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European Union Food Law Update

by

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EUROPEAN UNION FOOD LAW UPDATE

*Emilie H. Leibovitch**

I. INTRODUCTION

The following European Union Food Law Update will address significant changes in European Union (EU) food law that occurred between 2006 and early 2008. The update will be different from the previous ones, as it will instead be organized by the subject areas addressed by the developments. The published regulations, proposals, cases, and other relevant news will thus be incorporated under their corresponding topic headings.

The European Union has faced major changes since 2006. A number of proposals for new regulations have been published, and all of them have a common objective: simplification and consistency across the Member States. The areas of novel foods, feed safety, organic farming, labeling, and nutrition claims were subject to significant regulatory changes. Aside from legislation, the EU has also faced important new developments since 2005. Indeed, since the last update, the EU admitted Bulgaria and Romania on January 1, 2007, thereby bringing the number of Member States to twenty-seven.[1] According to the list of rotations for Presidency of the Council of the European Union, in 2006, Austria and then Finland held the position. In 2007, the Presidency was held by Germany and then Portugal. This year the Presidency went to Slovenia until June, and in July it will be France's turn.

Furthermore, at the end of February 2008, Health Commissioner Markos Kyprianou announced his resignation in order to join the new Cypriot government as Foreign Minister. Commissioner

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1. Treaty Concerning the Accession of the Republic of Bulgaria and Romania to the European Union, 2005 O.J. (L 157) 11.

Kyprianou was replaced by Androulla Vassiliou, wife of former Cypriot president George Vassiliou.[2]

II. Genetically Modified Organisms

On September 5, 2006, the Commission published Commission Decision 2006/601/EC (which was later amended by Commission Decision 2006/754/EC) on emergency measures regarding the unauthorized LL RICE 601 that had been found in rice products.[3] This decision was made after the United States reported that commercial long-grain rice had been contaminated with LL RICE 601, a genetically modified organism (GMO) that is not authorized under Community legislation. The Commission decided to require Member States not to place on the market certain rice products coming from the United States. On February 26, 2008, the Commission issued a Decision again amending Decision 2006/601/EC, addressing conditions for placing products on the market and control and sampling measures.[4]

On March 7, 2007 the Commission issued Commission Decision 2007/157/EC to repeal Commission Decision 2005/317/EC on emergency measures regarding maize products containing the unauthorized genetically modified organism Bt10.[5] Decision 2005/317/EC had been issued to ensure that maize products coming from the United States would be placed on the EU market only if they did not contain maize or feed produced from Bt10 maize. Furthermore, some genetically modified foods are authorized in the European Union under the Novel Food Regulation (EC) 258/97.[6] The list is updated regularly.

On March 28, 2008, the Commission approved a Decision authorizing the genetically modified maize GA21 for feed and food use and for import and processing.[7] Although the commercialization of GA21 was already authorized in the EU, this decision extends the authorization to maize grains derived from GA21. This Decision thus allows for import from third countries that cultivate this GA21 maize. The cultivation of GA21 remains unauthorized.

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2. Press Release, European Comm'n, Nomination of Mrs. Androula Vassiliou as successor to Mr. Markos Kyprianou (IP/08/363, Feb. 29, 2008).
3. Commission Decision 2006/601, 2006 O.J. (L 244) 27 (EC).
4. Commission Decision 2008/162, 2008 O.J. (L 52) 25 (EC).
5. Commission Decision 2007/157, 2007 O.J. (L 68) 8 (EC).
6. *See* Council Regulation 258/97, 1997 O.J. (L 43) 1.
7. Commission Decision 2008/280, 2008 O.J. (L 87) 19.

Over the past months, GMOs have been the subject of many debates. On February 12, 2008, the European Commission decided "to require compulsory certification for the imports of Chinese rice products that could contain the unauthorized GMO Bt63."[8] In 2006 and 2007, rice products coming from China and containing the unauthorized genetically modified rice Bt63 were discovered in the EU. Despite the measures that the Chinese authorities had taken in 2006, additional traces of Bt63 rice were found in February 2007. Thus, the Commission adopted emergency measures that are to take effect on April 15, 2008, which allow for the entry of only specific consignments listed in the Annex of the Decision.[9] In addition, these consignments must be tested by a specific laboratory or official using a specific testing method.[10]

Moreover, in February 2008, the Commission asked the European Food Safety Authority (EFSA) to provide scientific advice on France's decision to invoke the safeguard clause over the genetically modified maize MON810.[11] Germany had previously suspended the authorization of MON810 on the market in April 2007 but then reauthorized it in December 2007, after Monsanto provided an implementation plan consisting of observation of the effects that the cultivation of MON810 has on biodiversity.[12]

III. Novel Foods

Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the Community before May 15, 1997, since the initial regulation on novel foods took effect on May 1, 2007.[13] Regulation EC 258/97 of January 27, 1997, of the European Parliament and the Council gov-

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8. Press Release, European Comm'n, Commission requires certification for Chinese rice products to stop unauthorised GMO from entering the EU (IP/08/219, Feb. 12, 2008).

