Practical experiences with the REACH Regulation

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1. Introduction

The 850 pages of the EU Regulation 1907/2006, commonly known simply as REACH, were officially published on 30th December 2006. It was a bold new step in chemicals legislation for all the European countries involved. REACH brought together in a single regulation many different existing Directives and chemical regulations and introduced ground-breaking new procedures. Instead of the authorities in each country being charged with the responsibility for determining the chemical safety of the products, it reversed this responsibility. The chemical industry became responsible for the chemical safety of their chemical substances and for determining the impact they have on the human health and environment. A new EU authority (ECHA) was to be established to co-ordinate this new chemicals legislation

The REACH regulation now has many 1000s of pages of guideline documents issued by ECHA and covers many topics related to the regulation of chemicals. In this paper we will just focus on the aspects of the registration of chemicals and the restrictions on chemicals of concern.

2. Registration of Chemicals

Why was there a need in the EU to introduce a new registration process for chemicals when one already existed? In the existing system at that time, those chemicals that were already registered in the European market before 1981 under the EINECS classification system were known as "existing" substances. In many cases these chemicals substances had not been extensively evaluated for their safety and environmental impact. If any test data existed for these substances it was the property of the companies and was not publically available. Substances registered after 1981 under the ELINCS classification system were known as "new" substances and these chemicals had already undergone an extensive series of testing before approval was given. The testing and evaluation system operated at the country level, with the approval by one EU country being accepted by the others. After 25 years of this system only some 2800 new substances had been tested and registered, whereas some 30,000 existing substances were in the market and being used. There was a considerable cost barrier to introducing new substances compared to continuing with the existing substances.

REACH implemented a registration process for all chemical substances. This requires all the existing substances to be evaluated for their chemical safety and environmental impact. To co-ordinate the implementation of this legislation a new European regulatory authority, ECHA (European Chemicals Agency), was established in Helsinki. Within a few years there are now some 500 staff from 27 European countries working for ECHA. The ECHA experts

issue guidelines to help the chemical industry to better interpret and comply with the REACH Regulation. In addition, ECHA reviews the chemicals of concern and provides a platform where information on chemical substances can be found. Through harmonised classification and labelling regulations we will know better how to handle and use chemicals safely.

This new registration process is resulting in an enormous amount of work for the whole leather supply chain, initially especially for the chemical suppliers and as time progresses for the downstream users such as the tanners. REACH requires that all chemical substances manufactured or imported into the EU to be tested for their potential hazards, their risks and the safe use of them in given situations. In a series of steps, see Table 1, up to 2018 all chemical substances sold in volumes above 1 tonne per year will be required to be registered and evaluated according to a defined set of tests.

Table 1: Categories and deadline dates for submission of the dossier to ECHA

More than 1000 tonnes / year*	November 2010
1000 to 100 tonnes / year	May 2013
100 to 1 tonnes / year	May 2018

* including substances more than 1 tonne / year for CMR carcinogenic substances and more than 100 tonnes / year for substances dangerous to aquatic organisms.

REACH covers all chemical substances manufactured in or imported into the EU. Only those chemicals specifically mentioned in the regulation are exempted; for example, natural substances, fuel for transport and those substances covered by other EU Regulations such as biocides. Another group of chemical products exempted are polymers (with a chain length of 3 or more).

The safety and environmental testing depends on the volume sold, the largest volume substances having to undertake a full programme of tests. The smaller volume substances are considered to be a lower risk and are required to undergo a less extensive series of tests. The manufacturers and importers of the chemical substances are responsible for obtaining the required chemical safety data and to provide data on exposure scenarios so it can be established how to safely use them.

ECHA, in its technical, scientific and administrative role for REACH, is responsible for receiving all the data and to evaluate if the data meets the required standard. ECHA will make much of the data received freely available to the public.

2.1 Registration process for chemical substances

In the first step ECHA asked all involved in the manufacture of or the importation of chemical substances to pre-register their substances if the volume was more than 1 tonne per year. Each registrant of these phase-in substances (those substances with an EINECS number) was required to provide the chemical name, chemical identification numbers and the volume per year of each substance they were using. This gave ECHA a basic list of chemical substances that were being used in the EU and this list of chemical substances can be accessed on the ECHA website.

