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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

Review of EU normative documents and legislation and their relevance for the tanning industry in developing countries

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

UNITED NATIONS

INDUSTRIAL DEVELOPMENT ORGANIZATION

Review of EU normative documents and legislation and their relevance for the tanning industry in developing countries

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Prepared for the Seventeenth Session of the Leather and Leather Products Industry Panel in Addis Ababa, Ethiopia, 18-21 January 2010,

by

Jakov BULJAN

Project Manager

Ivan KRÁL

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1. Introduction

The Regulation of the European Union (EU) on Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH entered into force on 1st June 2007. Its proclaimed aim is to ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.

REACH also streamlines and improves the former legislative framework on chemicals in order to improve the protection of human health and the environment from the risks that can be posed by chemicals. The purpose of this desk study is to give some background information and practical advice to the leather industry so as to maintain or establish business in the EU market.

2. Legal context

2.1. As the starting point in this matter it could be taken the Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances together with a long list of Amendments.

2.2. The purpose of this Directive was to approximate the laws, regulations and administrative provisions of the Member States on classification, packaging and labelling of dangerous substances which are placed on the market in the Member States of the Community (now EU).

2.3. The Directive did not relate to: (a) medicinal products, narcotics and radioactive substances; (b) the carriage of dangerous substances by rail, road, inland waterway, sea or air; (c) munitions and objects containing explosive matter in the form of igniters or motor fuels. In this context (a) "substances" means chemical elements and their compounds as they occur in the natural state or as produced by industry; (b) "preparations" means mixtures or solutions composed of two or more substances.

2.4. Substances and preparations considered "dangerous" are: (a) explosive (b) oxidising (c) easily flammable (d) flammable (e) toxic (f) harmful (g) corrosive (h) irritant

2.5. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.[1]

2.6. This Directive in effect amends and updates the 1967 Directive, launches the REACH administrative procedures and establishes the European Chemicals Agency.

2.7. As said earlier, REACH does not invalidate the former regulations; it rather aims to supplement, expand and refine them; for example, all notified substances under NONS are

[1] *Some of 131 articles (Appendix 1) together with the Table of Contents (Appendix 2) of the Regulation are intended to provide a general picture of this important but rather bulky (278 pages) EU legislative document.*

considered as being registered under the REACH regulation.[2] In that context there is a particular emphasis on better monitoring, information sharing along the entire supply chain, information sharing among producers of chemicals as well as on much better consumer protection.

2.8. The European Chemicals Agency, ECHA, is the key operational body for implementation of REACH regulations. For any communication with ECHA be it a query or any data submission it is necessary to sign-up and create an account for your company using the REACH-IT entry into the system.

A general impression of the character and content of the EU Regulation (EC) No. 1907/2006 caused a lot of commotion primarily among suppliers of chemicals but later on in the tanning industry itself and ultimately downstream, among leather products manufacturers as well.

3. Definitions

For good understanding of REACH regulations it is important to know the exact meaning of terminology used. Here are a few most relevant definitions according to REACH[3]**:**

- ***substance***: a chemical element and its compounds in the natural state or obtained by any manufacturing process (including any additive, but excluding any separable solvent);
- ***preparation***: a mixture or solution composed of two or more substances;
- ***article***: 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;
- ***producer of an article***: any natural or legal person who makes or assembles an article within the Community;
- ***registrant***: the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
- ***manufacturing***: production or extraction of substances in the natural state;
- ***manufacturer***: any natural or legal person established within the Community who manufactures a substance within the Community;
- ***downstream user***: 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. A distributor or a consumer is not a downstream user.
- ***distributor***: any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;
- ***Agency***: European Chemicals Agency, ECHA;
- ***competent authority***: the authority or authorities or bodies established by the (EU) Member States
- ***phase-in substance***: a substance listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or manufactured or placed on the EU market before certain dates
- ***use***: any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

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[2] *The Notification of New Substance Regulations 1993 (NONS 93) are a set of regulations applicable across the European Community.*

[3] *For the full list see Appendix 3*

- ***identified use***: a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
- ***per year***: per calendar year, unless stated otherwise; for phase-in substances quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
- ***registration***: the process by which any manufacturer or importer (or producer of articles), of a substance within the scope of REACH must submit certain prescribed information to ECHA
- ***restriction***: any condition for or prohibition of the manufacture, use or placing on the market;

Thus, according to the definitions in the REACH Regulation, leather is an "article" and not a chemical "substance"; leather is an article, which does not intentionally release chemicals like a pen or an ink jet printer which means that leather *per se* is exempt from REACH registration.

4. National and international regulation regarding chemicals

There is already a lot of international agreements regarding production, transport, uses of chemicals, environmental impact, workers' and consumer protection as well as disposal of chemicals. There is, for example the Globally Harmonized System of Classification and Labeling (GHS). It has been promoted by the UN family bodies and organizations (The Economic and Social Council, ECOSOC, through its Committee of Experts on the Transport of Dangerous Goods, TDG and the UN Conference on Environment and Development (UNCED). It was also strongly supported by the World Summit on Sustainable Development (WSSD), held Johannesburg in 2002.[4] Another UN level endeavour is the Strategic Approach to International Chemicals Management (SAICM). Furthermore, taking a leaf from EU regulations, some leading multinationals have developed their own list Restricted Substance List (RSL) etc.

However, REACH is without doubt the leading chemicals management scheme – complex, sophisticated, expensive and bureaucratic, but it is likely to bring about much better information and control on potentially harmful substances than any system to date. Furthermore, it can be safely assumed that substances the use of which is limited or banned under REACH are very likely to be similarly restricted under other national or international legislations.

In addition, the case of DMF containing products sold on EU market has clearly shown that the impact of various consumers' protection organizations and NGO establishments and the resulting (often misguided) public opinion cannot be underestimated either (Appendix 8).

5. Some specific features of the REACH

REACH is conceived to generate information on substances as well as on their uses so that the data can be used not only by the *actors* along the supply line but also in the wider context, for example various voluntary instruments such as the eco-labelling scheme or, possibly, in establishing a European quality mark.

REACH insists that only registered *substances* and *preparations* (chemicals) i.e. only those which properties, including possible risks in application and use have been thoroughly investigated and made widely known, can be used in manufacture[5].

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[4] *The EU has decided to implement GHS in parallel with REACH.*

[5] *Unless exempted for registration, see items 6.1.1. and 6.1.2. below*

Possibly the most important specific feature of REACH is the obligatory and extensive exchange of information along the entire supply line.

A particular emphasis is on monitoring, control and avoidance of substances considered carcinogenic, mutagenic, toxic for reproduction, persistent, bioaccumulative and toxic or having endocrine disrupting properties.

A new feature under REACH is that some Safety Data Sheets (SDS) will have an exposure scenario attached; its scope will depend on the perceived risks associated with its application and use and on the quantity produced or imported.

Actually, throughout REACH the extent of control is directly linked to the volume of substance manufactured or imported (see item 6.2. below)

Protection of the ultimate user of article(s) – consumer – is one of the main aims of the entire REACH legislation.

A good example of the REACH concept of sharing the information is the Substance Information Exchange Forums (SIEF). The purpose of SIEF is the exchange of information mainly among chemicals manufacturers (registrants) but also among downstream users in order to avoid the duplication of studies and synchronise classification and labelling of substances and preparations.

Companies acting as importer and/or manufacturer must also start data sharing in Substance Information Exchange Forums (SIEF). The important role of the active Lead Registrant is laid down by the REACH regulation and it is mandatory.

6. Classification of chemicals according to REACH

Somewhat freely interpreting and possibly oversimplifying the relevant articles of the EC Regulations it could be said that REACH groups all substances and preparations into following categories:

6.1. Substances exempted from registration

6.1.1. As per ARTICLE 2(7)(a), Annex IV

Here are listed substances on which sufficient information is already known; also, because of their intrinsic properties they are considered to cause minimum risk. Some examples : Carbon dioxide, distilled water, corn oil, tallow, starch, limestone, argon, carbon, nitrogen, distilled water, graphite, sunflower oil, soybean oil, linseed oil, corn oil, castor oil, rape oil, some fatty acids and glycerids etc.

6.1.2. As per ARTICLE 2(7)(b), Annex IV

Here are listed substances for which registration is considered inappropriate or unnecessary without prejudicing the objectives of the Regulation. More specifically:

- Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial

organisms or sunlight; result from incidental chemical reaction; not placed on the market, result from a chemical reaction that occurs using:
(a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant,
(b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.

- By-products, unless they are imported or placed on the market themselves.
- Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
- Substances which occur in nature, if they are not chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.
- Basic elemental substances for which hazards and risks are already well known: hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen.

