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MESSAGE FROM THE CHAIRS OF THE INTERNATIONAL ENVRIONMENTAL LAW COMMITTEE AND THE AGRICULTURAL MANAGEMENT COMMITTEE

Jane Luxton
Chair, International Environmental Law Committee
General Counsel, National Oceanic and Atmospheric Administration, U.S. Department of Commerce

Brandon W. Neuschafer
Chair, Agricultural Management Committee
Bryan Cave LLP

Time and again we are reminded that the most significant environmental issues of the day transcend our borders and the categories in which we try to place them. Energy and food security, the benefits and risks of biotechnology, and protection of biodiversity and marine resources—all are pressing issues and important subjects for our practices. In recognition of these common interests, we again link our committees and practitioners together for the second annual Joint Newsletter of the ABA SEER's Agriculture Management and International Environmental Law Committees.

This year's joint edition covers a broad and exciting array of issues and analyses. Tim Pomeroy and Emilie Leibovitch first provide context with a survey of some of the major international environmental regulatory programs of 2007. The newsletter then delves more deeply into these issues with Tim Pomeroy reporting separately on developments in the Biosafety Protocol to the Biodiversity Convention concerning rules for liability and redress related to the trade in living modified organisms. This topic particularly represents a fascinating intersection of biotechnology, biodiversity, and international liability concepts.

Next, illustrating the connections between climate change and agricultural policy, Jane Earley provides a detailed look at the state of international regulation and trade in biofuels such as ethanol and biodiesel, and examines both the promises and concerns raised by these new fuel sources. Brett Grosko then examines a growing and severe environmental problem that threatens waters around the world—the development of dead zones and harmful algal blooms. These occurrences have been linked to agricultural practices and nutrient runoff, and implicate the emerging biofuels industry as well. Keeping the focus on maritime matters, Anna Burghardt will provide an update on international law and policy regarding the placement of artificial reefs in the marine environment. This an expansion of programs originally developed for aquaculture but now being used to study, protect, and restore degraded marine, coastal, and recreational resources, while mitigating the impacts of coastal erosion and flooding from development and sea-level rise.

Finally, returning to biotechnology rules, Tom Redick, James Andreasen, and Brandon Neuschafer explain

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Jim Rubin, Editor and
Brett Grosko, Issue Editor

In this issue:

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.

how the United States is developing a program to ensure the safe import and use of foodstuffs developed with the latest technologies, a matter that has already been a subject of high-level concern and friction in the European Union and developing world. We hope you will enjoy this wide-ranging and informative exploration into these new developments and critical matters.

Note that, as a new feature of the International Environmental Law Committee Newsletter, we will feature an interview with an experienced practitioner who is a member of the International Environmental Law Committee. In the inaugural interview, Jennifer Wills interviews Brandon Neuschafer, an author of the article on biotechnology above.

INTERNATIONAL AGRICULTURE-ENVIRONMENTAL REGULATORY UPDATE

Tim R. Pomeroy
Emilie Leibovitch

This update, current as of Dec. 1, 2007, seeks to cover significant events concerning various environmental treaties and overseas laws that relate to both agriculture and the environment. Readers interested in writing the next such update for the International Environmental Law Commitee should contact Jim Rubin at jrubin@hunton.com or Brett Grosko at brett.grosko@noaa.gov.

Major Environmental Treaties Relating to Agriculture

Climate

European Union Commissioner Reiterates the Leading Role of United Nationas as United States Conference Fails to Produce Results

From Sept. 18-28, 2007, the United States gathered the seventeen largest CO_2 emitters in Washington, D.C., to discuss the issue of energy security and climate change. The meeting itself appeared to reflect a new approach of the United States, one that

acknowledges the challenges associated with climate change and the need for international action. Nonetheless, the event failed to bring about any remarkable results and reached no agreement on binding targets.

European Union (EU) Environment Commissioner Stavros Dimas, in a speech delivered on Oct. 1, 2007, reaffirmed the leading role of the United Nations in conducting international negotiations on the matter and questioned the need for a parallel mechanism without any added value. In contrast, the commissioner vested great hopes in the conference to be held in Bali, Indonesia, in December 2007. The speech elaborated on the priorities of the EU with regard to a future international agreement, such as the importance of cooperation in the field of technological research and technology transfer, or the need to address emissions from aviation and maritime transport.

See the upcoming Winter/Spring International Environmental Law Committee Newsletter issue for updates on climate change and the Bali meetings.

WTO Case Law

Brazil—Measures Affecting Imports of Retreaded Tires

In a landmark case concerning trade and the environment, on June 12, 2007 a World Trade Organization (WTO) dispute resolution panel issued its decision in a case concerning the import of retreaded tires from the EU into Brazil. The panel found, first, that several of Brazil's trade measures, which effectively banned retreaded tire imports, violated an article of the General Agreement on Tariffs and Trade 1994 (GATT 1994) prohibiting the imposition of quotas and import licenses. Second, the panel agreed with Brazil that these measures could, despite the violation, be in principle justified on the basis of the GATT 1994 provision exempting violations based on the need to protect human, animal, or plant life or health—Article XX(b). The panel agreed that Brazil's measures sought to avoid the further accumulation of waste tires, thereby preventing mosquito-borne illnesses and emissions from tire fires. The panel noted the "serious nature" of the human pathologies Brazil identified: mosquito-borne dengue, yellow fever, and malaria, learning disabilities, cancer, and premature mortality from exposure to toxic fumes. The panel concluded, however, that because at present Brazil does not block the import of *used* tires—a policy undermining the measure's stated objective—the retreaded tire ban was being applied in a manner that constituted unjustifiable discrimination and a disguised restriction on international trade. Reliance on Article XX(b), therefore, was not, in the final analysis, justified.

Subsequently, Brazil announced its plan to rectify the inconsistencies identified by the panel, while keeping in place its import restrictions. The EU, opposing the import ban, has requested an appeal, which met strong disapproval from European non-governmental organizations (NGOs).

The Cartagena Protocol on Biosafety

As discussed more fully below in Tim Pomeroy's article, Article 27 of the Biosafety Protocol to the Convention on Biological Diversity requires the parties to establish a process for the "appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs." The Fourth Meeting of the Open-Ended *Ad Hoc* Working Group on Liability and Redress in the Context of the Cartagena Protocol on Biosafety (Technical Expert Group, or TEG)—the group charged with drafting a working text for the Convention on Biological Diversity Conference of the Parties—took place in Montreal, Canada, from Oct. 22-26, 2007. At this meeting, the TEG consolidated previous textual proposals, and was successful in eliminating a number of pages of text under consideration.

The resulting working document, Annex II to the report on the work of the fourth meeting, focuses on the following issues: (a) state responsibility for international wrongful acts (as currently drafted, states' rights and obligations under international law would not be affected); (b) the functional, geographic, and temporal scope of a Living Modified Organism (LMO) liability scheme; (c) the definition, valuation, and causation of

damages; (d) compensation schemes, including the channeling of liability; (e) the settlement of claims; (f) complementary capacity-building measures; and (g) choice of instrument (*e.g.*, whether the instrument should be binding or non-binding).

Several aspects of the meeting bear mentioning. First, while there remained a divide concerning whether Article 27 mandates a legally-binding regime, the TEG did agree to remove primary state liability as an option. This suggests any agreed-to definition of damage, or primary compensation scheme, will be based on an administrative or civil liability approach (or some combination of the two). An administrative approach would focus on the allocation of costs and response and restoration measures. One such proposal is to place an obligation via national law on the operator to inform the authorities in the event of damage. A civil liability approach would focus more on, and seek to harmonize, judicial standards, such as whether fault-based or strict liability should apply.

Second, differences remain regarding the breadth of the definition of "damage" as well as the appropriate standard of liability. Some delegates argued that damages to human health or socioeconomic damage should be covered. Others would prefer to limit the definition to damage to the conservation and sustainable use of biodiversity. On the appropriate standard of liability, developing countries, supported by the EU and Norway, argued for strict liability. Japan and New Zealand, among others, lobbied for a fault-based approach. Delegates are also still considering certain limitations on, and exceptions to, liability.

Delegates will continue to debate these issues at the fifth meeting, scheduled for March 2008 in Bogota, Colombia.

EU Developments (De Facto Global Standards?)

Program to Help Small and Medium-Sized Enterprises (SMEs) to Comply with Environmental Rules

An EU Commission Communication published on Oct. 8, 2007 outlines a plan to reduce the negative environmental impacts of small and middle sized businesses. The Environmental Compliance Assistance Programme facilitates the implementation of European environmental law as well as promotes training and information networks. According to the commission, while accounting for 99 percent of EU enterprises, SMEs tend to underestimate their impact on the environment. For this reason, raising the level of awareness of these entities is an important element of the communication.

Registration, Evaluation, and Authorisation of Chemicals Initiative (REACH)

Companies that import to, export from or even use chemicals from the EU in any appreciable quantity, are now learning that their regulatory postures are about to change—and not for the better. On June 1, 2007, The Environmental Protection Agency (EPA) began implementation of the REACH (Registration, Evaluation and Authorisation of CHemicals) program, a far reaching chemical regime that has few rivals in its breadth and impact on broad sectors beyond chemical manufacturers and importers. The central text of the new regulation can be found at Regulation (EC) No. 1907/2006.

REACH was formally adopted on Dec. 18, 2006 by the European Council of Ministers. The explicit goal of REACH is to do away with the previously-existing patchwork system of over forty different chemical regulations and implement in their place a single EU-wide system. The new system regulates all non-exempted substances in an effort to promote European economic competitiveness as well as protect human and environmental health.

More fundamentally, REACH shifts the regulatory burden from governmental authority to industry self-enforcement. EU governmental involvement is now focused on clarifying the regulation's provisions through guidance documents and generally ensuring industry compliance with REACH's basic elements; registration, evaluation, and authorization.

- Registration of a substance places the burden on manufacturers (exporters and importers) to obtain relevant data and to use that data to

manage the use of the substance safely. So called "downstream users" are also brought in to the system and often share the burden of managing hazards and risks—part of which is the sharing of data whenever vertebrate testing is required.

- Evaluation of a substance is conducted by the European Chemicals Agency (ECHA) to ensure compliance with testing proposals and registration requirements, such as demonstrating that the risks of the chemical are outweighed by the benefits or are somehow controlled and that there is no other suitable, less dangerous alternative.
- Authorization of a chemical includes publishing the substance on an ECHA-approved list that notes any restrictions on its use in the EU, the substance's designation on a classification and labeling inventory, and its placement on a publicly-available online platform that provides information on any given authorized substance while also attempting to protect intellectual property related to the substance.

The "reach," if you will, of REACH is breathtaking. It includes all substances, whether manufactured, imported or used as intermediates or placed directly on the market, either on their own, or in preparations or articles. Substances are only exempted if they are specifically listed as exempt, such as: radioactive substances, waste, food, or items covered by another equivalent legislation (such as customs or defense programs of member states). The bottom threshold for registration of these substances described above is manufacture or importation of one or more ton per year with a sliding scale of registration requirements increasing from 1-10 tons, 10-100 tons, and 100 tons or more per year.

The European Commission hopes to ensure a smooth changeover as implementation proceeds. To this end, several REACH Implementation Projects (RIP's) were planned; the first two of these RIP's have been completed (on overall process and the role of IT) and can be found at http://ecb.jrc.it/reach/rip. The smoothness of this changeover for downstream users and chemical manufacturers and suppliers is, however, highly dependent on the degree to which they can prepare for the new regulatory regime with sound guidance.

Editor's Note and Update

At a Nov. 9, 2007 meeting of the World Trade Organization's (WTO's) Committee on Technical Barriers to Trade (TBT), at least nine nations, including Canada and the United States, asserted that the REACH law, which took effect June 1, 2007, violates the WTO's TBT agreement. The European Commission had already defended the WTO aspects of its proposal in a detailed paper. See Response from the European Communities to Comments Submitted by WTO members under G/TBT/N/EEC/52, REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS, REACH – COM((2003) 644 FINAL *(Oct. 28, 2004) available at http://ec.europa.eu/enterprise/reach/docs/reach/eu_wto_response_041028.pdf; see also Alice Palmer,* REACH and Proportionality under WTO Rules, FIELD report for WWF UK*, available at http://www.wwf.org.uk/filelibrary/pdfreach_prop_0604.pdf. As the impacts of this regulation are being felt, however, the WTO may be asked to rule on the legal issues raised by REACH.*

In the United States, the American National Standards Institute (ANSI) and the National Association of Manufacturers have initiated a multi-stakeholder "Network on Chemical Regulation" that recognizes the broad impact that substitution of commonly used industrial chemicals could have on product safety and sustainability.

Biofuel E-Forum

The executive secretary of the Convention on Biological Diversity (CBD) launched an electronic forum last year to gather information on emerging biofuel issues.

Of all the topics commented on in the electronic forum, three stood out as the most recurrent: first, the types of biomass used for liquid biofuel production; second, the

positive and negative impacts of biofuel production; and third, recommendations on how to promote the advantages and reduce the disadvantages of biofuel production and use.

The following is a summary of the observations posted on the forum.

Types of Biomass Used for Liquid Biofuel Production

Liquid biofuel is manufactured from different types of biomass and can be of two main variants: bioethanol and biodiesel. Currently, Brazil and the United States lead in bioethanol production, while the EU leads in biodiesel production.

Sugar cane is the biomass of choice for Brazil's production of bioethanol and has the distinct advantage of reducing greenhouse gas (GHG) emissions in the country. This is not a perfect solution, however, given the concerns over erosion and water use.

Sugar beet ethanol and wheat-based ethanol are quite popular in Europe. The United Kingdom's wheat yields are some of the highest in the world.

Soy and palm oil remain popular sources for biodiesel production despite the deforestation required to harvest the necessary amount of oil. Deforestation, which mainly contributes to climatic change, is a concern particularly in South America, Indonesia, and Malaysia.

