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Chemicals

Marketing and Use Restrictions on PFOS

On 12 December, the Parliament and Council adopted [Directive 2006/122/EC](#) amending for the 30th 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 (perfluorooctane sulfonates). PFOS may not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0.005 % by mass. The text contains several derogations for photoresists or anti reflective coatings for photolithography processes, photographic coatings applied to films, papers, or printing plates, mist suppressants for non-decorative hard chromium (VI) plating and wetting agents, hydraulic fluids for aviation and fire-fighting foams. This legislation must be implemented by Member States by 27 December 2007 and will apply from 27 June 2008. The Directive furthermore highlights the similarities with substance PFOA and the need to propose all necessary measures to reduce identified risks for this substance.

Marketing and Use Restrictions on Arsenic Compounds

On 20 December, the Commission adopted [Directive 2006/139/EC](#) amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of arsenic compounds for the purpose of adapting its Annex I to technical progress. Arsenic compounds shall not be placed on the market or used as substances and constituents of preparations intended for use to prevent the fouling by micro-organisms, plants or animals of:

- The hulls of boats
- Cages, floats, nets and any other appliances or equipment used for fish or shellfish farming

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- Any totally or partly submerged appliances or equipment

They shall not be placed on the market or used as substances and constituents of preparations intended for use in the treatment of industrial waters, irrespective of their use, or in the preservation of wood. This legislation must be implemented by Member States by 30 June 2007 and apply from 30 September 2007.

Export and Import of Dangerous Chemicals

On 30 November 2006, the Commission adopted a Proposal for a Regulation of the European Parliament and of the Council concerning the export and import of dangerous chemicals (COM(2006)745).

This issue is currently under the scope of Regulation 304/2003 of 28 January 2003 implementing the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade.

On 10 January 2006, in its judgment in Case C-178/03, *Commission v. Parliament and Council*, the Court of Justice annulled Regulation 304/2003, ruling that there should have been a dual legal basis including both Articles 133 and 175 first paragraph of the Treaty. The Court however maintained the effects of the Regulation until the adoption, within a reasonable period of time, of a new regulation founded on appropriate legal bases. The Regulation goes significantly beyond the requirements of the Convention. The key differences are summarized by the Commission as follows:

- The rules apply to exports to all countries, whether or not they are Parties to the Convention.
- A wider range of chemicals are subject to annual export notification. For the purposes of determining which chemicals should be subject to the procedure, the two Convention use categories (pesticides and industrial chemicals) are divided into two subcategories each (plant protection products and other pesticides such as biocides; and chemicals for professional use and chemicals for consumer use). Moreover, export notification has to be made irrespective of the chemical's intended use and whether or not that use is banned or severely restricted in the EU. Furthermore chemicals subject to the international PIC procedure ('PIC chemicals') and certain articles are also covered.
- PIC chemicals and chemicals that are banned or severely restricted in the Community in a Convention use category cannot be exported without the explicit consent of importing countries.
- Certain articles and chemicals (like the chemicals that are subject also to the Stockholm Convention on Persistent Organic Pollutants) are banned for export.
- All dangerous chemicals exported to third countries have to be labelled and packaged in the same way as they must be within the Community.
- Consistency with the other policies and objectives of the Union.

In the proposed new Regulation, the definitions of exporter and preparation are clarified, as well as the procedure for explicit consent; the custom control is furthermore strengthened. On the same day, the Commission adopted a Report on the operation of Regulation 304/2003 (COM(2006)747). The report covers the period from 2003 to 2005 and reviews implementation of the procedures, it also considers implementation problems that have been encountered and possible changes to the Regulation that could further improve its functioning.

Prior Informed Consent

On 25 September 2006, the Council adopted a Decision on the conclusion, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous

chemicals and pesticides in international trade.

Ban On Metallic Mercury

On 26 October 2006, the Commission adopted a Proposal for a Regulation of the European Parliament and the Council on the banning of exports and the safe storage of metallic mercury ([COM\(2006\)636](#)). The Proposal aims at banning the export of metallic mercury from the Community as well as at ensuring that this mercury does not re-enter the market and is safely stored, in line with the Community Strategy on Mercury ([COM\(2005\)20](#)).

REACH Final Adoption After Three Years of Negotiation

On 13 December 2006 the European Parliament adopted in Second Reading the compromise package agreed with the Council. The Council then adopted the final REACH text (Regulation **1907/2006/EC**) at the Environment Council on 18 December 2006 and the Regulation was published in the Official Journal on 30 December 2006.