6.2. Substances requiring registration (Regulations[6], Annex VI and Annexes VII – XI)

In this group are substances and preparations not specifically listed in other categories. In addition to basic data about structure and properties, the standard information to be provided to ECHA has to cover areas such as: safe use - Safety Data Sheet (first-aid/fire-fighting/accidental release measures), handling and storage, exposure controls/personal protection, stability and reactivity, disposal considerations, human exposure (oral, dermal, inhalatory); environmental exposure (water, air, solid waste, soil); pattern of exposure (accidental/infrequent, occasional, continuous/frequent); toxicological and ecotoxicological information. The depth of information is linked to the scale of manufacture – import per year. The threshold levels are:

- one tonne or more
- 10 tonnes or more
- 100 tonnes or more
- 1 000 tonnes or more

6.3. Restricted substances (Regulations, Annex XVII)

REACH places restrictions on the marketing and use of certain chemicals substances and preparations if they are believed to cause harm to human health or to the environment and they can be found in Annex XVII (17) of the REACH Regulations. In fact, all restrictions on chemicals contained in earlier EU Directives have been now put in Annex XVII of REACH and most tanners are already familiar with them. Some items of interest to tanners:

22. Pentachlorophenol
23. Cadmium and its compounds
42. Short-chain chlorinated paraffins)
47. Cement and cement-containing preparations, if they contain, when hydrated, more than 0,0002 % soluble chromium VI of the total dry weight of the cement.
46. (a) Nonylphenol
    (b) Nonylphenol ethoxylate

[6] *Article 10 stipulates the content of the technical dossier to be submitted for general registration purposes.*

Exception: in concentrations equal or higher than 0.1 % by mass for 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);

Furthermore here are some carcinogenic and toxic to reproduction chromium compounds as well as azocolourants.

6.4. Substances of very high concern, SVHC (Regulations, Annex XIII)

There are substances which are considered extremely harmful for being carcinogenic, mutagenic, toxic for reproduction, persistent, bioaccumulative and toxic, very persistent and very bioaccumulative, as having endocrine disrupting properties or having a combination of the mentioned properties.

In the REACH system such substances are classified as Substances of Very High Concern (SVHC). Since 28 Oct 2008 the first 15 from that category are included in the European Chemical Agency (ECHA) Candidate List (Appendix 6). The list will be expanded with other substances for which there will be sufficient scientific evidence for falling into some of the listed categories.

The inclusion of a substance in the list has certain legal consequences – obligations concerning the substance:

i) on its own
ii) in preparations
iii) present in articles. It means that there are some obligations both for producers as well as downstream users of such substances. The threshold value is 0.1% weight weight (w.w).

While towards the end of 2009 there were only 15 substances and 15 more being added in January 2010, some believe that ultimately the list might include more than a thousand substances.

In that context it is useful to know that there is also the SIN (Substitute It Now) List promoted by an NGO Advisory Committee which includes (amongst others) WWF, Friends of the Earth and Greenpeace. This is a list of substances that in the view of the Advisory Committee fulfil the criteria for Substance of Very High Concern as defined by REACH. Although it certainly not official, the list is used by NGOs to lobby Member States for proposing substances for inclusion into the 'Candidate List'.

6.5. SVHCs requiring special authorisation (Regulations, Annex XIV)

Since 1 June 2009 seven substances from the Candidate List should not be used without specific authorization as they are classified as toxic to reproduction, one as carcinogenic and three fulfil the criteria for being persistent, bioaccumulative and toxic *(PBT)* or very persistent and very bioaccumulative *(vPvB)* and they are all used in some products to which consumers and workers could be exposed. This also applies to substances produced or imported in volumes below 1 tonne per year, normally exempt from REACH registration.

It is very likely that these substances will be included in the SVHC list in Annex XIV of the REACH regulation requiring specific authorisation.

7. REACH and leather and leather products sector

According to REACH regulations, tanneries fall into category of *downstream users* (DU) - unless they manufacture some substances by themselves. The same applies to leather footwear, apparel and leather goods companies. In turn, all of them, including tanneries, are producers of *articles*.

7.1. Leather and leather products companies as downstream users

One of the main elements of REACH is registration of substances, which obliges manufacturers and importers of substances to provide a defined set of information, in the form of a registration dossier, to the European Chemicals Agency (ECHA). This information concerns the hazards of the substances and whether they could pose risks when being used. Manufacturers and importers of certain dangerous substances need to assess the exact nature and extent of these risks in a 'chemical safety assessment'. Certain very dangerous substances will require authorisation before they can be used and restrictions may be placed on the use of certain substances.

Under REACH, downstream users must not place on the market or use any substances which are not registered in accordance with REACH. Downstream users will receive information on dangerous substances and preparations, including risks from their use and measures to control these risks, in Safety Data Sheets, just as today.

In practice, tanners but also footwear, apparel and leather goods manufacturers should make sure that their suppliers are aware of REACH and comply with its requirements. It means that it is necessary to obtain statements from all suppliers confirming that they fully conform to REACH requirements; this in turn implies that they do the same while procuring their own materials and substances (chemicals).

If you consider the hazard and PBT assessments of substance(s) reported in the Safety Data Sheet to be appropriate, then no further hazard assessment or PBT and vPvB assessment is necessary and you can use the relevant information reported by the supplier for the risk characterization. However, as already said, it is important to verify whether all possible uses are properly covered in the Safety Data Sheet provided by the supplier (Regulations, *ANNEX XII*).

As a rule, it is manufacturers of substances who have to prepare Chemical Safety Reports required for registration with ECHA; however, it might be also useful for downstream users to be familiar with its content (Appendix 7).

7.1.1. Main obligations of downstream users

Based on what is said earlier, the main obligations of downstream users under REACH are to:

1. Follow the instructions in the Safety Data Sheets you receive and in the exposure scenarios attached to some Safety Data Sheets. If your use is not covered by an exposure scenario, you can communicate with your supplier with the aim of having your use covered by an exposure scenario or you may need to develop your own chemical safety report.

2. Contact your suppliers if you have new information on the hazard of the substance or preparation or if you believe that the risk management measures are not appropriate.

3. Provide your customers with information

a. on hazards, safe conditions of use and appropriate risk management advice for your preparations, if you are a formulator
b. if the content of certain very dangerous substances, which are candidates for authorisation, exceeds a concentration of 0.1 %w/w in the articles you produce.

7.1.2. Downstream users' compliance with REACH

REACH entered into force on 1 June 2007, and from this date the obligations related to communication in the supply chain, for example, the duty to provide safety data sheets when supplying dangerous substances and preparations, started to apply. However, obligations linked to the registration of substances apply since 1 June 2008. For instance, the obligation to comply with the exposure scenario developed by the supplier (or to develop them for uses not covered) applies twelve months after the downstream user has received a safety data sheet with a registration number.

Downstream users must not place on the market any substances which are not registered in accordance with REACH. This means that your products may contain only substances which are either:

- produced/imported by the supplier in amounts below 1 tonne per year, or
- exempted from registration (as given in the scope and the exemptions in Annex IV and V of REACH), or which
- have been pre-registered and have a later registration deadline, or
- have been registered.

In practice, you should make sure that your supplier is aware of REACH and complies with his requirements. You should obtain a statement confirming that your supplier knows his requirements, follows them and also checks that his suppliers are in compliance with REACH, and request a confirmation that pre-registration has taken place or is going to take place.

According to REACH regulations, tanneries fall into category of *downstream users* (DU) - unless they manufacture some substances by themselves. The same applies to leather footwear, apparel and leather goods companies. In turn, all of them, including tanneries, are producers of *articles*.[7]
In reality, most chemical suppliers have already informed their tannery customers about substances registered as well indicated the tannery use in their safety assessment.

7.1.3. The Safety Data Sheet

Some Safety Data Sheets will have an exposure scenario attached; this is a new feature under REACH. It will depend on whether the substance is dangerous and the quantity produced by the manufacturer or importer who registers it. If you receive an exposure scenario with the safety data sheet, you need to check whether you comply with it. You should note that, as well as complying with REACH, you must continue to comply with existing legislation to protect workers' health and the environment. A *caveat* here: even if the substance does not have a

[7] *Within its series "Guidance for the implementation of REACH" documents ECHA has published "Guidance for downstream users" (January 2008) and "Guidance on requirements for substances in articles" (May 2008)*

Safety Data Sheet, you still need to implement (and communicate down the supply chain) the risk management measures which are communicated to you by the supplier by other means.

Finally, should your company produce preparations, you have to continue providing Safety Data Sheets; however, now you have to include the exposure scenarios and forward information to your customers on exposures and conditions of use. Therefore, you required to:

- Follow the instructions in the Safety Data Sheets and in the exposure scenarios attached to some Safety Data Sheets you receive from the supplier of chemicals. If your use is not covered by an exposure scenario, you should ensure with your supplier that it is included into *identified use.* However, your duty is to provide him with detailed information on the way how that particular substance or preparation is used in your process enabling him to develop the appropriate exposure scenario. To do that it is necessary to use the ECHA methodology – terminology rather roughly shown in the table below:

Table 1. Descriptors

DESCRIPTOR	CATEGORY & APPLICATION
Descriptor for sector of use (SU)	SU5, Manufacture of textiles, leather, fur
Descriptor for types of preparations (PC=Chemical Product Category)	PC23, Leather tanning, dye, finishing, impregnation and care products
Descriptor for process categories (PROC)	There are 25 typical industrial operations, several of them applied by tanners
Descriptors for substances in articles with no intended release – Article Categories (AC)	AC6, Leather products: apparel and upholstery

Full details can be found in ECHA document Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system.