An increasingly popular biofuel alternative is cellulosic ethanol. Cellulosic ethanol is essentially waste, and its production entails neither land use nor conversion of standard crops. In 2006, Aquaflow Bionomic Corporation, located in New Zealand, produced the world's first biodiesel derived from wild micro-algae originating from local sewage ponds.

Regardless of the type of biomass used, biofuel production is responsible for numerous positive and negative impacts.

Positive Impacts of Biofuel Production

Biofuels present both environmental and economic advantages. GHG emissions are reduced significantly with the use of liquid biofuels as compared to traditional fossil fuels. Economically, the production of liquid biofuels helps alleviate poverty since biofuel production is often a local endeavor. Local production results in the creation of local jobs and business opportunities as well as the reduction of local energy costs. This benefits developing countries tremendously.

Negative Impacts of Biofuel Production

Biofuel production also presents environmental and economic disadvantages. Large-scale biofuel production threatens biological diversity and causes depopulation of rural areas by compelling deforestation, which in turn threatens natural habitats. In Indonesia, for example, palm oil-based biofuel production has caused deforestation and land and water pollution significant enough to have destroyed natural habitats, and further endangered tigers and other local species.

Biofuel production is also resource intensive. Extensive quantities of water are often required, which reduces the supply available to local populations for household and commercial use. Similarly, where local food sources are the preferred biomass, food prices increase as the crops that used to be harvested for food are now harvested to produce biofuels.

Furthermore, pesticides are used on biomass crops such as corn to ensure quality, despite the potential of such practices to exacerbate environmental effects.

These issues were explored and further developed at the 12th meeting of the CBD's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), in Paris, July 2-6, 2007. In particular, the SBSTTA made a submission regarding biodiversity and biofuel production entitled Recommendation XII/7. This document requested that the CBD executive secretary, *inter alia*, (a) assist in compiling and synthesizing information on the impact of biofuel production on biodiversity; and (b) urge the CBD

Conference of the Parties to note several of the issues raised. These issues included: (i) the wide range of systems and conditions that exist under which biofuels are produced, including different feedstocks, production schemes, and management practices used; (ii) the fact that biofuel production and use can have both beneficial and adverse effects on biodiversity and human well-being; (iii) the identification of gaps in our knowledge associated with the impact of biofuel production and use on biodiversity; and (iv) whether these gaps can be addressed by compiling additional information and promoting research on biofuel impacts, as well as through international cooperation and technology transfer.

Recommendations

Additional research needs to be done before biofuels become both sustainable as well as viable alternatives to current fossil fuel reserves. In order to accomplish this, solutions to the impacts of biofuel production on biodiversity loss must be found and the impacts on food and water resources must be minimized. Cellulosic ethanol is a promising alternative in that it limits deforestation and minimizes the impact on resources critical to developing countries; however, cellulosic ethanol is still technologically-intensive and, as a consequence, not accessible to a large portion of the world's population.

World Wetlands Day

Wetlands are one of the world's most productive environments as innumerable species of animals and plants depend on them for survival. Feb. 2 of each year is World Wetlands Day, marking the anniversary of the signing of the Convention on Wetlands on Feb. 2, 1971 in Ramsar, Iran. The Wetlands Convention provides for both national action and international cooperation in wetlands protection and management. For the last decade, many government agencies, NGOs, and citizen groups have used this day to raise public awareness of the necessity to protect local wetlands.

The theme of the 2007 World Wetlands Day was: "Fish for Tomorrow?" The purpose of this theme was to call attention to the over-fishing of many species to their biological limits. Fish and other water species are not the only victims of such practices; the many people who rely on fish as their main source of protein and cultures that thrive on fishing are also impacted. Indeed, as over-fishing continues unchecked, future biological diversity itself is threatened.

On Feb. 2, 2007, the most recent Wetlands Day, a number of international and national organizations around the world highlighted the necessity for wetland conservation by undertaking various activities. Local events were held with the intent of informing the public about the dangers of land and water pollution, as well as encouraging action to preserve local wetland resources. More information on World Wetlands Day 2007 can be found at: http://www.ramsar.org/wwd/7/wwd2007_reports.htm.

The Convention's theme for World Wetlands Day 2008 is "Healthy Wetlands, Healthy People." This will also be the theme for Ramsar's 10th meeting of the Conference of the Parties in October-November 2008 in the Republic of Korea. The theme aims to emphasize the strong relationship between functioning wetland ecosystems and human health. Several of the chosen subtopics will include the importance of healthy wetlands to: (a) food production (*e.g.*, fish and plants), (b) clean water (*e.g.*, purification of freshwater), (c) water pollution (*e.g.*, serving as filters for pathogens), (d) mental well-being, and (e) flood protection.

Tim R. Pomeroy *is an associate in Klinedinst, P.C.'s San Diego, California office.* **Emilie Leibovitch** *practices international law in Belgium.*

THE NEGOTIATION OF RULES FOR LIABILITY AND REDRESS RELATED TO THE INTERNATIONAL SHIPMENT AND USE OF LIVING MODIFIED ORGANISMS UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Tim R. Pomeroy

In May 2008, the fourth meeting of the parties to the Cartagena Protocol on Biosafety (Protocol) will convene in Bonn, Germany. One of the purposes of this fourth meeting is to consider a working draft of options regarding liability and redress from damage caused by the international shipment of living modified organisms (LMOs). Put more simply, the international shipment of genetically modified products (*e.g.*, grains, seeds) may soon become more complicated. This article provides an overview of some of the issues debated in two recent meetings of the Protocol's Open-Ended *Ad Hoc* Working Group on Liability and Redress in the Context of the Cartagena Protocol on Biosafety (Technical Expert Group, or "TEG").

I. Introduction

The parties to the United Nations Convention on Biological Diversity adopted the Protocol on Jan. 29, 2000 in an effort to ensure the safe transfer, handling and use of LMOs. Entering into force on Sept. 11, 2003 with its fiftieth signature, the Protocol focuses specifically on LMOs that may have an adverse effect on biodiversity, also taking into account human health. This does not include food products that contain no viable organism (grain-exporting states, including many non-parties like the United States and Canada, influenced the proceedings and blocked the effort by the European Union (EU) and other "like-minded" nations to include the "products thereof"). As part of the package negotiated, Article 27 of the Protocol, subtitled "liability and redress," directs the parties to adopt a process for elaborating international rules and procedure in the field of liability and redress.

Given the increasing frequency of shipments and use of genetically modified commodity crops around the world, addressing the issue of liability requires a breadth of experience from an array of people representing all 142 parties to the Protocol. For instance, what exactly constitutes "damage" in this context? What would the rules regarding duty, breach, and causation of the damage be? And what evidentiary rules would one employ to support or challenge any of the preceding legal determinations? To this end, a working group of legal and technical experts, the TEG, was established to answer these questions.

The third TEG meeting under Article 27 of the Protocol was held from Feb.19-23, 2007, in Montreal, Canada, and a fourth meeting was held in October 2007 (summarized above in the International Agriculture-Environmental Regulatory Update). A fifth session is planned for March 2008 in Bogota, Colombia. Nearly 200 participants attended the February and October 2007 meetings, representing governments, non-governmental organizations (NGOs), industry and academia.

The TEG operates with a simple three-part mandate: (a) review policy options for liability and redress for damage from the trans-boundary movement of LMOs; (b) evaluate issues relating to potential and/or actual damage scenarios; and (c) debate options for rules, elements, and procedures for redress. Participants fulfill the first two parts of this broad mandate at the beginning of each session by attending a series of expert presentations reviewing various issues related to the trans-boundary movement of LMOs. At the February 2007 session, delegates heard presentations on possible techniques for the valuation of biodiversity, insurance, and financial security, as well as international private law options for dispute resolution. Delegates then used this information in subsequent discussions related to the third part of their mandate, establishing options for rules, elements, and procedures related to liability and redress.

The TEG completed a working draft of options and elements at this meeting, which meeting co-chair Rene Lefeber called the "blueprint" (contained at Appendix I to the meeting's report). This working draft of textual options was synthesized by the co-chairs of the working group from the texts submitted by the major

stakeholders. The blueprint was the focal point of deliberations at the October 2007 meeting (TEG IV report available at http://www.cbd.int/doc/meetings/bs/bswglr-04/official/bswglr-04-03-en.pdf) and will also be the focus of the remaining meeting of the working group. Needless to say, only a portion of the eleven chapters in the blueprint can be mentioned here. Accordingly, this article shall discuss the following issues: standing, various legal standards of liability, factors affecting exemption and/or mitigation ,and choice of instrument/jurisdiction.

II. Standing/Right to Bring Claims

Deliberations on standing and the right to bring a claim focused on two disputed fronts. The first issue considered the definition of an "interested party" vis-**B**-vis different types of damage. For example, TEG members considered whether NGOs should have standing to sue and seek remediation of natural resource damages. The second issue was the role of various member governments concerning damage to the environment, specifically, and biodiversity more generally. The chairs of the third TEG meeting made it clear that the difficult question of defining "damage" must be resolved for the law in this area to have meaning once it is final and enters into the ratification and implementation phase. In this respect the TEG may be seeking to avoid the fate of other international liability protocols, such as the Basel Convention's ill-fated protocol on liability, which has not entered into force due to disinterest on the part of Basel Convention parties.

The United States, for its part, emphasized that from a legal perspective Article 27 of the Protocol applies only to trade between parties to the Protocol. Canada, on the other hand, pointed out that some options, such as the choice of instrument, may attract the interest of non-parties in applying the regime in their own nation, thereby providing greater coverage. Norway and Ethiopia stressed that the scope of the regime should not be limited to Protocol parties only. The EU, meanwhile, indicated that because its domestic law will be implemented regardless of whether trade is with parties or non-parties, there is no need for separate rules for non-parties. Indeed, in a recent court filing in Arkansas, a European rice importer attached the EU's Traceability Directive to a complaint alleging wrongful shipment of biotech rice to the EU, triggering a food recall for that unapproved-in-the EU variety. This EU Directive, number 1829-2003, requires growers, grain shippers, and other handlers of export commodity crops to maintain records for five years in the event a recall of an unapproved biotech crop (and the tracing back of liability to those responsible) is one day required. Some nations would like Article 27 to operate as a strict liability recall-and-remediation law for any straying biotech crop shipped to a location that does not approve of it.

Not surprisingly, compensation proved to be an important factor, as was suggested by Greenpeace International. As the filing of an action against a growers' cooperative in the United States illustrates, Protocol non-parties may nonetheless be affected by some provisions of the Protocol. One example would be the requirement that a bond be posted as a condition of export, or the applicability of an industry-funded compensation fund to defray the costs of recalls and remediation arising in trade between non-parties and parties who enact traceability and liability directives under Article 27.

Indeed, presentations at the outset of the session asserted, incorrectly, that commercial insurance does not currently cover most risks associated with LMOs. Developing nations present at the discussions immediately used this information to call for the inclusion of supplementary subsidiary financial mechanisms to provide coverage in the event of damage. In actuality, wherever biotech crops are grown in sufficient quantity under non-discriminatory liability law (United States, Canada, etc.), there is standard insurance available that covers the growers of biotech crops.

Nonetheless, some major steps have been taken in negotiations to date. In the final synthesis, the co-chairs noted that the delegates considered a variety of factors related to the threshold decision of who has the right to bring a claim:

1. The level of regulation in place for an LMO involved in the given fact pattern;
2. The distinction between inter-state and intra-state civil procedures;

3. The level of involvement by the parties in the trans-boundary movement of the particular LMO; and
4. The type of damage (traditional, cost of response measures, damage to environment/ biodiversity, damage to human health, and socioeconomic damage, etc.).

III. The Identification of the Liable Person and the Standard of Liability

Debate in this area centered on two main issues: first, the preferability of civil or an administrative regime, with and without state liability; and, second, whether the standard for liability should be strict- or fault-based, and the impact of each option on innovation and continued research and development.

As to the identification of the liable person, the EU called for a civil liability regime that would focus on producers and importers and would include exemptions and defenses. China preferred that there be no state liability and called for an operator-based liability regime. A group of academic scientists, the Public Research and Regulation Initiative (PRRI) suggested administrative procedures would be the best approach regarding damage to biodiversity and restoration, and highlighted immediate applicability and access to justice as the key advantages.

As to the standard of liability, Norway called for a strict standard of liability governing the acts of those responsible for the transboundary movement. Japan, however, expressed support for fault-based liability. The Global Industry Coalition went further in suggesting that only a fault-based liability system would be consistent with the continuing innovation and use of biotech crops, since these crops are not inherently dangerous and pose no devastating threat in transport (in contrast with oil transport). PRRI further suggested that with risk assessments and regulatory reviews already in place through the Protocol, there is no need for strict liability, and that indeed the imposition of strict liability would chill continued innovation.

The delegates considered five factors in this regard:
1. Type of damage;
2. Location where the damage occurred;
3. The degree of risk involved in a specific type of LMO;
4. Any unexpected adverse effects; and
5. Operational control of LMOs in place at the time of the injury.

IV. Exemptions and Mitigation

Any attempt to identify a liable person, much less to impose liability under some enforcement regime, raises the issues of exemptions to liability and factors that would mitigate liability. The TEG was no exception. Delegates considered a series of exemptions for liability and mitigating factors that might function well within the context of a trans-boundary LMO incident:
1. Act of God/*force majeure*;
2. Act of war or civil unrest;
3. Intervention of third parties;
4. Compliance with compulsory measures imposed by a competent national authority;
5. Permission of an activity by means of applicable law; and
6. The "state of the art" defense.

Several countries called for more consideration of some of these exemptions. Ecuador, for example, suggested completing the definition of damage *before* addressing possible exemptions and recognition and enforcement of judgments or arbitral awards.

V. Jurisdiction/Choice of Instrument

A threshold question in any LMO-based cause of action would be jurisdiction. Even assuming a party has standing, and the existence of evidence that would allow for prosecution under the given standard of liability against an identifiable person, a putative plaintiff would still need to establish jurisdiction before liability could attach. Jurisdiction, however, implies a decision as to choice of instrument, *i.e.*, whether the legal instrument used to implement the elements of liability discussed above would be binding, or simply participatory. No decision has been made on this important part of the regime.

