European Union Food Law Update

by

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EUROPEAN UNION FOOD LAW UPDATE

*By Nicole Coutrelis**

The purpose of this update is to present the main events that have taken place each six months in the food law sector in the European Union (E.U.). This presentation will cover June through December 2004, but is not exhaustive. This update will not include detailed discussions of regulations, such as authorizations of new additives for animal feed or registrations of new geographic names. Instead it will concentrate on fundamental topics and focus on food, which excludes from our scope questions regarding the management of agricultural products (Common Agricultural Policy, or CAP). However, some questions which legally pertain to the CAP (such as specification or presentation of some agricultural products when they are delivered to the final consumer) will be addressed when it appears they are relevant for those who are involved in food law.

Within each issue, the presentation of this update will follow the same pattern. The update will be divided into four main sections: published regulations, pending draft regulations, cases, and other relevant news.

I. Published Regulations

1. General Food Law and the European Food Safety Authority

On August 25, 2004, the Commission published a decision creating an advisory group concerned with food and feed safety, food and feed labeling and presentation, human nutrition, animal health and welfare, and various matters related to crops and seeds.[1] This advisory group will be composed of representatives from European bodies with

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1. Commission Decision 2004/613, 2004 O.J. (L 275) 17.

the objective of protecting the interests of the various fields covered by food legislation, such as industry, retailers, and consumers.[2] It replaces the former Advisory Committee on Foodstuffs.[3] Applications for membership were initiated in September,[4] but the composition of the group had not been announced as of the submission of this article for publication.

On December 24, 2004, the Commission published a regulation "laying down detailed rules for the implementation of the European Parliament and Council Regulation 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's [EFSA] mission."[5] This regulation lays down the basic rules governing the Member States's authorities, which form part of the network related to EFSA (i.e., national Food Safety Agencies) and the functioning of such network. The objective of this network is to assist EFSA in scientific tasks which can be distributed among those entities according to their competence.[6] The regulation includes specific requirements regarding tasks related to genetically modified organisms (GMOs).[7]

2. Novel Foods

Since GMOs have been removed from the scope of the "novel food" regulation[8] by the enforcement of Regulation 1829/2003,[9] this section only deals with non-GM novel foods.

On December 11, 2004, the Commission published a decision authorizing the marketing of milk-based beverages with added phytosterols as novel foods.[10] Phytosterols, which are well-known for their cholesterol lowering effects, were not on the E.U. market before May 1997, which was the effective date for the "novel food" regulation. Therefore, products containing phytosterols have been subject to the

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2. Decision 2004/613, 2004 O.J. (L 275) at 18 (limiting the group to forty-five members).
3. Decision 2004/613, 2004 O.J. (L 275) at 17.
4. Decision 2004/613, 2004 O.J. (L 275) at 18.
5. Commission Regulation 2230/2004, 2004 O.J. (L 379) 64.
6. Regulation 2230/2004, 2004 O.J. (L 379) at 65.
7. Regulation 2230/2004, 2004 O.J. (L 379) at 65-66.
8. Parliament and Council Regulation 258/97, 1997 O.J. (L 43) 2 (defining a novel food as a food or food ingredient that was not used for "human consumption to a significant degree" within the E.U. before May 1997).
9. Council Regulation 1829/2003, 2003 O.J. (L 268) 1, 2 (stating that, for the most part, "foods covered by an authorisation granted under this Regulation will be exempted from the requirements . . . concerning novel foods and novel food ingredients" and referencing some specific exceptions).
10. Commission Decision 2004/845, 2004 O.J. (L 366) 14.

novel food procedure and must obtain pre-market approval based on a scientific dossier.[11] The first authorization was delivered in July 2000 for margarine.[12] Considering the development of such products, the Commission also adopted a general regulation regarding the labeling of food and food ingredients with added phytosterols in order to avoid excessive intake.[13] With the present decision, the Commission has granted an approval for the marketing of milk drinks where the milk fat has been partially or fully replaced by vegetable fat, provided certain conditions are met regarding their composition.[14]

3. Genetically Modified Organisms

On September 18, 2004, the Commission published a decision "concerning the placing on the market . . . of a maize product (*Zea mays* L. line NK603) genetically modified for glyphosate tolerance."[15] This decision authorized the importation of a new variety of GM maize, and is the first authorization since Directive 2001/18 "on the deliberate release of genetically modified organisms into the environment" became effective.[16] For political reasons, this Decision was extremely difficult to reach because there was not a sufficient majority of Member States in support of the authorization, which had been requested by Spain and proposed by the Commission. The decision had to be sent to the Council, but since a majority was not reached at the Council, the latter did not make decision there either. According to the "Comitology" procedure, the Commission then took the decision itself despite the lack of majority in support of its decision.

It is important to note that the scope of this decision and its practical effect are extremely limited. The authorization is only for importation of the products and for use in animal feed only; the product was not authorized for cultivation or for use in food for human consumption. Furthermore, the entry into force of the decision was delayed until the product was also authorized for human food. On

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11. *See* Regulation 258/97, 1997 O.J. (L 43) at 4.