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

- Contact your suppliers if you have new information on the hazard of the substance or preparation or if you believe that the risk management measures are not appropriate.
- It is important to request suppliers of the main raw material as well to provide you with information on substances used in manufacture and/or present in their product. In practice it means that, for example, a tanner shall advise the shoe manufacturer about the presence of a SVHC in his leather enabling him to inform his buyers/exporters accordingly.

Some standardized templates for communication along the supply line have been developed by various establishments such as the Downstream Users of Chemicals Coordination (DUCC)-Group in Brussels or TEGEWA, Germany (Appendix 12)[8]

A good and illustrative example of the new developments is a letter on behalf of the REACH Lime Consortium to Downstream Users (Appendix 13) together with an exhaustive questionnaire asking them to provide information about process and product, specific operations/flow-chart,

[8] *It is quite likely that this apparently extremely complicated process in practice will be greatly facilitated by the fact that identified uses will be already well established and that suppliers of substances and preparations (chemicals) will be able to assist.*

emissions into environment, occupational exposures, protective equipment for the lime substances - CaO, $Ca(OH)_2$ etc.; www.ima-reach-hub.eu

For the benefit of European tanners the COTANCE has reportedly established an Expert Group on REACH with the aim of defining the way substances and preparations are used in various applications and developing exposure scenarios for the leather industry sub-sectors.

7.1.4. Importers of substances, preparations or articles from outside the EU

Regardless of the type of commercial activity you carry out, you should check whether you purchase chemical substances or preparations (including e.g. cleaning agents, solvents and similar products) from outside the EU. If you are responsible for the physical introduction of substances or preparations into the EU, you have the role of an importer under REACH and you may have to register the substances. If you import articles, you may also have to fulfil requirements under REACH.

If you purchase from a supplier in another EU country, you are not an importer and do not have to register. If you purchase substances or preparations from a non-EU supplier who has an '*only representative'*, you are a downstream user under REACH and you do not have to register.

7.2. Leather and leather products companies as producers of "articles"[9]

7.2.1. Registration with ECHA

Since leather and leather products do not contain substances for intended release there is no need for Registration according to Article 7(1) (and 7(5). However, in some cases ECHA may decide that an article producer or importer must submit a registration for any substance contained in an article if the amount of the substance exceeds 1 tonne per year and if there is a suspicion that the substance is released from the article resulting in risks to human health or the environment. This may apply to any substance which has not yet been registered for that use under Article 6 or Article 7.1.

7.2.2. Notification with ECHA

Notification of substances in articles is required when all conditions of Article 7(2) are met:

- The substance is included in the candidate list for authorisation (Article 59(1)) and
- The substance is present in all articles produced or imported by one actor in an amount totalling over 1 tonne per year (per producer or importer)
- The substance is present in articles above a concentration of 0.1% weight by weight (w/w)

If, however, one or both of the following conditions are met, no notification is required:

[9] *According to ECHA website there is no full EU consensus yet on the content of the document "Guidance on requirements for substances in articles" (May 2008); thus, the only official document in this respect is still Regulation (EC) No 1907/2006.*

- The producer or importer can exclude exposure of the substances to humans or the environment during normal or reasonable foreseeable conditions of use including disposal (Article 7(3)).
- The substance has already been registered for that use according to Article 7(6) (See also Chapter 9).

The substance concentration threshold of 0.1 % (w/w) applies to the article as produced or imported. It does not relate to the homogeneous materials or parts of an article, as it may in some other legislation, but relates to the article as such (i.e. as produced or imported). Only substances with specific properties can be identified as SVHC on the candidate list for authorisation.

The obligation to notify substances in articles also applies to packaging materials, which may be produced or imported separately as packaging of imported goods. Packaging is to be assessed separately from any object it contains.

A notification is not required for a substance in articles which have been produced or imported before the substance has been included on the candidate list for authorisation.

7.2.3. Obligation to communicate

The aim of Article 33 is to ensure that sufficient information is communicated with articles to allow their safe use.[10] Producers, importers and other suppliers of articles containing substances of very high concern (SVHC) included on the candidate list for authorisation in a concentration above 0.1% (w/w) have to provide respective information available to them to the recipients[11] of the articles and as a minimum the name of the substance. This information is to be provided 'automatically'

There is no tonnage trigger for this obligation (i.e. it also applies below 1 tonne/a) and the obligation cannot be exempted neither via Article 7(3) (exclusion of exposure) nor via Article 7(6) (already registered for that use).

Information available to the article supplier necessary to ensure safe use of an article has to be provided also to consumers upon request (Article 33 (2)). Consumers have to be provided with information within 45 days of the request, free of charge.

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

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

[10] *See also Appendices 6 and 9*

[11] *Under REACH the term "recipients'' does not include consumers.*

Thus, if the imported buttons or the imported jackets were packaged in plastic packaging material, the content of such substances in this packaging material would have to be assessed separately. The obligation to provide available information on substances of very high concern to the recipients of the articles applies as soon as a substance has been included on the candidate list for authorisation.

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

7.2.4. Restrictions

The content of substances in articles can be restricted or banned under the restrictions procedure. Article producers and importers have to follow the conditions outlined in Annex XVII of REACH from June 1, 2009.

7.2.5. Timelines under REACH

The obligation to register substances in articles applies from 1 June 2008. A notification of substances in articles shall be made at the latest 6 months after it has been included on the candidate list for authorisation but only starting from 1 June 2011 (See the table below). Information on substances on the candidate list contained in articles is to be forwarded to the recipients of article directly after a substance is included in that list. The candidate list will be updated continuously.

POTENTIAL OBLIGATIONS FOR ARTICLE SUPPLIERS	TIME
Participation in SIEFs (potential registrants according to Article 6 and 7.1)	1 June, after pre-registration
Communication regarding substances on the candidate list in articles according to Article 33	As per the published Candidate List, Appendix 8
Notification of substances in articles according to Article 7.2	6 months after substance is included in the Candidate List. No notification required before 1 June 2011
Registration of pre-registered phase-in substances • in amounts ≥ 1000 tonnes per year or more, • in amounts ≥ 1 t/a if the are known carcinogens, mutagens or reprotoxic substances (category 1 and 2) and • in amounts ≥ 100 t/a substances if they are classified with R50/53	By 30 November 2010
Registration of pre-registered phase-in substances in amounts between 100 and 1000 tonnes per year	By 31 May 2013
Registration of pre-registered phase-in substances between 1 and 100 tonnes per year	By May 2018

7.2.6. Other relevant legislation

The ban of certain azo-colorants in textiles, will continue to apply. Other legislation concerning restrictions, reducing the use of or the risks from hazardous substances in articles still apply separately from REACH. Examples are the General Products Safety Directive 2001/95/EEC and product specific legislation such as Directive 88/ 378 on toys.

7.2.7. Obtaining information about SVHCs on the Candidate list

Article suppliers should consider how to document their compliance checking. For example, they could include for statements by their suppliers that substances of very high concern on the Candidate List for authorisation are not used, calculations proving that the concentrations in articles remain equal to or under 0.1 % (w/w), Safety Data Sheets of input materials, supply contracts and documentation of their implementation and auditing etc.

If the content of SVHC cannot be excluded, initially it is only necessary to know whether or not the article contains a SVHC on the Candidate list. The information may be obtained via Safety Data Sheets, Article 32 information, supply chain requests etc.

When no Safety Data Sheet or other standardised information is available for the substances and/or preparations in the article or the presence of an SVHC cannot be excluded, the following actions could be performed:

Article producers
Request the supplier of substances/preparations included in the article to provide the registration number and the identity and concentration range of any SVHC on the Candidate List and contained therein. For article components, ask the supplier to either confirm that no SVHCs on the candidate list are contained in concentrations > 0.1% (w/w) in the article or to specify the identity and concentration of the SVHC in the article.

Article importers and only representatives
Request the supplier to confirm whether or not an article contains any SVHC on the Candidate List in concentrations > 0.1% (w/w). If the supplier cannot confirm this, ask for the identity and the amount (or concentration) of these substances in the article. If he is not willing or able to provide these, ask him to forward your request to the next actor up his supply chain or to provide you with the contact details of his suppliers.

Example of calculation of the amount of a SVHC:

A company imports 20000 pairs of shoes, 3000 belts, and 60000 bags per year to the EU market. A pair of shoes contains 0.05% (w/w) of a SVHC, a belt contains 0.15% (w/w), and a bag contains 2% (w/w) of the same SVHC. The weights of the articles are 0.7 kg per pair of shoes, 700 g per belt and 1 kg per bag.

Concentration in belt and bag > 0.1% (w/w) ⇒ calculate the total volume of the SVHC for each of the articles.

The total volume of the SVHC imported by the articles:

• Belts: Vol_{SVHC} [t/a] = (0.15% · 0.01) · (700 [g] · 10^{-6}) · 3000 = 0.0032 t/a

• Bags: Vol_{SVHC} [t/a] = (2% · 0.01) · (1000 [g] · 10^{-6}) · 60000 = 1.2 t/a

Sum up the total volume for all sorts of articles with a concentration of the SVHC > 0.1%:
ΣVol_{SVHC} = (0.0032 + 1.2) t/a = 1.2032 t/a, which is > 1 t/a

Conclusion: The company has to submit a notification for the SVHC in the bag and the belt. Furthermore, the company has to provide information for both the belt and the bag according to Article 33 of REACH.

