The Implementation of REACH:

Initial Perspectives from Government, Industry, and Civil Society

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The European Union's 2006 Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) legislation represents a new wave in regulating chemicals and has set far-reaching goals for protecting and enhancing public health, the environment, and markets. Despite substantial public debate during the development and passage of the REACH legislation, in interviews conducted from 2009–2010, respondents from government, industry, and civil society expressed general agreement on some key issues in the implementation of REACH, which are addressed in this study. At the same time, respondents expressed nuanced differences in how some of the outstanding implementation issues should be addressed. Industry respondents' main concern was their ability to comply with REACH; while government respondents reported wanting to ensure they can implement and enforce it; and civil society respondents wanted to ensure that REACH accomplishes its ambitious goals. *Key words*: chemicals control; EU chemicals regulation; policy implementation; REACH; stakeholders.

INT J OCCUP ENVIRON HEALTH 2011;17:57–62

The European Union's Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) legislation, which was passed in 2006, and went into effect in 2007, transformed the chemical regulatory paradigm by shifting the burden of proof of a chemical's safety onto chemical manufacturers and importers, rather than tasking government with proving a chemical's harm. While REACH is not the only regulation to place the burden of proof on manufacturers, no other chemical regulation has had as wide a reach or scope. This regulation, rooted in the precautionary principle,[1] applies to both new and existing industrial substances manufactured in or imported to the European Union (EU) at more than 1 ton per year; REACH has no legal authority to regulate chemicals manufactured or imported at smaller volumes.

REACH's four primary goals, as outlined in Article 1, are to: protect human health and the environment, promote alternative methods for hazard assessment, ensure free circulation of chemicals in the (European) internal market, and to enhance market competitiveness and innovation.[2]

In order to achieve these goals, REACH has four key processes: registration, evaluation, authorization, and restriction. The first step, registration, is governed by the principle "no data, no market"—all registrants of chemicals manufactured or imported at more than 1 ton per year must provide the European Chemical Agency (ECHA) information about a substance's chemical properties and uses, and some (but not all) registrants must also provide toxicity and ecotoxicity data; if they fail to do so by the specified deadline, the substance cannot be on the market. Registration deadlines span from 2010 to 2018, based primarily on the volume at which a substance is manufactured/imported. In the second step, evaluation, government evaluates the information provided in the registrations to ensure compliance with REACH: there is both a dossier evaluation, in which compliance with information requirements is checked, and substance evaluation, during which ECHA and member states determine if the substance may cause harm to health or the environment. Evaluated substances that are determined to be harmful may then be regulated. It is important to note that the REACH text implies that the majority of registered chemicals will not be evaluated, authorized, or restricted. For chemicals that government chooses to regulate after conducting the evaluation, there are two paths: authorization and restriction. In authorization, EU member states and/or the European Commission can identify substances of very high concern (SVHCs) based on the criteria outlined in Article 57[2] and prepare a dossier to nominate them to the candidate list; substances on the candidate list can then be prioritized by ECHA for authorization. For chemicals regulated under the authorization route, individual companies must apply to have their continued use of the substance authorized, which is only allowable if they describe how they will manage the substance's risks and/or if socioeconomic concerns are deemed to outweigh the potential health and/or environmental harm. In comparison to authorization, which allows for the manufacture and importation of substances with ECHA permission, restriction provides means for severely curtailing or banning certain uses of some chemicals after such action is proposed by a member state and approved by EU-wide governing bodies.

REACH is bringing a variety of new actors into the world of chemical regulation for the first time, includ-

Received from: University of California, Berkeley, School of Public Health. This research was funded by a 2009–2010 Fulbright-Schuman grant. Send correspondence to the author at: <alison.cohen@fulbrightmail.org>.

Disclosures: The authors declare no conflicts of interest.

ing downstream users, or companies who do not directly manufacture or import chemicals but instead use them further down the supply chain. In addition, a new EU agency, ECHA, was created to oversee and manage the implementation of REACH. REACH also encourages and requires cooperation between entities that do not report having a history of collaboration beyond general trade associations, including companies producing the same chemical substance and the public health and customs divisions of EU member states.

While some criticisms have been voiced regarding REACH, including how chemicals are prioritized and what information is available, REACH has largely been heralded as the most proactive and innovative chemical regulation in the world. Other countries, including the United States, China, India, and Japan, are looking toward REACH as a model to consider and improve upon as they work to reform their own chemical policies.[3–6] Scholars note that the United States' Toxic Substances Control Act (TSCA) had good intentions, but implementation failed.[7] REACH has similarly good intentions and even higher expectations, so we must carefully monitor its implementation. Although implementation has only recently begun, key decisions related to the interpretation and implementation of REACH are being made, and this is an opportune time to take a first look at them.

