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Chemicals

▶ 29th Adaptation to Technical Progress of the Dangerous Substances Directive (67/548/EEC)

On April 29, the Commission adopted Directive 2004/73 on the 29th adaptation to technical progress of Directive 67/548 on dangerous substances. It concerns the classification and labeling requirements for approximately 400 substances included in Annex I to Directive 67/548/EEC and it amends Annex V to the Directive on the methods authorized for determining physico-chemical properties, toxicity and ecotoxicity of substances and preparations in a way to minimize animal testing.

(Ref.: Directive 2004/73 / OJ L216)

▶ Risk Reduction Recommendations for Existing Chemicals

On April 29, the Commission adopted a Recommendation on the results of the risk evaluation and the risk reduction strategies for 11 "existing substances". These are: acetonitrile, acrylamide, acrylonitrile, acrylic acid, butadiene, hydrogen fluoride, hydrogen peroxide, methacrylic acid, methyl methacrylate, toluene and trichlorobenzene.

In the Annex to this Recommendation, Part 1-11, the Commission summarizes the risk assessment findings for each of the substances and lists the priority legislative measures it will propose to implement the risk reduction strategy.

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▶ **Marketing Restrictions for Toluene and TCB**

In the framework of the above mentioned risk reduction strategy, the Commission adopted a proposal for a Directive amending Directive 76/769/EEC to include restrictions on the marketing and use of substances toluene and trichlorobenzene (TCB). The Commission proposes restrictions on toluene in adhesives and spray paints intended for sale to the general public, and for all uses of TCB except as an intermediate.

(Ref.: COM(2004)320)

▶ **POPs Regulation**

On April 29, the European Parliament and Council adopted at First Reading Regulation 850/2004 on Persistent Organic Pollutants (POPs) and amending Directive 79/117/EEC. The Regulation implements the Stockholm Convention and the Long Range Transboundary Air Pollution Protocol on POPs in EU law. It also prohibits the re-use, recycling or recovery of contaminated waste and creates a Committee for waste matters. It further introduces so-called "name and shame" provisions, which require the information on infringements and names of contravening companies to be published. The Regulation applies as of May 20, 2004.

(Ref.: Regulation 850/2004/OJ L229)

▶ **Fluorinated Gases**

On March 31, the European Parliament adopted its First Reading position on the Commission's proposal for a Regulation on certain fluorinated greenhouse gases. The purpose of the Commission's proposal is to reduce emissions of hydrofluorocarbons (HFCs), perfluorocarbons (PFCs) and sulphur hexafluoride in refrigeration, air conditioning, fire-fighting equipment and various industry processes.

The Parliament deleted the new quotas system proposed by the Commission and required that starting January 1, 2011 Member States can no longer issue EC type approval for vehicles if the global warming potential of the fluorinated greenhouse gases used in air-conditioning systems is higher than 50. Furthermore, after January 1, 2014, the cars will be banned for sale or import. The Parliament also notably wishes to promote alternatives to F-gases and prevention of their leaking in all sectors where they are used.

(Ref.: COM(2003)492)

▶ **Detergents**

On March 31, the European Parliament and Council adopted a Regulation on Detergents. The Regulation harmonizes the rules for placing on the market of detergents and surfactants for detergents mainly with respect to their biodegradability (including restrictions or bans on grounds of biodegradability), their labeling (including fragrance and allergens) and the information that producers must hold at the disposal of Member States' competent authorities and medical personnel. The Regulation repeals Directives 73/404/EEC, 73/405/EEC, 82/242/EEC, 82/243/EEC and 86/94/EEC. It will enter into force on October 8, 2005.

(Ref.: Regulation 648/2004)

▶ **European Reference Materials**

On May 11-14, a new European Trade Mark "ERM[®] - European Reference Materials", guaranteeing a quality system for measuring chemicals, biological and GMO elements in products was launched at the Analytical Fair conference in Munich. The Commission supports this initiative which is believed to reinforce public confidence in food consumption, healthcare and environmental protection by ensuring that measurements are based on reliable reference materials.