7.2.8. Notification of a substance in articles

The information to be notified according to Article 7(2) shall include the following items:

- The identity and contact details of the producer or importer of the article
- The registration number(s) for the substance(s), if available
- The identity of the substance(s) (cf. Annex VI of REACH). This information will be available on the Candidate List
- The classification of the substance(s), which will be available from the Agency
- A brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s) (cf. Section 8.8.1)
- The (estimated) tonnage range of the substance contained in the articles, i.e. 1-10 tonnes, 10-100 tonnes etc.

Consequently, a potential registrant or notifier of a substance in articles checking whether a substance has been registered 'for that use' has to check by which process the substance has been included in the article, and into which type of article the substance has been incorporated in line with the use descriptor system. Otherwise the substance is not considered registered for that use.

You may also be exempted if a Registration of your use of the substance has been made by an actor in another supply chain.

A supplier of any article containing substances on the Candidate List above 0.1% threshold must inform the customer and consumer to ensure safe use of the article and from 1 December 2011 the European Chemicals Agency.

7.3. EU suppliers

It might be useful to know that EU suppliers are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom.

Suppliers in Switzerland are not EU-suppliers.

Suppliers in Norway, Iceland and Liechtenstein will be considered as EU-suppliers once these countries have implemented REACH.

7.4. Import of substances, preparations or articles from outside EU

If you import substances or preparations into the EU, you have the role of an importer under REACH and you may have to register the substances.

If you purchase substances or preparations from a non-EU supplier who has an 'only representative' you are a downstream user under REACH and you do not have to register. However, in such a case make sure that your non-EU suppliers have **an only representative**.

If you import articles, you may also have to fulfil requirements under REACH.

In practice it means that a manufacturer of chemicals established outside the EU must appoint a natural or legal person in the EU as his only representative for registration or mandate the importer.

The registrant is obliged to register substances as such, including all substances in a preparation (compound).

This is <u>not required</u> for downstream users (producer of leather and leather products) unless the total amount of any of SVHC substances in articles exceeds 1 tonne/year. This unlikely situation

could possibly arise in case of large scale exports of leather and leather products (more than 1000 tonnes/year) containing any of SVHC close to the limit of 0.1% weight/weight.

Documents: Although normally there are no specific record-keeping requirements for article suppliers ECHA recommends documenting the results of their compliance checking, even when it has been identified that no obligations under REACH exist. Documentation facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.

Possible approaches could be:

- Article suppliers with implemented management systems could incorporate REACH conformity as a criterion – with clear indications of how conformity will be secured and documented.
- Article suppliers without a management system may follow a kind of "good practice for supplying articles", which could be developed by the respective industrial associations. This might include:

  - Following the workflows given in ECHA document "Guidance on requirements for substances in articles" (May 2008)
  - Describing whether registration/notification or communication on SVHC is required
  - Supporting documents including letters from suppliers, certificates, results of analysis etc.

8. REACH and its impact on the European leather industry

It is not surprising that EU based tanners and manufacturers of chemicals (*substances* and *preparations* according to REACH terminology!) promptly reacted to new Directive. They were of the view that they had been put into unfavourable position in comparison with competitors outside EU. They also claimed that the new regulations did not protect EU consumers of from risks associated with potentially hazardous substances contained in imported articles – leather products.

The content of and statements following the Round Table organised by COTANCE, sponsored by Lineapelle, co-hosted by GERIC (association of European leather technical centres) and with IULTCS participation held in Bologna in October 2008 reflects the prevailing feelings at that time (Appendix 7)**.** Quite active was also the Working Group "Consequences of the new EU chemical policy for leather producers"comprising representatives from VDL (German Leather Industry Association), VCI (Association of the Chemical Industry), TEGEWA (Association of the Textile Auxiliaries, Tanning Agents and Detergent Materials), UK chemicals industry and COTANCE (Confederation of National Associations of Tanners and Dressers of the European Community).

9. REACH and the non-EU producers

The practical consequences for non-EU producers exporting to EU market are evident from item 7.4. of this report and are not repeated here.

Obviously, in the globalised economy it hardly conceivable that any significant producer – be it a tanner, footwear, apparel or leather goods maker can afford to ignore the EU market; it is also quite possible that, for example, finished leather sold in the non-EU country might be used for leather products converted into leather products marketed in EU. Therefore, understanding of and compliance with REACH is a must regardless of the location of the production base.

In that context is the crucial role of the EU based only representative who takes over the role of *registrant* and is the only line of communication with ECHA. The ECHA "services" are not free but at the moment the costs are not widely known.

10. The cost of REACH to the industry

It is not surprising that it is hard to find any publicly available estimates of the cost implications of REACH to the manufacturers of chemicals and, ultimately, to the leather industry. Obviously, there are significant difference in cost depending on the specific nature of the *substance/preparation* and its potential risks to health and related cost of testing. Some are produced in huge quantities and applied in many industries whereas some are specialty compounds developed for a very specific purpose. Finally, it is very likely that each manufacturer of chemicals will devise its own strategy of spreading the added costs of compliance with REACH.

It is reported that the EC estimates of the total cost of REACH to European chemicals industry are at the level of EUR 2 - 6 billion spread uniformly over 5 – 10 years The chemicals industry own estimates place it much higher, to more than EUR 8 billion (testing, exposure scenarios, risk assessment, documentation etc.).

In comparison with other sectors, production of chemicals for the leather industry is rather small; even after allowing for the fact that many substances and basic preparations are derived from other sectors, there is still a lot of specialty, low-volume chemicals with proportionally high testing and registration costs.

Table 1: Estimated costs for individual substances

Production volume	Total estimated cost *EUR*	Estimated cost *EUR/kg*
1 - 10 t/a	50000	5.000 - 50.00
10- 100 t/a	140000	1.400 -14.00
100- 1000 t/a	370.00 - 410000	0.370 - 4.100
> 1000 t/a	650.00 - 740000	0.650- 0.740 for 1.000 t/a 0.065 - 0.074 for 10000 t/a

Source: Puentener/Association of the Chemical Industry, VCI

In one TEGEWA report – presentation by Dr. Volker Schröder from 2006, the REACH related costs of registration were estimated as follows:

Table 2: Estimated costs of substance registration

QUANTITY	RATE, EUR
1 – 10 t/a	approx. 25 - 40000
10 – 100 t/a	approx. 200 - 250000
100 - 1.000 t/a	approx. 400000
> 1.000 t/a	approx. 0,5 - 2 million

In the same report it is estimated that due to cost of registration – spread over five years, the price of a particular hydrophobing agent would be increased by about 35 %.

11. Conclusions

It is important to understand that REACH spreads the responsibilities along the full supply chain: from raw hide preservation and storing, tanneries, chemical suppliers, footwear, leather apparel and leather goods, brand houses and retailers. Close upstream and downstream communication is mandatory. Now more than ever they have to share similar or identical concerns.

REACH regulations have to be considered also by all non-EU tanneries unless they are sure that neither their leather nor articles made thereof will be marketed in EU, they have to observe the REACH regulations; leather and leather goods containing non-registered or restricted and, in particular, substances of very high concerned (SVHC) exceeding certain concentrations and total volumes cannot be imported into the EU.
It is beyond any doubt that REACH regulative framework opens a new chapter in use but possibly much more in distribution of information on *substances* and *preparations* and their presence in articles.

Evidently, the main brunt of the extensive testing and documentation work will be borne by producers of chemicals whereas the cost is likely to be passed on *downstream users* such as leather and leather products companies.

Inevitably, primarily tanneries but also footwear, apparel and leather goods producers acting globally will have to upgrade their occupational health and safety at work (OSH) and chemicals management systems. Most of them will have to introduce a rather new segment: passing the information to buyers/the only representative in the EU market/consumers on any potential risks arising from the presence of some *substances* present in *articles*.

12. References

DIRECTIVE 2006/121/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency,
Official Journal of the European Union 30.12.2006

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
Official Journal of the European Union 29.5.2007

European Chemical Agency http://echa.europa.eu/; info@echa.europa.eu;
http://guidance.echa.europa.eu/guidance_en.htm;

ECHA Guidance documents:
Guidance on registration, Guidance on data sharing, Guidance on C&L notification, Guidance for articles, Guidance for Downstream Users, Guidance on authorisation application, Guidance on Socio-Economic Analysis – Authorisation, Guidance on evaluation, Guidance on Annex XV for C&L, Guidance on identification of SVHC, Guidance on Annex XIV inclusion, Guidance on Annex XV for restrictions, Guidance on Socio-Economic Analysis – Restrictions, Guidance on substance identification, Guidance on Classification, Packaging and Labelling, Guidance on information requirements and chemical safety assessment
http://echa.europa.eu/restrictions
http://echa.europa.eu/chem_data/candidate_list_en.asp;
http://guidance.echa.europa.eu/authorisation_en.htm
http://echa.europa.eu/home_en.asp
http://ec.europa.eu/dgs/jrc/
http://echa.europa.eu/reach_en.asp).
Registered substances can be found at:
http://echa.europa.eu/doc/LRnom_monit.xml
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Leather International Magazine
http://www.chinaleather.org/download/2-6/2-214.pdf
http://www.blcleathertech.com/blc_Leather_REACH_Testing.aspx
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www.ima-reach-hub.eu
DMF in footwear:
http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/190
http://textilebulletin.blogspot.com/2009/03/ban-of-dimethyl-fumarate-dmf.html
http://www.specchemonline.com/Default.aspx.LocID-05ynew03q.RefLocID-05y004001.Lang-EN.htm
http://www.satra.co.uk/bulletin/article_view.php?id=229
http://www.prlog.org/10349724-himfrcome-reports-ningbo-good-footwear-exports.html

Some other links:
http://www.blcleathertech.com
http://www.thereachcentre.com
http://www.encapafrica.org/EGSSAA/leather.pdf
http://www.g-forse.com/archive/news341_e.html
http://www.nikebiz.com/responsibility/considered_design/restricted_substances.html
http://www.encyclopedia.com/doc/1G1-189938979.html
www.reach-support.com

APPENDICES

The appendices attached provide some supplementary and/or more detailed information on the topics covered in the body of the report.

