Step 2 Sustainability

Online Course

UNIT 7

REACH and consumer safety – legislation for the footwear industry

How to Implement Sustainable Manufacturing in Footwear
- New Occupational Profile and Training Opportunities -

Lifelong Learning Programme

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How to Implement Sustainable Manufacturing in Footwear - New Occupational Profile and Training Opportunities

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IRCUO development and testing center for leather and footwear industry Elche
ars sutoria SCHOOL
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1. Introduction

Nowadays, compliance with European legislation ensures a high degree of protection uniformly applied to consumer health and safety. Products sold on the domestic market are subject to general safety requirements. They are regulated by Directive 2001/95/EC, relating to general product safety. This Directive imposes a general safety obligation for any product to be used by consumers or that could be used by consumers, including those used by consumers in the framework of providing a service. This Directive will be applied if there are no specific European rules to regulate the safety of specific categories of products, and if there any gaps in those specific rules (for each sector).

At the same time there is a specific European regulation applicable for all chemical substances present in day-to-day life, whether as such, in the form of mixtures or contained in articles whose main objective is the greater protection of health and the environment against risks involved in their preparation, marketing and use in the manufacture of products, that is to say, before reaching the consumer. This European regulation is the REACH Regulation.

REACH (Regulation nº 1907/2006 of the European Parliament and of the Council) is the European regulation relative to the Registration, Evaluation, Authorisation and Restriction of Chemicals. This Regulation assigns the industry with the responsibility of managing the risks associated with the substances that it manufactures, imports, sells and uses in its processes. To do so, each company must comply with one or more of the requirements established by the Regulation depending on the type of chemical and preparations that it manufactures, uses and/or imports, their origin (whether they are from the European Union or not) and how they are applied in their industrial process. The future of the footwear industries and of their components, such as tanneries, the manufacture of adhesives, outer soles for footwear, etc., is conditioned within the European Union by this Community regulation.

The European Chemicals Agency (ECHA) is the official body charged with coordinating all the Member States of the European Union to comply with that Regulation. It is at the helm of the regulating authorities for applying UE legislation on chemicals in benefit of human health and the environment, and also of innovation and competition. The ECHA advises companies on how to comply with legislation, it advocates a safe use of chemicals, provides information on chemicals and attends to chemicals that give rise to concern.

On the ECHA web site news items and publications can be found on chemical safety in the 24 languages of the EU. It can be consulted using the following link:
http://echa.Europe.eu/home

The companies involved in the footwear sector manufacture, use and trade products, therefore the object of this unit is to make it easier for footwear companies to comply with the Directive for product safety and the REACH Regulation.

2. Definition of a safe product

A safe product is one that can be used normally and foreseeably by users without causing them any harm.

The Law specifically says that a safe product: shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

(iv) the categories of consumers at risk when using the product, in particular children and the elderly.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'dangerous';

Furthermore, the law obliges business owners to inform of the risks for the safety of products and services: Business owners shall provide prior information for consumers and users, using the appropriate means, on the risks that could arise from a foreseeable use of the goods and services, taking into account their nature, characteristics, duration and the people for whom they are intended.

Chemicals and all articles that contain substances classified as hazardous must be packaged with due guarantees of safety and clearly display the appropriate indications warning of the risk involved in manipulating them.

2.1. General Product Safety Directive (GPSD)

The purpose of the general product safety directive is to ensure that products placed on the market are safe. This Directive shall mean any product, including in the context of providing a service, which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

Manufacturers shall be obliged to place only safe products on the market. Within the limits of their respective activities, manufacturers and distributors must collaborate with the competent authorities, at the request of the latter, in any actions undertaken to prevent risks present in the products they supply or have supplied. The procedures for that collaboration, especially the procedures for dialogue with the manufacturers and distributors in question on issues related to product safety, shall be defined by the competent authorities.

Depending on each case, the measures adopted by the competent authorities shall be aimed at:

- the manufacturer;
- within the limits of their respective activities, the distributors and, in particular, the person responsible for the initial distribution on the domestic market;
- if necessary, any another person who could be involved in collaborating in the actions undertaken to prevent risks arising from a product.

In order to effectively monitor the market with the aim of guaranteeing a high level of protection for the health and safety of consumers, which entails cooperation between the competent authorities, the Member States shall ensure that procedures are established which include adequate means and measures, which may include, in particular,

- establishing, regularly updating and implementing programmes for monitoring each sector according to categories of product or risk, and also following-up the activities of monitoring, observations and results;

- the monitoring and updating of scientific and technical knowledge on product safety;
- periodic evaluations and inspection of the functioning of monitoring activities and their effectiveness and, if it should be necessary, reviewing the procedure and organising surveillance.

In 2004 the General Product Safety Directive established the Rapid Alert System for dangerous non-food products (RAPEX). RAPEX allows the 31 participating countries (EU countries, Norway, Iceland and Liechtenstein) and the European Commission to exchange information on products posing a risk to health and safety of consumers and on the measures taken by these countries to do away with that risk.

The system also covers products posing risk to health and safety of professional users and to other public interests protected by relevant EU legislation (e.g. environment and security).

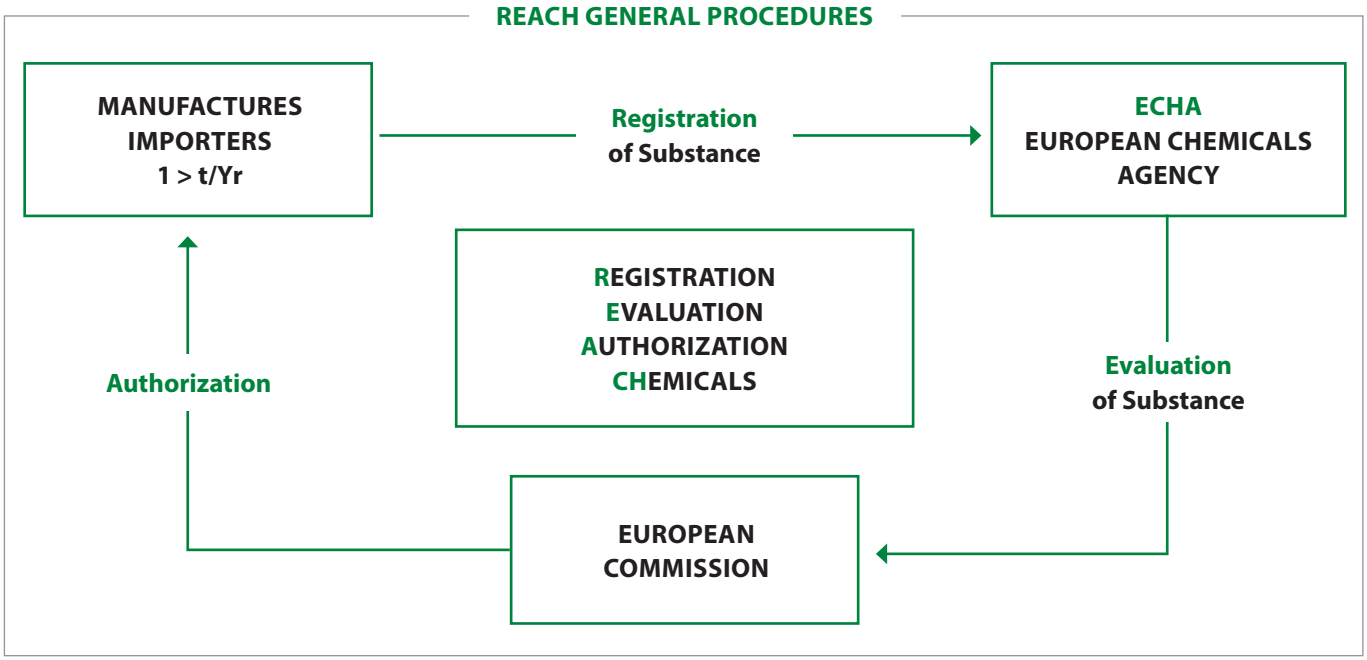
National authorities take measures to prevent or restrict the marketing or use of those dangerous products. Both measures ordered by national authorities and measures taken 'voluntarily' by manufacturers and distributors are reported via the system. Every Friday, based on this information provided by the national authorities, the Commission publishes a weekly overview of latest alerts. The published alerts include:

- information on the product, identified risk and measures taken in the notifying country;
- list of other countries where the notified product was found on their market and where measures were also taken;
- notifications on products posing serious risk and less than serious risk;
- notifications on professional products and on those posing risk to other public interests.

When using the RAPEX system, the Member States must provide the Commission with, at least, the following information:

- the information that allows the product to be identified;
- a description of the risk involved in the product, and also any documents for evaluating it;
- the measures adopted;
- the information on product distribution.

3. General procedures of the REACH regulation: Registration, Evaluation, Authorization and Restriction of Chemicals



Regulation (EC) nº 1907/2006 of the European Parliament and of the Council, of 18 December 2006 on the registration, evaluation, authorisation and restriction of chemicals, whose initials in English are **REACH.**

This Regulation came into force on 1 June 2007 and reformed the framework for legislation on chemicals in the European Union. Its main objective is to ensure a high level of protection of **human health and the environment.** The REACH system replaces over 40 Directives and regulations and creates a single system applicable to all chemicals.

The principal characteristic of this regulation is that it introduces the obligation of registering all chemical substances that are sold within the territory of the European Union and therefore no substance may be put on the market if it is not registered, based on the principle of precaution.

It assigns the industry with the responsibility of managing the risks associated with chemical substances. They must guarantee that they only manufacture, sell or use substances that have no adverse effects on human health or the environment. Furthermore there has to be more information on chemical substances and their associated risks and this must be conveyed to users and consumers. The principal stages of the process are:

Registration

Registration is compulsory for all substances manufactured or imported in the European Union in quantities of one tonne or more per year per manufacturer or importer, except those which are exempt from the obligation to be registered. This includes substances as such, in the form of mixtures or contained in articles when they are intended to be released under normal or reasonably foreseeable conditions.

The manufacturers and importers of substances in quantities greater than 1 tonne/year must apply for registration with the Agency, providing, amongst other things, the information relative to the identity of the substance, the physical, chemical and toxicological characteristics, uses, anticipated quantities and proposal for classification and labelling. No substances may be traded or manufactured in the Community if they are not registered. Specific groups of substances (listed in the Regulation) are exempt from the obligation to register (polymers, although the monomers of which they are composed must be registered, specific substances whose risk is estimated to be minimal such as water or glucose, specific substances that exist in nature and whose chemical composition has not been altered, and the substances used in the scope of research and development, under specific conditions).

In order to have a registered substance, some preliminary tasks need to be performed to meet the necessary information requirements. Those tasks are set out in several stages that need to be complied with first, which are as listed below:

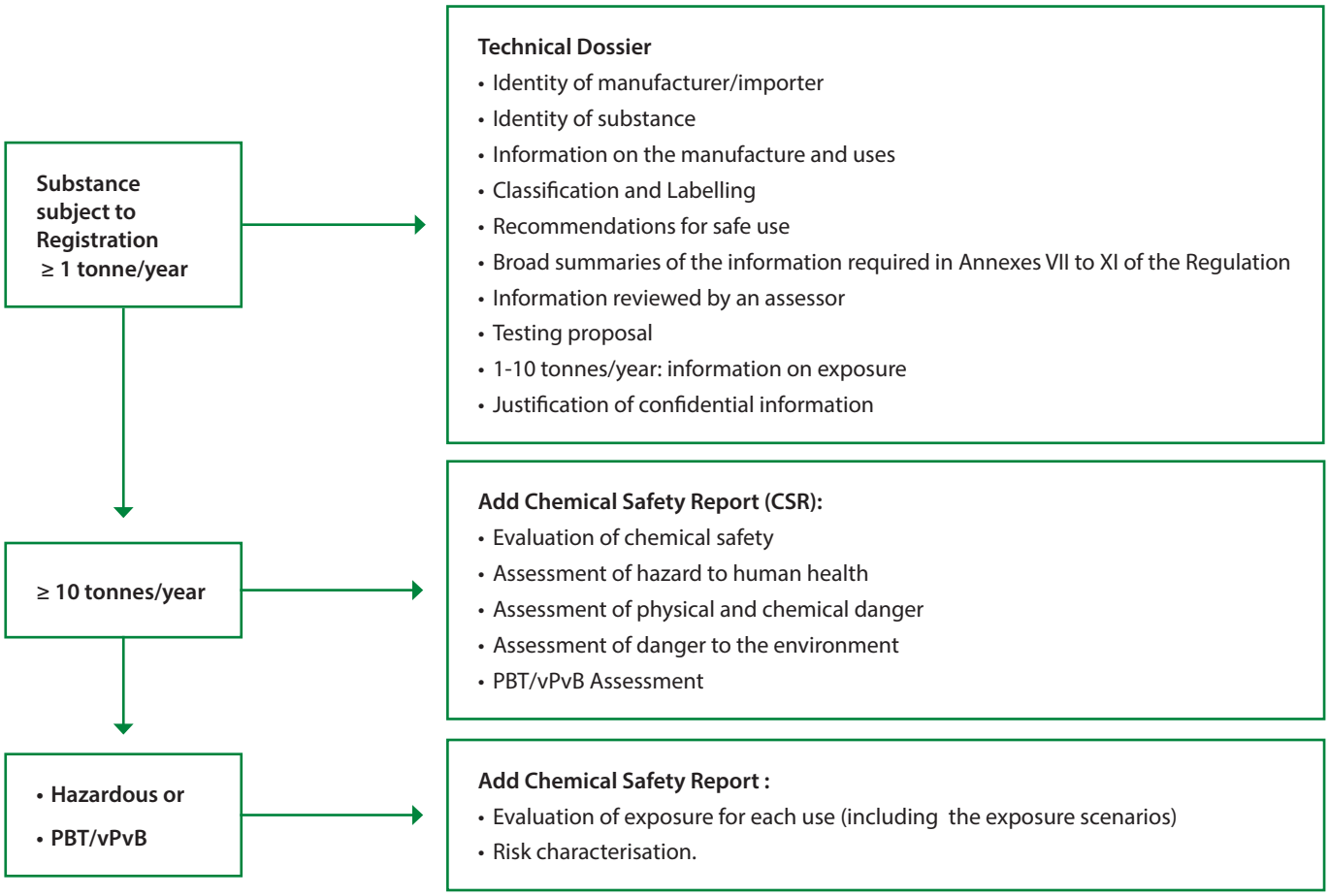
- Gather together all the existing information, including a data search of literature on the substance in question. Information from alternative sources should be attached, if any (extrapolation of other substances, (Q)SAR, etc.).
- Identify the information necessary for registration:
  - First of all, see which Annexes are applicable depending on the tonnage.
  - Determine which are the standard requirements, and if any others are justifiably applicable.
  - Specifically, the information on exposure, use and risk management measures has to be considered.
- Ensure that the data available is pertinent and of sufficient quality to meet the requirements. Compare the data available with what is required, and locate omissions.
- In cases where more information is needed, new data shall be generated or a testing strategy shall be proposed depending on the tonnage.