METHODS

Semi-structured interviews were conducted from fall 2009 through spring 2010 with key informants ($n = 67$) from diverse sectors encompassing government, civil society, and industry, with substantial variations of role and type of actor within these three sectors. The key informant sampling strategy relies on interviewing diverse respondents until content saturation—different respondents discussing the same types of topics and, within the same sector, sharing similar perspectives—was achieved.[8] The semi-structured interview format allowed for respondents to discuss issues of particular interest to them, but this was also a limitation in that not all respondents shared their perspectives on all potentially relevant issues. Participants were identified through snowball sampling, recommendation by other interviewees, attendance at conferences and meetings, and tracking names in the news. Participants explained and discussed their own work and their involvement in the implementation of REACH. Participants then described the implementation of REACH to date, noting both what was and was not working, and identifying both best practices that are working particularly well and what should be improved. Participants also were asked how they would define the successful implementation of REACH, or the vision that they hoped REACH would move toward. Almost all of the interviews ($n = 65$) were conducted in person; two were conducted over the phone because an in-person meeting was logistically infeasible. All but one interview was conducted in English; the non-English interview was conducted in the language of that EU member state, in which both the interviewer and interviewee were fluent.

Interview data were supplemented with content analysis of public documents and speeches ($n = 14$), providing stakeholder perspectives for those with whom interviews were not possible. These materials, some of which were observed in person and others of which were accessed through library and/or news records, included public speeches, testimonies at public hearings, remarks in public discussions, conference presentations, press releases, and written reports.

RESULTS

The 81 perspectives gathered can be divided into three sectors: government ($n = 46$, 40 of which were interviews), civil society ($n = 14$, 8 of which were interviews), and industry ($n = 21$, 19 of which were interviews). Government stakeholders worked for three member states in the Scandinavian, western, and southern regions of Europe selected for prominence in and/or diverse experiences with chemicals regulation in Europe ($n = 21$); the European Commission, includingthe two Directorate Generals overseeing REACH ($n = 7$) and the European Chemicals Agency ($n = 13$); the European Parliament ($n = 2$); and a non-EU country's delegation to the EU ($n = 3$). Civil society stakeholders included academic researchers ($n = 5$), staff of environmental and/or health non-governmental organizations ($n = 8$), and trade union staff ($n = 1$). Industry stakeholders included chemical manufacturers and/or importers ($n = 5$), downstream users ($n = 1$), consultants ($n = 8$), and industry association representatives ($n = 7$).

REACH and ECHA

Among respondents from each of the three sectors who spoke broadly about REACH, there was general agreement that the concept of REACH as a centralized chemical regulation overseen by a central implementation agency is a good idea and is performing well in its initial stages, as of spring 2010. However, changes were still desired: some industry respondents stated they would like all legislation related to chemicals in the EU to be included under REACH, and most civil society respondents expressed that they would like stronger requirements for replacement of hazardous substances with safer alternatives. A few industry and civil society respondents noted that tonnage is an inadequate proxy for risk. Across sectors, most respondents who addressed the topic noted that REACH's prioritization of substances for registration based on tonnage limits was the simplest approach.

Focusing on the implementation of REACH rather than the legal text of REACH itself, respondents from all sectors indicated overwhelmingly positive support for ECHA's work implementing REACH, with few exceptions. Many government respondents emphasized that ECHA's rapid growth and preparatory work has made feasible the implementation time line, which is fixed in the REACH legislation and cannot be changed. Respondents from all three sectors noted that government has positioned itself as being thoroughly responsive to its stakeholders. For example, many government respondents acknowledged that language barriers exist, which are of particular concern to small and medium-sized enterprises (SMEs) who may not have staff who speak English. Numerous government respondents emphasized that ECHA has dedicated a substantial amount of time and resources to translation efforts, and member states' REACH help desks are working with ECHA to overcome these barriers as well. Another example involves guidance documents: industry (as reported by multiple industry respondents and government respondents) had complained that guidance documents, which advise companies and enforcers how to comply with a particular portion of the REACH text, are not user-friendly. ECHA consequently developed "guidance-in-a-nutshell" documents to help make these tools more approachable and facilitate translation efforts to simultaneously reduce language barriers. Similarly, many industry respondents complained impatiently about the length of time it takes to develop a guidance document, but government respondents noted that the careful development of guidance documents is the only way to reach consensus from all relevant stakeholders, including industry, in interpreting REACH. Respondents from all three sectors agreed that ECHA's policy for engaging non-governmental stakeholders is strong.

