

Chemical Control: Environmental Law in a Deindustrialised Society

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Doug Bryden of Travers Smith and Russell LaMotte of Beveridge & Diamond, reflect on combined EU, US and international efforts to regulate the use of chemicals in products.



Global legislatures have sought over recent years to react to the growing interest in the use of certain chemicals, particularly in relation to consumer products.

In 2007, the EU overhauled its management of chemicals through the introduction of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regime. REACH, along with other more focused EU environmental product or chemical law regimes, has matured over recent years and market understanding of these product-level environmental controls has improved.

However, following a phase of legislative establishment, there is now a discernible ratcheting up of restrictions on the use of hazardous chemicals in products in the EU.

In the United States, although the details differ, similar initiatives are also on the rise, reflecting new assertions of regulatory authority under longstanding existing statutes at the federal level as well as wholly new approaches to product regulation in California.

Meanwhile, global obligations and protocols on specific types of chemicals in products have also continued to develop, such as for persistent organic pollutants and ozone depleting substances. In addition, the UN is promoting non-regulatory initiatives, which, like activist campaigns led by NGOs such as Greenpeace, are likely to proliferate ever more widely.

This turning of the regulatory screw at international, national and state level has created a new series of global market access, compliance and information sharing challenges for product manufacturers and importers alike. Given that a number of these newer chemical regimes include transparency and reporting obligations, reputation and brand management are increasingly driving decision making as much as the threat of traditional regulatory action or censure.

This continued focus on the environmental impacts and risks posed by products (and, in particular, the chemicals they contain) should be of no surprise: with the steady but sure deindustrialisation of much of the EU and North America, it is now these products that pose some of the most likely yet uncontrolled threats to both the environment and human health in these regions.

EU spotlight

The past decade has seen a revolution in the way in which the EU has sought to manage chemicals. The entry into force of the EU's REACH regime and the establishment of the European Chemicals Agency (ECHA) in 2007, followed by the Classification, Labelling and Packaging (CLP) Regulations in 2009,

represented a seismic shift in chemicals regulation in the EU. Certain sub-sectors, including cosmetics and biocides have been subject to their own specific revisions, with earlier EU directives being upgraded to more comprehensive harmonised regulations.

A key theme in these developments has been the recognition that substances and mixtures are increasingly placed on the EU market embedded in industrial and consumer products or 'articles'. REACH contains specific structures to manage the use of substances in articles, while the EU's Restriction of Hazardous Substances (RoHS) regime, to take an example of a more sector-specific regime, contains focused provisions with respect to certain listed hazardous substances in electrical and electronic equipment.

As these legislative regimes have matured over recent years, operators have grown to understand the market access restrictions these regimes impose on business. Indeed, the high regulatory barrier to entry has, to a certain extent, acted to benefit established EU operators. However, as the examples of REACH and RoHS below show, today's challenges for product manufacturers and importers include in particular: (i) tracking the various amendments to these flexible legislative instruments; (ii) controlling production techniques; and (iii) managing the flow of information throughout the value chain.

In addition to traditional regulatory controls, a growing theme of EU environment and chemicals law is transparency and disclosure. This is proving a powerful tool with regard to consumer products, as illustrated by the recent campaigns by non-governmental organisations against leading clothing manufacturers.

REACH: substances in articles

The use of certain substances and mixtures in articles is regulated by REACH's restrictions procedure, under which substances and mixtures in articles can be restricted or prohibited from being placed on the market. There are a variety of general restrictions, for example in respect of asbestos fibres in articles (subject to very limited exemptions), and more sector-specific restrictions, for example, a 0.0005 per cent benzene restriction in toys. Further, the manufacture of certain products may be impacted by the inclusion of substances on the authorisation list, unless such uses are either authorised or exempted.

In addition, REACH contains a broad spectrum of further obligations in respect of substances in articles. In cases where articles intentionally release substances, fully fledged registration of the substance to the ECHA may be required. An example would be a T-shirt which intentionally releases a fragrance under its normal conditions of use. At a level down from full registration, EU producers or importers of articles must notify ECHA if their articles contain any 'substances of very high concern' (SVHCs) listed on REACH's Candidate List where the SVHC in question is present in those articles above a concentration of 0.1 per cent (w/w) and in quantities totalling over one tonne per year. In addition, suppliers of articles have both pro-active customer communication obligations and reactive consumer information obligations where SVHCs are present in articles in a concentration above 0.1 per cent (w/w).

