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## SECTION I: European Union Developments

### ▶ Commission Proposes Regulation on Fluorinated Gases

On August 12, 2003, the Commission adopted a proposal for a Regulation on certain fluorinated greenhouse gases (Ref.: COM(2003)492). These measures, taken in the Framework of the Kyoto Protocol objectives, aim at reducing emissions of these gases by 25 percent (25%) by 2010. The main sources of emissions are cooling systems, fire fighting equipment, some aerosols, and some other industrial uses. The Commission proposes, among other things, provisions to improve the containment and recovery of fluorinated gases, as well as marketing and use restrictions and the phasing out by 2013 of the substance HFC-134a. The proposed Regulation will be adopted by the Parliament and Council through the codecision procedure.

[Ursula Schliessner](#)

### ▶ Commission Develops Strategy for Coexistence of GM and non-GM Crops

On July 23, 2003, the Commission published guidelines for the development of strategies and best practices to ensure co-existence of genetically modified (GM) and non-GM (conventional and organic) crops (Ref.: C(2003) 2624, /O.J. (2003) L 189/36). The guidelines aim to help Member States develop national or regional measures on the issue and propose a list of possible actions to avoid unintended presence of genetically modified organisms (GMOs) in non-GM crops and vice versa. The measures taken by Member States shall be proportionate, crop- and region-specific, and science-based. The Commission also recommends continuous monitoring and sharing of best practices for coexistence.

[Ursula Schliessner](#)

### ▶ Commission Seeks Comments on Use of Cadmium in Fertilizers

On August 1, 2003, the Commission launched an eight-week Internet stakeholder consultation on harmonizing cadmium content in fertilizers. For this purpose, the Commission has published draft Community measures as well as several studies and a CSTE opinion on risk assessment. Cadmium is not yet regulated at EU level under the Directive 76/116/EEC on fertilizers. Although there is no EU restriction on the

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use of cadmium in fertilizers, derogations have been granted to Austria, Finland, and Sweden, which are allowed to maintain the concentration limits they had fixed before their accession to the EU. Furthermore, other Member States have taken informal measures on the issue, which has led to a fragmented fertilizer market in Europe. Stakeholders are asked to submit comments by September 26, 2003. The Commission will issue a proposal for a Regulation by the end of the year.

### **Robert Matthews**

#### **▶ Commission Proposes Directive on Heavy Metals in the Air**

On July 16, 2003, the Commission adopted a proposal for a Directive aimed at minimizing the harmful effects of heavy metals (arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons (PAHs)) in the air (Ref.: COM(2003)423). Adopted within the framework of Directive 96/62/EC on ambient air quality assessment and management, the proposed new Directive proposes limit values and air quality monitoring by Member States. Arsenic, cadmium, mercury, certain Nickel, and PAHs (a group of more than 20 carcinogens of similar chemical character, which are mainly emitted by incomplete combustion) are carcinogens for which no threshold for adverse effects on human health can be identified, according to the Commission proposal.

### **Koen Van Maldegem**

#### **▶ New European Case Law on Pharmaceuticals**

On July 24, 2003, the European Court of Justice dismissed the Commission's appeal against a first instance judgment (Case Artogodan T-74/00). On March 9, 2000 the Commission had taken a Decision to withdraw marketing authorizations of anti-obesity drugs containing certain anorectics. Artogodan and other pharmaceutical companies had sought annulment of the Commission's Decision. On November 26, 2002, the Court of First Instance (CFI) annulled the Decision on the ground that the Commission lacked competence to withdraw marketing authorization that were granted by national authorities pursuant to purely local legislation, i.e., not the applicable EU directive. The Court of Justice confirmed the CFI's judgment (Ref.: Case C-39/03, Artogodan).

### **Claudio Mereu**

#### **▶ Commission Standardizes Food Claims**

On July 16, 2003, the Commission adopted a proposal for a Regulation harmonizing nutrition and health claims made on food and food supplements (Ref.: COM(2003) 424). The proposed Regulation aims to ensure that food claims will be based on scientifically proven nutritional benefits and will specify the conditions for their uses. The proposed Regulation also will harmonize the meaning of certain food-related claims. As a result, claims such as "low fat," "sugar free," "no added sugars," "high fiber," and "light" are prohibited, unless they fully conform to the definitions contained in an annex to the proposed Regulation.

### **Ruxandra Cana**

#### **▶ Recently Adopted Environmental Legislation**

On July 22, 2003, the Council formally adopted new Regulations on labeling and

tracking genetically modified organisms (GMOs), and on the approval and labeling of genetically modified food and feed. The first set of Regulations shall come into force 20 days after its publication in the Official Journal of the European Communities. The provisions on tracking GMOs await the Commission's decision on a system for developing and assigning unique identifiers. This second set of Regulations is effective six months after its publication. During the same meeting, the Council also adopted a new Directive on greenhouse gas emissions trading. This Directive shall be implemented by Member States by December 31, 2003. The three texts were adopted as amended by the Parliament on July 2, 2003 and are awaiting publication in the Official Journal.

