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# Better Living through Green Chemistry

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To paraphrase Plato, necessity is the mother of invention. A prime example is the green chemistry movement embraced by the European Union (EU) and California. Green chemistry, as the name implies, is part of the “greening” of corporate practices that has monoliths like Wal-Mart Stores, Inc., touting “earth-friendly” products. It is an approach to product manufacturing that seeks to reduce or eliminate the use or generation of hazardous substances in the design, manufacture, and application of chemical products.

The relevance of Plato’s aphorism comes from widespread acknowledgment that the existing “cradle to grave” approach to regulating the use of chemicals is too inefficient and costly to perpetuate. For the past thirty years, regulation on end-of-pipe, after-product use of chemicals has meant that agencies only engage once the chemicals become waste, discharges, and emissions.

For example, California’s Environmental Protection Agency (Cal-EPA) has estimated that groundwater monitoring for the state’s largest hazardous waste sites costs insurers, businesses, and the public around \$30 million annually. The U.S. EPA has stated that it costs more than \$1 billion annually to clean Superfund sites, and costs for future site clean ups are estimated at \$250 billion. Businesses pay for lost productivity and health care costs attributable to air and water quality impaired by toxins. Economists estimate that preventable diseases from workplace chemical exposure cost California businesses and families \$1.4 billion annually in direct medical costs and indirect costs, such as lost wages, benefits, and years of productive life.

Several recent consumer product scares—contaminated pet food and peanut butter and lead in children’s toys—also have resulted in a public cry for government action. Rather than parse the product world chemical by chemical, green chemistry seeks to provide an omnibus approach that regulates hazards in products at the design stage, provides transparency to the public, and rewards manufacturers that bring safer alternatives to the marketplace.

Despite enactment of the Toxic Substances Control Act (TSCA) in 1976, there is a consensus in the legal and government communities that existing federal and state chemicals policies are insufficient to protect human health and the environment and do not promote innovation in chemicals markets. Stakeholders, including government, academics,

health advocates, and some within the chemical industry, view shifting the paradigm of hazardous chemical regulation from “cradle to grave” to “cradle to cradle” and delegating more information-gathering and reporting tasks to businesses as the way to improve oversight.

The EU and California have emerged as governmental leaders in green chemistry. The EU’s Regulation, Evaluation and Authorisation of Chemicals program (REACH) was enacted in December 2006 and became active in June 2007. California’s green chemistry legislation, AB 1879 and SB 509, was enacted in 2008, and the California Department of Toxic Substance Control (DTSC) is in the midst of a public participation process to vet prospective implementing regulations.

To date, neither the federal government nor any states other than California have adopted green chemistry legislation. This is not likely to remain the case. The Obama administration and Congress appear poised to reform TSCA. To what extent such reform would incorporate green chemistry principles is unknown. However, the breadth of products subject to REACH and California’s legislation signals that the paradigm shift from regulating products on the front end to the back end has occurred.

REACH is the first regulatory system to invoke green chemistry principles. As California’s DTSC begins to shape the regulations that add flesh to AB 1879 and SB 509, the breadth of REACH is a good indicator of the system that California will build upon and presumably seek to improve.

As an initial matter, REACH regulates “substances,” whether on their own, in a mixture, or in articles, but REACH’s use of the term “substances” is nearly synonymous with California use of the term “chemical.” Thus, for simplicity’s sake, this discussion refers to REACH as regulating “chemicals.”

REACH’s regulations break down into four basis components: registration, evaluation, authorization, and restriction.

Registration and evaluation are REACH’s information-generating provisions. Registration is the engine that provides the information to make the rest of REACH go. Generally speaking, a chemical cannot be manufactured in or imported into the EU unless the chemical has been registered with the European Chemical Agency (ECHA), the agency that administers REACH. Registration requires industry to generate and submit certain information about chemicals to ECHA so that the agency and EU Member States may evaluate whether the use of those chemicals should be restricted. A complete registration consists of a technical dossier, which describes the properties and classifications of a chemical. Additionally, if more than 10 tons of a chemical is manufactured or imported

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annually, the registration must also include a Chemical Safety Report, which contains an exposure assessment chronicling the hazards of the chemical and discusses whether the chemical is persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

If registration is REACH's engine, evaluation is the pedal that ECHA and Member States use to drive toward chemical regulation. REACH provides for "dossier evaluation" and "substance evaluation." In dossier evaluation, ECHA selects a small percentage of technical dossiers to determine whether the submissions comply with the registration requirements. Substance evaluation, however, provides ECHA and Member States with the ability to require additional information from industry, as well as to recommend restriction or authorization of particular chemicals. When either ECHA or a Member State believes a chemical may pose a risk to human health or the environment, ECHA will include that chemical on a list for substance evaluation. Thereafter, a single Member State will evaluate the chemical to determine whether regulatory action is required.

