

International Environmental Law Committee Newsletter

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MESSAGE FROM THE CHAIR

Richard ("Tad") Ferris
Beveridge & Diamond, P.C.

The relationship between politics, economics and development, and legal cultures comes into sharp focus when discussing regional and country-specific environmental law initiatives. For example, the European Union (EU) continues to grapple with the challenges of implementing a cohesive set of overarching laws and regulations that protect the human health and environment while preserving and promoting the economic strength and stability that has become a cornerstone for the EU. Moreover, these policies are developing in an ever-changing milieu, as evident by the recent addition of ten Eastern European member countries on May 1, 2004.

Nowhere is this challenge more obvious than in the EU's current consideration of the Registration, Evaluation and Authorization of Chemicals proposal, commonly referred to as "REACH." The REACH proposal is likely to be adopted as EU law in the next several years, ushering in a comprehensive new regulatory regime for the sale and management of chemicals in the EU. While the exact form of the law is yet to be finalized, member nations and non-member nations alike are well aware that the new chemicals initiative will have far-

reaching impacts on global trade and the environment.

In light of these impacts, we are pleased to present two very timely articles on the REACH initiative. Bob Matthews and Claudio Mereu, partners in the Washington, D.C. and Brussels offices of McKenna Long & Aldridge, provide our readers with a legal perspective on the REACH initiative. In doing so, Bob and Claudio benchmark the proposed initiative by comparing it to the existing chemicals management regime in the EU. Norine Kennedy offers further commentary on the REACH proposal from an international business perspective. Norine, vice president of Environmental Affairs for the United States Council for International Business, argues that in its current form, the REACH proposal will have significant impacts on international trade, resulting in increased costs to the industry and public alike. Norine argues that much work needs to be done to redraft the REACH proposal to make it more cost-effective and less trade restrictive while still fulfilling the underlying objectives of the initiative.

As one of the primary objectives of this Newsletter is to provide our readers with timely commentary and analysis of recent developments and trends impacting our international environmental law practice, we are pleased to present several articles

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Committee Newsletter
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David Ross, Editor**

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This newsletter is a publication of the ABA Section of Environment, Energy, and Resources, and reports on the activities of the committee. All persons interested in joining the Section or one of its committees should contact the Section of Environment, Energy, and Resources, American Bar Association, 321 N. Clark St., Chicago, IL 60610.



describing recent developments in various regions of the world. First, Ellen Proctor, the Asia Environment, Health & Safety director for General Electric, and I provide an overview and analysis of recent trends affecting the practice of environmental, health and safety law in China. Tzvi Levinson and Thomas Julian Page of the Ben Mayor & Levinson Law Offices in Haifa, Israel then provide us with a report on a recent seminal ruling of the Supreme Court of Israel recognizing that the Israeli people have a Basic Law right to “minimum environmental quality.” Finally, Mateo Davis, an attorney with Beveridge & Diamond in Washington, D.C., provides us with an analysis of the environmental aspects of the U.S.-Chile Free Trade Agreement, an accord that is certain to serve as a model for future bilateral and regional trade agreements in the Western Hemisphere.

Consistent with this country-specific focus, the Committee is also pleased to provide our readers with an update on the Afghanistan Environmental Law Project. This valuable project involves an extensive pro bono effort by members of our Committee to assist the Transitional Islamic State of Afghanistan in the development of its environmental and natural resources laws.

I would like to take a brief moment to thank the Committee’s vice chairs for their ongoing work in support of Committee activities over the past year. Hiroko Muraki Gottlieb is our Programs vice chair. Barbara Finamore is our Public Service vice-chair and Sandra Ikuta is our Membership vice chair. Mateo Davis is the Committee’s Technology vice chair and Margaret (“Meg”) Caldwell supervised the publication of another excellent Committee contribution as our vice chair for *The Year in Review*. The Committee also welcomed this year David Ross as our Newsletter vice chair and liaison to *Trends*. Lastly, the Committee is well served by four at-large vice chairs, including Aimee Christensen, Ellen Proctor, Bill Thomas and Vail Thorne.

It is my continuing pleasure and privilege to serve as the chair of the Committee. As always, I look forward to meeting and hearing from our current and prospective members. Please do not hesitate to contact me at rferris@bdlaw.com or contact our vice-chairs by going to <http://www.abanet.org/enviro/committees/intenviron/home.html#leadership> if there are issues that you would like to see addressed in upcoming issues of the Newsletter, if you would like to submit articles for the Newsletter or participate in Committee activities, or if there are programs that you would like to see the Committee sponsor or co-sponsor. We are always pleased to hear from our members, particularly with respect to how the Committee can better serve the international environmental law community.

UPCOMING COMMITTEE EVENTS AND OTHER ANNOUNCEMENTS

Committee Programs

We are pleased to report that our Committee has hosted or co-sponsored several exciting programs on a variety of important international environmental issues over the past year, including programs at the 2003 ABA Annual Meeting, the 11th Section Fall Meeting in October 2003, and the 33rd Annual Conference on Environmental Law at Keystone, Colorado, in March 2004. Readers are encouraged to visit the Committee's Web page at <http://www.abanet.org/enviro/committees/intenviron/home.html> for additional detail regarding these and other programs that the Committee has hosted for the benefit of our members.

The Committee's strength in providing cutting edge programs will continue at this year's ABA Annual Meeting and 12th Section Fall Section Meeting and upcoming Quick Teleconferences. For example, the

Committee will co-sponsor with the Special Committee on Environmental Disclosures a program entitled "Global Corporate Environmental Disclosure — New U.S. Requirements Combined With Accelerating Global Pressure for More Extensive Environmental Reporting — Are Mandatory Performance Reporting Regimes on the Horizon?" at the 2004 ABA Annual Meeting in Atlanta. At the 12th Section Fall Meeting, the Committee will co-sponsor a program with the Agricultural Management Committee and the Innovation, Management Systems and Trading Committee, entitled "Trends in Trade and the Environment in Mexico: New Regulations from Maize to Mobile Phones." This program will address common problems that the U.S. and Mexico share involving management schemes for various products, ranging from biotech corn (maize) to end-of-life electronic products, such as mobile phones. Over the last several years, Mexico has taken bold steps to improve environmental management via legislation, including its recently adopted waste law. This program will explore these and other hot topics affecting trade and the environment in Mexico.

Readers are encouraged to visit the Committee's Web page or participate in the Committee's list serve to monitor upcoming programs and events.

Afghanistan Environmental Law Project Update

Background

The ABA's Asia Law Initiative is currently implementing a pro bono commercial law reform project in partnership with the Afghan Embassy and the Center for International Management Education. As part of this effort, the International Environmental Law Committee was asked to collaborate with and identify team leaders for a working group of experts that are identifying models for the

development of Afghanistan's environmental and natural resource laws and proposing changes to those models that are consistent with the Afghan government's goals for such legislation. This working group will support Afghanistan's Transitional Authority, per the Bonn Agreement, in rebuilding Afghanistan's justice system in accordance with Islamic principles, international standards, the rule of law, and Afghan legal traditions.

The Asia Law Initiative's report on Afghanistan's legal system is available at <http://www.abanet.org/environ/committees/intenviron/afghan.pdf>.

Review of Project Developments

The International Environmental Law Committee has formed a pro bono Environmental Law Team (ELT) to assist the Transitional Islamic State of Afghanistan in the development of its environmental and natural resources laws. The ELT is part of the Afghanistan Transitional Commercial Law Project, and is operating under the direction of the ABA Asia Law Initiative and the Center for International Management Education. While the Afghanistan Transitional Commercial Law Project is designed to assist Afghanistan's development of its commercial laws, the project aims to balance the needs of development by providing input related to environmental and natural resources protection.

On July 3, 2003, ELT met with His Excellency Dr. Yusef Nuristani, minister of Irrigation and Environment, Maryam Abolfazli, the minister's advisor/assistant, and Mariam Nawabi, the project coordinator. At the meeting, topics discussed included the Ministry's priorities for ELT's input and the scope of its representation.

Over the course of the meeting, Minister Nuristani identified several projects as

priorities for ELT's input, such as providing commentary on Afghanistan's draft Environmental Framework Law and proposing language to strengthen the environmental article in Afghanistan's draft Constitution. The minister also asked ELT to consider revisions to the existing water law administrative framework and to review environmental impact assessment models that the Transitional Islamic State of Afghanistan may wish to consider. Further, ELT also agreed to provide counsel on discrete environmental issues as necessary and appropriate.

ELT's pro bono assistance will end after the general elections, approximately in September 2004, marking the end of the term for the Transitional Islamic State of Afghanistan.

Since ELT's initial 2003 meeting with Minister Nuristani, the team has prepared a memorandum to guide team members on Shari'a (Islamic law) considerations in the development of environmental law, a report recommending language addressing environmental protection for the draft Constitution, and an article authored by ELT member Prof. Dan Tarlock and James McMurray reviewing and analyzing transboundary water allocation issues that affect Afghanistan. Most recently, the ELT submitted to Minister Nuristani their recommendations for a draft Environmental Protection Act.

