

In This Issue:

- [Section One: European Union Developments](#)
- [Section Two: United States Developments](#)
- [Section Three: International Developments](#)

SECTION I: European Union Developments

▶ Political Agreement on VOCs

On October 27, 2003, the Council reached a Political Agreement, Greece abstaining, on a proposal for a Directive (Ref.: COM(2002)750) on the limitations of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products. This future Directive will impose stricter limits for ready use paints in 12 groups of products used as decorative paints and varnishes and 5 groups of products used in vehicles refinishing to be implemented from 2007. The Commission will propose further restrictions for a second phase due to begin in 2010.

On October 25, 2003, the European Parliament had adopted its First Reading position in which it notably required that the paints and varnishes label shall be rated based on existing best practices, a derogation could be granted to old and treasured cars (up to 0.5% of total sale). It also required that paint and varnishes should not contain CMR (carcinogenic, mutagenic and toxic to reproduction) substances. The Council shall now formally adopt its Common Position at a forthcoming session and it will be transmitted to the European Parliament for Second Reading.

Claudio Mereu
Brussels

▶ Conciliation Agreement on SEVESO II Directive

On September 9, 2003, the Council and European Parliament reached an agreement in Conciliation (Third Reading of the Codecision procedure) on the future Directive (Ref.: COM(2001)624) on the control of major accident hazard involving dangerous substances. The conciliation text shall be formally adopted by the Council and Parliament in November and will be published in the Official Journal in the following weeks.

This amendment will notably extend the scope of the Directive to mining activities and disposal facilities containing dangerous substances, and to potassium nitrate industrial uses. It also requires mandatory training for staff on emergency and prevention, and Member States to establish detailed maps showing the areas of potential risks. Furthermore, the Commission shall issue by end 2006 a proposal on

■ Contact Info

If you would like more information, please contact any of the McKenna Long & Aldridge environmental attorneys with whom you regularly work. You may also contact:

Tom Johnston
202.496.7656

Michael Boucher
202.496.7729

the creation of a technical database on risk dates and risk scenarios. It should further be noted that the Council rejected the Parliament amendment on financing the relocation of dangerous sites.

Koen Van Maldegem
Brussels

▶ **Emissions Trading**

On October 13, 2003, the European Parliament and Council adopted in Second Reading Directive 2003/87/EC establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC. It will have to be implemented by Member States very soon, namely by December 31, 2003. Greenhouse gas emission permits will have to be required by January 1, 2005, unless the installation is temporarily excluded under Article 27. If installations are also covered by the IPPC Directive (Directive 96/61/EC) conditions and procedures for IPPC and greenhouse gas emissions permits have to be coordinated. The Directive aims to reduce greenhouse gases in the framework of the Kyoto Protocol obligations. It sets a first phase of trade 2005-2007, which precedes the Kyoto's first commitment period, 2008-2012.

During the first period of the Community scheme, 95% of the emission allowances granted by the Member States to the industrial plants shall be free of charge. The scope of the scheme is restricted to those large industrial activities listed in Annex I (energy (combustion, mineral oil, refineries, coke ovens), steel, cement, glass, ceramics and pulp/paper/board production) and to the greenhouse gases listed in Annex II (6 gases: CO₂, CH₄, N₂O, HFCs, PFCs, SF₆, whereas the initial proposal contained only CO₂). Member States may, however, apply to the Commission to have certain installations excluded until the end of the first phase. In the meantime, the Commission is due to issue a proposal on the inclusion of other sectors and a guidance document on the force majeure circumstances.

As a next step, Member States will now on short notice have to develop national allocations plans (Article 4) stating the total quantities of allowances to be allocated and a proposal how to allocate them. Those Member States that do not have the data at hand are expected to now demand emissions data from industry.

Ursula Schliessner
Brussels

▶ **Future Chemicals Policy**

On October 29, 2003, the Commission released its long awaited final proposal for a Regulation concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and the Regulation on Persistent Organic Pollutants (Ref.: COM (2003)644).

