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SECTION I: European Union Developments

▶ EU Continues to Uphold Bans on Biotech Crops

The EU recently upheld bans on genetically modified crops in Austria, Germany, Luxemburg, France and Greece in direct contradiction to the decision by the European Commission, which requested the five countries to lift their bans as they had no jurisdiction to continue them. In addition to this decision, the EU approved, and then withdrew, its authorization of GT73 – genetically modified rapeseed variety for use as animal feed and industrial processing – after a “bureaucratic error” caused the decision to be prematurely released. EU Environment Ministers also were deadlocked on a vote to approve the genetically modified corn variety, MON 863. Despite this deadlock, the European Commission’s environment directorate indicated that the Commission will approve the variety in its future decision. The date for this decision has not yet been set.

[Sarah Lukie](#)
Washington, DC

▶ Restriction of Hazardous Chemicals in Electrical and Electronic Equipment

On June 6, the Commission adopted a proposal for a Council decision (COM(2005) 241) adapting to technical progress the Annex to Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive). The RoHS Directive provides that as of July 1, 2006 new electrical and electronic equipment put on the market cannot contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers. The Commission proposes to exempt certain materials from the prohibition since the elimination or substitution of these hazardous substances in those specific materials is still impracticable. Furthermore, the Commission wishes to exempt the substance Deca-BDE from the prohibition since the risk assessment carried on under Regulation 793/93 has concluded that there is no need for further risk reduction. The Commission will review the exemptions listed in the Annex every four years.

The Commission had proposed this adaptation to the Regulatory Committee, established according to Article 18 of the RoHS Directive, which could not reach a qualified majority on the issue. According to the comitology procedure, the Council has three months to either adopt or reject the Commission proposal by qualified

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majority; after this time limit, if no qualified majority could be reached the file would go back to the Commission for final adoption.

Claudio Mereu Brussels

▶ **Shipment of Waste**

On June 24, the Council adopted a Common Position on the proposal for the Regulation on shipment of waste (COM(2003)379). This would revise the existing Regulation 279/93 and strengthen the current control procedures.

There has been unanimity in the Council to amend the Commission proposal's legal basis, from Articles 133 (Common Commercial Policy) and 175 (environment) jointly to Article 175. The Council also allows Member States to raise objections and block shipments of waste destined for recovery on the grounds of "*lower treatment standards*" in the country of destination. The Commission considers that this provision will create barriers in the European waste recycling and recovery market while failing to improve the environmental standards of waste management in the EU. Furthermore, it fears this provision may lead to an increase in illegal shipping of waste and trigger court cases.

Moreover, the Council excludes from the scope of the Regulation shipments which are subject to the approval requirements of Regulation 1774/2002 on health rules concerning animal by-products not intended for human consumption.

Ursula Schliessner Brussels

▶ **GMOs: Commission Reaction to Council Votes on Safeguards**

The Environment Council voted today on a package of proposals from the Commission concerning genetically modified organisms (GMOs). The proposals require the lifting of bans or restrictions (so-called national safeguard clauses) imposed by Austria, France, Germany, Greece and Luxembourg on 8 authorized GM products. The Council voted against all 8 Commission proposals. This is the first time that the Council reached a qualified majority against a Commission proposal on GMOs, thus creating a new situation in terms of subsequent action. The Commission will have to carefully consider the legal and scientific bases that underpin any further proposals, as well as the implications for EU internal market and trading partners.

Stavros Dimas, Commissioner for the Environment, said, "The Commission has a legal obligation to make sure that the existing regulatory framework governing the release of GMOs is correctly applied by Member States. That is why we proposed to lift the current bans or restrictions on certain GMOs in Austria, France, Germany, Greece and Luxemburg. The fact that the Council rejected all 8 proposals raises a host of questions. What is certain is that today's vote sends a political signal that Member States may want to revisit some aspects of the existing system."

The complete text of the EC news release, which includes a table showing the eight country bans is posted at: <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/793&format=HTML&aged=0&language=EN&guiLanguage=en>.

Edwin L. Johnson

TSG, Washington, DC

▶ Mercury Strategy

On June 24, the Council adopted its Conclusions concerning the Community Strategy on Mercury (COM(2005)20). The mercury strategy outlines six objectives for the EU including phasing out exportation by 2011, reducing the supply and demand, requiring safe storage of surpluses, reducing its emissions, protecting against exposure, promoting international action and continuing research and information programs.