For an assessment of the significant environmental issues facing Afghanistan, the Asian Development Bank's report, "*Afghanistan: Environment in Transition*" is available at http://www.abanet.org/environ/committees/intenviron/afg_environment_transition.pdf. For questions on the Committee's involvement in this project and opportunities for participation, please contact Tad Ferris, chair of the Section of Environment, Energy, and Resources' International Environmental Law Committee,

at rferris@bdlaw.com or David Wagner, chair of the Section of International Law and Practice's International Environmental Law Committee, at dwagner@bdlaw.com.

**INTERNATIONAL ENVIRONMENTAL LAW –
FOCUS ON EUROPEAN UNION
CHEMICALS POLICY**



**INTERNATIONAL ENVIRONMENTAL LAW
COMMITTEE NEWSLETTER**

Like to Write?

The International Environmental Law Committee welcomes the participation of members who are interested in preparing this Newsletter.

If you would like to lend a hand by writing, editing, identifying authors or identifying issues, please contact the editor David Ross at 202/624-2682 or dross@crowell.com.

Committee on the Web

Committee Web Page

Visit the Committee's Web page for back issues of the Newsletter and other useful information:

<http://www.abanet.org/environ/committees/intenviron/home.html>

Committee List Serve:

Communicate with your colleagues via e-mail:

environ-intl-law@mail.abanet.org

Note from the Editor: As indicated in the Message from the Chair, the following articles provide timely commentary on the European Union's REACH initiative. Given the importance of this initiative, the International Environmental Law Committee invites our committee members and other interested parties to submit additional commentary regarding the potential economic, public health, environmental, societal and cultural benefits and/or costs of REACH. The Committee welcomes the submission of additional and varied viewpoints for future publication in the Newsletter. If you are interested in contributing to this effort, please contact the Newsletter vice chair David Ross at dross@crowell.com.

**A LEGAL PERSPECTIVE ON THE
EU REACH PROPOSAL**

**Robert Matthews
Claudio Mereu
McKenna Long & Aldridge LLP**

I. Introduction

For the past several years, the European Union's REACH (Registration, Evaluation and Authorization of Chemicals) initiative — a major legislative vehicle that would overhaul the existing chemical regulatory controls system in the European Union (EU) and, in its place, impose a vast, costly and burdensome system — has been a train hurtling down the tracks toward ultimate adoption by the European Parliament. The speed of this particular train has changed over time, as have its contents, and its final content and

arrival date remain unknown. But there is enough currently known about REACH to raise significant concerns among potentially affected members of industry about the manner and extent to which REACH will impact their ability to continue to manufacture and market their products in the EU.

Several articles (including Norine Kennedy's article in this edition of the International Environmental Law Committee Newsletter) have addressed the nature of these business implications and concerns. This article will explore some of the legal issues raised in REACH, particularly as they relate to the procedures and criteria for the adoption of the measures that will have the most significant impacts on certain substances and products. Beyond the costs REACH will impose on industry and society, which arguably are not in balance with the benefits to human health and the environment that REACH is intended to achieve, it is clear that REACH is significantly flawed in the legal and procedural bases by which the EU Commission will adopt many of the most aggressive measures contemplated by REACH.

In undertaking a legal analysis of REACH, we proceed from the premise that some form of REACH is likely to be adopted by the EU Parliament. In that regard, there remains considerable controversy and, as a result, considerable pressures continue to be brought to bear by industry, by foreign governments (e.g., the United States and Japan), and by EU Member States. (During a period of political and policy discord among the United Kingdom, Germany and France, REACH managed to bring Messrs. Blair, Schroeder and Chirac together long enough to jointly sponsor a written statement of concerns regarding the REACH proposal.) Although it remains unclear when, and in what form, REACH will arrive at its final destination, because of the significant potential business implications of the REACH initiative, industry

has no choice but to analyze and prepare for REACH as it is now proposed.

II. The Current EU Regulatory Scheme

An appreciation of the flaws in REACH is best approached by first, briefly, summarizing the flaws in the current chemical regulatory system in the EU and equally, in the current law in the EU regarding the rights of industry to challenge regulations that limit, or sometimes prohibit, the placement on the market of substances and products. Directive 67/548/EEC, as amended (the "Dangerous Substances Directive"), lays down the rules and procedures for the notification of "new" substances and the classification and labeling (C&L) of dangerous substances. The C&L provisions of Directive 67/548 set forth fifteen categories of danger based on the intrinsic properties of a substance. The Directive establishes, in its Annexes, the test methods and criteria to be utilized in making C&L determinations.

The institutions of the EU that make C&L recommendations for specific substances are the so-called EU Working Groups. These are advisory bodies which have no written rules of procedures and a history of ignoring the specified C&L methods and criteria set forth in the Directive. For example, a recent C&L Working Group recommendation, adopted by the European Commission (Commission), classified a substance as "highly flammable," based on test methods not found in the Directive's Annex. Specifically, according to the applicable testing methods, a designation of "highly flammable" can only be made for a substance for which a flash point is established using tests conducted between 10 degrees Centigrade and 110 degrees Centigrade. Every test conducted within that range failed to demonstrate that the substance has a flash point. One test, conducted at minus 10 degrees Centigrade, allegedly did demonstrate a flash point. On that basis,

notwithstanding that the test was conducted outside the range specified in the criteria, the C&L Working Group and the Commission decided to classify the substance as highly flammable.

In another example of failed compliance with Directive 67/548, the Commission originally classified a particular substance as a skin sensitizer. Subsequently, additional testing revealed that the original tests on which the sensitization classification was based were actually conducted on a related, but different, form of the substance. In addition, more sophisticated test methods subsequently developed demonstrated that neither the classified substance nor the related substance is in fact a skin sensitizer when the testing exposure pathway reflected “normal handling and use,” another criterion under the Directive for C&L decisions. Notwithstanding these subsequent testing results, the C&L Working Group and the Commission declined to declassify the substance because “declassification is scientifically justified but would decrease the level of protection.” This invocation of the so-called precautionary principle is completely inappropriate in that C&L decisions under Directive 67/548 are to be based solely on the intrinsic properties of a substance, while the precautionary principle applies to “risk” assessment decisions, which fall outside the scope of 67/548.

Such clear misapplications of the criteria for regulatory decision-making would, in the United States, almost inevitably result in a challenge by affected industry members to the final regulation. Arguably, agencies such as EPA are constrained from committing such arbitrary and capricious acts because of the availability of judicial review. The problem in the EU, however, is that rules of general application are often beyond the ability of industry to challenge. The specific problem in the European judicial system is standing; unless a regulation has a “direct and

individual” effect on a specific company (e.g., the regulation is “nominative,” that is, it identifies the specific company(ies) which, because their products are subject to such regulation, belong to a so-called “closed class” of affected operators), the manufacturer of that product will not have standing to challenge such regulations.

Accordingly, under Directive 67/548, arbitrary and capricious decisions by the working groups and, ultimately, by the Commission, such as the decisions reflected in the two case studies cited above, are often beyond the ability of industry to challenge. Knowing this, of course, the working groups and the Commission do not feel constrained by the looming presence of the European judiciary. (The applicants in these two cases have brought proceedings against the Commission before the European Court of First Instance. In both matters, the Commission challenged Applicants’ standing, and the Court will rule on this issue in the coming months.)

III. REACH

REACH will pull approximately 30,000 chemicals into its Registration, Evaluation, Authorization, and Restrictions provisions. Accordingly, whether and to what extent REACH will solve or exacerbate the problems experienced under the current system is an important aspect of industry’s analysis of and preparation for REACH.

In a nutshell, REACH would require: (1) the *registration* in a central database of chemical substances that are manufactured or imported in the EU in quantities of more than 1 ton/year (approximately 30,000 chemicals); (2) the *evaluation* of chemical substances that are manufactured or imported in the EU in quantities of more than 10 tons/year (approximately 5,000 chemicals); (3) the *authorization* of chemical substances of “very high concern” (approximately 1,350

chemicals), which will be banned unless it is demonstrated that the risks to human health or the environment arising from their properties can be adequately controlled, or socio-economic benefits outweigh those risks and there are no suitable alternative substances or technologies; and (4) the *restriction* of the manufacture, marketing and use of certain substances.

A. Registration

Substances manufactured or imported in the EU in excess of 1 ton/year enter REACH through the Registration portal. Registrants are required to present testing proposals (with increasing testing requirements as tonnages increase) for every use identified for such substances. Accordingly, a manufacturer that supplies its product to so-called downstream users, and/or the downstream users who rely on a manufacturer/supplier of their product, must ensure that each such use is identified and, with respect to each such use, that the appropriate testing and other Registration obligations are undertaken. A category of substances defined as “phase-in” may benefit from longer registration deadlines, depending on their yearly tonnages or intrinsic properties and provided they are pre-registered no later than eighteen months before the relevant deadlines.

At this initial stage of the REACH process, a first series of issues may arise in connection with regulatory decisions concerning testing proposals, exemptions, data sharing and the completeness of the registration dossier. These decisions will be made by the European Chemicals Agency, a new body of the Community established for handling and coordinating registrations and other aspects of REACH. Some agency decisions, albeit not the most critical ones under REACH, may be appealed before a newly created Board of Appeal.