(Ref.: www.erm-crm.org)

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Pesticides/Biocides

▶ **Directive 91/414/EEC on Plant Protection Products**

On April 23, the Commission adopted a Directive on the addition of six active substances (alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmediphan) to Annex I to Directive 91/414/EEC on plant protection products. The Annex I listing permits the marketing of plant protection products containing the active substances under certain conditions for a period of ten years. Member States must adopt the necessary implementing measures by August 31, 2005. The Commission also adopted a Directive on the Annex I listing of quinoxifen. Member States must adopt the necessary implementing measures by February 28, 2005.

On April 26, the Commission adopted a Directive to include active substance mepanipyrim in Annex I to Directive 91/414. Member States must re-evaluate products to check that they conform with Annex VI to Directive 91/414/EEC by September 30, 2004.

The Commission also adopted a Decision according to which Member States may extend authorization for products containing the active substance profoxydin up to April 26, 2006 and a Decision on non-inclusion of the active substance mefluidide. Plant protection products containing these active substances must be withdrawn from the EU market by October 26, 2004. Member States may grant grace periods that will end by October 26, 2005.

On April 28, the Commission adopted a Regulation on the continued use of certain active substances not included in Annex I to Directive 91/414/EEC, by reason of the accession of the ten new Member States. The Regulation provides grace periods of one year or six months for products which shall be withdrawn from the market. The derogations are granted only for the listed active substances (use-specific and Member State-specific derogations).

(Ref.: Directives 2004/58/EC, 2004/60/EC and 2004/62/EC, Decisions 2004/400/EC and 2004/401/EC and Regulation 835/2004)

▶ **Maximum Residue Limits**

On April 20, the European Parliament adopted its First Reading position on the proposal for a Regulation harmonizing the maximum residue limits (MRLs) of pesticides permitted in products of plant and animal origin.

On April 26, the Council reached a Political Agreement on this proposal. The future regulation would replace and simplify the four existing Council directives on MRLs (Ref: Directive 76/895 on MRLs in and on fruits and vegetables; Directive 86/362/EEC on MRLs in and on cereals; directive 86/363 on MRLs in and on food of animal origin; Directive 90/642/EEC on MRLs in and on certain products of plant origin, including fruit and vegetables).

All MRLs for pesticides will become harmonized after a transitional “phase in” period and will be set exclusively at the EU level. The Commission will then be solely responsible for setting MRLs on the basis of risk assessments made by EFSA. During the phase-in period, the Commission will establish temporary MRLs based on existing national ones.

The Political Agreement will be formalized in the form of a Common Position and sent back to the European Parliament for the Second Reading.

(Ref.: COM(2003)117)

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Life Sciences

▶ Health and Consumer Protection Council

On June 2, the EU Ministers in charge of health and consumer protection discussed a number of issues, including:

- Food Claims: Presentation of the Irish Presidency progress report. The Council is awaiting the European Parliament First Reading position, to be adopted by the newly elected Parliament in the autumn.
- Vitamins and Minerals added to Food: Presentation of the Irish Presidency progress report.
- Heart Health: Conclusions
- E-Health: Conclusions
- Childhood Asthma: Conclusions

(Ref.: 9507/04)

▶ Commission Detailed Rules on GM Authorization

On April 6, the Commission adopted a Regulation on detailed rules for the implementation of Regulation 1829/2003 on the application for the authorization of new GM food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material which has benefited from a favorable risk evaluation. The Regulation is applicable as of April 18, 2004.

(Ref.: Regulation 641/2004)

▶ GM Maize Authorization

As expected, the Council, like the Standing Committee, failed to reach a qualified majority position on the Commission proposal authorizing the Syngenta GM Maize Bt 11 as a novel food under Regulation 258/97. The Council had a 3-month deadline

from the Commission proposal to either adopt or reject the text by qualified majority. After this time limit, the Commission was obliged to adopt the Decision (*Note: Decision of May 19 not yet published*). The authorization is valid for 10 years and is applicable to Syngenta only.

