

# Comment on Regulating Industrial Chemicals: Lessons for U.S. Lawmakers From the European Union's REACH Program

by Lynn L. Bergeson

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## Summary

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It is entirely appropriate to consider how REACH may influence reconsideration of the U.S. chemical regulatory environment, and the report provides some critical insights. But REACH is not the only consideration—Canada's Chemical Management Plan should be considered as well. Further, REACH should be considered from a practitioner's, not an academic's, perspective to learn lessons relevant to U.S. chemicals management.

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The report, *Regulating Industrial Chemicals: Lessons for U.S. Lawmakers From the European Union's REACH Program*, is a welcome contribution to the growing body of work intended to assist the U.S. Congress in its long-overdue reconsideration of the Toxic Substances Control Act (TSCA).<sup>1</sup> The *Lessons* article is especially useful as, despite objections to the contrary by some in the domestic chemical community, the Registration, Evaluation, Authorization and Restriction of Chemicals Program (REACH) (in whole or in part) can be expected to serve as a template for TSCA reform. This eventuality is all the more probable given the noticeable absence of any known alternative legislative construct proffered to date by the domestic chemical community in response to Sen. Frank R. Lautenberg's (D-N.J.) multiple proposed legislative reform measures. Nature abhors a vacuum, and REACH offers a serviceable regulatory construct from which to draw the outline of a new and improved TSCA. Rather than provide a detailed critique of the *Lessons* article, I offer a few general thoughts on the article as a whole, and then focus on the article's findings.

## I. General Remarks

The article's premise is that TSCA reform will occur, perhaps not any time soon, but "eventually" and as a "thought experiment," REACH should be considered so U.S. policymakers can build upon the considerable work of European Union (EU) officials "rather than 'reinvent the wheel.'" While it is true that there are elements of REACH that could prove instructive and even useful in the context of TSCA reform, the utility of the article would be all the greater if core elements of Canada's Chemical Management Plan were also compared and contrasted with REACH and TSCA. There are many winning aspects of the Canadian approach to chemical management, and a critical review of it would offer a more complete menu of options for congressional consideration.<sup>2</sup>

Inclusion of Canada's Chemical Management Plan would also dispel a possible inference that flows from the article, namely that REACH is the only viable chemical management construct that U.S. policymakers should consider in modernizing TSCA. This is an incorrect inference and likely not the authors' intent. Nonetheless, the near-total absence of Canada's Chemical Management Plan from consideration, as well as an explanation for its absence, might contribute to the false impression that REACH is the only game in town.

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1. 15 U.S.C. §§2601-2692, ELR STAT. TSCA §§2-412.
  2. See Richard Denison, *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*, Environmental Defense Fund report in cooperation with Pollution Probe (Apr. 2007).

Second, as good as the article is, it would be enhanced if it were infused with more information that reflects hands-on experience with REACH. The authors' perspective is largely academic and the analysis, while well-cited and thoughtful, is devoid of the reality of REACH. REACH's implementation has been far from perfect, and the reality of REACH in practice is an essential component of an analysis of REACH in theory. This is especially so as the article is intended to distill what lessons can be extrapolated from REACH to inform TSCA reform efforts. REACH is more than an objectified regulation. The day-to-day reality of REACH, the commercial disruption, the REACH-IT challenges, the competitive distortions created by bad actors in the Substance Information Exchange Forum (SIEF) community, and a long list of other implementation issues and commercial distortions have seriously and adversely impacted REACH's effectiveness. This is not to suggest that REACH lacks teachable moments for TSCA reform, as it clearly offers useful instruction in targeted areas. The good and the bad of REACH in practice are essential components of REACH's reality, and few of these real-world issues are discussed in any detail. The absence of a more experiential view of REACH's implementation runs the risk of distorting the EU chemical regulatory experience.