B. Evaluation

From a legal perspective, one of the more troubling aspects of REACH is that many of its terms and provisions are poorly defined, providing little guidance to the regulators or to the industry on how such terms and provisions are intended to be interpreted and implemented. As a consequence, a significant level of discretion is placed in the hands of regulators (which, under REACH, will include both the European Commission and the Competent Authorities at the Member State level).

This significant discretion, and its potential for abuse, begin to emerge in the Evaluation process. Based on the testing results submitted in the first phase of the REACH system, the Commission or Competent Authorities can determine to approve, modify, or reject the technical dossiers submitted by industry members to satisfy their Registration obligations. More specifically, the regulatory authorities may “draft any appropriate decisions,” e.g., imposing additional testing requirements on individual substances. A Competent Authority that has “reasons for suspecting” that a substance presents a risk can require the submission of additional information, even if the existing information merely “suggests” that a substance has “properties of concern.” Likewise, if only for purposes of “clarifying the suspicion” that a substance poses a risk, a Competent Authority may require additional testing. With respect to proposals to impose additional testing obligations, the Registrant has only a very limited involvement. Specifically, the regulatory authorities must provide Registrants and downstream users the opportunity to “comment” on their testing proposals; if such comments are submitted, the authority must take such comments “into account” and, on that basis, “may amend the draft decision.”

Clearly, the regulatory authorities have significant discretion to impose costly

additional testing obligations with limited input from and involvement of industry. With no guidance on the proper interpretation of these provisions, there is a real opportunity for inconsistent and/or arbitrary decisions. As a result, the cost to continue to support a product in the EU may rise significantly, without any corresponding reduction in the risks to human health and/or the environment posed by such product.

C. Authorization

These same issues, *i.e.*, broad discretion in the hands of regulatory authorities and limited input by industry, pose even greater risks and concerns during the Authorization process. It needs to be noted at the outset that the term Authorization in REACH is quite misleading. Substances that are subject to Authorization and thereby placed on Annex XIII are not so much authorized as they are limited. An Annex XIII substance may not be placed on the market in Europe unless specific use Authorizations have been provided. The critical issue, therefore, is the basis on which a substance can or will be placed on Annex XIII. Some of the criteria for placing substances on Annex XIII are reasonably objective, although somewhat novel and therefore of unclear practical application in the EU (*e.g.*, persistent, bioaccumulative, and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances). On the other hand, one criteria for placing a substance on Annex XIII is that it “meets the criteria” for classification as a CMR (carcinogen, mutagen or reproductive toxicant), Category 1 or 2. Note, in this regard, that this language does not require that the substance has been actually defined as a CMR Category 1 or 2, only that, in the opinion of a regulatory authority, the substance meets the criteria. This provision becomes particularly troubling when considering the litigation matters and issues referenced earlier, *i.e.*, the proceedings against the Commission regarding the

interpretation and application of the CMR criteria under Directive 67/548, and the related difficulties faced by industry to challenge legally and scientifically unsound decisions. Similarly, substances can be placed on Annex XIII if, in the judgment of the Competent Authority, they produce effects that are equivalent to the effects of substances included on the Annex, *i.e.*, CMRs Category 1 or 2, PBTs or vPvBs.

The Member State Competent Authority can play a significant role in Annex XIII listing. A Member State can initiate proceedings for substances which “in its opinion meet the criteria” for CMR, PBT, vPvB or endocrine disruptor substances. In contrast to the Competent Authority’s role in proposing inclusion of a substance on Annex XIII, the Registrant has no incisive role or rights and, at most, may just “comment” on the issue during an Internet consultation phase, along with other interested parties.

Once a substance is on Annex XIII, the criteria for granting Authorizations, *i.e.*, for permitting certain uses of substances placed on Annex XIII, also present significant issues and concerns. An Authorization under REACH is to be granted if “risks to human health and/or the environment are adequately controlled.” Once again, definitions or guidance for the key terms in that provision, *e.g.*, the concept of adequate control of risks, are nowhere to be found and Registrants, once again, have no role in the process. REACH further provides that if it is determined that a risk can not be controlled, then Authorization may still be granted *if* socioeconomic benefits outweigh the risks *and* there are no suitable alternative substances or technologies. The guidance that is so desperately needed to interpret and apply these provisions — regarding the critical concept of socioeconomic benefits outweighing human health and/or environmental risks — is, again, nowhere to be found. Similarly, guidance on the language

that appears to impose the “principle of substitution,” which is destined to be a highly controversial issue in the implementation of REACH, is completely lacking. Without such guidance, EU Working Groups and Competent Authorities (including, in this case, the newly created Socioeconomic Analysis and Risk Assessment Committees) will again enjoy significant discretion.

The Authorization provisions of REACH do not stop there, however. With respect to any use Authorization, REACH provides that: “Notwithstanding any conditions of an Authorization, the holder shall ensure that the level of exposure is reduced to as low as is technically possible.” This is another provision that will certainly create consternation and controversy. It appears to effectively marginalize considerations of economic or social benefit factors which the Authorization provisions otherwise direct the Competent Authority to consider.

Without question, Registrants should seek to avoid inclusion of their substance on Annex XIII. That said, for substances which find their way on to the Annex, Registrants who must then seek Authorization for specific uses must place a high premium on generating data that will address these key terms and conditions.

D. Restrictions

Substances placed on Annex XVI or XVII may not be manufactured, placed on the market or used unless specific conditions are met. Unlike substances on the Authorization Annex, substances on the Restriction Annexes do not require that individual Registrants obtain use Authorizations. Instead, the use limitations are applicable to all Registrants and users. In addition to CMRs Category 1 or 2 for which consumer uses are proposed and substances identified as persistent organic pollutants (POPs), substances can be proposed for inclusion on the Restrictions Annexes by

either the Community or Member State Competent Authorities based on their perception of the risk and control issues. In the case of the Member States, the Competent Authority can initiate the listing procedure if it concludes that the technical dossier “demonstrates” that action is needed. Substances which may be added to the Restrictions Annexes are those which pose a risk to human health or the environment where such risks are not adequately controlled and need to be addressed at the community level. Once again these terms are not defined. Particularly troubling, in this respect, is the absence of guidance on what risks are adequately controlled and, similarly, what risks need to be addressed at the Community level. In the latter regard, the logical implication of this provision is that there are risks which are not adequately controlled but which do not need to be addressed at Community level, leaving, arguably, a residual authority in Member States to address such risks. That interpretation would, however, directly contradict the “harmonization” goal of REACH.

III. Conclusion

The Registration, Evaluation, Authorization, and Restriction provisions of REACH are poorly defined and, as a consequence, create many uncertainties regarding the manner in which they will be interpreted. Companies who ultimately will be required to comply with these provisions must grapple with this uncertainty as they plan for the entry into force of REACH and attempt, in that context, to apply product stewardship and product defense principles. REACH also presents a number of other important legal and procedural issues and concerns, not the least of which are the data sharing and confidential business information provisions.

There is no mistaking that one intended consequence of REACH is the removal of certain substances and products from the

market in the EU. It is presumed, for example, that substances will be limited and/or prohibited by virtue of their inclusion on the Authorization and Restrictions Annexes. Similarly, it is likely that some companies, anticipating such results, will no longer support their products, *i.e.*, they will not bother to initiate and/or complete the Registration process and, instead, will “voluntarily” remove their products from the market.

The law of unintended consequences is also likely to come in to play during the implementation of REACH. Substances which do not create significant risk to human health and the environment may, nevertheless, be withdrawn if the testing requirements impose significant costs and the margin of profit for such substances is narrow. The competitive disadvantage suffered by such companies will be off-set by the inevitable competitive advantage enjoyed by those companies who are able to support their products throughout the entire REACH process.

With all this at stake, companies who will be impacted by REACH, including U.S. companies who export substances and products to the EU, must begin to prepare to confront the many business, regulatory and legal challenges posed by REACH.

Section of Environment, Energy,
and Resources

12TH SECTION FALL MEETING

SAN ANTONIO, TEXAS

OCT. 6-10, 2004

SAVE THE DATE!

A BUSINESS PERSPECTIVE ON THE EU REACH PROPOSAL

Norine Kennedy
United States Council for
International Business

I. Summary

The European Union's (EU) proposed broad chemical regulatory framework, known as REACH (standing for Registration, Evaluation and Authorization of Chemicals), is moving ahead for European Parliament (EP) and Council consideration. For many in business, REACH appears to be a costly and trade restrictive end-run around international chemicals management cooperation.

REACH promises to change the global face of chemicals commerce. The proposed system has the potential to reduce chemical industry trade, inhibit innovation by small and medium-sized enterprises, and raise costs and regulatory burdens for downstream users of chemical products. It could also undermine a number of consensus based international chemicals management initiatives and programs that have emerged since the U.N. Conference on Environment and Development was held in Rio de Janeiro in 1992.

The European Commission (Commission) has recognized that REACH will result in negative commercial impacts on affected chemicals and downstream industries. In fact, the Commission has stated that the competitive impacts could only be justified if the REACH approach establishes itself as a new international standard, raising regulatory costs worldwide.