The first pre-registration step was without cost, after this the registration process began with ECHA charging for each registration dossier submitted to them based on a sliding scale depending on the size of the company. In addition, the manufacturer or importer submitting the dossier is responsible for the cost of the testing needed to complete the dossier. This testing cost can be quite considerable, from several 100,000 Euros for the large volume substances to several 1000 Euros for the very smallest substances. The REACH Regulation has a strict requirement to minimise animal testing, which require registrants to purchase data from those who already have made tests. In general, ECHA sees joint submissions to minimise costs as a basic principle to be followed for REACH registration. So in the last years many of the chemical manufacturers and importers have grouped together to prepare the registration of similar types of chemical structures. These groups allow the collection of available original test data and the ability to share costs in preparing the Registration dossier detailing the identification and chemical properties of the substance. Others who opt not to participate can purchase access to the dossier through a Letter of Access. As part of the dossier, each registrant has to submit their own identification analytical data. There are several different categories for substances, such as isolated intermediates (on-site only and off-site), and this determines what degree of safety and risk assessment is required.

The first submission deadline ended in November 2010 for those chemical substances with a sales volume in the EU above 1000 tonnes. In May 2013 the next deadline for chemical substances above 100 tonnes is fast approaching. In Table 2 there is an overview of the numbers of substances involved for the registrations.

Table 2: Registrations submitted to ECHA

Phase-in substances pre-registered by December 2008	ca. 28,000
Phase-in substances registered by November 2010 deadline	ca. 900
Foreseen total phase-in registrations by May 2013 deadline	ca. 4000

The volume of new registrations means that the available safety and environmental testing resources are more than fully occupied, many have taken on extra staff for the REACH registration testing. In addition to the REACH registrations there are the ELINCS substances which have been already registered with test data. REACH allows the possibility to use “read-across” interpretation of safety and environmental test data from similar substances. Consequently the ELINCS substances are proving very useful as a data base for read-across without having to repeat expensive testing to get the same results.

2.2 Examples of registration

By choosing a few examples relevant to the tanning industry we would like to give an insight into some of the interesting situations that have occurred in the REACH registration process.

Example 1

In the previous registration system before REACH, it was possible to register a manufacturing process if the resulting chemical substance structures were difficult to define. Today there are much more sophisticated methods for analysing chemical substances and REACH is focused on identification of the individual components in a substance as much as possible. In the case of a number of chemical products used by the leather industry the REACH registration has

shown that small differences in the manufacturing procedures between different suppliers can result in varying amounts of each chemical component. This can result in a problem to define which substance is the correct composition for this registered CAS and EINECS number. In addition, the sameness analyses required for the Chemical Report can be rejected by ECHA in case companies registering the same substance have a significantly different analytical profile.

Example 2

Many of the syntans used by the leather industry can be defined as polymers, exempting them from REACH registration as long as the monomers are registered. The difficulty with the syntan type structures can be to determine the number of units in the polymer chain. Some of the normal analytical techniques are proving less suitable for syntans. Also interesting is that now detailed analyses are being made of many older chemical substances, in the process some of the leather industry chemicals, such as dyes, have been identified as polymers.

The polymer assignment can also cause problems, consequently in some cases both the substance is being registered and also the "monomers" of the polymer. In cases where the polymer is manufactured in the EU then the registration of the monomers can be the preferred way. However, for the imported products often the registration of the substance (even if it could be exempted as a polymer) can be the easiest way to proceed.

Example 3

For many years the anionic dyes used by the leather industry have had various cationic counter-ions depending on the production techniques. Some cations, e.g. K^+, were chosen because they gave a precipitate that had a better filtration performance. But with changes to spray drying procedures there was no need to make a precipitation and other cations, e.g. Na^+, could be used. For liquid dyes, the Li+ salt was used to increase the dye solubility and make a stable liquid formulation. Now the residual NaCl salt formed during the manufacturing process can be almost completely removed with reverse osmosis, allowing a stable liquid dye formulation without the need to use the higher solubility of the Li^+ salt. In terms of the dye performance on leather the various cationic counter-ions often had little significant influence. For REACH, where the exact chemical structure composition is required, the cationic counter-ion has become important. For several dyes it has been found that the EINECS substance is registered as a K^+ or mixed Na^+/K^+ salt form, but the dyes are now commercially all made as the Na^+ salt form. For REACH this change in the counter-ion means it is a new chemical substance and must be treated as such. Where test data exists for the original structure it can be used as read-across to reduce the amount of new testing required. An example, see Fig. 1, is the largest volume leather black dye, C.I. Acid Black 210, which for many years was commercially sold as the K^+ salt but is now manufactured as the Na^+ salt.

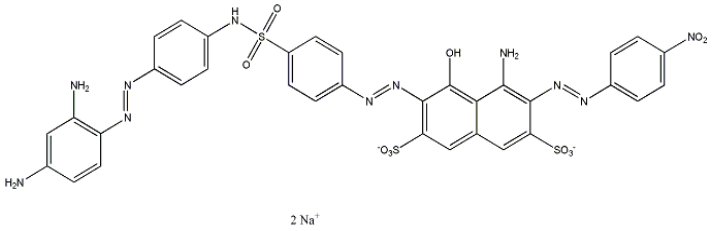

Fig. 1. Structure of C.I. Acid Black 210 (as Na salt)

3. Restricted Substances and Chemicals of Concern

An important part of the REACH Regulation was that it included all the existing EU Directives that restricted the use of certain chemical substances with toxic or hazardous properties. All these Directives were placed in Annex XVII and as a result the restrictions in the Directives continued on as previously.

