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SECTION I: European Union Developments

▶ Commission Consults on Nanotechnology

On July 30, the Commission launched an open consultation on its Communication entitled "Towards a European Strategy for Nanotechnology" (Ref.: COM(2004)338 of May 12). The Deadline for submission of comments on the web-site www.nanoforum.org is September 30, 2004. The Commission will prepare a report based on the outcome of this survey and an "Action Plan" will follow later this year.

You can access the text of the Commission Communication at the following location:
http://europa.eu.int/eur-lex/en/com/cnc/2004/com2004_0338en01.pdf

The preliminary risk analysis published by the Commission in May located at:
http://europa.eu.int/comm/health/ph_risk/documents/ev_20040301_en.pdf

You also can consult MLA's *EU Environmental Law Bulletin* at the following location:
<http://www.mckennalong.com/attachment.html/articles/976/European+Strategy+for+Nanotechnology.pdf>

[Ursula Schliessner](#)
Brussels

▶ New Non-Food Scientific Committees Replace Former Committees

On July 23, the Commission published the list of experts appointed as members of three new Scientific Committees (Ref.: OJ (2004) C188/2). The experts are appointed for a term of three years. These experts have been named following the Commission Decision of March 3, 2004 (Ref.: Decision 2004/210/EC) setting up Scientific Committees in the field of consumer safety, public health and the environment. These Committees replace the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP), the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD).

Below you will find the name, mandate and web page of each new non-food Scientific Committee:

■ 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

Scientific Committee on Consumer Products (SCCP)

- **Mandate:** Questions concerning the safety of consumer products (non-food products intended for the consumer). In particular, the Committee will address questions about the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing.
- http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/04_sccp_en.htm

Scientific Committee on Health and Environmental Risks (SCHNER)

- **Mandate:** Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment. In particular, the Committee will address questions about new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g., new organic substances), drinking water and indoor and ambient air quality. It will also address questions relating to human exposure to mixtures of chemicals, sensitization and identification of endocrine disrupters.
- http://europa.eu.int/comm/health/ph_risk/committees/04_scher/04_scher_en.htm

Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)

- **Mandate:** Questions concerning emerging or newly-identified risks and on broad, complex or multi-disciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk-assessment bodies.
- http://europa.eu.int/comm/health/ph_risk/committees/04_scenihhr/04_scenihhr_en.htm

Ruxandra Cana
Brussels

► **New European Commission**

On August 12, the incoming President of the European Commission, José Manuel Barroso, designated the portfolios of 25 new Commissioners.

The new Commission will take office on November 1, for a term of five years. The list of Commissioners must be adopted by the Council, then approved by the European Parliament. The hearings of individual candidates by the Members of the European Parliament (MEPs) will begin on September 27.

Several of the current Directorates General (DGs) have been split, and some were renamed. The Commission's structure will be as follows:

Commission President: José Manuel Barroso (Portugal)

Institutional Relations and Communication Strategy	Margot Wallström (Sweden) <i>Vice-President</i>
Enterprise and Industry:	Günter Verheugen (Germany) <i>Vice-President</i>
Transport:	Jacques Barrot (France) <i>Vice-President</i>
Administrative Affairs, Audit and Anti-Fraud:	Siim Kallas (Estonia) <i>Vice-President</i>
Justice, Freedom and Security:	Rocco Buttiglione (Italy) <i>Vice-President</i>
Information Society and Media:	Viviane Reding (Luxembourg)
Environment:	Stavros Dimas (Greece)
Economic and Monetary Affairs:	Joaquim Almunia (Spain)
Regional Policy:	Danuta Hübner (Poland)
Fisheries and Maritime Affairs:	Joe Borg (Malta)
Financial Programming and Budget:	Dalia Grybauskaite (Lithuania)
Science and Research:	Janez Potocnik (Slovenia)
Education, Training, Culture and Multilingualism:	Ján Figel (Slovakia)
Health and Consumer Protection:	Markos Kyprianou (Cyprus)
Enlargement:	Olli Rehn (Finland)
Development and Humanitarian Aid:	Louis Michel (Belgium)
Energy:	László Kovács (Hungary)
Competition:	Neelie Kroes-Smit (Netherlands)
Agriculture and Rural Development:	Mariann Fischer Boel (Denmark)
External Relations and European Neighbourhood Policy:	Benita Ferrero-Waldner (Austria)
Internal Market and Services:	Charlie McCreevy (Czech)
Employment, Social Affairs and Equal Opportunities:	Vladimir Spidla (Czech)
Trade:	Peter Mandelson (United Kingdom)
Taxation and Customs Union:	Ingrida Udre (Latvia)

