substance



mixture



substances or mixtures are stored (long term and short term)



substances or mixtures are used



substances or mixtures are purchased



materials possibly containing chemicals are stored



materials possibly containing chemicals are used



materials possibly containing chemicals are purchased



materials possibly releasing chemicals are stored



materials possibly releasing chemicals are used



materials possibly releasing chemicals are purchased



article



articles are produced



articles are stored



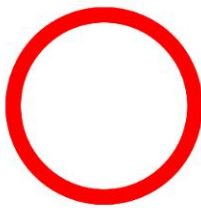
human health can be affected



human health

5. IMPLEMENTATION

Marking examples:



high risk



medium risk



low risk



5. IMPLEMENTATION

Evaluate the company specific risks resulting from your visits

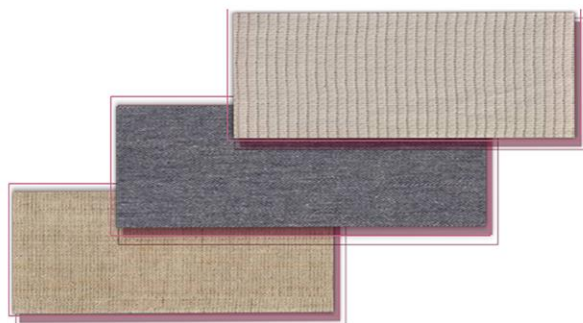
Hazards without preventive safety measures = HIGH RISK

Hazards with sound preventive safety measures = LOW RISK

Identify the REACH Critical Control Points (RCPs).

Critical Control Points are areas or departments where risks on non-compliance with REACH can occur.

Take some pictures to visualise these points and explain them to the company management or to colleagues.



5. IMPLEMENTATION



Risk related to outdated and not well maintained machinery and equipment.



Risk of mix up or alteration of chemical products that are not clearly labelled and/or unsealed.

5. IMPLEMENTATION



Risk of contamination due to outside drying process without coverage or other safeguard measures.



Risk of improperly cleaned printing pattern. High risk when different chemical products for local and EU market are used.

5. IMPLEMENTATION



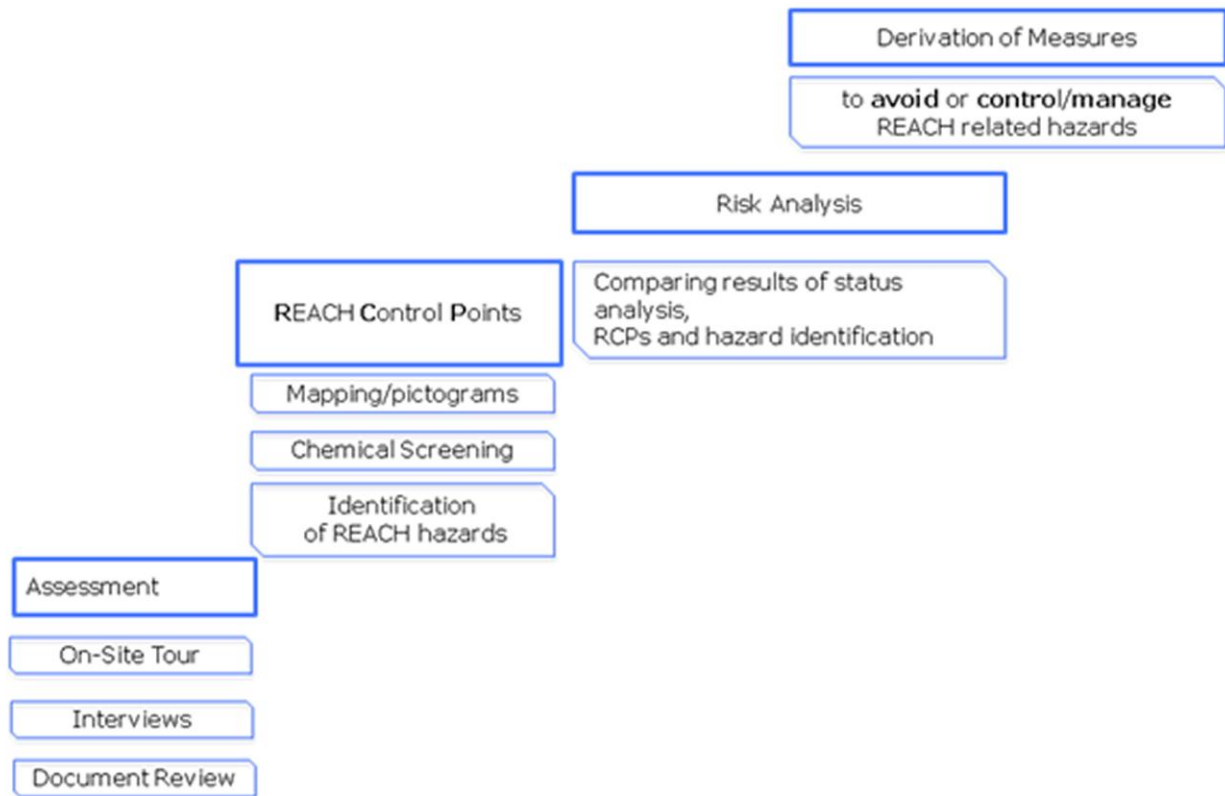
Risk originates from a disorganised dyeing laboratory. Correct calculation of recipes and eventual SVHC content is not assured.