The delegates did consider a private law solution, presented at the beginning of the meeting, which focused on the following aspects of jurisdiction:

location, choice of law, and enforceability of judgments. Using this approach, a putative plaintiff would be able to sue, based on the Protocol, in one of the following places: (a) the state of domicile of the defendant, (b) the state where the injury occurred, or (c) the state where an injury first arose. After choosing the location for the action, the injured party could choose from the following bodies of law: (a) the law of the "polluter's" domicile, or (b) the law of the place of damage.

VI. Conclusion

While there was no clear consensus, some trends were identifiable. It appeared the primary focus for liability would likely be "operators" (manufacturers and exporters), though some residual state liability would almost certainly attach. Preferences concerning the regime of choice, meanwhile, have tended to depend on the basis of damage caused by the LMO: when damage to biodiversity is considered, an administrative approach appears preferable. On the other hand, consideration of more "traditional" damage, *e.g.*, bodily or physical injury to property, seemed to favor civil liability rules.

The various options and approaches were reduced to a textual working draft, with an accompanying matrix of options to be considered at the October meeting. The working group is due to finalize a text to submit for consideration at the fourth meeting of the CBD parties in May 2008.

For further information, please see: http://www.cbd.int/biosafety/default.shtml.

Tim R. Pomeroy *is an associate in Klinedinst, P.C.'s San Diego, California office.*

BIOFUELS AND CLIMATE CHANGE—STATE OF INTERNATIONAL REGULATION AND TRADE

Jane Earley

There are many assumptions and claims about biofuels and climate change but fewer agreed facts than one might think. Even as this policy debate progresses, crops are being planted to meet ambitious biofuels mandates and a regulatory framework is growing rapidly around present policy structures and planned energy uses.

Biofuels for transport use are thought to be an innovative response to energy needs in the face of climate change, as well as a way to empower rural populations. It is hoped that biofuels, among all the renewables, might more sustainably reduce carbon emissions over the long term than other alternatives. But critics argue that biofuels compete with food for land, cause massive land use change in the face of increased food demand, and raise food prices. Some also argue that biofuels make a net contribution to carbon loss rather than carbon sequestration.

Biofuels regulators have been busy. Research and development is underway. Standards are under construction. Trade effects and barriers are being assessed. State and local mandates are accompanying federal mandates and procurement directives are proliferating. On the environmental front, pressure is growing to measure the contribution of biofuels to climate change in terms of their life cycles—these would include production-related carbon emission values. Efforts are also underway to generate sustainability standards. Finally, carbon credits for agricultural production will add another overlay to the already complex biofuels regulatory picture.

Biofuels and Climate Change 101. Producing the crops currently used for the bulk of biofuels production has implications for climate change that do not significantly differ from those of other crops, but the sheer scale of the land use change required to meet current and contemplated biofuels mandates deserves some consideration. So do a few of the attributes of

the crops themselves. For biodiesel, agricultural crops currently used for the bulk of current production include soybeans, rapeseed or canola, oil palm, sunflowers, and jatropha, a form of castor bean. In some areas, rendered animal fat and recycled cooking oils are also feedstocks. Ethanol is currently being made from corn and sugar cane at scale, the former in the United States and the latter in Brazil, but is also being made from wheat, barley, sugar beets, sweet sorghum, and tree crops. The latter are also important feedstocks for electricity production.

"Second-generation" technology will use more crop residues (cellulosic) and other feedstocks (algae, switchgrass, and other non-food plants). Although cynics observe that these technologies are always "around the corner," ever-receding as ambitious mandates and present investment opportunities outpace implementation, the new investment in new technologies will eventually become cost competitive. Exclusive reliance on food crops for fuel use cannot therefore be assumed to continue indefinitely.

In the meantime, the potential climate change impacts of increased production of biofuels using current technology include both carbon loss associated with deforestation, and carbon loss accompanying large-scale agricultural development. Another negative environmental factor of biofuels involves water use, since water scarcity in many of the producing regions is expected to increase due to climate change, and the ethanol refining process is also water-intensive.

Deforestation from large-scale production of certain biofuel feedstocks is an environmental impact that must be managed. For example, palm oil development has cut large swathes into native forest in Borneo and in other countries, such as Honduras, but logging is often the first forest despoiler with palm oil development following logging onto already "degraded" land. Similarly, impacts may arise from sugarcane planting in Brazil. This is disputed, with some studies indicating that there is unlikely to be any real effect on protected areas (such as the Amazon) and others alleging a very large potential indirect effect as sugar cane production in Sao Paulo province pushes out soy, plantings of which then push cattle further into forested areas.

The environmental effects of biofuel production using present technologies are similar to the environmental effects of any large-scale agricultural development. Some of these environmental impacts could be more difficult to manage given the anticipated effects of climate change. Many crops cannot be produced today at the expected level of productivity without degradation of soil resources (soil loss), erosion, chemical overuse, water overuse and pollution, loss of biodiversity and unnecessary loss of soil carbon due to tilling methods. In particular, the climate change implications are complex—and could provide payments or "credits" for some growers—so these merit particular investigation.

Most studies of soil degradation, including soil loss and general soil depletion due to loss of organic content, have concluded that it is a genuine threat worldwide. The most significant impacts will be on agricultural production near densely-populated marginal lands, rainfed lands, and high-quality irrigated lands. Although there is no consensus that soil depletion alone poses a serious threat to food security, there is agreement that soil degradation is exacerbated by global warming, as organic materials will decompose more rapidly at higher temperatures and release more carbon into the atmosphere.

Conservation tillage does not expose soil to wind erosion and carbon loss from gas emissions and repeated plowing, and these no-till methods can be used extensively with biotech crops to prevent carbon loss. Soybeans and corn are one common crop rotation in the United States that is well-suited to "conservation tillage" methods. However, successive plantings of "corn-on-corn" replacing corn-soy rotations will require extensive fertilization and may lead to increased run-off of nitrogen-containing fertilizers. When the fertilizer is made from petrochemicals, the high cost of energy (and climate gases associated with it) create another environmental impact to consider.

Water use is another environmental impact to manage in biofuel production scenarios. Large scale agriculture is already a large water user. Agriculture is generally thought to use at least 70 percent of the water used on

the planet. Many food crops currently used as biofuel feedstocks are intensive water users. Sugar cane is a particularly thirsty crop that must be irrigated in many of the places where it is planted. Corn's water requirements are also relatively high compared to crops suggested for use in cellulosic production, like switchgrass. Among the effects attributed to climate change by the Intergovernmental Panel on Climate Change (IPCC) is water scarcity, particularly in tropical regions where efficient biofuel production is expected to increasingly be located, given various efficiencies found in certain locations.

While large-scale agricultural production does not contribute to a loss of biodiversity *per se*, its displacement of natural systems along with accompanying use of monocultures, chemical use, and often use (and misuse) of marginal land, can have significant impacts on biodiversity. Agricultural runoff is also a significant contributor to water pollution and loss of marine diversity in places like the "dead" zone in the Gulf of Mexico. A switch to cellulosic crops for ethanol production would presumably take some of the pressure off some of the food crops, but there is no guarantee that these would be more sustainable in the long run. The life-cycle carbon attributes of each crop in the place where it is grown, together with its production and use, need to be assessed in order to determine its relative costs and benefits in a climate change context.

In the United States, land use change, water use, and infrastructure demands due to increased ethanol use in vehicles will all present significant environmental management challenges. Corn production is increasingly replacing soy, cotton, and other crops on U.S. farmland, with an increase of 19 percent in its 2007 acreage over the 2006 season. The National Corn Growers Association (NCGA) at www.ncga.com, reported a projection of 89.7 million acres planted to corn by the 2012-2013 crop year, an increase of about 9 percent from 2005-2006, but the U.S. Department of Agriculture reports that U.S. farmers already planted 92.9 million acres of corn in 2007. Some of this acreage has come out of the Conservation Reserve Program, which provides an incentive for farmers to set aside marginal land for conservation.

Corn's water requirements increase where it must be irrigated. An Institute for Agriculture and Trade Policy (www.iatp.org) study estimated that irrigated corn grown in southwest Nebraska used about 1,568 gallons of water to produce one gallon of ethanol. Refining that corn into ethanol uses about 3 gallons of water to produce one gallon of ethanol. Water use efficiency in ethanol refining is improving, but it can still be a significant user of water at a local level.

Biofuel Production and Trade. Given current and anticipated mandates for use of renewables, of which biofuels are most likely a significant part, large-scale planting of agricultural crops to fulfill these mandates is already taking place in the United States and other countries. Almost every country in the world has a bioenergy mandate. Many of them will need to fuel the mandate with imports. Importers include the United States, the EU, Japan, and China. Exporters will include Brazil, Indonesia, other Latin states, and many African ones.

The rapid growth of ethanol production in the United States was partly a response to the end of the use of MBTE as a gasoline additive, but also a response to the perceived need for energy security. However, the United States will need to import ethanol if ambitious mandates are to be met. The Energy Policy Act of 2005 (2005 Act) set a consumption mandate of 7.5 billion gallons of renewable fuel by 2012, but the expectations of the 2005 Act have already been exceeded. The Renewable Fuels Association (RFA) (www.ethanolrfa.org), reported that U.S. demand in 2006 amounted to 5,377 million gallons**,** necessitating imports of 653 million gallons, mostly from Brazil, Central America, and the Caribbean. The U.S. ethanol industry is likely to oversupply the domestic market this year; while demand is expected to hit 6.7 billion gallons, production could exceed 8 billion gallons. Production in 2008 is projected at 11 billion gallons.

But a new mandate of 36 billion gallons by 2022, currently attached to the House version of the Farm Bill, almost a five-fold increase over the 2012 target, would use more than the entire U.S. corn crop. Producers hope that it will also raise currently low ethanol prices, which are currently benefiting blenders. RFA reported that at the end of 2006, seventy-three

biorefineries were under construction and eight expanding that would add 6 billion gallons of new production capacity by 2009. Refinery capacity is predominantly located in the corn belt, but facilities are also being built in Arizona, Oregon, Texas, and New York. Twenty-six states now host such facilities. *[Editors note: President Bush recently signed a comprehensive energy bill, subsequent to the writing of this article, which contained new mandates and incentives for ethanol and other biofuels]*.

In addition to building refinery capacity, the United States will also need to retrofit a lot of infrastructure to use substantial percentages of ethanol domestically. Ethanol is too corrosive to flow through pipelines currently dedicated to oil, or be stored in underground tanks designed for petroleum. A lack of assets dedicated to ethanol blending creates the "blend wall" to ethanol use, as rail lines to refineries and dedicated tankers and pipelines are off-limits to ethanol. These barriers to entry could limit demand in the near future.

Changes to state blending specifications for fuels will help ease the situation to some extent by allowing discretionary blending, but industry experts expect continued consolidation among producers, more oil company penetration of the ethanol market, and increased scale and marketing of ethanol in regional markets. There will also be increased development of the relatively small U.S. biodiesel market, which is limited by consumers' choices of vehicles. The European Union (EU) has a much larger percentage of biodiesel vehicles in use, making its usage of biodiesel a major policy issue.

EU mandate. Like the United States, the EU is also engaged in debate on how to craft an ambitious biofuels mandate, imposed in part to satisfy greenhouse gas(GHG) emission reductions, but primarily using biodiesel rather than ethanol. A 2003 EU Directive called for 7.5 percent bioenergy in fuel by 2010. A more recent directive by EU energy ministers approved a binding biofuels mandate of 10 percent in transport fuels by 2020, with at least 20 percent of energy used in the EU to come from renewable sources by 2020, and EU emissions reduced to 20 percent below 1990 levels by 2020. This is in part conditional on sourcing sustainable biofuels. Consequently, new fuel standards, which require suppliers to reduce GHG emissions per unit of energy by 1 percent a year from 2010 levels, will require life-cycle analysis of biofuels to determine if they actually provide a benefit in reducing GHG.

The EU is under particular pressure to source sustainable biofuels because it will continue to rely on imports. Although Germany is at present the world's largest biodiesel producer, rapeseed production alone will not be able to supply all of the biofuels demand, and German biodiesel producers at present find it cheaper to import B99 and to export rapeseed oil than to supply the domestic biofuels market. The European Commission estimates that implementing the 10 percent by 2020 mandate would consume production from 15 percent of the utilized agricultural area, but that 30 percent of biofuel production would be from second generation biofuel and 20 percent of the supply would be imported. Biodiesel production capacity has already increased by an estimated 35 percent since 2002, reaching close to 2.2 million tons a year.

Elsewhere, palm oil is the transport fuel feedstock of choice for first generation technology. However, palm oil is generally blamed for massive deforestation and species extinction in Borneo. (*Newsweek* magazine recently reported that global production went from 4.5 million tons in 1980 to 20.9 million tons in 2000, and is expected to rise to 30.4 million by 2010.) European firms are under pressure not to let market forces destroy the same forests that European consumers are trying to save with reduced emissions.

To meet these concerns, several EU Member States are engaged in generating sustainable production standards for imported biofuels. These include the Netherlands, which has called for sustainable import conditionality (a multi-stakeholder process named the "Cramer" process has been drafting such standards), the United Kingdom, whose Low Carbon Vehicle Partnership has been developing standards for the purpose of voluntary reporting, and Germany, which has been discussing mandatory sustainability criteria.

These efforts have recently been overshadowed by a multi-stakeholder process called the "Roundtable on Sustainable Biofuels" (RSB), at www.bioenergy wiki.net, led by the Swiss École Polytechnique Fédérale de Lausanne, which is expected to produce standards in the Spring of 2008. The roundtable will build on the work already done by other processes aimed at sustainable commodity production, like the Roundtable on Sustainable Palm Oil (www.rspo.org), the Roundtable on Responsible Soy (www.responsiblesoy.org), and the Better Sugarcane Initiative (www.bettersugarcane.org).