The main compromises reached during the last adoption stages were:

- An ease of the registration obligations for substances manufactured or imported in yearly quantities between 1 to 10 tons, which are exempt from undergoing sophisticated health and safety tests.
- Companies are no longer obliged to demonstrate lack of alternatives in order to obtain an authorization of substances of very high concern in all cases, they may still demonstrate "adequate control".
- Ease of the substitution principle, which was one of the last outstanding issues. Under the final text, producers will have to submit a substitution plan for more hazardous substances to progressively phase them out. Where there is no alternative, producers will have to present a research plan aimed at finding one. Substitution obligations will not be imposed in all cases. For persistent and bio-accumulative substances, they will be authorized if no suitable substitute is available and if it is demonstrated that there is "adequate control".
- Companies now have a duty of care *i.e.* they are now legally compelled to handle chemicals safely when manufacturing, importing or placing a substance on the market.
- On the authorization procedure and time limits on authorizations, which were one of the most controversial points, it was agreed that the time-limits will be decided on a case-by-case basis, and not a fixed period of five years, as proposed by the Parliament.
- The issue of data sharing was also a source of fierce debate, the industry fearing that the mandatory data sharing system would cover both animal and non-animal related data. For both phase-in and non-phase-in substances, there is an obligation to share the data gained by vertebrate animal testing, in exchange for "proportionate" payment. The obligation also lies upon the registrant who has the obligation to request the sharing of these studies. As for studies involving non vertebrate animals, data sharing is only mandatory upon request of the potential registrant.

The main obligations stemming from REACH are safety screening and registration which will take place in three stages, depending on the volumes of substances and the risks they pose. The registration deadlines are the following:

- 1 June 2008 to November 2008: pre-registration of the so-called "phase-in substances"

- December 2010: registration deadline for substance in quantities of 1000 tons and above as well as carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) above 1 ton per year and substances classified as very toxic to aquatic organisms (R50/53) above 100 tons.
- June 2013: registration deadline for substance in quantities of 100 tons and more and substances toxic for the aquatic environment.
- June 2018 : registration deadline for substances in quantities of 1 ton and more.

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Pesticides/Biocides

Review of PPP Active Substances

The following directives and decisions provide for the inclusion or non inclusion of active substances to Annex I to Council Directive 91/414/EEC on Plant Protection Products:

- Commission Directives on the inclusion as active substances of dinocap (2006/136/EC), carbendazim (2006/135/EC), fenarimol (2006/134/EC), flusilazole (2006/133/EC), procymidone (2006/132/EC), methamidophos (2006/131/EC), fenamiphos (2006/85/EC), chlorothalonil (2006/76/EC), dimoxystrobin (2006/75/EC), dichlorprop-P, metconazole, pyrimethanil and triclopyr (2006/74/EC).
- Commission Decisions on the non-inclusion of and the withdrawal of authorisations for plant protection products containing alachlor (2006/966/EC), phosalone (2006/1010/EC), dimethenamid (2006/1009/EC), ammonium sulphamate, hexaconazole, sodium tetrathiocarbonate and 8-hydroxyquinoline (2006/797/EC).

Statistics on Pesticides

On 11 December 2006, the Commission adopted a Proposal for a Regulation of the European Parliament and of the Council concerning statistics on plant protection products ([COM\(2006\)778](#)).

The proposed Regulation creates a legal framework and lays down harmonised rules for the collection and dissemination of data concerning the placing on the market and use of plant protection products in order to establish a transparent system for reporting and monitoring the progress made towards the objectives of the Strategy on the sustainable use of pesticides ([COM\(2002\)349](#)).

EFSA Completes 2nd Stage of EU-Wide Pesticides Peer Review Process

In October 2006, EFSA has completed its work on the 2nd stage of the EU-wide peer review of active substances used in pesticides, and issued conclusions on 50 substances that have been peer reviewed for safety by experts from the EU Member States and EFSA. The Commission and the Member States are finalising decision-making on these, which will determine whether these substances can continue to be used in the EU. Meanwhile, EFSA has begun work on the 137 substances covered by the 3rd stage of the review which is to be completed by 2008.

(Ref:http://www.efsa.europa.eu/en/press_room/press_release/pr_praper-2nd-stage.html)

Biocides

On 14 December 2006, the Commission adopted [Regulation 1849/2006](#) amending Regulation 2032/2003 concerning the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC

on biocidal products.

