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## THE REGULATION OF CHEMICALS AND CHEMICAL INGREDIENTS IN CONSUMER PRODUCTS: A GLOBAL APPROACH

The introduction and sale of chemicals and chemical ingredients in consumer products, including their import and export, are increasingly subject to national and international requirements. The regulation of chemicals is receiving closer attention as legislators and environmental regulators become more concerned about the content of products in the marketplace. Existing regulatory programs addressing this concern are the focus of aggressive monitoring and enforcement, and new programs are rapidly developing. These programs affect the sale, import and export of chemicals and products containing chemicals. Pre-approval processes are often required, and can take a significant amount of time and planning. Thus, in today's market, as new products are

introduced, and as goods routinely move through countries and across borders, it is essential to understand national and international programs regulating chemicals and chemical ingredients. Jones Day attorneys are located in offices throughout the world and have the experience to successively navigate existing regulatory requirements and position your company to prepare for those of the future.

Provided below are brief descriptions of some major regulatory programs addressing the chemical content of products. These programs are in addition to other regulations that may address specific chemicals, products, or concerns.

## CHEMICAL IMPORT AND MANUFACTURING REQUIREMENTS IN THE EUROPEAN UNION (REACH)

The manufacture in, import into, and introduction on the European Union (“EU”) market of substances, on their own or in mixtures or articles, are subject to Regulation No. 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (“REACH”) administered by the European Chemicals Agency (“ECHA”). Each of these terms has a specialized meaning:

**Registration.** Substances, on their own or in mixtures or articles, may not be manufactured in the EU or introduced on the EU market unless they have been registered pursuant to REACH. Therefore, companies that plan to manufacture in, or import into, the EU market more than one ton/year of a given substance, on its own or in a mixture, must first submit a registration file for that substance to the ECHA in order to: (i) generate data on the substances they manufacture or import; (ii) use such data to assess the risks related to these substances; and (iii) develop and recommend appropriate risk-management measures. Any producer or importer of an article may also have to register the substance contained in that article pursuant to defined conditions (e.g., if the substance, totaling more than one ton/year, is intended to be released under normal or reasonably foreseeable conditions of use).

**Evaluation.** Evaluation under REACH refers to: (i) an assessment by the ECHA of the registration files (review of the testing proposals and compliance verification of the registrations); and (ii) an assessment by the EU Member States of the substances and the risks they pose.

**Authorisation.** REACH provides for a list of Substances of Very High Concern; such a substance cannot be placed on the EU market unless its use has been authorized either on its own or in the mixture or article for which it was introduced.

**Restriction.** REACH provides for a list of restrictions applicable to the manufacture, introduction on the market, and use of certain hazardous substances, mixtures, and articles. No substance, mixture, or article shall be manufactured, introduced on the EU market, or used unless it complies with such restrictions.

Each EU Member State is required to establish an enforcement program with penalties to address violations of the REACH provisions.

Jones Day attorneys have been advising clients on REACH since the earliest proposals and have been engaged in significant representations in connection with the implementation of this very complex regulation. They will be happy to assist you in complying with applicable requirements.

## CHEMICAL IMPORT AND MANUFACTURING REQUIREMENTS IN THE UNITED STATES (TSCA)

**Current Requirement.** The manufacture in, import into, and export from the United States of chemicals and products containing chemicals are subject to the Toxic Substances Control Act (“TSCA”) administered by the United States Environmental Protection Agency (“EPA”). Companies planning to introduce on the U.S. market a chemical or product containing a chemical must first determine whether the chemical is listed on an inventory maintained by EPA. If the chemical is not listed on the inventory, and if one or more of several exemptions do not apply, the company must submit a premanufacture notification to EPA along with responses to any EPA requests for information about the chemical. Products imported into the U.S. must be accompanied by a certification stating that the chemical complies with TSCA (generally because the chemical is on the TSCA inventory or because a premanufacture notice has been submitted and EPA has not objected to its importation) or that the chemical is not subject to TSCA. Shipments without the certification can be denied entry into the U.S. There are other aspects to the program, including whether the use of a chemical is a significant new use subject to special rules. Drawing on their extensive experience with these programs, Jones Day attorneys can evaluate the application of TSCA to proposed transactions and map out strategies to comply effectively and efficiently with applicable requirements.