Iraxte Ballesteros **Brussels**

▶ European Parliament Questions New Future Environment Commissioner

On September 1, the Environment Committee of the European Parliament adopted a questionnaire for the new Commissioner for Environment, Stavros Dimas. The hearing of Mr. Dimas by the Parliament should take place at the end of September.

The Members of the European Parliament (MEPs) notably focused their questions on (1) the implementation of the principle of integration of environmental concerns into all EU policies, (2) the Kyoto Protocol, (3) the reinforcement of the concept of environmental liability, (4) the promotion of voluntary instruments on certain issues, and (5) the need

for a broader access to documents on the environment and the reduction of documents classified as sensitive.

The MEPs also want to compare Mr. Dimas' views with his predecessor's, notably on the proposed REACH Regulation. REACH is presented as the biggest challenge for the new Commission in the field of environment. MEPs wish to question the Commissioner on his commitment to meet the Spring 2006 target for the implementation of the future Regulation. They also are concerned by the limitations on animal testing and the need to ensure resources for the validation of non-animal alternative test methods.

MEPs further require the Commissioner to take measures to support successful implementation of the Walter Framework Directive, and to present legislative measures in the framework of the environment and health strategy and on obsolete pesticides disposal. They further suggest that the comitology procedure should be modified in order to give a role to the European Parliament in cases where the Council cannot reach a qualified majority on Commission proposals (notably on the Genetically Modified Organism (GMOs) cases).

Claudio Mereu
Brussels

▶ **Implementation of Environmental Law**

On July 7, the Commission adopted the fifth annual survey on the implementation and enforcement of Community environmental law for the year 2003 (Ref.: SEC(2004) 1025). According to this report, transposition of environmental law presents serious shortcomings in many Member States: One third of all complaints and infringements cases concerning non-compliance with EU law concern environmental legislation. In 2003, there were 88 cases of late transposition, 118 cases of incorrect transposition and 95 cases where Member States did not adopt the requested secondary measures. France, Greece, Ireland, Italy and Spain present the worst records. The full text of the report is available at the following location:

http://europa.eu.int/comm/environment/law/5th_en.pdf

Koen Van Maldegem
Brussels

▶ **Commission Creates Food Chain Advisory Group**

On August 6, the Commission adopted a Decision creating an advisory group on the food chain and animal and plant health (Ref.: Decision 2004/613/EC). The group will be composed of 45 members from representative European bodies in the fields of consumer protection, food industry, retailers and farmers.

The Commission will consult the group on food and food safety, food and feed labeling and presentation, human nutrition, food legislation, animal health and welfare, crop protection, plant protection products and residues thereof, and the marketing of seed and propagation material, including matters pertaining to industrial property.

Some experts and representative bodies may be invited by the group. However, a number of documents and discussions will be confidential and will not be made available to the public. The advisory group on the food chain and animal and plant health is replacing the Advisory Committee on Foodstuffs and the standing groups on veterinary

matters, plant health, animal welfare and feedingstuffs.

Ursula Schliessner
Brussels

▶ **Commission Publishes New Maximum Residue Limits for Pesticides**

On August 27, the European Commission published its MRLs sorted by crop, pesticide and food committee, which are posted at the following locations respectively:

<http://europa.eu.int/comm/food/plant/protection/resources/08-04.pdf>

<http://europa.eu.int/comm/food/plant/protection/resources/08-04-2.pdf>

<http://europa.eu.int/comm/food/plant/protection/resources/08-04-3.pdf>.