12. Commission Decision 2000/500, 2000 O.J. (L 200) 59.

13. Commission Regulation 608/2004, 2004 O.J. (L 97) 44.

14. The Commission issued four decisions on March 31, 2004 that authorized products enriched with phytosterols/phytostanols. *See* Commission Decision 2004/333, 2004 O.J. (L 105) 40; Commission Decision 2004/334, 2004 O.J. (L 105) 43; Commission Decision 2004/335, 2004 O.J. (L 105) 45; Commission Decision 2004/336, 2004 O.J. (L 105) 49.

15. Commission Decision 2004/643, 2004 O.J. (L 295) 35.

16. Council Directive 2001/18, 2001 O.J. (L 106) 1. This Directive replaced Council Directive 90/220, 1990 O.J. (L 117) 15.

October 26, 2004, the Commission announced that the authorization for food use had also been granted.[17]

On November 24, 2004, the Commission published a Recommendation, dated October 4, 2004 "on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation 1830/2003."[18] Regulation 1830/2003 on traceability and labeling of GMOs provides for controls and inspections to be undertaken by the Member States on all GM products—whether they are produced within the Community or imported, whether for domestic consumption or for exportation.[19] The Regulation also states that the Commission should provide guidance on sampling and testing to help the Member States undertake this task. Although the guidance issued in November is not legally binding, as it is a "recommendation" and not a decision or a Regulation, it certainly provides a basis on which the Member States should rely and which should provide some legal certainty to operators. This document provides precise indications as to the sampling and makes reference to certain International Organization for Standardization (ISO) standards. However, it is also acknowledged that there may be several methods for the detection and quantification of GMOs, and that there may well be situations where no validated method exists. Therefore, despite this Recommendation, it is not certain that all litigation regarding the presence of GMOs (or of a particular GMO event) in a lot will be avoided.

4. Food Contact Material

On November 13, 2004, the European Parliament and Council published Regulation 1935/2004 of October 27, 2004 "on materials and articles intended to come into contact with food."[20] This regulation entered into force on December 3, 2004, has replaced Directive 80/590 (which introduced a symbol that may accompany materials and articles in contact with food) and Directive 89/109 (which discussed the laws of the Member States related to materials that come into contact with foodstuffs). This new Regulation lays down fundamental rules governing food contact material (including packaging) and states that certain specific materials are subject to other directives

17. *See* Press Release, European Commission, Genetically Modified NK603 Maize Authorised for both Food and Feed (IP/04/1305, Oct. 26, 2004).

18. Commission Recommendation 2004/787, 2004 O.J. (L 348) 18.

19. Parliament and Council Regulation 1830/2003, 2003 O.J. (L 268) 24.

20. Parliament and Council Regulation 1935/2004, 2004 O.J. (L 338) 4.

(for example Directive 2002/72 "related to plastic material and articles intended to come into contact with foodstuffs"). Thus previous directives will remain in application, even though they may need to be amended according to new principles laid down in Regulation 1935/2004.

One of the most important modifications introduced by Regulation 1935/2004 is the reference to new categories of packaging material known as "active and intelligent materials and articles." "Active materials and articles" are defined as "articles and materials that are intended to extend the shelf-life or to maintain or improve the conditions of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food."[21] "Intelligent materials and articles" are defined as "materials and articles which monitor the condition of packaging food or the environment surrounding the food."[22] The specificity of such material is that they may release substances into the food, which is contrary to the traditional principle that food packages must be inert, and must not change the composition of the food or cause a deterioration in the food's organoleptic properties.[23]

"Active and intelligent materials" may now bring changes to the composition or the organoleptic properties of food, provided that they are not used to mislead the consumer. For example, they may not be used to mask a defect or a spoilage. More specific rules may be adopted in the future. In the meantime, the substances released into food are considered ingredients, and must therefore comply with general rules regarding additives and ingredients.

5. Contaminants

On October 22, 2004, the Commission published a Recommendation "on the monitoring of background levels of dioxins and dioxin-like PCBs in foodstuffs."[24] This text has to be read within the general context regarding dioxins, furans, and PCB-type dioxins in food—dioxins and furans are currently subject to maximum levels,[25] but PCB-type dioxins are not yet subject to maximum levels because there was

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21. *See* Regulation 1935/2004, 2004 O.J. (L 338) at 7.
22. *See* Regulation 1935/2004, 2004 O.J. (L 338) at 7.
23. Regulation 1935/2004, 2004 O.J. (L 338) at 4-6.
24. Commission Recommendation 2004/705, 2004 O.J. (L 321) 45. The term PCBs refers to polychlorinated biphenyls, a type of synthetic organic materials suspected to have harmful effects.
25. *See* Recommendation 2004/705, 2004 O.J. (L 321) at 45.

no sufficient information available. The Recommendation, which includes the possibility of fixing maximum levels for PCB-type dioxins, is to be reviewed by December 31, 2006. In the meantime, Member States are asked to monitor the situation by taking samples and analysis in their own territories. The Recommendation addresses each category of foodstuffs in each Member State, and gives an indication of the minimum samples to be analyzed each year. It also provides a format to register the results and communicate them to the Commission. The Member States are also encouraged to analyze other types of PCB residues. The ten new E.U. Member States that joined on May 1, 2004 are not yet included in the list of minimum samples to be performed by each country, but they are encouraged to participate in the program as soon as possible.