A previous draft had been released in May for stakeholder consultation purposes. This proposal is now sent to the Council and the European Parliament for Codecision procedure. Due to the length of the procedure, its broad impact of the whole industry and the environment, as well as the existing intensive lobbying, it is expected that this Regulation should not be in place before 2006.

See

<http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm> and
MLA's News Advisories at <http://www.mckennalong.com/news-advisory.html>.

[Robert Matthews](#)
Washington, DC

▶ **Amendment to the WEEE Directive**

On October 21, 2003, the European Parliament adopted in First Reading the proposal for an amendment to Directive 2002/96/EC on Waste Electrical and Electronic Equipment. Directive 2002/96/EC was adopted on January 27, 2003 to introduce mandatory collection, re-use and recycling of waste electrical and electronic equipments financed by the producers. The proposed amendment intends to clarify the rules applying to the financing of historical waste from non-household sources in a way not to over burden historical producers.

[Ruxandra Cana](#)
Brussels

▶ **Integrated Product Policy**

On October 27, 2003, the Council adopted its conclusion on the Commission Communication on the Integrated Product Policy, Building on Environmental Life Cycle Thinking (Ref.: COM(2003)302). The Commission had sent this proposal to the Council and the European Parliament for a consultation on a future Community policy. The Parliament has not yet begun its work on this procedure.

The Council notably underlined the role of IPP as a link between production and consumption and the sustainable use of natural resources and recalled that the IPP approach should be extended to services. The IPP also requires improving the quality of the environmental information provided to consumers and strengthening the Community guidelines on green claims.

[Ruxandra Cana](#)
Brussels

▶ **Groundwater Protection**

On September 19, 2003, the Commission adopted a Proposal for a Directive on the protection of groundwater against pollution (Ref.: COM(2003)550). It will introduce monitoring requirements and quality objectives, obliging Member States to monitor and assess groundwater quality and will prohibit or limit discharges of chemicals. Notably it proposes a maximum limit of 0.1 µ / liter for active ingredients in pesticides, including their relevant metabolites from 2006. Member States would also provide by that date a list of the pollutants for which they have established threshold values.

[Koen Van Maldegem](#)
Brussels

▶ **Århus Convention**

On October 24, 2003, the Commission adopted the last three proposals for the ratification and the implementation into the EU legal framework of the 1998 Århus

Convention on access to information, public participation in the decision-making process and access to justice on the environment (Ref.: COM(2003)622, 624 and 625). On this issue two Directives (2003/4 and 2003/35) were already adopted this year.

The proposals aim to complement the existing measures, notably in guaranteeing public access to documents from all EU bodies and institutions (and not only from Commission, Parliament and Council) and recognizing to NGOs a status of qualified entities at EU or national level, which means they are qualified to have access to environmental proceedings, including interim relief within the sole condition that the matter is covered specifically by their statutory and geographical activities. The qualified entities can furthermore request the internal review of administrative acts or omissions taken at EU level. Where the qualified entity is not satisfied by the institution's answer, it can seize the Court of Justice on the issue. This right is not recognized for private companies or industrial representatives, who still need to demonstrate direct and individual concern to gain admission before the EU Court.

The proposals also notably set basic conditions on access to justice on environmental matters, leaving to Member States to determine the implementation details, such as which courts and which instances will be responsible for handing these cases. It recognized the right of citizens and their representing organizations to challenge not only actions or omissions of the public authorities, but also actions or omissions of private persons or companies which infringe environmental law. The sole condition for action is to be directly affected by the challenged act. The draft legislation also does not recognize similar right to private companies at the national level.

Claudio Mereu
Brussels

▶ **Energy Tax**

On 27 October, 2003, the Council adopted the Directive 2003/96/EC restructuring the Community framework for the taxation of energy products and electricity. This Directive widens the scope of the 1992 Community minimum rate systems, currently limited to mineral oils.

Energy products covered by the Directive (numerous exemptions, see Article 2 (4)) and used or offered as motor or heating fuel shall be taxed according to their use. Unless a level of taxation is specified in this Directive (Annex I), the product is taxed at the rate for the equivalent heating fuel of motor fuel. Business use of energy products may be taxed at a lower rate than non-business use. The Directive sets minimum levels of taxation applicable from January 1, 2004 in a first step. At a latter stage, the Council shall adopt minimum taxation levels applicable to gas oil for a further period beginning on January 1, 2013. Annex II to this Directive lists numerous national tax reductions or exemptions which will remain applicable.