What are the shortcomings of REACH? In the view of business, there are three primary areas where substantial revision is still necessary:

- If implemented in its current form, REACH will result in an unnecessary increase in costs for chemical producers, users and the general public;
- REACH raises the potential for trade discrimination disadvantaging non-EU companies from many sectors; and
- REACH could overtake existing efforts for global harmonization and cooperation on chemicals.

II. REACH: Background and Status

The road to REACH began when the Commission published its White Paper on a Future Chemicals Strategy in February 2001, expressing its intention to overhaul the regional patchwork quilt of chemical regulation in the EU. The EU's existing chemical regulatory system has been in place since 1993 and has identified 140 chemicals of high concern. Some 100,000 chemical substances are registered in the EU, of which around 30,000 are manufactured or imported in quantities greater than one ton.

Following a review by the EU Council of Ministers and the EP, the Commission drafted legislation and issued a proposal for the REACH framework. This framework is intended to replace 40 plus EU directives and regulations. After an extensive on-line comment period in the summer of 2003, during which over 6,400 comments were filed, the Commission approved a revised version of REACH on Oct. 29, 2003. It is this draft proposal and its significance to international commerce and environmental cooperation that this article will address.

The Commission made a number of improvements in the new draft. According to EU Environment Commissioner Margot Wallstrom, these and other changes slashed the projected costs of the regulation by 80 percent. However, fundamental difficulties

remain, and REACH still requires that any enterprise manufacturing or importing more than one metric ton of a chemical substance per year would be obliged to register that chemical with a new EU chemicals agency. REACH provisions also require registration of substances contained in downstream products. An EU impact assessment estimates that these provisions could touch some \$750 billion in EU imports every year.

The EP is currently considering the REACH proposal. Despite earlier more ambitious timelines, it now appears increasingly unlikely that the EP will be able complete a "first reading" prior to the May 2004 EP elections. Disagreements about which EP Committee would have jurisdiction have slowed progress. Moreover, Italian Socialist Guido Sacconi, EP Environment Committee rapporteur, issued a report in January 2004 proposing nearly 100 amendments to the legislation before any EP discussions had even taken place. Meanwhile, the EU Council (Council) has also taken the REACH proposal under consideration. Competitiveness Ministers are expected to debate REACH in mid-May, and different proposals have been put forward by United Kingdom, the Netherlands and Germany.

It should also be noted that the Oct. 29, 2003 proposal is a starting point, a floor rather than a ceiling for additional revisions that might occur in the course of EP and Council discussions. Still, Sacconi's report could be seen as one indication of the direction of EP deliberations. In the draft report, Sacconi disputes the concept that adequate control of dangerous substances should be a primary consideration for authorization of their use. Instead, he recommends that the availability of substitutes should prevent the authorization of a dangerous chemical — based on the so-called concept of substitutability. Another proposed amendment would eliminate a provision that would require the registration of

chemicals and consumer products and other “articles” only when the chemical is intended to be released in sufficient quantities to cause harm. Under that amendment, substances would be required to register whether or not those substances are intended to be released into the atmosphere. Sacconi also proposes the insertion of a “duty of care” provision into the legislation that would require chemical companies to adopt safe manufacturing and use practices.

The REACH proposal’s timing raises additional challenges, coming as it does during a period of global trade tension and the enlargement of the EU membership with the addition of ten Eastern European member countries. It is reasonable to assume that the REACH system will not go into effect until 2006; until then, much can happen in both the near and medium terms. Moreover, the parliamentary phase comes at an interesting time, particularly if parliamentary elections do precede the Proposal’s first Parliamentary reading, as now expected. With the EU membership expansion occurring on May 1, 2004, the EP will expand from 626 to 732 seats after the elections. This could result in up to a 70 percent turnover according to some observers, and influence of the Green Party — which has been supportive of ambitious chemical regulation — is expected to lessen somewhat. A more general shift in attitude away from support for unreasonably stringent environmental regulation by Eastern European parliamentarians could also be anticipated.

III. Business Concerns About REACH: High Economic Costs, Questionable Environmental Effectiveness

The European Commission has estimated that the assessments called for by REACH could cost up to € billion, while industry is estimating that it will cost between €4 and 26 billion to carry out tests and related administration. Eggert Voscherau, deputy

chairman of BASF, anticipates that approximately 2 million European jobs would be in danger if the new legislation were approved. On the other hand, environmental organizations like Greenpeace point to studies that indicate potential savings of up to €83 billion based on medical costs and lost productivity as a result of diseases thought to be linked to chemicals in the environment.

Business organizations representing many nationalities and sectors have continued to express broad economic and social concerns about the REACH proposal. In its July 2003 letter to the European Union last year, the United States Council for International Business (USCIB) stated that:

“given the pervasiveness of chemicals in almost every product, we believe REACH poses problems for U.S. companies representing a wide range of industries seeking to access EU markets. American firms relying upon chemicals or products manufactured in the EU will be seriously effected as well. REACH will have significant consequences not only for U.S. chemical manufacturers, but also for U.S. companies along the value chain that use chemicals in the manufacture or formulation of their products.”

The International Chamber of Commerce (ICC) also weighed in:

“The REACH proposal does not adequately reflect economic, development and trade aspects of sustainable development, and would have negative economic impacts throughout the global economy with questionable environmental benefit. ICC is particularly concerned by its lack of consideration for trade impacts and the special circumstances of developing countries.”

For businesses, specific problematic features include:

- *Registration:* Mandatory data requirements define the registration requirements. The chemical safety report requirements impose a significant burden, as registrants must assess all identified uses of a chemical.
- *Evaluations:* The draft contains no guidelines for evaluation, meaning that governments may reach non-uniform decisions. Reviewing governments are allowed to aggregate all production and import volumes — possibly resulting in an increase in the testing requirements applicable to any particular chemical. The effect of this authority may be to increase testing requirements for importers beyond the requirements they would otherwise have to meet under the tonnage thresholds.
- *Authorization:* Chemicals are identified for authorization (use-specific licensing) on the basis of hazard characteristics alone. Authorization will operate in parallel to the registration system.
- *Downstream Users:* Downstream users of chemicals retain significant responsibility to assess their uses, provide information up and down the supply chain, and notify the government authorities of their uses.
- *Information Disclosure/Protection of Confidential Information:* The draft requires disclosure of all non-confidential information. Individual EU governments will be able to decide on confidentiality requests, which must be fully justified. Mandatory data sharing and compensation requirements could be imposed.
- *Sanctions:* Individual EU member governments are to establish penalties and sanctions for failure to comply. Sanctions and varying enforcement

capabilities raise concerns about uniformity of application.

According to Dr. Neville Reed, director of Communication Services at the Royal Society of Chemistry:

“The chemicals sector in the UK . . . has an annual turnover of ca £50 billion; employs 235,000 people; supports several hundred thousand additional jobs throughout the economy; contributes 2% of GDP; contributes in excess of £5 billion annually to balance of payments; and pays [with employees] a further £5 billion (including tax, national insurances and business rates) annually to government and local authorities. Faced with an indiscriminate testing regime for chemicals, many of which are known to be safe, many companies — especially SMEs — may decide to relocate their businesses outside of the UK and the EU. We would then have to import the chemicals, giving a double whammy on our economy: loss of economic activity and costs of imports. And moving this industrial sector out of the EU will hamper the Lisbon EU Council objective to make Europe the most competitive and knowledge based economy by 2010.”

German, Belgian, Japanese and Czech business analyses have also signaled that high costs would presumably be passed on to consumers and increase overall compliance costs to society.

Yet it is not only business that has raised concerns. On Sept. 20, 2003, British Prime Minister Blair, French President Chirac and German Chancellor Schroeder sent a joint letter on REACH to Romano Prodi, president of the European Commission. In that letter,

the leaders set out concerns about the workability of the draft proposal and its ability to deliver adequate levels of protection for human health and the environment. The letter also faults the REACH proposal for failing to describe a rapid, efficient system for collecting the necessary information on chemicals and for prioritization to tackle the chemicals of greatest concern first, whilst maintaining industry competitiveness.

IV. REACH and Trade Disciplines

The REACH proposal was discussed in last year's July meeting of the WTO Committee on Technical Barriers to Trade (TBT Committee), following information on the proposal submitted to the TBT Committee earlier in May. At that time, the United States, Australia, Mexico, Japan, China, Malaysia, Korea, Ecuador and Australia outlined a number of problems that could arise from the legislation, including its complexity and cost of compliance. Some WTO Members also questioned why the EU was taking a unilateral approach on this issue, as work was ongoing under the Organisation for Economic Cooperation and Development (OECD) and in the UN to create harmonized procedures on chemicals.

On Jan. 21 of this year, the EU filed a notification on REACH to the TBT Committee, seeking comments from governments over a 90-day period, ending April 20. This comment period was subsequently extended to June 22.

For businesses and governments alike, the REACH proposal raises a panoply of trade concerns. Possible trade restriction issues arise from REACH in its registration and authorization procedures, in the way in which it proposes to address articles, and in its treatment of downstream users. Its volume-based requirements may violate the Agreement on Technical Barriers to Trade (TBT Agreement). Moreover, restricting the importation of chemical substances solely

based on hazard criteria — contemplated under the Authorization component of REACH — is inconsistent with accepted international practices on risk management and WTO rules.