On December 22, 2004, the Commission published Directive 2004/115 "amending Directive 90/642 regarding the maximum levels for certain pesticide residues fixed therein."[26] New maximum residues have been fixed and will enter into application on June 23, 2005. The relevant substances are: methomyl, thiodicarb, myclobutanil, maneb group, fenpropimorph, metalaxyl, metalaxyl-m, penconazole, iprovalicarb, azoxystrobin and fenhexamid. The regulated foods include fruit, nuts, vegetables, pulses, oil seed, and potatoes.

6. Organic Farming

On December 29, 2004, the Commission published Regulation 2254/2004 "amending Regulation 2092/2001 on organic production of agricultural products and indication referring thereto on agricultural products and foodstuffs."[27] This Regulation allows the introduction of non-organic pullets for organic egg production under certain conditions. Such derogation had already been granted as a transitional measure in 2003, and the Commission accepted that there was a need for the renewal of such derogation.

7. Specific Products: Wine and Eggs

Commission Regulations 1427/2004 and 1428/2004 of August 9, 2004, both amended Regulation 1622/2000 "laying down certain detailed rules for implementing Regulation 1493/1999 on the common organisation of the market in wine and establishing a Community Code of oenological practices and processes."[28] The Regulation also

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26. Commission Directive 2004/115, 2004 O.J. (L 374) 64.
27. Commission Regulation 2254/2004, 2004 O.J. (L 385) 20.
28. Commission Regulation 1427/2004, 2004 O.J. (L 263) 3; Commission Regulation 1428/2004, 2004 O.J. (L 263) 7.

allowed for new categories of practices and new varieties of wines (for instance, taking into account the manufacturing practices for Tokaj in Hungary). At the same time, E.U. regulations were amended to introduce new categories of wines in some other Member States, and to take into account the specificities of "icewines" from Canada.

Commission Regulation 1429/2004 of August 9, 2004 was also adopted, "amending Regulation 753/2002 laying down certain rules for applying Council Regulation 1493/1999 as regards the description, designation, presentation and protection of certain wine sector products."[29] This Regulation amended the list of Community wines bearing a geographical indication and particularly, but not exclusively, addressed wines from the ten new Member States.

Another regulation regarding wine was published on November 20, 2004.[30] The purpose was to apply the general rule requiring compulsory labeling of allergens in foodstuffs to the wine sector. Wines must now indicate the presence of allergens, even though they are not generally required to list all of the ingredients on the label. The list includes sulphur dioxide and sulphites at certain concentrations. In such cases, wine labels should bear the term "contains" followed by "sulphites" or "sulphur dioxide."

The Commission published Regulation 1515/2004 on August 26, 2004 "amending Reg. 2295/2003 introducing detailed rules for implementing Council Regulation 1907/90 on certain marking standards for eggs."[31] Some conditions of transportation, control, and marking of eggs have been modified in order to improve traceability and avoid frauds related to the destination of eggs (eggs destined to the industry are subject to less marking obligation than those destined to the final consumer). Surveillance measures were implemented for eggs imported from third countries.

8. International Trade

On December 23, 2004, the Council published its Decision of February 24, 2004 "concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture."[32] According to this Decision the Council of the European Community deposited instruments of approval to the Director-General of the Food and Agriculture Organization (FAO), who is the Depositary of the Treaty. The Member States

29. Commission Regulation 1429/2004, 2004 O.J. (L 263) 11.
30. Commission Regulation 1991/2004, 2004 O.J. (L 344) 9.
31. Commission Regulation 1515/2004, 2004 O.J. (L 278) 7.
32. Council Decision 2004/869, 2004 O.J. (L 378) 1.

of the Community were also invited to deposit their own instruments of ratification by March 31, 2004. Nine Member States had ratified as of January 2005 (Denmark, Finland, Germany, Greece, Ireland, Italy, Spain, Sweden, and the United Kingdom).

On July 13, 2004, the Council published its Decision of June 21, 2004 "on the signing of the European Convention for the protection of animals during international transport."[33] This Decision authorizes the President of the Council to designate the person empowered to sign said Convention on behalf of the European Community. The Convention is a revised version of the Convention of 1968. Parties to the new Convention are members of the Council of Europe. The Council of the European Union simultaneously adopted a new regulation[34] on the protection of animals during transport which takes into account this revised Convention. Comments on that new regulation, published on January 5, 2005, will be provided in the next issue of the *Journal of Food Law & Policy*.