The content of the registration application consists of:

(i) A technical dossier with general and specific information on the substance;

(ii) A Chemical Safety Report for registrations with tonnages ≥10 tonnes/year.

The information to be submitted in both documents basically depends on the hazard level of the substance and the tonnage, according to the following outline:



F2. Content of a Registration Dossier

Registration can be submitted individually or jointly. Joint registration is made with the companies that initially pre-registered the substance in question and created the substance information exchange forum (SIEF). The fact of forming part of a forum entails:

- The possibility of assigning a forum coordinator (voluntary) for internal management.
- Appointment of a Lead Registrant whose function will be to submit the joint information for the registration on behalf of the other registrants. This must be done before any another registration to cover all members of the forum, so it is recommended that it should be one of the registrants with the highest tonnage.

Regarding the information that could be necessary for the joint registration:

- Agree on the classification and labelling of the substance.
- Exchange the information required for the joint registration, attending to the petitions for information from other members and providing the existing reports through fair economic arrangements. The objective is to prevent duplicating testing.
- Identify the information gaps for registration and organise the strategy for obtaining data to complete it (tests).

New members can join the forums, once they are set up, as there could be companies manufacturing or importing a substance for the first time.

It is possible to not make joint registration in circumstances of disagreement between the members of the forum, but this procedure entails resources and added costs, which would probably give rise to an inadvisable situation.

Specifically in the supply chain for the footwear sector, the registration of substances must be made by the **manufacturer and importers of substances** who are, for example, the manufacturers or importers of solvents, oxides, tanning agents, etc., the **importers of preparations**, who have to register each one of the substances of which the preparation is made (for example, adhesives, finishes, etc.) and the **manufacturers and importers of articles that contain some substance that is released** in conditions of normal or reasonably foreseeable use (for example, aromas that might be contained in the outer soles or insoles, etc.). In the case of substances that in the end are not registered for specific uses of interest to a company, the company may choose to adopt any of the following actions:

- Reformulate the preparations in question using other substances that are registered for the use required,
- Use substances in accordance with the uses for which they were registered,
- Contact another supplier who includes their use in the registration of the substance,
- Directly communicate the use to the European Chemicals Agency (ECHA) and the company shall have to draw up its own Chemical Safety Report (CSR).

For drawing up the CSR the whole life cycle of the substance must be considered, both for its own use and for the uses identified in the subsequent stages of the supply chain, taking into account the information provided by the supplier of the chemical (with the work entailed in preparing the information and the costs involved in this process).

Evaluation

The European Chemicals Agency (ECHA) is charged with assessing the registration dossiers. That evaluation will be compulsory for all applications that include any of the tests listed in Annexes IX and X of the REACH Regulation.

Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants
- Compliance check of the dossiers submitted by registrants
- Substance evaluation

Once the evaluation is done, registrants may be required to submit further information on the substance.

Any additional testing proposals will be evaluated. The competent authorities of the Member States, together with the Agency, carry out the evaluation of the substances.

The evaluation is made of substances produced or imported in quantities greater than 100 tonnes/year and those representing a significant risk for human health and the environment (carcinogenic, mutagenic or toxic...), regardless of the quantities.

The result of the evaluation can be:

- that the substance must be subject to restriction or authorisation procedures,
- the classification and labelling of the substance must be harmonised,
- information must be supplied to the other authorities so that they can adopt appropriate measures, for example of risk management.

In line with Article 54 of the REACH Regulation, by 28 February of each year, ECHA has to publish a report on the progress it has made over the previous calendar year on its obligations in relation to evaluation. ECHA is specifically required to include recommendations to potential registrants to foster improvement in the quality of future registrations, in these reports.

Authorisation

This procedure is used for substances that are of extremely high concern (SVHC). The main objective of the Authorisation is to ensure the correct functioning of the domestic market and guarantee that the risks arising from the Substances of Very High Concern (SVHC) are property controlled. The Commission only grants authorisations for specific uses of a substance in order to guarantee the control of risks and that these substances are gradually replaced by other appropriate substances or technologies where this is economically and technically viable.

The Agency publishes and regularly updates a list of substances (list of candidate substances) identified as being of extremely high concern (CMRs: carcinogens, mutagens and reproductive toxins), PBTs: persistent, bioaccumulative and toxic substances; vPvBs: very persistent and very bioaccumulative substances, and some substances of concern which have irreversible serious effects on humans and the environment, such as endocrine disruptors).

After a two-stage regulatory process, the Substances of Very High Concern can be included in the Authorisation List (Annex XIV) and, therefore, be subject to authorisation. The manufacturers, importers or downstream users of these substances cannot sell them or use them after a specific date unless authorisation has been granted for a specific use, or the use is exempt from authorisation. If the risks arising from the use of that substance can be suitably managed, authorisation will be given. Otherwise, and if there are no alternatives, the Commission will assess the level of risk and the socio-economic advantages of using the substance and decide whether to authorise it or not. Some substances, such as PBTs and vPvBs can be authorised only if the socio-economic advantages override the risks and there are no alternatives.

Manufacturers, importers or downstream users of a substance included in the Authorisation List can apply for authorisation. Downstream users who do not apply for their own authorisation may use an SVHC substance included in Annex XIV, providing that it is used in accordance with the conditions of authorisation granted to an agent further up the supply chain for that use.

Holders of an Authorisation, and also downstream users making use of the authorisation given to an agent further up the supply chain, must include the Authorisation number on the label of the substance or preparation containing the substance for an authorised use.

Restriction

The restrictions are an instrument for protecting human health and the environment from unacceptable chemical risks. The restrictions can limit or prohibit the manufacture, marketing or use of a substance and can be applied to any particular substance in a mixture or in an article, including those not requiring registration. They can also be applied to imports.

A Member State, or the ECHA, at the request of the European Commission, can propose restrictions if the risks need to be addressed at Community level.

Any individual or company can submit observations on a proposal for restricting a substance. Greater interest will probably be shown by companies, organisations representing industry or the civil society, private citizens, and also the public authorities. Observations are accepted from both the EU and from third countries.

This procedure permits managing risks that are not adequately covered by other provisions under the regulation. A Member State or ECHA (on behalf of the Commission) could conclude that restriction is the best risk management option during the authorisation process in cases where restriction of a substance of very high concern (SVHC) at the EU level would be more appropriate than its inclusion on the authorisation list (REACH Annex XIV). Furthermore, a follow-up to substance evaluation may also trigger a restriction process carried out by a Member State. In addition, the Commission can also propose a restriction for CMR category 1 and 2 substances without the involvement of ECHA's Committees. The restriction proposal may end up as a new entry or as an amendment of the current entry in REACH Annex XVII containing the list of restrictions of certain dangerous substances, mixtures and articles for their marketing and use on the European market.

4. Important definitions to understand the implementation of the REACH regulation in the footwear sector

There is a series of important definitions given within the REACH Regulation, some of which will be explained shortly:

SUBSTANCE: means a chemical element and its compounds 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;

Monomers, solvents, plasticizers, catalysts, antioxidants, etc. are considered as "Substances".

PREPARATION: reparation means a mixture or solution composed of two or more substances.

Some "preparations" are adhesives, finishing products, dyes, etc.

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;

Textiles, leather, products for use in an intermediate or final production process, or the finished product itself are considered as "Articles".

MANUFACTURER: means any natural or legal person established within the Community who manufactures a substance within the Community.

IMPORTER: means any natural or legal person established within the Community who is responsible for import.

DOWNSTREAM USER: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.

NON-COMMUNITY MANUFACTURER a manufacturer of preparations or substances established outside the Community.

ONLY REPRESENTATIVE FOR A NON-COMMUNITY MANUFACTURER means any natural or legal person established in the Community who represents a non-Community manufacturer of substances or preparations to fulfil, as his only representative, the obligations on importers under the REACH Regulation.

5. Critical substances regulated by the REACH potentially present in footwear

In the footwear manufacturing industry there are three groups of substances likely to appear in footwear components or in the finished products and that generate legal obligations regarding the components that contain them. The substances to be taken into account are:

Substances of Very High Concern (SVHC), Substances Subject to Authorisation (Annex XIV of the REACH) and restricted substances (Annex XVII of the REACH).

5.1. Substances of Very High Concern (SVHC)

As informed in the previous subsection, Substances of Very High Concern (SVHC) are those identified as CMRs (carcinogenic, mutagenic or toxic for reproduction), PBTs (persistent, bioaccumulative and toxic), vPvB substances (very persistent and very bioaccumulative) and some substances of concern which have irreversible serious effects on humans and the environment, such as endocrine disruptors.

Any Member State, or the ECHA at the request of the European Commission, can propose a substance to be identified as an SVHC. If it is identified as such, it will be added to the list of candidate substances, which contains all substances that might be included on the Authorisation List (Annex XIV of the REACH).

The intention of proposing a substance to be identified as an SVHC is made public, on the ECHA web site, in the Register of Intentions before presenting the proposal. One of the purposes of this Register is to enable any interested parties to be up-to-date with those substances that could be catalogued as SVHC before being included on the list of candidate substances. This makes it possible to prepare for complying with any possible obligations arising as result of a substance being finally included in the list of candidate substances. Therefore, manufacturers, importers and suppliers of articles are recommended to regularly check the Register of Intentions on the ECHA web site.

The proposal is prepared in accordance with Annex XV of REACH, and consists of two basic parts. The first provides the information and evidence for identifying a substance as SVHC. The second, examined during the monitoring stages in the identification process, contains information on the quantities of the substance in the EU market and its uses, the emissions and resulting exposure and any possible alternatives to the substance.

After publication of the proposal, anyone who so wishes can put forward any comments or add more information, for example, in relation to the properties, uses and risks of the substance proposed or its alternatives. If no comments are received, the substance will be included in the list of candidate substances. The proposals and comments will be forwarded to the Member State Committee (MSC), which decides on the identification of the substance as an SVHC. If the Committee does not reach a unanimous decision, the case will be sent to the European Commission.

The inclusion of a substance on the list of candidate substances gives rise to legal obligations for the companies that manufacture, import or use the substance, whether as such, in preparations or in articles.

REACH defines 'article' as 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. According to REACH, articles are, for example, t-shirts, floor coverings or plastic packaging. The components that after assembling, as in the case of footwear, form the final product are also considered as articles and of course, footwear.

Manufacturers and importers of articles can obtain information on SVHCs and the concentration contained in each from the agents in the supply chain, such as suppliers of components of the articles in or outside the EU and suppliers of substances and mixtures.

The List of candidate substances is available on the ECHA web site. It should be noted that the list of candidate substances is regularly updated with new substances identified as SVHC.

The link for accessing the List of Substances of Very High Concern is: ***http://echa.Europe.eu/candidate-list-table***

If any of the substances on this list is contained in the articles, the supplier must provide the recipient of the article with sufficient information to allow safe use, including, at least, the substance name if it is found in the article in a concentration higher than 0.1 % in weight/ weight (w/w).

If a consumer requests information on the safety of the article that he is buying, the supplier of the article containing an SVHC on the list of candidates in a concentration higher than 0.1 % in weight/weight must give, at least, the substance name. He must provide the corresponding information, free of charge and within 45 days from when the request was received.

Furthermore, manufacturers and importers of articles may have to notify the 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 tonne in total per year per company. If you import or produce several articles containing the same SVHC you need to consider the total tonnage, which is calculated by adding the tonnages of the substance for each article that contains the substance at 0.1% (w/w) or higher.

Below is the list with the Substances of Very High Concern (SVHC) that are candidates for Authorisation up until the last incorporation (15/06/2015) with substances shaded where they are most likely to be found in footwear according to the document FprCEN/TR 16417:2014 drawn up by the European Committee for Standardization CEN TC 309 "Footwear", in the working group 2 of "Environmental aspects and Footwear".