## **Ruxandra Cana**

### **▶ Recent Additions to Annex I of Plant Protection Products Directive**

The following active substances were recently added to Annex I of Directive 91/414/EEC:

Commission Directive 2003/70/EC of 17 July 2003 included the herbicides mecoprop, mecoprop-p (Rapporteur Denmark, for both) and the fungicide propiconazole (Rapporteur Finland) as active substances. All are list 1 substances.

Commission Directive 2003/68/EC of 11 July 2003 included trifloxystrobin (fungicide Rapporteur UK), carfentrazone-ethyl (herbicide, Rapporteur France), mesotrione (herbicide, Rapporteur UK), fenamidone (fungicide, Rapporteur France), and isoxaflutole (herbicide, Rapporteur Netherlands) as active substances.

Commission Directive 2003/79/EC of 13 August 2003 included the organism *Coniothyrium minitans* (fungicide, Rapporteur Germany) as an active substance.

## **Nick Leeming** **TSGE, Knaresborough, UK**

### **▶ Commission Creates European Food Safety Authority**

In January 2002, the Commission created the European Food Safety Authority (EFSA). In the future, EFSA will provide opinions on evaluations of active substances. On 11 July 2003, the Commission published Regulation (EC) 1304/2003 establishing the procedure that EFSA will follow when requested to give an opinion and when rendering an opinion on its own initiative. Opinions may be sought by the Commission, by the Parliament, or by a Member State. EFSA is the EU authority responsible for the quality of human food and animal feed, including the evaluation of pesticides and residue limits. EFSA was established by Regulation (EC) 178/2002. When requested, EFSA must provide an opinion within 45 days. EFSA will form an advisory Committee, the Committee on the Food Chain and Animal Health, to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs, and the Standing Committee for Feedingstuffs. The new advisory committee also will replace the Standing Committee on Plant Health with respect to plant protection products and maximum residue levels.

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### **▶ New Regulation Extends Essential Uses of Active Substances**

Commission Regulation (EC) 1336/2003 of 25 July 2003 amends Regulation (EC) 2076/2002, which listed in its Annex II active substances for which various Member States had requested an extension of essential uses not supported in Lists 2 and 3 of Directive 91/414/EEC. Regulation (EC) 1336/2003 amends the Annex II list, adding several essential use derogations. These essential uses are now extended until 30 June 2007.

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#### **▶ EuropaBio Publishes Guidance on GM Crop Safety**

New industry guidance documents provide a common industry approach to meeting the health, environmental, food and feed safety standards for genetically modified (GM) crops, complementing the EU, WHO, FAO and OECD safety guidelines. "We wanted to create a harmonized industry approach to meeting the technical requirements of EU authorities who are responsible for approving GM crop products. We believe a common industry approach will help ensure a high standard of safety and consistency in meeting requirements in the EU," says Dr. Hilde Willekens, Chair of the Technical Advisory Group (TAG), which brings together scientific and regulatory experts from the major plant biotechnology companies operating in Europe. TAG is a specialist advisory group to the Plant Biotechnology Unit of EuropaBio - the European Association for Bioindustries. The industry guidance documents are designed for industry, international organizations and Competent Authorities involved in the safety assessment of GM crops. The guidance documents will be added to and updated over time. They are freely available to all interested parties. Copies can be downloaded from the EuropaBio web site:  
[http://www.europabio.org/upload/articles/article\\_207\\_EN.doc](http://www.europabio.org/upload/articles/article_207_EN.doc)

**Edwin L. Johnson**  
**TSG, Washington, DC**

#### **▶ New Decisions on Plant Protection Products**

The Commission recently prepared two Decisions that are not yet published in the Official Journal of the European Communities. The first Decision extends the review program for the 146 substances supported in stage 4 until 31 December 2008, unless a decision on Annex I inclusion is taken earlier, or further prescribed extensions are granted to products containing active substances unsupported in stage 4, which are scheduled to be withdrawn by 31 December 2003 with existing stocks allowed for sale until 31 December 2004. The second decision lists the active substances in stages 2 and 3 that have lost support since Regulation (EC) 2076/2002 was published, plus active substances that have not been supported in stage 4 of the review (106 substances in total). Annex II to the second Decision lists essential use derogations for seven of these active substances.

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#### **▶ Commission Lowers MRLs for Unsupported Active Substances**

Maximum residue levels (MRLs) for unsupported active substances will be reduced to the level of detection (LOD) when a proposed Regulation consolidating the four existing MRL Directives is in place. The Regulation will likely come into force in 2005,

and the MRLs for unsupported active substances should not be reduced to the LOD before then. Substantive residue levels probably will be set to permit imports of agricultural commodities into the European Union.