An important point made by multiple government respondents was that technology has made the implementation of REACH possible. REACH-IT, the IT system used to manage all of the information and tasks involved in implementing REACH, is operational, even if, like all other public-sector IT systems, it is not problem-free. And although more tools need to be created to automate tasks well in advance of their desired use, government respondents noted that the tools that have been created so far have made possible REACH's time scale and scope of substances covered, which respondents from all three sectors agreed is ambitious.

Registration

Among the respondents from each of the three sectors who discussed registration, most agreed that the underlying principle for registration, "no data, no market," is good and is effective: the market is driving compliance, and downstream users are applying pressure on their suppliers to prepare for and comply with REACH. The other key tenet of registration is the joint submission process; the "one substance, one registration" principle reduces resource and time costs for companies and reduces unnecessary animal testing. All companies manufacturing or importing the same substance are required to work together in Substance Information Exchange Forums (SIEFs) and compile a joint submission for their registration. Some respondents from each of the three sectors acknowledged that this is a good idea in theory, but many government and industry respondents both noted that one registration per substance is difficult to achieve in practice due to general company hesitancies to collaborate and share information with competitors and challenges operating and overseeing SIEFs.

The first real test for implementing REACH was when all of the existing chemicals on the market pre-registered in 2008 (a pre-registration allows substances to continue to be on the market while the registration dossiers are being assembled). In general, government respondents viewed pre-registration as successful, despite receiving substantially more pre-registrations than expected due to industry uncertainty in interpreting REACH. Many of these pre-registrations have since been identified as duplicate or unnecessary, but, as these pre-registrations are used to create a SIEF, SIEFs currently include many companies that do not actually intend to register the substance in question. Many interviewees referred to examples of companies registering the entire EINECS list, or the list of all known existing substances, and other companies registering articles such as a "shoe," which is not a single substance and therefore outside of the scope of REACH. In addition, multiple industry respondents expressed particular concern that pre-registration was misused by some—for example, consultants who wanted to be part of the discussion about a particular substance, or companies that wanted to keep a substance off the market—and hypothesized that a small fee, or a down payment on the registration fee, would help ensure that only those who were serious about registering their substance in the future would actually pre-register, and they would reduce the number of inactive participants in a SIEF. Despite the higher than anticipated number of pre-registrations, government respondents still anticipated that the number of registrants in the first round (those registering by November 30, 2010) would remain as originally estimated, although most government and industry respondents tended to be uncertain as to who, then, would actually register.

Industry respondents' most often expressed and most thoroughly discussed complaint about the implementation of REACH was that SIEFs are not operating smoothly so far. Some respondents from government and civil society also thought this was a problem as well. This may be due, in part, to the chaotic transition for many companies from pre-registration to registration,

despite the assistance of pre-SIEFs and SIEF formation facilitators, two entities unmentioned in the REACH legal text but created to assist in registration preparation. This could also be due, in large part, to what many industry and government respondents characterized as a design flaw. It is difficult for industry competitors to now work together to create and share information. While 93% of SIEFs are what government respondents define as a manageable size (under 100 companies), industry respondents felt that SIEFs were too large. Industry respondents identified consortia, or pre-existing networks with similar responsibilities, as the most functional unit within SIEFs, but cooperation between consortium and non-consortium members in a SIEF—especially the non-consortium members who are SMEs—must improve. Many industry and government respondents described SMEs as being at a particular disadvantage in SIEF participation because of potential language barriers and the high cost of accessing data, through joining consortia or paying for letters of access (which recognize that costs have already been borne by companies who have already taken steps toward regulatory compliance). Government respondents noted that reduced registration fees for SMEs are part of government efforts to reduce these disadvantages, but registration fees are only a small component of the total costs of legal compliance; data sharing fees (set within SIEFs and used to compensate companies for conducting tests that the whole SIEF will benefit from when compiling their joint submission) and time costs (which vary for each company depending on the extent of their involvement within the SIEF) are significantly higher. Respondents from governmental agencies and industry associations noted that they have offered support beyond REACH's legal requirements, through webinars, workshops, the Directors Contact Group, and other modalities, to try to help address persisting SIEF problems.