The Regulation amends the list of substances of the Annexes I to VII to Regulation 2032/2003 (adding and removing entries). It also requires Member States to ensure that, after 1 September 2006, biocidal products containing existing active substances for which a non-inclusion decision was taken for certain or all of their notified product types, are no longer placed on the market in their territory for the product types concerned, with effect from 12 months after the date of such decision entering into force; unless otherwise stipulated in that non-inclusion decision.

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Cosmetics

Consultation on the Simplification of the Cosmetics Directive

On January 12, the Commission has launched a consultation round for stakeholders on the simplification of the Cosmetics Directive. This new framework should replace the existing EU Cosmetics Directive 1976/768, which has been amended almost 50 times. Stakeholders can participate to this consultation by 16 March 2007 and a new framework should be adopted by 2010.

(Ref:http://ec.europa.eu/enterprise/cosmetics/html/cosm_simpl_dir_en.htm)

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Life Sciences

GM Approval Procedure

Commission [Decision](#) of 5 September 2006 on emergency measures regarding the non-authorized genetically modified organism LL RICE 601 in rice products.

GMO Guidance Document

EFSA has published a [guidance document](#) of the Scientific Panel on Genetically Modified Organisms to assist applicants in the preparation and presentation of the application for renewal of authorization of GM food and/or feed.

GMO/WTO Trade Dispute: WTO Rules EU Ban Illegal

In May 2003, the US, Canada and Argentina launched a WTO dispute against the EU alleged *de facto* moratorium on the approval of new GMOs as well as a number of marketing and import bans. The Panel issued the interim report on 7 February 2006. The Panel found that:

- The general EU *de facto* moratorium violated the SPS Agreement by causing undue delay
- The delay in the approval of certain biotech products was violating the SPS Agreement
- Some of the safeguard measures taken by some EC Member States after products had been approved by the EC to be marketed EC-wide failed to meet the requirement of the SPS Agreement relating to risk assessment. A final decision is expected in 2007.

EFSA Opinions:

- [Opinion](#) of the GMO Panel related to the safeguard clause invoked by Greece to provisionally prohibit the cultivation of the authorized genetically modified maize MON810 on its territory. It was adopted on

a request by the Commission to determine as to whether there were an imminent danger for human health and the environment due to the cultivation of the maize varieties with the genetic modification MON810 expressing CRY1Ab protein. The GMO Panel concluded that MON810 maize is unlikely to have adverse effects on human and animal health or on the environment due to the cultivation of the maize varieties with the genetic modification MON810 in Greece.

- Opinion of the GMO Panel related on an application (Reference EFSA GMO UK 2004 08) for the placing on the market of products produced from glyphosate tolerant genetically modified sugar beet H7-1, for food and feed uses, under Regulation (EC) No 1829/2003 from KWS SAAT AG and Monsanto. The GMO panel concluded that products produced from sugar beet H7-1 are unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses.
- Opinion of the GMO Panel related on an application (Reference EFSA-GMO-NL-2005-13) for the placing on the market of glufosinate-tolerant genetically modified LLCotton25, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience [1]. The GMO Panel concluded that LLCotton25 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

New Rules for Medical Products for Pediatric Use

On 12 December 2006, the European Parliament and Council adopted Regulation 1901/2006/EC on medicinal products for pediatric use. It was further amended by Regulation 1902/2006/EC. It aims to improve the health of the children of Europe by stimulating the research, development and authorization of medicines to treat children. It lays down the rules concerning the development of medicinal products intended for the pediatric population. The text notably introduces new marketing authorizations procedures (PUMA) and a system of waivers as to avoid unnecessary studies in children. Further, it aims at increasing the availability of information on clinical trials. It will enter into force on 26 January 2007.

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Food

Nutrition and Health Claims Made on Food

On 20 December 2006, the European and the Council adopted Regulation 1924/2006. It aims to prevent consumers from being misled by claims by tying the use of health or nutrition claims to certain conditions related to nutrient profiles (*i.e.* level of fat, sugar, salt etc) of foods and substantiation of claims made under the Regulation, claims must not be false, ambiguous or misleading, nor give rise to doubt about safety or nutritional adequacy of other foods. Claims on alcoholic beverages above 1.2 % are banned. Health and nutrition claims will only be allowed if there is generally accepted scientific evidence and the ingredient, on which the claim is based, is present in a quantity that would produce the said effect. Claims are subject to pre-marketing approval. The regulation entered into force on 19 January 2007. The first provisions will begin to apply 6 months from entry into force, but there will be transition periods of several years for products already on the market.