NAME	Nº CAS	POSSIBLE USES
2-Ethoxyethyl acetate	111-15-9	
Anthracene oil	90640-80-5	
Anthracene oil, anthracene-low	90640-82-7	
Anthracene oil, anthracene paste	90640-81-6	
Anthracene oil, anthracene paste, anthracene fraction	91995-15-2	
Anthracene oil, anthracene paste, distn. lights	91995-17-4	
Acetic acid, lead salt, basic	51404-69-4	
1,2-Benzenedicarboxylic acid, di-C7-11- branched and linear alkyl esters	68515-42-4	This is a phthalate plasticiser that in theory can be present in any of the plastic components used in footwear manufacturing.
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	This is a phthalate plasticiser that in theory can be present in any of the plastic components used in footwear manufacturing.
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	Phthalate. Possible use as plasticiser in plastic materials
1,2-Benzenedicarboxylic acid, dihexylester, branched and linear	68515-50-4	Phthalate. Possible use as plasticiser in concentrations higher than 0.1%.
Boric acid	10043-35-3 / 11113-50-1	Possible use in adhesives and paints. In textiles. As additives to chemicals for finishes. As a preservative of raw hides (sheepskin-large hides)

NAME	Nº CAS	POSSIBLE USES
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	7738-94-5 (ac. Chromic) 13530-68-2 (ac. Dichromic)	Chromic acid: Possible use as pesticide Dichromic acid: possible use in metallic finishes and surfaces. As a catalyst, detergent, use in the electroplating. As a fixative, oxidant, pigment, in paints and coverings.
Fatty acids, C16-18, lead salts	91031-62-8	Possible use in PVC processing
Arsenic acid	7778-39-4	
Pentacosafluorotridecanoic acid	72629-94-8	
Tricosafluorododecanoic acid	307-55-1	
Henicosafluoroundecanoic acid	2058-94-8	
Heptacosafluorotetradecanoic acid	376-06-7	
Methoxyacetic acid	625-45-6	
Pentadecafluorooctanoic acid (PFOA)	335-67-1/ 206-397-9	Possible use as water repellent in hides and textiles
Silicic acid, lead salt	11120-22-2	
Sulfurous acid, lead salt, dibasic	62229-08-7	Possible use in PVC processing
Acrylamide	79-06-1	Possible use in the production of plastics and glues. in not fully polymerised polymers.
Alkanes, C10-13, chlorine (Short Chain Chlorinated Paraffins)	85535-84-8	Substance widely used as a flame retardant or plasticiser in several applications as high-performance rubbers, sealants, paints or textile coverings. Possible use as greasing agent tanning although in the EU it is subject to restriction by the Regulation on persistent organic pollutants (519/2012).
[4-[[4-anilino-1-naphthyl] [4-(dimethylamino)phenyl]methylene] cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	2580-56-5	Possible use in the formulation of dyes, cleaning agents and coverings, and also for dying paper, packaging, textiles and plastic products.
4-Aminoazobenzene	60-09-3	
Anthracene	120-12-7	PAH compounds. Possible pollutant (recycling materials, greased leather, black plastic, rubber)
Lead hydrogen arsenate	7784-40-9	
Calcium arsenate	7778-44-1	
Pitch, coal tar, high temp.	65996-93-2	

NAME	Nº CAS	POSSIBLE USES
Benzyl butyl phthalate (BBP)	85-68-7	Plasticiser used for example in polymer-based products and in particular PVC for use in floors, textile coverings and hides, and also in other preparations or mixtures as sealants, coverings and dyes or adhesives. In the manufacture of outer soles for footwear.
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	Possible use as ultraviolet protection agent for plastics, rubbers and polyurethanes
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	Possible use as ultraviolet protection agent
Biphenyl-4-ylamine	92-67-1	
4,4'-bis(dimethylamino) benzophenone (Michler's ketone)	90-94-8	
[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	548-62-9	
4,4'-bis(dimethylamino)-4''-(methylamino) trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	561-41-1	
α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	6786-83-0	
Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	Plasticiser widely used in PVCs and other polymer applications, coated fabrics and leathers, and also in several preparations as sealants, adhesives and dyes. Manufacture of outer soles for footwear.
Lead (II) bis(methanesulfonate)	17570-76-2	
Bis(2-methoxyethyl) ether	111-96-6	Possible uses as solvent in sealants and adhesives.
Bis(2-methoxyethyl) phthalate	117-82-8	Possible use as plasticiser in polymer-based materials, paints, lacquers and varnishes.
1,2-bis(2-methoxyethoxy)ethane (TEGDME,triglyme)	112-49-2	
Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	1163-19-5	Possible use as flame retardant in plastics, textiles and adhesives
Lead bis(tetrafluoroborate)	13814-96-5	
1-bromopropane (n-propyl bromide)	106-94-5	Possible use in textiles, adhesives and coverings

NAME	Nº CAS	POSSIBLE USES
Cadmium	7440-43-9	Substances containing cadmium. Use in pigments for plastic materials. Possible use as PVC stabiliser.
Cobalt(II) carbonate	513-79-1	
Cadmium chloride	10108-64-2	Substance containing cadmium. Possible use as pigments for polymers and synthetic materials. Preservative for PVC.
Potassium chromate	7789-00-6	Possible use as corrosion inhibitor for the treatment and the coating of metals, textiles and in the manufacture of pigments/dyes. Leather tanning.
Sodium chromate	7775-11-3	Possible use in the manufacture of pigments for paints and dyes and other chromium chemicals.
Lead chromate	7758-97-6	Possible uses in the manufacture of pigments and dyes. Possible pigment in certain surface coatings.
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	12656-85-8	Possible use as a colouring agent, paint and coating in the rubber and plastic sectors.
Dichromium tris(chromate)	24613-89-6	
Strontium chromate	7789-06-2	
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	85-42-7 13149-00-3 14166-21-3	
Cobalt(II) diacetate	71-48-7	Possible use but less than 1% as bonding agent with rubber.
4,4'- Diaminodiphenylmethane (MDA)	101-77-9	Possible hardener used for example in epoxy resins and adhesives. Aromatic amine due to the degradation of certain azo dyes. Can be in skins and textiles but normally in concentrations lower than 0.1%.
Trilead diarsenate	3687-31-8	
Diazene-1,2-dicarboxamide (C,C`-azodi(formamide)) (ADCA)	123-77-3	Possible use as expanding agent in plastics and rubbers
Lead di(acetate)	301-04-2	Possible use in paints and coverings
Dibutyl phthalate (DBP)	84-74-2	Possible use as special plasticiser used particularly in polymer applications (PVC/non-PVC) as flooring and as a component of various preparations or mixtures as adhesives or paints. Can be used as coating for materials used in footwear and the manufacture of outer soles.

NAME	Nº CAS	POSSIBLE USES
Dibutyltin dichloride (DBTC)	683-18-1	Possible use in textiles and in plastics. PVC stabiliser. Additive in rubbers
Potassium dichromate	7778-50-9	Used in electroplating for chroming other metals, in leather manufacturing, in the manufacture of pigments, for zinc and magnesium anti-corrosion coatings. Can also be used as a mordant on textiles.
Sodium dichromate	7789-12-0 10588-01-9	Can be used for the production of leather tanning agents. Can be found in tanned hide but in concentrations lower than 0.1%
Ammonium dichromate	7789-09-5	Possible use as mordant in the textile industry for purifying fats and oils. Amongst its minority uses is metal treatment. Leather tanning
Cobalt dichloride	7646-79-9	
1,2-Dichloroethane	107-06-2	
2,2'-dichloro-4,4'-methylenedianiline	101-14-4	Possible use as curing agent in resins and in the production of PU polymer articles and also for manufacturing other substances.
1,2-Diethoxyethane	629-14-1	
Diethyl sulphate	64-67-5	Possible use in textiles
Dihexyl phthalate	84-75-3	Possible use as plasticiser
Dimethyl sulphate	77-78-1	Possible use in polyurethane adhesives
Trilead bis(carbonate) dihydroxide	1319-46-6	
Diisobutyl phthalate	84-69-5	Possible use as plasticiser for nitrocellulose, cellulose ether, polyacrylate and polyacetate dispersions, and to help in combination with other plasticisers, which are extensively used for plastics, lacquers and adhesives.
Diisopentylphthalate	605-50-5	Possible use as plasticiser for PVC and other polymers in concentrations higher than 0.1%.
Dipentyl phthalate (DPP)	131-18-0	Possible use as plasticiser in PVC
1,2-dimethoxyethane,ethylene glycol dimethyl ether (EGDME)	110-71-4	
Cobalt(II) dinitrate	10141-05-6	
Lead dinitrate	10099-74-8	
Dinoseb (6-sec-butyl-2,4-dinitrophenol)	88-85-7	Possible use as polymerization regulator in the processes for the production of rubber, resins, polymers…
N,N-dimethylformamide	68-12-2	Possible use in adhesives and in polyurethane coverings for skins

NAME	Nº CAS	POSSIBLE USES
2,4-Dinitrotoluene	121-14-2	
[Phthalato(2-)]dioxotrilead	69011-06-9	Possible use in PVC processing
Dioxobis(stearato)trilead	12578-12-0	Possible use in PVC processing
Trilead dioxide phosphonate	12141-20-7	Possible use in PVC processing
Lead dipicrate	6477-64-1	
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	Used as dye (colorant) in hides, textiles and polymers
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	Used as dye (colorant)
Lead styphnate	15245-44-0	
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	Possible use in paints for polyurethane, polyurethane finishes, PU materials and sealants
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	
Silicic acid (H2Si2O5), barium salt (1:1), lead-doped	68784-75-8	
2-Ethoxyethanol	110-80-5	Possible use as additive, solvent, stabiliser, pesticide. Possible in the finishing for hides
Phenolphthalein	77-09-8	
Aluminosilicate Refractory Ceramic Fibres	Extracted from Index no.: 650-017-00-8	
Zirconia Aluminosilicate Refractory Ceramic Fibres	Extracted from Index no. 650-017-00-8	
Formaldehyde, oligomeric reaction products with aniline	25214-70-4	Possible use as epoxy resin hardener, for manufacturing adhesives. Textile biocide.
Formamide	75-12-7	Possible use in EVA materials in concentrations higher than 0.1%
Cadmium fluoride	7790-79-6	
Furan	110-00-9	Possible use in adhesives
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	25637-99-4 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)	
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans-stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	25550-51-0 19438-60-9 48122-14-1 57110-29-9	Possible use as epoxy resin hardener

NAME	Nº CAS	POSSIBLE USES
Potassium hydroxyoctaoxodizincatedichromate	11103-86-9	
Tetraboron disodium heptaoxide, hydrate	12267-73-1	Possible flame retardant for plastics
Hydrazine	302-01-2 / 7803-57-8	Possible use in PVC processing
Imidazolidine-2-thione (2-imidazoline-2-thiol)	96-45-7	Possible use in the production of rubber products. Vulcanization accelerator.
Methyloxirane (Propylene oxide)	75-56-9	
2-Methoxyethanol	109-86-4	Possible use as additive, solvent and stabiliser. Possible in certain leather finishes
2-Methoxyaniline,o-Anisidine	90-04-0	
1-Methyl-2-pyrrolidone (NMP)	872-50-4	Possible use as solvent for paints and in adhesives. and as solvent in the leather industry and leather finishes.
4-methyl-m-phenylenediamine (toluene-2,4-diamine)	95-80-7	
4,4'-methylenedi-o-toluidine	838-88-0	
6-methoxy-m-toluidine (p-cresidine)	120-71-8	Amina that can be found in some azo dyes
Lead monoxide (lead oxide)	1317-36-8	Possible use in pigments for rubber and in PVC
N-methylacetamide	79-16-3	
N,N-dimethylacetamide	127-19-5	
N,N-dimethylformamide	68-12-2	Possible use as solvent. Used in adhesives. Possible use in materials with PU coating by immersion
N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	Possible use as intermediary in the manufacture of dyes and other substances.
4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]		Possible use in the manufacture of phenol formaldehyde resins used in rubber. Possible use in adhesives and sealants and in textiles
4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]		Possible use in processing hides and textiles. Surfactant that can be used in leather.
Pentazinc chromate octahydroxide	49663-84-5	
o-Toluidine	95-53-4	Possible use in synthetic rubber

NAME	Nº CAS	POSSIBLE USES
o-aminoazotoluene	97-56-3	
4,4'-oxydianiline and its salts	101-80-4	
Bis(tributyltin) oxide (TBTO)	56-35-9	Possible use as polymer preservation agent. Can be in coated material and outsoles but in concentrations lower than 0.1%
Cadmium oxide	1306-19-0/ 215-146-2	Possible use in pigments for plastic materials or as a PVC stabiliser
Lead titanium zirconium oxide	12626-81-2	
Pyrochlore, antimony lead yellow	8012-00-8	
Lead diazide, Lead azide	13424-46-9	
Orange lead (lead tetroxide)	1314-41-6	Possible use in the vulcanisation of rubber
Lead titanium trioxide	12060-00-3	
Lead cyanamidate	20837-86-9	
Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	Possible use as water repellent in hides and textiles
Diarsenic pentaoxide	1303-28-2	
Pentalead tetraoxide sulphate	12065-90-6	
N-pentyl-isopentylphthalate	776297-69-9	Phthalate. Possible use as plasticiser in concentrations higher than 0.1%.
	-	
Sodium peroxometaborate	7632-04-4	Substance that contains boron. Possible traces from using it as a raw hide preservative
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1344-37-2	Possible use as a dye agent, paint and coating in the rubber and plastic sectors.
Cobalt(II) sulphate	10124-43-3	
Lead oxide sulfate	12036-76-9	Possible use in PVC processing
Tetralead trioxide sulphate	12202-17-4	Possible use in PVC processing
Cadmium sulphate	10124-36-4/ 31119-53-6	Possible use in pigments
Cadmium sulphide	1306-23-6	Possible use as pigment. In the semiconductor industry. As a stabiliser in plastics.
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	81-15-2	Possible use as fragrance enhancer used for example in detergents, fabric softeners and conditioners.
Disodium tetraborate, anhydrous	1303-96-4/ 1330-43-4/ 12179-04-3	Possible use as components in many applications, as adhesives and biocides.
Tetraethyllead	78-00-2	
4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	Possible use as a component of adhesives, coverings, dyes and rubber articles. Used as a surfactant in skins and textiles.