Other work on criteria for sustainable biofuels includes the Global Bioenergy Partnership, launched in 2006 by the G8, and an international working group under the Bioenergy Agreement of the International Energy Agency, (IEA) Task 40. This group is focused on certification, standardization, and terminology in an international trade context. While these standards will be primarily aimed at the production effects (both social and environmental) of the specific commodities involved as biofuel feedstocks, they will also necessarily involve carbon lifecycle accounting. This would assign carbon values to each stage of a feedstock's production, processing, and use. While carbon values are somewhat of a proxy for sustainability, they are also essential to implement climate change commitments (and to combat critics of biofuels who charge that biofuels production and use in Europe has caused a net increase in GHG). Carbon accounting is also essential for carbon trading and for offset payments to producers, including agricultural ones.

So far, work on lifecycle carbon valuation for different biofuels feedstocks indicates that their carbon values diverge as much as their energy yields, but there is little consensus on the extent to which these differ from place to place or agreement on the actual values derived. A 2006 study concluded (for the United States) that ethanol yields 25 percent more energy than the energy invested in its production, whereas biodiesel yields 93 percent more. Compared with ethanol, biodiesel releases less nitrogen, phosphorus, and pesticide pollutants to yield energy. Relative to the fossil fuels they displace, GHG emissions are reduced 12 percent with ethanol and 41 percent with biodiesel. Hill et al, PNAS 2006 103: 11206-11210 at http://www.pnas.org/cgi/collection/ss_highlights?ck=nck.

Whether these values will become the basis for policy and investment decisions in the United States remains unclear. The United States is getting closer to federally mandated emissions reductions, a federally enabled cap and trade system, and government-awarded offsets for carbon sequestration, but it could be some time before these become effective. The elements have been considered at state levels, however, and some forms of these standards may follow for large carbon emitters. So far in 2007, energy legislation has fallen short of requiring life cycle assessment of biofuels, but some groundwork has been done by U.S. agencies. In the meantime, the Chicago Climate Exchange, a private-sector trading mechanism, is awarding payments for carbon offsets to agricultural producers who use no-till production methods.

Finally, regardless of how efficiently biofuels might reduce carbon emissions, production of first-generation feedstocks will be tainted by their effect of forcing up food prices. There is no question at present that high prices for energy have led to high prices for food products using corn and other crops, which has forced U.S. producers of various foodstuffs to raise their prices. Producers of pork and poultry have complained about paying high prices for corn. Food processors dependent on low-cost supplies of high fructose corn sugar (HFCS) are also recoiling at high corn prices and increased demand for HFCS in other markets. Reduced supplies of soy have increased soy prices. In Europe, food processors have been faced with reduced supplies of canola oil and increased demand for palm oil at the same time that U.S. soy oil, disfavored because of genetically modified (GM) labeling requirements, is also in short supply.

There is also some evidence that biofuel production is reshaping the global food security outlook. Humanitarian groups have found that since the price of white maize has jumped 186 percent over the past two years in sub-Saharan Africa they have had to look elsewhere for supplies to feed the poor. According to

World Bank price indexes, worldwide basic food commodities now cost 21 percent more than in 2005 and important commodities such as grain and vegetable oil have gone up in price more than 30 percent. Many have observed that with developing countries being both the largest recipients of food aid and increasingly the most important source of biofuels, it is likely that the greatest impacts of the biofuel industry and its resulting economic and environmental effects will be experienced in these regions. Added to the environmental effects of climate change in the same countries, this will make for some very challenging policy and regulatory choices.

Jane Earley *is a principal at Earley & White Consulting Group, LLC.*

DEAD ZONES AND HARMFUL ALGAL BLOOMS

Brett Grosko

I. Introduction

This article discusses hypoxic or "dead" zones as well as harmful algal blooms (HABs) (sometimes referred to as "red tides"), which occur in coastal zones worldwide and constitute pressing issues for coastal managers. It briefly describes the nature of the challenges presented, and then discusses several policies employed to confront them in the United States and Denmark. These examples illustrate the scientific complexity of the issues and the many-pronged approaches necessary to tackle them.

II. Background

This section discusses hypoxia, then HABs, and finally touches on possible connections between hypoxia and HAB events with climate change.

A. Hypoxia

Hypoxia occurs when the dissolved oxygen concentration in a body of water falls below 2 milligrams per liter. It can occur naturally, but often results from stress caused by excess nutrient enrichment from point and non-point source pollution. Over 50 percent of U.S. estuaries now experience natural or human-induced hypoxia for some period annually. The frequency and duration of hypoxic events, moreover, appear to have increased over the last several decades.

In the United States, perhaps the most well-publicized hypoxic area occurs each year from early spring through late summer in the Gulf of Mexico. This area, often called the Gulf of Mexico dead zone, is the largest hypoxic area in the United States, often extending from the mouth of the Mississippi River to the coast of Texas.

The main cause of the Gulf of Mexico dead zone is agricultural nutrient input carried south by the Missouri and Mississippi rivers, which have watersheds draining over 40 percent of the continental U.S. landmass. The U.S. Geological Survey has noted that approximately 89 percent of the annual total nitrogen flux to the gulf comes from non-point sources, whereas the remaining 11 percent stems from municipal and industrial point sources.

This discharge of nutrients in turn supports an overabundance of algal growth. When these algae die, they sink. Bacteria then decompose them, exhausting the oxygen available in the water column. Meanwhile, fresh water continues to flow in from the river. The input of freshwater, coupled with the warming of surface waters, prevents deep mixing. This "caps" the heavier, saltier, and oxygen-deprived water below. Animals in the resulting temporary low-oxygen layer must flee or perish.

Louisiana scientists recently announced the size of the zone this year was the third-largest on record since measurements began in 1985. It extended 7,900 square miles, an area about the size of New Jersey—more than one and a half times the average measured since 1990. Based on nutrient input studies earlier this year, it is thought only stormy conditions in July and a tropical low pressure disturbance prevented the zone from extending an additional 600 square miles, which would have been its largest size ever.

Dead zones have also been observed elsewhere. For example, high nutrient levels are thought to be the cause of the Chesapeake Bay dead zone, which encompasses about 41 percent of the bay's area—about 250 square miles. Low-oxygen zones also occur off of Oregon, Namibia, and Chile, although in these locales they appear to result from an ocean-mixing condition called upwelling. Upwelling brings low-oxygen and nitrogen-rich waters from deep in the ocean to shore.

Internationally, dead zones occur worldwide and seem to be increasing in number. In 2006 the United Nations. reported scientists had found about 200 hypoxic zones in the world's oceans, up 34 percent from just two years before. The report stated the number of dead zones has grown each decade since the 1970s, and projected by 2030 anthropogenic nitrogen flowing into seas and oceans will increase by 14 percent over 1990 levels. If this trajectory is followed, hypoxic conditions around the world can be expected to further increase in frequency and magnitude.

B. Harmful Algal Blooms

Another coastal zone problem related to algal growth and excess nutrients is HABs. HABs can take on a red or brown hue (hence the name "red tides"), or be colorless. While they do occur naturally, and have done so for millennia, it is thought humans are contributing to their increasing frequency. As Congress has noted, "the factors causing or contributing to [HABs] may include excessive nutrients in coastal waters, other forms of pollution, the transfer of harmful species through ship ballast water, and ocean currents."

HABs occur when certain species of algae, single-celled plants at the bottom of the food chain, bloom as the result of high concentrations of the nutrients they need to grow. Some species of algae that bloom produce potent neurotoxins that can be transferred to and concentrated in food webs, for example, through bivalves (clams, oysters, etc.). Once ingested, they can affect and even kill higher life forms, including shellfish, fish, birds, and marine mammals. When humans consume some types of affected shellfish in large quantities, they can suffer paralysis, breathing difficulty, and death. HABs can also cause economic injury by forcing swimming grounds, shellfish beds, and wild fisheries to close, affecting aquaculture operations, and poisoning marine mammals.

As one Senate Report stated, not unlike dead zones, HAB events have increased in the United States over the past 30 years. They are also costly. A recent report by the National Oceanic and Atmospheric Administration (NOAA) stated the economic effects of HABs reach at least $82 million per year in lost income for fisheries, lost recreational opportunities, decreased tourism, public health costs of illness, and expense of monitoring and management. One example of such a costly event was a 2005 outbreak off the coast of Massachusetts. The event was the largest red tide ever detected in Massachusetts waters and affected most of the state's 1.7 million acres of shellfish beds. On the West coast, meanwhile, in June 2007 acid poisoning from a HAB event in southern California harmed or killed sea lions, dolphins, a minke whale, and other marine life.

Outside the United States, HABs have been reported off the coast of China; South Korea, where the country's well-developed aquaculture industry lost $100 million worth of fish to a devastating bloom in 1995; and in Hong Kong, where in 1998 a HAB leveled half the country's annual aquaculture fish stocks. Authorities estimated direct losses after the Hong Kong event at $32 million.

C. The Possible Climate Change Nexus

Experts have suggested several ways that climate change could play a role in the formation of dead zones and HABs. First, scientists have noted the Oregon hypoxic zone, discussed above, first appeared six years ago and has returned annually since, and speculated it results from shifting wind and current patterns associated with climate change. Second, warming lowers oxygen solubility in water, which prevents mixing between upper and lower water layers. This, it is thought, could lead to greater degrees of stratification and more frequent or extensive dead

zones. Third, with respect to HABs, increases in rainfall may augment water column flushing and exchange rates. This may help disperse HABs into less toxic concentrations before damage results.

Separately, research is now being conducted on whether biofuel incentives recently enacted as a climate change policy response could inadvertently increase nutrient runoff. Because growing corn, the main biofuel crop in the United States, entails especially large applications of nutrient fertilizers, investigators are considering the extent to which increased corn acreage and intensity could add to nutrient runoff from fields. In this regard, the U.S. Department of Agriculture recently predicted that U.S. corn acreage planted this year increased approximately 20 percent, and the corn crop increased 27 percent, over last year (13.3 to 10.5 billion bushels). In addition to displacing more environmentally friendly crops, some have expressed unease that corn acreage may expand into marginal lands previously retired through various government programs. Such outcomes raise concerns because nutrient runoff is a major cause of the Gulf of Mexico dead zone and a possible cause of HABs. The National Research Council of the National Academies has noted the potential effects of increased biofuel production on hypoxic regions in two recent reports.

III. Policy Responses

Increasing concern in various countries has led to a number of strategies deployed to reduce the incidence of hypoxic zones and HABs. This section discusses several examples of these responses.

A. United States

Research-based efforts: The primary legislation addressing HABs and hypoxia is the Harmful Algal Bloom and Hypoxia Research and Control Act (HABHRCA). Originally passed in 1998 and reauthorized in 2004, Congress developed HABHRCA to combat the growing threat of HABs and hypoxia in U.S. waters through research. The goal of HABHRCA is to increase scientific understanding and the ability to detect, monitor, assess, and predict HABs and hypoxia and to develop programs for research into methods of prevention, control, and mitigation. Through HABHRCA, NOAA and its partners are working to better understand, detect, monitor, assess, and predict HABs and hypoxia in coastal ecosystems.

For example, NOAA recently announced a new research model indicates nutrients flowing from the Mississippi River may be responsible for stimulating HAB growth on the continental shelf off the west coast of Florida. This and other advances hold the potential to help coastal managers undertake short- and long-term efforts to prevent and mitigate the effects of HABs and dead zones on human health and coastal resources. HABHRCA research efforts complement several other activities, described below, that aim to reduce the impacts of these two pressing issues.

For instance, the northern Gulf of Mexico dead zone has been scrutinized by many, including the Mississippi River/Gulf of Mexico Watershed Nutrient Task Force. Formed in 1997, led by the U.S. Environmental Protection Agency (EPA), the task force was comprised of six federal, seven state, and two tribal organizations. In 2001, based mainly on research results from HABHRCA programs, the task force produced the Gulf of Mexico Action Plan. The plan set a goal of lowering nitrogen inputs by 30 percent from the 1980-1996 average and suggested, among other methods, increasing assistance to upstream landowners and businesses for voluntary actions to restore or create riverine wetlands or forested buffers within priority watersheds. It also recommended additional funding for landowners and businesses to implement best management practices (BMPs), which hold the promise of reducing nutrient inputs at their source. The Task Force's five-year reassessment is currently underway.

Non-point Source Programs: Several broad-based programs aim to reduce non-point source (NPS) pollution, including nitrogen runoff, thereby potentially decreasing the threat of hypoxia and HABs. For example, under the Clean Water Act (CWA), EPA through the total maximum daily load (TMDL) program requires states to identify all waters for which point source limitations are insufficient to attain

applicable quality standards. States are obligated to establish a TMDL that includes both point sources and NPS pollutants impairing such waters. States have the option of establishing TMDLs for nutrients such as nitrogen and phosphorous.

Additionally, Section 319 of the CWA established a national program to control NPS water pollution. States and territories are required to (a) submit reports identifying waters that require additional NPS pollution control actions, and (b) adopt management programs to control NPS pollution. EPA also operates programs encouraging smart growth and aimed at reducing pollution flowing from concentrated animal feeding operations and air deposition.

Outside the CWA, another attempt to reduce non-point source pollution comes from states' obligation to establish coastal NPS pollution control programs as part of the Coastal Zone Management Act. This requirement was enacted as part of the 1990 the Coastal Zone Act Reauthorization Amendments. NOAA and EPA jointly implement the program. These programs are developed in coordination with state and local water quality plans and programs required under the CWA. A state's program must contain enforceable policies and mechanisms which aim to control pollution from forestry and agricultural practices, urban areas, marinas, shoreline and stream channel modification, wetlands, and vegetated shorelines. Some of the practices NOAA recommends states adopt include preserving natural vegetation, avoiding development within sensitive habitats and erosion-prone areas, and limiting the extent of impervious surfaces such as pavement and roof tops.

