

Evolving global chemical management programs and why they matter

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Chemicals play a central role in our personal and professional lives. As consumers, we focus keenly on the chemicals in the products we use and with which we come into contact. Globalization and the emergence worldwide of sophisticated chemical management programs invite complex legal, commercial, and scientific challenges. These challenges extend far beyond compliance questions that, by comparison, seem now nostalgically straightforward. Understanding these programs and their evolution can only help inform our judgment as lawyers, consultants, and educated consumers.

The challenge

Product formulation is a delicate balancing of performance, cost, and safety considerations. As part of this balancing, the following questions all must be addressed:

- Are the preferred chemical ingredients believed to be hormone disruptors, carcinogens, persistent, bioaccumulative, and/or toxic (PBT)?
- If so, are there efficacious alternatives to the preferred chemicals available?
- Will the presence of a nanomaterial ingredient compel product labeling or disclosure under a European Member State nano inventory?
- Will substitute ingredients perform “well enough” and are they cost competitive?

A confluence of legal trends, social phenomena, and scientific developments has contributed to this new complex calculus.

One of the social phenomena in play is the public’s insatiable pursuit of its right to know product composition and impacts. This has resulted in far greater transparency in government oversight and management of environmental health and safety risk from regulated industries, especially the chemical industry. Disclosure is a core tenet in many companies’ implicit and explicit compacts with their customers, and failures can breach contractual agreements as well as erode the customer’s and public’s trust.

Hyper-connectivity and advances in information technology translate into global instant messaging of information about products, both sanctioned and unsanctioned by the product manufacturers. Search engines optimize the availability of huge chunks of data (reliable or otherwise), which enables the production of “arm-chair” product risk assessments in record time. Domestically, the E-Enterprise Leadership Council is a case in point. This organization is marketed as a group of federal and state officials working to improve “service to the regulated community and the public by maximizing the use of advanced monitoring and information technologies, optimizing operations, and increasing transparency.” E-Enterprise asserts that it is designed to leverage new technologies and data management. This is code for empowering all stakeholders—regulators, nongovernment organizations, and citizens—to develop new tools to access and evaluate data and draw conclusions from those data, regardless of the stakeholders’ qualifications to do so. These evaluations and conclusions can have dramatic implications for product manufacturers—not all of them positive.

Finally, globalization has greatly complicated the manufacture and marketing of products, especially those with a chemical component. The legal practitioner’s familiarity with global and regional differences in law, policy, and regulation; consumer perception; and cultural norms is essential to making one’s way through the wiles of the commercial jungle this space has become over the years. For example, assume a Restriction of Hazardous Substances (RoHS) exemption has expired after having been in place for several years. A U.S. company manufactures a chemical that is now banned under RoHS because the exemption has expired. The company sells the chemical to downstream customers in the European Union (EU), and the chemical is then included in manufactured articles offered for sale in Europe. The U.S. chemical manufacturer, the EU product manufacturer, and entities offering the articles for sale could all be liable for stiff penalties, the article could be banned from further sales, and the offending entities, including the U.S. chemical manufacturer, could be subject to significant commercial tort liability.

The solution

Whether you are a legal practitioner with a need to know, or an inquiring consumer asserting your right to know more about how chemicals are managed globally, a new ABA Section of Environment, Energy, and Resources book, *Global Chemical Control Handbook: A Guide to Chemical Management Programs*, can help. Organized by country and as outlined below, this Handbook helps familiarize readers with the key global chemical control programs and enables them to anticipate associated issues that may arise in legal and commercial settings by providing essential background information as well as observations and commentary by experts who routinely work with these programs. The Handbook also identifies trends in each emerging program and suggests resources for additional information.

United States—TSCA/FIFRA—The Toxic Substances Control Act (TSCA) establishes the United States’ comprehensive structure to protect human health and the environment from chemicals. The Handbook provides an in-depth discussion of TSCA’s key provisions, how they work, and recent efforts on Capitol Hill to update and modernize TSCA.

TSCA exempts chemical substances regulated under other federal laws. Key among these substances are pesticides, which are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The key FIFRA provisions include pesticide registration, data compensation, risk control options available to the U.S. Environmental Protection Agency (EPA), export and import requirements, and confidential business information and trade secrets.

State Laws from the United States—The two states with the most comprehensive chemical programs are California and Massachusetts. California’s Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) in many respects was the spark that ignited the chemical disclosure revolution. Under Proposition 65, California maintains and publishes a list of chemicals determined by the state to cause cancer or reproductive toxicity, and businesses have a corresponding obligation to warn of hazards and label products. A bold new program, California’s Safer Consumer Products Regulations (SCPR), goes even further and requires manufacturers to evaluate the availability of safer alternative ingredients for products containing “candidate chemicals.”