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Authorization and restriction are where the rubber meets the road. Industry members may not use a chemical subject to authorization without obtaining individual, use-specific permission from the European Commission (Commission). The chemicals that may eventually be subject to authorization are "substances of very high concern," which include chemicals that are—as identified by Member States or ECHA with stakeholder input—carcinogenic, mutagenic, or toxic to reproduction (CMR, PBT, or vPvB), as well as chemicals that, on a case-by-case basis, present similar threats to humans or the environment. ECHA places substances of very high concern on a candidate list. Then, in a process called prioritization, ECHA determines, with further input from stakeholders, whether a substance of very high concern will be subject to authorization, the date that use of the chemical will become prohibited without authorization, and what uses of the chemical will not require authorization because of sufficient controls under other EU programs.

To obtain the required individual, use-specific authorization, an industry member will have to submit an application detailing the risks posed by the chemical and an analysis of

alternative chemicals and technologies. If there is a technically and economically feasible lower-risk alternative, the applicant will also have to submit a substitution plan explaining how the applicant will transition to the substitute over time. Finally, the Commission may grant authorization if the applicant demonstrates (1) that the risk of the chemical is adequately controlled or (2) that there is no suitable alternative and socio-economic benefits outweigh the chemical's risks.

Restriction is the final avenue available under REACH by which the manufacture of chemicals in or import of chemicals into the EU may be limited. Restriction empowers the Commission to disallow specific uses of particular chemicals throughout the EU. Assuming the restricted chemical is not also subject to authorization, uses of the restricted chemical that are not specifically restricted are allowed. ECHA and Member States may submit chemical-specific proposals for restrictions to the Commission. If the Commission finds that a particular application of the chemical poses an unacceptable risk to health or the environment, the Commission may require that the chemical no longer be used in that manner.

It would not be surprising to see California's green chemistry regulations emerge in a way that builds on the initial steps of REACH. But the debate about the bureaucratic requirements of REACH leaves some doubt over when that impact may be felt. This debate may be instructive on what impact California's eventual green chemistry regulations will have and when.

### *Debating the Near- and Long-Term Reach of REACH*

Green chemistry programs such as California's AB 1879 and SB 509 and REACH entail a potentially unprecedented amount of work for regulatory agencies. Under REACH, a manufacturer or importer of currently used chemicals could "pre-register" by submitting a minimum amount of information to ECHA by December 1, 2008, in order to postpone full-registration obligations until at least November 2010. ECHA reported on March 27, 2009, that approximately 143,000 chemicals had been pre-registered by 65,000 companies. What are uncertain are the immediate impacts on industry once regulatory agencies such as ECHA and DTSC begin to execute their responsibilities with respect to these chemicals.

In late 2008, Environmental Defense Fund (EDF) issued a report entitled *Across the Pond, Assessing REACH's First Big Impact on U.S. Companies and Chemicals* (EDF Report), in which EDF asserts that REACH will have significant impacts on companies manufacturing and using chemicals in, importing into, and exporting from the United States. Soon after EDF released its report, the American Chemistry Council (ACC) responded that the reasoning and conclusions in the EDF Report are misleading because of the list of chemicals considered. While there is some merit to EDF's conclusions, the report may exaggerate the manner in which U.S. companies will be affected by REACH in the near term and may obfuscate the ways in which companies may protect themselves

from negative impacts.

The EDF Report focuses on REACH's regulation of substances of very high concern and correctly observes that once a chemical is determined to be a substance of very high concern under REACH, it is possible, and perhaps likely, that entities will be required to obtain authorization from the Commission before manufacturing the chemical in or importing it into the EU. EDF attempted to demonstrate the likely impact of this process on U.S. companies by analyzing the extent to which chemicals that EDF believes should be substances of very high concern are used and manufactured in the United States.

If the purpose of the EDF Report is to outline the immediate impacts of REACH on U.S. companies, the report may overestimate those risks because of the catalogue of chemicals considered. Currently, no chemicals are subject to authorization, and the candidate list contains fewer than twenty chemicals. EDF, though, performed its analysis using a list of 267 chemicals that may exhibit the characteristics of substances of very high concern and may, at some point, be subject to authorization. By deemphasizing the fact that nearly all of these chemicals must go through the designation process before they could be subject to authorization, the EDF Report overstates the near-term impacts of REACH. A more accurate assessment of near-term impacts would have focused on ECHA's currently proposed candidate chemicals and left the much longer list of chemicals to a discussion of possible medium- or long-term impacts.