NAME	Nº CAS	POSSIBLE USES
4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	Possible use as a component of adhesives, coverings, dyes and rubber articles. Used as a surfactant in skins and textiles.
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]		
1,2,3-trichloropropane	96-18-4	Solvent in rubbers
Trichloroethylene	79-01-6	Possible uses for cleaning and degreasing of metal parts and as a solvent in adhesives.
Triethyl arsenate	15606-95-8	
Diboron trioxide	1303-86-2	Possible use in a great many applications, e.g. flame retardants, adhesives, paints, biocides, insecticides, detergents, cleaning agents, etc.
Diarsenic trioxide	1327-53-3	
Chromium trioxide	1333-82-0	Possible use for the surface treatment of metal, for synthesising other chrome compounds.
Tris(2-chloroethyl)phosphate	115-96-8	Possible use, mainly, as a plasticising additive and viscosity adjuster with flame retardant properties for acrylic resins, polyurethane, polyvinyl chloride and other polymers. Other possible applications are adhesives, coverings, fire resistant paints and varnishes.
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	2451-62-9	Possible use, mainly, as hardener in resins and coverings. Also in adhesives and plastic stabilisers.
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)	59653-74-6	Possible use in resin casting systems, coverings, adhesives, plastic stabilisers ….
Trixylyl phosphate	25155-23-1	Possible use as flame retardant in polymers (plastics) and textiles. Also as additive in lubricants.
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	-	
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5 / 68648-93-1	Possible use as plasticiser and lubricant in adhesives, coverings and PVC compounds.

5.2. Substances Subject to Authorisation (REACH Annex XIV)

The REACH Regulation establishes that the ECHA must identify, from within the "list of candidates", those substances that are to be included first and foremost in Annex XIV of the REACH Regulation (the "Authorisation List") and recommend the entries in Annex XIV (i.e. transitional provisions and, when appropriate, exemptions and periods of review) for those substances to the European Commission, taking the opinion of the Member State Committee into account. The European Commission will make the final decision on which substances will be included in Annex XIV and with which entries.

Once the European Commission has placed an SVHC on the Authorisation List (Annex XIV of the REACH Regulation), companies can submit a request to the ECHA to apply for authorisation for specific uses. REACH allows companies to request authorisation to continue or commence the use of the substances included on the Authorisation List. Those substances included in Annex XIV cannot be used, unless they have authorisation for the specific uses or the Authorisation is being processed.

The process of requesting authorisation includes a period of public consultation on the ECHA web site, lasting eight weeks.

The Substances Subject to Authorisation are listed in Annex XIV of the REACH Regulation. That list is shown below with details of the Substances of Very High Concern (SVHC) subject to Authorisation, covering up to the last time substances were incorporated in August 2014. It highlights the substances with more likelihood of being found in items of footwear according to the document FprCEN/ TR 16417:2014 drawn up by the European Committee for Standardization CEN TC 309 "Footwear", in the working group 2 of "Environmental aspects and footwear".

		TRANSITIONAL ARRANGEMENTS	
SUBSTANCE	**Nº CAS**	***LATEST APPLICATION DATE**	****SUNSET DATE**
5-tert-butyl-2,4,6-trinitro- m-xylene (Musk xylene)	81-15-2	21 February 2013	21 August 2013
4,4'-Diaminodiphenylmethane (MDA)	101-77-9	21 February 2013	21 August 2013
1,2,3-trichloropropane	96-18-4		Solvent in rubbers
Hexabromocyclododecane (HBCDD)	3194-55-6 25637-99-4 134237-50-6 - alpha 134237-51-7 - beta 134237-52-8 - gamma	21 February 2014	21 August 2015
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	21 August 2013	21 February 2015
Benzyl butyl phthalate (BBP)	85-68-7	21 August 2013	21 February 2015
Dibutyl phthalate (DBP)	84-74-2	21 August 2013	21 February 2015
Diisobutyl phthalate (DIBP)	84-69-5	21 August 2013	21 February 2015
Diarsenic trioxide	1327-53-3	21 November 2013	21 May 2015
Diarsenic pentaoxide	1303-28-2	21 November 2013	21 May 2015
Lead chromate	7758-97-6	21 November 2013	21 May 2015
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1344-37-2	21 November 2013	21 May 2015
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	12656-85-8	21 November 2013	21 May 2015

		TRANSITIONAL ARRANGEMENTS	
SUBSTANCE	Nº CAS	*LATEST APPLICATION DATE	**SUNSET DATE
Tris (2-chloroethyl) phosphate (TCEP)	115-96-8	21 February 2014	21 August 2015
2,4-Dinitrotoluene (2,4-DNT)	121-14-2	21 February 2014	21 August 2015
Trichloroethylene	79-01-6	21 October 2014	21 April 2016
Chromium trioxide	1333-82-0	21 March 2016	21 September 2017
Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	Chromic acid, CAS: 7738-94-5 Dichromic acid, CAS: 13530-68-2 Oligomers of chromic acid and dichromic acid, CAS: not yet assigned	21 March 2016	21 September 2017
Sodium dichromate	7789-12-0 10588-01-9	21 March 2016	21 September 2017
Potassium dichromate	7778-50-9	21 March 2016	21 September 2017
Ammonium dichromate	7789-09-5	21 March 2016	21 September 2017
Potassium chromate	7789-00-6	21 March 2016	21 September 2017
Sodium chromate	7775-11-3	21 March 2016	21 September 2017
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	25214-70-4	21 February 2016	21 August 2017
Arsenic acid	7778-39-4	21 February 2016	21 August 2017
Bis(2-methoxyethyl) ether (diglyme)	111-96-6	21 February 2016	21 August 2017
1,2- dichloroethane (EDC)	107-06-2	22 May 2016	22 November 2017
2,2'-dichloro-4,4'- methylenedianiline (MOCA)	101-14-4	22 May 2016	22 November 2017
Dichromium tris(chromate)	24613-89-6	22 July 2017	22 January 2019
Strontium chromate	7789-06-2	22 July 2017	22 January 2019
Potassium hydroxyoctaoxodizincatedichromate	11103-86-9	22 July 2017	22 January 2019
Pentazinc chromate octahydroxide	49663-84-5	22 July 2017	22 January 2019

*Latest application date: Deadline for requesting Authorisation.

**Sunset date: Date after which the substance cannot be used without Authorisation for Use being granted.

5.3. Restricted Substances (REACH Annex XVII)

Substances subject to restrictions are listed in Annex XVII of the REACH Regulation. The restrictions can be in respect of the conditions of manufacture, use and marketing. This means that all manufacturers, importers, distributors, sellers and end users must comply with them. The competent authorities of the Member States shall be responsible for complying with the restriction.

Below are details of some of the Restricted Substances under the REACH Regulation. Hazardous substances that can affect footwear and its components.

Annex XVII. Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

NUMBER OF INPUT	SUBSTANCE, GROUP OF SUBSTANCES OR MIXTURE	CONDITIONS OF RESTRICTION
4	Tris (2,3 dibromopropyl) phosphate	FLAME RETARDANTS Tris (2,3 dibromopropyl) phosphate (TRIS), Tris(aziridinyl)phosphinoxide (TEPA) and Polybromobiphenyl (PBB): Shall not be placed on the market, or used, in textile articles intended to come into contact with the skin.
7	Tris(aziridinyl)phosphinoxide	
8	Polybromobiphenyls; Polybrominatedbiphenyls (PBB)	
18	Mercury compounds	Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture. Shall neither be used in the treatment of industrial waters, irrespective of their use.
20	Organostannic compounds	Tri-substituted organostannic compounds: Tributyltin (TBT) compounds and Triphenyltin (TPT) compounds shall not be used in articles where the concentration in the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin. Dibutyltin (DBT) compounds shall not be used in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin. Dioctyltin (DOT) compounds shall not be used in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin.
22	Pentachlorophenol	Shall not be placed on the market, or used, as a substance, as a constituent in other substances, or in mixtures, in a concentration equal to or greater than 0.1 % by weight (1.000 mg/kg).

NUMBER OF INPUT	SUBSTANCE, GROUP OF SUBSTANCES OR MIXTURE	CONDITIONS OF RESTRICTION
23	Cadmium and its compounds	Shall not be used in mixtures and articles produced from the following synthetic organic polymers (hereafter referred to as plastic material): polymers or copolymers of vinyl chloride (PVC), polyurethane (PUR), low-density polyethylene (LDPE), with the exception of low-density polyethylene used for the production of coloured masterbatch, cellulose acetate (CA), cellulose acetate butyrate (CAB), epoxy resins, melamine-formaldehyde (MF) resins, urea-formaldehyde (UF) resins, unsaturated polyesters (UP), polyethylene terephthalate (PET), polybutylene terephthalate (PBT), transparent/general-purpose polystyrene, acrylonitrile methylmethacrylate (AMMA), cross-linked polyethylene (VPE), high-impact polystyrene, polypropylene (PP). Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight (100 mg/kg) of the plastic material. Mixtures and articles produced from plastic material shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.01 % by weight (100 mg/kg) of the plastic material. However, this limit shall not apply to mixtures produced from PVC waste (recovered PVC). Painted articles shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.1 % by weight (1.000 mg/kg) of the paint on the painted article. Shall not be used or placed on the market if the cadmium concentration is equal to or greater than 0.01 % by weight (100 mg/kg) of the metal in metal parts of jewellery and imitation jewellery articles.
27	Nickel and its compounds	Nickel and its compounds shall not be placed on the market or used in articles (such as rivet buttons, tighteners, rivets, zippers and metal marks) intended to come into direct and prolonged contact with the skin if the rate of nickel release is greater than 0.5 µg/cm2/week. It shall neither be placed on the market or used in articles where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release will not exceed the indicated limit for a period of at least two years of normal use of the article.
41	Hexachloroethane	Shall not be placed on the market, or used, as substance or in mixtures, where the substance or mixture is intended for the manufacturing or processing of non-ferrous metals.

NUMBER OF INPUT	SUBSTANCE, GROUP OF SUBSTANCES OR MIXTURE	CONDITIONS OF RESTRICTION
43	Azocolourants and Azodyes	Azodyes that may release one or more of the aromatic amines listed below shall not be placed on the market, or used, in textile and leather articles, in concentrations greater than 30 mg/kg, which may come into direct and prolonged contact with the human skin or oral cavity. 1. Biphenyl-4-ilamine 2. Benzidine 3. 4-Chloro-o-toluidine 4. 2-Naphthylamine 5. o-amino azotoluene 6. 5-Nitro-o-toluidine 7. 4-Chloroaniline 8. 4-Methyl-m-phenylenediamine 9. 4,4'-Methilenedianiline 10. 3,3'-Dichlorobenzidine 11. 3,3'-Dimethoxybenzidine 12. 3,3'-Dimethylbenzidine 13. 4,4'-Methylenedi-o-toluidine 14. 6-Methoxy-m-toluidine 15. 4,4'-Methylene-bis-(2-chloroaniline) 16. 4,4'-Oxydianiline 17. 4,4'-Thiodianiline 18. o-Toluidine 19. 4-Methoxy-m-phenylenediamine 20. 2,4,5-Trimethylaniline 21. o-Anisidine 22. 4-Aminoazobenzene "Blue dye": shall not be placed on the market, or used, as a substance, or in mixtures in concentrations greater than 0.1 % by weight (1.000 mg/kg), where the substance or the mixture is intended for colouring textile and leather articles.
45	Diphenylether, octabromo derivative	Diphenylether, octabromo derivative (octaBDE): Shall not be placed on the market, or used, as a substance or as a constituent of other substances, or in mixtures, in concentrations greater than 0.1 % by weight (1.000 mg/kg). Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than the indicated amount.
46	Nonylphenol and nonylphenol ethoxylates	Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0.1% by weight (1.000mg/kg) textiles and leather processing, except processing with no release into waste water, systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin).
47	Chromium VI compounds	Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations equal to or higher than 3 mg/kg chromium VI of the total dry weight of the leather.
50	Polycyclic-aromatic hydrocarbons (PAH)	Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity contain more than 1 mg/kg of any of the following PAHs: benzo[a]pyrene, benzo[e]pyrene, benzo[a]anthracene, chrysen, benzo[b]fluoranthene, benzo[j] fluoranthene, benzo[k]fluoranthene and dibenzo[a,h]anthracene. Similarly, toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components contain more than 0.5 mg/kg of any of the above-listed PAHs. (*) ** Although strictly speaking, in the definition of childcare products infant's shoes are not specified (sizes 16-22), manufacturers should take into account that these shoes are susceptible of being placed in the mouth by babies.*

NUMBER OF INPUT	SUBSTANCE, GROUP OF SUBSTANCES OR MIXTURE	CONDITIONS OF RESTRICTION
51, 52	Phthalates	a. Bis(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP). These shall not be used as substances or in mixtures, in concentrations greater than 0.1 % by weight (1.000 mg/kg) of the plasticised material, in toys and childcare articles. Such articles shall not be placed on the market. b. Also, in toys and childcare articles which can be placed in the mouth by children the following phthalates shall be limited: Di-isononyl phthalate (DINP), Di-isodecyl phthalate (DIDP) and Di-n-octyl phthalate (DNOP). These phthalates shall not be used as substances or in mixtures in concentrations greater than that indicated, and such articles containing these phthalates in a concentration greater than that indicated shall not be placed on the market. * The sum of the three phthalates, both of paragraph (a) and (b), shall not exceed the limit value of 0.1% (1.000 mg/kg). *** Although strictly speaking, in the definition of childcare products infant's shoes are not specified (sizes 16-22), manufacturers should take into account that these shoes are susceptible of being placed in the mouth by babies.*
60	Acrylamide	Shall not be placed on the market or used as a substance or constituent of mixtures in a concentration, equal to or greater than 0.1 % by weight (1.000 mg/kg) for grouting applications.
61	Dimethylfumarate (DMF)	Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg. Articles or any parts thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market.
16, 17 and 63	Lead and its compounds	a. Lead carbonates and Lead sulphates shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. b. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight.