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#### ▶ **United Kingdom Publishes Operator Exposure Models**

The UK's Pesticide Safety Directorate (PSD) has put two operator exposure models on its website, namely, UK's POEM and PSD's interpretation of the German (BBA) model. (See <http://www.pesticides.gov.uk> under Applicant Advice/Registration Guidelines/Data requirements Handbook/Chapter 4, Section 3).

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#### ▶ **Commission Sues Eleven Member States over Biotechnology Directive**

The European Commission has referred France, Luxembourg, Belgium, Netherlands, Germany, Italy, Ireland, Greece, Spain, Austria and Finland to the European Court of Justice for failing to adopt and notify national legislation implementing an EU law on the deliberate release of genetically modified organisms (GMOs) into the environment. The eleven Member States cited have failed to meet an agreed deadline of 17 October 2002 for the adoption and notification of national legislation. On 17 October 2002, a new Directive revising the original framework for regulating the release of GMOs in the EU came into force. The revised Directive strengthens the rules on the release of GMOs into the environment. It improves the strictness and transparency of the Directive, notably creating a more effective and efficient authorization procedure.

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## **SECTION II: United States Developments**

#### ▶ **Hazmat Rules Amended to Conform with International Standards**

A Department of Transportation final rule will amend hazardous materials regulations to harmonize them with international standards and to facilitate the transport of hazardous materials in international commerce. The rule applies to shippers and carriers of hazardous materials, chemical users and suppliers, packaging manufacturers, distributors, battery manufacturers, and radio pharmaceutical companies.

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#### ▶ **Senate Approves Bill to Allow Ratification of Chemical Treaties**

The Senate Environment and Public Works Committee approved legislation that would allow the United States to ratify three international treaties controlling

persistent and other hazardous chemicals. The legislation would give the Environmental Protection Agency authority to regulate persistent organic pollutants that may be added to two of the treaties. France ratified an international treaty that bans or restricts 16 persistent organic pollutants, triggering the protocol's entry into force.

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#### **▶ Food and Drug Administration Publishes Policy for Foods with Pesticide Residues for which Tolerances Have Been Cancelled**

The FDA has published for comment a proposed channels of trade policy for food commodities that have pesticide residues for which tolerances have been cancelled. As part of the tolerance reassessment under the 1996 Food Quality Protection Act, registrants have cancelled pesticides and pesticide uses to reduce overall exposure. Following such cancellations, EPA will cancel associated tolerances once it has determined that pesticide products labeled for those cancelled uses have cleared the channels of trade. FDA is now proposing to establish a policy for determining when a food commodity is adulterated by virtue of having residues of these cancelled pesticides and pesticide uses. The increased scrutiny may also turn up residues on imported commodities for which import tolerances were never established, or for which the domestic use has been cancelled, but uses off-shore remain. Comments on the proposed policy are due to be submitted by September 22, 2003.

**Robert R. Stewart, PhD**  
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#### **▶ EPA Begins to Consider Pesticide Review**

In the 1996 Food Quality Protection Act, section 3(g) was established and requires the review of pesticides every 15 years. EPA has begun to consider what it should require under this statutory provision and how it will implement it. A working group under the auspices of the Pesticide Program Dialog Committee has met to begin discussions, and it appears that the positions of the industry and EPA are far apart. EPA is considering a new reregistration program modeled after the 1988 FIFRA reauthorization legislation, in which all pesticides were considered. Industry wants the review to be conducted on a chemical-by-chemical basis, beginning 15 years after the first registration or the issuance of the Registration Eligibility Decision. Meetings are scheduled for October 2003 to continue discussions.

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#### **▶ OSHA to Address MSDS Problems**

Occupational Safety and Health Administration (OSHA) Administrator John Henshaw recently acknowledged that there is a need to improve the reliability of material safety data sheets (MSDSs). The Administrator made his comments in response to a recent letter he received from Senator Mike Enzi (R-WY) and another letter he received from a member of the National Advisory Committee on Safety and Health expressing concerns about the reliability and accuracy of MSDSs. According to the Administrator, a review of the Hazard Communication Standard and MSDS requirements will be completed by the end of 2003. Working with the Society for Chemical Hazard Communication, OSHA also is considering offering a course

regarding MSDS preparation with the goal of increasing their reliability. In addition, OSHA intends to issue new guidance documents concerning the hazard determination, hazard communication training, and MSDS preparation requirements of the Hazard Communication Standard.