9. Commission Decision 2008/289, art. 1, 2008 O.J. (L 96) 29, 31.

10. Decision 2008/289, at 31.

11. European Comm'n Directorate-General, Envt., Assessment of the Scientific Studies Supporting the Suspension of Cultivation of MON810 in France (Feb. 27, 2008).

12. GMO Compass, *German authority clears MON810*, http://www.gmo-compass.org/eng/news/312.german_authority_clears_mon810.html (last visited July 15, 2008). The observation is to be conducted by a network of public institutions, associations, and scientists, and will include the effects on the soil ecosystem, as well as insects, birds, and wild game. *Id.*

13. Council Regulation 258/97, 1997 O.J. (L 43) 1.

erns the authorization of novel foods and novel food ingredients.[14] Foods that were placed on the market in at least one Member State before the entry into force of the Regulation on Novel Foods on May 15, 1997, can be commercialized on the EU market under the principle of mutual recognition. However, since products that can be marketed must be safe for human consumption, novel foods have to be submitted for a safety assessment before being placed on the EU market in order to determine whether they meet this standard.[15] Thus, companies wishing to commercialize novel foods in the EU must submit an application.[16] Nevertheless, when a national food assessment body deems a novel food to be "substantially equivalent to existing foods or foods ingredients," companies can follow a simplified procedure whereby the company merely notifies the Commission of the commercialization of the novel food.[17]

Since 2006, the Commission has authorized the placing on the market of several novel foods or novel food ingredients under Regulation (EC) 258/97. On January 13, 2006, Commission Decision 2006/68/EC authorized "the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863."[18] On the same day, the Commission published Commission Decision 2006/69/EC authorizing "the placing on the market of foods and food ingredients produced from genetically modified Roundup Ready maize line GA21."[19] On January 24, 2006, Commission Decision 2006/58/EC authorized the request from Pharmaconsult to place on the market "rye bread with added phytosterols/phytostanols."[20] On that same day, the Commission authorized a similar request from Karl Fazer Ltd., through Commission Decision 2006/59/EC.[21] On October 23, 2006, the Commission published Commission Decision 2006/720/EC authorizing "the placing on the market of diacylglycerol oil of plant origin," and Commission Decision 2006/721/EC, which authorized "the placing

14. Regulation 258/97, at 1.
15. Regulation 258/97, art. 6, at 4.
16. Regulation 258/97, art. 4, at 4; Commission Recommendation 97/618, 1997 O.J. (L 253) 1 (EC).
17. Regulation 258/97, art. 3(4), 5, at 3-4.
18. Commission Decision 2006/68, 2006 O.J. (L 34) 26.
19. Commission Decision 2006/69, 2006 O.J. (L 34) 29.
20. Commission Decision 2006/58, 2006 O.J. (L 31) 18.
21. Commission Decision 2006/59, 2006 O.J. (L 31) 21.

on the market of lycopene from *Blakeslea trispora*."[22] On October 24, 2006, the Commission published Commission Decision 2006/722/EC, which authorized "the placing on the market of 'rapeseed oil high in unsaponifiable matter,'" and Commission Decision 2006/723/EC, which allowed the "placing on the market of 'maize-germ oil high in unsaponifiable matter.'"[23] On May 15, 2007, the Commission published Commission Decision 2007/343/EC, which authorizes "the placing on the market of oil enriched with phytosterols/phytostanols.[24] Finally, on January 10, 2008, the Commission published Commission Decision 2008/36/EC authorizing "the placing on the market of rice drinks with added phytosterols/phytostanols as novel food."[25]

In January 2008, the Commission adopted a proposal to revise the Novel Foods Regulation (EC) 258/97 in order to improve the access of innovative foods to the EU market while at the same time ensuring food safety.[26] The Proposal attempts to simplify the procedure by creating a centralized authorization procedure.[27] The Commission would receive the application for authorization, and the EFSA would carry out the scientific assessment of the product.[28] The Commission will therefore determine whether to include a novel food in the Community list of novel foods based on the EFSA's issued opinion.[29] The final decision to authorize the novel food would be made by the Commission via the comitology procedure.[30] The standard that would be used to determine whether novel foods can be authorized would be whether the foods "present a danger to or mislead the consumer and in the case of replacement [are] of nutritional disadvantage[] for the consumer."[31] Another significant change is the exclusion of genetically modified organisms

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22. Commission Decision 2006/720, 2006 O.J. (L 296) 10; Commission Decision 2006/721, 2006 O.J. (L 296) 13. *Blakeslea trispora* is a fungus known for its production of large quantities of carotenoids.

23. Commission Decision 2006/722, 2006 O.J. (L 296) 17; Commission Decision 2006/723, 2006 O.J. (L 296) 20.

24. Commission Decision 2007/343, 2007 O.J. (L 129) 63.

25. Commission Decision 2008/36, 2008 O.J. (L 8) 15.

26. *Proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX*, COM (2007) 872 final, *available at* http://ec.europa.eu/food/food/biotechnology/novelfood/COM872_novel_food_proposal_en.pdf [hereinafter *Novel Foods Proposal*].

27. *Id.* at 3.

28. *Id.* at 7.