On December 23, 2004, the Commission published a Decision of November 19, 2004 "terminating the examination procedure concerning obstacles to trade consisting of trade practices maintained by Canada in relation to certain geographical indications for wines."[35] This decision puts an end to a procedure that was initiated in December 2001, following a complaint lodged with the Commission by the Bordeaux wine producers regarding the Canadian Trademarks Act. Under the Canadian Act, the words "Bordeaux," "Médoc," and "Medoc" were considered generic, which the French producers and the Commission considered an infringement to the standstill clause contained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Following a bilateral agreement between Canada and the European Community, which was initiated in April 2003 and entered into force on June 1, 2004, these three words have been removed from the Canadian list of generic names. The Commission has thus closed its "examination procedure."[36]

On December 23, 2004 the Commission published a regulation "establishing the allocation of export licences for cheese to be exported to the United States in 2005 under certain [General Agreement on Tariffs and Trade] GATT quotas."[37] Quotas for the import

33. Council Decision 2004/544, 2004 O.J. (L 241) 21.

34. Parliament and Council Regulation 1/2005, 2005 O.J. (L 3) 1.

35. Commission Decision 2004/891, 2004 O.J. (L 375) 28.

36. The publication of Decision 2004/891 annuls and replaces a previous publication of the same decision which had been issued on November 30, 2004. Decision 2004/891, 2004 O.J. (L 375) at 30.

37. Commission Regulation 2221/2004, 2004 O.J. (L 375) 9.

of E.U. cheeses into the United States have been established under the Uruguay Round and the Tokyo Round, and these quotas are allocated each year to E.U. exporters following a call for applications.[38] Since the demand for export licenses has been much higher than the quantities available in most categories, high reduction coefficients have been adopted (from 0.12 to 0.83 depending on the categories of cheese) and preference has been given to those operators who had previously exported to the United States.

On July 28, 2004, the Commission published a Decision "amending Decision 92/452 as regards embryo collection teams in the United States of America."[39] Two new United States entities (Lutz Brookview Farm in Fairfield, Kentucky and Cashton Veterinary Clinic in Cashton, Wisconsin) were added to the list of places from which bovine embryos can be imported into the E.U. Import of such material from third countries is subject to official approval from the veterinary services for obvious sanitary reasons.

On August 19, 2004 the Commission published a regulation "amending Annex XI to Regulation 999/2001 as regards the import of cervid products from Canada and the United States."[40] Following reported cases of chronic wasting disease involving farm-raised and wild deer and elk in Canada and the United States, the importation of meat and meat preparations from cervid products are subject to a specific declaration issued by official authorities stating that the products have tested negative for that disease. This regulation is only applicable to meat and meat products since the importation of live animals, semen, ova, and embryos is already prohibited. The Regulation became effective on January 1, 2005.

II. Pending Draft Regulations

1. Labeling: Health Claims

A proposal laid down by the Commission in July, 2003 for the "regulation on nutrition and health claims made on foods," has been intensively debated.[41] The current law provides only two basic rules for health claims: claims should not mislead the consumer, and should not make disease-related claims. These rules are subject only to *a posteriori* controls in most Member States.

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38. Commission Regulation 1847/2004, 2004 O.J. (L 322) 19 (opening the allocation procedure for export licenses).

39. Commission Decision 2004/568, 2004 O.J. (L 252) 5.

40. Commission Regulation 1471/2004, 2004 O.J. (L 271) 24.

41. Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods, COM(2003)424 final at 2.

In contrast, the proposal provides for a much more comprehensive and stringent set of rules. The main idea is that claims will only be authorized if they are provided for in the regulation (such as nutrition claims), or upon individual approval following a scientific dossier for the strongest claims (such as risk reduction claims). Claims addressed to children would be banned, as would claims related to products which do not meet a "nutritional profile" based on the sugar, salt and fat content of the product. The Commission also agreed that claims that are "too vague" (such as those regarding well-being in general) should be banned, as well as claims related to slimming properties (except for express authorizations). The proposed regulation has to be approved by the Council and the Parliament following a complex and long procedure.

In the past few months the Parliament and the Council have asked for many improvements to the proposed regulation regarding health claims. The discussions were initially delayed because of the changes in the E.U. Parliament (elections) and in the Commission (renewal of the Commission in December 2004). On November 4, 2004, however, the Committee on Industry, Research and Energy of the European Parliament issued a draft opinion that was extremely critical of the Commission view. The opinion rejects the very idea of prior approval for claims, the banning of "vague" and behavioral claims, and the concept of nutritional profiles which were perceived as contrary to the idea of a balanced diet. This opinion also emphasizes that there is no legal vacuum for the proposed regulation to fill since there are laws prohibiting false and misleading advertising. However, such an opinion is not decisive because it does not come from the Parliament Committee that was first in charge of this project—the Committee on the Environment, Public Health and Food Safety. This latter Committee was less critical of the basic principles of the Commission proposal, although it did suggest many amendments.[42]

42. European Parliament Committee on the Environment, Public Health and Food Safety, Draft Report on the Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods, COM (2003)0424 - C5-0329/2003 – 2003/0165 (COD), *available at* http://www.europarl.eu.int/meetdocs/2004_2009/documents/PR/553/553203/553203en.pdf.