Massachusetts enacted the Toxics Use Reduction Act (TURA), which requires businesses using large quantities of listed chemicals annually (defined as 25,000 pounds for manufactured/ processed chemicals and 10,000 pounds for chemicals “otherwise used”) to report on chemical use and pay toxics use fees. TURA also requires large quantity toxics users either to prepare a Toxics Use Reduction plan that examines their use of the chemicals and sets forth a plan to reduce toxics use or to demonstrate how an environmental management system might be implemented in lieu of a Toxics Use Reduction plan. Users must file a summary of the plan every other even-numbered year thereafter.

Canada—CEPA 1999—Those with a working knowledge of TSCA will find many familiar concepts in the Canadian Environmental Protection Act, 1999 (CEPA 1999). Becoming conversant with one statute and its implementing regulations gives an environmental professional a leg up in mastering the other. Similar to the U.S. TSCA Inventory, Canada maintains a Domestic Substances List, and new chemicals are subject to notification requirements. Those who are familiar with the EU’s approach will notice that some elements found in CEPA 1999 also appear in the EU’s subsequently adopted Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation. Similar to the EU, the precautionary principle of protecting human health and the environment guides the Canadian government’s actions.

Europe—The EU’s REACH regulation is three decades younger than TSCA and arguably significantly more ambitious by virtue of its multinational coverage, extending to—and harmonizing chemical regulation in—all countries in the EU and the European Economic Area. Mastering the application of REACH can be a daunting task because of its broad scope, its relative newness, and the fact that it is still a work in progress. All chemical substances manufactured in, or imported into, the EU at a volume exceeding one metric ton per annum must be registered pursuant to REACH, but the deadline for registration is not until May 31, 2018. The Handbook illuminates features of REACH that may not be immediately apparent based on expectations formed through experience with TSCA, or that are otherwise novel or potentially confusing.

Other relevant EU legislation complementary to, or contrasting with, REACH includes (1) RoHS, aimed at restricting the use of hazardous substances in electrical and electronic equipment and (2) WEEE, aimed at reducing waste from electric and electronic equipment through collection and recycling, as well as more stringent controls on cross-border trading in such wastes. Differences in application of these rules among Member States mean that before placing electrical or electronic equipment or components on the EU market, it is worthwhile to become familiar with each Member State's legislation adopting RoHS and WEEE.

Another key piece of EU legislation expected to become increasingly significant is the Biocidal Products Regulation (BPR). This regulation became effective in 2013, superseding, building upon, and expanding an earlier Biocidal Products Directive. The BPR's objective is to harmonize the regulation of active substances and biocidal products on an EU-wide basis, rather than solely at the Member State level, and to control articles treated with biocidal products more stringently.

Mexico, Central America, and South America—The chemical management regulations of Mexico, Central America, and South America are not harmonized. To practice in these jurisdictions, there is no substitute for acquiring a basic familiarity with the regulatory regime in the country of interest, and it is unwise to go forward based simply on assumptions that regulatory approaches are similar. With significant U.S. investment in South America's domestic chemical production capacity, particularly in Brazil, several South American countries are coming up to speed quickly and significantly modernizing their chemical management governance systems.

Asia—As a cost-effective locale for the manufacture of chemical substances, Asia is a draw for multinational companies and others seeking to import chemicals from abroad. Multinational corporations accustomed to Western regulatory systems typically anticipate a detailed regulatory framework characterized by rigid rules, with compliance driven by the imposition or threat of penalties. In Asian nations, the regulatory framework often is markedly different from that in the West, as is the case with business in general. The Asian regulatory implementation schemes rely on gray areas—what is not articulated—to provide flexibility in interpretation, as circumstances may warrant.

For example, two Chinese government decrees are key to chemical management. The Ministry of Environmental Protection's (MEP) Decree No. 7, implemented largely through the MEP's Chemical Registration Center (CRC), addresses notification and registration of chemical substances, data submission and testing requirements, the compilation of an inventory of existing chemical substances, use restrictions, and related functions. The management of chemicals considered to be hazardous, including safe transportation, safe handling, accident prevention, and the maintenance of a standardized hazardous chemicals inventory, is implemented under the State Council's Decree No. 591. Decree No. 591 also is the primary vehicle in China for implementing the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Two South Korean regulations that address chemicals include the Toxic Chemicals Control Act (TCCA) and the Act on Registration and Evaluation, etc. of Chemical Substance (the official name), commonly known as Korea REACH or K-REACH, enacted in 2013 and scheduled to take effect January 1, 2015.

TCCA focuses on managing industrial chemicals. K-REACH is intended to be a broad regulatory measure, setting up a process for the registration, evaluation, and assessment of the risks and effects of chemical substances and products containing hazardous chemicals. When K-REACH takes effect in 2015, it will not replace TCCA but will strengthen registration activities for both new and existing substances.

Each of the focused chapters in the Handbook, in addition to the commentary and listed resources, help to ground environmental professionals and readers-at-large in the diverse regulatory structures that they may encounter in hands-on interactions with chemical management regulations in the United States or abroad. Knowing what to expect and how to prepare for it are essential steps in successfully navigating these systems.