



REACH, a ground-breaking EU Regulation

Dr. Alois Püntener

VESLIC (Association of Swiss Leather Chemists and Technologists)

On October 29, 2003, the European Commission adopted a proposal for a new EU regulatory framework for chemicals. Under the proposed new system called REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), enterprises that manufacture or import more than one tonne of a chemical substance per year will be required to register it in a central database.

The aim of the proposed new regulation is to improve the protection of human health and the environment, while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. REACH will also put industry under greater responsibility for managing the risks from chemicals, and for providing safety information on the substances. This information will be passed down the chain of production. The so-called 'downstream user', such as a tannery, will also have to perform new tasks. In particular, they will have to check that the chemicals being used are covered by the Safety Data Sheets (SDS) and the chemicals used must meet the conditions described in the exposure scenarios in the Annex to the Safety Data Sheets.

The status of REACH today

The first reading in the European Parliament took place on November 17, 2005. Following its political agreement on December 13, 2005, the Commission Communication stating the Commission's opinion on the Common Position of the Council and Parliament was adopted on July 12, 2006 (Inter-institutional File: 2003/0256 (COD)).

At the time of writing (mid-November 2006), the final adoption of the REACH legislation is expected by the end of 2006. The current timetable for REACH is set down as *Panel 1*.

Panel 1:

The Timetable for REACH

Date	Activity
September 2006	Second reading
October 10, 2006	Vote in the Environment Committee
Mid-December 2006	Vote in Parliament
End of December 2006	Vote in the Council
Beginning of 2007	REACH comes into force

If the Parliament and Council fail to agree, a special Conciliation Committee will be convened to iron out any remaining differences. Nevertheless, it is estimated that the REACH legislation will come into force around April 2007. The new European Chemicals Agency has to be fully operational 12 months after the legislation is brought into effect, and must co-ordinate all activities between industry and the Member States.

The Environment Committee of the Parliament has accentuated the existing compromise by adding stricter criteria. Given that the Environment Committee often has a different

approach to the Plenary, it is noted that the Parliament's chief negotiator on REACH, the Italian socialist Guido Sacconi MEP, received a massive show of support at the Parliament's Environment Committee on October 10, winning 42 votes out of 63. The position of Mr. Sacconi remains the most outstanding and divisive issue. If the modified version of the Environment Committee is adopted in the Plenary, it will create very serious problems for the whole European industry.

The stricter criteria for granting authorisation and mandatory substitution, even when there is no alternative, will lead to the banning of certain substances even though there are clear socio-economic benefits for the continued use of these substances, and no alternative is available. This situation could encourage a lot of producers to move out of Europe. Despite these negative aspects, on the positive side small businesses should get more support. The main elements of the stricter criteria agreed and changed by the Environment Committee are:

- Mandatory substitution of the most toxic substances whenever this is economically and socially acceptable.
- A review of the authorisations granted to these chemicals every five years in order that they are eventually replaced.
- A 'duty of care' principle to ensure that producers and importers of chemicals take responsibility for the safety of their products when the risks can be 'reasonably foreseen'.
- The introduction of a 'REACH quality label', to be proposed by the Commission after REACH is approved, so that products complying with EU law can be easily identified by consumers.
- The promotion of alternatives to animal testing.
- More support measures for small businesses.

REACH guidance

The Commission—in close co-operation with Member States, industry and other stakeholders—is preparing technical guidance documents for industry and authorities to help implementation of the future REACH regulation.

The work is being carried out in the framework of the so-called 'REACH Implementation Projects' (RIPs). RIP 3 relates to technical guidance to enable industry to develop the appropriate guidance documents and tools for industry, to facilitate a smooth implementation of the legislation. These documents are as follows:

- RIP 3: Technical Guidance Documents (TGD) and Tools for Industry
- RIP 3.1: Guidance Document on Preparing the Technical Dossier for Registration
- RIP 3.2: TGD on Preparing the Chemical Safety Report
- RIP 3.3: TGD on Information Requirements on Intrinsic Properties of Substances
- RIP 3.4: Guidance Document on Data Sharing (pre-registration)
- RIP 3.5: Guidance Document on Downstream User Requirements ➤



REACH, A GROUND-BREAKING EU REGULATION

- RIP 3.6: Guidance on Classification and Labelling under Global Harmonised System
- RIP 3.7: Guidance on Preparing an Application Dossier for Authorisation
- RIP 3.8: Guidance on Fulfilling the Requirement for Articles
- RIP 3.9: Technical Guidance Document on Carrying out a Socio-Economic Analysis or Input for One
- RIP 3.10: Technical Guidance Document for Characterisation and Checking of Substance Identity

Information on the implementation of this regulation should be easily accessible, in particular for small and medium enterprises. However, the REACH Implementation projects documents available to date are very comprehensive and may well make REACH even more complicated!