6. REACH´s effect on companies

The REACH Regulation affects companies in the footwear sector. Specifically, footwear manufacturers, producers of components, tanneries, manufacturers of substances and chemical mixtures. That is to say, what is known in general as the "supply chain".

6.1. Role and obligations of company in the supply chain

In the supply chain for the footwear sector there are a number of participants identified according to the activity engaged in and the position they occupy in the chain, as can be seen in the following illustration:

F3. Supply chain in the footwear sector

Manufacturer of substances.

An individual or company established in the European Community which manufactures a substance in the Community, for example, solvents, fillers, tanning substances, etc.

These companies must register the substances manufactured in quantities of 1 tonne or more per year for that specific use. See subsection 3 of the unit, Registration, for knowing which processes are to be taken into consideration.

Furthermore, they must indicate the possible uses and registration number of each substance in the safety data sheets.

Importer of substances.

An individual or company established in the European Community and responsible for importing of the substance. These companies must register the substances imported in quantities of 1 tonne or more per year for that specific use. See subsection 3 of the unit, Registration, which processes are to be taken into consideration.

Furthermore, they must indicate the possible uses and registration number of each substance in the safety data sheets.

Manufacturer of preparations.

Companies that are manufacturers of preparations such as adhesives, finishes for leathers and terminations for footwear, etc., act as "Downstream users". The downstream user is an individual or company established in the European Community, other than the manufacturer or importer of substances, which uses a substance, as such or in the form of a preparation, in the course of their industrial or professional activities.

Downstream users must provide information on their uses **to the suppliers of substances.** This enables Registrants to include these uses in the assessment of the chemical safety of the substances.

When a downstream user receives a Safety Data Sheet (SDS) from its substance supplier, it must identify, through the safety data sheets or on the ECHA web site, whether the substances it uses are registered for the use given to them and ask for the appropriate measures for adequately controlling the risks in their company. This must take place within 12 months from the date of receiving the safety data sheet (SDS) of a registered substance.

In the event that the substances are not registered for specific uses of interest to a company, it may choose to adopt any of the following actions:

- Reformulate the preparations in question using other substances that are registered for the use required,
- Use substances in accordance with the uses for which they have been registered,
- Contact another supplier to include their use in the Registration of the substance,
- Directly communicate the use to the European Chemicals Agency (ECHA) with the company having to prepare its own Chemical Safety Report (CSR).

In order to prepare the CSR it must consider the whole life cycle of the substance, both for its own use and for the uses identified in the subsequent stages of the supply chain, taking into account the information provided by the chemical supplier (with the work involved in preparing information and the costs generated by this process).

This Chemical Safety Report will not need to be prepared when:

- A safety data sheet is not necessary
- It is not necessary for the Registrant to fill out a report on chemical safety
- The substance is present in a mixture in a concentration less than 1 tonne per year and therefore does not require a chemical safety report
- The downstream user uses the substance or mixture in a total quantity of less than one tonne per year
- The downstream user uses the substance for product and process oriented research and development (PPORD)

The CSR (DU) must be completed within twelve months from receiving the safety data sheet for a registered substance. Downstream users must inform the ECHA that they intend to prepare a chemical safety report within six months. However, it is not necessary to submit the CSR (DU) to the ECHA.

Furthermore, manufacturers of preparations who supply agents further down the supply chain with their chemical mixtures, for example, adhesives, dyes, finishing products, etc. must provide **their customers** with suitable information on the risks and conditions for the safe use of their mixture.

More specifically, those companies must ensure that their mixtures do not contain any substance on the list of restricted substances (substances in Annex XVII of the REACH) in excess of the maximum limit.

They must also check whether any substance is used in their mixtures that is subject to authorisation (substances in Annex XIV of the REACH). If so, they should apply to the Agency European of Chemicals (ECHA) for authorisation for that specific use.

They should inform their customers, through the safety data sheets, if the preparations contain any substance of very high concern (SVHC).

Furthermore, as a downstream user, they might have other roles such as those listed below:

Re-fillers: they transfer substances or chemical mixtures from one container to another, generally in the course of repackaging or changing a brand image.

Reimporters: they import substances, as such or in the form of a mixture, that were originally produced in the EU and registered by another agent belonging to the same supply chain.

Importer of preparations.

The importer of preparations is an individual or company established in the European Community and responsible for importing the preparation.

These companies must register each of the substances of which the preparation is composed if the amount of each substance imported per year in the preparations exceeds 1 tonne. See subsection 3 of the unit, Registration, for know which processes are to be taken into consideration.

Furthermore, they shall inform their customers of the registration number of each substance in the safety data sheet.

They shall also ensure that their preparations do not contain any of the substances included in the Restricted Substances List (substances in Annex XVII of the REACH) in concentrations above the maximum limit allowed.

They shall verify if their preparations contain any of the substances included in the List of Substances Subject to Authorisation. If so, they shall ask the ECHA for authorisation for that specific use.

They shall inform their customers about the presence of a Substance of Very High Concern in their preparations through the safety data sheets.

They shall verify, in the safety data sheets or in the ECHA's website, if the substances they use are registered for the intended use.

When the importers of preparations have a «sole representative» then they will be considered as downstream users because their non European Union supplier has appointed a «sole representative» to act as the Registrant established in the Community.

Producer of components

Manufacturers of components are downstream users who use substances or chemical mixtures to manufacture an article. In this case it is not a finished article such as footwear, for example, but a component that forms part of the final product.

The manufacturer of components have the obligation of registration of substances, only those that are intended to be released under normal or reasonably foreseeable conditions of use, present in articles in quantities of more than 1t/Yr.

Manufacturers of components shall ensure that their components do not contain any of the substances included in the Restricted Substances List (substances of the Annex XVII of the REACH) in concentrations above the maximum limit allowed.

They shall verify if their components contain any of the substances included in the List of Substances Subject to Authorisation (substances in Annex XIV of the REACH). If so they should ask their supplier of substances or mixtures if they have applied to the ECHA for authorisation for that specific use and if they have not done so, the manufacturer of components, as a user of that substance, must apply for it.

They need to inform their customers if a Substance of Very High Concern is present in their components in concentrations above 0.1% by weight.

Furthermore, they should verify, in the safety data sheets or on the ECHA's website, if the substances they use are registered for the intended use.

If the components contain Substances of Very High Concern their manufacturers must notify the ECHA if the following three conditions are present simultaneously:

- The substance is present in the component above a concentration of 0.1% by weight.
- The total amount of the substance used or imported exceeds 1 tonne/year.
- The substance has not yet been registered for that specific use

The notification of information must include the following data:

- the identity and contact details of the manufacturer or importer of the articles,
- the registration number of the substance, if he has it,
- the identity of the SVHC,
- the classification of the substance,
- a brief description of the uses of the substance present in the articles and of the uses of the articles,
- the tonnage band of the substance contained in the articles, that is to say, 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or ≥ 1000 tonnes.

Importer of components

The importer of components is an individual or company established in the European Community and responsible for their importation.

The importer of components, the same as for the manufacturer, is obliged to register substances, only those that are intended to be released under normal or reasonably foreseeable conditions of use, present in articles in quantities of more than 1t/Yr.

Importers of components must ensure that the articles they import do not contain any of the restricted substances (substances in Annex XVII of the REACH) above the limit permitted.

They need to inform their customers if the components include any substance of very high concern in a concentration higher than 0.1% in weight.

If the components contain Substances of Very High Concern their importers must notify the ECHA if the following three conditions are present simultaneously:

- The substance is present in the component above a concentration of 0.1% by weight.
- The total amount of the substance used or imported exceeds 1 tonne/year.
- The substance has not yet been registered for that specific use.

Manufacturers or importers of finished goods

The principal function for manufacturers of finished products such as footwear and leather goods (handbags, belts, etc.) is to assemble pieces or components. During the assembly, manufacture and finishing of the articles they use substances or chemical mixtures, for example, adhesives, solvents, etc.

Therefore, these companies should ask their suppliers for information in order to check if the preparations and components they use contain any substance of very high concern.

Furthermore, they should check whether any substance subject to authorisation is used in the manufacture of their articles.

They should also ensure that their components do not contain any of the restricted substances above the maximum limit permitted.

6.2. Communication in the supply chain in the footwear sector

The main tool for transferring the information will be the Safety Data Sheet (SDS). The SDS have to be expanded with an Information annex containing a summary of the Chemical Safety Report (CSR, a new document introduced by REACH and that will be prepared by the suppliers of chemical substances for each one if they manufacture or import them in quantities greater than 10 T/year).

The major issue for these "article suppliers" is how to determine whether any of the Candidate List SVHCs are present in their products and at what level. This task is made more difficult by the continuous extension of the Candidate List. SVHCs have been shown to be contained in a range of consumer products, including shoes but manufacturers and retailers are not always aware of their presence.

In general, there in an obligation to pass on information on these substances if they are contained in the articles. All suppliers of an article that contains any substance included in the list of candidates for Authorisation in a concentration higher than 0.1% in weight, must provide their customers or any consumer who asks, with information to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 calendar days of receipt of the request
With regard to the obligations of communicating information on the substances contained in articles in general (i.e. communication with receivers and consumers), the following must be noted:

- This obligation does not depend on the tonnage (i.e. it is also applicable for quantities less than 1 t/yr).
- The packaging is always considered as an article separate from its content. Therefore, the obligations of providing information on the substances contained in articles are equally applicable to the packaging materials.
- The maximum 0.1% (w/w) concentration limit of a substance is applied to the article as it is supplied. In practice, however, companies may have the information already compiled not only for the complete article but also for the parts thereof. They may, voluntarily, follow this procedure when making any notifications.
- The obligation continues in the case of articles produced or imported before the substance was included on the list of candidate substances but supplied after being included. Consequently, the pertinent detail is the date when the article was supplied.
- The substance name to be provided is the one appearing on the list of candidate substances requiring authorisation.

6.3. Letters for communication in the supply chain for the footwear sector

In the Spanish Technological Institute for Footwear (INESCOP), several standard letters have been drafted to help establish communication in the supply chain for the footwear sector, both with suppliers and customers, with regard to the substances regulated under the REACH Regulation. Below are some draft letters:

Standard letter for communicating with chemical suppliers:

Factory
C/ address nº xx
xxxxx – town
PROVINCE

Place, date XX-XX-XXXX

Dear Sirs,

We are writing to you, as one of our suppliers, with regard to Regulation (EC) No. 1907/2006 relating to the Register, Evaluation, Authorisation and Restriction of Chemicals (hereafter, REACH Regulation). Please complete the relevant section below and return this letter to us, duly signed and stamped, in order to certify in writing that chemicals that you supply to our company:

1. They are prepared with substances that are pre-registered or registered for the appropriate use .
2. Do not contain Restricted Substances (REACH Annex XVII Regulation) above the maximum content allowed.
3. They do not contain Substances Subject to Authorisation (Annex XIV of the REACH Regulation).
4. Do not contain substances included in the List of very high concern substances candidate for eventual inclusion in Annex XIV.

   In case your articles contain any of the substances included in the List of very high concern substances, please inform us in writing about the substance name and if this is present in a concentration higher than 0.1% by weight.

Annexes XIV and XVII of REACH Regulation can be found in the following link:
http://echa.Europe.eu/eu/regulations/reach/legislation (consolidated version).

The List of very high concern substances can be found in the following link:
http://echa.Europe.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Yours faithfully,

[signature and stamp of the sender]

(to be filled in by the supplier)

Our company ……..……., VAT No. ..……., having the registered office in ……., hereby certifies that the products supplied by us comply with the two points mentioned above.

Signature & Stamp of supplier

Standard letter for communicating with suppliers of articles:

Factory
C/ address nº xx
xxxxx – town
PROVINCE

Place, date XX-XX-XXXX

Dear Sirs,

We are writing to you, as one of our suppliers, with regard to Regulation (EC) No. 1907/2006 relating to the Register, Evaluation, Authorisation and Restriction of Chemicals (hereafter, REACH Regulation). Please complete the relevant section below and return this letter to us, duly signed and stamped, in order to certify in writing that the articles that you supply to our company:

1. Do not contain Restricted Substances (REACH Annex XVII Regulation) above the maximum content allowed.
2. Do not contain substances included in the List of very high concern substances candidate for eventual inclusion in Annex XIV.

   In case your articles contain any of the substances included in the List of very high concern substances, please inform us in writing about the substance name and if this is present in a concentration higher than 0.1% by weight.

REACH Annex XVII Regulation can be found in the following link:
http://echa.Europe.eu/eu/regulations/reach/legislation (consolidated version).

The List of very high concern substances can be found in the following link:
http://echa.Europe.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Yours faithfully,

[signature and stamp of the sender]

(to be filled in by the supplier)

Our company ……..……, VAT No. ..……, having the registered office in ……, hereby certifies that the products supplied by us comply with the two points mentioned above.

Signature & Stamp of supplier

Standard letter for communicating with suppliers of articles:

Factory
C/ address nº xx
xxxxx – town
PROVINCE

Place, date XX-XX-XXXX

Dear Sirs,

In accordance with Regulation (EC) No. 1907/2006 relating to the Register, Evaluation, Authorisation and Restriction of Chemicals (hereafter, REACH Regulation), we would like to hereby inform you that our articles comply with the obligations set out in REACH Regulation.