Appendix 1 SELECTED ARTICLES FROM THE EU REACH REGULATIONS

(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.

(6) This Regulation should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.

(14) This Regulation will generate information on substances and their uses. Available information, including that generated by this Regulation, should be used by the relevant actors in the application and implementation of appropriate Community legislation, for example that covering products, and Community voluntary instruments, such as the eco-labelling scheme. The Commission should consider in the review and development of relevant Community legislation and voluntary instruments how information generated by this Regulation should be used, and examine possibilities for establishing a European quality mark.

(17) All available and relevant information on substances on their own, in preparations and in articles should be collected to assist in identifying hazardous properties, and recommendations about risk management measures should systematically be conveyed through supply chains, as reasonably necessary, to prevent adverse effects on human health and the environment. In addition, communication of technical advice to support risk management should be encouraged in the supply chain, where appropriate.

(18) Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, in particular for SMEs.

(19) Therefore, the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency. Registered substances should be allowed to circulate on the internal market.

(20) The evaluation provisions should provide for follow-up to registration, by allowing for checks on whether registrations are in compliance with the requirements of this Regulation and if necessary by allowing for generation of more information on the properties of substances. If the Agency in cooperation with the Member States considers that there are grounds for considering that a substance constitutes a risk to human health or the environment, the Agency should, after having included the substance in the Community rolling action plan for substance evaluation, relying on the competent authorities of Member States, ensure that this substance is evaluated.

(25) The responsibility to assess the risks and hazards of substances should be given, in the first place, to the natural or legal persons that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Natural or legal persons handling chemicals should take the necessary risk management measures in accordance with the assessment of the risks of substances and pass on relevant recommendations along the supply chain. This should include describing, documenting and notifying in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance.

(26) In order to undertake chemical safety assessments of substances effectively, manufacturers and importers of substances should obtain information on these substances, if necessary by performing new tests.

(28) Scientific research and development normally takes place in quantities below one tonne per year. There is no need to exempt such research and development because substances in those quantities do not have to be registered in any case. However, in order to encourage innovation, product and process oriented research and development should be exempted from the obligation to register for a certain time period where a substance is not yet intended to be placed on the market to an indefinite number of customers because its application in preparations or articles still requires further research and development performed by the potential registrant himself or in cooperation with a limited number of known customers. In addition, it is appropriate to provide for a similar exemption to downstream users using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

(45) The European Inventory of Existing Commercial Chemical Substances (EINECS) included certain complex substances in a single entry. UVCB substances (substances of unknown or variable composition, complex reaction

products or biological materials) may be registered as a single substance under this Regulation, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification.

(55) Manufacturers and importers of a substance on its own or in a preparation should be encouraged to communicate with the downstream users of the substance with regard to whether they intend to register the substance. Such information should be provided to a downstream user sufficiently in advance of the relevant registration deadline if the manufacturer or importer does not intend to register the substance, in order to enable the downstream user to look for alternative sources of supply.

(56) Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. This important responsibility should also apply throughout the supply chain to enable all actors to meet their responsibility in relation to management of risks arising from the use of substances.

(58) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if those uses are not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks. For the same reason, downstream users should manage the risks arising from their uses of substances. In addition, it is appropriate that any producer or importer of an article containing a substance of very high concern should provide sufficient information to allow safe use of such an article.

(76) Experience at international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case-by-case basis. The criteria in Annex XIII should be reviewed taking into account the current and any new experience in the identification of these substances and if appropriate, be amended with a view to ensuring a high level of protection for human health and the environment.

(82) To allow effective monitoring and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance.

Appendix 2 REGULATION (EC) No 1907/2006, TABLE OF CONTENTS

APPENDIX 3 CHAPTER 2, DEFINITIONS AND GENERAL PROVISION

For the purposes of this Regulation:

1. ***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;

2***. preparation***: means a mixture or solution composed of two or more substances;

3. ***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;

4. ***producer of an article***: means any natural or legal person who makes or assembles an article within the Community;

7. ***registrant***: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

9. **manufacturer**: means any natural or legal person established within the Community who manufactures a substance within the Community;

10. ***import***: means the physical introduction into the customs territory of the Community;

13. ***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. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2 (7)(c) shall be regarded as a downstream user;

14. ***distributor***: means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;

15. ***intermediate***: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis).

16. ***site***: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

17. ***actors in the supply chain***: means all manufacturers and/or importers and/or downstream users in a supply chain;

18. ***Agency***: means the European Chemicals Agency as established by this Regulation;

19. ***competent authority***: means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

20. ***phase-in substance***: means a substance which meets at least one of the following criteria:

(a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
(b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;
(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation.

21. ***notified substance***: means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;

24. ***use***: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

26. ***identified use***: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

27. ***full study report***: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

30. **per year**: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;

31. ***restriction***: means any condition for or prohibition of the manufacture, use or placing on the market;

32. ***supplier of a substance or a preparation***: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;

33. ***supplier of an article***: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;

34. ***recipient of a substance or a preparation***: means a downstream user or a distributor being supplied with a substance or a preparation;

35. ***recipient of an article***: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;

36. ***SME***: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium sized enterprises;

37. ***exposure scenario***: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

38. ***use and exposure category***: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

39. ***substances which occur in nature***: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

40. ***not chemically modified substance***: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;

Article 4, **General provision**

Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

Appendix 4 SOME RESTRICTED SUBSTANCES (REGULATIONS, ANEX XVII)

(Selected items of particular interest to the leather industry)

22. Pentachlorophenol and its salts and esters

1. Shall not be used in a concentration equal to or greater than 0,1 % by mass in substances or preparations placed on the market.

2. Transitional provisions (*omitted as not relevant for this paper*)

23. Cadmium and its compounds

42. Alkanes, C_{10}-C_{13}, chloro (short-chain chlorinated paraffins)

Shall not be placed on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 %:
— in metalworking,
— for fat liquoring of leather.

47. Cement and cement-containing preparations shall not be used or placed on the market, if they contain, when hydrated, more than 0,0002 % soluble chromium VI of the total dry weight of the cement.

46. (a) Nonylphenol $C_6H_4(OH)C_9H_{19}$
(b) Nonylphenol ethoxylate $(C_2H_4O)_nC_{15}H_{24}O$

Shall not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0,1 % by mass for the following purposes:

(1) industrial and institutional cleaning except:
— controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,
— cleaning systems with special treatment where the washing liquid is recycled or incinerated;
(2) domestic cleaning;
(3) 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);

Point 28 — Carcinogens: category 1 & 2

Chromium (VI) trioxide, Potassium dichromate, Ammonium dichromate, Sodium dichromate anhydrate , Sodium dichromate, dehydrate, Chromyl dichloride; chromic oxychloride, Potassium chromate, Calcium chromate, Chromium III chromate; chromic chromate, Chromium (VI) compounds, with the exception of barium chromate and of compounds specified elsewhere in Annex I to Directive, Sodium chromate, Chromium (VI) trioxide, Potassium dichromate, Ammonium dichromate, Sodium dichromate anhydrate, Sodium dichromate, dehydrate, Chromyl dichloride; chromic oxychloride, Potassium chromate, Sodium chromate

Point 30 — Toxic to reproduction: category 2

Potassium dichromate, Ammonium dichromate, Sodium dichromate anhydrate, Sodium dichromate, dehydrate, Sodium chromate

Azocolourants

1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:
— clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags,
— footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,
— textile or leather toys and toys which include textile or leather garments

Note 1:

There are also specific restrictions pertaining to use of benzene, lead carbons and sulphates. Restrictions for mercury and arsenic containing compounds are mainly related to marine activities. Formaldehyde as such is not listed.

Note 2:

1. In the original text, whenever possible, all substances listed are designated by their EINECS (European Inventory of Existing Commercial Chemical Substances) or ELINCS (European List of Notified Chemical Substances) names. These are referred to as EC numbers in the table. Other entries not listed in EINECS or ELINCS are designated using an internationally recognised chemical name (e.g. ISO, IUPAC). An additional common name is included in some cases.
Their Index number (the identification code given to the substance in Annex I of Directive 67/548/EEC), EINECS number (the code starts at 200-001 8), ELINCS number (it starts at 400-010-9) and the CAS number (Chemical Abstracts Service) are also provided for easy and accurate identification.