**Potential Future Requirements.** Congress is under pressure from various groups to modify and expand TSCA. Jones Day attorneys are tracking the bills seeking to amend TSCA and can advise companies on probable new legislation and how best to prepare for its potential passage and implementation.

Individual states are also developing additional programs to regulate chemicals in consumer products. For example, in 2008 California amended its statutes to include a new regulatory program known as the “Green Chemistry Initiative,” which is intended to result in safer consumer products. The statute directed California’s Department of Toxic Substances Control (“DTSC”) to adopt regulations establishing a process for identifying chemicals of concern in consumer products and for evaluating such chemicals and their alternatives. In response, DTSC proposed regulations to implement the statute on September 7, 2010, and subsequently revised its proposal to reflect post-hearing changes. The proposed regulations establish a three-step process. First, DTSC will establish a list of priority products that contain chemicals of concern. Second, producers or importers of priority products are required to conduct rigorous assessments of their products with the objectives of identifying and selecting safer alternative chemicals or supporting a decision to retain the existing priority product or chemical in lieu of an alternative. And third, DTSC will identify regulatory responses in light of the alternative assessments. Such responses can include prohibition of the sale of the product in California if the agency concludes that a safer alternative exists which is technologically and economically feasible. As DTSC continues to examine the issues raised during the public-comment process, Jones Day attorneys can work with companies to help them prepare for the changes resulting from this challenging new program.

## CHEMICAL IMPORT AND MANUFACTURING REQUIREMENTS IN JAPAN

**Current Requirement.** The manufacture and import of chemical substances are regulated in Japan by the Chemical Substances Control Law (“CSCL”), administered by the Ministry of Economy, Trade and Industry; the Ministry of Health, Labour and Welfare; and the Ministry of the Environment (the “Ministries”). The CSCL was established in 1973 in the wake of environmental pollution caused by PCBs. The purposes of the CSCL are: (i) to evaluate, before manufacture or import, whether or not new chemical substances have properties such as bioaccumulation potential or toxicity for humans, flora, or fauna; and (ii) to implement necessary regulations in order to prevent environmental pollution caused by chemical substances that pose risks to human

health or the habitation and/or growth of flora and fauna. “New chemical substances” are chemical substances newly manufactured or imported on or after 1973 that have not yet been evaluated.

In general, a person planning to manufacture or import a new chemical substance must provide prior notification to the respective Ministries and furnish certain information on the substance. Following such notification, the new chemical substance will be subject to evaluation by the Ministries. Depending on the result of such evaluation, the new chemical substance may be subject to regulation, such as a limitation on its manufacture, import, and/or use. In addition, the CSCL requires companies handling specified chemical substances to label the products with any information necessary for transactions. “Chemical substances” under the CSCL means compounds that are obtained by a chemical reaction on an element or compound.

In addition, under the Industrial Safety and Health Act, a person planning to manufacture or import certain chemical substances generally must undertake an investigation of toxicity and provide advance notification to the Ministry of Health, Labour and Welfare of the names of the new chemical substances, the result of such investigation, and other related information.

**Potential Future Requirements.** In order to enhance the control system for chemical substances, the Law on the Partial Amendment of the CSCL was promulgated on May 20, 2009, with the unenforced part of the Law coming into force on April 1, 2011. Companies that manufacture or import any chemical substance, including an existing substance, in excess of a specified amount now have a new obligation to report the amount being manufactured or imported for each fiscal year, in addition to certain other information. Although chemical substances will continue to be subject to regulation depending on their nature, the regulatory regime will change from the current system, which is based solely on the hazardous nature of chemical substances, to a “risk-based” system, in which “environmental release (exposure)” (i.e., the potential effect of the chemical substance on humans and/or flora and fauna) is also considered. Jones Day attorneys can provide you with continuous updates on this evolving area of regulation.

## ADDITIONAL INFORMATION

For additional information on our Global Chemical Regulation team or any of our other practice areas, please contact your principal Jones Day representative or one of the lawyers listed in this publication. General email messages may be sent using our "Contact Us" form, which can be found at [www.jonesday.com](http://www.jonesday.com).

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