Beyond exaggerating the immediate impact of REACH, EDF's analysis obscures the manner in which U.S. companies can insulate themselves from the impacts of REACH. If the EDF Report accurately portrayed the immediate, short-term risks of REACH, it would be clear that U.S. companies using the fewer-than-twenty candidate-list chemicals should—if they prefer not to change their chemical uses—seek to purchase those chemicals from a company that manufactures them outside the EU. Therefore, while REACH may impact many U.S. companies, its near-term impacts are not likely to be as pervasive, devastating, or inevitable as suggested by the EDF Report because of the delay likely associated with attendant bureaucratic processes.

What should not be lost, though, is that REACH, and eventually AB 1879 and SB 509, may have a significant impact on companies. Potentially affected companies, both within the United States and abroad, should not be paralyzed by this possibility. Rather, companies should understand that implementation may be slow, and they should analyze their operations to uncover ways to mitigate impacts as well as take advantage of opportunities.

### *The California Approach*

California considered green chemistry for some time before enacting AB 1879 and SB 509. In 2004, its legislature commissioned a report from the University of California's (UC's) Policy Research Center to identify California's chemical

issues, causes, and possible responses. The report, produced by UC Berkeley, was released in 2006, but no legislation resulted.

In 2007, California Governor Schwarzenegger called for a "Green Chemistry Initiative" mandating that DTSC and Cal-EPA meet with other agencies and interested parties to generate ideas and policy options to develop a green chemistry program in California. Cal-EPA commissioned the Centers for Occupational and Environmental Health at UC Berkeley and University of California, Los Angeles, to build on the 2006 study and report on the cost estimates attributable to hazardous wastes. The Initiative's "Final Report of Recommendations" was released in December 2007 and presented six recommendations that reflect the requirements of AB 1879 and SB 509. In September 2008, the bills became law.

The backbone of AB 1879 is its directive that DTSC adopt regulations by January 1, 2011, to establish processes for identifying, prioritizing, and evaluating chemicals of concern in consumer products and their potential alternatives. The statute compels DTSC to use an interagency consultative process that includes public participation. DTSC must prepare a "multimedia life cycle evaluation" that considers thirteen life-cycle criteria, including the product's manufacturing process, use characteristics, environmental impacts, and its waste and end-of-cycle disposal. "Multimedia" means that DTSC will consider the effects of chemicals at all stages of the chemicals' life, in all media (air, surface water, land, and groundwater). DTSC had to establish and appoint members to a Green Ribbon Science Panel by July 1, 2009. The panel will be authorized to act and advise DTSC on science, technical, and policy matters. DTSC also must establish confidential business information (CBI) procedures to protect and exempt from public release trade secret information.

SB 509 requires DTSC to establish a Toxics Information Clearinghouse for the collection, maintenance, and distribution of information regarding chemical hazard trait and environmental and toxicological end-point data. The clearinghouse must be online so that consumers can search for information on chemical hazards in "consumer products." Several types of products are exempt from the definition of "consumer product," including dental restorative materials and food.

Information in the clearinghouse will be shared with a "sister" agency of DTSC—the Office of Environmental Health Hazard Assessment—which is required by SB 509 to conduct its own evaluations of hazard traits and toxicological end-points of listed chemicals by January 1, 2011. SB 509 also requires DTSC to consult with other states, the federal government, and other nations with regard to creating a comprehensive database of chemical data.

Environmentalists, regulators, and, largely, the chemical industry, have supported California's legislation. Keys to industry support were the elimination of labeling requirements from SB 509 and a related provision allowing for civil suits over labeling issues. Manufacturers also have the opportunity to prove that product information should be classified as a

trade secret, in which case DTSC will not publish it. Industry also approved of the requirement that DTSC consider a cost-benefit analysis—the economic impact to industry of requiring use of an alternative to the chemical—as part of its evaluation of alternatives to a chemical of concern.

In many ways, AB 1879 is merely the blueprint for a process. However, DTSC must produce implementing regulations by 2011. Stakeholders have already begun to devise their preferred system, and DTSC has a calendar of public participation workshops, and even an online “wiki,” to encourage dialogue about what the regulations should look like. There are many ideas about what the regulations should be. While REACH is certainly an existing model for review, California is not likely to borrow much from it. California’s regulations more likely will be an extension of REACH, building a second phase atop REACH’s initial efforts, to try to streamline the registration and evaluation process.

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To date, much of the discussion around green chemistry has been about the creation of a “list” of chemicals of concern, prioritization of that list, criteria for that list, or whose list from which to borrow or build. Not surprisingly, some in industry seek a small universe of chemicals of concern, believing that a smaller list will be more administratively feasible and that additional chemicals can be added later. On the opposite side, health and environmental advocates are pushing for as broad an initial list as possible, their thinking being that chemicals of concern subsequently will be prioritized, with the chemicals deemed most hazardous subject to risk assessment/life-cycle analysis first.