2. Derived no-effect level (DNEL); predicted no-effect concentration (PNEC)

Appendix 5 ANNEX XIII CRITERIA FOR THE IDENTIFICATION OF *PBT* AND *vPvB*-SUBSTANCES (*PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES*)

This Annex lays down the criteria for the identification of:

(i) persistent, bioaccumulative and toxic substances (PBT-substances), and
(ii) very persistent and very bioaccumulative substances (vPvB-substances).

A substance is identified as a PBT substance if it fulfils the criteria in Sections 1.1, 1.2 and 1.3. A substance is identified as a vPvB substance if it fulfils the criteria in Sections 2.1 and 2.2. This annex shall not apply to inorganic substances, but shall apply to organo-metals.

1. PBT-SUBSTANCES

A substance that fulfils all three of the criteria of the sections below is a PBT substance.

1.1. **Persistence**

A substance fulfils the persistence criterion (P-) when:

— the half-life in marine water is higher than 60 days, or
— the half-life in fresh- or estuarine water is higher than 40 days, or
— the half-life in marine sediment is higher than 180 days, or
— the half-life in fresh- or estuarine water sediment is higher than 120 days, or
— the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

1.2. **Bioaccumulation**

A substance fulfils the bioaccumulation criterion (B-) when:

— the bioconcentration factor (BCF) is higher than 2 000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

1.3. **Toxicity**

A substance fulfils the toxicity criterion (T-) when:

— the long-term no-observed effect concentration (Noec) for marine or freshwater organisms is less than 0,01 mg/l, or
— the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
— there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

2. vPvB-SUBSTANCES

A substance that fulfils the criteria of the sections below is a vPvB substance.

2.1. **Persistence**

A substance fulfils the very persistence criterion (vP-) when:

— the half-life in marine, fresh- or estuarine water is higher than 60 days, or
— the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or
— the half-life in soil is higher than 180.

2.2. **Bioaccumulation**

A substance fulfils the very bioaccumulative criterion (vB-) when:
— the bioconcentration factor is greater than 5 000.

Appendix 6 TITLE IV, INFORMATION IN THE SUPPLY CHAIN

Article 31, **Requirements for safety data sheets**

1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:
(a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or
(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or
(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

2. Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a preparation and the actor in the supply chain has prepared a chemical safety assessment for that preparation, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:
(a) in an individual concentration of ≥ 1 % by weight for nongaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance posing human health or environmental hazards; or
(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous preparations at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or
(c) a substance for which there are Community workplace exposure limits.

4. The safety data sheet need not be supplied where dangerous substances or preparations offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

5. The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State(s) concerned provide otherwise.

6. The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/preparation and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI. Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).

8. A safety data sheet shall be provided free of charge on paper or electronically.

9. Suppliers shall update the safety data sheet without delay on the following occasions:
(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
(b) once an authorisation has been granted or refused;
(c) once a restriction has been imposed.
The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

Article 32

Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required

1. Any supplier of a substance on its own or in a preparation who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:
(a) the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;
(b) if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;
(c) details of any restriction imposed under Title VIII;
(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex XI.

2. The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a preparation after 1 June 2007.

3. Suppliers shall update this information without delay on the following occasions:
(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
(b) once an authorisation has been granted or refused;
(c) once a restriction has been imposed.
In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

Article 33, **Duty to communicate information on substances in articles**

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and

identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, 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 days of receipt of the request.

Article 34, **Duty to communicate information on substances and preparations up the supply chain**

Any actor in the supply chain of a substance or a preparation shall communicate the following information to the next actor or distributor up the supply chain:
(a) new information on hazardous properties, regardless of the uses concerned;
(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses. Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 35, **Access to information for workers**

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or preparations that they use or may be exposed to in the course of their work.
Article 36, **Obligation to keep information**

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or preparation. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the Agency, without prejudice to Titles II and VI.

2. In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or preparation concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

Appendix 7 CHEMICAL SAFETY REPORT FORMAT

CHEMICAL SAFETY REPORT FORMAT

PART A

1. SUMMARY OF RISK MANAGEMENT MEASURES
2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED
3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

PART B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

2. MANUFACTURE AND USES
   - 2.1. Manufacture
   - 2.2. Identified uses
   - 2.3. Uses advised against
3. CLASSIFICATION AND LABELLING

4. ENVIRONMENTAL FATE PROPERTIES
   - 4.1. Degradation
   - 4.2. Environmental distribution
   - 4.3. Bioaccumulation
   - 4.4. Secondary poisoning

5. HUMAN HEALTH HAZARD ASSESSMENT
   - 5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)
   - 5.2. Acute toxicity
   - 5.3. Irritation
     - 5.3.1. Skin
     - 5.3.2. Eye
     - 5.3.3. Respiratory tract
   - 5.4. Corrosivity
   - 5.5. Sensitisation
     - 5.5.1. Skin
     - 5.5.2. Respiratory system
   - 5.6. Repeated dose toxicity
   - 5.7. Mutagenicity
   - 5.8. Carcinogenicity
   - 5.9. Toxicity for reproduction
     - 5.9.1. Effects on fertility
     - 5.9.2. Developmental toxicity
   - 5.10. Other effects
   - 5.11. Derivation of DNEL(s)

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES
   - 6.1. Explosivity
   - 6.2. Flammability
   - 6.3. Oxidising potential

7. ENVIRONMENTAL HAZARD ASSESSMENT
   - 7.1. Aquatic compartment (including sediment)
   - 7.2. Terrestrial compartment
   - 7.3. Atmospheric compartment
   - 7.4. Microbiological activity in sewage treatment systems

8. PBT AND VPVB ASSESSMENT

CHEMICAL SAFETY REPORT FORMAT

9. EXPOSURE ASSESSMENT
    - 9.1. (Title of exposure scenario 1)
        - 9.1.1. Exposure scenario
        - 9.1.2. Exposure estimation
    - 9.2. (Title of exposure scenario 2)
        - 9.2.1. Exposure scenario
        - 9.2.2. Exposure estimation
        - (etc.)

10. RISK CHARACTERISATION
    - 10.1. (Title of exposure scenario 1)
        - 10.1.1. Human health
            - 10.1.1.1. Workers
            - 10.1.1.2. Consumers
            - 10.1.1.3. Indirect exposure to humans via the environment
        - 10.1.2. Environment
            - 10.1.2.1. Aquatic compartment (including sediment)
            - 10.1.2.2. Terrestrial compartment
            - 10.1.2.3. Atmospheric compartment
            - 10.1.2.4. Microbiological activity in sewage treatment systems
    - 10.2. (Title of exposure scenario 2)
        - 10.2.1. Human health
            - 10.2.1.1. Workers
            - 10.2.1.2. Consumers
            - 10.2.1.3. Indirect exposure to humans via the environment
        - 10.2.2. Environment
            - 10.2.2.1. Aquatic compartment (including sediment)
            - 10.2.2.2. Terrestrial compartment
            - 10.2.2.3. Atmospheric compartment
            - 10.2.2.4. Microbiological activity in sewage treatment systems\
            - (etc.)
    - 10.x. Overall exposure (combined for all relevant emission/release sources)
        - 10.x.1. Human health (combined for all exposure routes)
            - 10.x.1.1.
        - 10.x.2. Environment (combined for all emission sources)
            - 10.x.2.1.

Appendix 8 ECHA CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN (SVHC)

STATUS DEC 2009 (REGULATIONS, ANNEX XIII)

Substance name	EC (CAS No.)	Reason for inclusion	Examples of use/found in/potential use
Triethyl arsenate	427-700-2	Carcinogenic (article 57a)	Cosmetics, biocide, glass beads for road markings, plastic/PVC products (including garden articles, travel/leisure time articles, electronic equipment (EEE) etc.
Anthracene	204-371-1	PBT (article 57d)	Plastic and rubber products Preservative used in wood and coating.
4,4'- Diaminodiphenylmethane (MDA) *	202-974-4	Carcinogenic (article 57a)	Textiles, shoes, polyurethane (PU) Hardener, epoxy resins and adhesives
Dibutyl phthalate (DBP)	201-557-4	Toxic for reproduction (article 57c)	Plasticiser, PVC, synthetic leather Floor covering, primary packaging of medicinal products; in adhesives & paints.
Cobalt dichloride	231-589-4	Carcinogenic (article 57a)	Paints and inks Moisture indicator
Diarsenic pentaoxide	215-116-9	Carcinogenic (article 57a)	Colorants, glass and wood
Diarsenic trioxide	215-481-4	Carcinogenic (article 57a)	Glass and wood products, electronics.
Sodium dichromate	234-190-3 (7789-12-0 and 10588-01-9)	Carcinogenic, mutagenic and toxic to reproduction (articles 57a, 57b and 57c)	Leather tanning – leather products, pigments
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) *	201-329-4	vPvB (article 57e)	Fragrances - detergents, fabric softeners and conditioners.
Bis (2-ethylhexyl)phthalate (DEHP) *+ (Dibutyl phtalate,DBP* + Benzil butyl phtalate, BBP*)	204-211-0	Toxic to reproduction (article 57c)	Plasticisers, PVC, paints, synthetic leather Floor covering, packaging; in adhesives & paints.