The Council particularly stressed that an international commitment is needed in addition to this strategy with a view to agreeing on legally-binding instruments. It underlined that the Community should focus on the residual uses of mercury and implement best available techniques for further reduction of mercury emissions from combustion processes. Furthermore, it required the Commission to present proposals (1) on the phasing out of the exports of mercury from the Community and on actions to pursue the safe storage or disposal of mercury inter alia from the chlor-alkali industry to a timescale consistent with the intended phase out of mercury exports, and (2) on marketing restrictions for consumer use and health care non-electrical or non-electronic measuring and control equipment containing mercury.

Ruxandra Cana Brussels

▶ Commission Adopts an Action Plan on Nanotechnologies

The European Commission is searching for the ways in which to keep Europe at the forefront of the fast-moving field of nanotechnology in a safe and responsible way. On May 12, 2004, the Commission adopted the Communication *Towards a European Strategy for Nanotechnology*. A public consultation on the communication was organized in Autumn 2004. It revealed a strong stakeholder consensus that nanotechnology will have a powerful impact on European industry and on European citizens within ten years.

Following this, on June 7, 2005, the Commission adopted another Communication *Nanosciences and Nanotechnologies: an Action Plan for 2005-2009*. This action plan complements the Commission's strategy on life sciences and biotechnology.

Measures in the action plan include:

- fostering industrial exploitation of R&D on nanosciences and nanotechnologies (N&N) by bringing together stakeholders to discuss best practices for commercialization, the societal, political and psychological barriers to entrepreneurship in Europe and license arrangements between industry and R&D organizations;
- working on common standards;
- boosting funding for nanotechnology in the Seventh Framework Program (FP7), including specific support for research into the impact on human health and the environment;
- specific support to research in nanoelectronics under the Information and Communication Technology (ICT) priority of FP7;
- fostering technology platforms to implement a strategic R&D agenda for N&N;
- developing an N&N research infrastructure and poles of excellence;

- establishing a true dialogue with citizens and informing all stakeholders about progress and expected benefits of N&N;
- ensuring that ethical principles are respected and citizens' concerns and expectations taken into account;
- integrating risk assessment related to human health, the environment, consumers and workers at all stages of the life cycle of the technology;
- a European Award for nanotechnology to highlight best practice.

The action plan has been sent to the European Parliament and the Council for approval. A reassessment of the current EU legislation on N&N is foreseen.

Koen Van Maldegem
Brussels

▶ **Consultation for the Review of the EU Emissions Trading Scheme**

The European Union's Emissions Trading Scheme began in January 2005 and is an intermediary step towards an international carbon emissions trading scheme to help meet emissions reductions goals under the Kyoto Protocol.

Article 30 of Directive 2003/87/EC on emissions trading requires the Commission to review the emissions trading scheme by June 30, 2006, and lists a number of issues that should be addressed. At the beginning of June 2005, European Environment Commissioner Stavros Dimas announced that the Commission is about to start its review of the EU's Emissions Trading Directive and launched a wide ranging consultation.

The consultation is expected to reveal the views of around 500 stakeholders. Companies in trading sectors and their associations, NGOs and Member States will be contacted directly and invited to participate in the survey. Other stakeholders will be provided access if they express an interest to participate. The survey covers a wide range of issues such as the functioning of the allowance market, the harmonization of allocation methods, the treatment of new entrants and closures, the feasibility of including further sectors and gases in the EU ETS, accounting and taxation issues and last, but not least, it addresses competitiveness issues.

The results of the survey will feed into the report that the Commission should submit to the European Parliament and to the Council. This report may be accompanied by proposals for amendments to the scheme, such as inclusion of additional sectors and additional greenhouse gases. The results of the survey will help the Commission to establish whether such proposals would be appropriate. However, any amendments to the Emissions Trading Directive that the Commission proposes in 2006 would only have an effect from the third trading period onward, which will begin in 2013. This is because of the time needed for the legislative procedure and because the national allocation plans for the second trading period have to be submitted already in mid-2006, at the same time as the report is published. The survey will also tackle the elaboration of allocation plans for the second trading period 2008-2012.

Ursula Schliessner
Brussels

▶ **Competence to Rule on Environment Protection through Criminal Law**

In April 2003, the European Commission filed a lawsuit against the Council of the

European Union before the European Court of Justice (C-176/03), for having allegedly chosen an incorrect legal basis for a Council's Framework Decision on protecting the environment through criminal law (2003/80/JAI).