Multiple respondents from all three sectors agreed that REACH has, so far, had the positive effect of increasing knowledge about chemicals and has the potential to continue to do so in the future. Registration dossiers have the potential to inform a number of future initiatives. Some industry and many government respondents recognized that these dossiers will increase companies' knowledge about what they manufacture and import and the supply chain in which they operate, which could help spur greater efficiency and innovation. In particular, some industry respondents, including those who were downstream users, noted that there has been an increase in knowledge due to communication up and down the supply chain, especially for downstream users. Nevertheless, communication remains both difficult and slow, which hampers notification regarding the presence of substances of very high concern in articles down the supply chain and to consumers, as required by Article 33 of REACH. The majority of government respondents expressed interest in using registration dossiers to inform the creation of authorization and restriction dossiers on substances of very high concern. Among the civil society respondents who discussed using registration information, they uniformly expressed hope that this information would be used by consumers to inform choice of products. However, they were skeptical that this would happen, given that the consumer's right to know is not always realized under REACH, with requests for information on substances of very high concern often going unanswered or inadequately answered.[9]

In addition, multiple respondents from both civil society and government hoped to use information from registration dossiers to inform risk assessment and risk management. Government and civil society respondents remain concerned that even this increased information will be insufficient for conducting risk management. In particular, the amount of information that will be available for chemicals manufactured or imported at low volumes remains contentious. For example, academics Ruden and Hansson (2010) have calculated that there will be inadequate health and safety information for lower-volume chemicals (especially those produced at less than 1 ton/year, for which no data is required).[5] While some government respondents agreed with Ruden and Hansson, other government officials and industry representatives responded that it would be unfeasible and/or unnecessary to require more information for these chemicals, regardless of whether or not this limits risk assessment and risk management endeavors.

An added complexity to the information in registration dossiers is the distinction between what will be made publicly available and what will be claimed as confidential business information. Respondents from all three sectors agreed that confidentiality criteria must still be determined and clarified. In general, industry respondents wanted to maintain confidential business information, and felt assured that they would be able to keep confidential information confidential. Civil society respondents, on the other hand, generally wanted as much information as possible to be made publicly available. Government respondents tended to want public access to information as well, and believed that the confidentiality fees in place will effectively dissuade unnecessary claims and ensure that a balance between public access to information and confidential business information is achieved.

Evaluation

In comparison to registration, very few respondents discussed evaluation, and those who did had little to say. No one yet has a sense of what the quality of the information in the registration dossiers will be like, but civil society and government respondents who mentioned evalua-

tion acknowledged that ECHA will not have the capacity to check the quality of all of the registration dossiers, and some respondents raised questions as to whether evaluation would be stringent enough to ensure that registrants are in full compliance with REACH. This is an emerging issue and one that will require further attention as the implementation of REACH progresses.

Authorization

The candidate list is composed of chemicals that have been identified as substances of very high concern through a governmental process involving both member states and ECHA (as of June 18, 2010, there were 38 substances of very high concern[10]). That process considers public comments from stakeholders from industry, civil society, and beyond. The candidate list is among the topics for which the three sectors demonstrated the greatest divergence in opinions. Respondents from all three sectors agreed that the candidate list creates market-based pressure for substitution from consumers and retailers, but disagreed from there. Industry respondents generally believed that the candidate list is a *de facto* blacklist and wanted the candidate list to be kept small. Civil society and some government respondents declared that there were too few chemicals on the candidate list and that the candidate list was increasing too slowly, whereas industry and other government respondents found the pace and size of the candidate list to be satisfactory, given government capacity and resources. Interlinked with debates about the size of the candidate list were outstanding questions as to the role of the candidate list: Is it a tool that should be used to get more information about chemicals that could then be used to inform future regulatory decisions, or should it serve as a first step for chemicals that already have a full body of evidence supporting their candidacy for authorization?

Restriction

As with evaluation, stakeholder attention was rarely placed on restriction. When respondents discussed restriction, it was acknowledged as a familiar regulatory tool but received paltry attention in comparison to authorization, which was discussed more extensively and in greater detail than restriction. How restriction will be utilized under REACH remains an emerging issue: Stakeholders, especially bureaucrats in EU member states, are beginning to think about when authorization should be used and when restriction is a better strategy, but these discussions are only beginning.

Enforcement

Government is working to harmonize enforcement both within and across member states, and this was a topic discussed almost exclusively by government respondents. Government respondents thought that the harmonization effort had been expertly spearheaded by the Forum, an EU-wide body overseen by ECHA, to discuss matters related to enforcement that has representatives from all member states. Respondents from across government agreed that the Forum is successfully coordinating enforcement across member states, but there were still challenges rooted in different interpretations of REACH legal text that hindered harmonized enforcement across Europe. For example, in fall 2009, member states differently interpreted a provision of REACH concerning substances in articles, causing protracted debate about implementation and enforcement authority; this experience led respondents from all three sectors to recommend clarifying the policy in the future in order to make the practical enforcement more straightforward.

