Regulatory requirements with an impact on leather manufacture

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On May 31, the registration phase of REACH closed with the last deadline for substances in the volume bands 1 to 100 tonnes per year. But, registration is not the only development on the regulatory front that has a potential impact on leather manufacturing and on leather articles. As per REACH Annex XVII, there are new restrictions on isocyanates and CMR (carcinogenic, mutagenic, or toxic for reproduction) substances in articles. Cyclosiloxanes are in the focus of authorities with three processes in parallel: the Stockholm convention on persistent organic pollutants (POPs), REACH restriction, and authorisation.

This article offers a concise overview of important regulatory developments in recent months and tries to outline their potential impact on the manufacture of leather and on the sale of leather articles.

1. REACH & registration

On June 1, 2007, European Regulation 1907/2006 on the registration, evaluation and authorisation of chemicals (REACH) came into force, the most complex regulatory framework for chemicals the world has seen so far. It requires that every chemical substance be registered at the European Chemicals Agency (ECHA) with a package of scientific, application and commercial data before it can be manufactured in or imported into Europe.

Contrary to the previous inventory of chemicals substances, EINECS, registration under REACH needs to be filed not just once per substance, but once for every manufacturer or importer. If registration identifies a high concern linked with the use of a certain substance, further steps such as restriction of use or authorisation may follow in the course of the REACH process.

As such a mammoth project cannot be completed in a day, filing of the necessary registration documents has taken place in three batches, depending on manufacturing volume. The deadlines were in 2010, 2013 and finally on May 31 this year. With the final deadline having passed, the REACH maxim "no data, no market" now applies to all substances manufactured in or imported into Europe with a volume of 1 to 100 tonnes per year, without exception.

In the past decade, 13,000 companies from across Europe have filed 88,000 dossiers related to more than 21,000 different substances, 7,000 of which fell in the volume band of 1 to 100 tonnes per year to be registered in 2018. Although these numbers seem large, they fall well short of what authorities had forecast after receiving REACH pre-registrations.

Many are wondering what the implications of this discrepancy are. There is some concern that European manufacturers may have stopped the production of small-volume chemicals when they calculated that the profit they could make on them would not cover the costs of registration. This might have a much bigger impact on their downstream user industry. Such an effect would be even more severe for a relatively small sector like the leather manufacturing industry, as many substances used here do not break the 100 tonnes per year barrier.

However, a check on the ECHA dissemination page shows that market leaders including Stahl, Lanxess and TFL have all registered a three-digit number of substances to cover their product portfolio. Smaller suppliers have not been inactive either. The REACH & Colours project, launched in Italy, has registered more than 400 dyestuff and dyestuff intermediates for the leather, textile and paper industry. This will play a crucial role in ensuring that leather manufacture will not be black and white after 2018. Combined with proactive portfolio management, the established European suppliers of chemicals can continue to support their customers with a full portfolio of chemical formulations for the manufacture of leather.

2. REACH enforcement

While chemical companies had been busy compiling their dossiers for the final deadline, European authorities launched a number of enforcement projects to check compliance with existing REACH requirements.

A report published in February 2018 outlined the results of testing more than 5,000 chemical formulations and consumer articles from across Europe for various substances, subject to restrictions. Roughly 18% of the tests ended in a fail for one or more substances, with banned phthalates heading the list. Chrome VI in leather articles was not in the top three of the ranking, but with a failure rate of 13% it is still far from the desired outcome. It also gives a negative image despite the majority of manufacturers working according to best practices to eliminate the risk of the formation of Chrome VI.

In the sixth enforcement project, which began in January this year, authorities have turned their attention to the checking of safety data sheets, this time with a focus on formulations, composition, classification and labelling.

3. REACH beyond registration

With the registration phase complete, the legal framework foresees various potential follow-up activities:

- Substance evaluation – to check if all hazards have been correctly identified
- Classification, labelling and packaging (CLP) – to link identified hazards to classification and labelling
- Restriction – in cases when a risk is associated with a specific use of a substance
- Authorisation – in cases when all uses of a substance of 'very high concern' need special attention

While the authorisation process in general has attracted a lot of attention, a number of specific restriction cases have been processed which either have the textile, leather and apparel industry as their focus, or could have an impact on this sector. They are discussed below.

3.1. Isocyanates

Diisocyanates are used in a wide range of sectors and have a variety of applications (e.g. foams, sealants, coatings) in the European Union, with a total tonnage of around 2.5 million tonnes per year.

ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) support Germany's proposal to restrict the use of diisocyanates in the workplace. The main goal of this restriction proposal is to prevent new cases of respiratory sensitisation among workers. The final decision regarding the restriction is expected during the second half of 2018 and will include a transition period for implementation.

Should it be approved, the restriction would mean diisocyanates could not be used or placed on the market as substances or in mixtures for industrial and professional uses, unless:

- the cumulative concentration of diisocyanates in the substance or mixture is less than 0.1% by weight; or
- the employer or self-employed worker ensures that measures are taken or that training takes place prior to use.

Manufacturers and importers of diisocyanates would be obliged to develop teaching materials in an official language of the EU member state where the product enters the market. They would also have to ensure that training courses are available to the recipients of such products. Formulators of mixtures containing diisocyanates within the EU would need to provide information for the development of the teaching materials upon request. All downstream users may be consulted for the development and updating of the teaching materials.

In leather manufacture, concentrated aromatic diisocyanates (e. g. TDI, toluene-diisocyanate or MDI methylenediphenyl diisocyanate can be used as one part of two-component systems for leather coating. In crosslinkers for leather finishing, traces of aliphatic diisocyanates (e.g. hexamethylene-diisocyanate (HDI)) can be contained in the raw materials. There are no issues with aqueous polyurethane dispersions, as any isocyanate is consumed during manufacture.