Edwin L. Johnson
TSG, Washington, DC

▶ **CGIAR and GM Presence in *ex situ* Germ Plasma Collections**

The Genetic Resources Policy Committee of the Consultative Group on International Agricultural Research (CGIAR) is working with industry (including Monsanto and DuPont) and other organizations to develop a policy response to the spread of DNA from genetically modified plants to other varieties. The two-and-a-half-day meeting was held in Rome beginning on Monday, August 30, 2004. The workshop focused on the following issues:

- Overview of EU, U.S. and other codes of practice on adventitious DNA.
- Identification of critical issues in *ex situ* germ plasma management.
- Cost estimates and procedures for carrying out screening and safe depositing in *ex situ* collections.

The meeting was limited to 30 invited participants. Some civil society groups have complained that they, farmers' organizations and development agencies have not been invited. We can expect a report of the meeting to be posted in the future. The meeting agenda can be found at the following location: www.etcgroup.org.

Edwin L. Johnson
TSG, Washington, DC

▶ **EU Accedes to IPPC**

On July 19, 2004 the Council of the European Union approved the application for accession of the European Community to the International Plant Protection Convention (IPPC). This convention was adopted by the UN Food and Agriculture Organization (FAO) in 1951, with subsequent revisions in 1979 and 1997, the latter as part of the Uruguay Final Round Act. Forty three countries, including four EU Member States, have accepted the revised text. One of the primary objectives of the IPPC is to secure "common and effective action to prevent the spread and introduction of pests of plants and plant products, and to provide appropriate measures for their control." The Council Decision (published in the OJ, L267, dated 14 August) also includes the text of the IPPC. This includes outlines of restrictions by member countries to prevent entry of potentially

diseased or disease-carrying plant or animal materials.

Nick Leeming
TSGE, Knaresborough, UK

▶ **Pesticide News**

On August 31, the Commission of the European Communities adopted a decision to extend the provisional authorization granted for the new active substances etoxazole (application in 1998 by Sumitomo Chemical Agro Europe SA, rapporteur Spain, draft assessment report submitted October 2001) and carvone (application in 1997 by Luxan BV, rapporteur Netherlands, draft assessment report submitted October 2000). Provisional authorizations were granted for up to three years. However, it has been necessary to request additional information from both applicants, and to have the rapporteurs assess that information and submit their assessments to the European Food Safety Authority (EFSA). As there are no immediate adverse concerns, the existing provisional authorizations have been extended for 24 months, by which time it is anticipated that a decision on possible Annex I inclusion will have been made.

Work is still progressing on drafting the enabling regulation for the Fourth Phase of Directive 91/414, which will deal with the remaining active substances not already covered by the first three phases. This document is available as doc 10157 Rev 6 on the Commission website:
http://europa.eu.int/comm/food/plant/protection/evaluation/review_programme_en.pdf.

It is anticipated that the approach will be modified (i.e., less stringent) for low-risk actives, but not necessarily for low-volume actives. There will be emphasis on scientifically-based arguments for data waivers. The notified active substances are listed in annexes IA to IF. Dossiers are due June 30, 2005 for actives in Annex IA, and by November 30, 2005 for active substances in Annex IB to IF. Substances already authorized for use in food and feedingstuffs do not require a dossier at present, but Member States may require renewal of authorizations. Similar active substances will be grouped together, and there will be one 'lead' rapporteur for each group, although individual actives will have their own rapporteurs within each group. The lead rapporteur will attempt to ensure that the individual actives within a group are assessed fairly. Each Member State will be able to charge a fee for the evaluation, and there is provision for the lead rapporteurs to also charge for their time.

The EU Commission website also gives the latest contacts within the Member States regulatory authorities:
http://europa.eu.int/comm/food/plant/protection/evaluation/index_en.htm.

Nick Leeming
TSGE, Knaresborough, UK

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SECTION II: United States Developments

▶ **USDA Required to Disclose Field-Testing Locations**

A judge ruled in late August that the U.S. federal government must reveal where companies are growing genetically modified pharmaceutical crops in the state of Hawaii. In 2004, a group of public interest groups led by the Center for Food Safety filed a

lawsuit against the U.S. Department of Agriculture (USDA), arguing that the agency issued permits for open-field testing without conducting the appropriate environmental and public health assessments that would identify potential risks to the environment, people and the food supply. They stated that the reason for the lawsuit was to force the government to study the environmental impact of the crops that they see as potentially dangerous. The Biotechnology Industry Organization (BIO) was subsequently granted intervener status in the lawsuit on behalf of the biotech industry. The government and the industry joined together to state that public disclosure could possibly lead to crop vandalism and corporate espionage of trade secrets.