The U.S. Department of Agriculture also works with landowners and land users to encourage the use of conservation-oriented BMPs or other methods to reduce nutrient runoff on their lands. Among the relevant programs is the Environmental Quality Incentives Program (EQIP). The EQIP provides technical, financial, and educational assistance to farmers who engage in agricultural or livestock production on eligible land while protecting environmental quality by implementing BMPs. The entity in charge of the EQIP, the Natural Resources Conservation Service (NRCS), also operates the Wetland Reserve Program, which offers 30-year easements or restoration cost-share agreements, and the Conservation Reserve Program (CRP). Since 1985, the CRP has worked to allow landowners to take environmentally sensitive areas out of production and to take conservation oriented activities such as planting native grasses, filter strips, or riparian buffers.

Additionally, the NRCS implements the Wildlife Habitat Incentives Program (WHIP), which allows landowners to improve fish and wildlife habitat. Under WHIP, landowners develop five to ten-year wildlife habitat development plans in consultation with local conservation districts. The plans describe goals for improving habitat, and may be part of a larger conservation plan that addresses other needs, such as water quality.

Reflecting the fact that the large majority of HABs occur in state waters, in addition to federal efforts, at least twenty-five states are also engaged in HAB prediction and response activities. For example, in the Chesapeake Bay region in 2000, states adjacent to the bay and EPA reaffirmed their 1987 goal of reducing nutrient inputs by 40 percent. In 2003, they established a target of conserving or restoring 10,000 miles of riparian forest buffer by 2010, and over the longer term preserving or restoring forests along at least 70 percent of all streams and shorelines.

Also, through a pilot "nutrient farming" program on the Illinois River, government agencies and other polluters have begun paying farmers, hunting clubs, and other landowners to convert their fields to nutrient-assimilating wetlands.

Internationally, the United States has signed the 1999 Protocol Concerning Pollution from Land-Based Sources and Activities, adopted pursuant to the 1983 Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region. While the protocol addresses NPS pollution reduction, the United States has not ratified it. Separately, the United States has taken part in elaboration of a soft law agreement of world-wide scope, the U.N. Global Programme of Action for the Protection of the Marine

Environment from Land-Based Activities (GPA). Adopted in 1995, the GPA seeks to encourage cooperation and adoption of action plans concerning, among other issues, NPS pollution.

Mitigation Efforts: A number of potential control methods are also being assessed for HABs. One of these involves physical removal of algae from the water column by spreading clay particles over the surface. As the clay settles, it adheres to algal cells and carries them to the bottom. Researchers have observed removal efficiencies of 95-99 percent. This method has been tested in the United States, but has been used more extensively in South Korea and China to protect aquaculture operations. Other methodologies being studied are use of barley straw by-products as algicides, and deployment of certain naturally-occurring bacteria, viruses, and parasites that target specific toxic algae species.

B. Denmark

Like the United States, Denmark has an extensive coastal zone, with the Danish coast stretching 7,300 kilometers. Also like the United States, Denmark has been forced to deal with a number of dead zones and HAB outbreaks. In the 1970s, Danish coastal officials began detailed observations of chronic fish kills, algal blooms, and low oxygen readings in the Kattegat strait between Denmark and Sweden. A lobster die off in 1986 further raised public consciousness, and in 1987 the Danish Parliament enacted the first Action Plan on the Aquatic Environment. The plan set the ambitious goal of reducing nitrogen releases by 50 percent and phosphorous by 80 percent from point and diffuse sources in the agricultural and industrial sectors and from sewage treatment plants—all within six years.

By 1991, while progress was made in other sectors, the government recognized that initial measures taken in the agricultural sector were having little effect. The Danish Parliament responded by extending the deadline for nutrient runoff reductions to 2000 and instituting additional measures. These included requiring farmers to account for the fertilizer and manure they applied to their fields. Farmers were also no longer permitted to spread manure in late autumn and winter. The government implemented a second action plan in 1998. The plan included (a) government buy-outs of land to reestablish wetlands and forests, (b) payments to farmers for agreements to take land out of cultivation, and (c) requirements that farmers reduce nitrogen use to a level representing 90 percent of economically optimal levels.

By 2003 the country had attained its goal of reducing nitrogen runoff from agriculture by 50 percent compared to mid-1980s levels. A third plan, established in 2004, aims to reduce nitrogen runoff from agriculture by an additional 13 percent by 2015 compared to 2003 levels. The latest plan utilizes a mixture of requirements including the sowing of winter crops, and creating or restoring forests or additional wetlands to meet this goal.

International instruments also help define Denmark's anti-hypoxia and HAB strategy. For example, recognizing the substantial deterioration of Baltic Sea water quality, in 1992 Baltic nations signed the Convention on the Protection of the Marine Environment of the Baltic Sea Area, otherwise known as the Helsinki Convention. The Helsinki Convention, to which Denmark is a party, entered into force in 2000. It requires parties to implement BMPs for agricultural non-point sources and establish guidelines for animal density, safe manure storage, correct manure application, fertilizer application rates, winter crop cover, riparian buffer zones, ground water protection zones, and wetland retention and restoration.

Separately, in 1992 the North Sea nations signed the Convention for the Protection of the Marine Environment of the North-East Atlantic, or OSPAR Convention. Denmark and other parties agreed to subject point source discharges into the North Sea to strict regulation, require the use of BMPs for non-point sources, and establish programs and measures for reducing nutrient inputs from urban, municipal, industrial, and agricultural sources. The OSPAR Eutrophication Strategy sets the goal of "achiev[ing], by 2010, a healthy marine environment where eutrophication does not occur."

EU rules have also played a role. Perhaps the most important instrument from an agricultural perspective

was the 1991 Nitrates Directive. This legislation required EU members by 2003 to: (a) identify waters affected by nitrogen pollution and waters that could be affected if not protected, (b) designate as vulnerable all watershed areas draining into nitrogen-polluted or potentially polluted waters, and (c) establish action programs for zones designated as "vulnerable." One of the more difficult action program components for Danish authorities to meet was the restriction of manure application to fields to 170 kilograms of nitrogen per hectare annually. Presently, Denmark operates under a derogation from the Nitrate Directive allowing the use of up to 230 kilograms of nitrogen per hectare applied annually on cattle farms. Individual farms can take advantage of the derogation provided they cover at least 70 percent of its fields with fodder crops.

IV. Conclusion

Looking forward, given the global trend toward population concentration along the coasts, and pressure to increase food and biofuel production, the United States, Denmark, and other countries will be confronted by a number of synergistic challenges. If not well managed, not only will dead zones and HABs continue to plague coastal zones, they could become more frequent and disruptive. Denmark and the United States have adopted similar policies to address these problems, with Denmark opting for a somewhat more direct and comprehensive approach at this stage. Its policies are also driven by regional and international regulation and cooperation to a greater extent than in the United States. Regardless of their differences, however, the Danish and U.S. cases demonstrate that the lessons learned now about the causes of dead zones and HABs and how to manage, reduce, and mitigate their effects will likely only increase in importance in the years to come.

Brett Grosko *is an attorney-adviser at the National Oceanic and Atmospheric Administration Office of the General Counsel. The views expressed here are solely the author's and do not reflect the views of NOAA, the Department of Commerce, or any other agency*.

INTERNATIONAL LAW AND POLICY REGARDING THE PLACEMENT OF ARTIFICIAL REEFS IN THE MARINE ENVIRONMENT

Anna Burghardt

I. Introduction

A. Background Information Regarding Artificial Reefs

An artificial reef is a man-made underwater structure, resembling and mimicking a natural reef in its purpose. In essence, hard surfaces are used as a point of attachment and colonization for algae and invertebrates such as, *inter alia*, barnacles, corals, and oysters. Once encrusted with organisms, the attached marine life provides habitat for marine species, thereby potentially mitigating habitat loss elsewhere as well as supporting marine life.

In light of the multitude of their potential benefits and current threats to the marine environment, artificial reef projects have moved beyond their initial use as algaculture and fishing devices to multi-use reefs. Today, reef proponents pursue objectives such as scientific research, protection and restoration of marine life and habitat, recreational surfing, diving, and fishing, as well as coastal protection, erosion control, and stabilization to reduce flooding. Hence, a variety of different building methods and materials have been employed, including scuttling vessels, rubble, tires, construction debris, old vehicles, cement blocks, and pipes, or specifically built and designed structures, such as "reef balls." The designated purpose of the reef is, thus, the key aspect of the project: it justifies the installation and determines both its location and design.

Artificial reefs are generally placed on the seabed near the coast. In the United States, project proponents often must comply with state management programs and obtain permits from the U.S. Corps of Engineers and the Environmental Protection Agency (EPA). While there is no specific international instrument regarding artificial reefs, international conventions, such as the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other

Matters (LC or London Convention) and its 1996 Protocol (LP), address disposal of material into the sea, setting forth international law on ocean dumping. The Contracting Parties to the LC agree that placement should not be used as an excuse for disposal at sea of waste and should not be contrary to the aims of the Convention. Int'l Maritime Org. (IMO) Doc. No. LC/SG 29/7.

The growing artificial reef industry and coastal community desires to stimulate economic activity have led to the extensive and worldwide use of artificial reefs. This in turn has caused concern in some quarters. Both during the actual construction as well as during their entire life span, artificial reefs can cause damage to the marine environment in the form of marine debris, displacement of naturally-occurring species and habitats, unnatural fish concentration—leading to greater vulnerability to overfishing—or the introduction of toxins and pollutants. For this reason, the suitability of artificial reefs for addressing problems of resource depletion, marine pollution, and increasing coastal erosion and flooding, should be subject to careful evaluation. This evaluation, furthermore, should aim to assess the appropriate role of artificial reefs as part of an integrated coastal management approach. To produce the desired benefits, it would seem essential to ensure that the process is not driven by commercial interests as an inexpensive way to dispose of trash rather than interests in long-term sustainable coastal assets.

B. Topicality of the Issue: International Efforts to Develop "Placement Guidelines"

In light of the global practice of placing artificial reef structures on the seabed for a variety of purposes, and a growing international interest in ensuring that such installations serve appropriate purposes and not contravene the LC or LP, the parties to these instruments requested the development of global guidelines for the placement of artificial reefs. In June 2006, at the 29th session of the Scientific Group to the London Convention, it was noted that a number of national and regional artificial reef practices and guidelines exist and that the development of the requested guidelines should be entrusted to the Scientific Group, headed by Spain.

The guidelines on the placement of artificial reefs consistent with the aims of the LC, taking into account current national and regional artificial reef guidelines, practices, and case studies, are to be submitted for approval by the 30th Consultative Meeting at the end of 2007. Since 2000, the Consultative Meeting has agreed that:

1. Placement should not be used as an excuse for disposal at sea of waste materials;
2. Placement should not be contrary to the aims of the LC;
3. Information on placement activities by Contracting Parties should be provided to the Secretariat; and
4. Materials used for placement activities should be assessed in accordance with the relevant Specific Guidelines.

Moreover, in June 2007, the Scientific Group agreed on the following working definition of an "artificial reef":

> *[A] submerged structure deliberately constructed, placed, or left on the seabed to imitate some characteristics of a natural reef, such as protect, regenerate, concentrate, and/or increase populations of living marine resources.*
>
> *The objectives of an artificial reef may include enhanced aquatic habitat, marine resources, fisheries resources, research, recreational opportunities, educational opportunities, erosion control, or shoreline stabilization.*
>
> *The term does not include the deliberate placement of a submerged structure on the seabed to perform a specific function that does not relate to or depend upon imitating any characteristics of a natural reef, such as breakwaters and/or similar structures, mooring, cables, pipelines, marine research devices or platforms, but which may incidentally imitate some characteristics of a natural reef.*

See IMO Doc. No. LC/SG 30/WP.4 (June 19, 2007).

It is submitted that in relation to the scope of the LC regime, the primary purpose of the guidelines should be to ensure the prevention of pollution or degradation of

the marine environment from the installation and maintenance of any artificial structure. Thus, the scope of guidance should be broad and not limited to structures aiming at marine life or habitat enhancement and protection. Moreover, the guidance should deal not only with the placement, but extend to long-term maintenance issues, *i.e.*, cover the entire "life span" of such artificial structures.

II. "Placements" and the Definition of Dumping

International instruments address the problem of dumping as a major threat to the marine environment, thereby aiming at protecting and preserving it from all sources of pollution. *See, e.g.*, Articles 192 and 194 of the 1982 U.N. Law of the Sea Convention (LOSC) and Article 2 of the LC and LP. However, ecologically responsible re-usage of structures as artificial reefs seems to be an environmentally and economically viable waste management option. This is because "placement of a matter for a purpose other than the mere disposal thereof" is generally not regarded as "dumping," provided such a placement is not contrary to the aims of the governing instrument. *See, e.g.*, Article 1(5)(b)(ii) of the LOSC and Article 3(1)(b)(ii) of the LC). Accordingly, questions arise as to the acceptability of this practice under the applicable legal regime, *i.e.*, whether placements of artificial reefs are indeed consistent with the aims of these conventions.

III. Existing International Regimes

A. The 1982 United Nations Convention on the Law of the Sea (LOSC)

In the absence of a specific international instrument addressing artificial reefs, the LOSC, providing the international framework for all activity affecting ocean use and the marine environment, is to be considered.

According to the establishment of ocean zones of juridical competence, the LOSC distinguishes, *inter alia*, between waters of the Exclusive Economic Zone (EEZ) and the high seas. In the EEZ, the coastal State has jurisdiction over the establishment and use of artificial islands, installations, and structures as well as the protection and preservation of the marine environment (LOSC Article 56(1)(b)(i) and (ii)). Pursuant to article 60(1), artificial structures and installations placed for a purpose provided for in article 56, *i.e.* exploring, exploiting, conserving and managing natural resources, whether living or non-living, or protection and preservation of the marine environment, are under the exclusive prescriptive jurisdiction of the coastal State.

Pursuant to Article 87(1)(d), on the high seas, States are free "to construct artificial islands and other installations permitted under international law subject to Part VI." However, Article 192, read in conjunction with Articles 194(3) and 195, further restricts this freedom by requiring States to "protect and preserve the marine environment" from any source of pollution—in any ocean area. While ocean dumping, perceived as a major threat to the ocean's well-being, is addressed by LOSC Article 210, "placement" for a purpose other than mere disposal, is governed by Article 208(1), since it is not considered dumping. Basically identical, both provisions call upon States, "acting especially through competent international organizations … to establish global and regional rules, standards and recommended practices and procedures to prevent, reduce and control pollution of the marine environment [arising from artificial islands, installation and structures under their jurisdiction pursuant to articles 60 and 80]."