Finally, the jury on REACH is still out, and whether the regulation fulfills its mandate is entirely unclear. Even the authors admit that it is "far too early to know whether REACH has produced measurable improvements in public health or the environment or even what the total costs of REACH implementation will be." This admission begs the question of whether REACH should be considered by U.S. policymakers at this time (or perhaps ever) as a model for TSCA reform. To the extent that REACH is considered (as it must for the reasons noted above), more focused reference to REACH's impacts to date would be useful.

Of particular relevance to this issue is a recently issued report prepared by the Centre for Strategy & Evaluation Services at the request of the European Commission (EC) as part of its review of REACH.<sup>3</sup> The report examines the impact of REACH on innovation. According to the report, 43% of companies think REACH has had a negative impact on innovation, compared to the 13% that reported a positive impact. Other report findings suggest that these effects are largely short-term as companies are expected to reorient their research and development (R&D) and inno-

vation programs. It is not clear on what this expectation is based and how exactly R&D programs will be reoriented. Other impact analyses are available, and a review of at least some of the more extensive works and significant impacts would better quantify whether REACH has yielded measurable results and thereby provide more explicit guidance to U.S. policymakers on what is working under REACH and what is not.<sup>4</sup>

## II. Comments on Findings

### *Finding #1: U.S. Policymakers Should Consider Simplifications of the REACH Program.*

On the whole, the authors' findings are sensible and expressed in a way that makes serious opposition difficult. Yes, REACH is complicated, and if U.S. policymakers were to embrace REACH as a regulatory construct, simplification of the REACH program would be desirable. In hindsight, the authors may regret making this the first finding, as it seems less consequential than the other, more substantive findings. In addition, that a program is complicated is only a problem if the complexity gets in the way of the program's utility and effectiveness. Since the authors confess that it is too early to determine if REACH is producing the intended results, whether the program is complicated or not seems immaterial.

To simplify some aspects of REACH, the authors propose combining registration with a restriction process or retaining only registration and restriction authority. A third option for TSCA reform is to embed authorization in the registration process, empowering the U.S. Environmental Protection Agency (EPA) to review and assess specific chemical uses and phasing out uses that cannot be supported unless adequate justification for them can be made. The argument is that by linking authorization to registration, "one can also avoid the situation where EPA might try to propose restrictions before a substance has been registered or before the authorization process has begun." It is difficult to understand how this collapsing of

3. Centre for Strategy & Evaluation Services, Final Report: Framework Service Contract for the Procurement of Studies and Other Supporting Services on Commission Impact Assessments and Evaluations—Interim, Final and Ex-Post Evaluations of Policies, Programmes and Other Activities (June 14, 2012), available at [http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/innovation\\_en.htm](http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/innovation_en.htm).

4. In addition to the EC's most recent thematic studies that are intended to inform the 2012 review process, the EC carried out earlier studies on REACH to assess issues such as the benefits of REACH or what effect adding substances to the candidate list of substances subject to authorization will have on their use in the market. See REACH Impact Assessments, available at [http://ec.europa.eu/environment/chemicals/reach/background/i\\_a\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/background/i_a_en.htm). A more recent article was based on interviews conducted in 2009-2010. Alison Cohen, *The Implementation of REACH: Initial Perspectives From Government, Industry, and Civil Society*, 17(1) INT'L J. OCCUPATIONAL & ENVTL. HEALTH 57-62 (2011). The European Chemicals Agency (ECHA) has published reports on its evaluation of registration dossiers, most recently in 2012, and these reports discuss issues ECHA has found in the dossiers. ECHA, *Evaluation Under REACH: Progress Report 2011* (2012), available at [http://echa.europa.eu/documents/10162/13628/evaluation\\_report\\_en.pdf](http://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf).

REACH stages would avoid the presumptive deselecting of chemicals that have been identified as candidates for authorization. Indeed, by linking authorization to registration, it would seem that the reflective deselection and market distortion that inevitably occurs would happen sooner in the process and exacerbate the very conditions the proposal was intended to avoid.