The REACH program appears to have taken the start-small approach. Its list of substances of very high concern that will be subject to the authorization process has yet to be finalized, and, as noted above, the candidate list currently contains fewer than twenty chemicals. In contrast, a European nongovernmental organization has created a list of 267 chemicals that could be subject to regulation. Canada also has a “domestic substances list” that categorized 23,000 substances into groups based on hazardous characteristics. Of the initial 23,000 chemicals, about 4,000 will be subject

to screening assessment, research, and potential regulatory control. Given the breadth of issues raised during the studies about the need for green chemistry, it seems unlikely that DTSC will confine itself to a small number of chemicals.

Moreover, while lists have proven comforting to business and government—evidenced by the California Proposition 65 lists of chemicals or the TSCA Inventory—consistent with the shift in thinking that green chemistry represents, the list of chemicals of concern that trigger an analysis could be less a list and more a concept. The trigger could be something akin to standing under the California Environmental Quality Act whereby a person has a “concern” about a particular chemical on the initial list, hence that chemical merits analysis. Or it could be based on biomonitoring, as would be the case were the chemical found in umbilical cord blood. This could produce a *res ipsa loquitur* result whereby all products sold in California that contained that ingredient would have to perform an alternatives analysis.

Putting aside the initial list of chemicals of concern, the more important effort will concentrate on establishing the regulations that describe the alternatives analysis required of chemicals of concern. What kind of analysis will DTSC require of manufacturers of products when a chemical of concern is at issue? Possibilities include an algorithm based on life cycle, a narrative analysis of multimedia, life-cycle effects, or even a risk assessment.

Equally important are what the regulatory responses and enforcement will look like. Following completion of the multimedia evaluation of a chemical of concern, AB 1879 confers DTSC with broad authority to take a range of actions deemed necessary to protect the public and the environment. These include a no-action alternative, requesting additional information, labeling requirements, imposing restrictions, or prohibiting the use of a chemical of concern. DTSC is also authorized to impose requirements on manufacturers to manage a product “at the end of its useful life,” including recycling or “responsible disposal” of the product.

The questions about what the regulations will look like will be answered by January 1, 2011. This will give some certainty to the marketplace about how one of the world’s biggest economies will regulate products that contain certain chemicals within its borders. Although that date is less than two years away, California is ahead of the federal government and other states in implementing green chemistry. The question is: for how long?

### *The New Administration’s Approach*

Were there any doubt that the green chemistry philosophy marks a shift in regulatory thinking, one need only mention TSCA for proof. Since its enactment in 1976, TSCA has not generated meaningful information on the majority of chemicals and, consequently, has not significantly affected how chemicals are used in the United States. TSCA’s widely acknowledged shortcomings are in large part attributable to the high burden on EPA before it can compel industry to

develop and publicize information. To compel industry to develop information on chemicals in use when TSCA was passed, EPA must demonstrate potential risks posed by the chemical, show a lack of data on the chemical, and engage in noticed rulemaking on a chemical-by-chemical basis. This process can take up to ten years for each rule, and, to date, it has only covered about 200 chemicals.

Also, while TSCA includes an Inventory Update Rule that requires manufacturers or importers to report on the TSCA-listed chemicals, they must do so only every four years and only if the use of the chemical is greater than or equal to 25,000 pounds (lbs.)/year at any site. The 25,000 lbs. itself is a barrier to data collection, especially in light of the increasing awareness of the dangers posed by virtually weightless nanoparticles. TSCA also provides little incentive for the development of safer chemicals.

Lisa Jackson, the new EPA administrator, has listed TSCA reform as one of her top five priorities. Jackson wrote in a memo to EPA employees on January 23, 2009, that

[m]ore than 30 years after Congress enacted the Toxic Substances Control Act, it is clear that we are not doing an adequate job of assessing and managing the risks of chemicals in consumer products, the workplace and the environment. It

is now time to revise and strengthen EPA's chemicals management and risk assessment programs.

Congress has already taken up the debate on reforming TSCA. On February 26, 2009, the Subcommittee on Commerce, Trade, and Consumer Protection of the House Energy and Commerce Committee held a hearing to "revisit" TSCA. The hearing is rumored to be the first of several on the issue, and among its themes was the extent to which the United States should look to REACH as a model for prospective TSCA reform. A federal counterpart to California's green chemistry legislation seems inevitable, and it may come via TSCA reform.

The shift of hazardous waste regulation toward a green chemistry paradigm has been made. As California continues toward its 2011 due date for regulations implementing its green chemistry legislation and REACH continues to develop, chemical and product manufacturers and importers will have to continue to adjust their research, design, data-collection, and permitting practices. Front-end regulation embodied by the green chemistry movement may appear daunting. However, there is hope on all sides that this new treatment will manifest greater efficiencies for government, industry, and consumers alike, while it helps to create a less-toxic world. 🌳