### [Scott Kauff](#)

#### ▶ **California Bans Two Brominated Flame Retardants**

On August 9, 2003, California banned the sale of products containing more than 0.1 percent (0.1%) of either of two types of brominated flame retardants, pentabromodiphenyl ether (CAS RN 32534-81-0) or octabromodiphenyl ether (CAS RN 32536-52-0), which studies have shown are accumulating in people, animals, and the environment. Penta-BDE is a component of polyurethane foam, and octa-BDE is included in plastics. A third compound, decabromodiphenyl ether, is unaffected by the ban. The European Union already has banned penta-BDE and octa-BDE. Industry did not oppose the legislation, and the January 2008 effective date for the ban allows significant time for chemical companies to develop commercial alternatives to the banned compounds.

### [Michael Boucher](#)

#### ▶ **Industry Expresses Concern about Inventory Update Rule Amendments**

In the January 7, 2003 Federal Register, the EPA published a final rule under TSCA section 8(a) that significantly revised the IUR reporting requirements for 2006. Manufacturers and importers of chemicals have been required to submit IUR reports since 1986 and in subsequent four-year intervals, with the last report due in 2002. The IUR amendments include higher reporting thresholds, the inclusion of inorganic chemicals and additional, comprehensive chemical use and exposure information, which had not been previously required. The amendments have substantially increased the reporting burden, but EPA has stated that the chemical use and exposure information is necessary for their chemical risk screening process.

Shortly after the Federal Register publication, several chemical industry associations filed a lawsuit challenging the authority of the EPA to collect detailed, chemical use and exposure information under an IUR rule. Parallel with the lawsuit, which has been stayed, the chemical industry has been involved in a dialogue with the EPA to better understand the rationale behind EPA's amended IUR rule. It is unknown at this time whether all of the issues will be resolved to the chemical industry's satisfaction through the dialogue process or whether the lawsuit will be pursued.

### [Richard A. Jourdenais, PhD](#) [TSG, Washington, DC](#)

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## **SECTION III: International Developments**

#### ▶ **FAO Provides New Resource on Biotechnology**

The Food and Agriculture Organization (FAO) of the United Nation's Crop and Grassland Service is developing Crop Biotech Bites, an on-line information tool containing a series of short articles designed for the non-expert to understand the

status of important topics in crop biotechnology. The articles are to be prepared by experts in the different topics to provide updates on what is happening in their respective areas and indicate the implications, especially for decision makers. In the preliminary version of Crop Biotech Bites, most articles are classified under one of seven themes - research and development, abiotic stress, biotic stress, environment, human health, regulatory issues, and ethics. The focus is very much on crop biotechnology applications/implications for developing country agriculture.

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#### ▶ **Cartagena Protocol Enters Into Force**

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 required to comply with and implement all its provisions. However, many of the countries that have ratified the Protocol have not yet developed national legislation implementing the Protocol. For this reason, the extent of the obligation on exporters shipping LMOs to Party countries is unclear. Further, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (the committee mandated to undertake the preparations necessary for the first meeting of the Parties to the Protocol) reached a basic understanding but did not come to a final agreement as to what, in practice, is actually required by some of the provisions of the Protocol. The Parties to 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.

[Sarah Lukie](#)

#### ▶ **Status of the WTO Case on EU GMO Ban**

On August 18, 2003, the European Union blocked a formal request from the United States, Canada, and Argentina to form a dispute panel for their case before the World Trade Organization (WTO) regarding the EU's five-year moratorium on approving agricultural biotechnology products. EU Commissioner for the Environment Margot Wallstrom explained that the panel would "muddy the waters" of the debate on genetically modified organisms (GMOs) in Europe, stating "it is not our intention to create trade barriers... We have to create confidence among citizens for GMOs and allow them to choose, and this is what our new legislative framework is designed to do. The EU stance on GMOs is in line with WTO rules." The United States, Canada, and Argentina resubmitted their request at the August WTO Dispute Settlement Body (DSB) meeting, and the request was accepted at that time. Under WTO rules, second requests must automatically be accepted unless all countries in attendance, including the complaining countries, block the request. Dispute panels typically take approximately 12 to 18 months to reach a judgment.

[Sarah Lukie](#)

#### ▶ **Pew Initiative Updates Brief on GM Crops**

In light of recent developments, the Pew Initiative on Food and Biotechnology has updated its brief on the trade dispute between the U.S. and the EU over agricultural biotechnology. The new issue brief provides the following:

- A summary of the trade dispute between the U.S. and the EU regarding GM food.
- A timeline of critical events, and discussion of factors that have influenced EU consumer wariness of GM crops and food products.
- Views on the trade dispute from EU and U.S. officials.
- Estimates of the impact that the EU de facto moratorium on GM crop approvals has had on U.S. trade and discussion of the potential further impact of the new EU rules on labeling and traceability.

The full issue brief is available at the following location:  
<http://pewagbiotech.org/resources/issuebriefs/europe.pdf>

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