U.S. District Court Judge David Ezra ruled against USDA and BIO and issued an order for the agency to identify where four companies had received permits for plant-made pharmaceutical field trials in Hawaii and to inform the public interest groups of the field-trial locations. He also gave USDA 90 days to prove that releasing this information to the public would cause "irreparable damage to the biotech industry." If USDA is not successful in making this argument, it will be the first time in the U.S. that locations of biopharm tests would be revealed to an outside party, which could set a precedent for similar disclosure in other jurisdictions.

[Sarah Lukie](#)
Washington, DC

▶ **Mars Subsidiary in Mexico Recalls Products Containing Lead**

On August 20, the California Department of Health Services announced that candy manufacturer Mars, Inc. agreed to withdraw three Lucas brand products which may have high levels of lead from their Mexican subsidiary, Effem Mexico y Compania. The seasoning products or candies, which are comprised of chili powder, salt and sugar combinations, are alleged to pose a high risk for children and pregnant women. A lawsuit was recently brought by the California Attorney General's office under California Proposition 65 (Safe Drinking Water Toxic Enforcement Act of 1986) in order to persuade the manufacturer to provide the consumer with a printed warning regarding the lead content.

The company has denied that the powders contain harmful levels of lead, blaming the findings on faulty testing procedures in the United States. However, public health departments in California, Chicago and Milwaukee have warned consumers about the products, which are sold mostly in Hispanic grocery stores in 16 states and are popular with children.

This lawsuit has been compared to the 2002 enforcement action against domestic chocolate manufacturers, including Hershey and Mars, which were said to have high levels of lead in their products. However, the main difference between the two cases is in the manufacturing process. The Attorney General considered that the lead and cadmium found in chocolate were "naturally occurring" and that the manufacturers used the best manufacturing practices to reduce the amount of these substances in the products. The matter was dismissed as lacking merit. This time, however, the Attorney General believes that the Mexican manufacturers are not doing enough to remove or lower the exposure. A bill (AB 2451) to limit lead in candies containing chilies and tamarind and require the State of California to test these types of products for lead won Senate approval but still faces a vote in the Assembly. It is unknown whether Governor Schwarzenegger will sign the bill.

[Ann Grimaldi](#)
San Francisco, CA

▶ California Proposition 64 - B&P 17200 Initiative

Over the years, hundreds of companies doing business in California have been sued under California's Unfair Competition Law, codified at Business & Professions Code section 17200. Unfair Competition Law claims usually are also alleged in Proposition 65 enforcement actions.

Unfair Competition Law litigation is seen by many as the effort of unscrupulous attorneys abusing the law to generate monetary settlements. There is a perception too that the abuses of this law goes even further when those same lawyers represent themselves as plaintiffs. In an effort to reform this perceived controversial practice, many companies, including Microsoft, Nike, General Motors, Bank of America, Blue Cross, State Farm, and an array of car dealerships, are supporting Proposition 64, a November ballot initiative to overhaul the Unfair Competition law. The proponents of Proposition 64 contend that this proposition will stop unscrupulous attorneys from filing lawsuits with no actual clients and no evidence of harm.

The legislation being contemplated would provide fixes to many perceived problems regarding Unfair Competition Law litigation. Proposition 64 would limit an individual's right to sue to situations in which the person suffered actual injury or financial loss because of an allegedly unfair practice. Additionally, it would allow only the state attorney general or local public officials to sue on behalf of the public at large to enforce the Unfair Competition Law. Interestingly, however, the initiative contains a provision that prevents it from being amended by the Legislature in any way. Opponents maintain that the initiative is a guise for large corporations to limit their liability, accountability, and unfair practices, which could mean millions of dollars in savings to these companies.