Based on the information provided by our suppliers and the completion of the relevant tests, our products:

1. Do not contain restricted substances (REACH Regulation, Annex XVII) above the maximum content allowed.

(Select the point 2 that applies)

2. Do not contain substances included in the List of very high concern substances that are candidate for eventual inclusion in Annex XIV, in a concentration above 0.1 % by weight.

3. Do contain some of the substances included in the List of Substances of Very High Concern that are candidates for inclusion in Annex XIV, in concentrations higher than 0.1 % in weight, specifically:

   - **(xx %), substance name and CAS nº**
   - **(xx %), substance name and CAS nº**

Due to all the above, our company ……..., VAT No. ……, having its registered office in ……...……., hereby declares that the articles that we supply are in compliance with the three points mentioned above.

In witness whereof, this certificate is issued in XXXXXXX, on XX of XX of XXXX.

Yours faithfully,

Signature & Stamp of supplier

7. REACH for non-EU companies

In the supply chain of the footwear sector, we must also consider the use of substances originating from outside the EU. Depending on the way in which these substances, preparations or articles are introduced into the Community, they must comply with one set of requirements or another. These obligations depend on the way in which the products are introduced, that's to say whether it is done through an only representative or whether it is done through an importer.

If an **only representative** is chosen, there will be more control over the information to be given about the substances or preparations. For better confidentiality, it is better to choose an only representative.

If the choice is made to place the products on the market through **importers**, the information about the substances or preparations must be given to each importer that buys them.

The main obligations of importer of substances or preparations are:

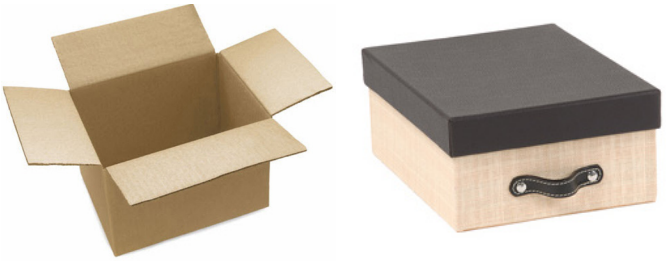
- Carry out the registration of substances. See subsection 3 of the unit.
- Share the information about conditions of use and properties of the substance.
- Prepare a technical dossier.
- Prepare a chemical safety report if the volume is more than 10t/Yr.
- Prepare the exposure scenarios for the hazardous substance if the volume ≥ 10t/Yr.
- Implement risk management measures for both the production and the use of the substance.

ATTENTION, it is important consider the following: If a non-Community manufacturer of **preparations** uses substances that are already registered in the EU, they do not need to be registered again upon introduction of the preparation into the EU; therefore, there is no need to appoint an only representative, or give information to the importers. The only thing that needs to be done is show proof that the substances are registered.

It must be noted that **substances restricted** in the EU cannot be used or placed into the market unless the conditions set forth in the restriction are met. These substances can be seen in Annex XVII of the REACH Regulation. The non-Community manufacturers, importers and manufacturers wishing to place their products in the EU market must also follow the instructions in REACH Annex XVII. This annex details the limitations on the placing on the market and use of certain hazardous substances and preparations. This annex was amended and updated by Regulation (EC) No. 552/2009. Information about the restrictions on substances can be found at the following section of the ECHA website:http://echa.Europe.eu/eu/web/guest/addressing-chemicals-of-concern/restriction

If non-Community manufacturers wish to introduce **articles** into the EU, it is advised that they have information about whether the articles contain any substance of very high concern (SVHC), (the substance name in question must be mentioned if in concentrations of more than 0.1% by weight in the article). Also, they must ensure that the product does not contain any restricted substance.

Packaging and containers: The obligation of providing information about substances of very high concern also applies to packaging materials. These materials are treated as a separate "article". In this context, when introducing a new product into the EU market, you must also consider the packaging materials and give information on the possible SVHC content of these and ensure that they don't contain any EU restricted products.



Information must be exchanged between the non European Union manufacturers and the European importers or downstream users on the chemical substances that they manufacture or use when producing preparations or articles.

What happens if there is no communications between suppliers and buyers about the substances contained in articles? The manufacturer, importer of articles (intermediate or finished) or non-Community exporter must carry out chemical analyses in order to determine the possible presence of SVHCs and restricted substances in articles, assuming the high economic cost it could involve.

F4. Test for the determination of lead.

8. Enforcement. Inspection bodies

Enforcement of REACH means, generally, a range of actions that national authorities initiate to verify the compliance of the duty holders with REACH Regulation. For example, this includes checking whether the substance has been registered or pre-registered or verifying the presence and correctness of the Safety Data Sheets.

Enforcement of REACH and is a national responsibility, therefore each EU Member State, Norway, Iceland and Liechtenstein must ensure that there is an official system of controls and lay down legislation specifying penalties for non-compliance with the provisions of REACH.

ECHA has no enforcement responsibilities, since it is a Community-level institution. However, ECHA does host the Forum for Exchange for Information on Enforcement (Forum). The Forum is a body composed of representative of national enforcement authorities, which works towards coordinating the enforcement of REACH in the EU Member States, Norway, Iceland and Liechtenstein.

The Forum for Exchange of Information relating to compliance with legislation (Forum), in accordance with Regulation (EC) 1907/2006, coordinates a network of authorities from the Member States responsible for complying with them, and they have the following functions:

- to broadcast good practice and reveal the problems that are brought up at community level;
- to propose, coordinate and evaluate projects of harmonisation in compliance with legislation and joint inspections;
- to coordinate the exchange of inspectors;
- to identify the strategies for complying with legislation, and also the best practices in terms of compliance;
- to develop useful working methods and instruments for local inspectors;
- to develop an electronic information exchange procedure;
- to act as a link with the industry, taking particularly into consideration the specific needs of SMEs and other interested parties, including the pertinent international organisations, where necessary;
- to examine proposals for restrictions in order to assess whether they are applicable;
- to agree on the common issues that have to be included in the annual reports of the Member States in relation to the application.

The Forum is composed of members designated by the Member States. Each Member State shall appoint a member in the Forum; they shall be chosen for their experience in enforcement of chemicals legislation and shall maintain relevant contacts with the competent authorities of the Member States. A maximum of five additional members chosen on the basis of their specific competence.

The Forum shall designate its President. The members of the Forum shall be appointed for a period of three years, which shall be renewable . When appropriate, interested parties may also be invited to attend meetings, as observers, at the request of the members of the Committee or of the Management Board. The Forum may set up working groups.

National inspectorates of some European Union countries.

Spain

As defined in the Spanish Sanctions Regime Law the responsibility for REACH enforcement in Spain lies with the regional authorities (Autonomous Communities). Each of them has its own legal arrangements to organise enforcement.

At the central level there are two Competent Authorities for REACH responsible for two aspects of implementing REACH - protection of the environment and of human health. These two authorities help in the coordination of all Spanish Enforcement Authorities.

The Ministry of Environment and Rural and Marine Affairs coordinates the work of the Environmental Inspections by running a technical coordination group allowing the regional inspections to exchange information, knowledge and experiences.

The Ministry of Health and Social Politics coordinates the public health authorities of the regions through a public health inspectors' coordination group. It has established a Rapid System on Information Exchange on Chemicals (SIRIPQ) which allows regional public health inspectors to exchange information on cases of non-compliance.

The REACH Enforcement Authorities (EA) in Spain are the 17 Autonomous Communities but to facilitate and centralise communication with the relevant EA, we provide below the links to the two central REACH Competent Authorities:

- The Ministry of Environment and Rural and Marine Affairs - REACH Competent Authority responsible for the coordination of environmental related Spanish enforcement authorities
- The Ministry of Health, Social Politics and Equality - REACH Competent Authority responsible for the coordination of human health related Spanish enforcement authorities

Portugal

The responsibility for controlling compliance with REACH in Portugal is given to the following authorities:

- the General Inspectorate for Agriculture, the Sea, the Environment and Spatial Planning (IGAMAOT) focusing on manufacturers and formulators,
- the Authority for the Economy and Food Safety (ASAE) focusing on distributors, wholesalers and retailers, and
- the Tax and Customs Authority, (AT) focusing on importers.

In general all the infringements of REACH are classified as serious or very serious environmental administrative offences.

Where the gravity of the infringement so justifies, the competent authority, in addition to the fine, may decide to impose additional penalties as deemed appropriate. The competent authority may also, where necessary, order the provisional seizure of assets and documents.

Authorities responsible for REACH enforcement:

- General Inspectorate for Agriculture, the Sea, the Environment and Spatial Planning (IGAMAOT) - Focuses on manufacturers and formulators.
- Tax and Customs Authority (AT) (AT) - Focuses on importers.
- Authority for the Economy and Food Safety (ASAE) - Focuses on distributors, wholesalers and retailers.

Germany

In Germany the competent authority for REACH and CLP is the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BauA). It is the general focal point to the European Commission on both regulations. The BAuA is also responsible for risk management and operates the national REACH/CLP Helpdesk.

As Germany is a federal republic, enforcement is under the sole responsibility of the individual federal states (Länder). The BAuA provides legal support, informational services (such as training events, brochures, guidelines, etc.) and contact to other European authorities.

The regional enforcement authorities of the Länder conduct regular inspections on companies and products on the German market. They also run focused enforcement projects and check up on reasonably suspicious cases. They also check up on imports in cooperation with national customs authorities.

The above mentioned authorities meet regularly in various working groups and committees in order to solve common issues and to ensure harmonised REACH and CLP enforcement.

Authorities responsible for REACH and enforcement:

- Federal Institute for Occupational Safety and Health - Division for Chemicals and Biocides Regulation.
- Various regional enforcement authorities - Follow the link to the ICSMS search engine for contact details.

Italy

The Italian Competent Authority for REACH is the Ministry of Health, DG Health Prevention as established with Parliament law n. 46 of 2007. Moreover, national Inter- Ministerial Decree 22 November 2007, O.J. n.12 of 15 January 2008 establishes the cooperation between Competent Authority and other administrations (Ministry of Environment, Ministry of Economic Development, National Institute of Health, National Institute for Environmental Protection and Research and Regions).

The Permanent Conference "State-Regions" Agreement of 29 October 2009 concerning "The system of official controls and related guidelines for the enforcement of REACH Regulation" establishes the Ministry of Health, DG Health Prevention is the Italian REACH Enforcing Authority and is responsible for controls to be conducted by a central pool of inspectors. The cooperation with of other bodies such as police task forces and border authorities is foreseen. At local level, surveillance plans will involve the 21 regional enforcing authorities who act trough existing territorial units represented by Local Health Boards (ASL) and Regional Environmental Agencies (ARPA). The coordinated system of cooperation between centre and periphery will allow a homogeneous control management.

The first controls were performed by the central inspectors, started in 2010 and will continue in 2011. At present controls are mainly focused on the pre-registration requirements and SDS.

Authorities responsible for REACH enforcement:

- Ministry of Health - The Italian REACH Competent Authority's is also responsible for REACH enforcement.

Romania

The system of Competent Authorities for REACH Regulation in Romania is represented by:

- The Ministry of the Environment (MM) – as coordinating authority
- The National Environment Protection Agency (NEPA) – for REACH implementation;
- The National Environmental Guard (NEG) – for REACH enforcement.

For the REACH enforcement activity of NEG, there are protocols of collaboration with other national enforcement authorities:

- State Sanitary Inspection;
- National Labour Inspection;
- National Customs Authority
- National Authority for Consumer Protection
- General Police Inspectorate

NEG also participates in European enforcement networks for chemicals (CLEEN) and for the environment (IMPEL).

Authorities responsible for REACH enforcement:

- The National Environmental Guard - The authority is responsible for the enforcement of duties relating to registration, authorization, restrictions and exchange of information.

Czech Republic

The Czech Ministry of the Environment is a competent authority for the REACH Regulation. REACH enforcement in the Czech Republic is guaranteed by several national institutions such as the Czech Environmental Inspection, Czech Customs Administration and Regional Public Health Authorities. The enforcement authorities inspect all legal and natural persons having obligations under REACH. Authorities responsible for REACH enforcement:

- The Czech Environmental Inspectorate - Controls duties of manufacturers, importers, downstream users and distributors.
- Customs Administration - Focuses on safety data sheets.
- Regional Public Health Authorities - Controls duties of manufacturers, importers, downstream users and distributors concerning substances in articles in contact with water and food, in toys and in cosmetic products.

Slovenia

The responsibility for enforcement of REACH in Slovenia is placed within chemicals Office of the Republic of Slovenian (CORS) which is a constituent body within the Ministry of Health. The responsibility for REACH Regulation was enacted in the Official Gazette of the Republic of Slovenia, No. 23/2008.

Authorities responsible for REACH enforcement:

- Ministry of Health - Chemical Office of the Republic of Slovenia (CORS)
- Chemical inspectors are responsible for enforcement of Regulation 1907/2006/EC. The Slovenian REACH Helpdesk is under CORS.
- Ministry of Health - Health Inspectorate of the Republic of Slovenia (HIRS)
- HIRS is responsible for inspection of the implementation of Regulation 1907/2006/EC in the section relating to restrictions on production, marketing and use of certain dangerous substances, preparations and products in toys and childcare articles, in accordance with Annex XVII.
- Ministry of Labour, Family and Social Affairs - The Labour Inspectorate of the Republic of Slovenia (LIRS). LIRS conveys inspections of working environment and accessibility of information pursuant to Article 35 and use of substances or preparations in the fifth and sixth paragraph of Article 37 of REACH Regulation.