On June 16, in the Regulatory Committee, the 25 representatives of EU Member States also failed to reach a qualified majority agreement for authorization of Monsanto's genetically modified oilseed rape GT73 under Directive 2001/18/EC.

Similarly, on June 28 in the Environment Council, the Ministers could not reach a qualified majority position on the Commission proposal for authorization of import and processing of Monsanto's GM Maize NK603 under Regulation 258/97.

(Ref.: IP/04/663/COM(2004)439)

▶ **WHO Conferences**

On May 22, the WHO/FAO annual assembly adopted a global strategy on diet, physical activity and health.

On June 23-25, the WHO organized a ministerial conference on Environment and Health and adopted a children's environment and health Action Plan (CEHAPE).

(Ref.: http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf)

▶ **European Strategy for Nanotechnology**

The Commission issued a preliminary risk analysis on nanotechnologies (NTs) (based on a workshop organized in Brussels by the European Commission's DG SANCO on March 1-2, 2004). The Commission subsequently also issued a Communication on a European Strategy for Nanotechnology.

(Ref.: COM(2004)338 / EU Environmental Law Bulletin, June 28, 2004, Vol. II . No. 6)

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Food

▶ **Official Food and Feed Control**

On April 26, the Council adopted at First Reading the proposed Regulation on official feed and food controls. This Regulation lays down general rules for the performance of official controls to verify compliance with rules aiming at preventing, eliminating or reducing to acceptable levels risks to humans and animals. It streamlines and reinforces the existing control system by introducing tougher enforcement systems, including criminal sanctions. Member States continue to be responsible for controls but the Commission checks the standards through visits of the Food and Veterinary Office (FVO). The Regulation repeals and replaces Directives 70/373/EEC, 89/379/EEC, 93/99/EC and 95/53/EC. It applies as of January 1, 2006.

(Ref.: Regulation 882/2004)

▶ **Novel Foods**

On March 31, the Commission authorized the marketing of a series of food products enriched with phytosterols or phytostanols as novel foods or food ingredients under Regulation 258/97.

(Ref.: Decision 2004/333/EC, 2004/334/EC, 2004/335/EC and 2004/336/EC)

▶ **Food Additives**

On April 16, the Commission adopted a Directive amending Directive 96/77/EC laying down specific purity criteria for food additives other than colors and sweeteners. Member States must implement the Directive by April 1, 2005. Products put on the market or labeled before that date and which do not comply with the Directive's purity criteria may be marketed until stocks are exhausted.

(Ref.: Directive 2004/45/EC)

▶ **Register of Flavoring Substances**

On April 7, the Commission adopted a Decision amending Decision 99/217/EC regarding the register of flavoring substances based on Member States notifications of the substances which may be used in or on foodstuffs marketed in their territory. Substances listed in the register will be evaluated to verify compliance with the general criteria set out by Regulation 2232/96.

(Ref.: Decision 2004/357/EC)

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Environment General Issues

▶ **Environment Council**

On June 28, the 25 EU Ministers for environment met for the last Environment Council under the Irish Presidency. The discussions mainly covered:

- Shipment of waste: Political Agreement could not be adopted for reasons of disagreement with the Commission on the issue of the legal basis of the future Regulation.
- Thematic strategy on the prevention and recycling of waste: Conclusions
- Mining waste: Policy debate in view of Political Agreement in October
- REACH Regulation proposal: Policy debate
- Marketing authorization for GM maize NK 603: No qualified majority could be attained
- Halting the loss of biodiversity by 2010: Conclusions
- Sulphur content of marine fuels: Political Agreement
- Revision of the bathing water Directive: Political Agreement

(Ref.: 10746/04 Presse 203)

▶ **Competitiveness Council**

On May 17-18, the 25 EU Ministers for industry/competition met for the Competitiveness Council. The discussions mainly covered:

- Unfair Commercial Practices Directive: Political Agreement (European Parliament 1st Reading on April 20)
- REACH: Policy debate
- Community Patent: No agreement, file to be referred to the President of the European Council (proposal could be withdrawn)
- Software Patentability: Political Agreement
- Consumer Protection Cooperation: First Reading Agreement
- Sales Promotions: Discussions
- Community Customs Code: Political Agreement

(Ref.: 9081/1/04 REV1 Press140)

▶ **Health and the Environment Action Plan 2004-2010**

On June 9, the Commission adopted an action plan to reduce diseases caused by a polluted environment. It identifies 13 actions which aim at improving the information chain by developing integrated environment and health information, better understanding the environment-health link, filling the knowledge gap (by strengthening research on environment and health and identifying emerging issues) and reviewing policies and improving communication by developing awareness raising, risk communication, training and education. The action plan focuses on four identified priority diseases: asthma/allergy, neuro-developmental disorders, cancers and endocrine disrupting effects.

(Ref.: COM(2004)416 / IP/04/728 / MEMO/04/143)

▶ **Environmental Liability**

The European Parliament and the Council of the European Union recently adopted Directive 2004/35/EC on environmental liability, which aims to prevent and remedy environmental damage and is based on the "*polluter pays*" principle.

The Directive covers future damages and imminent threats of damages to biodiversity, waters, land or human health. It introduces minimum requirements only and allows Member States to adopt or maintain more stringent national legislation. Member States must implement the Directive within three years of its publication (which is an unusually long implementation period), i.e., by April 30, 2007.

(Ref.: Directive 2004/35/EC, OJ [L143](#) / EU Environmental Law Bulletin, May 10, 2004, Vol. II . No. 4)

▶ **Quality of Ambient Air**

On April 20, the European Parliament adopted its First Reading position on the Commission's proposal for a Directive on arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air. This position reflects a compromise deal with the Council and should be formally adopted unamended in the coming weeks.

The Parliament wanted to impose limit values to the heavy metals in ambient air instead of the monitoring requirements proposed by the Commission. The compromise deal with the Council sets target values, defined as a "*concentration in the ambient air fixed with the aim of avoiding, preventing or reducing harmful effects on human health and the environment as a whole, to be attained when possible over a given period*". Member States must take all necessary measures not

to be exceeded the target values after December 31, 2012. The Directive also fixes upper and lower assessment thresholds for the application of measurement techniques.

The Commission has already mandated the preparation of CEN standards for the measurement of these substances in ambient air. Until such standards are adopted, the international and national ones will be applicable.

By December 31, 2010, the Commission will present a report on the impact of these substances on human health and the environment and the progress on measurement methods. It will also evaluate the possibility to introduce limit values in a future amendment to the Directive (due to take place in 2010). The Member States will have to implement this Directive within two years from its entry into force.

(Ref: COM(2003)423)

► **Consultation on Mercury**

On March 15, the Commission launched a stakeholders' consultation on a future mercury strategy.

Mercury is considered an issue of high concern because this heavy metal is a long-range transboundary air pollutant, its levels of exposure are often above recommendations and it bioaccumulates and biomagnifies in organisms, it contaminates waters and is found in fish. Furthermore, it constitutes a specific current issue because the chlor-alkali industry (current largest user of mercury) is currently phasing out mercury-based processes (according to the IPPC Directive, ref.: 96/61/EC). This is expected to create a surplus of mercury which should be stored, recycled or phased out.

The objective of this strategy is to reduce the quantity of mercury in the environment, to tackle the issue of its surplus due to the conversion of the chlor-alkali industry and to encourage the new Member States to phase out mercury-based processes.

The consultation lasted until May 11, and the Commission is expected to adopt a mercury strategy by the end of the year.

(Ref.: <http://europa.eu.int/comm/environment/chemicals/mercury/>)

► **Volatile Organic Compounds**

On March 30, the European Parliament approved the Council Common Position on the proposed Directive "on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC."