In the case of crosslinkers, suppliers are preparing to comply with the restriction by optimising their high-performance crosslinkers to contain a lower residual amount of diisocyanates. Where this is not possible, a close cooperation between supplier and user will become necessary to establish training and monitoring strategies.

3.2. N-1Methyl-2-Pyrrolidone (NMP)

NMP is an organic solvent which mixes well with water and with other solvents. It has a low acute toxicity and has therefore been commonly used as a co-solvent in water-based finishing products, predominately PUDs (Polyurethane Dispersions).

NMP was found to be reprotoxic (H360D, may damage the unborn child) and the CLP adjusted so that preparations containing more than 5% of NMP must be labelled.

NMP became a candidate for 'substance of very high concern (SVHC)' classification in June 2011 and was proposed for prioritising to authorisation in March 2017. This process is ongoing and has been overtaken by two restrictions that were passed in 2018. From May 2020, mixtures containing more than 0.3% can only be manufactured or sold if manufacturers and downstream users take the appropriate measures to demonstrate Derived No-Effect Level (DNEL)-compliance in the workplace. In addition, any article, such as leather or leather substitutes, must not contain more than 0.3% of NMP.

3.3. Cyclosiloxanes D4, D5 and D6

Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) are non-toxic, colourless, odour-free liquids. Used as solvents in cosmetics, they evaporate without a cooling effect and leave a pleasant touch. A larger volume is used as raw material in the manufacturing of polysiloxanes with a multitude of applications, from hydraulic liquids to sealants.

Due to its volatility, traces of cyclosiloxanes can be found even far away from populated areas.

The physical-chemical properties of cyclosiloxanes fulfil the criteria for classification as persistent and bioaccumulative, although more complex studies under environmental conditions call into question these conclusions (no biomagnification, degradation in air, etc.).

Nevertheless, a restriction against their use in wash-off cosmetics was passed in January 2018 (entry 70 of Annex XVII), and a second one against stay-on cosmetics in progress at ECHA.

A study carried out for CLP evaluation then offered evidence that D4 may have an effect on fertility if inhaled at a high concentration. This delivered the last piece of evidence for its classification as persistent, bioaccumulative and toxic (PBT), which according to REACH article 57d qualifies a substance as an SVHC candidate. The process of SVHC identification was concluded in record time and D4 was listed as a candidate in June 2018. This included D5 and D6 if they contain traces of D4 above 0.1%, which is usually the case for technical material.

Cyclosiloxanes are used as raw materials for silicone oils and functional silicones, which are themselves used for waterproofing, anti-soiling, and as touch and fastness enhancers in leather manufacture. Trace concentrations above the SVHC declaration threshold of 0.1% in the ready-to-use chemical formulation are not uncommon. However, exceeding this value in the leather or leather article is very unlikely based on the amount used during the manufacturing process.

It remains to be seen if cyclosiloxanes will be prioritised for authorisation with the same speed at which they appeared on the regulatory radar. This would trigger another very complex authorisation case.

3.4. CMR substances in textiles

In 2016, the German Federal Institute of Occupational Safety and Health (BAuA) proposed modifications to entries 28, 29 and 30 of REACH Annex XVII to include a clause that would ban the presence of CMR-classified substances in textile-based consumer articles at a default concentration of 50 mg/kg. As this would have been only an update of an existing entry, a fast-track procedure without stakeholder consultation was planned.

After feedback from the industry, the fast-track approach was discarded and an intensive two-year cooperation led to the drafting of a new entry for Annex XVII that contains the CMR substances that are technically relevant for textile manufacture with individual threshold values.

Although leather and leather articles are explicitly excluded, it is expected that this restriction will have an effect on the leather industry because brands will use it as orientation for all materials, and it might serve as a precedent.

3.5. Sensitising substances in textiles and leather

In June 2018, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Swedish Chemicals Agency (KEMI) announced their intention to compile a restriction to reduce consumer risk of dermal allergies caused by skin contact with hazardous substances in textile- and leather-based materials. They have issued a call for evidence and composed a list of all substances that are classified as skin sensitising, corrosive or irritant.

It is obvious to those with a technical and chemical background in textile or leather making that a restriction in this form would be impossible to enforce and would be extremely inefficient in increasing consumer safety levels. The industry is reacting to the call for evidence, but it is not clear if constructive cooperation with ANSES and KEMI can be established. As a result, the outcome of the project is completely open.

4. REACH globally

In the wake of REACH implementation in Europe, other regions of the world have expressed their intentions to establish a similar chemical register. The most advanced processes in this regard are in South Korea and Turkey.

South Korea's Act on the Registration and Evaluation of Chemicals (AREC), which came into force in 2015, is now aligned with European REACH principles, with a new law added for technical biocides, similar to the European Biocidal Products Regulation (BPR). Volume-dependent registration for phase-in substances extends from July 2018 to December 2030.

Turkey's KKDIK regulations came into force in December 2017, with requirements that are technically very close to those of REACH. There is one registration deadline, in December 2023, for all volume bands. All documents need to be filed in Turkish by someone with a special qualification that can only be obtained in Turkey. Given the size of the market for chemicals in Turkey, it is not yet clear what impact this will have on the activities of global suppliers.

5. Conclusion

Passing the final REACH registration deadline is just one milestone in chemical regulation in Europe, with substance evaluation, authorisation and restrictions creating an ever-growing workload for chemicals suppliers and their customers in the European market.

Restrictions that have been recently passed, such as those on diisocyanates or NMP, require measurements for implementation in the leather supply chain. New registrations on the horizon, as those for cyclosiloxanes or sensitisers, promise future challenges.

With REACH approaching maturity in Europe, countries such as South Korea and Turkey are now starting the same process.