Risk of mix-up of trimmings within disorganised storage for trimmings. High risk if 'approved' trimmings and trimmings for local market production are used in one factory.

5. IMPLEMENTATION

The following table shows the steps to be taken from assessment and identification of risks to rectification.



- Derived measures must be thoroughly developed
- The measures must be controllable through binding objectives
- The company management must agree on the implementation of the measures
- Implementation of measures have to be regularly checked
- The success of the measures must be measurable

5. IMPLEMENTATION



STEP 3

Learn about the substances and mixtures in use, their interaction and concentration.

To make a judgement on the presence of SVHCs in mixtures the suppliers of those need to provide necessary and reliable information. It is important that the given data are directly from the manufacturing source and not transmitted by wholesalers or traders who do not have access to these data.

How to find the relevant data:

The most detailed data are provided on the Safety Data Sheet. Other sources of information are specific questionnaires completed by the chemical manufacturer.



5. IMPLEMENTATION

Example of a REACH conform Safety Data Sheet

Example safety data sheet for a substance

SAFETY DATA SHEET Date of issue: xx/xx/09

1. Identification of the substance/mixture and of the company/undertaking

Identification of the product

Catalogue No: 12345

Product name: 1,2,3-Chemhazane

Use of the substance/mixture: Solvent for degreasing mixture

Manufacturer/supplier identification

Company: CHCS Chemicals Ltd
Nowhere Industrial estate
Notown
XY12 3AB
UK
Tel No.: +44 (0)1234 456890
E-mail: jbloggs@chcscem.co.uk

Emergency telephone No.: +44 (0)1234 567800 (08.00-18.00 UK time, weekdays only)

2. Hazards identification

Highly flammable. Irritating to skin. Harmful: may cause lung damage if swallowed. Vapours may cause drowsiness and dizziness. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Mucosal irritation (skin, eyes, respiratory tract) when vapours/aerosols are generated.

- After inhalation of vapours: drowsiness, dizziness, nausea, coughing, vomiting. In high concentrations: respiratory paralysis, unconsciousness, collapse. Inhalation may lead to the formation of oedemas in the respiratory tract.
- After eye contact: local irritation symptoms
- After skin contact: Degreasing effect on the skin, possibly followed by secondary inflammation/absorption.
- After ingestion: gastric pain, gastrointestinal complaints, respiratory paralysis, unconsciousness, of aspiration upon vomiting.

3. Composition/information on ingredients

Chemical characterization

Hydrocarbon solvent

Product name: 1,2,3-Chemhazane

Supply classification: F: R11 Xi; R65 Xi/R38 R67 N: R50, 53

CAS number: 110-82-8

Molecular formula: C_7H_{12} , C_7H_{10} = 84.16 g/mol

EC-No.: 203-805-3

4. First-aid measures

First aiders – ensure you do not contaminate yourself.