The question raised is who exactly holds the legal competence to oblige Member States to impose criminal sanctions via their national legal systems in cases of infringements of Community environmental laws. The Commission takes the view that this is a Community issue whereas the Council believes it is an issue of Police and Judicial Co-operation in Criminal Matters that has to be dealt with by intergovernmental co-operation. The Advocate General Damaso Ruiz-Jarabo Colomer delivered his Opinion on this case on May 26, 2005 finding that common definitions of environmental crimes and rules for determining penalties to fight them are Community issues and therefore, should be dealt with on a Community basis rather than by intergovernmental co-operation.

If the Council's Framework Decision is annulled by the ECJ, this might allow the rebirth of a proposal for a Directive presented by the Commission on March 13, 2001 (COM(2001)139), which gives a stricter and more severe perspective on the same matter.

Claudio Mereu
Brussels

▶ **Phthalates in Toys**

Common Position (EC) No 22/2005 of April 4, 2005 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a Directive of the European Parliament and of the Council amending for the 22nd time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations- namely, phthalates in toys and childcare articles, to no more than 0.1% by mass of the plasticized material.

Nick Leeming
TSGE, Knaresborough, UK

▶ **Agricultural Chemical Developments in Europe**

Commission Directive 2005/34/EC of May 17, 2005 (OJ L125/5, May 18, 2005) announced that the active substances etoxazole (acaricide, Sumitomo Achemical Agro Europe SA, Rapporteur Member State France) and tepraloxydim (herbicide, BASF AG, RMS Spain) are to be included on Annex I to Directive 91/414/EEC.

Commission Regulation (EC) 833/2005 of May 31, 2005 (OJ L138/5, June 1, 2005) permanently authorizes the enzyme preparation endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), and the enzyme preparation endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94), and the enzyme preparation endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC

2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107). In all three cases, the preparations are for use in weaned piglets. The enzymes preparations endo-1,3(4)-betaglucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) are permanently authorized for use in pigs for fattening and chickens for fattening, respectively. Commission Regulation (EC) 943/2005 of June 21 also permanently authorized the micro-organism preparation of *Enterococcus faecium* (NCIMB 10415) for chickens for fattening and for pigs for fattening, and the enzyme preparation of endo-1,3(4)-betaglucanase and endo-1,4-beta-xylanase produced by *Penicillium funiculosum* (IMI SD 101) for laying hens and for turkeys for fattening.

Commission Directive 2005/37/EC of June 3, 2005 (OJ L141/10, June 4, 2005) amends Maximum Residue Levels (MRLs) previously defined in Directives 86/362/EEC and 90/642/EEC for isoxaflutole, trifloxystrobin, carfentrazone-ethyl, mecoprop, mecoprop-p, maleic hydrazide and fenamidone in various crops. Similarly, MRLs for propyzamide previously defined in Directives 86/362/EEC and 90/642/EEC are re-defined, and MRLs for maleic hydrazide, previously defined in Directive 90/642/EEC are also re-defined.

Commission Decision of June 22, 2005 recognized in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pinoxaden (Syngenta, submitted to the UK) in Annex I to Council Directive 91/414/EEC.

Commission Decision 2005/465/EC of June 22, 2005 concerned the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line), notified by Monsanto Europe SA, genetically modified for tolerance to the herbicide glyphosate. The product was to be placed on the market for a period of 10 years, in the Netherlands . However, Corregia dated June 25, 2005 declared the publication of the above decision null and void.

Nick Leeming
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SECTION II: United States Developments

▶ EPA to Establish Rulemaking Process for the Use of Human Clinical Data

The use of scientific research with human subjects for the purposes of risk assessment and determining pesticide safety has long been subject to much ethical and legal debate. In response, the U.S. Environmental Protection Agency is currently developing a policy on the extent to which the Agency will consider or rely on third-party research involving human subjects in making its regulatory decisions. The Agency has been charged with "establishing a course of action that protects the welfare of human research subjects and adheres to rigorous ethical and scientific standards." Previously this year, the Agency announced in a Federal Register notice (70 FR 6661) the initiatives it will undertake to evaluate and adopt the recommendations it received from the National Academy of Sciences' 2004 report, *Intentional Human Dosing Studies for EPA Regulatory Purpose: Scientific and Ethical Issues*.