The Member States shall implement this Directive by December 31, 2003 and apply it as of January 1, 2004.

Ursula Schliessner
Brussels

▶ **EU Introduces Biosafety Regulation**

Regulation No. 1829/2003 implementing the Cartagena Protocol on Biosafety has

been published in the EU's Official Journal and will become part of Community law on November 7, 2003. Member States have until April 18, 2004 to bring national legislation into line with the new Regulation, which covers the transboundary movements of genetically modified organisms (GMOs). The European Commission must review the Regulation no later than November 7, 2005. The European Parliament passed the second reading of the proposed Regulation in June 2003.

Claudio Mereu
Brussels

▶ **EU Posts Information on Regulation of Ag Biotech Crops and Food**

The European Union has posted a document on its web site a document titled "Questions and Answers on the Regulation of GMOs in the EU" which is a fact sheet that covers legislation in force in the EU and the regulations on traceability and labeling which will soon enter into force. The document deals with questions such as -What is the current legislation on GMOs? How does the environmental risk assessment procedure work? What is the procedure for approval for release of GMOs into the environment? Are the new labeling rules in line with the international trade rules? The document can be found at the following address:

http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/03/196|0|RAPID&lg=EN.

Edwin L. Johnson
TSG, Washington, DC

[▶ Back to top](#)

SECTION II: United States Developments

▶ **Democrats Consider Changes Based on EU Chemical Policy**

On November 14, 2003, EPA reported that influential Democrats in Congress, including Senator Frank Lautenberg (N.J.), are considering an overhaul of the chemical regulatory scheme in the United States based on the REACH proposals developed by the European Commission, which would greatly increase the authority of U.S. regulators to control the marketing and use of chemicals in the United States. U.S. companies are concerned about strict testing requirements and about use of the precautionary principle, which would prohibit the use of a chemical until its safety were affirmatively proven. Democrats are expected to introduce legislation next year to rewrite TSCA to bring it in line with the European Commission's REACH proposals, but getting such changes approved will be difficult in the Republican-controlled Congress. Alternatively, Democrats may wait until the Europeans finalize their REACH proposals and/or conduct further discussion regarding implementation in Europe, before proposing any new chemicals legislation in the United States. Meanwhile, Congress continues work to amend existing chemicals laws (TSCA and FIFRA) to implement obligations of the United States under a treaty governing persistent organic pollutants (POPs).

Michael Boucher
Washington, DC

▶ **Institute Reports on Perceptions of GM Food**

A report entitled "Public Perception of Genetically Modified Foods: A National Study of American Knowledge and Opinion" was released by the Food Policy Institute at Rutgers University. The report presents the results from the second phase of the study of Americans' knowledge and feelings about agricultural biotechnology, and how those perceptions and attitudes have changed over time. Highlights of the study indicate that Americans pay little attention to agricultural biotechnology and opinions on GM food are easily influenced. The study concluded that continuing developments in biotechnology will significantly impact the future of food and agricultural, and in coming years important policy decisions will determine the direction of these developments. Because of the important economic, social and environmental consequences of these decisions, public perceptions of the technologies should play a key role in them. Copies of the report are available at www.foodpolicyinstitute.org.

Edwin L. Johnson
TSG, Washington, DC

▶ **EPA Revises Pesticide Labeling Manual**

The EPA Office of Pesticide Programs (OPP) announced that an updated version of the Agency's revised Pesticide Label Review Manual was posted on the Agency's website. The purposes of the Manual, which has not been revised since 1996, are to serve as a training tool for OPP's employees and guidance for project management team members responsible for performing label reviews. In addition, the Manual may be useful to state regulators, registrants and other individuals interested in producing readable, unambiguous pesticide labels. The Manual may be found at <http://www.epa.gov/oppfead1/labeling/lrm/>.