The development of international guidelines regarding the placement of artificial installations and structures under the auspices of the IMO-London Convention regime would fulfill this mandate.

B. 1972 LC and the 1996 Protocol

The LC is global in scope and establishes differing categories of waste. Article IV(1) prohibits the dumping of "wastes or other matter" listed in Annex I, while all other matter may be authorized to be dumped at sea, taking into account Annexes II and III.

Annex I(11) blacklists "industrial waste" but excludes "vessels, platforms and other man-made structures at sea, provided that material capable of creating floating debris or otherwise contributing to pollution of the

marine environment has been removed to the maximum extent." Furthermore, "containers and other bulky wastes liable to sink to the sea bottom, which may present a serious obstacle to fishing or navigation" may be disposed of at sea, subject to a prior special permit, provided "material capable of creating floating debris or otherwise contributing to pollution of the marine environment has been removed" (Annex II(C) to LC). Thus, the proponent of a reef can modify typical reef materials, such as offshore installations, vessels, vehicles and concrete blocks to ensure they qualify for disposal under Annex II. The disposal permit may be issued in accordance with Annex III, *i.e.*, after considering the composition of waste or other matter, the characteristics of the dumping site and method of deposit, the possible effects on marine life, amenities and other legitimate uses of the sea, as well as the practical availability of alternative land-based disposal and treatment methods.

The 1996 LP reflects a more modern and comprehensive agreement on protecting the marine environment from dumping than the original 1972 Convention. Pursuant to the precautionary approach, it generally prohibits the dumping of wastes or other matter except for those materials specifically enumerated in the reverse list of Annex 1. Having finally entered into force in 2006, the 1996 Protocol and its Reverse List approach (prohibition of dumping except for wastes on the Annex 1-Reverse List) represents a much more precautionary use of the sea as a repository for waste materials.

Annex 1 to the Protocol sets forth a step-by-step procedure for evaluating waste disposal at sea and enumerates the materials that may be disposed of in accordance with adopted guidelines. Under Article I.4.1.4 of the LP, dumping includes the abandonment and toppling *in situ* of platforms or other man-made structures at sea for the sole purpose of disposal. However, "vessels and platforms or other man-made structures at sea" from which "material capable of creating floating debris or otherwise contributing to pollution of the marine environment has been removed to the maximum extent" are included in Annex 1, provided they "[pose] no serious obstacle to fishing or navigation." (Annex 1, ¶ 2).

To "ensure, as far as practicable, that environmental disturbance and detriment are minimized and the benefits maximized," Annex 2 establishes a comprehensive list of assessment criteria for considering long-term acceptability of waste for dumping, mandating impact evaluations in the pre-permit stage. Annex 2 focuses "particular attention . . . [on] opportunities to avoid dumping in favour of environmentally preferable alternatives" as well as outlining compliance and field monitoring. Accordingly, a contracting party should avoid dumping in favor of environmentally-preferable alternatives, such as reuse, off-site recycling, destruction of hazardous constituents, and land disposal.

Generic and Specific Guidelines intended for use by national authorities responsible for regulating dumping of wastes have been created for the assessment of wastes that may be considered for dumping consistent with the provisions of the LC and LP. By providing that "[w]hen applying these Guidelines uncertainties in relation to assessments of impacts on the marine environment will need to be considered and a precautionary approach applied in addressing these uncertainties," both the LC and LP reiterate that re-use is the preferred waste management option. Accordingly, the environmental hierarchy of reuse, off-site recycling, destruction or removal of hazardous constituents, and disposal on land, into air or water, favors ecologically-responsible reuse of structures as artificial reefs.

IV. The International Guidelines Currently under Construction

Considering the increasing global practice of artificial reefing and the potential for abuse, environmental standards are important to prevent the degradation of the marine environment.

International instruments address the issue of placements only indirectly because they expressly distinguish it from dumping or pollution. However, to be eligible for this exclusion, a project must not be contrary to the aim of the applicable convention. Thus, artificial reefs should be understood as a means for proper ocean management, with the goal of protecting the oceans.

National permitting and environmental systems are a means to achieving ecologically sustainable placements in the territorial sea and EEZ waters. On the high seas, however, regulation and monitoring are likely to encounter managerial problems and questions about appropriateness. Indeed, because artificial reefs are supposed to imitate natural reefs, which generally do not exist in the high seas, placement on the high seas should be discouraged.

Furthermore, it is emphasized that the key aspects of decision-making can already be found in the existing Generic and Special Guidelines. These entail the necessity of: (a) waste characterization; (b) waste prevention audits to assess management alternatives; (c) site selection considerations, such as the physical, chemical, and biological characteristics of the water-column and seabed; (d) location of amenities, values, and other uses of the sea in the area under consideration; (e) the comprehensive determination of potential impacts; and (f) compliance and field monitoring.

A. Permit Applications

In this process, the pre-placement planning stage is of utmost importance. It provides the tool to prevent negative impacts and subsequent damages, as well as costs. The living environment needs to be considered, including ecosystem relationships, life stages, species communities and populations, as well as geographic characteristics of the envisaged site. Reefs must be designed to withstand the physical stresses of the marine environment, both as individual units and as an overall structure. Moreover, a systematic monitoring program evaluating the performance of the artificial reef throughout its life needs to be established.

It is suggested that applications should specify in detail the purpose of the reef, since it justifies the placement at sea and determines its design, siting, and management. Furthermore, such specification should be supplemented by an overview of how to bring about the identified objective.

B. Secondary Use Materials

Concerns about increasing artificial reef construction arise due to the utilization of materials and structures initially intended for another purpose. Originally called "materials of opportunity," this phrase has now been abandoned to emphasize that artificial reefing, although utilizing materials no longer in use, is not merely an opportunity to dispose of waste.

Typical secondary use materials include vehicle bodies and railroad cars, vessels, disused offshore platforms and structures or parts thereof, and light gauge metal items such as refrigerators, washing machines, and clothes dryers. The use of these and in particular other matter listed in Annex 1 to the LP should be considered for their long-term suitability as reefing structures. Materials of concern should be addressed with clean-up goals and information on how to achieve these goals prior to sinking. Materials unsuitable for reefing should be listed. Use of unsuitable materials likely to result in marine debris is not only expensive to cleanup, but may also seriously damage natural reefs and otherwise degrade the marine environment. As known from tire reefs, materials of immediate opportunity may be permitted under the LC regime, but may later become an expensive marine debris cleanup problem. Thus, materials must be stable and environmentally safe in order to be considered suitable. Sustainable and long-lasting monitoring and management approaches need to be established in order to avoid or minimize negative impacts and take appropriate preventive and remedial action.

Consideration should be given for each material to its risks and benefits, compatibility with their intended function and environment, as well as durability and stability of the material in the marine environment. This ensures cost effectiveness and minimizes and/or prevents degradation, since subsequent cleanup of deteriorated materials, turned into marine debris, can be costly. Additionally, structures should be completely cleaned and stripped of potentially harmful material to ensure that artificial reefs are not used as an inexpensive alternative to land filling. Extensive guidance for both the cleanup and preparation can be found in the Specific Guidelines for the Assessment of

Vessels and Specific Guidelines for Assessment of Platforms or other Man-made Structures at Sea.

So-called "tire reefs" are a prime example of the ecologically and economically disastrous consequences of using unsuitable materials and the need to re-examine the concept of artificial reefs: millions of tires, strapped together for artificial reefing, were cast into the sea off of Australia, New Zealand, Malaysia and the U.S. states of New York, New Jersey, North Carolina, California and Florida. Today, disintegrated tires are a global problem, destroying living natural reefs while migrating shoreward, and littering beaches. In 2005 alone, volunteers for the Ocean Conservancy's annual international coastal cleanup removed more than 11,000 tires worldwide. The complete removal of the Osborne Reef off of Florida, approximately 2 million tires covering 36 acres in the waters off of Broward County, is expected to take three years. The cost estimated for full abatement of this "artificial reef gone bad" is about $3.4 million, a figure that does not include funding estimates for military participation. *History and Overview of the Osborne Reef. Waste Tire Removal Pilot Project* (March 2007), *available at* http://www.dep.state.fl.us/waste/quick_topics/publications/shw/tires/reef/tirereefhistoryoverviewwebMarch2007.pdf. Indeed, employing private constructors in lieu of the military would have cost an estimated $30 million. G. Allen, *Fallout from Bad '70s Idea: Auto Tires in Ocean Reef* (Sept. 21, 2007), *available at* http://www.npr.org/templates/story/story.php?storyId=11462066.

In addition to visible damage in the form of reef destruction and littered beaches, there is also concern that tires emit toxins. Overall, tire reefs turned into an "environmental disaster," doing more harm than good. In fact, U.S. states now discourage tire reefs. *See Position Statement of the Gulf States Marine Fisheries Commission on the Use of Tires as Artificial Reef Material* (Mar. 21, 2002).

The lesson taught by the Osborne Reef is not only that tires are unsuitable and should be "black listed" in the Guidelines on Placements, but also that the cost-benefit analysis for artificial reefs needs to be re-examined. Potential multi-million-dollar cleanups should be included in the cost-benefit-analysis before placement. Liability for such activities should be determined before the permit is granted. Responsibility for future removal should be accepted as a key component of the placement activity. Any analysis should consider the short and long-term costs and benefits. This includes information about how long the artificial reef is expected to remain to carry out its identified purpose, and whether the reef will degrade and create marine debris requiring subsequent disposal.

V. Conclusion

The development of Guidelines undertaken within the LC's ambit need to further its objective of ocean protection and preservation. International guidelines will help governments and industry pave the way for laws, policies, and practices that do not permit reef projects to degrade, but rather benefit the marine environment. A comprehensive instrument would be more beneficial than a narrow one. Adopting the latter approach may cause a shift of a variety of practices so as to avoid coming under the purview of any new agreement, and further delay addressing potential risks and problems. The objective of the LC is to promote the effective control of all sources of marine pollution and to take all practicable steps to prevent pollution by dumping of wastes and other matter. Accordingly, the broader the variety of activities covered, the less room left for abuse due to non-regulation. In this regard, the guidelines should provide for prerequisites on suitability. In principle, the LOSC and the LC and its Protocol allow for placements of man-made structures at sea, whether their placement is secondary or primary, provided it does not harm the marine environment. Thus, the intended purpose and actual impacts should be looked at when determining the acceptability of a specific project. Arguably, under the precautionary approach, any uncertainty as to the harm a reef placement could cause should be given appropriate weight. Such uncertainty could even be determinative of whether further consideration is warranted until potential harm to is adequately addressed.

In order to qualify as permissible "placement," artificial reefs should meet their purposes throughout their entire

life-spans and include plans to address issues arising when the reef (or portions thereof) becomes marine debris or otherwise negatively impact the marine environment. Thus, long-term management, including monitoring and liability for reefing structures, should be in place before placement is permitted. This should involve on-going monitoring to assess the effects of an artificial reef on the marine environment and to ensure its safety; particularly with regard to natural decomposition as well as possible natural hazards such as storms, hurricanes, and tsunamis.

Anna Burghardt *is an S.J.D. candidate at Tulane University School of Law, and a former intern at the NOAA Office of General Counsel for International Law (GCIL). She would like to thank Ole Varmer, attorney-aAdviser at GCIL, for his support and guidance in preparing this article, as well as Gwendolyn Whitby-Logan, a J.D. candidate at Howard University School of Law and current GCIL intern, for her editorial assistance. The views expressed here are solely the author's and do not reflect the views of NOAA, the Department of Commerce, or any other agency.*

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MEMBER PROFILE: INTERVIEW WITH BRANDON NEUSCHAFER

This is a new feature of the International Environmental Law Committee newsletter, which will begin to profile a range of international environmental legal practitioners. Since this is a joint issue with the Agricultural Management Committee, we profile a practitioner in St. Louis, Missouri, Brandon Neuschafer, who has positioned himself to work on important international environmental matters as a mid-level associate with the firm of Bryan Cave LLC. The role of interviewer is played by Jennifer Wills with the Environmental Protection Agency.

(Q1) How does your present work involve issues of international environmental law?

(A1) My current international environmental practice primarily involves providing regulatory assistance to agricultural and chemical companies worldwide. I provide advice regarding product registration, regulatory compliance, transportation, marketing, and import/export. I also assist our commercial attorneys with their transactional work (e.g., due diligence, contract negotiation and drafting).

When people think of hot locations in the practice of international environmental law, not many think of St. Louis. However, St. Louis is home to a significant number of companies competing internationally, many of which are in the agriculture and biotech industries. International law practice is alive and well in St. Louis. Additionally, my firm has offices throughout the world and is committed to providing broad-based legal assistance to a diverse client base, which increasingly includes advice on international issues. Although our client base is much larger than just St. Louis or the Midwest, my work often reflects local trends and needs in industry and innovation.

(Q2) Which aspects of international environmental law practice do you find the most interesting, and which do you consider the most difficult?

(A2) To me, the most interesting aspect of the practice comes with learning about the approaches to issues that are different than the approach taken by a U.S.-

trained lawyer working primarily in the U.S. This comes on both the business side, in working directly with my international colleagues, and on the legal side, in developing an understanding of different legal systems and regimes. The most difficult aspect to me is often finding available resources to help understand the legal issues involved, setting aside some concepts instilled during my common law-based legal education.

(Q3) What training and/or previous experience do you consider to have been helpful to your ability to effectively analyze and solve problems in this field?

(A3) With respect to international studies, I spent a lot of time in college, graduate and law school studying languages, international relations, and comparative government and legal systems. This helped develop my appreciation for and desire to do international work, but the most useful practical experience came from more traditional legal training in analytical and critical thinking. On-the-job training has been significant as well. My practice is not solely international in nature, and I do a lot of domestic environmental and agriculture work. Also, my practice has regulatory, commercial, and litigation aspects, which gave me complementary skills.