There are also numerous de facto and practical trade impacts. Small and medium enterprises and economies that depend on commodity exports for their economic growth would be affected. Smaller foreign producers, including specialty chemical suppliers and downstream suppliers, simply do not have the capacity for the data generation required under REACH. As a result, there is a potential for EU importers to deselect imported supplies, which are not only chemical substances but also articles containing chemical substances. Thus, REACH may create an inherent bias in favor of domestic EU suppliers.

Broadly speaking, two aspects of compliance with WTO obligations are of particular concern in connection with REACH. The first relates to the TBT Agreement, in which Article 2.2 states that parties should ensure that technical regulations do not establish “unnecessary obstacles to international trade” and are not “more trade-restrictive than necessary to fulfill a legitimate objective.” The requirements of REACH, by duplicating requirements for registering products already approved in other registrations and by requiring companies to perform assessments that duplicate other consumer product safety requirements, would appear to be inconsistent with these principles. In this same vein, REACH's predominantly hazard-based (rather than risk-based) basis seems to run afoul of WTO nondiscrimination provisions, because differentiating between products based on their hazards is not the same as differentiating based on “health risks.” TBT Agreement Article 2.2 sets out a risk-based approach, requiring that domestic regulation protecting legitimate policy objectives focus on risk, not on hazards.

The second aspect relates to discrimination between EU and non-EU companies regarding the marketing of certain intermediate products. Under REACH, non-EU importers are required to register both substances that they import directly and substances contained in preparations. EU-based manufacturers, however, are only required to register the substances they manufacture and not the preparations containing the substances. This would appear to run afoul of WTO “national treatment” principles.

V. Impacts on Developing Countries

As the ICC has pointed out, REACH could present particular difficulties and uncertainties for business communities in developing countries. It is indicative to consider recent discussions in the Asia Pacific Economic Council (APEC) to get more insight into those issues.

APEC has 21 members — including numerous developing countries as well as the United States, Japan and New Zealand — which account for more than a third of the world’s population (2.6 billion people), over 50 percent of world GDP (US\$19,254 billion) and in excess of 41 percent of world trade. It also represents the most economically dynamic region in the world having generated nearly 70 percent of global economic growth in its first 10 years.

The APEC Chemical Dialogue (ACD) agreed to send a collective comment to the European Commission expressing concerns over the proposed REACH legislation. In its letter to the European Commission dated March 11, 2004, the ACD stated that the REACH system adopted by the Commission posed potential trade restrictions. The ACD also warned that the greatest negative impact of the new European regulations would be felt by developing economies and small and medium enterprises. The ACD also noted that the rules being imposed by the European

Commission go beyond what is technically required to meet these ends, as called for in the TBT Agreement.

It is also not defined how the REACH framework will recognize and accommodate developing countries, whose chemical manufacturers and exporters stand to face tremendous disruptions in market access as a result of the REACH system, and may be poorly positioned to comply with its burdensome requirements. Failure to do so would be contrary to TBT Agreement Article 12 concerning special and differential treatment of developing country members.

VI. REACH Could Undermine International Chemicals Cooperation

Businesses operating in international markets prefer internationally defined cooperative frameworks. Global chemical sales have increased nine-fold since 1970 and will continue growing, with production shifting increasingly to developing countries. In 1998, the industry generated US\$1,500 billion in sales, accounting for 9 percent of international trade and employing over 10 million people, according to a 2001 report prepared by the OECD.

Both business communities and governments have questioned the apparent disconnect between REACH and other longstanding international cooperative efforts on chemicals, including those under the United Nations Rotterdam Convention on Prior Informed Consent (PIC), the United Nations Stockholm Convention on Persistent Organic Pollutants (POPs), and ongoing chemical regulatory cooperation agreed in the World Summit for Sustainable Development (WSSD). EU representatives have been engaged in all of these consensus deliberations, yet now the Community has embarked on the development of a regulatory framework which is redundant, and potentially undermines these international cooperative efforts.

Instead, there are two initiatives with particular relevance to chemical testing information and risk management that could represent emerging alternatives that already meet the objectives of REACH.

A. Strategic Approach on International Chemicals Management (SAICM)

The concept of SAICM has been discussed by the United Nations Environment Programme (UNEP) Governing Council in various forms since 1995. The first session of the Preparatory Committee for the Development of a SAICM (PrepCom1) took place at the United Nations Conference Center in Bangkok, Thailand, in November 2003.

The SAICM process is jointly convened by UNEP, the Intergovernmental Forum on Chemical Safety (IFCS), the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), the World Bank, and the United Nations Development Programme (UNDP). Prepcom1 brought together more than 400 participants representing over 120 countries, 14 UN bodies, four intergovernmental organizations (IGOs), 24 non-governmental organizations (NGOs) and other observers.

There was broad support at Prepcom1 for the idea that the SAICM adopt a three-tier approach, which would comprise (1) a global program of action with targets and timetables, (2) an overarching policy strategy, and (3) a high-level or ministerial declaration to adopt the former two. Many delegates stressed that the SAICM should avoid duplication with other international agreements, and called for implementation of, and synergies among, existing chemicals-related agreements.

B. OECD Chemicals Safety Programme

Unlike SAICM, which is under development in the context of a broad web of international

treaties and institutions, the 30 OECD Member countries have worked together over many years to develop and coordinate international chemical and pesticide related activities, guidelines and tools. While an important focus of this work is on the production, processing and use of industrial chemicals, it also covers pesticides and chemical accidents. OECD also maintains databases on chemical risk assessment models and on uses/releases of chemicals.

The main objectives of the OECD Chemicals Programme are to:

- Assist OECD Member countries' efforts to protect human health and the environment through improving chemical safety;
- Make chemical control policies more transparent and efficient and save resources for government and industry; and
- Prevent unnecessary distortions in the trade of chemicals and chemical products.

A major component of OECD's work on chemicals — in which the EU is actively engaged — is its program on the Mutual Acceptance of Data. OECD recognized that the testing of chemicals is labor-intensive and expensive, and that often the same chemical is being tested and assessed in several countries. To relieve some of this burden, the OECD Council adopted a Decision in 1981 stating that data generated in a Member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other Member countries for assessment purposes and for other uses relating to the protection of human health and the environment. The 1981 Council Decision, agreed to by all OECD Member countries, established that safety data developed in one Member country will be accepted for use by the relevant registration

authorities in assessing the chemical or product in another OECD country (*i.e.*, the data does not have to be generated a second time for the purposes of safety assessment). A further Council Act was adopted in 1989 to provide safeguards for assurance that the data is indeed developed in compliance with the Principles of GLP.

The OECD chemicals initiatives have already demonstrated their relevance to developing countries. South Africa was the first non-member country to sign on to the OECD's Mutual Acceptance of Data in the assessment of chemicals in the course of the OECD Chemicals Committee meeting in Paris in February 2004.

VII. Conclusions and the Way Ahead

WSSD highlighted the synergy among development, trade, commercial activity, and environmental protection, emphasizing the need for actions that will integrate economic, social and environmental considerations built on cooperation and partnership. This process was reinforced in the Monterrey Financing for Development process. Certainly, given their broad commercial importance and potential environmental impact, chemicals safety rules have to be formulated in the context of sustainable development and globalized markets that will support economic growth and technological innovation.

There is no doubt that a framework known as REACH will come into existence sometime in late 2005 or early 2006, although its exact shape is uncertain. Between now and then, there is an opportunity to make improvements through a transparent and consultative process that takes into account economic and trade concerns, while achieving environmental objectives cost effectively.

The EU should continue to work within the broadest context of the international

community to promote cooperation, harmonize testing and assessment procedures, share data, and manage the transboundary movement and use of chemicals that pose the greatest risk to people and the environment. We have seen that the SAICM and OECD both afford robust and workable avenues in this regard. In lieu of that, we can anticipate that REACH may cause disruptive and unnecessarily costly measures that risk neglecting the imperatives of the WSSD and Monterrey.

Before the EP begins its first reading of REACH, the EU should take the opportunity to consult more widely with trading partners in developed and developing countries. The Commission could consider preparing a socio-economic assessment of the REACH proposal to evaluate both its impacts in the EU member states (current and incoming) and on EU trading partners. Indeed, the REACH proposal itself provides for consideration of socio-economic impacts in authorization decisions and includes procedures to ensure transparency and public comment in that connection. In light of this, it would be appropriate to undertake the same type of socio-economic assessment of REACH itself and share it publicly for comment.

In mid-April, the Commission did agree to initiate a new economic assessment of REACH that will focus on the supply chain of chemicals, impacts on innovation and the impact on the ten new EU member states. This study is envisioned to be completed in a six-to-nine month time period. The findings of such an analysis and subsequent societal dialogue is warranted by the broad commercial and regulatory impacts of REACH, and should be utilized to inform and improve the final form of REACH so that it pursues the most cost-effective and least trade-restrictive approaches to meet its objectives.

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INTERNATIONAL ENVIRONMENTAL LAW REGIONAL UPDATES

Note from the Editor: The following articles and commentary reflect recent developments and trends impacting the practice of law in China, Israel, and the Americas. As one of the key objectives of the International Environmental Law Committee Newsletter is to provide our members with valuable, up-to-date information regarding developments that may affect the everyday practice of our members, the Committee intends to devote a portion of every newsletter to region- or country-specific legal analysis in an effort to broaden our international horizons. The International Environmental Law Committee invites all committee members and other interested practitioners, regulators and researchers to submit articles and commentary on topics that may be of interest to the international environmental law community. If you are interested in contributing to this effort, please contact the Newsletter vice chair David Ross at dross@crowell.com.