Edwin L. Johnson
TSG, Washington, DC

▶ **FDA Releases New Bioterrorism Regulations**

On October 10, 2003, the U.S. Food and Drug Administration (FDA) published the interim final regulations that require (1) registration with FDA of all domestic and foreign food facilities that manufacture/process, pack or hold food for human or animal consumption in the United States and (2) advance notice to FDA of any shipment of human or animal food imported or offered for import. The first regulation will allow the agency to maintain a complete roster of foreign and domestic food facilities in order to enable quick responses in the event of accidental or deliberate contamination of food. It is expected that approximately 420,000 facilities will register under this requirement. The second regulation will allow FDA to know in advance when food shipments will be arriving at U.S. ports, where they will be arriving, and what they contain. This is key to enable FDA to work with U.S. Customs to more effectively target cargo inspections. FDA expects to receive approximately 25,000 such notifications each day.

Both regulations will be effective and enforceable on December 12, 2003. They were issued as part of the plan to bolster the safety and security of America's food supply and implement several key provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This Act provided FDA with the authority to protect the nation's food supply against actual or threatened terrorist acts and other food-related emergencies. To view the Regulations and fact sheet, visit <http://www.fda.gov/oc/bioterrorism/furls/>.

Sarah Lukie

Washington, DC

▶ EPA Scientists Publish Journal Article on Safety of Bt Crops

A recent publication by EPA scientists and regulators described the approach that has been taken by federal agencies in the evaluation of crops that have been genetically engineered to express genes from *Bacillus thuringiensis* (Bt). The article, published in *Nature Biotechnology* in September by Mike Mendelsohn and others, noted that crops genetically engineered to have pesticidal traits are overseen by three federal agencies: the EPA, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). EPA's oversight focuses on the safety and potential environmental impacts of the pesticidal substance, the delta-endotoxin in the case of BT plants. FDA may be consulted to determine whether the crop itself is equivalent to conventional counterparts and USDA determines whether the crop will be regulated as a plant pest.

EPA prepares a comprehensive scientific assessment to assess potential impacts of the genetically modified crop on human health and the environment. The health assessment of the engineered plant evaluates the fate of the protein after ingestion and the potential for allergenicity or other forms of the toxicity. The environmental assessment includes evaluation of the potential gene transfer to other plants, toxicity to non-target organisms such as butterflies, and the fate of the protein in the environment.

The authors of the *Nature Biotechnology* article concluded that none of the plants genetically engineered to express the BT gene shows characteristics of food allergens or other toxic substances. The EPA review also noted that, for the most part, the engineered plants "do not have a reasonable possibility of passing their traits to native plants" and that the proteins, once released into the environment, do not have effects on biota. BT crops are not expected to cause widespread or irreversible harm to insect populations. While extending the time-limited registrations, EPA requested additional confirmatory data to show protection of non-target insects, breakdown of the protein in soil and that measures are being taken to limit gene flow from BT cotton to weedy relatives.

Gary Burin, PhD TSG, Washington, DC

▶ EPA Expedites Reviews for Certain Experimental Use Permits

Pesticide Registration Notice (PR Notice) 2003-2 provides guidance to applicants for Experimental Use Permits (EUPs) for products that may replace methyl bromide or organophosphates or which otherwise qualify as reduced-risk pesticides. Dietary risk assessments required by the FQPA and ecological risk assessments required by the ESA have caused the review times for EUP applications to approach the time required for approval of a full registration under FIFRA § 3. As a result, fewer EUP applications have been filed in recent years. EPA has determined that it can review the foregoing types of EUP applications on an expedited schedule, without impacting its review priorities for other pesticide actions, in the following circumstances:

1. The EUP application is not for a food use, a tolerance or tolerance exemption for the active ingredient exists, or the application provides for the destruction of the treated crop.

2. The proposed use rates, application methods and exposure levels are similar to already approved products having the same active ingredient.
3. The proposed use does not result in increase in residential, worker or bystander exposure.
4. The proposed use would not result in aggregate or cumulative exposure exceeding the acute or chronic population adjusted dose.
5. The application proposed use on less than 2,000 total acres for a major use or less than 100 total acres for an aquatic or a minor use.
6. The proposed use includes no more than 100 acres for watershed.
7. The use will occur where no endangered species exist or the Level of Concern for species that are present will not be exceeded.