France

The French Competent Authority is the Ministry in charge of ecology, sustainable development and energy. The French Environmental Code allocates responsibility for REACH enforcement to a number of enforcing authorities, especially environmental inspectorate, labour inspectorate, consumer protection authority or customs. It provides them with the powers they need and sets down the offences and penalties (both administrative and criminal) for contraventions of REACH requirements. An annual inter-ministerial circular organises the work of REACH enforcers. Each REACH enforcement authority works in its own field of competence (e.g. labour inspection on the REACH requirements related to workers). The first controls started in 2009. At present controls are mainly focused on the pre-registration requirements.

Authorities responsible for REACH enforcement:

- Ministry of ecology, sustainable development and energy - The French REACH Competent Authority's website for information on the roles of enforcement authorities and the arrangements for cooperation between them.

9. Practical exercises

9.1. Calculation of the substance volume released in footwear

A child's slipper contains strawberry fragrance that is intended to be released. The fragrance accounts for a maximum of 5% of the weight of the slippers, which is produced in the EU in an amount of 100 t/year. That fragrance is not present in any other article of the same manufacturer. What is the volume of fragrance used by the slipper manufacturer in a year? Does the slipper manufacturer have to register the substance for that specific use?

Either of the following two equations can be used according to the data available:

$Vol_{subst.}=(Weight_{article})x(N^{o}_{articles})x(Conc_{max.mixture\ in\ article})$ x(Concmax.subst.in mixture)
$Vol_{subst.}=(Vol_{article})x(Conc_{max.subst.in\ article})$

$Vol_{subst.}=(Vol_{article})x(Conc_{max.subst.in\ article})$=100 t/a x 0.05= 5 t/a

The tonnage threshold of 1 t/year has been exceeded, so the slipper manufacturer has to register the fragrance for that use as it is a substance intended to be released during use and it exceeds the regulation tonnage.

Considerations for calculating the tonnage of the substance intended to be released:

- Not only the amount intended to be released should be considered but the total amount contained in the article. If the substance is part of the matrix, these quantities must also be taken into consideration.
- Only the amount of actual substance present in the finished products should be considered. Any amount that is incorporated and then lost in subsequent production stages should not be taken into consideration.
- If the same substance is intended to be released in different articles of the same manufacturer/importer, the volumes of the substance of all the articles shall be added together.

9.2. Calculation of SVHC in footwear including different components

A footwear manufacturer uses different leathers for cutting (leather A), lining (leather B) and the insole (leather C) and their total weight is 500g. What is the concentration of SVHC in the whole shoe?

Insole (leather A)= 0.2% of an SVHC and the cut weighs 3g.
Lining (leather B)= 0.5% of the same SVHC and weighs 5g.
Cut (leather C)= 1% of the same SVHC and weighs 10g.

If one or more of the leathers used contain more than 0.1% (w/w) of an SVHC, the manufacturer should ascertain the concentration of SVHC in each leather and the weight of the component by asking the supplier.

He should calculate the weight of the SVHC in each component:

$mSVHC_{component}=m_{component}$ x Conc. $_{SVHC\ in\ component}$ [%] x 0.01

To calculate the average concentration in the shoe and check whether it exceeds 0.1% (w/w).

$Concentration_{SVHC\ in\ shoe}$ [%]=(m $_{SVHC\ leather\ A}$+m $_{SVHC\ leather\ B}$+ m $_{SVHC\ leather}$ C/ (weight total shoe) x 100

The weight of the SVHC in each component:

m $_{SVHC\ A}$ =3 x 0.2 x 0.01= 0.006
m $_{SVHC\ B}$ =5 x 0.5 x 0.01= 0.025
m $_{SVHC\ C}$ =10 x 1 x 0.01= 0.1

The average concentration in the shoe is:

Concentration $_{SVHC\ in\ shoe}$ [%]=(0.006+0.025+0.1/ (500) x 100= 0.026%

If the concentration in the shoe does not exceed 0.1% there will no obligation to communicate anything.

9.3. Calculation of SVHC imported in different articles

Example of an importer of footwear and leather goods.

A company imports 20,000 pairs of shoes, 3,000 belts and 60,000 handbags per year.

- A pair of shoes contains 0.05% (w/w) of an SVHC; weight of the pair of shoes = 700 g
- A belt contains 0.15% (w/w) of the same SVHC; belt weight = 700 g
- A handbag contains 2% (w/w) of the same SVHC; handbag weight = 1,000 g

What is the total volume of SVHC for the articles whose concentration of that substance is greater than 0.1%?

Concentration of substances SVHC in belts and handbags > 0.1 % (w/w)

Vol $_{SVHC}$ (g/year) = [conc.$_{SVHC}$ in art.(%) x 0.01] x [weight art.(g) x 10-6] x [nº art./year]

Tot vol SVHC for each article:

- Belts: Vol$_{SVHC}$ (t/year)= (0.15%x0.01)x(700 g x10-6)x3000 = 0.0032 t $_{SVHC}$/year
- Handbags: Vol$_{SVHC}$ (t/year)= (2%x0.01)x(1000 g x10-6) x60000 = 1.2 t $_{SVHC}$/year

Total sum of the volume for the two articles whose SVHC concentration > 0.1 %

Vol $_{SVHC}$ = (0.0032 + 1,2) t/year = 1.2 t/year > 1 t $_{SVHC}$/year

If the SVHC **is not registered** for the use identified, the importer must **notify the ECHA that** the **handbags** and **belts** contain an SVHC in a concentration > 0.1 %, and also **submit information** both for the **belt and for the handbag** (information that allows the safe, innocuous use of the article, including, as a minimum, the substance name and its CAS number).

10. Relevant guidance documents, manuals and legislation

This subsection of the unit contains links to some guidance documents of interest to the footwear sector that are available on the ECHA web site (http://echa.Europe.eu/eu/guidance-documents/guidance-on-reach). These documents have been drawn up with the participation of many interested parties (industry, Member States and NGO's) as part of projects managed by the European Commission. The objective of these documents is facilitate the application of REACH, describing good practices on how to comply with the obligations.

Guidance on downstream users

http://echa.Europe.eu/documents/10162/13634/du_eu.pdf Guidance on Registration

http://echa.Europe.eu/documents/10162/13632/registration_eu.pdf

Guidance Document for monomers and polymers

http://echa.Europe.eu/documents/10162/13632/polymers_eu.pdf

Guidance on the requirements for substances contained in articles

http://echa.Europe.eu/documents/10162/13632/nutshell_guidance_articles2_eu.pdf

Guidance on the preparation of a request for authorisation

http://echa.Europe.eu/documents/10162/13643/sea_authorisation_eu.pdf

The document titled **Footwear-Footwear industry guideline for substances of very high concern (REACH Annex XIV)** is also of interest. Document FprCEN/TR 16417:2014 drawn up by the European Committee for Standardisation CEN TC 309 "Footwear", in working group 2 of "Environmental aspects and footwear". This contains the substances subject to and candidates for Authorisation and their possible use in footwear or in footwear components.

11. Test of knowledge

Choose the correct option:

Q1. What is a safe product?

- ○ An article with rounded edges
- ○ A product that can be used without causing any harm
- ○ A product sold to the general public

Q2. Who is obliged to inform of the dangers of a product?

- ○ The tradesmen
- ○ The business owners
- ○ The buyers

Q3. What is the RAPEX?

- ○ The Product Safety Agency
- ○ The Customs Exporting Register
- ○ The Rapid Alert System for dangerous non-food products

Q4. What is the general REACH process?

- ○ Registration, Evaluation and Certification
- ○ Registration, Analysis of substances and Harmonisation.
- ○ Registration, Evaluation, Authorisation and Restriction of Chemicals

Q5. The REACH Regulation:

- ○ Attributes the industry with the responsibility of managing the risks associated with chemicals
- ○ Attributes the Member States with the responsibility of managing the risks associated with chemicals
- ○ Attributes the laboratories with responsibility of managing the risks associated with chemicals

Q6. Registration is compulsory

- ○ for all substances manufactured or imported in the European Union in quantities of one tonne or more per year
- ○ for all substances manufactured or imported in the European Union in quantities of 10 tonnes or more per year
- ○ for all substances manufactured or imported in the European Union in articles

Q7.	**Who should assess the registration dossiers?**

- ○ The manufacturers and importers of substances
- ○ The sole representatives
- ○ The ECHA

Q8.	**Authorisation is a procedure intended for:**

- ○ Substances under Annex XVII
- ○ Substances on the list of substances very high concern
- ○ Substances under Annex XIV

Q9.	**Restrictions:**

- ○ Only restrict the marketing of a substance
- ○ Do not apply to imports
- ○ Apply to any specific substance, in a mixture or in an article

Q10.	**What is an article?**

- ○ An adhesive
- ○ A handbag
- ○ The pigments

Q11.	**What is a sole representative?**

- ○ Someone from Tunisia
- ○ An individual or company established in the EU representing a non-EC manufacturer of substances or mixtures
- ○ An individual or company established in the EU trading exclusive products

Q12.	**The list of candidate substances for Authorisation:**

- ○ Is published on the ECHA web site
- ○ Is published in Annex XIV of the Regulation
- ○ Is published in Annex XVII of the Regulation

Q13.	**If any of the substances on the list of SVHC is present in an article, the supplier must provide the receiver of the article with sufficient information to ensure safe use when:**

- ○ It is present in quantities higher than 0.01%
- ○ It is present in quantities of 0.1% or more
- ○ It is present in quantities of 1% of more

Q14. When a substance is in Annex XIV:

- ○ the company must submit a request to the ECHA applying for the authorisation for specific uses
- ○ the company must submit a request to the ECHA applying for restriction
- ○ the company must submit a request to the ECHA applying for evaluation

Q15. What is a Sunset date:

- ○ Date after which a substance under Annex XIV cannot be used unless an authorisation of use is granted.
- ○ Date after which a substance under Annex XIV can be used .
- ○ Date after which Authorisation of use must be applied for with the ECHA.

Q16. The substances subject to restrictions are found:

- ○ In Annex XIV of the REACH Regulation
- ○ In Annex XVII of the REACH Regulation
- ○ In Annex XV of the REACH Regulation

Q17. Chromium (VI) compounds are restricted:

- ○ In buckles, trimmings, zippers and rivets
- ○ In plastic components
- ○ In leather components

Q18. Nickel and its compounds are restricted:

- ○ In cardboard packaging
- ○ In buckles, zippers, rivets and shanks
- ○ In plastic components

Q19. The Phthalates DEHP, DBP, BBP, DINP, DIDP and DNOP are restricted:

- ○ In buckles, zippers, rivets and shanks
- ○ In plastic components
- ○ In cardboard packaging

Q20. Manufacturers or importers must indicate the possible uses and registration number of each substance

- ○ In the safety data sheets
- ○ In a letter of recommendation
- ○ In a REACH certificate

Answer Key:

Q1.	A product that can be used without causing any harm
Q2.	The business owners
Q3.	The Rapid Alert System for dangerous non-food products
Q4.	Registration, Evaluation, Authorisation and Restriction of Chemicals
Q5.	Attributes the industry with the responsibility of managing the risks associated with chemicals
Q6.	for all substances manufactured or imported in the European Union in quantities of one tonne or more per year
Q7.	The ECHA
Q8.	Substances under Annex XIV
Q9.	Apply to any specific substance, in a mixture or in an articler
Q10.	A handbag
Q11.	An individual or company established in the EU representing a non-EC manufacturer of substances or mixtures
Q12.	Is published on the ECHA web site
Q13.	It is present in quantities of 0.1% or more
Q14.	the company must submit a request to the ECHA applying for the authorisation for specific uses
Q15.	Date after which a substance under Annex XIV cannot be used unless an authorisation of use is granted.
Q16.	In Annex XVII of the REACH Regulation
Q17.	In leather components
Q18.	In buckles, zippers, rivets and shanks
Q19.	In plastic components
Q20.	In the safety data sheets

12. Annexes

Below are details of the regulations under which substances are added to Annex XIV and Annex XVII of the REACH Regulation and the substances in question. In the case of substances that are added to Annex XVII, only those that might affect footwear and their components are shown.