- Eye contact: Irrigate thoroughly with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. If discomfort persists, obtain medical attention.

Annotations on the SDS:

- The trade name of substance or mixture!
- Manufacturer/Supplier!
- Hazard identification!
- The composition and information on ingredients!
- Chemical Characterisation (CAS, EC...)
- The first aid measures!

Based on their activities on REACH compliance some chemical and component suppliers provide written declarations on the REACH compliance of their products.

It is recommended to ask suppliers that do not actively communicate on their REACH compliance status for more detailed information on their REACH activities.

5. IMPLEMENTATION

It is recommended to transfer the data from single Safety Data Sheets and supplier declarations into a file where all data are accumulated and easy to review.

The following example shows a chemical assessment list for components used by a garment manufacturer. Cells marked as orange or red show missing data needed to verify whether SVHCs are present and might lead to a risk of non-compliance with REACH.

Data for REACH Component Assessment - Proposal Company Name												
SAMPLE GARMENT MILL												
Type of component	Internal code	Name of supplier	Name of manufacturer	Manufacturer producing in the EU	Availability of product information	Date of Product Information	Material composition	Intended release	Total amount of the substance intended to be released	Hazard identification	Safety instructions	Availability of REACH conformity declaration
Trimming & Accessories												
Snap Button	Snap 004	Wing Hing	Wing Hing	NO	Material sheet 'Ok' Information	14.05.2005	Metal	NO	N.A.	N.A.	N.A.	NO
Plastic Button	PBS 471-23	VT Trading	Shanghai East Dragon	NO	NO	03.12.2004	PES	NO	N.A.	N.A.	N.A.	NO
Zipper	00 427-13	HCC	Dragon	NO	Ok Tex 100 Certification	01.03.2009	Metal	NO	N.A.	N.A.	N.A.	NO
Interlining	EL 832-57	Freudenberg	Freudenberg	YES	Ok Tex 100 Certification	30.04.2009	PES	NO	N.A.	N.A.	N.A.	NO
GOCCO transparent 955, 910, 911		Subitex	Minglo	YES	Product Sheet		PES film transparent resin	NO	N.A.			
Raw Fibres & Yarns												
PVE fibre		Meriton S.p.A.	Meriton S.p.A.	YES	MSDS	26.05.2007	PPE	NO	N.A.	N.A.	N.A.	YES
PA Fibre		Invista	Invista	YES	MSDS							
										Not respirable. Thermal processing may generate fumes and vapors which may cause irritation to throat.	No special handling requirements	
Standard PET		Performance Fibres		NO	MSDS	06.2006	Polyethylene terephthalate	NO	N.A.			NO
							I Styrene-Butadiene copolymer CAS: 9003-55-8 II Carbon black CAS: 1333-86-4 III Heavy Paraffinic Distillate Solvent Extract CAS: 64742-04-7 IV Disproportionated Tall Oil CAS: 61790-12-3			Aromatic Oil is listed as human carcinogen by IARC and OSHA. Heating may release small amounts of volatile irritants.	Wear suitable gloves	NO
Carbonix Masterbatch black 5608		Lion Copolymer	Lion Copolymer	NO	MSDS	22.06.2007		NO	N.A.			