In addition, a new category of Substances of Very High Concern, SVHC, was established and these substances are to be listed in Annex XIV. ECHA calls for proposals for inclusion in this category from the EU member countries. If an initial assessment by the industry and member countries shows the potential substance is likely to meet the SVHC criteria, it goes into a Candidate SVHC List. At this stage a risk assessment is made using the available data and possibly new data. The final step in the nomination of SVHC substances is that ECHA proposes to the EU Parliament that the Regulation be amended to include the substance in Annex XIV and details for the phase-out period for this substance are defined. The SVHC substances can still be used but require the specific authorisation from ECHA. A list of the SVHC substances and SVHC Candidate substances is available on the ECHA website at: http://echa.europa.eu/candidate-list-table.

For the leather industry the lists of restricted substances and SVHC substances has required a considerable increase in testing to comply with legal and customer specifications. It has resulted in an increased growth in test houses across the world to cater for this fast growing new market. To ensure valid test procedures are used it has been important that analytical techniques suitable for the complex substrate leather are used. Initially many methods from waste water or plastic industries were used and detection limits much less than, for example, the noise level in a chromatogram from a leather extract were being proposed. The development by the IUC Commission of the IULTCS of International (ISO) Standards for the chemical analysis of leather has helped to improve this situation. A summary of the chemical test methods suitable for analysing leather are given in Table 3.

4. Conclusion

The introduction in the EU of the REACH Regulation has caused a lot of changes in a short period of time. It is requiring the whole chain from the manufacturer, importer to the tanners and their customers to evaluate the chemical safety and environmental aspects of all the chemical substances being used. As the legislation and responsibilities were new there have been a lot of grey areas which are slowly being clarified. There is still some way to go until in 2018 the registration process is completed. The aim of REACH is to encourage new, innovative chemical products with a better safety profile. Currently, rather than developing innovative substitute substances, many chemical suppliers are too busy with the registration process and compliance with restricted substance specifications.

The practical consequences of the REACH Regulation are that in the next years some chemical substances will no longer be manufactured, but most substances are likely to remain available for the European tanning industry. Time will tell if the REACH Regulation has achieved its aim of “improving the human health and the environment by ensuring that chemicals are used safely”.

Table 3: Leather test methods for restricted substances relevant to the leather industry

Alkylphenols and alkylphenol ethoxylates	EN ISO 18218-1 / IUC 28-1 (NPEO, OPEO) EN ISO 18218-2 / IUC 28-2 (NP, OP)
Aromatic amines - released from the breakdown of azo dyes	EN ISO 17234-1 / IUC 20-1 EN ISO 17234-2 / IUC 20-2 (for 4-aminoazobenzene)
Chlorinated Paraffins (SCCP)	EN ISO/DIS 18219 / IUC 30
Chlorophenols	EN ISO 17070 / IUC 25
Chromium (total)	EN ISO 5398-1 / IUC 8-1 EN ISO 5398-2 / IUC 8-2 EN ISO 5398-3 / IUC 8-3 EN ISO 5398-4 / IUC 8-4 ISO 17072-2 / IUC 27-2
Chromium VI (Cr VI)	ISO 17075 / IUC 18
Dimethylformamide (DMF)	CEN ISO/TS 16189 (Footwear)
Dimethyl fumarate (DMFU)	CEN ISO/TS 16186 (Footwear)
Formaldehyde	EN ISO 17226-1 / IUC 19-1 (HPLC method) EN ISO 17226-2 / IUC 19-2 (Colorimetric method) EN ISO 17226-3 / IUC 19-3 (Emission from leather) EN ISO 27587 / IUC 26 (free formaldehyde in chemicals)
Fungicides	EN ISO 13365 / IUC 29
Heavy metals	EN ISO 17072-1 / IUC 27-1 (extractable) EN ISO 17072-2 / IUC 27-2 (total)
PFOS	CEN/TS 15968
Phthalates	CEN ISO/TS 16181 (Footwear)
Organotin (Sn) compounds	CEN ISO/TS 16179 (Footwear)

5. References

http://echa.europa.eu The ECHA website contains detailed information on the REACH Regulation.

www.sdc.org The Colour Index (C.I.) system for dyes is a registered trademark of the Society of Dyers & Colourists (SDC).