(Q4) Within the field, what issues or areas do you expect to pose the most significant challenges for policymakers, industry, and nongovernmental organizations (NGOs) in the year 2007 and beyond?

(A4) Climate change. Everybody is talking about it, with good reason. With growing public concern about the issue, publicly-traded companies are determining how to respond to shareholder concerns, while industry and regulators are exploring methods to regulate emissions. In the courts, private parties are attempting regulation via litigation. With alternate energy, sustainability, and other issues linking up to climate change, I think it's clear that the practice of environmental law is heading in some very interesting and ground-breaking directions.

(Q5) What words of encouragement or counsel would you offer to students of environmental law or to young environmental law practitioners interested in working in the area of international environmental law?

(A5) Seek out and create your own opportunities to practice in the field. Within your firm, find the people doing the work you are interested in and make yourself known and available to them. Write articles, get involved in ABA committees, attend CLEs and other conferences, and try to develop a name for yourself in the field. Get involved in local international business and/or legal organizations, such as your local World Trade Center group, to help build contacts. Don't get discouraged—it won't happen overnight, and it is a constantly evolving process.

(Q6) Give a specific example of a matter, including how you got involved, level of participation, and issues involved in the matter.

(A6) For years, our firm represented Kuwait and Saudi Arabia with respect to environmental (and other) claims submitted to the United Nations Compensation Commissions (UNCC) arising out of environmental damage caused during the first Gulf War. In keeping with the above advice, I sought out the work and helped with research and preparing filings from St. Louis. During a "crunch" period for presentations to the UNCC, we traveled to the Gulf region and Europe, doing research, expert prep and both oral and written submissions before the UNCC in Geneva. The claims phase is now over and the remediation phase has begun. It was an absolutely amazing opportunity, and one that still motivates me to this day. With a mutli-disciplinary team and throughout three continents, we studied treaties and international precedents, worked with experts and government officials from around the world, and presented scientific and legal claims to international agencies. It really doesn't get any more international than that.

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U.S. BIOTECH FOOD-FEED IMPORT INSPECTION PROCESS AND REGULATORY TRANSPARENCY

Thomas Redick
James Andreasen
Brandon W. Neuschafer

The development and commercialization of plants modified by use of recombinant DNA methods (biotech plants) is an accelerating phenomenon. The United States has been at the forefront of this new technology with exports of biotech plants and biotech seeds to other nations, but the United States has not generally been an importer of biotech varieties beyond some food and feed imports from Canada. Some aspects of U.S. policy on domestic biotech plants are well-established, and easily understood by developers of new varieties at home and abroad, but provisions for imports for food and feed use currently are in need of clarification.

In general, key U.S. trading partners have their own approaches to controlling the use of biotech plants, including their growth by farmers and their use in food or feed or for processing. Planting biotech varieties before approval is restricted by trading partners such as Mexico, the European Union (EU), China, and Japan. The EU's current regulatory process is based on the "precautionary principle," which allows regulation, or even an outright ban, unless the substance, material, or activity in question is proven safe. This can be interpreted as requiring a party to prove the negative—that no imaginable risk exists—before approval. In contrast, the United States and Canada assess known risks of a new technology (including a biotech plant variety) and determine whether the benefits outweigh the risks.

Recent developments may push the EU forward in allowing new biotech varieties. In 2006, a dispute resolution panel of the World Trade Organization (WTO) upheld a U.S.-Canada-Argentina challenge to the EU's regulatory "moratorium" on approval of biotech food, feed, and seeds. The WTO substantially upheld challenges to the EU's failure to act on several applications for approval of specific biotech varieties, forcing the EU to move forward in approving sales of biotech crops. The panel held that a *de facto* moratorium on biotech approvals existed, and that the EU had not demonstrated an appropriate scientific basis for its failure to approve several of the biotech varieties. The WTO panel made it a point to rule that the "precautionary approach" language of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (BSP) did not apply to allow a barrier to trade with non-parties to the BSP.

The EU's effort to find support for its "precautionary approach" to biotech crops in BSP meetings continues. In March 2006, the Conference of the Parties to the BSP issued draft rules for handling, transport, packaging, and identification of biotech plants. These rules require that documentation state that a shipment contains GMOs, and identify, where known, the identity of the specific biotech variety present.

Another development may also push toward greater acceptance of biotech varieties worldwide. In 2007, the Codex Alimentarius Commission, an arm of the United Nations Food and Agriculture Organization and the World Health Organization, adopted its Working Principles for Risk Analysis for Food Safety for Application by Governments. The Codex expressly rejected the precautionary principle as part of the risk analysis for food safety, partly because countries might use the precautionary principle to defend trade restrictions that lack scientific support.

America's major export target nations, including Japan, Mexico, Taiwan, and the nations of the EU, have developed detailed policies that set specific standards for handling imports of biotech crops**,** whether they arrive as raw shipments of commodity crops such as corn or soybeans, or as ingredients in processed or finished foods. Around the world, many of the major exporters of food products to America, including developing countries such as China, are engaged in biotech innovations that take the breath away in their scope, and these trading partners are pursuing ambitious timetables for deployment of their newly-developed biotech varieties. In China and other nations serving U.S. markets, new varieties of biotech plants will increasingly be widely cultivated. Many of these

nations avoid using biotechnology to keep their exporting options open in light of the restrictive import policies of some potential customers.

For example, China has not launched its biotech soybean varieties, although twenty such varieties are reported to be in its pipeline. On the other hand, China has commercial interests in biotech rice and corn that may improve production and nutrition for its own population, but that also could complicate exports to a world where there is significant concern over biotech crops that are not approved for import. Since there is at least a possibility that biotech crops developed abroad could be shipped to the United States, whether intentionally or through accidental commingling, the U.S. Department of Agriculture (USDA) has sought input from the public on the scope of its oversight for such crops.

This article discusses the regulatory framework and evolving policy of the United States for food or feed imports (as opposed to imports for planting or other environmental release), including the current and proposed inspection and certification processes and relative regulatory transparency (*i.e.*, how readily accessed and understood these policies may be). While importers should develop a detailed understanding for particular products in consultation with regulatory counsel and the current applicable regulations, this overview summarizes the process and provides a chart tracking laws based on categories of products.

I. Federal Transparency

Compared to some nations, which tend to hide their policies and planting of biotech crops behind a veil, the United States has a very transparent system for agency regulations and disclosure of biotech crops planted in the United States. This includes field trial records tracking the counties in the United States where crops are planted. Before a biotech crop is planted, a notice and comment rulemaking procedure is followed, requiring the U.S. agency involved to do the following:

- File documents with the Office of the Federal Register;
- Post documents online for public inspection and comment;
- Publish documents in the Federal Register to allow the public to participate in the rulemaking process by commenting on proposed rules;
- Allow at least 30 days from the date of publication to the date it is effective; and
- Publish the agency organization and procedural rules.

For importers of biotech crops, this transparency makes it easier to identify potential barriers to entry before they arise. For example, in response to the recent notice of a Programmatic Environmental Impact Statement regarding the USDA's Biotechnology Regulatory Services (Draft EIS), some industry commenters suggested that the proposed import policy for certain biotech food, feed, and processing (FFP) products would be too strict and would create a U.S. precedent that might be adopted by other nations. This would hinder the export of biotech crops from the United States because traces of unapproved biotech crops might be present at low levels—a scenario recognized within the Draft EIS itself. This transparency at the earliest stages of rule-making (*i.e.*, in the environmental assessment process prior to rule proposal) gives both the importers of biotech crops into the United States and the foreign exporters that hope to supply them an opportunity to have their voices heard as the rules that will govern them are being established.

In September 2006, the Pew Initiative on Food and Biotechnology held a two-day seminar discussing imports of biotech plants and food-feed (but not biotech animals or animal products), inviting input from those on all sides of the issue, including federal regulators, representatives from food and agribusiness concerns, biotech crop testing services, and public interest groups. *See Commercial, Safety and Trade Implications Raised by Importation of Genetically Engineered Ingredients, Grain or Whole Foods for Food, Feed or Processing, available at* http://pewagbiotech.org/events/0907/WorkshopReport.pdf. The speakers at this session included regulatory officials and representatives of the seed industry, producers, and grain buyers.

II. Agencies Governing Food and Feed Imports

U.S. food safety regulation can be confusing, particularly for overseas importers. It is a shared responsibility, and several departments of the United States government exert jurisdiction over distinct aspects of biotech crops that are imported into the United States.

A. U.S. Department of Agriculture

USDA's primary enforcement arms for regulatory violations are the Animal and Plant Health Inspection Service (APHIS), the Food Safety Inspection Service (FSIS), Grain Inspection Packers and Stockyards Administration (GIPSA)/Federal Grain Inspection Service (FGIS), and Agricultural Marketing Service (AMS). In addition, the U.S. Customs Service participates in this effort by detaining imports when USDA requirements have not been met.

1. Animal and Plant Health Inspection Service (APHIS)

APHIS is responsible for enforcing import regulations for biotech agricultural products. APHIS' Biotechnology Regulatory Services (BRS) regulates and conducts control programs to protect and improve animal and plant health for the benefit of people and their environment. In cooperation with state governments, APHIS administers federal laws and regulations pertaining to animal and plant health and quarantine, humane treatment of animals, and the control and eradication of pests and diseases. It defends U.S. borders against entry of foreign pests and diseases, protects endangered species, makes sure veterinary biologics are safe, pure, potent, and effective, and ensures the safety of agricultural biotechnology products.

Importers should also be aware that APHIS' Plant Protection and Quarantine (PPQ) program conducts programs and activities at various U.S. ports to prevent the introduction and spread of foreign pests. APHIS' Veterinary Services (VS) has responsibility for protecting the health of livestock, poultry, and other animals. The laws APHIS enforces are numerous and varied. Some of the most important statutes and regulations are: Plant Quarantine Act, Plant Protection Act, Honey Bee Act, Federal Seed Act, Animal Import-Export Regulations, Endangered Species Act (Plants), Swine Health Protection Act, and the Virus Serum Toxin Act. If feasible during high-volume periods, foreign exporters may request APHIS offices to conduct a pre-clearance inspection in the country of origin. Pre-clearance can reduce the risk of introducing foreign pests into the United States, and this process could apply as well to traces of unapproved-for-import biotech genetic events.

Because of the sheer quantity of certificates that the PPQ program issues and because many countries have vastly different entry requirements for agricultural products, PPQ developed a database to track the phytosanitary requirements for many countries. This database, called *EXCERPT*, allows PPQ officers, state and county officials, and even industry members to access export information. The database also lists the status of endangered plant species, the commodities that are not eligible to be exported to specific countries, and any changes in other countries' entry requirements.

2. Food Safety Inspection Service (FSIS)

FSIS is responsible for ensuring that meat derived from cattle, sheep, swine, goats, and horses and poultry products moving in interstate and foreign commerce are safe, wholesome for consumption, and accurately labeled. Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Biotech processes for improving meat quality, including cloning of sheep, pigs, and cattle, may become more commonplace as this technology improves its success rate to the point of achieving wide-spread consumer acceptance.

3. Grain Inspection Packers and Stockyards Administration (GIPSA), Federal Grain Inspection Service (FGIS)

GIPSA runs the FGIS to oversee imports of U.S. grain into the marketplace by providing farmers, grain handlers, processors, exporters, and international

buyers with information that accurately and consistently describes the quality and quantity of grain being bought and sold.

B. U.S. Food and Drug Administration (FDA)

FDA is the scientific regulatory agency responsible for the safety of all foods (except meat, poultry, frozen and dried eggs, and the labeling of alcoholic beverages and tobacco). FDA does not require that biotech foods, imported or domestic, undergo a safety review before being sold to consumers, but it can prohibit shipments when it believes they pose a risk, or require recalls of foods it determines are unsafe. For imports of biotech crops into the United States, there is a "voluntary" review process for any biotech crop imported as food or animal feed. FDA wants to ensure that parties involved in import of biotech foods are aware of this voluntary process, and increase participation. FDA is concerned enough about the safety of imported biotech food products that it is making it easier for foreign firms to participate and engage FDA voluntarily before exporting biotech food products to the United States. While U.S. producers are participating as if it were mandatory, the overseas vendor may see "voluntary" participation as optional.

Any importer avoiding FDA oversight, however, runs a serious risk, since it is the vendor (and, either directly or by contract, upstream suppliers) who would be responsible if FDA feels there is any risk whatsoever in the biotech crop at issue (*e.g.*, a protein that resists prompt digestion—one criteria for food allergy). Such an FDA determination could trigger a nationwide food recall on the scale of the 2000 recall of Starlink corn. The Starlink corn variety was sold by Aventis Crop Sciences and was approved only for feed use in the United States, but when it became commingled with food in the United States, the cost of the resulting recall ensuing litigation and lost shareholder value were measured in the billions of dollars.

As a result, importers can and should consult with FDA as a matter of mandatory liability management—even if the word "voluntary" remains on the books. The mass tort liability system in the United States proved, with Starlink, that it can punish the slightest misstep that leads to arguable concerns with food safety.

Within the United States, FDA ensures compliance with the Federal Food, Drug and Cosmetic Act (FD&C Act) via periodic unannounced inspections of facilities and products, analysis of samples, educational activities, and legal proceedings. It is the responsibility of the owner of the food in interstate commerce to ensure that the article complies with the provisions of the FD&C Act, the Fair Packaging and Labeling Act, and their implementing regulations. FDA relies on other food companies to report competitors' violations.

FDA knows that is it not commercially feasible for nations overseas to grow, harvest, and process crops that are totally free of natural defects such as molds, rodent-insect debris, etc. Accordingly, FDA publishes *Food Defect Action Levels*, which are established to rule out hazard to health. Any products that may be harmful to consumers can be subject to regulatory action, however, without regard for the defect levels. Also, FDA has the authority to issue an "import alert" for any unsafe food product, even those still *en route* to the United States. For example, recent FDA import alerts include rice sticks and rice vermicelli made in China that were contaminated with filth (rodent feces and insects). Similar steps addressed pet food containing melamine. This procedure can work for commingling incidents that are reported to the United States (*e.g.*, pharmaceutical rice from overseas in food rice), but it will not detect whether food contains a never-before-reviewed biotech ingredient, or even simply an unapproved biotech variety, particularly where the low level commingling is inadvertent or unexpected. FDA may review its standards for import alerts if policymakers see the potential for economic or health impacts of biotech crops grown overseas.