Assess

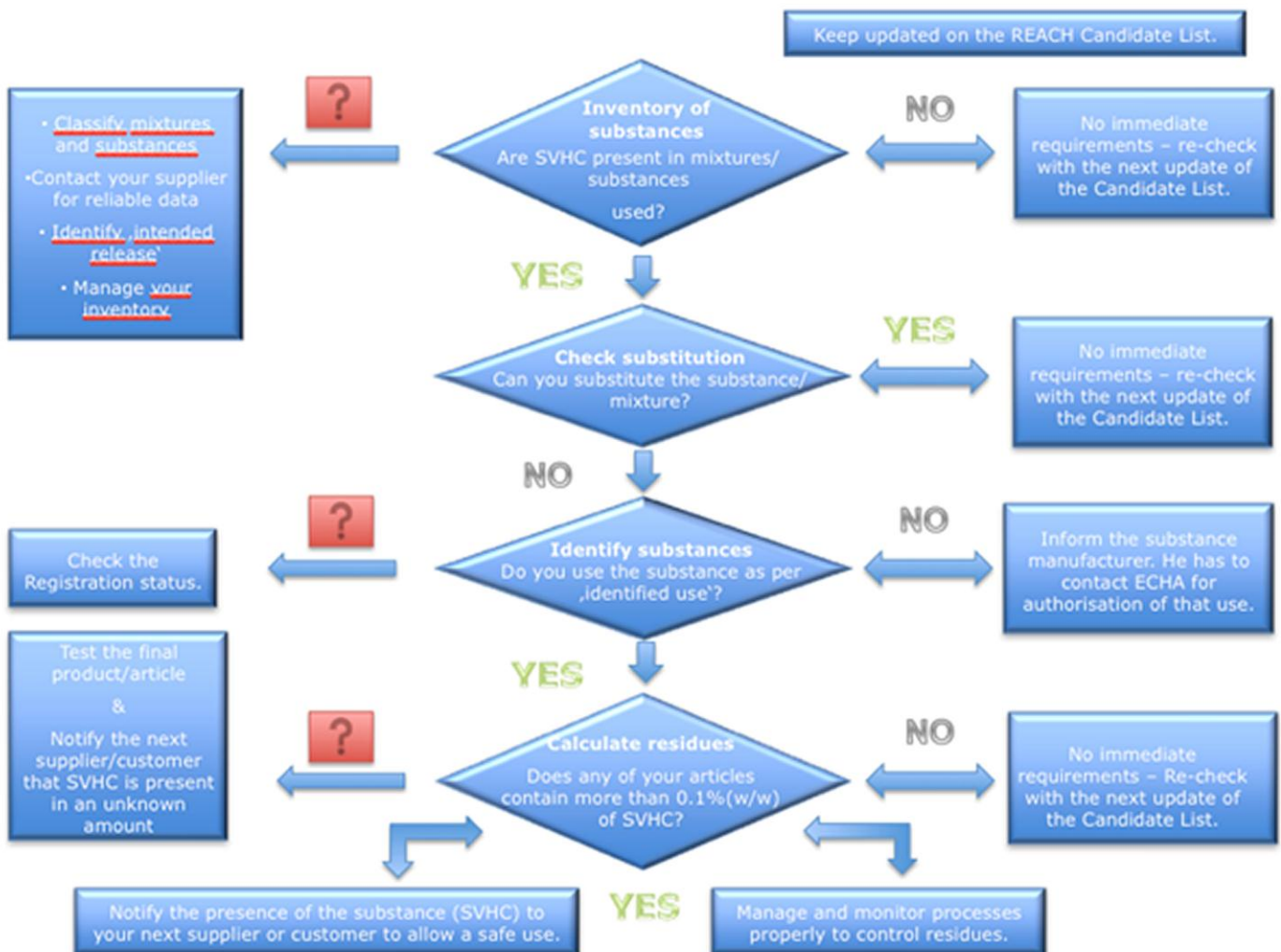
Based on the knowledge on information and source of data, a REACH responsible person/team is able to manage the chemicals in compliance with the REACH regulation.

5. IMPLEMENTATION

The following is to be done on a regular basis:

- inventory lists — identification of all substances in use
- checking of implementation tools — test, inspect & audit to ensure effective implementation
- validation — identify and rectify the information/data gaps and prepare corrective actions in case of need

The decision tree shows tasks and chronology of action to be taken for a successful REACH management:



In case the procedure demonstrated above identifies SVHC containing products are in use, the amount of SVHC in the final products must be calculated.