Expedited EUP applications must meet all of the FIFRA § 5 and 40 C.F.R. part 172 requirements and include a justification as to why the application poses a minimal burden on the Agency. PR Notice 2003-2 is found at http://www.epa.gov/opppmsd1/PR_Notices/pr2003-2.pdf.

Robert R. Stewart, PhD
TSG, Washington, DC

[↗ Back to top](#)

SECTION III: International Developments

▶ Philippines Issues Guidelines for Small Quantity Importation Exemption

On October 2, 2003, the Philippines' Department of Environment and Natural Resources (DENR) issued guidelines describing the requirements for the "Small Quantity Importation" (SQI) exemption from new substance notification requirements under the country's Toxic Substance, Hazardous and Nuclear Waste Act. SQI is any importation into the Philippines of a new chemical substance below an accumulated total of 1,000 kg/year, either in neat form or as a component of a commercial mixture (product). Importers wishing to obtain a SQI exemption must file an application with DENR containing the following information: identity of the new chemical substance (chemical name, CAS number, chemical structure); the percentage of the new substance in the product or mixture (if applicable); and the weights (kg) in which the product or mixture will be supplied. The applicant also must ensure that imports do not exceed 1,000 kg/year, keep records of imports, submit such records within 60 days of an arrival, and file an annual report by January 15 of the following calendar year. If the applicant complies with the foregoing requirements, DENR will provide the Philippines' Bureau of Customs a copy of the SQI, to facilitate lawful importation of the new chemical substance.

Michael Boucher
Washington, DC

▶ China Issues New Chemical Notification Law

Effective October 15, 2003, China has a new chemical notification law, "Provisions on the Environmental Administration of New Chemical Substances." A copy of the new law is available at <http://www.crc-sepa.org.cn/newchem/ewchem.htm>. Chemical substances not in commerce in China as of October 15, 2003 are deemed "new chemical substances" and are subject to notification to the State Environmental Protection Agency (SEPA). How an exporter will be able to prove that a chemical

substance was in commerce in China on October 15, 2003 is not presently clear. Importers will be able to obtain a "registration certificate" for their chemical substances by submitting a notification package to SEPA, including required toxicity and ecotoxicity testing (data). For the time being, ecotoxicity testing must be performed in China, and toxicity and other testing done outside China must be pre-approved by SEPA. The new law contains notification exemptions for small quantities used in scientific research, monomers in polymers below 2 percent (2%) by weight, and chemical samples intended for ecotoxicity testing in China. A special "technology" exemption also is available to qualified research-and-development substances for a period of up to one year, but there no detailed guidance yet interprets or further explains this exemption. Industry eagerly awaits further guidance and clarifications from SEPA regarding the new law, to resolve a variety of questions and issues.

Michael Boucher
Washington, DC

▶ **Cartagena Protocol on Biosafety Impacts Non-Parties**

On September 11, 2003, the Cartagena Protocol on Biosafety (Protocol) entered into force - the first legally binding international agreement governing the movement of living modified organisms (LMOs) across national borders. Following entry into force, those countries that ratified the Protocol became Parties to the Protocol and are now required to comply with and implement all its provisions. However, Party countries are not the only countries that are affected by its requirements. Article 24 of the Protocol states that transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objectives of the Protocol - in other words, countries like the United States and Canada that have not ratified the Protocol but that export LMOs to Parties must also comply with the Protocol's provisions implemented in the importing country. Thus, entry into force will ultimately impact both Party and non-Party countries that export LMOs to countries that are Parties to the Protocol and that have national implementing legislation.

Although the Protocol is now in effect, many Party countries have not yet developed and implemented national biosafety legislation. Further, it has not yet been defined as to what, in practice, is actually required by many of the provisions of the Protocol. The member countries of the Protocol will convene to address topics related to the operation and implementation of the Protocol; however, this meeting does not take place until February 2004. As such, until that date, non-Party countries often do not have any legislation, regulations or directives that outline how they are to abide by the provisions of the Protocol in many countries to which they export LMOs. For information on how this problem may be addressed by companies and governments alike, please contact the author.