Vitamins and Minerals Addition in Food

In 20 December 2006, the European Parliament and the Council adopted Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to food. It provides for the harmonisation of fortification of food and drinks. The term "*other substance*" refers to substances other than vitamins or minerals that have nutritional or physiological effects (e.g. antioxidants). Under that Regulation, fortification will only be allowed where there is a deficiency in the population or specific group of the population or where there is potential to enhance nutritional status. The regulation will enter into force within 20 days of its publication in the Official Journal (20 December 2006) and it shall apply from 1 July 2007.

New Ingredients for Labeling of Foodstuffs

On 17 February 2006, the Commission adopted [Directive 2006/142/EC](#) listing the ingredients which must under all circumstances appear on the labeling of foodstuffs. It amends Annex IIIa of Directive 2000/13/EC on the labeling of foodstuffs by adding a list of new ingredients. Lupins and Mollusks products thereof are added to the list. The Regulation will enter into force within 20 days of its publication in the Official Journal (23 December 2006). As of 23 December 2007, Member States shall authorize the sale of products which comply with the Directive and prohibit those which do not comply as of 23 December 2008.

Good Manufacturing Practices

On 22 December 2006, the Commission adopted Regulation [2023/2006](#) on good manufacturing practice for materials and articles intended to come in contact with food. This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles. It shall apply from 1 August 2008.

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Environmental General Issues

Protection of Groundwater Against Pollution and Deterioration

On 12 December 2006, the Parliament and Council adopted in Conciliation (Third Reading) Directive [2006/118/EC](#) on the protection of groundwater against pollution and deterioration. The Directive establishes specific measures as provided for in the Water Framework Directive (Article 17 of Directive 2000/60/EC) in order to prevent and control groundwater pollution. Measures include in particular criteria for the assessment of good groundwater chemical status. The Commission will have to review every 6 years the Annexes listing quality standards of water and threshold values for some chemicals.

Environment Council

On December 18, the Ministers for Environment met for an Environment Council meeting. Among other issues, the Ministers discussed:

- Marine strategy: political agreement on a draft Directive establishing a framework for community action in the field of marine environmental policy
- Halting the loss of biodiversity - Council Conclusions
- Climate change - Council Conclusions
- Genetically modified organisms (GMOs) : by qualified majority, two decisions rejecting two proposals from the Commission (13764/06 and 13767/06), requesting Austria to repeal the temporary precautionary measures concerning the use and sale on its territory of two genetically modified types of maize.
- Proposal for a Directive on waste: Progress report from the Presidency
- Thematic strategy on the sustainable use of pesticides, information from the Presidency
 - Proposal for a Directive establishing a framework for Community action to achieve a sustainable

use of pesticides

- Proposal for a Regulation concerning the placing of plant protection products on the market
- Aarhus Convention – GMOs. The Council adopted a decision on the conclusion, on behalf of the European Community, of an amendment to the Convention on access to information, public participation in decision making and access to justice in environmental matters (Aarhus Convention), to impose more specific obligations concerning public participation in decision-making on genetically modified organisms.

Council Press Release:

http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/envir/92249.pdf

Allocation of Emission Levels Under the Kyoto Protocol

On 14 December 2006, the Commission adopted [Decision 2006/944/EC](#) determining the respective emission levels allocated to the Community and each of its Member States under the Kyoto Protocol pursuant to Council Decision 2002/358/EC. The Annex of the Decision sets the emission levels in terms of tons of carbon dioxide equivalent allocated to the Community and to Member States for the first quantified emission limitation and reduction commitment period under the Kyoto Protocol. The Commission reduced the allowances by almost 7 per cent below the emissions proposed by the national allocation plans and 7 per cent below the 2005 emissions.

Air Transport to Enter EU Emission-Trading Scheme

On 20 December 2006, the Commission adopted a Proposal for a Directive of the European Parliament and of the Council amending Directive 2003/87/EC so as to include aviation activities in the scheme for greenhouse gas emission allowance trading within the Community ([COM\(2006\)818](#)). The proposed Directive will cover emissions from flights within the EU from 2011 and all flights to and from EU airports from 2012. Both EU and foreign aircraft operators would be covered.