5. IMPLEMENTATION

Example of identified SVHCs in chemical products

SVHC calculation

$$\text{Concentration of SVHC} = \text{Amount of SVHC [g]} * 100 / \text{Weight of the whole article}$$

	Product	Weight	SVHC	Import Quantity	Necessary Action
■	Trousers	200g	0.4%	500.000	Notification to ECHA (not required, SVHC < 1 tonne) Information in the Supply Chain (required, SVHC > 0.1%)
■	Underpants	100g	0.025%	2.000.000	Notification to ECHA (not required, SVHC < 0.1%) Information in the Supply Chain (not required, SVHC < 0.1%)
■	T-Shirt	150g	0.5%	1.000.000	Notification to ECHA (not required, SVHC < 0.1%) Information in the Supply Chain (not required, SVHC < 0.1%)

The t-shirt produced contains a certain phthalate (SVHC) in the print. A consumer in Europe makes an official request if the t-shirt is REACH-conform. To assure REACH compliance the producer has to assure that the concentration of the SVHC is below the 0.1% (w/w). In the example case he must trace back the usage of the substances and printing inks, due to using an authorised dosage system.

Concentration of SVHC

$$= \text{Amount of SVHC [g]} * 100 / \text{Weight of the whole article}$$

The t-shirt has a weight of 210 g and the print is a 20% of the total weight. The print contains 20 mg of a SVHC. The SVHC concentration in the t-shirt is:
 $0.2 \text{ g} * 100 / 210 \text{ g} = 0.095 \% \text{ (w/w)}$.

In this example communication of information down the supply chain according to article 33. is not necessary as the t-shirt is REACH-conform (below SVHC limit value).

5. IMPLEMENTATION

Example of identified SVHCs in ready-made trimmings

SVHC testing

A. Phthalates



The chemical assessment at a garment manufacturing unit revealed that Diisobutyl phthalate (SVHC) is present in a plastic patch for t-shirts which are bought from a Chinese supplier.

The supplier was able to provide a product sheet of the patch which declares the softener DIBP is present in the plastic. It is not clear how much weight by weight of DIBP is in the patch.

The next user in the supply chain has to be informed to assure safe handling of the article. At least the name of the substance and information on safe handling according to the Safety Data Sheet had to be communicated.

If a consumer in Europe makes an official request the patch has to be tested and the costs for the testing has to be covered by the company.

5. IMPLEMENTATION

B. Nickel release



A pair of infant's trousers is produced, made of brown coloured cotton with pockets on the knee area. The trousers are fastened with a metal zipper. Testing unveils that the product poses a chemical risk due to nickel migration from metal parts (0.29% weight by weight).

The trousers do not comply with the REACH Regulation and the release of the SVHC is so high that all 200.000 produced items have to be removed from the market.

Substitute & Reduce

Knowing that SVHC is present in certain chemical products or product components, the REACH responsible person/team has to decide how to manage this risk. One option is to simply substitute the products/components.

Here is one example on how to deal with the substitution:

A company revealed that there is Pigment Yellow 34 (lead sulfochromate yellow — SVHC) in one of the printing inks in use. The company contacted the supplier and manufacturer of the printing ink and discussed the issue with him.

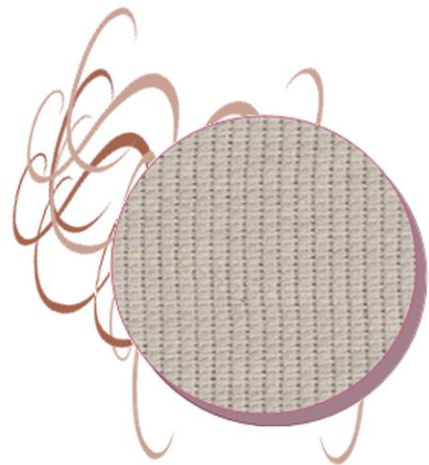
The producer will keep the printing inks composition as there is a large demand for the colour. But the producer has an alternative printing ink in the programme that he can be recommend as a substitute.

5. IMPLEMENTATION

The colourant Pigment Yellow 34 could be replaced by and ink based on Pigment Yellow 42 which is classified as not persistent and not harmful to human health.

Example for reduction:

A detergent containing 15% Nonylphenol Ethoxylate (NPEO) is in use by a Chinese dyeing mill. Due to the fact that NPEO is regularised under REACH Annex XVII and known as disturbing a sound function of effluent treatment plants. The dyeing mill products containing NPEO shall be replaced. As the dyeing mill complies with the requirement of Annex XVII (processing with no release into waste water) the dyeing mill decides to use a product with low NPEO concentration — here 2,5 %. They plan to use a NPEO free detergent in the future.