CHINA: DEVELOPMENTS AFFECTING THE PRACTICE OF ENVIRONMENTAL, HEALTH AND SAFETY LAW IN CHINA

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The views expressed in this article are those of the authors in their personal capacities and do not necessarily represent the views of General Electric or Beveridge & Diamond, P.C.

I. Introduction

Many factors are contributing to the world's intense focus on China's environment, health

and safety (EHS) policies and laws. Among other things, China's economy is large and dynamic, multinational companies are increasingly choosing China as a focal point for manufacturing, sourcing and sales, and the country faces numerous challenges ranging from water scarcity to infrastructure development. International counsel should be aware that China's environment, health and safety legislative and enforcement environment is evolving rapidly. This article highlights several key areas to watch in 2004, including chemicals management, product-related environmental requirements, general work safety and medical waste management, as well as overall enforcement trends in the EHS areas.

II. Chemicals Management

Numerous agencies are involved in regulating chemical issues in China, but two agencies deserving special attention are the State Environmental Protection Administration (SEPA) and the State Administration of Work Safety (SAWS).

SEPA's Regulations on the Environmental Management of New Chemical Substances (Regulations) became effective on Oct. 15, 2003. The Regulations establish a comprehensive pre-manufacture/pre-import registration and testing process for "new" chemicals not listed on China's Inventory of Existing Chemical Substances or otherwise not proven to the government authorities to have been in use in China prior to Oct. 15, 2003. Similar in some respects to the U.S. Toxic Substances Control Act (15 U.S.C.A. §§ 2601 *et seq.*), this Regulation also includes unique provisions, such as a requirement for records to be filed with county-level environmental bureaus recording data concerning the manufacturing, import or transfer of new chemical substances within five days of the event.

The Regulation also provides penalties that are quite severe when compared to those set forth under other Chinese laws. For instance, those manufacturing or importing new chemical substances without receiving a registration certificate can be subject to a fine up to 30,000 Chinese Renminbi (RMB), publication of the violation and refusal by SEPA to accept any new chemical substance notifications made by the violator for three years. Thus, SEPA essentially reserves the right to block violators' market access for a significant period of time. While the SEPA Chemical Registration Center (CRC) issued implementing measures in the form of "Guidelines on New Chemical Substance Registration" in December 2003, given the relative newness of the chemical registration requirements, the slow-development of administrative infrastructure (e.g., fee schedules, testing protocols) to support the new laws, and the need for national government training of local government regulators on the new chemical registration requirements, companies should expect the new chemical notification process to be time-consuming.

It is also extremely important for companies involved in chemical manufacturing, storage, transportation and use to monitor regulatory developments at SAWS. Among other matters, SAWS is responsible for administering and enforcing the Regulations on the Control of Dangerous Chemical Safety (sometimes referred to by the Regulations' numerical designation, "Decree No. 344"), which entered into force in March 2002.

In 2004, SAWS is focusing on enhancing the implementation of Decree No. 344 and related measures. Much of this work represents a response to the rise in serious chemical accidents in China. For instance, toxic fumes were emitted from a gas well at PetroChina, a subsidiary of the China National Petroleum Corporation (CNPC), killing approximately 245

individuals in December 2003. As a result, the Chinese government moved to require the resignation of the CNPC general manager on April 14, 2004. Furthermore, on March 2, 2004, synthetic ammonia and nitrogen leaked into Sichuan's Tuo River and led to a water stoppage for more than 1 million Chinese residents.

Responding to such crises, SAWS is undertaking intensive law drafting efforts. SAWS rulemakings in the pipeline for 2004 include "Methods on Safe Production Permitting for Manufacturers of Dangerous Chemicals," "Management Methods for Safety Evaluation of the Status of Facilities and Equipment that Produce, Store and Use Dangerous Chemicals," and "Guidelines on Establishing Emergency Response Plans for Dangerous Chemical Accidents."

The SAWS Department of Dangerous Chemicals Safety Supervision and Management, the establishment of which was authorized during China's March 2003 government reorganizations, is responsible for the lion's share of this work. Companies should anticipate that SAWS and other agencies will sense increasing pressure from China's top leaders to exert greater control over the EHS aspects of chemical operations.

III. Product-Related Environmental Requirements

The European Community (EC) is generally perceived to be driving a number of product-related environmental requirements around the world through EC measures such as the Directives on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS Directive) (Jan. 27, 2003), available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_037/l_03720030213en00190023.pdf, and Waste Electrical & Electronic Equipment ("WEEE Directive") (Jan. 7, 2003), available at <http://>

europa.eu.int/eurlex/pri/en/oj/dat/2003/l_037/l_03720030213en00240038.pdf. Partially from a desire to ensure that Chinese manufacturers can compete in the EC, China is taking steps to adopt similar measures. It is also noteworthy that the Chinese government views such measures as important because of widespread media and other reports pointing to the country's looming electronic waste-management challenges.

More specifically, China's Ministry of Information Industry (MII) is taking the lead to promulgate a regulation that is generally based on the RoHS Directive. The working title of the draft regulation is "Management Methods for Pollution Prevention and Control in the Production of Electronic Information Products." Based on publicly circulated drafts, the MII regulation is expected to follow the RoHS Directive model with the aim of driving reductions of the use of mercury, lead, cadmium, chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) in electronic equipment, as well as imposing labeling and marking requirements. Industry watchers expect a final draft rule could be published as early as fall 2004, although it is unclear whether this schedule will prove too ambitious in light of the significant implementation issues posed by such a measure in China.

Other product-related policy and law-making activities are underway, largely drawing from the regulatory authority provided in the Clean Production Promotion Law (http://www.chinacp.com/eng/cppolicystrategy/cp_law_2002.html), a national statute which entered into force on Jan. 1, 2003 to prompt improvements in product and production design to protect human health and the environment. The State Development Reform Commission (SDRC, sometimes also referred to as the National Development Reform Commission or NDRC) is taking a lead role in the development of take-back and related

measures affecting the electronics and other industries. Among the SDRC's current rulemaking plans is a national regulation addressing electronic product take-back. SEPA is also engaged in the development of numerous "Technical Policies" (sometimes also translated as "Technology Policies"). The Technical Policies are not laws, but akin to "white papers" that serve to drive policy discussions on product and other issues, as well as form the bases for rulemaking activities. Product-related Technical Policies that SEPA has issued include a Technical Policy for the Prevention and Control of Pollution from Discarded Batteries. Further, SEPA is working on a draft Technical Policy for the Prevention of Pollution Caused by Waste Electrical and Electronic Products. SEPA plans to finalize this draft policy document by the end of 2004.

Needless to say, international counsel involved in China operations and market issues would be well advised to monitor the rapid growth of laws and policy recommendations in this area. Counsel should also take note of China's use of EC product-related EHS initiatives as models.

IV. Work Safety

Given the intense domestic and international media focus on China labor practices and accidents in recent months, practitioners should expect to see greater efforts by regulatory agencies to enforce safety requirements for the remainder of 2004 and beyond. The rise in chemical accidents mentioned earlier is also representative of an increase in more general worker and workplace safety problems in China. Spurred by these accidents, the Chinese government has already issued numerous laws and is undertaking a significant number of rulemaking activities concerning "workplace safety" (referred to in China as "safe production") this year. Recently, for instance,

the State Council issued Regulations on Safe Production Permits (promulgated Jan. 13, 2004 and effective the same date). The Regulations require certain hazardous operations, including mining, construction and production of dangerous chemicals, fireworks and explosives for civilian use, to obtain special safety permits. Further, the Regulations lay out a number of criteria that must be satisfied in order for a license to be issued, including: establishment of a safe-production responsibility system; adequate safety investment; trained managers and personnel, including licensed personnel for specialized tasks; compliance with occupational injury insurance requirements; compliance with occupational disease prevention requirements; established emergency response plans; and compliance with other safety requirements.

Also in 2004, Chinese agencies issued or began to enforce various measures focusing on occupational injury insurance, safety training, accident prevention, safety management in specific industries and among certain worker populations, and occupational disease prevention. These measures include “Regulations on Occupational Injury Insurance” (promulgated by the State Council April 27, 2003 and effective Jan. 1, 2004), “Key Points for Education Work Concerning Safe Production in 2004” (promulgated by SAWS Feb. 9, 2004 and effective the same date), the “Urgent Circular on Enhancing Safe Work” (promulgated by the State Council Feb. 16, 2004 and effective the same date), and the “Circular on Enhancing Occupational Health Protections for Temporary Workers” (promulgated by the Ministry of Health Jan. 2, 2004 and effective the same date).

All of these activities are supported at the inter-agency level by the State Council Safe Production Committee, an *ad hoc* group reorganized in late 2003 that is comprised of Party, various agency, government-sponsored

union and military representatives, that focuses on worker and workplace safety policies. SAWS serves as the administrative office for the Committee. It is clear, with the senior-level support of groups such as this, that the expansion of workplace safety regulatory measures and inspections in China will continue. Representing the importance of the Committee’s activities, the head of the Committee is Vice Premier, Huang Ju.