Growth of SVHCs

The SVHC list has grown rapidly since its inception, and since the beginning of 2014, a further 12 substances have been added to REACH's Candidate List, taking the total to 163 substances. Eventually, it is expected that the Candidate List will grow to around 400 substances. The rapid growth in the number of SVHCs along with the growth in restrictions and substances subject to authorisation present

significant chemicals and product stewardship management challenges for economic operators in the product space.

Recent product-relevant REACH case law

In addition to a growing body of ECHA Board of Appeal decisions, the Court of Justice of the European Union (CJEU) is currently considering the application of the 0.1 per cent threshold for substances in articles under REACH. The question as to whether the 0.1 per cent SVHC threshold applies to articles as a whole or their component parts is one which has generated divergent views within the EU, with a group of member states openly dissenting from the EU Commission's stated position.

In a recent opinion, the Advocate General has encouraged the CJEU to approve a system by which the 0.1 per cent threshold applies to component articles for importers and entire articles for producers. While, at the time of writing, the CJEU's judgment is still awaited, the Advocate General's opinion on the application of this threshold is of considerable weight. The CJEU's final judgment on this matter will affect both the ECHA notification and information obligations in respect of products and will be followed closely.

In addition, the General Court of the EU has recently considered the scope of those substances that may be placed on the Candidate List as SVHCs. In two parallel judgments in April this year, the General Court upheld a broad interpretation of the scope of substances that may be determined to be SVHCs. In reaching their judgment, the Court reaffirmed the broad discretion of ECHA with regards to the assessment of highly complex scientific issues and the limited scope for judicial intervention. These judgments are presently subject to appeal. However, the open scope of SVHC determinations would appear likely to be preserved.

Further RoHS restrictions

The RoHS Directive provides a further example of the ratcheting up of chemicals management within the EU's existing legislative structures. On 4 June 2015, the European Commission added phthalates DEHP, BBP, DBP and DIBP to the list of restricted substances under RoHS via its delegated powers. These restrictions will impact the majority of electrical and electronic equipment products from 2019 giving manufacturers, importers and distributors just over four years to manage compliance issues. These changes, coupled with the recently added self-reporting obligations, are likely to pose significant compliance challenges.

US federal regulation

In the United States, meanwhile, the US Environmental Protection Agency (EPA) has dramatically expanded the scope of its regulatory initiatives focusing on chemicals in articles, primarily under the Toxic Substances Control Act (TSCA).

TSCA has always given the EPA authority to regulate chemical substances contained in articles, but the EPA has historically chosen to exempt chemicals in articles from many regulations, including information-gathering rules, export and import notifications, pre-manufacture notifications, and Significant New Use Rules (SNURs). For SNURs – the primary vehicle that the EPA has to regulate existing chemicals – the EPA previously relied on a general articles exemption to avoid imposing chemical-related obligations on imported articles.

More recently, however, the agency has shifted course: numerous important SNURs proposed and adopted by the EPA have disallowed the exemption for import of covered substances as part of an

article. These include benzidine, HBCD, PBDEs and long-chain perfluoroalkyl carboxylate chemicals.

This initiative likely serves as a harbinger of future TSCA rules targeting chemicals in articles. Importers of finished manufactured articles and components for further manufacturing will need to assess whether these chemicals are present. This will pose significant supply chain management challenges. Importers face difficulty determining the identity of each chemical in the articles that they import. In many cases, an importer has no way of knowing whether an imported article contains a SNUR chemical. In addition, the cost of determining whether a SNUR chemical is present can be very high, particularly for complex articles with a diverse supply chain. Yet the SNUR obligations are essentially strict liability provisions. The EPA has rejected suggestions to determine compliance based on due diligence efforts alone.

Industry groups have raised concerns about this trend, including a request that the EPA complete a separate public comment process to develop a general “policy framework for the issuance of article SNURs”. This request, along with most industry concerns, have to date been rejected by the EPA, which shows no sign of decelerating its focus on controlling risks from chemicals in products.