***Finding #2: If a REACH-like system is adopted in the United States, more public disclosure of safety-related information and opportunities for public participation should be provided.***

This finding reflects concern that has been made before and with considerable merit. Concerns have been expressed with the scope of Article 64(2) of REACH, which states that “the Agency [European Chemicals Agency (ECHA)] shall make available on its web-site information on uses . . . for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.” According to some, Article 64(2) allows ECHA to interpret and self-select the information it wishes to disclose.<sup>5</sup> This interpretation has inspired concerns regarding transparency and inclusiveness.

Additionally, while the public dialogues ECHA frequently convenes on a wide range of REACH issues are laudable and help to solicit public participation, it is also true that the more structured exchanges between REACH registrants and ECHA are, as has been noted, “more conducive to genuine deliberation than those with other interested parties.”<sup>6</sup> In other words, there is a qualitative difference between structured and unstructured dialogue, and the former is typically more influential than the latter.

***Finding #3: In considering how to streamline REACH for application in the United States, more focus should be on priority-setting based on risk and the opportunity to reduce risks to human health and the environment.***

Few would disagree that REACH is ambitious, far-reaching, and suffers from a lack of prioritization. The cascading impacts of the priority-setting deficit have been the subject of considerable discussion. Likewise, the TSCA reform debate on priority-setting is equally robust, and there is no consensus on how to assess priorities, which chemicals pose the greatest risk, and what scheme should be used to identify potentially risky chemicals and their uses. All of the authors’ suggestions are good (more focus on risky uses, target more effectively the universe

of substances to be registered, to name two). U.S. stakeholders will no doubt continue vigorously to debate these options and others. The more difficult questions of how to prioritize, against what criteria, what resources will be available to achieve prioritization targets, and related questions are, regrettably, beyond the scope of the article.

***Finding #4: Since some of the frustration and burden in the early years of REACH implementation have been linked to ambiguity in program design, a REACH-like system in the United States should provide clarification about critical standards, processes, and tools.***

Finding #4 is critically important. The absence of a “clear and consistent standard of safety” throughout REACH has hampered and will continue to hamper REACH’s implementation and effectiveness. Likewise, a large portion of the TSCA reform debate has centered on the safety standard. That TSCA reform demands a clear and consistent safety standard is not the issue; what the safety standard is and how to achieve consensus on such a standard remain very much the issues, and on these points, the article is less-instructive.

Similarly, information technology (IT) challenges, which are noted in Finding #4, and included in the broad category of “tools,” are critically important. Clients have expressed considerable frustration with REACH-IT, the primary document submission tool under REACH. While the authors are correct in flagging IT issues as important, U.S. policymakers would benefit from a far more-detailed discussion on information collection and dissemination technology to ensure that they appreciate how critically important IT and related tools are to the success of a regulatory program.

***Finding #5: If the United States chooses to adopt a REACH-like system of registration, unnecessary burdens on industry can be lessened by allowing the mutual, cross-Atlantic recognition of registration dossier.***

The article’s last finding—mutual, cross-Atlantic recognition of registration dossiers—is another critically important point and one that has been discussed and recommended repeatedly. It is fair to speculate that there is vigorous agreement on the desire for cross-Atlantic recognition of registration dossiers. As the expression goes, however, this is easier said than done. Two of several 800-pound gorillas in the room are data access and data compensation. While TSCA contains data compensation provisions, they have never been implemented, and thus no data compensation infrastructure exists, as one does under the Federal Insecticide, Fungicide, and Rodenticide Act<sup>7</sup> for pesticide chemicals. The REACH regulation

5. See Veerle Heyvaert, *The EU Chemical Policy: Towards Inclusive Governance?*, LSE Law, Society and Economy Working Papers (June 2008).

6. *Id.* at 18.

7. 7 U.S.C. §§136-136y, ELR STAT. FIFRA §§2-35.

addresses data compensation, but the system is fraught with a lack of clarity, and ECHA does little to address the ambiguities in the regulation. The point is while mutual cross-Atlantic recognition of dossiers is very much a

desirable outcome, the devil is in the details, and much work remains to be done to develop an effective program to achieve this result.