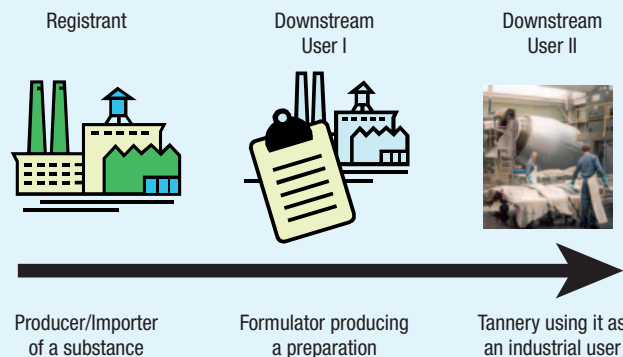
Responsible actors - all in the supply chain

Actors in the supply chain mean all manufacturers and/or importers and/or downstream users in a supply chain. Responsibility for the management of the risks of substances should lie with the Registrant. A registrant is the manufacturer or the importer of a substance.

Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process. This includes 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. *(It is noted that to*

Panel 2:

A simple supply chain



interpret this simple term the first REACH Implementation Projects draft needed approximately 100 pages.)

The registration provisions will require manufacturers and importers to generate data on the substances they manufacture or import, to use this 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 requires them to submit a dossier containing all this information to the European



I knew I should have
subscribed to **leatherbiz.com**



Chemicals Agency. This will be located in Helsinki and will have several hundred employees.

People handling chemicals, such as workers in tanneries, will need to take the necessary risk management measures in accordance with the assessment of the risks of substances and on relevant recommendations from the supply chain. A simple supply chain is given as *Panel 2*.

Risk management includes describing, documenting and notifying the risks stemming from the production, use and disposal of each substance in an appropriate and transparent fashion. Use means any processing, formulation, consumption, storage, retention, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation by a downstream user.

A distributor or a consumer is not a downstream user. The distributor, including a retailer, is a person who only stores and places a substance on the market, on its own or in a preparation, for third parties. He has the duty to inform the registrant and downstream users about the intended uses of the chemicals.

The existing SDS is already being used as a communication tool within the supply chain of substances and preparations. It will be developed further as an integral part of the system established by the REACH Regulation.

The three main stages of REACH

Part of the responsibility of the registrant for the risk

management of substances is the communication of information on these substances to other professionals such as downstream users or distributors. This important responsibility will also apply throughout the supply chain to enable all participants to meet their responsibility in relation to the management of risks arising from the use of substances. There are three stages to take into account:

- **Registration:** Importers and manufacturers of substances in quantities over one tonne per year must register their substances with the new European Chemicals Agency.
- **Evaluation:** Member State competent authorities will review registration packages and may request further information and/or testing to determine the impact of the substance on human health and the environment.
- **Authorisation/Restriction:** Decisions regarding what substances require authorisation or restriction will be carried out at EU level by the Commission for substances that pose the most concern, such as carcinogens and mutagens.

The registration is proposed to take place in three stages based on production and usage in terms of tonnage:

- 1,000 tonnes/year - must be registered within 3 years
- 100 - 1,000 tonnes/year - must be registered within 6 years
- 1 - 100 tonnes/year - must be registered within 11 years

In addition certain substances which are identified as being of very high concern to human health or the environment have to be registered early i.e. within three years. ➤

**Waterproof Chemicals
for Performance Leather**

Chemtan® R-106

Chemtan® S-35

CHEMTAN

Tel: (603) 772-3741 • Fax: (603) 772-0796 • www.CHEMTAN.com

TUV
ISO 9001



One proposal submitted jointly by the UK and Hungarian governments is 'One Substance One Registration' (OSOR). This proposal is for a system of registration that would allow groups of producers, importers and users of substances to join together and register a substance between them as a consortium. This would minimise the need for duplicate testing effort and facilitate the sharing of animal testing data, which is mandatory under REACH. Although much of the detail still needs to be confirmed regarding how such a system would work in practice, the proposal has raised much interest.

Primarily, it will be the supplier (*importer or manufacturer*) of a substance that will be responsible for registration. However, all downstream users of a substance must check that their supplier has registered the substance for their intended use. Therefore, a downstream user or distributor has to provide information to assist in the completion of a registration.