Substance name	EC (CAS No.)	Reason for inclusion	Examples of use/found in/potential use
Hexabromocyclododecane (HBCDD) and all major diastereoisomers *	247-148-4 and 221-695-9	PBT (article 57d)	Hard plastics, textiles applications. Flame retardant - polystyrene; insulation panels/boards or packaging
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) *	287-476-5	PBT and vPvB (article 57d - e)	Flame retardant and/or plasticizer; leather, high performance rubber, sealants, textiles coating, adhesives
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT (article 57d)	Textiles, leather. Wood preservative, marine anti-biofouling agents.
Lead hydrogen arsenate	232-064-2	Carcinogenic and Toxic to reproduction (articles 57a and c)	Biocide – wood treatment ; plant insecticides
Benzyl butyl phthalate (BBP) *	201-622-7	Toxic to reproduction (article 57c)	Plasticiser. PVC, rubber, synthetic leather; leather coating; sealants, inks, adhesives

* ***Prioritised by ECHA to be included in the list of substances requiring authorisation (Annex XIV or Authorisation List)***

ECHA - 15 new substances of very high concern to be officially added to the Candidate List in January 2010:

1. – 5. Various categories of anthracene oils and anthracene paste under different CAS numbers
6. Pitch, coal tar, high temp.
7. Acrylamide
8. Aluminosilicate, Refractory Ceramic Fibres
9. Zirconia Aluminosilicate, Refractory Ceramic Fibres
10. 2,4-Dinitrotoluene
11. Diisobutyl phthalate
12. Lead chromate .
13. Lead chromate molybdate
14. Lead sulfochromate yellow (C.I.
15. tris (2-chloroethyl)phosphate

Decisions on the need to subject these substances to authorisation will be taken later.

Appendix 9 AVAILABILITY OF INFORMATION IN THE SUPPLY CHAIN

INFORMATION / REACH ACTOR	RELEVANT INFORMATION THAT MUST BE PROVIDED 'AUTOMATICALLY' FOR NON-CLASSIFIED SUBSTANCES / PREPARATIONS	RELEVANT INFORMATION THAT MUST BE PROVIDED 'AUTOMATICALLY' IF SUBSTANCE/ PREPARATION IS CLASSIFIED	RELEVANT INFORMATION THAT MAY BE PROVIDED ON A VOLUNTARY BASIS
Substance manufacture /importer (registrant)	Substance name (label). If non-classified SVHC on candidate list (Article 32) information: registration number, specific risk management information.	Substance name, registration number, classification, relevant registered uses	Information on the identification of a substances, e.g. composition, impurities etc. All registered uses.
EU supplier of preparations	Name of preparation and contact information (label). If SVHC(s) on candidate list are contained above cut-off limits in Article 14: registration numbers and specific risk management information.	If above cut-off limits of Article 14: name and registration number of classified substances and SVHC on the candidate list, their concentration ranges in the preparation, risk management measures, relevant uses of the preparation	Identity of suppliers of substances and preparations used to produce the preparation. Exact amount of substances and preparations in the preparation
EU article producer (user substances /preparations)	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	Identification and amounts of substances / preparations included in the article and the identity of their suppliers
Article distributor /retailer	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	Identity of article producer
Only representative or article supplier outside the EU	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	If SVHC(s) on candidate list in concentrations above 0.1%, sufficient available information to enable safe use	Identity of article producer

Appendix 10 REACH AND ITS IMPACT ON THE EUROPEAN LEATHER INDUSTRY

The Round Table organised by COTANCE, sponsored by Lineapelle and co-hosted by GERIC (association of European leather technical centres) held in Bologna in October 2008, considered the likely consequences of REACH regulations on the European leather sector. IULTCS also participated in the Round Table. Below are the salient points of the conclusions of the meeting.

- REACH raises a big question regarding how it will affect the leather industry and the leather trade. At present this is just one of a number of uncertainties, including first the oil crisis, and then the financial crisis, with its accompanying major fluctuations in currencies.
- While the leather industry is growing – production is up overall by some 30% over the last 25 years, the growth has been focused in the developing countries.
- There are still some 3000 tanners in Europe producing 250 million square metres of leather with a value of around 8 billion Euros, and the market for leather chemicals in Europe is worth 1 billion Euros. This is a valuable market.
- While the largest share of the leather trade is as a commodity, Europe's production and trade is an exception to this, because it produces and trades leather as a high value product.
- REACH should put an end to the use of sub-standard chemicals in Europe, and everyone should benefit from this.
- Competition outside Europe is not going to be a level playing field for tanners or chemical suppliers – unless the authorities in other regions follow the lead set by Europe.
- One of the biggest fears for the European leather industry is the potential deselection of chemicals for reasons of cost and administrative time, rather than health and safety, along with concerns about the impact on the development of new formulations.
- The other major concern is the potential for imports of articles containing unregistered substances, at a time when there are already some examples of health and safety problems for consumers caused by imported products.
- This raises the joint threat of unfair competition and of devaluing the product, and the whole chain needs to work together to make sure that this does not happen.
- Co-operation throughout the chain is vital and the tanning industry needs to work closely with the chemical industry. The industry needs continued access to the chemicals required to make their high quality leathers, to remain competitive with overseas suppliers and to maintain their market position with their customers.

A further view from the chemical industry:

"REACH is not a threat. It is a bureaucratic monster that will take up resources that could be better utilised elsewhere. It is the brands and the ecolabels that pose the biggest risk; they are proactive at proposing standards, but often without the knowledge or understanding of what they are dealing with." Furthermore:

- Is the challenge of REACH over? No, it is just beginning.
- Deadlines:

2010 : Registration of chemicals sold at amounts over 1000 tonnes should not be a problem, these would all be registered.

2013: Registration of chemicals over 100 tonnes – the leather industry might begin to see some impact in relation to the chemicals available

2018: Registration of chemicals over 1 tonne – the process would then be complete and the tanning industry would see some further effects

- The general view was that the initial list of Substances of Very High Concern (SVHCS) did not include any substances that would be expected to be found in most types of leather, at the level of 1000 ppm or 0.1% by weight.

Appendix 11 CONSUMERS' PROTECTION - EU BAN ON DIMETHYLFUMARATE (DMF)

(*In consumer products such as sofas and shoes*)

An interesting example of EU mechanism of monitoring and control of chemical substances outside REACH is the case of EU ban on dimethylfumarate (DMF) in consumer products, such as sofas and shoes. According to the European Directive (2009/251/EC) of 17 March 2009, products containing DMF in one or more pouches or in a concentration greater than 0.1 mg/kg of the weight of the product or part of the product cannot be sold anymore; those already on the market were to be withdrawn by 1 May 2009 and consumers to be made aware of the potential risks.

The motive for such decision have been claims from France, Finland, Poland, Sweden and the UK, supported by TV coverage, that consumers exposed to products containing DMF, had experienced serious health problems including skin itching, irritation, redness, burns and, in some cases, acute respiratory difficulties.

The credit for quick reaction leading to this decision is given to the Rapid Alert System for Dangerous Non-food Consumer Products (RAPEX).

Dimethylfumarate (DMF) is used by producers as a biocide to kill moulds that may cause furniture or shoe leather to deteriorate during storage and transportation in a humid climate. Placed in sachets, which are fixed inside the furniture or added to the footwear boxes (similar to those containing silica gel desiccant), DMF evaporates and impregnates the leather*, protecting it from moulds. However, it has been found to seriously affect consumers who were in contact with the products. DMF penetrated through the clothes onto the skin of many consumers, where it caused painful dermatitis. Concentrations as low as 1ppm may produce allergic reactions and there are only a few of equally potent sensitisers. The fact that in serious cases it produces extensive, pronounced eczema that is difficult to treat. The presence of DMF is thus a serious risk.