5. IMPLEMENTATION

Control

Knowing that SVHC is present in certain chemical products or product components the REACH responsible person/team has the option to let the production use the product/component in a controlled way in the future.

e.g. a garment manufacturer knows that the snap buttons used (always originating from the same supplier) release nickel in a small amount. A testing procedure is implemented on the snap buttons from the supplier. The test history shows that the limit value for nickel has never been exceeded (the test result is always clearly under the SVHC limit value).

This systematic monitoring allows the company to reduce the testing frequency as long as the results conform to REACH.

E.g. a printing mill uses a printing paste containing Dibutyl phthalate (DBP). This printing paste is used only for a specific customer for a small motive print/logo. The percentage weight by weight for this specific application is under 0,1% of the final article.

1. It has to be ensured that the DBP based printing paste is used only for the specific application/print (where it has been calculated that 0,1% (w/w) DBP will never be exceeded).

2. It has to be ensured that the paste is not used (by accident) for other customers, where it is not assured that DBP is in conformity with their restricted substance list and the limit of 0,1% DBP (w/w) is kept.

5. IMPLEMENTATION

Document

There are no specific record-keeping requirements in the REACH regulation (article 7 or article 33) for article suppliers except for those needed when registration, notification or communication are required.

However, article suppliers may also be suppliers and users of substances or preparations and in relation to these roles shall assemble and keep available relevant information for at least 10 years (article 36 of REACH).

Article suppliers should consider documenting the results of their compliance checking, even when it has been identified that no obligations under REACH exist. Documentation facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.

It is recommended that each producer/importer **establishes routines to ensure high quality documentation.**

Possible approaches could be:

- article suppliers with implemented management systems could incorporate REACH conformity as a criterion — with clear indications of how conformity will be secured and documented.
- article suppliers without a management system may follow a kind of “good practice for supplying articles” . This might include:
 - Following the workflows of this guidance
 - Describing whether registration/notification or communication on SVHC is required
 - Supporting documents including letters from suppliers, certificates, results of analysis etc.

5. IMPLEMENTATION

Communicate

INFORMATION VIA THE SUPPLY CHAIN

For article suppliers, communicating with the suppliers is the most important and efficient way to gather information on substances contained in their articles.

Communication along the supply chain is one of the core instruments to ensure controlled use of substances.

As stated also in the introductory clauses to REACH (the recitals), communication on substance hazards and risks as well as advice to control risks, is an important purpose of REACH. Identifying substances in articles and quantifying their amounts in order to assess whether or not these may pose a risk is in many cases only possible if the respective information is made available by the actors in the supply chain. Supply chain communication is therefore the most important way of gathering the information needed.

Chemical analysis, although a possible way to identify and quantify constituents of substances, preparations or articles, is time consuming, costly and difficult to organise.

However, supply chains may be complex and non-EU companies may not be prepared to provide the information.

Article importers may have to inform their suppliers outside the EU of the requirements of REACH and make special arrangements to receive information. Establishing communication policies and standards for substances in articles is an important task for private sectors in order to facilitate the implementation of REACH.

5. IMPLEMENTATION

Information needed to check whether or not the requirements of REACH article 7 apply can relate to the identity of substances as well as to the amounts/concentrations in the article itself or in preparations used in its production.

The communication of the information related to substances contained in articles according to article 33 shall enable safe use of the article and should consider the entire life cycle of the article.

What information is actually needed depends on a case-by-case assessment and is explained in the respective sections in this guidance.

Only representatives responsible for the importer requirements on behalf of non-EU article producers/suppliers have to comply with the obligations of article 7 as well as article 33 when these apply.

Thus, they will be responsible for the upstream communication with the non-EU supplier on behalf of the importers.