Representatives from environmental organizations have been attempting to craft a legislative compromise with the current administration. Governor Schwarzenegger may sponsor a last-minute bill that could undergo less public scrutiny and the business lobby is concerned that the Governor could support a bill that would fine-tune the Unfair Competition Law to curb abuses, which could reduce the chance that Proposition 64, with its broader approach to fixing perceived problems, would pass.

Others contend that much abuse could be eliminated by adopting ideas spelled out nine years ago by the California Law Revision Commission. Those recommendations are being considered for inclusion in a bill authored by Senator Byron Sher. His bill may contain provisions that prohibit plaintiffs who represent the general public from having financial or legal conflicts of interest. Other parts of the bill call for ensuring that the state attorney general be notified of all lawsuits brought under the Unfair Competition Law and all settlements be approved by judges at an open hearing. If Proposition 64 is adopted by voters in November it could have a profound impact on future Proposition 65 enforcement actions, which often include claims under the Unfair Competition Law.

[Ann Grimaldi](#)
[San Francisco, CA](#)

▶ Update on EPA/Industry Perfluorooctanoic Acid (PFOA) Activities

In a recent interview, an Environmental Protection Agency (EPA) official stated that the EPA is not considering any regulatory controls for PFOA in the near future. Regulatory controls would have to be directed to the source of PFOA release and scientists have yet to determine how the environmental exposures of PFOA to humans occur. PFOA is of concern to the EPA because of various studies that have concluded that the chemical persists in the environment, may be associated with deaths and delayed sexual maturity

of laboratory animals and has been discovered, in low levels, in the blood of U.S. residents. In order to determine the environmental sources of PFOA, industry workgroups are investigating the incineration products of fluoropolymers and fluorotelomers and evaluating the biodegradation of fluorotelomers. In addition, facilities that manufacture fluoropolymers and fluorotelomers are monitoring air, water, sediment and wildlife near the facilities to measure any concentrations of PFOA that might be present.

Richard Jourdenais, PhD
TSG, Washington, DC

▶ **EPA's Registration Division Issues Schedules and Task Lists for Actions Subject to Pesticide Registration Improvement Act of 2003 (PRIA) Time Lines**

The EPA's Registration Division has issued a description of the Fast Track Registration Process and descriptive schedules for Non-Fast Track, New Use, and New Active Ingredient/First Food Use applications. It also has issued a description of the IR-4 Process needs. These documents are for use in organizing the process within EPA to achieve the statutory deadlines and to inform the regulated community of the schedule for each of these actions. The documents also serve to identify the milestones for each application and the information necessary to meet the milestone requirements.

Robert R. Stewart, PhD
TSG, Washington, DC

▶ **FIFRA SAP Considers Probabilistic Exposure Models for Fumigants**

On August 24-27 and September 9-10, 2004, the Environmental Protection Agency (EPA) Office of Pesticide Programs convened the FIFRA Scientific Advisory Panel to review three fumigant bystander exposure models developed by industry representatives. The first model considered was the Probabilistic Exposure and Risk Model for Fumigants (PERFUM), developed by Arvesta Corporation using iodomethane as a case study. The second model presented was Fumigants Modeling System (FMS) using metam sodium as a case study, and third was the Soil Fumigant Exposure Assessment system (SOFEA©), developed by Dow AgroSciences LLC using telone as a case study.

In past years, EPA estimated exposures to bystanders near fields treated with soil fumigants prior to planting crops such as strawberries or tomatoes solely based on monitoring data for each fumigant. The current EPA approach to assessment of bystander exposure to fumigants applied to soil is based on monitoring data and deterministic modeling. These probabilistic models represent a potential evolution of the Agency's current methodology for estimating bystander exposure to soil fumigants.