2. *Additives*

On October 11, 2004, the Commission issued a proposal for amending previous Council Directives on additives and sweeteners.[43] The purpose of the proposal was to revise existing authorizations for specific additives, authorize new additives, and extend the use of other additives.

If the proposal is adopted, the level of nitrates and nitrites used in meat processing will be lowered and based on the incorporated dose rather than the residual dose. Two additives will also be suppressed (E 216 and E 217), and there will be a ban on the use of a number of jelling agents used in mini-cups due to the risk of suffocation (E 400, E 401, E 402, E 403, E 404, E 406, E 407, E 410, E 412, E 413, E 414, E 415, E 417 and E 418). This last proposal follows a decision taken by the Commission in February 2002 to withdraw jelly mini-cups containing Konjac, and all jelly mini-cups in April 2004.[44]

The Commission also proposes to authorize several new additives: Erythritol (a new polyol, which will also be authorized as a sweetener), 4-hexylrésorcinol (for preventing black stains on shell-fish), and Soybean Hemicellulose and Ethylcellulose (already authorized for medicines, and which would be authorized for encapsulating food supplements and flavours). Additionally, an extension of use would be granted to some additives which are already authorized (E 500ii for some cheeses, E 200-203 and E 210-213 for all shell-fish, and E 551 for coloring agents, as well as some specific additives for traditional Hungarian products).

III. Case Law

1. *Judgments Issued*

A. Packaging

In two judgments dated December 14, 2004,[45] the Court ruled that a deposit and return system for the recovery of waste packaging (such as packaging used for drinks and mineral water) was justified by the need to protect the environment. However, it also decided that Germany had violated the rules governing the free movement of

43. Directive of the European Parliament and of the Council Amending Directive 95/2/EC on Food Additives Other Than Colours and Sweeteners and Directive 94/35/EC on Sweeteners for Use in Foodstuffs, COM(04)650 final.

44. Commission Decision 2002/247, 2002 O.J. (L 84) 69; Commission Decision 2004/374, 2004 O.J. (L 118) 70.

45. Case C-463/01, Commission v. Germany, Case C-309/02, Radlberger Getrankegesellschaft mbH & Co., S Spitz KG v. Land Baden Wurttemberg.

goods within the E.U. by installing such a system without a sufficient transitional period, thus causing disproportionate obstacles to the operators. This is a new illustration of a well-known principle in E.U. law, which states that any measure which restricts intra-community trade should be balanced with the principle of proportionality and must not cause more obstacles to trade than strictly necessary.

B. Geographical Names

By an Order delivered on July 6, 2004,[46] the Court of the First Instance (CFI) put an end to a long dispute related to the protection of the name "Feta," which has been restricted to Greek cheeses. Feta—or cheese marketed under this name—has been manufactured and sold in several Member States, but Greece has always claimed that it was a traditional name and the use should be restricted to Greek cheese. After a long dispute and a first Judgment of the Court on March 16, 1999[47] which annulled the registration of the name as an Appellation of Origin restricted to Greece,[48] the Commission adopted a new regulation on October 14, 2002 that once again restricted the name to Greek cheeses.[49] The 2002 regulation was challenged before the court once again. As a part of this challenge, several German companies claimed the regulation unlawful. However, without considering the merits of the case, the Court declared the applicants inadmissible. This ruling fully complies with the consistent case law of the European Court of Justice (ECJ), which has held that individuals—as opposed to Member States—are not permitted to directly challenge regulations.

C. Trademarks

On November 10, 2004,[50] the CFI confirmed a Decision of the Office for Harmonisation in the Internal Market (OAIM), which refused the registration of two three-dimensional trademarks composed of the shape of a sweet and that of a sweet wrapper for the candies known as "Werther's Original." These shapes were considered not distinctive enough for candies, and the Court considered, inter alia, whether the market share of manufacturer, August Storck, is based

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46. Case T-370/02, Alpenhain-Camembert-Werk v. Commission.

47. The Court issued three decisions related to this issue. *See* Case C-289/96, Case C-293/96, Case C-299/96, Denmark v. Commission.

48. Commission Regulation 1107/96, 1996 O.J. (L 148) 1.

49. Commission Regulation 1829/2002, 2002 O.J. (L 277) 10.

50. Case T-402/02, August Storck KG v. Office for Harmonisation in the Internal Market.

more upon the name, Werther's Original, which is well-known, than upon the shape of the candies.

By a judgment of November 16, 2004,[51] the ECJ ruled on a number of interesting points regarding the interpretation of the TRIPS Agreement within the Community as it relates to a conflict between a beer producer from outside the Community and a distributor in Finland. The Court first considered whether the TRIPS Agreement was applicable to a trademark dispute that arose before the entry into force of the TRIPS Agreement and continued after the enforcement date. The Court also stated that a trade name may be a "sign" within the meaning of the TRIPS Agreement, thus it may be compared with the trademark and prohibited if its use may prejudice the essential function of the trademark. However, the Court also stated that a trade name, even one that is not registered or established by use in a Member State, may be regarded as a prior-existing trade name, assuming the proprietor of that trade name had a right to this claim under the TRIPS Agreement prior to the trademark it is alleged to infringe. This is a question of fact to be examined by the national judge in a trademark case.