5. IMPLEMENTATION

INFORMATION TO CUSTOMERS

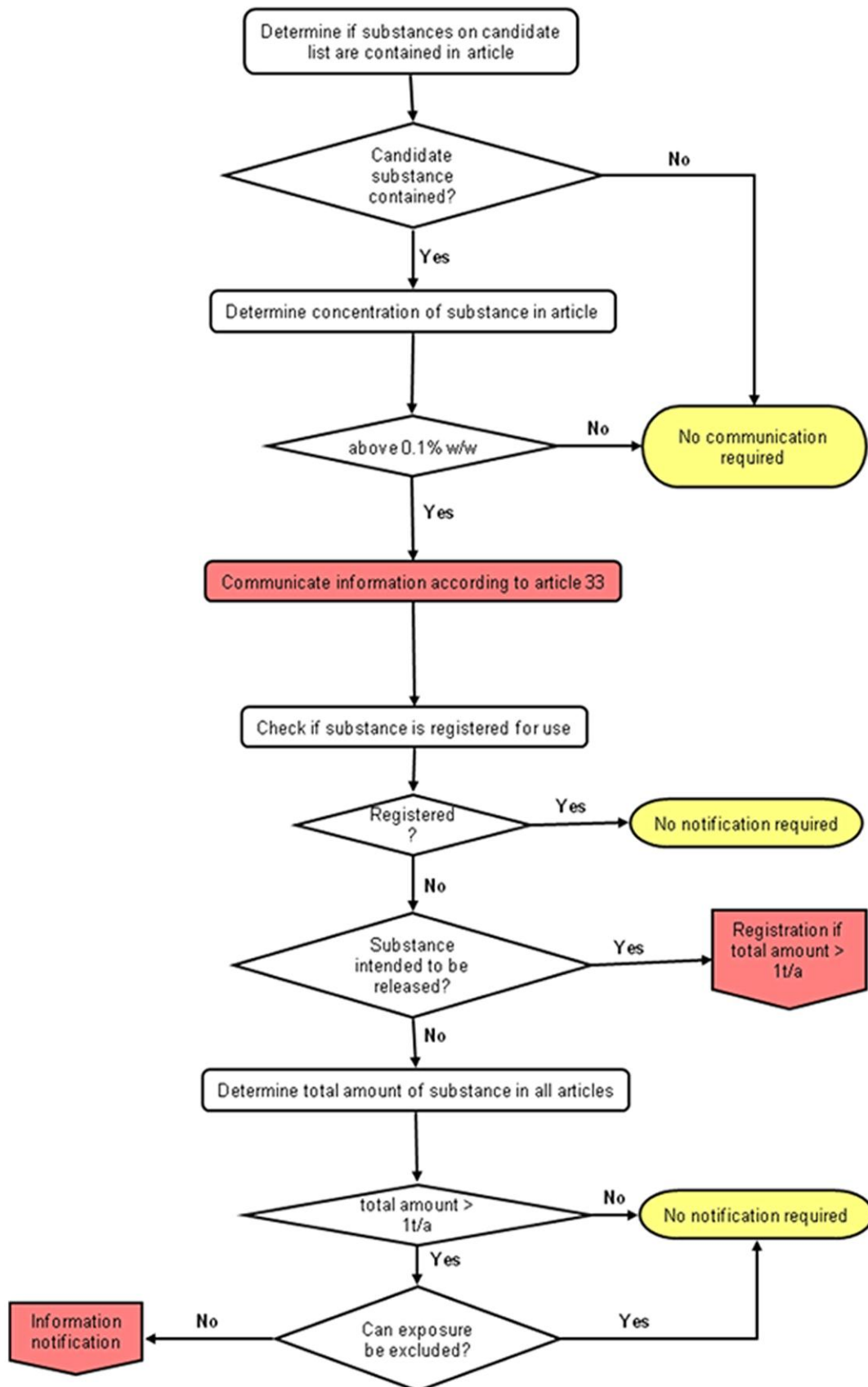
Article 33: Duty to communicate information on substances in articles. Producers, importers and other suppliers of articles containing substances on the candidate list may have to forward required information available to them down the supply chain (article 33(1) and to consumers on request (article 33(2)).

The aim of Article 33 is to ensure that sufficient information is communicated with articles to allow their safe use. Producers, importers and other suppliers of articles containing Substances of Very High Concern (SVHC) included on the candidate list for authorisation in a concentration above 0.1% (w/w) have to provide respective information available to them to the recipients of the articles and at a minimum the name of the substance. This information is to be provided 'automatically' (article 33(1)).