Special attention must be given if any products are purchased directly from outside of the EU. In this case the tannery is not only the downstream user but also the registrant. Foreign suppliers need to have an office in the EU for registration.

For substances manufactured or imported, or used in quantities over 10 tonnes per year (*according to the Common Position document of the Council and Parliament*), an additional more detailed Chemical Safety Report (CSR) is required as well. The company registering its substance must evaluate its impact for a range of uses and exposure scenarios. Information on the safe use of a substance or preparations must then be placed in an Annex to the SDS. However, after the Sacconi intervention, the quantities and condition requirements for establishing a Chemical Safety Report are still in discussion.

The Safety Data Sheets

SDS will be used to communicate the safe use of a substance through the supply chain. The registrant has to produce a SDS for the substance and indicate the intended use. The downstream user, who produces preparations—a mixture or solution composed of two or more substances, has to produce his own SDS.

The formulator has to include relevant exposure scenarios, and use other relevant information from the SDS supplied to him. By compiling its own SDS it has to define uses for its preparation and provide the relevant information to the users. If the intended use is not approved, the downstream user can request that his supplier register the substance for this use. If the supplier refuses, or the downstream user needs to keep the application confidential, the downstream user may directly notify the Agency and provide his own study.

The tanner as the downstream user

A tannery uses substances and preparations for the production of different leathers. Under REACH, leather is an article that receives a special shape, surface and design during production, which determines its function. Considering that leather is not made to release any chemicals—for example, the way a printer releases ink—the leather article does not come under the REACH Regulation in the same way as a printer. The tanneries have to clearly understand that leather manufacture belongs to REACH—but not the final leather product.

It is not finally decided when an exposure scenario or a chemical safety report is required. However in a simplified form, if a SDS is mandatory then one should consider a set of conditions that describe how the chemical is used during its life-cycle and recommend to the downstream users how to control it in terms of exposure to humans and the environment. These exposure scenarios may cover one

specific process or use several processes.

Any supplier of a substance or a preparation who does not have to supply a SDS because the chemical isn't a hazard, will need to provide the recipient with the following additional information:

- The REACH registration number(s)
- Whether the substance subject to authorisation or not
- Details of any restriction
- Any other relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions

However, industry associations recommend that a SDS should be supplied for all chemicals sold. The SDS, therefore, should contain the exposure scenario information. If this is not required, then the general information as described above applies.

A way forward

Industries fear the worst, due to the high registration costs of REACH and too much bureaucracy. For the tanner:

- Up to 30% of basic chemicals may disappear
- An estimated 10-20% rise in chemical costs
- 3-6% less profit on finished leather
- Confusion about exposure scenarios

The stricter criteria for REACH proposed by the Environment Committee will lead to the banning of more substances, even if there are clearly no alternatives available. This situation could encourage a lot of chemical suppliers, as well as tanneries, to move out of Europe. If the new Sacconi proposals are not accepted it may not be as bad as expected. Lobbying and a close watch on developments are imperative.

It is suggested that suppliers and tanneries should start to work together to design an easy instruction tool for tanneries' exposure scenarios. Communication between suppliers and tanneries must be optimised. The following is recommended as a target for improved communications:

- The development of a way for tanners and suppliers to handle the exposure assessment in a tannery in a robust and consistent manner
- Support of transparent (*and easy to understand*) communication within the supply chain (SDS)
- Preventing the disclosure of business information that is important for tanners and suppliers
- Providing flexibility in the uses of chemicals
- Reducing costs for registration and paperwork by suppliers and in tanneries

Industry associations (*and suppliers and tanneries*) should coordinate this work. We have to consider that the REACH Implementation Projects documents, which are now available, make REACH even more complex. One should take the first step soon as REACH will probably come into force during 2007. Finally, after the REACH regulation has been passed and the details are clearer, tanners have to discuss the REACH issue more deeply with their suppliers to make sure that the chemicals required are available and approved for their intended use in the tannery. 🌐

Sources and recommended reading:

<http://www.euractiv.com/en/HomePage>
http://ec.europa.eu/environment/index_en.htm
http://ec.europa.eu/enterprise/index_en.htm • <http://www.cefic.be/>
<http://www.europarl.europa.eu> • <http://www.reachready.co.uk>
<http://ecb.jrc.it/REACH/> • <http://www.cotance.com/reach.htm>
<http://www.vci.de/default.htm> • <http://www.reach-info.de/>