The purpose of the Directive is to limit the total content of volatile organic compounds (VOCs) in paints and varnishes. It implements a two-phase approach to be in place by January 1, 2007 and by January 1, 2010. It also provides exemptions for paints for historic buildings or vehicles that require original paints. It does not prevent Member States from taking more stringent measures. Member States must implement the Directive's provisions by October 30, 2005.

(Ref.: Directive 2004/42/EC / OJ L143)

▶ **Batteries and Accumulators**

On April 20, the European Parliament adopted its First Reading position on the Commission's proposal for a Directive on batteries and accumulators and spent batteries and accumulators.

The Parliament wishes to fix stricter targets for recycling and recovery of batteries and accumulators. It sets a collection rate of 50% of the national annual sales of portable batteries (instead of a fixed weight per inhabitant) in a way to reflect the different consumption patterns of Member States. The Parliament also calls for a prohibition of all batteries containing more than 5ppm of mercury, 40 ppm of lead or 20 ppm of cadmium per weight. Annex II A provides a list of exemptions where no substitution to these metals is feasible.

(Ref.: COM(2003)723)

▶ **Waste from the Extractive Industry**

On March 31, the European Parliament adopted its First Reading position on the proposal for a Directive on the management of waste from the extractive industries. The Commission's proposal is aimed at tackling the issue of extractive waste, which constitutes 29% of the total waste by weight and is currently regulated by the waste framework Directive (Ref.: 75/442/EEC), the landfill Directive (Ref.: 99/31/EC) and national legislation. The objectives of the proposal are to prevent soil and water pollution, to ensure waste management stability and to regulate operating permits.

The Parliament's concerns focus on historical waste. It requires Member States to ensure rehabilitation of the most polluted sites within four years and to make available to the public an inventory of closed sites and disused facilities within three years. According to the Parliament's position, the operators must provide financial guarantees accompanying any application to construct a new waste facility on active sites.

(Ref.: COM(2003)319)

▶ **EU Waste Strategy**

On April 20, the European Parliament adopted an Opinion on the Commission Communication on a thematic strategy on the prevention and recycling of waste. It mainly expresses regret that the Communication does not include either re-use or recovery of waste, mainly for the purpose of energy production. The Opinion suggests that the Commission and Member States should set up a waste steering and advisory Committee monitoring and coordinating the implementation of waste legislation.

(Ref.: COM(2003)301)

▶ **National CO₂ Emission Allocation Plans**

On May 18, Commissioner Wallström confirmed that the Commission would send a letter of formal notice (first stage of the infringement proceedings) to six Member States (Spain, Greece, France, Italy, Belgium and Portugal) for not complying by

March 31 with Directive 2003/87/EC on greenhouse gas emission allowance trading. The Member States had to adopt by that date their national allocation plans for CO₂ emissions for the period 2005-2007 (some of these Member States have adopted their national plans in the meanwhile). The new Member States which joined on May 1 were also supposed to adopt their national plans by the accession date. However, the Commission granted them several additional weeks of grace.

(Ref.: SPEECH/04/254 / MEMO/04/44)

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Energy

▶ Eco-Design

On April 20, the European Parliament adopted its First Reading position on the proposal for a Directive establishing a framework for the setting of eco-design requirements for energy-using products and amending Council Directive 92/42/EEC. Its position focuses on clarity, better consumer information and transparency. The Parliament requires the Commission to propose within one year of the Directive's adoption implementing measures for those products that offer a high potential for cost-effective reduction of greenhouse gas emissions (such as heating and water heating equipment, electric motor systems, lighting, domestic appliances, office equipment, electronics and conditioning).

On June 10, the Council adopted a Political Agreement which still needs to be formalized into a Common Position before being sent to the Parliament for Second Reading.