V. Medical Waste

One of many effects of the recent Severe Acute Respiratory Syndrome (SARS) epidemic in China is the rapid growth of law and law-drafting efforts in the area of medical waste management. Chinese officials were alarmed at reports concerning the potential for widespread SARS contamination arising from unsound management of hospital/clinic wastes. A massive amount of biological wastes were generated during the epidemic, and it quickly became evident to government officials and the population at large that further legal measures were needed to help drive sound waste management practices in this area.

Many of the recently issued laws provide implementing or technical details needed to improve the sound management of medical waste as provided in the “Regulations on Medical Waste Management” (promulgated by the State Council June 16, 2003 and effective the same date). These laws include “Technical Requirements for Construction of Centralized Hospital Waste Incineration and Disposal Projects” (promulgated by SEPA Jan. 19, 2004 and effective the same date), and the “Circular on Enhancing the Management of Environmental Impact Assessment for Construction Projects Involving the Disposal of Hazardous, Hospital and Radioactive Wastes” (promulgated by SEPA Feb. 18, 2004 and effective the same date).

International counsel should expect that the focus on medical waste will involve broader re-assessments of China's law and policy concerning the management of hazardous waste. This is evidenced in the National People's Congress's current plans to revise the Law on the Prevention of Environmental Pollution from Solid Waste.

VI. Enforcement Trends

It is clear that there is increased focus and attention directed at effective enforcement. For example, SEPA sent Beijing-based inspection teams to six provinces last year to assess compliance, reportedly resulting in the issuance of shut-down orders to more than 6,000 non-compliant facilities. SEPA has indicated it plans to repeat this initiative in 2004.

On the issue of improving the effectiveness of EHS-law enforcement, several recent developments have the potential to affect the way EHS law is implemented in China. SEPA issued the "Circular on Issuing 'Management Methods on Administrative Transparency in Environmental Administrative Authorities'" on Jan. 30, 2003. The Circular entered into force on April 1, 2003. Among other things, the Circular provides that environmental protection bureaus will publish lists of companies that exceed environmental standards and require that such companies comply with additional public disclosure obligations. This law is representative of a trend in China toward the development of legal measures that reduce the enforcement burden of Chinese regulatory authorities. In the tradition of the Toxics Release Inventory program in the United States (<http://www.epa.gov/tri/>), these measures reportedly reduce the enforcement burden by requiring disclosure of information that can facilitate government monitoring of industrial or other activities affecting the environment "beyond the facility fence line," focus public attention on emissions/discharges

resulting from such activities, and perhaps encourage voluntary restrictions on potentially harmful activities, or at least restrictions on those activities that companies believe may be perceived as harmful.

Further, SEPA issued "The Six Bans for Nationwide Environmental Protection Institutions" on Dec. 3, 2003. Essentially, this document is a notice to environmental protection bureaus (EPB) throughout the country specifying national government prohibitions on: (1) EPB acceptance of bribes; (2) EPB requirements to use particular construction companies, environmental equipment or products; and (3) EPB project approvals that contravene environmental and other legal requirements applicable to those projects. This measure underscores increasing concern, throughout China's national leadership, with local government activities that serve to undermine the enforcement of EHS law.

ISRAEL: A CONSTITUTIONAL (OR BASIC LAW) RIGHT TO "MINIMUM ENVIRONMENTAL QUALITY"

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Adam, Teva ve'Din v. Prime Minister of Israel et al., No. 4128/02 (Mar. 16, 2004). In this seminal ruling, the Israeli environmental nonprofit, Adam, Teva ve'Din ("Human Being, Nature, and Law") brought a constitutional or Basic Law challenge to Article 76(c) of the Israeli Law on Planning and Construction, as amended in 2002 at the behest of the government of Prime Minister Ariel Sharon. (Israel does not have a constitution, but rather a collection of laws that constitute the Basic Law — or quasi-constitutional law — of the land.) This law established a new Committee

for National Infrastructure to expedite the process of building and construction projects involving national infrastructure (e.g., shortening the amount of time in which environmental impact statements must be completed for projects such as airports, desalination plants, water treatment plants and power stations).

Writing for the Supreme Court of Israel, Chief Justice Barak stated that there is a constitutional right to “minimum environmental quality” deriving from the constitutional right to “Honor of the Human Being and His Freedom.” However, the main discussion in the opinion emphasized that — absent action by the Israeli Knesset (Parliament) — this “minimum environmental quality” right does not extend to a higher “appropriate environmental quality” right. Moreover, the Court held that the constitutional right to property does not give rise to any right to environmental quality at all. Furthermore, the opinion emphasized that Article 76(c) of the Israeli Law on Planning and Construction is by nature a procedural law and not a substantive law. Therefore, despite rejecting the constitutional claims, the opinion stated in dicta that the desire to make quick decisions in order to promote more rapid development was inconsistent — from an Israeli administrative law point of view — with proper environmental review and suggested that the Knesset modify the law accordingly.

The ruling is significant because it establishes “minimum environmental quality” as a quasi-constitutional right, though it leaves undefined the constitutionally mandated “minimum,” beyond stating that the “minimum” level is below the “appropriate” level (similarly undefined). The ruling also implicitly clarifies that property rights — also enshrined in quasi-constitutional fashion — will invariably trump a claim to an “appropriate” level of environmental protection as a constitutional matter where a conflict between property rights and “appropriate” environmental quality

exists. However, because the line between the “minimum” and “appropriate” level of environmental quality is blurry, property rights advocates need not feel themselves secure after this ruling. For example, if a particular action may lead to potentially dangerous health consequences with regard to air or water quality, would the action entail an infringement of “minimal” or “appropriate” environmental quality rights? In short, this distinction leaves the field open for further constitutional challenges. In addition, the ruling will be significant for Israeli administrative lawyers because it suggests that there is a standard of arbitrary and capricious administrative action with regard to the consideration of environmental impact, an important dictum for the practice of administrative law.

THE AMERICAS: ENVIRONMENTAL ASPECTS OF THE U.S.-CHILE FREE TRADE AGREEMENT

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The U.S.-Chile Free Trade Agreement (FTA) entered into force on Jan. 1, 2004. The FTA gradually eliminates tariffs on goods between the countries, provides protections for foreign investors and intellectual property, increases access for professional services, and creates mechanisms for resolving trade and investment disputes. The FTA also includes specific provisions and commitments concerning the environment, which are supplemented by a separate agreement between the United States and Chile regarding environmental cooperation. The FTA has been hailed by both governments as an important precursor to the Free Trade Agreement of the Americas (FTAA) and as a model for future free trade agreements. Thus, the salient features of the FTA not only speak to trade relations and environmental cooperation between the

United States and Chile, but also to the approaches that may be taken in future bilateral and regional trade accords. However, the U.S. Congress was keenly aware of Chile's relatively strong environmental record when approving the FTA, so it is unclear how much of the FTA will be mimicked in future U.S. trade agreements.

I. Background

In Dec. 1994, during the first Summit of the Americas in Miami, the leaders of Canada, Mexico and the United States invited Chile to be the "fourth amigo" of free trade in the Americas. Nine years later Chile and the United States finalized negotiations on a FTA. While the reasons for delay were numerous, the most significant was the failure of Congress to provide President Clinton with trade promotion authority (commonly known as "fast track" authority). Trade promotion authority is a mechanism whereby Congress agrees to speedily and without amendment vote on trade agreements, provided that the president follows specific procedures for negotiating the agreement. Congress finally granted President Bush trade promotion authority in August 2002 with the passage of the Bipartisan Trade Promotion Authority Act of 2002 (TPA of 2002). Among other things, the TPA of 2002 requires improved transparency, expressly recognizes environmental issues as negotiating objectives, addresses environmental enforcement and recognizes the interaction between trade agreements and Multilateral Environmental Agreements (MEAs).

Consistent with this fast track authority, President Bush formally announced to Congress his intention to sign the U.S.-Chile FTA on Jan. 30, 2003. The FTA was signed in June and both Houses of Congress passed needed implementing legislation in late July. President Bush signed this legislation in September 2003, and the FTA went into effect on Jan. 1, 2004.

Chile and the United States also concluded a bilateral Environmental Cooperation Agreement (ECA) in June 2003 that supplements the FTA. The ECA augments the environmental provisions contained in Chapter 19 of the FTA and provides a framework for cooperation on a wide-range of environmental and conservation issues.

II. Key Provisions of the FTA

There are several noteworthy environmental aspects of the U.S.-Chile FTA, ranging from dispute settlement mechanisms to transparency requirements. These provisions are summarized below.

A. Environment and Labor Provisions in the Body of the FTA

Environment and labor issues are incorporated directly into the main text of the FTA. Since the negotiation of the North American Free Trade Agreement (NAFTA), the propriety of incorporating labor and environmental provisions into trade agreements has been hotly debated. In NAFTA, labor and environment issues were addressed in side agreements. This approach was roundly criticized from both ends of the debate: business interests viewed labor and environmental issues as improper topics for trade negotiations, while environmentalists and unions felt that such side agreements relegated the issues to a less formal rank and would be trumped by the main agreement in the case of any conflict. The U.S.-Chile FTA appears to signal that this debate is largely over, as labor and environment issues are included in the main body of the agreement.