To achieve a comprehensive policy on human testing, EPA is seeking public comment to include rulemaking, public engagement, and the development of additional policy guidance as necessary. As the rulemaking process proceeds, the Agency will continue to consider third-party human studies that have been submitted to determine whether they meet stringent ethical and scientific standards on a case-by-case basis. The issuing of EPA's Advance Notice of Proposed Rulemaking (ANPR) in May 2003 effectively began the Agency's notice-and-comment rulemaking process for the use of human research. Since the ANPR's inception, EPA has received over 600 submissions in response. Recent legislation passed in both the House and Senate this past June has sought to bar EPA from conducting or accepting any studies involving intentional human dosing of pesticides. EPA maintains that it will "continue to work on drafting the first-ever rule to address the ethical and scientific issues surrounding human studies."

Alyson Duggan
TSG, Washington, DC

▶ **Biodefense Products a Priority with the United States Senate**

Members of the United States Senate have stated their intent to push forward comprehensive legislation that would impact food security operations and requirements. Sen. Richard M. Burr, Chairman of the U.S. Senate Subcommittee on Bioterrorism and Public Health Preparedness, recently stated that he intends to include such provisions in a bill also designed to provide incentives to pharmaceutical manufacturers so that they will invest in and deploy biodefense products. Two versions of such bills are currently under consideration in the U.S. Senate. Sen. Burr stated that he will be holding a number of high profile hearings on the bills, and will be adding many provisions to the final version. Further, his stated goal is to generate a comprehensive bill that addresses food security and reforms the public health system as well. Others in the Senate, including Majority Leader Bill Frist strongly support Burr's efforts.

Brian Finch
Washington, DC

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SECTION III: International Developments

▶ **WHO Issues Report Recognizing Benefits of Biotech Foods**

In late June, the World Health Organization (WHO) released a report called "Modern Food Biotechnology, Human Health and Development" which finds that genetically modified foods can contribute to the enhancement of human health and development. The report states that genetically modified foods increase crop yield, improve food quality and diversify the foods that can be grown in specific regions, as well as lead to better health and nutrition which can then help to raise health and living standards. The report also notes that genetically modified food products are actually more thoroughly tested than conventional foods for their nutritional and environmental impacts. The report can be found online at:
http://www.who.int/foodsafety/biotech/who_study/en/.

Sarah Lukie
Washington, DC

▶ WHO Reports Current GM Foods Seem Healthy But Caution Necessary

The World Health Organization was cited as saying in a new study that genetically modified foods currently on the market are unlikely to present new risks for humans, while insisting that procedures for checking new food products and genetically modified organisms needed to be adapted regularly to fast-paced change and innovation in the biotechnology industry. Public perceptions or social concerns about the costs and benefits of GM foods must also be taken more seriously, the study said. WHO was further cited as saying that more international harmonization was necessary to prevent the forming of a "genetic divide" that could deprive more skeptical nations of acknowledging production or nutritional benefits of some GM foods, adding, "GM foods currently available on the international market have undergone risk assessments and are not likely to present risks for human health in any other form than their conventional counterparts." WHO also added that no health problems had been found so far. The story explains that the three-year study was compiled by ten national regulators and experts with the WHO's food safety department, to try to establish an international "knowledge base" for the evaluation of biotechnology in food production.

Edwin L. Johnson
TSG, Washington, DC

▶ China Sets Up Nanotech Standards Panel

A June 21, 2005, Reuters report, states that "... China has created a body to draw up standards for nanotechnology, the latest move by the country to encourage development of the emerging industry that aims to create materials and devices on the molecular or atomic scale. The National Nanotechnology Standardization Committee was set up earlier this week and is headed by Bai Chunli, director of the National Centre for Nanoscience and Technology, state media said on Tuesday ... China, trying to place itself at the front of the nascent industry and help shape its future globally, has released seven nanotech standards since 2001, saying they were the world's first batch of national standards ... The new panel will coordinate between government bodies and research institutes to speed up determination of terminology, measurement and manufacturing norms, the Xinhua news agency said in an English-language report ... A study released last week said that nanotech, while holding great promise for new kinds of products, from pharmaceuticals to fabrics, is not being properly evaluated for human and environmental risks. The study, by New York-based investment house Lux Research, said the nanotech industry could produce \$8 trillion in cumulative manufacturing output up to 2014, and noted that companies including Lockheed Martin and Kraft Foods had spent \$3.8 billion on nanotech research and development last year." - The complete text of the Reuters report is posted at <http://www.alertnet.org/thenews/newsdesk/SP29175.htm>