Sarah Lukie
Washington, DC

▶ **UN Groups Consult on Food from GM Animals and Fish**

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) are convening an expert consultation on "Safety assessment of foods from genetically modified animals including fish" on 17-21 November 2003 in Rome, Italy to provide advice to FAO/WHO and their Member countries on the safety assessment of foods derived from GM animals, including fish, and to discuss other potential risks (including environmental and ethical issues)

associated with these foods. A number of working papers plus the summary report will be provided (in English) on the web, once available. "Animal biotechnology: State of the art, risks and perspectives", a 40-page background document (available in English and French), describing technical, environmental, animal health and welfare, food safety, regulatory and societal aspects of GM animals, is currently accessible. See http://www.fao.org/es/ESN/food/risk_biotech_animal_en.stm or contact food-quality@fao.org for more information.

Edwin L. Johnson
TSG, Washington, DC

▶ **Canada Requires Environmental Emergency Plans**

On September 10, 2003, Environment Canada issued final regulations in the Canada Gazette requiring Canadian commercial and industrial facilities owning or controlling amounts of 174 listed substances to prepare and implement environmental emergency plans. Some of the substances serve as active ingredients in pesticides. The new regulations become effective on December 9, 2003. Environmental Emergency Regulations target small and medium-sized chemical plants, which are not likely to have emergency plans in place. The regulations are intended to better protect the environment and Canadians' safety against uncontrolled, unplanned, or accidental release of a toxic or hazardous substance into the environment.

Initially, facilities have 90-days from the above enforcement date to submit information to Environmental Canada on quantities of these substances they are storing. After the 90-day period, facilities have six months to submit a Notice of Preparation, or E2 plan, and up to one year to implement the plan. E2 plans must be tested and updated annually. The Environmental Emergency Regulations are similar to the Risk Management Planning Regulations in the United States under the Clean Air Act.

Under the E2 regulations, any facility storing or using a listed substance above specified thresholds, or that has a container with a capacity for the substance in excess of the specified quantity will have to notify Environment Canada of the place where the substance is held, along with the maximum expected quantity and size of the largest container for that substance. If both the above criteria are exceeded the facility is required to prepare and implement an environmental emergency plan and notify Environment Canada. Exemptions from the reporting requirements include:

1. Short-term storage of these substances (less than 72 hours);
2. Storage of 30 kilograms or less of the listed substance;
3. Gaseous or liquid substances at low pressure; and
4. Subdivision of the schedule of designated substances into flammable and other hazardous substances.

Environment Canada will provide limited public access to the E2 plans though it intends to keep confidential any information that might be the target of terrorist activity. Environment Canada estimates that 1,500 facilities will be affected by the new regulations. The complete list of the substances and notice are available at <http://canadagazette.gc.ca/partII/2003/20030910/html/sor307-e.html>.

Heather Bjornson
TSG, Washington, DC

■ About Us

McKenna Long & Aldridge LLP is a full-service law firm of approximately 375 lawyers and public policy advisors in the areas of corporate law, government contracts, IP and technology, litigation, public policy and regulatory affairs, real estate, environmental law and finance.

Technology Sciences Group Inc. (TSG) is a global consulting firm focused on regulatory issues relating to chemicals, pesticides, agriculture and the environment.

■ Subscription Info

If you would like others to receive our future mailings, please email their contact information to us at information@mckennalong.com

If you would like to be removed from our International Environmental Monitor mailing list, please email information@mckennalong.com

*This **International Environmental Monitor** is for informational purposes only and does not constitute specific legal or technical advice or opinions. Such advice and opinions are provided by McKenna Long & Aldridge LLP or Technology Sciences Group, Inc. only upon engagement with respect to specific factual situations.

• Atlanta • Brussels • Denver • Los Angeles • Philadelphia • San Diego • San Francisco • Washington D.C.

©Copyright 2003, [McKenna Long & Aldridge LLP](#)