B. Transparency and Public Participation

The U.S.-Chile FTA has been hailed for its vast improvements in transparency and public participation. In contrast, the World Trade

Organization (WTO) dispute settlement procedures have been roundly criticized for their lack of transparency and public participation. For example, the FTA dispute settlement procedures include the following improvements over the WTO model:

- Dispute hearings are open to the public;
- Written submissions and transcripts of oral statements are to be made public within 10 days of submission;
- Dispute panels will consider requests to submit amicus curiae briefs; and
- Final reports are released to the public within 15 days.

All of these improvements were specifically required by the TPA of 2002. Other measures to improve transparency and public participation include obligations for the governments to:

- Promptly publish laws, regulations, procedures and rulings;
- Publish in advance proposed measures (such as draft laws and regulations);
- Provide the public with an opportunity to comment on proposed measures;
- Establish and maintain appeals tribunals;
- Provide parties to legal disputes reasonable opportunity to support or defend their position; and
- Require final court decisions to be based on the evidence.

C. Specific Environmental Initiatives

Under Chapter 19 of the FTA, the governments have agreed to several new cooperative environmental initiatives. The most significant of these initiatives is the creation of a Pollutant Release and Transfer Register (PRTR) in Chile, a national pollutant release registry comparable to the U.S. Toxics Release Inventory (TRI). The Chilean PRTR

is to be a publicly available database of chemicals that have been released to air, water and land or transferred off-site for further waste management. Industrial facilities will report annually on the amounts of chemicals they have released or transferred and the final destination of those chemicals. This information will then be made publicly available.

Chile and the United States have also agreed to cooperate on improving environmental enforcement and compliance by exchanging information and providing training to enhance enforcement capacity. The Parties have also pledged to encourage companies to voluntarily incorporate “sound principles of corporate stewardship in their internal policies.” Cooperation between the two governments in these areas has already begun.

D. Environmental Cooperation Agreement

The Parties agreed in Article 19.5.1(b) of the FTA to complete an Environmental Cooperation Agreement (ECA). The ECA was completed and signed on June 17, 2003 in Santiago, Chile. The objective of the ECA is to “establish a framework for cooperation between the Parties to promote the conservation and protection of the environment, the prevention of pollution and degradation of natural resources and ecosystems, and the rational use of natural resources, in support of sustainable development.”

The ECA provides for several actions:

- Creating a Joint Commission for Environmental Cooperation to establish and develop programs of work, evaluate cooperative activities, and make recommendations to the Parties. The Joint Commission is co-chaired by officials from the U.S. State Department

and the Chilean Foreign Affairs Ministry, and each Party is to designate five representatives from its agencies. The Commission is to meet at least every two years, with the Under Secretary of State for Global Affairs as the U.S. co-chair;

- Exchanging information on domestic environmental policies, laws, indicators, enforcement activities and practices. The Parties have also agreed to exchange information on the implementation of multilateral environmental agreements that both are a party to;
- Promoting public participation in cooperative agreements and work plans;
- Facilitating direct contacts between government agencies; and
- Maintaining the confidentiality of business information.

The ECA also lists several areas of possible cooperation, such as exchanges of experts, organizing joint conferences, and facilitating linkages between academia, industry and government to promote best practices and exchange environmental information. More recently, the governments have agreed to address the impact of their longline fisheries on seabirds, including albatross.

E. Effective Enforcement of Environmental Laws

Another important aspect of the U.S.-Chile FTA is the language surrounding the key provision of the environment chapter. The provision mimics language in the TPA of 2002 that links environmental complaints to trade manipulation. Specifically, the provision states:

A Party shall not fail to effectively enforce its environmental laws, through a sustained or recurring course of action or inaction, *in a manner affecting trade between the parties*, after the date of entry into force of this Agreement.

Art. 19.2.1(a) (emphasis added). This language is narrower than comparable provisions adopted under NAFTA's environmental side agreement (known as the "NAAEC") regarding a Party's general commitment to effectively enforce its environmental laws. In contrast to the obligations set forth under the NAAEC, it suggests that a Party may fail to enforce its environmental laws, so long as such a failure does not affect trade.

This provision also has implications for environmental dispute settlement claims (which are only available to the Parties). Presumably, the grounds for challenging a Party's failure to effectively enforce its environmental laws are limited to instances where the action or inaction has an effect on trade. This requirement could limit the type of complaints that are brought for dispute settlement by the Parties.

F. Absence of Third-Party Dispute Mechanism

The U.S.-Chile FTA only provides for state-to-state dispute resolution for instances where a government may be failing to implement its environmental laws in an effective manner. Thus, individual citizens or corporations cannot bring a complaint to enforce this aspect of the agreement. This is a significant departure from the NAAEC, which created a novel mechanism that allows third-parties to bring environmental complaints before the Commission for Environmental Cooperation. The United States had indicated that a third-party dispute mechanism for environmental disputes was too costly in light of the low

volume of trade between Chile and the United States. However, the Canada-Chile Free Trade Agreement and the draft U.S.-Central American Free Trade Agreement (CAFTA) contain mechanisms similar to the NAAEC dispute mechanism.

G. Investor-State Dispute Mechanism

The FTA contains important provisions allowing private investors of a Party to submit to arbitration a claim that the other Party has violated one or more of the investment obligations, thereby causing loss or damage to the investor or investment. Such investor-state agreements are common, and the United States has similar agreements with over 40 different countries. In recent years, these agreements have garnered criticism as investors have challenged environmental regulations, claiming that these regulations violate investor-state agreements by creating a “regulatory taking” of private property. The United States, for example, has faced several multi-million dollar claims under similar investor-state dispute mechanisms available under Chapter 11 of NAFTA.

The U.S.-Chile FTA has attempted to respond to some of this criticism, adding novel language to the investment dispute provisions. In Annex 10-D(4), the FTA adopts language from a leading U.S. Supreme Court case on regulatory takings to clarify what is a legitimate claim. The new language explains that a regulatory taking analysis requires a case-by-case, fact-based inquiry that considers the economic impact of the government action, the extent of interference with reasonable investment backed expectations, and the character of the government action. The annex also explains that only in rare circumstances will regulatory actions designed to protect legitimate public welfare objectives constitute indirect expropriation.

H. Other Provisions

There are several other notable provisions of the FTA, including the following:

- Dispute settlement procedures for environmental disputes are only available for violations of Article 19.2.1(a) (failing to effectively enforce domestic environmental laws, through a sustained or recurring course of action or inaction, in a manner affecting trade between the Parties);
- Third parties may request Parties to investigate alleged violations of environmental laws and Parties should give such requests due consideration;
- The definition of environmental law excludes laws primarily addressing the commercial harvesting of natural resources;
- Environmental dispute penalties are capped at \$15 million;
- Penalties from environmental disputes are placed into a fund to assist the violating Party with its enforcement activities; and
- Corporate responsibility initiatives and partnerships between corporations, NGOs and government are formally encouraged.

III. Conclusion

Implementation of the U.S.-Chile FTA is not expected to significantly alter environmental laws and enforcement in Chile or the United States over the near term. While the FTA’s provisions can be expected to influence the negotiation of the Free Trade Agreement of the Americas and U.S. efforts to conclude other bilateral or regional free trade accords,

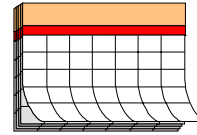
Chile's relatively strong history of environmental enforcement makes it an imperfect template. Thus, it is unsurprising that the text of the draft U.S.-Central American Free Trade Agreement, despite mimicking most of the U.S.-Chile FTA's provisions, has significant departures from the environmental provisions of the U.S.-Chile agreement. However, the inclusion of environmental provisions in the main body of the FTA and the conclusion of a cooperation agreement on the environment establish an important new framework that is likely to be followed in the future.

IV. Key Documents

- *U.S.-Chile Free Trade Agreement*, available at <http://www.ustr.gov/new/fta/Chile/text/index.htm>.
- *Trade Promotion Act of 2002*, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ210.107.pdf.
- *S. 1416, A Bill to Implement the United States-Chile Free Trade Agreement*, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_bills&docid=f:s1416is.txt.pdf.
- *Draft Text of the Central American Free Trade Agreement*, available at <http://www.ustr.gov/new/fta/Cafta/text/index.htm>.

AMERICAN BAR ASSOCIATION SECTION OF ENVIRONMENT, ENERGY, AND RESOURCES

Calendar of Section Events



Ethics Program: MJP and Environmental Practice

Teleconference with CLE Credit
June 15, 2004

Key Environmental Issues in U.S. EPA Region 2

June 18, 2004
New York

ABA Annual Meeting

Aug. 5-11, 2004
Atlanta

12th Section Fall Meeting

Oct. 6-10, 2004
San Antonio

Environmental Sciences

Nov. 4-5, 2004
Dallas

ABA Midyear Meeting

Feb. 9-15, 2005
Salt Lake City

23rd Annual Water Law Conference

Feb. 24-25, 2005
San Diego

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