Information available to the article supplier necessary to ensure safe use of an article has also to be provided also to consumers upon request (article 33 (2)). Consumers have to be provided with information within 45 days of the request, free of charge. As for the article 7(2) requirements, the substance concentration threshold of 0.1 % (w/w) applies to the article as produced, imported or supplied.

5. IMPLEMENTATION

The following flowchart shows the specific cases/circumstances in which external communication is required (communication, notification or registration).



5. IMPLEMENTATION

Example

If imported buttons for jackets contain such substance in concentrations of 0.5% (w/w), this needs to be communicated to the recipient. If these buttons are imported as part of jackets the concentration of the substance in relation to the imported article (the jacket) will probably be lower than 0.1% (w/w) and in that case no information would have to be communicated.

The obligation to forward available information on Substances of Very High Concern on the candidate list also **applies to packaging materials. This packaging material is always a separate 'article'**.

Thus, if the imported buttons or the imported jackets were packaged in plastic packaging material, the content of such substances in this packaging material would have to be assessed separately.

The obligation to provide available information on Substances of Very High Concern to the recipients of the articles applies as soon as a substance has been included on the candidate list for authorisation.

The obligations also apply to articles which were produced or imported before the substance was included on the candidate list and are supplied after the inclusion. Thus, the date of supply of the article is relevant.

How to approach this task:

Article producers shall appoint responsible persons who are authorised to communicate concerning REACH on behalf of the company. Only these persons can talk to customers, answer customer requests and sign REACH conformity declarations. It would be extremely dangerous for a company if for instance a sales person would sign such declaration to get an order without knowing the background and the consequences.

6. REACH IN A NUTSHELL

INTRODUCTION AND BACKGROUND INFORMATION ON REACH

The European Union chemical policy REACH Registration, Evaluation, Authorization and Restriction of Chemicals came into force on 1st June 2007. It replaces around 40 existing EU regulations and directives.

It manages all chemicals, about 30000 at European level, by providing procedures for risk assessment, decision taking, communication on the safe use of chemicals and the implementation of measures to adequately control chemical risks. The implementation of REACH will be a step-by- step process over a period of 11 years.

The current REACH legislative text and Technical Guidance Documents can be found at:
http://echa.europa.eu/legislation/reach_legislation_en.asp

AIMS OF REACH

- improve the protection of human health and the environment from the risks that can be posed by chemicals;
- enhance the competitiveness of the EU chemicals industry;
- promote alternative methods for the assessment of hazards of substances;
- ensure the free circulation of substances on the internal market of the European Union.



6. REACH IN A NUTSHELL

GENERAL DUTIES UNDER REACH

Regarding the REACH Regulation (EG) No. 1907/2006 producers, distributors and importers of substances and mixtures are obliged to register substances at the European Chemicals Agency (ECHA), if the amount of the produced or imported substance is more than 1 ton per year. Furthermore substances, which are contained at an amount over 1 ton per year in mixtures or articles and are released in accordance with the law, also have to be registered.

THE TEXTILE MANUFACTURER AS DOWNSTREAM USER

has to..

- be aware if the textile articles that fall under REACH;
- assure that they do not contain more than 0,1 % (weight by weight) of a Substance of Very High Concern;
- be aware of the duty to communicate along the supply chain;
- be able to define risky processes in the company and assess them;
- have technical documentation of the chemicals in use or in the product (technical/product data sheet, Safety Data Sheet);
- check, whether his specific usage of the chemical product is covered in the safety Data Sheet;
- follow the risk reduction measures described in the Safety Data Sheet according to REACH.

Links for further information

60

European Chemicals Agency

<http://echa.europa.eu/>

International Chemical Secretariat

<http://www.chemsec.org/>

REACH

http://www.reach-web.de/index_en.htm

E-Learning by German Federal Environmental Agency

<http://ereach.dhigroup.com/index.htm>

<http://www.fit4reach.eu/index.php/en/>

The Candidate List of SVHC

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