REGULATION	SUBSTANCES
COMMISSION REGULATION (EU) No 143/2011 of 17 February 2011 - Annex XIV	5-tert-butyl-2,4,6- trinitro-m-xylene (Musk xylene) 4,4'-Diaminodiphenylmethane (MDA) Hexabromocyclododecane (HBCDD) Bis(2-ethylhexyl) phthalate (DEHP) Benzyl butyl phthalate (BBP) Dibutyl phthalate (DBP)
COMMISSION REGULATION (EU) No 125/2012 of 14 February 2012 - Annex XIV	Diisobutyl phthalate (DIBP) Diarsenic trioxide Diarsenic pentaoxide Lead chromate Lead sulfochromate yellow (C.I. Pigment Yellow 34) Lead chromate molybdate sulphate red (C.I. Pigment Red 104) Tris (2-chloroethyl) phosphate (TCEP) 2,4-Dinitrotoluene (2,4-DNT)
COMMISSION REGULATION (EU) No 348/2013 of 17 April 2013 - Annex XIV	Trichloroethylene Chromium trioxide Acids generated from chromium trioxide and their oligomers Sodium dichromate Potassium dichromate Ammonium dichromate Potassium chromate Sodium chromate
COMMISSION REGULATION (EU) No 895/2014 of 14 August 2014 - Annex XIV	Formaldehyde, oligomeric reaction products with aniline (technical MDA) Arsenic acid Bis(2-methoxyethyl) ether (diglyme) 1,2-dichloroethane (EDC) 2,2?-dichloro-4,4?-methylenedianiline (MOCA) Dichromium tris(chromate) Strontium chromate Potassium hydroxyoctaoxodizincatedichromate Pentazinc chromate octahydroxide

REGULATION	SUBSTANCES
COMMISSION REGULATION (EC) No 552/2009 of 22 June 2009 - Annex XVII	Tris(aziridinyl)phosphinoxide Polybromobiphenyls; Polybrominatedbiphenyls (PBB) Tris (2,3 dibromopropyl) phosphate Lead carbonates Lead sulphates Mercury compounds Arsenic compounds Organostannic compounds Pentachlorophenol Cadmium Nickel Alkanes, C_{10} -C_{13} , chloro (short-chain chlorinated paraffins) (SCCPs) Azocolourants and Azodyes Diphenylether, pentabromo derivative Diphenylether, pentabromo derivative Nonylphenol Nonylphenol ethoxylates Chrome compounds (VI) Di(2-etilhexil)phthalate (DEHP) Dibutyl phthalate (DBP) Butilbencilphthalate (BBP) Diisononilphthalate (DINP) Diisodecilphthalate (DIDP) Din-octilphthalate (DNOP)
COMMISSION REGULATION (EC) No 276/2010 of 31 March 2010 - Annex XVII	Tributyltin compounds (TBT) and triphenyltin compounds (TPT) Dibutyltin compounds (DBT) Dioctyltin compounds (DOT)
COMMISSION REGULATION (EC) No 494/2011 of 20 May 2011 - Annex XVII	Cadmium
COMMISSION REGULATION (EC) No 412/2012 of 15 May 2012 - Annex XVII	Dimethylfumarate (DMF)
COMMISSION REGULATION (EC) No 835/2012 of 18 Sept 2012 - Annex XVII	Cadmium
COMMISSION REGULATION (EC) No 836/2012 of 18 Sept 2012 - Annex XVII	Lead and its compounds
COMMISSION REGULATION (EC) No 1272/2013 of 6 December 2013 - Annex XVII	Benzo[a]pyrene Benzo[e]pyrene Benzo[a]anthracene Chrysen Benzo[b]fluoranthene Benzo[j]fluoranthene Benzo[k]fluoranthene Dibenzo[a,h]anthracene

13. Glossary

A

Article: an object which during its production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

Authorisation: this process is used for the substances that are of extremely high concern (SVHC). The main objective of the Authorisation is to ensure the correct functioning of the domestic market and guarantee that the risks arising from the Substances of Very High Concern (SVHC) are property controlled. The European Commission gives authorisations only for specific uses of a substance, in order to ensure the control of risks and that these substances are gradually replaced by others.

C

Chemical Safety Report (CSR). For drawing up the CSR the whole life cycle of the substance must be considered, both for its own use and for the uses identified in the subsequent stages of the supply chain, taking into account the information provided by the supplier of the chemical.

Competent Authorities responsible for compliance with the REACH regulation in Czech Republic

The Czech Ministry of the Environment is a competent authority for the REACH Regulation. REACH enforcement in the Czech Republic is guaranteed by several national institutions such as

- The Czech Environmental Inspectorate - Controls duties of manufacturers, importers, downstream users and distributors.
- Customs Administration - Focuses on safety data sheets.
- Regional Public Health Authorities - Controls duties of manufacturers, importers, downstream users and distributors concerning substances in articles in contact with water and food, in toys and in cosmetic products.

Competent Authorities responsible for compliance with the REACH regulation in France

The French Competent Authority is the Ministry in charge of ecology, sustainable development and energy. The French Environmental Code allocates responsibility for REACH enforcement to a number of enforcing authorities, especially environmental inspectorate, labour inspectorate, consumer protection authority or customs.

Authorities responsible for REACH enforcement:

- Ministry of ecology, sustainable development and energy - The French REACH Competent Authority's website for information on the roles of enforcement authorities and the arrangements for cooperation between them.

Competent Authorities responsible for compliance with the REACH regulation in Germany

In Germany the competent authority for REACH and CLP is the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BauA).

The above mentioned authorities meet regularly in various working groups and committees in order to solve common issues and to ensure harmonised REACH and CLP enforcement.

Authorities responsible for REACH and enforcement:

- Federal Institute for Occupational Safety and Health - Division for Chemicals and Biocides Regulation.
- Various regional enforcement authorities - Follow the link to the ICSMS search engine for contact details.

Competent Authorities responsible for compliance with the REACH regulation in Italy

The Italian Competent Authority for REACH regulation control is the Ministry of Health, DG Health Prevention. There is cooperation between Competent Authority and other administrations (Ministry of Environment, Ministry of Economic Development, National Institute of Health, National Institute for Environmental Protection and Research and Regions). The Ministry of Health, DG Health Prevention is the Italian REACH Enforcing Authority and is responsible for controls to be conducted by a central pool of inspectors.

Competent Authorities responsible for compliance with the REACH regulation in Portugal

The responsibility for controlling compliance with REACH in Portugal is given to the following authorities:

- The General Inspectorate for Agriculture, the Sea, the Environment and Spatial Planning (IGAMAOT) focusing on manufacturers and formulators.
- The Authority for the Economy and Food Safety (ASAE) focusing on distributors, wholesalers and retailers.
- The Tax and Customs Authority, (AT) focusing on importers.

Competent Authorities responsible for compliance with the REACH regulation in Romania

The system of Competent Authorities for REACH Regulation in Romania is represented by:

- The Ministry of the Environment (MM) – as coordinating authority.
- The National Environment Protection Agency (NEPA) – for REACH implementation.
- The National Environmental Guard (NEG) – for REACH enforcement of duties relating to registration, authorization, restrictions and exchange of information.

For the REACH enforcement activity of NEG, there are protocols of collaboration with other national enforcement authorities:

- State Sanitary Inspection
- National Labour Inspection
- National Customs Authority
- National Authority for Consumer Protection
- General Police Inspectorate

NEG also participates in European enforcement networks for chemicals (CLEEN) and for the environment (IMPEL).

Competent Authorities responsible for compliance with the REACH regulation in Slovenia

The responsibility for enforcement of REACH in Slovenia is placed within chemicals Office of the Republic of Slovenian (CORS) which is a constituent body within the Ministry of Health.

Authorities responsible for REACH enforcement:

- Ministry of Health - Chemical Office of the Republic of Slovenia (CORS)
- Chemical inspectors are responsible for enforcement. The Slovenian REACH Helpdesk is under CORS.
- Ministry of Health - Health Inspectorate of the Republic of Slovenia (HIRS)
- HIRS is responsible for inspection of the implementation of Regulation
- Ministry of Labour, Family and Social Affairs - The Labour Inspectorate of the Republic of Slovenia (LIRS). LIRS conveys inspections of working environment

Competent Authorities responsible for compliance with the REACH regulation in Spain

At the central level there are two Competent Authorities for REACH responsible for two aspects of implementing REACH - protection of the environment and of human health. These two authorities help in the coordination of all Spanish Enforcement Authorities.

The Ministry of Environment and Rural and Marine Affairs coordinates the work of the Environmental Inspections by running a technical coordination group allowing the regional inspections to exchange information, knowledge and experiences. REACH Competent Authority responsible for the coordination of environmental related Spanish enforcement authorities.

The Ministry of Health and Social Politics coordinates the public health authorities of the regions through a public health inspectors' coordination group. It has established a Rapid System on Information Exchange on Chemicals (SIRIPQ) which allows regional public health inspectors to exchange information on cases of non-compliance. REACH Competent Authority responsible for the coordination of human health related Spanish enforcement authorities.

D

Downstream user: any natural or legal person established within the Community, who uses a substance, as such or contained in a mixture, in the course of his industrial or professional activities.

E

ECHA: the European Chemicals Agency is the official body charged with coordinating all the Member States of the European Union to comply with that Regulation. It is at the helm of the regulating authorities for applying UE legislation on chemicals in benefit of human health and the environment, and also of innovation and competition.

Evaluation: the European Chemicals Agency (ECHA) is charged with assessing the registration dossiers. That evaluation will be compulsory for all applications that include any of the tests listed in Annexes IX and X of the REACH Regulation. The evaluation is made of substances produced or imported in quantities greater than 100 tonnes/year and those representing a significant risk for human health and the environment (carcinogenic, mutagenic or toxic...), regardless of the quantities.

Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants
- Compliance check of the dossiers submitted by registrants
- Substance evaluation

F

Forum for Exchange of Information (inspection bodies): Relating to compliance with legislation (Forum), in accordance with Regulation (EC) 1907/2006, coordinates a network of authorities from the Member States responsible for complying with them, and they have the following functions:

- to broadcast good practice and reveal the problems that are brought up at community level;
- to propose, coordinate and evaluate projects of harmonisation in compliance with legislation and joint inspections;
- to coordinate the exchange of inspectors;
- to identify the strategies for complying with legislation, and also the best practices in terms of compliance;
- to develop useful working methods and instruments for local inspectors;
- to develop an electronic information exchange procedure;
- to act as a link with the industry, taking particularly into consideration the specific needs of SMEs and other interested parties, including the pertinent international organisations, where necessary;
- to examine proposals for restrictions in order to assess whether they are applicable;
- to agree on the common issues that have to be included in the annual reports of the Member States in relation to the application.

G

General product safety directive (GPSD), it proposed is to purpose of ensure that products placed on the market are safe. This Directive shall mean any product, including in the context of providing a service, which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

I

Importer: any natural or legal person established within the Community who is responsible for an import.

J

Joint registration is agree on the classification and labelling of the substance and exchange the information required for the joint registration, attending to the petitions for information from other members and providing the existing reports through fair economic arrangements. The objective is to prevent duplicating testing.

M

Manufacturers of components are downstream users who use substances or chemical mixtures to manufacture an article. In this case it is not a finished article such as footwear, for example, but a component that forms part of the final product.

Manufacturer of preparations are those companies that are manufacturers of preparations such as adhesives, finishes for leathers and terminations for footwear, etc., act as "Downstream users". The downstream user is an individual or company established in the European Community, other than the manufacturer or importer of substances, which uses a substance, as such or in the form of a preparation, in the course of their industrial or professional activities.
Manufacturer of substances are an individual or company established in the European Community which manufactures a substance in the Community, for example, solvents, fillers, tanning substances, etc.

N

Non-Community manufacturer a manufacturer of preparations or substances established outside the Community.

O

Exclusive representative: any natural or legal person established in the Community who represents a non-Community manufacturer of substances or preparations to fulfil, as his only representative.

P

Preparation: reparation means a mixture or solution composed of two or more substances.

R

RAPEX: Rapid Alert System for dangerous non-food products. The **RAPEX** covers products posing risk to health and safety of professional users and to other public interests protected by relevant EU legislation.

REACH (Regulation nº 1907/2006 of the European Parliament and of the Council) is the European regulation relative to the Registration, Evaluation, Authorisation and Restriction of Chemicals. This Regulation assigns the industry with the responsibility of managing the risks associated with the substances that it manufactures, imports, sells and uses in its processes.

Re-fillers: they transfer substances or chemical mixtures from one container to another, generally in the course of repackaging or changing a brand image.

Registration is compulsory for all substances manufactured or imported in the European Union in quantities of one tonne or more per year per manufacturer or importer, except those which are exempt from the obligation to be registered.

Registration can be submitted individually or jointly. Joint registration is made with the companies that initially pre-registered the substance in question and create the substance information exchange forum (SIEF).

Reimporters: they import substances, as such or in the form of a mixture, that were originally produced in the EU and registered by another agent belonging to the same supply chain.

Restrictions: the restrictions can limit or prohibit the manufacture, marketing or use of a substance and can be applied to any particular substance in a mixture or in an article. They can also be applied to imports.

S

Safe product: a safe product is any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

Substance: a chemical element and its compounds 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.

Substance information exchange forum of substance (SIEF) is made by several companies, including several countries, in order to streamline registration tasks. Thus, is joint registration is made with the companies that initially pre-registered the substance in question and created the The fact of forming part of a forum entails:

- The possibility of assigning a forum coordinator (voluntary) for internal management.
- Appointment of a Lead Registrant whose function will be to submit the joint information for the registration on behalf of the other registrants. This must be done before any another registration to cover all members of the forum, so it is recommended that it should be one of the registrants with the highest tonnage.

Regarding the information that could be necessary for the joint registration:

- Agree on the classification and labelling of the substance.
- Exchange the information required for the joint registration, attending to the petitions for information from other members and providing the existing reports through fair economic arrangements. The objective is to prevent duplicating testing.
- Identify the information gaps for registration and organise the strategy for obtaining data to complete it (tests).

Substances subject to authorisation: Substances that are found in annex XIV of the REACH regulation. Manufacturers, importers and intermediate users of these substances may not sell them or use them unless for a specific authorization is obtained.

Substances very high concern (SVHC) are those identified as CMRs (carcinogens, mutagens and reproductive toxins), PBTs: persistent, bioaccumulative and toxic substances; vPvBs: very persistent and very bioaccumulative substances, and some substances of concern which have irreversible serious effects on humans and the environment, such as endocrine disruptors. The supplier of the article containing an SVHC on the list of candidates in a concentration higher than 0.1 % in weight/weight must give, at least, the substance name.

Sunset date: is defined as the deadline which may not be used a substance in annex XIV without the licence of an authorisation for use.

14. Bibliography

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Lifelong Learning Programme

Project Number:
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How to implement Sustainable Manufacturing in Footwear - New Occupational Profile and Training Opportunities -

The project *STEP to SUSTAINABILITY* aims at:

Developing a new qualification profile and correspondent training in the field of sustainable manufacturing.

Training technicians with knowledge and skills to implement manufacturing strategies envisaging the sustainability in Footwear and Leather goods.

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