DMF has been found to sensitise human skin at very low concentrations, DMF is already banned for use in the manufacture of goods in the EU, since biocidal products containing DMF are not authorised under the Biocides Directive (98/8/EC). However, manufacturers outside the EU may

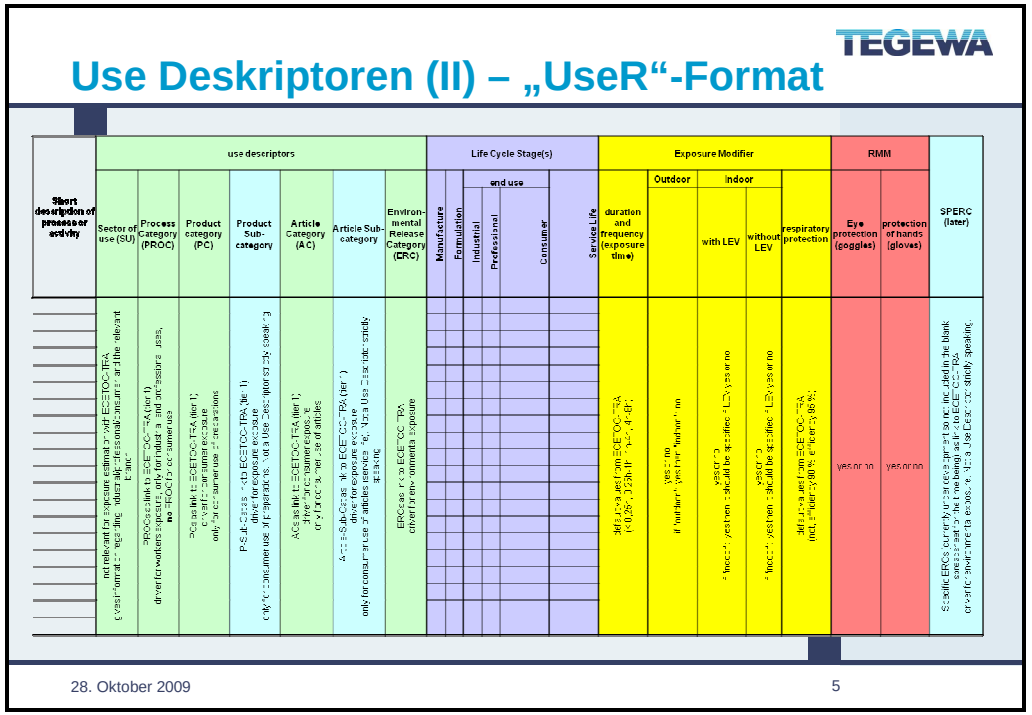
use these unauthorised biocides and then export their products to the EU. Thus, this Decision is expected to protect EU consumers from the risk of DMF in imported products in the same way as they are protected at home.

It is quite interesting that dimethyl fumarate is used to treat the skin condition psoriasis, as well as other medical conditions where it is administered orally. It is a lipophilic, highly-mobile molecule in human tissue. Tests have also been conducted as part of research into DMF with the aim of using it as part of a specific cancer treatment.

However, some tests have found that whilst DMF is volatile at temperatures above 50ºC (which may be encountered by footwear during transit), it is not absorbed by footwear and furniture materials such as leather, foam and textile.

http://ec.europa.eu/consumers/safety/rapex/index_en.htm

Appendix 12 ECHA USE DESCRIPTORS



Source: Association of the Textile Auxiliaries, Tanning Agents and Detergent Materials, TEGEWA, Germany

on behalf of the

REACH Lime Consortium

LIME SUBSTANCES

REACH DOWNSTREAM USER SURVEY

Introduction:

The EU REACH Regulation (EC No. 1907/2006), is essentially about ***safe use*** of chemical substances. As such, for each lime substance, manufacturers/importers need to develop Exposure Scenarios for inclusion in the REACH Chemical Safety Report that will be submitted to the European Chemicals Agency (ECHA) for substance Registration.

The purpose of this questionnaire is to collect the information necessary for developing Exposure Scenarios for uses of lime substances, including operational conditions, risk management measures and processes. It is also an important communication tool for **Downstream Users** seeking to comply with certain of their REACH obligations (see page 2).

Substances covered:

Chemical name	EINECS	CAS
Calcium oxide	215-138-9	1305-78-8
Calcium dihydroxide	215-137-3	1305-62-0
Calcium, magnesium oxide	253-425-0	37247-91-9
Calcium magnesium tetrahydroxide	254-454-1	39445-23-3
Dolomite calcined	281-192-5	83897-84-1
Calcium magnesium (di)hydroxide oxide	261-235-4	58398-71-3
Lime (chemical) hydraulic	285-561-1	85117-09-5

Notes on confidentiality:

The information provided in this questionnaire will be treated as confidential and only used for the purpose of compiling the Chemical Safety Assessment and Report for the REACH registration dossiers for Lime substances. The company identity and individual company data will remain strictly confidential to the Coordinator of the REACH Lime Consortium (i.e. IMA-Europe) and to the consultants engaged by the REACH Lime Consortium (i.e. ARCHE and EBRC) in the development of the registration dossiers. All data received will be reported in an aggregated and anonymised format only.

Technical notes on completing the questionnaire:

This questionnaire is specifically designed to be completed and submitted electronically, to enable automated data-transfer. Kindly avoid submission of hard copies under all circumstances.

This involves the use of specific input in the form of text fields, checkboxes and pull-down menus. Please note that entries in this questionnaire can only be made in these fields, which can be identified by their grey-coloured background. Pull-down menus with pre-selected items are included to facilitate your responses. However, most of these pull-down menus offer the possibility to select "Other". If "Other" is selected in any of these menus, you are kindly asked to specify information in a neighbouring text field.

This questionnaire is intended to be used on a substance- specific and sector-specific basis: Please use one questionnaire per substance and sector.

Please respond by sending your completed questionnaire to IMA-Europe via e-mail:
s.clarena@ima-europe.eu

Submission deadline: Friday, 18 December 2009

Summary of some of the pertinent obligations of a Downstream User (DU)[1]

A Notify identified uses to the supplier

A DU should notify its use(s) to its supplier(s) with the aim of encouraging its supplier(s) to include the use as an '**identified use'** in the Chemical Safety Report. The DU should provide the supplier(s) with sufficient information to allow the supplier(s) to prepare an Exposure Scenario (Art. 37.3). It is important to note that provision of the information on the manufacture and use(s) of the substance is mandatory in the REACH technical dossier, as specified in Art. 10 a) iii and i Annex VI, section 3 of REACH in order for the use to remain an "approved" use of the substance in the EU. If the use is not included as an identified use in the registration dossier submitted by the supplier(s), then the DU will no longer be permitted to use the Lime substance for that downstream use, **unless it submits the required information itself** (see below regarding DU submissions).

N.B.: The DU has **the right not to disclose uses** for commercial reasons (= unidentified use). In such cases the DU has to develop its own assessment and prepare a Chemical Safety Report (CSR), which it must **notify to ECHA and to its supplier.** This same process is available to the DU where the supplier(s) submitting the registration dossier do not include a particular use as an identified use.

If the DU uses the substance as an **intermediate** to produce another substance, it is advisable for the DU to mention this to its supplier, because the requirements under REACH may be different. If the initial intermediate manufacturer/importer can demonstrate that the intermediate is produced, transported and used under *strictly controlled conditions* along the supply chain, then the REACH information requirements for that substance (intermediate) are substantially reduced. It is therefore crucial for the manufacturer/importer of the intermediate to identify and exchange information with its DUs. The manufacturer/importer would need sufficient information from the DU to substantiate the strictly controlled conditions are adhered to by the DU.

B Provide workplace exposure data or exposure data on product use

In making a use known, the DU shall provide his supplier with all the relevant data needed to prepare an Exposure Scenario (ES). These data will allow the supplier to perform the occupational, environmental and product use assessments, for the objective of determining safe use. The main purpose of this questionnaire is to contribute to this obligation. It should be noted that an Exposure Scenario will generally be driven by the type of exposure resulting from the manufacturing and/or use of a substance and therefore, an Exposure Scenario can include one or several identified uses.

C Communicate the information throughout the supply chain:

A DU that has sold a substance (on its own, in a preparation or in an article) to other DUs or distributors further down the supply chain needs to provide them with information on this substance. The DU itself should implement the necessary Risk Management Measures in accordance with the assessment of the risks of substances (see above) and pass on relevant recommendations along the supply chain. This should include describing, documenting and notifying, in an appropriate and transparent fashion, the risks stemming from the production, use and disposal of each substance.

Communication up the supply chain is also essential to ensure that the supplier (manufacturer or importer) is taking your use into account when they fulfil their requirements for Registration. (i.e. that the use is included in the Chemical Safety Report). If the use is not included, then the relevant substance can no longer be used in that downstream use, unless the DU separately prepares and submits the necessary information to ECHA itself.

[1] This informal summary is provided for the convenience of the DU only and does not represent a legally binding interpretation of the DU's obligations under REACH. The REACH Lime Consortium and IMA hereby disclaim any liability whatsoever arising out of a DU's reliance on the information provided in this Summary. DUs are encouraged to review the REACH legislation carefully and to consult with their expert advisers to determine their obligations under REACH.

D Obligation of manufacturers or importers to include an identified use in the registration dossier

The REACH Lime Consortium will be working to assist the manufacturers and importers of the relevant lime substances to prepare their registration dossier and related materials to be submitted to ECHA for purposes of REACH registration.

The REACH Lime Consortium intends to include all downstream uses as "identified uses" in the registrations dossier of the appropriate substance. Where, having assessed the use(s) in accordance with Article 14 (CSR and RMMs), we are unable to include it as an identified use for reasons of protection of human health or the environment, we shall provide ECHA and affected Downstream Users with the reason(s) for that decision in writing and without delay in accordance with Article 37(3).

E REACH Definitions

Downstream User: means a 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**. A distributor or a consumer is not a downstream user.

Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.

Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an intermediate downstream user.

F Further information

REACH Guidance for **'Downstream Users'** is available from the European Chemicals Agency on:

http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm

Specific information regarding the REACH Lime Consortium and the list of lime uses is available from the IMA-REACH-Hub:

http://www.ima-reach-hub.eu