

The unavoidable implications of REACH on the leather industry

In the November 2003 issue of World Leather, readers were informed about the possible impact of pending European Chemical Legislation in the form of the REACH System (Registration, Authorisation and Restrictions of Chemicals EU Chemicals Policy) as outlined in the Internet Consultation Document published by the EU-Commission on May 15th 2003.

During the internet consultation, more than 6000 controversial comments were made regarding this document as well as from private individuals, industry, non-governmental organisations and governments.

The EU Commission Director General Enterprise and Director General Environment have reacted to this input, the original REACH Document being modified into a new draft for discussion within an Interservice Consultation. This version was finally adopted by the Commission on October 29th, the proposal being passed to the European Parliament and the Council.

Based on this document many important issues are raised, and in this paper a series of fundamental questions are addressed by Dr Schmidt-Sonnenschein of Bayer Chemicals:

Question: What are the next steps before REACH becomes law, and what might delay the process?

- Parliamentary discussion with proposals to modify the document. So far it is not clear whether the Committee on the Environment, Public Health and Consumer Policy, or industry will be responsible, but the decision is scheduled for the beginning of February 2004. Parallel to this there are negotiations in the Council of Member States. In this case the responsibility is with the Committee on Competitiveness.
- Second debate in parliament. If parliament and council cannot agree on one proposal a mediation committee will be formed. In the event that it cannot find a solution, the law-building process might still fail completely.
- European Law, planned as a decree. That is, it will immediately be valid in all member states, letter by letter, without modifications and become part of the local law system. The decree could become valid in 2006, if the first discussion in parliament is completed before the end of April, that is within this legislative period. After that, there will be European elections and the new constitution of the parliament in September 2004. The committees have to be assembled afterwards. If this schedule cannot be met the decision will be postponed into the next parliamentary period. In this event the timing is completely open again, since the ten new member states of the European Community will have to be

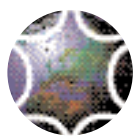
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included into the negotiations, and there is no formal time limit for the first debate.

Question: What are the most important changes compared with the Internet consultation draft of May 2003?

- From the view of the chemical industry and the tanners some changes have been made in the right direction.
- Chemical safety reports now only have to be drawn up for substances with an annual production of more than ten metric tons. This does not apply to intermediates. But, of even greater importance, those reports are only a part of the registration documents, and do not have to be forwarded along with the product to the downstream user.
- The principle of "duty of care" will be fulfilled similar to the existing system by an enlarged and standardised Material Safety Data Sheet. This refers to a chemical product as a whole and not to all ingredients as single substances.



- Polymers are (for the moment) completely exempted from registration.
- Treatment of intermediates on-site and “transported intermediates” has been simplified.
- Confidentiality has been improved. Non confidential information will no longer be actively published by the agency, and any access has to be requested. Confidential information is protected.
- The process of registration has been simplified. The agency will now decide matters concerning acceptance or denial of registration without consulting the national institutions. This will be within three weeks instead of 60 days.

Question: What has not been changed and is still a threat to the competitiveness of European industry?

- The basic concept and scope of the new draft does not differ from the older version. The process is still very complex, bureaucratic, and extensive. It does not reasonably decrease the costs connected with the registration, evaluation and authorisation of chemicals.
- The scope of the regulation is still too broadly drawn. This means that it can be at variance with other existing laws concerning certain groups of products such as pharmaceuticals, biocides or food additives.
- The registration itself is still very complicated, especially regarding the areas of “use and exposure”.
- Substances can still be forced into the authorisation process without clear scientific reasoning. This leads to an unpredictable situation for the producers and can overload the system.
- The evaluation of substances is still a complicated, decentralised process, and has been enlarged to cover all registered substances. The agency can be likened to a secretariat for local institutions and governments and cannot effectively prevent distortions in the European Market caused by single nations.
- Modification has been included which further complicate the situation:
 - a) When requesting the authorisation of a problematical substance, a producer will have to deliver a detailed plan for the substitution of such a substance.
 - b) Certain authorisations will have an expiry date and will not be renewable.

Question: How do these changes influence the situation for the “downstream user” of a chemical product?

- In one respect the situation is largely simplified. Any downstream user - such as a tannery - will only receive one material safety data sheet (although a volume of some pages) for every product acquired. This is instead of a collection of risk assessments for every ingredient of the said product, and this could have amounted to several hundred pages per product.
- On the other hand, the situation for “use and exposure” is still very complex. Large volume chemicals, such as sulfuric acid, might not be registered by the producer for the use in a tanning process, or specialties used by SME's to formulate

leather auxiliaries, or by the tannery directly.

In this case, the SME or tannery will have to collect data about “use and exposure” and inform the producer in detail about the use of a substance. But how this will be incorporated into the registration, and what happens if the producer refuses to do so for whatever reasons, is still unclear.

- If the downstream user company does not want to disclose its own use/application of the substance to the supplier, the company has to register this use making it its own responsibility.

Question: Regarding REACH, the word “substance” refers to a chemical compound or mixture, but not products/articles such as semi-processed or finished leathers that might contain chemicals that are viewed as unacceptable. How can the import of unacceptable chemicals within these products be controlled?

- Substances in semi-finished or finished goods have to be registered, if:
 - a) any substance is present in the article in quantities of more than one tonne per producer/importer per year, taking each type of article into separate consideration.
 - b) any substance meets the criteria for classification as dangerous (according to Directive 67/548/EEC),
 - c) the substance is intended to be released under normal and reasonably foreseeable conditions for use.
- Regarding leather and leather goods, in theory no such substance should be released. For intermediates which will be subjected to further production steps - especially in the wet end - this might be a different story. Nevertheless, this is practically impossible to control. It is to be expected that no producer - tanner, leather manufacturer - outside the EU will voluntarily declare any of his products (from wet blue to shoes) to release a chemical substance.

Question: It is understood that if guarantees are given by a manufacturer outside the EU to a chemical importer, but the product is found to contain unacceptable materials by a downstream user or end consumer, then the full responsibility and obligations of REACH are on the importer. Is it possible that similar obligations will be imposed on importers of semi-processed products or manufactured goods?

- Yes, the importers responsibility is to comply with the requirements of the regulation, and REACH always states the “producer” or “importer”. Moreover, a producer outside of the EU can only be made responsible if he himself is the importer via a EU-based affiliate or representative.

Question: Which changes are expected to happen during the next stages of the process towards implementation.

- It is expected that the Environment Committee of the EU Parliament will demand more stringent measures to strengthen the position of the environmentalists and consumerists lobbies. All efforts of industry are aimed to achieve a workable and future-oriented regulation which does not destroy the competitiveness of the Chemical Industry in Europe. 🌱