California

At the subnational level, California is leading the way in this new wave of product-focused environmental regulation. The Green Chemistry Law adopted in 2008 requires regulators to establish a process to evaluate chemicals of concern in consumer products and their potential alternatives. The resulting Safer Consumer Products Regulations provide for a four-step process to identify alternatives to chemicals of concern in certain categories of consumer products.

- Chemicals – Regulators published a list of candidate chemicals, drawing heavily on other chemical blacklists and the EU SVHC list.
- Products – Regulators next published a set of product-chemical combinations. These are product categories that contain candidate chemicals with the potential for exposure to consumers. Once finalised, this list of priority products will require that an alternatives analysis be conducted with respect to chemicals of concern in that product.
- Alternatives analysis – The responsible entity (manufacturers, importers, assemblers, and retailers) must notify the regulator of their priority products and then perform an alternatives analysis to eliminate risks from chemicals of concern.
- Potential further regulation – The regulator will then impose risk management measures based on those analyses to protect public health and the environment.

This unique focus on chemical-product combinations could serve as a precedent for other regulatory developments in other jurisdictions. It will certainly increase the level of attention to the emerging field of alternatives analysis for industrial chemicals in articles, a complex discipline that is still in its infancy and which many organisations, including the OECD, are devoting resources to.

Another consequence is that information generated will generally be made public on a website with highly visible information about the risks and compliance status of covered products. This emphasis on disclosure reflects a wider trend in product-related regulations, which use transparency initiatives as a companion to traditional regulation through de-selection pressure.

Finally, the California regulations illustrate the global impact of such rules. Even companies whose products are not directly identified as priority products may be drawn into complex data sharing

arrangements, global supply chain communications, and information requests from California regulators.

Global spotlight – UNEP Chemicals in Products Program

The impact of international law in this field is also starting to be felt by global product manufacturers, importers and distributors. Recent years have seen an expansion of product –related obligations under various international treaties. In particular, the Stockholm Convention on Persistent Organic Pollutants has seen the addition of several industrial chemicals in widespread use to the list of regulated substances, including PFOS (added in 2009), HBCD (added in 2013) and PFOA (proposed this year).

In addition, the UN Environment Program (UNEP) continues to promote a non-binding program focused on chemicals in products under the Strategic Approach to International Chemicals Management (SAICM). SAICM is a global multi-stakeholder framework dedicated to achieving sound management of chemicals throughout their life cycle. SAICM’s strategy and work plans are reviewed every three years at the International Conference on Chemicals Management (ICCM). At the fourth ICCM in October 2015, governments will consider actions on various emerging policy issues, including one on chemicals in products (CiPs).

This work stream was initiated in 2012. UNEP has been developing a programme to “facilitate and guide the provision, availability, and access to information on chemicals in products among all stakeholder groups”. After engaging industry and NGO stakeholders, UNEP released draft versions of two policy documents on *The Chemicals In Products Programme* and corresponding *Guidance for Stakeholders in Exchanging Chemicals in Products Information*. Industry raised concerns about earlier versions of these materials, which were highly prescriptive and inflexible. The latest versions are more flexible, but will be further modified based on the results of a workshop in Beijing in summer 2015.

Although the UNEP programme will be voluntary, it will establish an important technical and policy framework for the exchange of information on chemicals in products. It will likely influence future national, regional and global initiatives aimed at promoting or mandating the exchange of information on chemicals in products. Companies concerned about such initiatives, and the implications they have on protection of confidential business information and appropriate communication of risk to consumers, may wish to review the emerging guidance and assess their own approaches to obtaining and sharing information on chemicals in products.

This new wave of product-focused regulatory controls differ in their mechanics and details, but they all increase the pressure on manufacturers and importers of products to build capacity to learn from their supply chains whether chemicals of concern are present and if they are likely to be released. To meet these requirements, companies will need to develop more elaborate supplier arrangements to manage and share compliance information throughout the supply chain, together with provisions to monitor and audit those arrangements.

Are these current obligations just the tip of the iceberg? More progressive legislation is developing both in the EU and USA which, to accommodate the realities of a deindustrialised society, looks to what is happening outside its borders and to where the industrial or extractive activities are happening – recent examples include the conflict mineral regimes and the UK’s new modern slavery act. As such, it is becoming increasingly obvious to many that product related regulation is at the forefront of modern environment law.