Edwin L. Johnson
TSG, Washington, DC

▶ China Ratifies GMO Transparency Treaty

China, one of the world's largest importers of GMO crops, said it has ratified a U.N. treaty that aims for more transparency and control over trade in genetically modified foods. China's ratification of the U.N.'s Cartagena Protocol could give a boost to the agreement, which has been signed by more than 100 countries but not the United

States, the world's GMO giant. The next meeting to negotiate the protocol's implementation and enforcement is set for Montreal in late May and early June.

China's State Council, the cabinet, ratified the Protocol on April 27, an official at the State Environmental Protection Administration of China said. The protocol obliges exporters to provide more information on GMO products like maize and soybeans before any shipment to recipient countries, to help them decide whether to accept it. Crucially, it lets a nation reject GMO imports or donations, even without scientific proof if it fears they pose a danger to traditional crops or undermine local cultures.

Edwin L. Johnson
TSG, Washington, DC

▶ **Montreal Biosafety Protocol Conference Ends Without Agreement on GMO Shipping Documentation Rules**

The 118 countries and the European Union, who are members to the Cartagena Protocol on Biosafety, have ended their second meeting without agreement on the shipping documentation requirements for bulk shipments of living modified organisms (LMOs), (also known as genetically modified organisms (GMOs)), intended for food, feed and for processing.

According to the Protocol, (Article 18.2 (a)) delegates were required to take a decision on the detailed requirements for such documentation within two years of the entry into force of the Protocol. This timeframe expires on September 11, 2005.

Because no decision was adopted, discussions on this will continue at the third meeting of the Parties, scheduled to take place in Curitiba, Brazil from March 13-17, 2006. In the absence of a decision, Parties will in the meantime use the provisions outlined in Article 18.2 (a) of the Protocol, which requires member governments to take measures to ensure that documentation accompanying GMOs intended for direct use as food, or feed or for processing, clearly identifies that the shipment "may contain living modified organisms (LMOs) that are intended for use as food, or feed, or for processing and states that they are not intended for intentional introduction into the environment."

Parties will also apply the decision they adopted at their first meeting in Kuala Lumpur, Malaysia in 2004. In that decision, it was agreed that the documentation will also provide details of a contact point for further information. This contact point could be the exporter, the importer, or any appropriate authority designated by a government.

The Cartagena Protocol on Biosafety was adopted in January 2000 in Montreal, Canada. It was negotiated under the Convention on Biological Diversity in order to promote the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements. The Protocol entered into force on September 11, 2003 and so far 118 countries, as well as the European Community have ratified it.

Edwin L. Johnson
TSG, Washington, DC

▶ **First On-line Worldwide Register of GM Contamination Incidents**

GeneWatch UK and Greenpeace International launched the first on-line register of genetically modified (GM) contamination incidents on June 1, 2005 at www.gmcontaminationregister.org. The on-line, searchable web site gives details of all the known cases of GM contamination of food, animal feed, seeds and wild plants that have taken place worldwide.

"No Government or international agency has yet established a public record of contamination incidents or of other problems associated with GM crops. Turning a blind eye is not good enough when dealing with a technology like GM because it involves the uncontrolled release of living organisms into the environment," said Dr. Sue Mayer, GeneWatch UK's Director. "We hope this register will form an important resource for citizens and regulators in the future."

Since their introduction in 1996, GM crops have reportedly contaminated our food, animal feed and seeds across the globe. 62 incidents of illegal or unlabelled GM contamination have been documented in 27 countries on five continents, and those are only the recorded incidents. The largest number of contamination incidents have taken place in the USA (11 incidents). The register also gives links to more information about the incidents and associated agricultural problems that arise from them.

Contamination from 'Starlink' maize was found in seven countries: USA; Canada; Egypt; Bolivia; Nicaragua; Japan; and South Korea. Illegal releases of GM crops into the environment or food chain have taken place in India (cotton), Brazil (cotton and soya), China (rice), Croatia (maize), Europe, Germany (papaya) and Thailand (cotton and papaya). Six cases of negative agricultural side-effects have been recorded including deformed cotton bolls and the emergence of herbicide tolerant 'super-weeds'.

Edwin L. Johnson
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