In 2006, Greenpeace and the Union of Concerned Scientists suggested that unapproved biotech rice in products imported from China could be present in the U.S. food supply, but no regulatory authorities were testing food for the unapproved rice. While this rice was showing up at low levels in Europe in rice products imported from China, U.S. regulators were not looking for it because FDA had not determined

that the biotech rice would present a risk. FDA is monitoring the situation, but so far has seen no need for broad-based genetic testing of food products.

As this article was going to press, a biotech seed company in California, Arcadia Biosciences, was planning on selling its biotech rice seeds to farmers in China as a tool to help reduce greenhouse gas (GHG) emissions. These seeds, once they clear regulatory approval, could use less nitrogen fertilizer, a major source of GHGs. The strategy also may help Arcadia contribute to the $30 billion market for carbon credits, and it could also lead to imports of biotech rice from China into the United States. No commercial biotech rice is grown in the United States at present.

C. Environmental Protection Agency (EPA)

EPA establishes standards of tolerances for pesticides, herbicides, and fungicides used in agriculture, and its role in the import process, for now, is limited to varieties that contain pesticidal properties. Tolerance level regulations are applied to all chemically-treated products intended for human and animal consumption entering the United States. This includes the regulation of biotech crops that are plant-incorporated protectants (previously known as plant pesticides) that encode B.t. or other pesticidal proteins. Any import for purposes of food or feed need not undergo field trials for this insect resistance issue. As a result, EPA holds limited authority over the import of biotech food and feed.

This summary was derived and adapted from the U.S. food and agricultural import regulations report (FAIRS). For more detail on U.S. laws covering both imports and exports of various agricultural products, please visit www.fas.usda.gov/itp/ofsts/us.html. Readers should also be aware that pending legislation regarding import issues—after the high-profile recalls of pet food and lead-tainted toys from China—may pass in the coming legislative session. Importers need to be aware of the potential for new legislation reacting to recent events.

III. Food and Feed Import Issues in BRS Draft EIS and Comments

As noted above, BRS is the program within USDA-APHIS that regulates importation, interstate movement, and environmental release of biotech crops imported in the United States. To re-evaluate its regulatory program, BRS published the Draft EIS, which provided detailed analysis of the regulatory alternatives that BRS is considering, including changes to import policies for biotech crops. This noticed approach allowed for a wide range of public comments, which are posted online at www.regulations.gov (Docket No. APHIS-2006-0112). The comment period followed a January 2004 "notice of intent to prepare an EIS" that also triggered a range of stakeholder comments. The Draft EIS evaluates the environmental impacts of the current regulations and the potential environmental effects of biotech crops, including those imported into the United States.

In addition to assessing potential changes to nine other aspects of its biotech regulations, the Draft EIS assessed whether to institute expedited review for imports of biotech commodities that have not been fully approved in the United States, but are intended for use in FFP. Generally, BRS recognized that FFP uses typically pose fewer risks than release (planting) of seeds, since the imported material would enter the environment in a form that could grow and reproduce only inadvertently, and likely in very low volumes. This reduces the chances of the biotech food or feed becoming the source of a plant pest or other problem within the United States. After considering several options, BRS proposed to establish a new regulatory mechanism covering imports of commodities for non-propagative (FFP) use, in cases where the agency has not deregulated them. BRS would create criteria that specify which commodities will be exempted from BRS review. BRS stated that it would require the importer to certify that the commodity complies with the criteria and verify that the commodity will be used only for FFP before it would exempt a commodity that had not been deregulated. BRS says that its intent is to protect the environment without creating barriers to trade in biotech commodities.
(*text continues on p. 37...*)

Figure 1—Major U.S. Laws Affecting Agricultural Imports[1]

A. Sanitary and Phytosanitary Standards

Federal Agency	***Relevant Laws and Regulations***	***Summary***
Animal and Plant Health Inspection Service, an agency of the Dept. of Agriculture	Federal Plant Protection Act, 7 U.S.C. § 7701 *et seq.*; Animal Health Protection Act, 7 U.S.C. § 8301 *et seq.*, and implementing regulations contained at 7 C.F.R. Parts 300-380, 9 C.F.R. Parts 1-199 (particularly Parts 91-99)	APHIS administers laws and regulations relating to importation or fruits, grains, animals, animal products and other commodities. Import regulations are generally based on risk assessment, taking into account the product and country of origin. Pest-risk assessment generally follows guidelines published by the International Plant Protection Convention and the North American Plant Protection Organization. Risk analysis guidelines for imports of animals and animal products are found at 62 Fed. Reg. 56,027 (Oct. 28, 1997) and generally follow guidelines published by the World Organization for Animal Health. (*See* Select Agent and Toxin List maintained by APHIS, visit http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinslist.html). 7 C.F.R. Part 340 includes regulations relating to genetically modified organisms. USDA's Biotechnology Regulatory Services requires filing of Rule 2000 permits for entry of seeds or animals, but this permitting process does not yet apply with any clarity to food and feed (some shippers are seeking advisory permitting, however). Grain commodity imports are inspected by USDA APHIS for any noxious weed threat.

[1]This chart is intended to represent a summary of the major U.S. laws relating to agricultural imports; it is not intended to be a comprehensive survey of such laws or implementing regulations. Note that the distinction between a technical barrier to trade (TBT) and a sanitary or phytosanitary standard (SPS) is often not clear, and in the U.S., the same law or regulation may contain requirements that could be classified as either a TBT and/or an SPS measure. For biotech crop approvals, however, the WTO's Dispute Resolution Body favors the application of the SPS Agreement.

Food Safety and Inspection Service, an agency of the Dept. of Agriculture	Federal Meat Inspection Act, 21 U.S.C. § 601 *et seq.*; Federal Poultry Products Inspection Act, 21 U.S.C. § 451 *et seq.*; Egg Products Inspection Act, 21 U.S.C. § 1031 *et seq.*; Humane Slaughter Act, 7 U.S.C. § 1901 *et seq.*; Agricultural Marketing Act of 1946, 7 U.S.C. § 1621 *et seq.*; and implementing regulations at 9 C.F.R. Parts 300-599	FSIS has inspection authority over meat, poultry and egg products. FSIS will evaluate whether a country's regulatory system for these commodities attains the same level of protection as the U.S. regulatory system. Only meat, poultry and egg products certified by the inspection service of an FSIS-recognized system can be imported into the U.S.
Environmental Protection Agency	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and implementing regulations at 40 C.F.R. Parts 150-180 Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 *et seq.*, and implementing regulations at 40 C.F.R. Parts 700-789	FIFRA regulates the production and use of pesticides in the United States, as well as the importation of pesticides into the United States. All pesticides intended for use in the United States must be registered with the Environmental Protection Agency, which will evaluate the adverse impacts of the pesticide. TSCA regulates production and use of toxic chemicals in the United States, as well as the importation of toxic chemicals into the United States.
Food and Drug Administration, and agency of the Dept. of Health and Human Services	Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and implementing regulations at 21 C.F.R. Parts 1-1299; Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)	FDA regulates human and animal food and drugs, with the general exception of meat and poultry (which are regulated by the Dept. of Agriculture). FDA also regulates foods and feed derived from new plant varieties, and requires genetically engineered foods to meet the same safety standards as other foods. FALCPA was enacted in August 2004, and addresses, among other issues, the labeling of foods that contain certain food allergens. FDA's authority over food and feed does not involve import inspection, but if informed of the presence of an allergen or any unapproved plant pesticidal protein in

Food and Drug Administration, and agency of the Dept. of Health and Human Services	Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq*., and implementing regulations at 21 C.F.R. Parts 1-1299; Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)	FDA regulates human and animal food and drugs, with the general exception of meat and poultry (which are regulated by the Dept. of Agriculture). FDA also regulates foods and feed derived from new plant varieties, and requires genetically engineered foods to meet the same safety standards as other foods. FALCPA was enacted in August 2004, and addresses, among other issues, the labeling of foods that contain certain food allergens. FDA's authority over food and feed does not involve import inspection, but if informed of the presence of an allergen or any unapproved plant pesticidal protein in the food or feed supply, FDA has authority to order a recall of food or feed. FDA has issued guidance in 2006 allowing early food safety assessments for biotech crops in field trials in the U.S., which allows commingling of low levels in the food and feed supply pending regulatory approval.
Federal Grain Inspection Service, an agency of the Dept. of Agriculture	United States Grain Standards Act, 7 U.S.C. § 71 *et seq*., the Agricultural Marketing Act of 1946, 7 U.S.C. § 1621 *et seq*., and implementing regulations at 7 C.F.R. Parts 810, 868	Provides standards for marketing of grains in the U.S.

B. Potential Technical Barriers to Importation of Biotech Commodities

Relevant Laws and Regulations	***Summary***
Tariff Act of 1930, 19 U.S.C. § 1304, and implementing regulations at 19 C.F.R. Part 134	Requires labeling of goods.
Federal Meat Inspection Act, 21 U.S.C. § 601 *et seq.*	Requires labeling of goods.
Federal Poultry Products Inspection Act, 21 U.S.C. § 451 *et seq*.	Requires labeling of goods.
2002 Farm Act, and implementing regulations at 7 C.F.R. Part 60	Contains requirements regarding notification of country of origin for livestock, fish, shellfish, perishable agricultural goods and peanuts. Note that implementation has been temporarily delayed for all goods except fish and shellfish.

Textile Fiber Products Identification Act, 15 U.S.C. § 70, and implementing regulations at 16 C.F.R. Part 303	Requires country of origin labeling for textiles.
Agricultural Marketing Act of 1937, 7 U.S.C. § 601 *et seq*. Agricultural Marketing Act of 1946, 7 U.S.C. § 1621 *et seq*. Implementing regulations at 7 C.F.R. Parts 27-75, 944, 980, 999, 1000-1199 (including regulations for specific commodities)	Requires imported commodities meet the same or comparable grade, size, quality and maturity requirement as those established for domestic products.
Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C § 201 *et seq*., 21 U.S.C. § 341 *et seq.* and implementing regulations at 21 C.F.R. Parts 1, 10,11, 16 and 20; *see*http://www.fda.gov/oc/bioterrorism/bioact.html	Requires foreign facilities that manufacture, process, pack and hold food for consumption in the United States to register with FDA, provide notice to FDA prior to importation, and establish and maintain records identifying sources and recipients of food. Imposes FDA recordkeeping and traceability requirements; facility registration; recordkeeping and traceability; grain-handling and processing operations; hazard analysis and critical control point; cargo containers and conveyances; inventory management and traceability; country and export port elevators.

Industry comments on the USDA draft EIS, including biotech developer Syngenta and the trade group Biotechnology Industry Organization, objected to some aspects of BRS's preferred action on the grounds that it could harm exports by U.S. producers. A particular concern was the requirement that an importer certify that the shipment complies with BRS requirements. This approach differs from the regulatory approach used in countries to which U.S. producers ship grains for food and feed use. Moreover, if applied in the same way as the current import permit program, which requires a separate permit for each import, 7 C.F.R. § 340.4(c)(2), the system could become oppressive for importers and could have negative consequences on the ability of U.S. producers to export to other countries. Syngenta specifically commented: "[The] requirement of importer certification on a per shipment basis would be unworkable for U.S. exports if it were reciprocated in other countries. Most of our trading partners require only a single certification from the product developer, not the importer. That certification addresses the safety of the product only, not of the particular use of the product." The comment goes on to suggest that APHIS develop criteria to assess risks of unapproved biotechnology commodities for FFP by drawing on APHIS' previous experience in risk assessments for domestic products, and on risk assessments developed by international organizations the United States has joined.

Syngenta and others also suggested that APHIS take into consideration assessments by the country of origin if conducted under Codex Alimentarius or Organization for Economic Cooperation and Development standards. Syngenta also supported efforts to harmonize international approval processes, to address potential market barriers, increase consumer confidence in biotech products, and expand secure access to key export markets, while ensuring that

human, animal, plant and environmental health are upheld. BIO, the trade industry association representing Syngenta and other industry members, offered similar comments.

The overall approach to imports of biotech plants for FFP that the various U.S. agencies develop is likely to have not only a significant impact on the availability of safe and cost-effective food in the United States, but on the U.S. agricultural sector's ability to compete in the world marketplace. As the first developer and significant exporter of biotech varieties, the United States needs to take a leadership position that is consistent both with protection of U.S. consumers and with the needs of the agricultural sector. Adding unnecessary complication and expense to the process of importing new biotech varieties is not desirable. The United States's policies should be as protective as its existing strong regulatory arrangement covering non-biotech foods. They need not be more protective, and should not be more burdensome to commerce than absolutely necessary to provide the appropriate level of protection.

The BRS's Draft EIS for its revised regulations is merely the first step in the process of developing new regulations covering import of FFP biotech plants. Interested parties should pay close attention to the final EIS, and to the draft regulatory revisions when they come out. There will be a valuable opportunity to comment again on the overall approach proposed, as well as on those details that may contain the devil, when the USDA issues its proposed regulations.

Thomas P. Redick *practices environmental law with Global Environmental Ethics Counsel in St. Louis, Missouri, and is editor of the Agricultural Management Committee Newsletter*. **James H. Andreasen** *is of counsel at Shook, Hardy & Bacon L.L.P. in Kansas City, Missouri. He practices environmental law and is a member of the firm's Agribusiness & Food Systems practice*. **Brandon W. Neuschafer** *is chair of the Agricultural Management Committee and an associate at Bryan Cave LLP in St. Louis, Missouri. He practices environmental law and is a member of the firm's Agribusiness, Ag Biotechnology and Food Processing Team.*