D. Food Supplements

In a judgment rendered on October 28, 2004, the ECJ ruled that Austria had infringed European Community law (specifically art. 28 of the Treaty on Free Movement of Goods) by prohibiting the sale of food supplements by mail order.

E. Specific Products: Milk Products

By a judgment of October 28, 2004,[52] the ECJ provided explanations as to the definition of "milk products" referred to in Directive 92/46, for the purpose of veterinary controls on the occasion of importation within the E.U. The Court ruled that "milk for the manufacture of milk-based products" does not include milk constituents of a product which also contains non-milk constituents in those situations where those constituents cannot be separated. The Court also ruled that "milk-based products" included semi-finished products to be delivered to the industry. In order to assess whether semi-finished products are "milk-based products," a court must consider the proportion of milk, the use of the product, and its taste. The products at

51. Case C-245/02, Anheuser-Busch Inc. v. Budejovicky Budvar, narodni podnik.
52. Case C-124/03, Artrada NV v. Rijksdienst voor de kuering van Vee en Viees.

stake were a mixture of sugar, cocoa and skimmed-milk powder imported from Aruba.

F. Advertising of Alcoholic Drinks and Tobacco

By a judgment of July 13, 2004,[53] the ECJ ruled that France was allowed to prohibit "indirect advertising" of alcohol when the advertisements appeared on the television screen during the retransmission of bi-national sporting events taking place in other Member States. Such a national rule has been declared infringing neither the specific directive on television broadcasting[54] nor article 49 of the Treaty on the Freedom to Provide Services.[55]

Also, in two judgments rendered on December 14, 2004,[56] the ECJ confirmed that the prohibition on tobacco products for oral use, introduced by Council Directive 92/41 of May 15, 1992,[57] was valid and not disproportionate to the purpose of protecting public health.

G. International Trade

By a judgment of December 14, 2004,[58] the ECJ confirmed a Commission decision not to take action against the retaliatory measures taken by the United States in relation to "prepared mustard" imported from France. This case takes place within the broad context of the "hormone" dispute which began in 1999 when the United States was authorized by the Dispute Settlement Body of the World Trade Organization (WTO) to suspend tariff concessions, and to impose one hundred percent duties, on some products, including prepared mustard. The United States imposed these duties, but decided not to suspend tariff concessions with the United Kingdom. The French mustard producers believed the selective nature of those retaliatory measures to be contrary to the Trade Barriers Regulation (TBR). The Commission had opened an examination procedure for mustard, foie gras, Roquefort, and shallots, all of which were subject to the retaliatory measures. However, the Commission later terminated the procedure because it determined that the Unites States's

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53. Case C-429/02, Bacardi France SAS v. Television francaise 1 SA.

54. Council Directive 89/552, 1989 O.J. (L 298) 23.

55. Consolidated Version of the Treaty Establishing the European Community, Dec. 24, 2002, O.J. (C 325) 54 (2002).

56. Case C-210/03, Swedish Match AB v. Secretary of State for Health; Case C-434/02, Arnold Andre GmbH & Co. KG v. Landrat des Kreises Herford.

57. Council Directive 92/41, 1992 O.J. (L 158) 30.

58. Case T-317/02, Fédération des Industries condimentaires de France v. Commission.

measures did not cause adverse trade effects within the meaning of the TBR. The CFI backed this decision, finding that the French mustard producers did not demonstrate that, in the absence of the derogation in favor of the United Kingdom, they would have significantly increased their exports to the United States. The CFI also recalled that in such cases the Commission has a duty to balance the interests of the parties involved against those of the Community in general.

2. Conclusions of Advocate General

On December 16, 2004, Advocate General Jacobs delivered his opinion in a case involving the prohibition on the use of the word "Tocai" to designate certain Italian wines. The case involved an agreement between the E.C. and Hungary that was aimed at protecting the Hungarian geographic name "Tokaj" and will become effective as of March 2007.[59] The Advocate General found that the prohibition on Italian producers is not contrary to the TRIPS Agreement because the word "Tocai" refers to a grape variety, rather than a geographic name when it is used in Italy. Jacobs also rejected the Italian argument under which the Italian producers considered themselves deprived of a "possession" within the meaning of the European Convention on Human Rights. While conceding that the notion of "possession" may include the name of a wine variety traditionally used to sell a product, Jacobs concludes that in the present case the interests of the owners in this case had been sufficiently taken into account by allowing the owners a thirteen-year transitional period.

3. Pending Cases

A. Geographic Names for Wine

On October 15, 2004, Italian producers of "Tocai" brought a challenge before the CFI related to Commission Regulation 1429/2004, and its prohibition of the use of the word "Tocai" to designate Italian wines.[60] Advocate General Jacobs examined a similar claim,[61] but this case involved different legal argument. The plaintiffs in this case argued that, after the accession of Hungary to the E.U. provisions contained in previous treaties should lapse if they have not been in-

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59. Case C-347/03, Opinion of Advocate General Jacobs, Regione Autonoma Fruili-Venenzia Giulia v. Ministero per le Politiche Agricole e Forestali.