Within member states, member state governments have the challenge of coordinating enforcement between the multiple agencies or departments involved, including health, environment, chemicals, business, and/or customs. In particular, member state respondents noted that collaborating effectively with customs, which has a critical role to play given REACH's oversight of imported substances, was a particular challenge because there is not a history of collaboration and because of different priority-setting between agencies. Fortunately, the Forum is also helping to support intra-member state enforcement issues as well. Member state respondents also noted the difficulty of setting penalties for REACH non-compliance that are proportionate, dissuasive, and effective: Given the high cost of complying with REACH (registration fees, in addition to costs of data sharing), penalties for non-compliance must be even higher, and this is not always possible under member-state regulatory structures, some of which limit the maximum fine to a number less than the cost of compliance.

Because enforcement strategies are developed on the member state level, best practices, as identified by member state respondents, have emerged from unique enforcement strategies in different member states. Respondents from each of the three member states were asked what their country did particularly well. One member state's respondents described their centralized chemicals agency as particularly effective at harmonizing enforcement within a member state. Another member state's respondents identified building upon pre-existing enforcement networks from previous chemicals regulation and other related legislation. The third member state highlighted its proactive national help desks as a useful tool for raising awareness about REACH compliance within government and industry, which can help facilitate smoother enforcement in the future.

DISCUSSION

Civil society, industry, and government respondents tended to agree that REACH has good intentions and that they want it to succeed in accomplishing its goals. Respondents from all three sectors accepted REACH as part of the regulatory framework, regardless of how much they criticized the legislation while it was in development. Additionally, multiple respondents acknowledged that they exhibited much more moderate views when interviewed anonymously than when they were representing their sector or institution publicly, which may explain some of the convergence in opinions across sectors.

There are still emerging issues that may be causes for future disagreement and debate, including the use of structure activity relationships and socioeconomic analysis in authorization and restriction decisions, and how chemicals manufactured or imported at less than 1 ton per year should be regulated. Other issues, such as SIEFs, relate to the practical side of implementation. For example, industry's challenges with SIEF functionality may be rooted in a lack of leadership: Each SIEF is supposed to have a lead registrant, but, as of February 2010, only one-third of the SIEFs planning on registering by November 2010 had a lead registrant, perhaps because the lead registrant's responsibility and incentive is unclear. Within government, member states are still determining how to best implement and enforce REACH, and capitalizing on and sharing the best practices of the EU's 27 different member states should be encouraged, given the useful ideas that have already been generated.

In addition, there may be as-yet-unrealized impacts. For example, the full potential of the candidate list and the authorization route remain to be seen. All substance dossiers for the candidate list and proposals for authorization so far have been made based on information collected and work done under the previous general chemicals regulatory system (when, similar to the US Toxic Substances Control Act, the burden of proof was on governments to demonstrate an existing chemical's harm), and respondents from all three sectors speculate that the authorization landscape will be altered by the information that will be made available through the registration dossiers.

Each sector has carved out a different niche for itself regarding REACH's implementation. Industry respondents want to ensure that they can comply with REACH, whereas government respondents want to make sure that they can implement and enforce REACH's provisions, and civil society respondents hope to hold all parties accountable to ensure that REACH accomplishes its ambitious goals.

One industry respondent declared, "I think REACH is making the world a better place." Respondents from all three sectors agreed that the successful implementation of REACH will entail protecting and enhancing public and occupational health, the environment, and market competition and innovation. Secondary goals include increased and improved knowledge of chemicals in the general public and within the supply chain, and improved risk management due to safer use of chemicals by consumers and workers and reduced use and/or substitution of the chemicals of greatest concern.

Almost all respondents expressed cautious optimism, agreeing that, in general, REACH has the potential to achieve these goals. Now, as people from around the world interested in reforming their own countries' chemicals policies look to REACH in Europe, stakeholders from all three sectors must work to successfully implement REACH to ensure that REACH's good intentions and goals are realized.

Lisette van Vliet of the Health and Environment Alliance, Phil Brown of Brown University, and Rachel Morello-Frosch and Megan Schwarzman of University of California, Berkeley provided greatly appreciated guidance and support in the research process, and the anonymous reviewers and editors offered valuable feedback.

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