Beth Milesen, PhD
TSG, Washington, DC

▶ **Guidance on Submitting Prior Notice of Imported Food During Systems Outages**

The Food and Drug Administration (FDA) recently announced the availability of a contingency plan that provides guidance on submitting prior notice of imported food during systems outages affecting the applicable FDA and Customs and Border Protection (CBP) program systems. Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and its implementing

regulations require prior notice to FDA of all food imported or offered for import into the United States. FDA and CBP have developed a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and CBP program systems. The contingency plan identifies seven potential system downtime scenarios that could impact transmission, confirmation, and processing of prior notice submissions and explains recommended submission options for each of the identified scenarios. Almost all of the scenarios deal with problems with the system set up to submit information, and one discusses options for when there is a power failure or other regional emergency. FDA and CBP strongly encourage the use of email transmission in such scenarios, as they consider it the most efficient means. Food importers should be aware of this guidance to assist them in properly submitting information.

Brian Finch
Washington, DC

▶ **Revised Policy Guide: Prior Notice of Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

The Food and Drug Administration (FDA) and Customs and Border Protection (CBP) have released a revised compliance policy guide (CPG) entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." The CPG provides written guidance to FDA's and CBP's staff on enforcement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for all food imported or offered for importation into the United States. This document also describes certain date changes to the Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (revised joint plan). The document is very useful in that it provides guidance on what actions FDA and CBP might take when faced with item's that have not followed proper Prior Notice procedures. FDA and CBP note that for some violations they typically will consider not taking any regulatory action. If, however, a violation reflects a history of repeated conduct of a similar nature by a person who had been notified of such violations, then FDA and CBP might consider assessing civil monetary penalties.

Brian Finch
Washington, DC

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SECTION III: International Developments

▶ **Possible Approval of Biotech Rice in China**

An International Institute of Economics-sponsored report concludes that China will likely approve biotech insect resistant rice for planting within the next two years. China is currently in its fifth year of field trials of biotech rice, with India and the Philippines also running field tests. This conclusion is contrary to a recent announcement by the director of the International Rice Research Institute who stated that it would be three to five years before the first biotech rice crop was grown. The report, "Roots of Competitiveness: China's Evolving Agriculture Interests," also concludes that this decision will be followed by the commercial release of biotech wheat and corn. The authors of the report believe that China's approval of new biotech products will pave the

way for other countries to approve them and could have a significant impact on world trade as a result.

Sarah Lukie
Washington, DC

▶ **Pesticide Classification and Labeling Harmonization**

The Globally Harmonized System of Classification and Labeling (GHS) was formally adopted by the United Nations Economic and Social Council (ECOSOC) in July 2003. The GHS is intended to promote common, consistent criteria for classifying chemicals according to their health, physical and environmental hazard, and to develop compatible labeling, safety data sheets and other information based on these classifications.

The Office of Pesticide Programs (OPP) of the U.S. Environmental Protection Agency (EPA) presented a White Paper entitled "The Globally Harmonized System of Classification and Labeling: Implementation Planning Issues for the Office of Pesticides Program". The paper explains OPP's proposed approach to implementing the GHS for pesticide products that are registered in the United States. Comments were requested by October 25, 2004. A companion working paper that compares the current OPP system with the proposed system that meets the GHS is also available.

GHS differs from current practice in the use of more pictograms for various types of hazard, includes five categories of toxicity (EPA currently uses four) and uses only two signal words to indicate severity, danger and warning. EPA anticipates it will take up to two years to fully implement changes to the labeling of pesticides to harmonize with GHS. Both documents can be found on the OPP website:
<http://www.epa.gov/oppfead1/international/globalharmon.htm>

Edwin L. Johnson and Robert R. Stewart, PhD
TSG, Washington, DC

▶ **New Fumigant to Replace Gas that Damages Ozone Layer**

The Commonwealth Scientific & Industrial Research Organization (CSIRO) of Australia and the global industrial gas company (The BOC Group) have signed a deal to deliver to the international market a new environmentally safe fumigant for treating soil, insect pests, weeds and diseases.

CSIRO and BOC have agreed to commercialize ethanedinitrile (EDN) as a fumigant to replace the ozone-depleting methyl bromide that is being phased out under the Montreal Protocol.

EDN is a fumigant discovered by CSIRO in 1994. Field tests have shown it as more effective than methyl bromide in treating soil, timber and imported feed for livestock. "This agreement is a major achievement for Australia because it allows Australia to meet its obligations as a signatory to the Montreal Protocol," says Mehrdad Baghai, CSIRO's Executive Director of Business Development and Commercialization, of a new science industry partnership that is required for successful commercialization.