Thematic Strategy on Soil Protection

On 22 September 2006, the Commission adopted a Communication on a Thematic Strategy on Soil Protection ([COM\(2006\)231](#)). The Strategy aims to prevent further soil degradation and preserve its functions. When soil is used and its functions are exploited, action has to be taken on soil use and management patterns, and when soil acts as a sink/receptor of the effects of human activities or environmental phenomena, action has to be taken at source. It also seeks the restoration of degraded soils to a level of functionality consistent at least with current and intended use, thus also considering the cost implications of the restoration of soil.

Batteries and Accumulators

On 6 September 2006, the Parliament and the Council adopted [Directive 2006/66/EC](#) on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC. The old Directive needed to be revised to be put in line with the 6th Environment Action Program and Directive 2002/96 on Waste Electrical and Electronic Equipment. The new Directive notably enhances bans on the placing on the market of batteries containing mercury or cadmium, it also promotes a higher level of collection and recycling, and now applies to **all** batteries. Member States must implement this Directive by 26 September 2008.

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Energy

Energy Efficiency

The European Commission presented its Energy Efficiency Action Plan in October 2006. The Plan contains a package of priority measures covering a wide range of cost-effective energy efficiency initiatives. These include actions to make energy appliances, buildings, transport and energy generation more efficient. Stringent new energy efficiency standards, promotion of energy services, specific financing mechanisms to support more energy efficient products are proposed. Altogether, over 75 measures are set forth.

(Ref:<http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/6&type=HTML&aged=0&language=EN&guiLanguage=en>)

Renewable Energies and Emissions Trading

In January 2007, the Commission has proposed a comprehensive package of measures to establish a new Energy Policy for Europe to combat climate change and boost the EU's energy security and competitiveness. The package of proposals sets a series of ambitious targets for greenhouse gas emissions and renewable energy and aims to create a true internal market for energy and strengthen effective regulation. This should lead to a 30% cut in emissions from developed countries by 2020. On 29 November 2006, the Commission assessed the national allocations plans for the period 2008-2012 under the European Emission Trading Scheme and reiterated it will cut down emissions. Indeed, the Commission recommended that allowances be reduced by almost 7 per cent below the emissions proposed by the national allocation plans and 7% below the 2005 emissions.

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Social Affairs/ Workers Safety/ Consumers

Misleading and Comparative Advertising

On 12 December 2006, the Parliament and the Council adopted Directive [2006/114/EC](#) concerning misleading and comparative advertising. This text consist in the codified version of Council Directive 84/450/EEC concerning misleading and comparative advertising that had been amended several times.

Good Handling of Silica

On 17 November 2006, the Official Journal published the Autonomous Agreement signed on 25 April 2006, by 4 European social partners and 13 European industry organisations on protecting workers through the good use of Crystalline Silica. This is the first multi-sectorial Autonomous Social Dialogue Agreement adopted at European level.

Workers Equipment

On 3 November 2006, the Commission adopted a Proposal for a Directive of the European Parliament and of the Council concerning the minimum safety and health requirements for the use of work equipment by workers at work ([COM\(2006\)652](#)). The purpose of this proposal is to undertake a codification of Council Directive 89/655/EEC of 30 November 1989 on the same issue. The new Directive will integrate the various amendments into a single text.

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Institutional Issues

Enlargement

On 1 January 2007 Bulgaria and Romania joined the European Union, which now makes 27 Member States.

Bulgaria and Romania applied for EU membership in 1995 and began accession negotiations in 2000, which were successfully concluded in 2004. The last monitoring report on Bulgaria and Romania demanded further efforts, but concluded that both countries were fit to join the Union in 2007. The qualified majority rules included in the Council rules of procedure have been amended accordingly ([Decision 2007/4](#)).

Amended Comitology Rules: “ The Regulatory Procedure with Scrutiny”

On 17 July 2006, the Council published [Decision 2006/512/EC](#), which amended the so-called “Comitology” Decision. Comitology is a unique procedure for the adoption of implementing measures under EU legislation. Such implementing measures are adopted by the Commission after review by a Regulatory Committee made up of Member States’ officials (experts). Under the new rules, the European Parliament’s right of scrutiny already provided by Article 8 of [Decision 1999/468/EC](#) was expanded. In October 2006, a Joint Statement of the Council, Parliament and Commission was released, which provides that the new comitology procedure will also be applied to the WEEE, RoHS, and EuP directives and many other existing pieces of secondary Community legislation.

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