(Ref.: http://europa.eu.int/comm/energy/electricity/whatsnew/index_en.htm COM(2003)453)

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Consumers/Safety/Intellectual Property

▶ Consumer Credit Directive

On April 20, the European Parliament adopted its First Reading position on the proposal for a Directive on Consumer Credit. It is aimed at enhancing consumer protection to avoid over-indebtedness and provide optimum harmonization. However, Member States can adopt higher standards of protection in some areas. The Council will adopt its Common Position in the coming months.

(Ref.: COM(2002)443)

▶ Best Practice Guide on Product Safety

On June 24, Intertek Research presented the "European Guide to corrective action, including product recalls to protect consumers from dangerous products". This guide is not an EU communication from the Commission, but it was published in the 19 official languages of the Union and consists of voluntary best practices agreed between several EU associations on consumer protection, retail and industrial employers.

(Ref.: http://europa.eu.int/comm/consumers/cons_safe/action_guide_en.pdf)

▶ **Health and Safety at Work**

The Council and the European Parliament adopted a codified version of Directive 90/394/EEC on the protection of workers from risks related to exposure to carcinogens and mutagens at work.

On April 29, the European Parliament and Council also adopted a Directive on minimum health requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 18(1) of Directive 89/391/EC). In the original proposal in 1992, electromagnetic fields were included in a single proposal covering four types of physical agents. However, due to the complexity of the different agents, it was later decided to examine each one separately. Directives on vibration and noise have already been adopted in recent years.

The Directive introduces exposure limit values and action values based on the recommendations drawn up by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). It must be implemented by Member States by April 30, 2008.

(Ref.: Directive 2004/37, OJ L229 and Directive 2004/40, OJ L159)

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Institutional Issues

▶ **EU25**

As of May 1, the European Union counts 25 Members. The ten new Member States are: Estonia, Lithuania, Latvia, Poland, Czech Republic, Hungary, Slovenia, Slovakia, Cyprus, and Malta. As a result of the accession, most of the EU legislation is applicable to the new Member States from the accession date. The Union now counts 19 official languages.

▶ **European Summit / Constitution of the European Union**

On June 17-18, the 25 Heads of States and Governments met in Brussels for a European Summit. They adopted Europe's first Constitution, which must be ratified in each Member State. (Some Member States decided to organize a referendum prior to ratification). The Constitution has already been criticized as too influenced by Euro-skeptics and weak on social provisions.

Main provisions:

European Parliament (Article I-19§2):

- It sets a minimum number of 6 seats for the smallest Member States and 96 seats for biggest.
- The Parliament will count up to 750 Members.

Voting system in the Council:

- Qualified majority is 55% of Member States representing 65% of the population, without counting abstentions (Article I-24§1). This qualified majority will be applicable until 2014, unless the Council extends it itself by qualified majority.
- Super qualified majority is 72% of the Member States representing 65% of the population, applicable when the Council wants to adopt legislative documents that were not initiated by the Commission or the Foreign Affairs Ministers (Article I-24§2).

European Commission (Article I-25§3):

- There will be one Commissioner per Member State until 2014.
- After 2014, the number of Commissioners will equal two-thirds of the number of Member States, with strictly equal rotation.

On June 29, the Presidency organized an exceptional European Council to appoint Portugal's Prime Minister José Manuel Barroso as the next European Commission President as of November 2004.

▶ **Program of the Dutch Presidency**

From July to December 2004, the rotating presidency of the European Union is held by the Netherlands. Its priorities mainly cover:

- REACH Regulation proposal: The Netherlands wants to focus specifically on the most hazardous chemicals rather than on tonnage; a Common Position is not expected under the Dutch Presidency, however the Netherlands will attempt to make substantive progress on the file.
- Unfair Commercial Practices: Second Reading in the European Parliament
- Climate Change: Climate Conference "COP 10" in December 2004
- Mining waste: Second Reading in the European Parliament
- Fluorinated gases: Possible Political Agreement
- Aarhus package: Decision on ratification
- Mining Waste: Possible Political Agreement
- Urban Environment Strategy
- Mercury Strategy

(Ref.: <http://www.eu2004.nl/>)

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