The global market for methyl bromide is estimated to be more than \$500 million. With the phase out of methyl bromide scheduled in 2006, organizations worldwide are racing to find suitable alternatives.

[Edwin L. Johnson](#)
TSG, Washington, DC

▶ **Canada Bans New Toxic Chemicals**

On July 17, Environment Canada (EC) published three notices in the Canada Gazette, Part I banning the manufacture and importation of substances that are suspected of being toxic based upon analyses previously done by EC and Health Canada. EC issued the notices under the authority of paragraph 84(1)(b) of the Canadian Environmental Protection Act, 1999. The following substances are covered by EC's new ban: tert-Bu benzenecarboxperoxide; perfluoroalkyl esters; polymer with butyl 2-propenoate and unsaturated anhydride; 2-methyl, 2-methylpropyl ester; 1-alkanol; alkyl-branched alcohols; reaction products with alpha-fluoro-omega-2-hydroxyethylpoly (difluoromethylene); 1,6-diisocyanato-homopolymer; hexane; stearyl methacrylate; polymers with 2-hydroxyethyl methacrylate, gamma-omega-homopolymer; 2-methyl-hexadecyl ester; 2-propenoic acid.

[Michael Boucher](#)
Washington, DC

▶ **South Korea to Amend Chemicals Law**

On August 17, the Cabinet submitted to the Parliament final draft legislation to amend the Toxic Chemicals Control Act (TCCA), Law No. 06153. On August 18, the Ministry of the Environment (MOE) said that the National Assembly would approve the new legislation by the end of 2004 and that enforcement would begin sometime in the second half of 2005. The TCCA was originally enacted in August 1990 and last fully revised in December 1996. The main idea of the new legislation is to introduce the concept of hazard/risk assessment to measure and manage chemical risks to human health and the environment. The current law controls chemical "hazards," defined as chemical properties that lead to harmful effects. The new law also would cover "exposure," defined as an amount of intake or environmental concentration. Thus, under the new law, a substance with low toxicity still may be restricted or banned if sufficient exposure is shown in a hazard assessment. Starting in 2008, the MOE also will start publishing information in its toxic release inventory (TRI) about the environmental performance of workplaces, measured as quantities of chemicals released. Farm chemicals and many varieties of high-pressure gas will be included in the TRI for the first time. Finally, manufacturers, importers and exporters will be required to determine for themselves whether their chemicals are new or existing and to report to the MOE accordingly.

[Michael Boucher](#)
Washington, DC

▶ **Australia Publishes Guidance on New Regulatory Reforms**

On August 16, Australia published a special edition of the Commonwealth of Australia Gazette (No. C 8-Special) to explain changes to Australia's legislative framework for industrial chemicals, specifically the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), made by the Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concerns Chemicals) Act 2004 (the LRCC Amendment Act) and by the Industrial Chemicals (Notification and Assessment) Regulations (the LRCC Regulations). The LRCC Amendment Act and the LRCC Regulations provide a new legislative framework to implement a number of LRCC reforms that seek to improve

flexibility in the assessment processes for industrial chemicals.

The centerpiece of the new regulatory framework is a process under which companies can conduct self-assessments of polymers of low concern, non-hazardous chemicals, and non-hazardous polymers in order to obtain self-assessment certificates for commercializing new industrial chemicals. The existing polymers of low concern criteria serve as the framework for audited self-assessment. For non-hazardous chemicals and non-hazardous polymers, the criteria defining "non-hazardous" have been introduced by new definitions in the Act. Companies that conduct self-assessments and hold self-assessment certificates have to keep certain records and file annual reports. They also are subject to audits by inspectors from Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

Under the new scheme, notifiers also have the new option to request that a previously assessed chemical be placed on the Australian Inventory of Chemical Substances (AICS) before the five-year period following the assessment of the chemical has ended. In addition, Australia has introduced a new system of "controlled use" permits for industrial chemicals that present low risks to human health and the environment, because their use, handling and disposal are highly controlled. Such permits last for up to three years and are renewable.

Michael Boucher
Washington, DC

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