60. Case T-417/04, Regione Autonoma Friuli Venezia Giulia v. Commission; Case T-418/04, Confcooperative, Unione regionale della Cooperazione Fvg Federagricole and Others v. Commission.

61. *See supra* note 59 and accompanying text.

cluded in the Accession Treaty under the Vienna Convention on the Law of Treaties. Therefore, the Treaty between the E.C. and Hungary does not provide a legal basis for the prohibition of the use of the name "Tocai" in Italy. The plaintiffs also argue that the Commission has no power to prohibit the use of a variety in a Member State.

B. Sale Modalities for Confectionary

A reference for a preliminary ruling was sent to the ECJ on August 23, 2004 seeking interpretation of Articles 28 to 30.[62] The dispute involved a question about the free movement of goods within the E.U. The subject of the dispute is an Austrian rule that prohibits the sale of unwrapped sugar confectionary products in vending machines. The Austrian rule also applies to products that use sugar substitutes.[63]

IV. Other Relevant News

1. Regulations Entered Into Application

A. A Regulation 178/2002 of January 28, 2002 "laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety."[64]

The provisions of this regulation enter into application on January 1, 2005. On December 20, 2004, the Commission published "Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20" of said regulation. The guidance document was designed to help "food business operators" understand and implement the Regulation, and was published with the cooperation with the Standing Committee on the Food Chain and Animal Health which is composed of representatives of the Member States. This document deals with responsibilities, traceability, withdrawal, recalls and notifications, and imports and exports.[65] The document emphasized that the traceability requirement does not have any extra-territorial effect because the im-

62. Consolidated Version of the Treaty Establishing the European Community, Dec. 24, 2002, O.J. (C 325) 33 (2002).

63. Case C-366/04, Georg Schwarz v. Bürgermeister des Landeshauptstadt Slazburg.

64. Parliament and Council Regulation 178/2002, 2002 O.J. (L 31) 1.

65. *See* Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of EC Regulation 178/2002 on General Food Law (Dec. 20, 2004), *available at* http://europa.eu.int/comm/food/food/foodlaw/guidance/guidance_rev_7_en.pdf.

porter is only required to be able to identify "from whom the product was exported in the third country.

B. Reg. 1829/2003 of September 22, 2003 "on genetically modified food and feed."[66]

This Regulation provides for the labeling of food and feed products containing GMOs or GM material, and for a pre-market approval of such products. Those provisions were applicable on April 18, 2004. Existing products which were already on the market before that date may remain on the market, provided the Commission was notified before October 18, 2004. The list of notifications that were sent to the Commission is available on the Commission's website.[67]

2. Unofficial Documents and Announcements

A. Food and Health

The Commission held a roundtable discussion on obesity on July 20, 2004 in Brussels.[68] This roundtable was the first step of a global action, and was followed by a "Platform Document" that was issued on December 14, 2004 as part of the preparations for a second roundtable held on January 21, 2005. This document contains proposals for actions from the Commission.

On November 29, 2004 experts met in Brussels, under the aegis of the Commission, in order to examine the influence of nutrition on Alzheimer disease, osteoporosis, and other diseases related to age.

B. Genetically Modified Organisms

On September 8, 2004, the Commission announced the approval of the registration of a maize variety, MON 180, which had been authorized since 1998 under the European Union GM Legislation in the Common European Union Seed Catalogue.[69] This was the first time that a GM variety was listed in the E.U. Common Catalogue. MON 180 has been cultivated in Spain for years, and several derivatives of

66. Parliament and Council Regulation 1829/2003, 2003 O.J. (L 268) 1.

67. *See* Notification of Existing Products Received by the Commission Pursuant to Article 8 and 20 of Regulation (EC) 1829/2003 on GM Food and Feed, *available at* http://europa.eu.int/comm/food/food/biotechnology/gmfood/notifications_existing_products.pdf.

68. SANCO C4/MR/WK D (2004), *available at* http://europa.eu.int/comm/health/ph_determinants/life_style/nutrition/documents/ev_20040720_mi_en.pdf.

69. *See* Press Release, European Commission, Inscription of MON 180 GM maize varieties in the Common EU Catalogue of Varieties (IP/04/1083, Sept. 8, 2004).

this variety have been listed in national seed catalogues. For example, six varieties are listed in France and eleven are listed in Spain.

C. Contaminants

On October 13, 2004, the Commission announced that the Standing Committee on the Food Chain and Animal Health has approved a Commission proposal to establish minimum levels of ochratoxin A in coffee, wine, and grape juice.[70] Maximum levels already existed for cereals. This regulation was published in the Official Journal of the European Union on January 26, 2005 and will enter into application on April 1, 2005. More information will be available in the next issue of the *Journal of Food Law & Policy*.

Also on October 13, 2004, the Commission announced that maximum levels for Polycyclic Aromatic Hydrocarbons (PAH), in particular benzopyrene, have been set.[71] This will apply to certain foods containing fats, as well as oils and foods where smoking or drying processes might cause high levels of contamination.

D. E.U. and United States Cooperate on Food Safety

On September 16-17, 2004, a technical seminar was held at the Food and Veterinary Office in Ireland to discuss practical implementations of HACCP principles.[72] It was the first technical exchange of views between E.U. and United States experts on how HACCP is implemented and the first step towards the possibility of cooperation between governmental offices when differences exist in applicable regulations.

E. Hormone Dispute

In December 2004, the E.U. lodged a complaint with the WTO regarding continued sanctions United States and Canada against E.U. exports, whereas the E.U. has adopted new rules based on independent scientific evidence. The E.U. has asked for a formal consultation with the United States and Canada.

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70. European Commission, Summary Report of the Standing Committee on the Food Chain and Animal Health, Section on Toxicological Safety, Meeting of 12 October 2004, *available at* http://europa.eu.int/comm/food/committees/regulatory/scfcah/toxic/summary15_en.pdf.

71. *See id.*

72. *See* Press Release, European Commission, Midday Express of 2004-09-09 (MEX/04/0909, Sept. 9, 2004).

3. The E.U. Institutions

A. The Parliament

The Committee on Environment, Public Health, and Food Safety, which is primarily in charge of food law, has been renewed after the elections to the E.U. Parliament. It is composed of sixty-three members and is chaired by Mr. Karl-Heinz Florenz (Christian Democrat).

B. The Commission

The new Commissioner in charge of DG SANCO is Mr. Markos Kyprianou from Cyprus. Speaking to the European Parliament at his confirmation hearing, Mr. Kyprianou explained that "he wants to fight obesity, crack down on smoking, protect young people from alcohol abuse and empower consumers to shop with confidence in the E.U.'s internal market."[73]

C. The European Food Safety Authority (EFSA)

On November 9-10, 2004, an EFSA stakeholder Colloquium took place in Berlin. Delegates represented consumer groups, industry, university and research centers, retailers, distributors, farmers, food trade workers, and animal welfare and environment non-governmental organizations (NGOs). During the Colloquium, views were exchanged among the participants. Three sessions were organized: one devoted to the analysis of public perception and food safety, another to the involvement of stakeholders in risk analysis, and a third interactive session where participants were encouraged to identify strategies for EFSA's future policy on stakeholder relations.

On December 13-14, 2004, a scientific Colloquium took place in Brussels on the topic of the Qualified Presumption of Safety (QPS) and its possible application in harmonizing safety assessment approaches concerning micro-organisms used in food and feed production.

In December 2004, EFSA published a Guidance Document on the "Risk Assessment of GM plants"[74] to help operators prepare and

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73. *See* DG SANCO "Health and Consumer Voice" (Dec. 2004) *at* http://europa.eu.int/comm/dgs/health_consumer/newsletter/200412/index_en.htm (last visited May 14, 2005). This is the new name for DG SANCO newsletter, which was previously named "Consumer Voice."

74. *See* Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants Dervied from Food and Feed (European Food Safety Authority), *available at* http://www.efsa.eu.int/science/gmolgmo_guidance/660/guidance_docfinal1.pdf.

present applications in accordance with the GM food and feed regulation.[75]

A discussion paper on Botanicals and Botanical Preparations used as food supplements was also issued by EFSA,[76] EFSA Scientific Committee highlighted a number of health concerns associated with these products, such as chemical and microbial contamination, misidentification of plants, and mislabeling. The Committee advocated implementing a coherent risk assessment plan and communicating better information to the consumer of botanical supplements.

As to flavorings, the EFSA panel on Food Additives, Flavourings, Processing Aids and Material issued two opinions in November, 2004 that assessed seventy-seven substances.[77] This work is part of the general review of flavorings which is currently required under Regulation 2232/96 "laying down a Community procedure for flavoring substances used or intended for use in or on foodstuffs."[78]

Regarding Food Allergens, EFSA has examined applications from the industry regarding possible exemptions from the mandatory labeling rules for allergen derivatives.[79] Out of nine evaluations, EFSA concluded there can still be adverse reactions for eight substances.

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75. Parliament and Council Regulation 1829/2003, 2003 O.J. (L 268) 1.

76. European Food Safety Authority, Discussion Paper on *Botanicals and Botanical Preparations Widely Used As Food Supplements and Related Products: Coherent and Comprehensive Risk Assessment and Consumer Information Approaches*, *available at* http://www.efsa.eu.int/science/sc_commitee/sc_documents/616/scdoc_advice03_botanicals_en1.pdf.

77. European Food Safety Authority, *Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a Request from the Commission Related to Flavouring Group Evaluation 3 (FGE 03)*, 107 E.F.S.A. J. 1-59 (2004), *available at* http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html.

78. Parliament and Council Regulation 2232/96, 1996 O.J. (L 299) 1.

79. Parliament and Council Directive 2003/89, 2003 O.J. (L 308) 15.