29. *Id.*

30. *Id.*

31. *Novel Foods Proposal*, *supra* note 26, at 7.

from the scope of the proposed regulation.[32] Moreover, the new regulation would provide for data protection rules to protect newly developed foods and to encourage companies to invest in developing new and innovative food production techniques.[33] Additional labeling of novel foods would also be part of the regulation.[34] This Proposal is now being sent to the Parliament for discussion.

IV. FEED SAFETY

In March 2008, the Commission adopted a proposal Commission's proposal for a Regulation of the European Parliament and of the Council on "the placing on the market and use of feed."[35] This regulation would simplify and update the existing provisions.[36] Furthermore, the fact that the proposal is for a regulation and not a directive will make governance of feed materials more homogenous within the EU. Currently, several Directives govern commercialization and use of feed. Council Directive 79/373/EEC lays down the rules for the circulation of compound feedingstuffs.[37] Council Directive 93/74/EEC establishes the standards for feedingstuffs that are intended for particular nutritional purposes ("dietetic feeds").[38] Council Directive 96/25/EC contains the general rules for the circulation and use of feed materials.[39] Council Directive 82/471/EEC lays down the marketing conditions for bio-proteins that belong to the category of feed materials.[40] Moreover, Council Directive 93/113/EC lists the rules on "the use and marketing of enzymes, microorganisms and their preparations in animal nutrition,"[41] and Council Directive 70/524/EEC provides provisions for additives in feedingstuffs.[42] These directives are implemented by the following:

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32. *Id.* whereas 10, at 9-11.
33. *Id.* art. 12, at 20.
34. *Id.* whereas 21, at 9, 13.
35. *Proposal for a regulation of the European Parliament and of the Council on the placing on the market and use of feed*, COM (2008) 124 final, *available at* http://ec.europa.eu/food/food/animalnutrition/labelling/COMM_PDF_COM_2008_0124_F_EN_ACTE.pdf [hereinafter *Feed Proposal*].
36. *Id.* at 2.
37. Council Directive 79/373, 1979 O.J. (L 86) 30.
38. Council Directive 93/74, 1993 O.J. (L 237) 23.
39. Council Directive 96/25, 1996 O.J. (L 25) 35.
40. Council Directive 82/471, 1982 O.J. (L 213) 8.
41. Council Directive 93/113, 1993 O.J. (L 334) 17.
42. Council Directive 70/524, 1970 O.J. (L 270) 1 (repealed). Article 16 of Council Directive 70/524/EEC remained in force after the repeal of Council Direc-

Commission Directive 80/511/EEC, which authorizes the marketing of compound feedingstuffs in unsealed packages or containers in certain situations;[43] Commission Directive 82/475/EEC, which sets forth "the categories of ingredients which may be used for the purposes of labeling compound feedingstuffs for pet animals";[44] Commission Directive 94/39/EC, which establishes "a list of intended uses of animal feedingstuffs for particular nutritional purposes";[45] and Commission Decision 2004/217/EC, which adopts "a list of materials whose circulation or use for animal nutrition purposes is prohibited."[46] The new proposal provides for the repeal of Council Directives 79/373/EEC, 80/511/EEC, 82/471/EEC, 93/74/EEC, 93/113/EC, and 96/25/EC.[47] It calls for additional labeling requirements[48] and also modifies the situations entitled to derogations.[49] In addition, the Commission has updated the Community Register of Feed Additives several times since 2005.[50]

Furthermore, the Commission issued on August 14, 2007, a Report on Financial Guarantees in the Feed Sector,[51] as required by Article 8 of the Feed Hygiene Regulation 183/2005/EC.[52] Essentially, this report presents the systems that are currently in place in the Member States and proposes several options for a feasible and practicable system of financial guarantees at an EU level. Among the suggested options, the Commission seems to favor a mandatory insurance covering only major, large-scale incidents.[53] However, acknowledging that such a system is neither supported by the feed sector nor by the insurance sector and would be difficult to put in place in the short term, the Commission proposes to launch a two-

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tive 70/524/EEC by Council Regulation (EC) 1831/2003. *See* Council Regulation 1831/2003, whereas 33, 2003 O.J. (L 268) 29, 31.

43. Commission Directive 80/511, 1980 O.J. (L 126) 14.
44. Commission Directive 82/475, 1982 O.J. (L 213) 27.
45. Commission Directive 94/39, 1994 O.J. (L 207) 20.
46. Commission Decision 2004/217, 2004 O.J. (L 67) 31.
47. *Feed Proposal*, *supra* note 35, whereas 3, 4, at 10.
48. *Id.* art. 15, 16, at 23-24.
49. *Id.* art. 21, at 26-27.
50. European Commission Health & Consumer Protection Directorate-General, *Community Register of Feed Additives pursuant to Regulation (EC) No. 1831/2003*, http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf (last visited July 15, 2008).
51. REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL ON EXISTING LEGAL PROVISIONS, SYSTEMS AND PRACTICES IN THE MEMBER STATES AND AT COMMUNITY LEVEL RELATING TO LIABILITY IN THE FOOD AND FEED SECTORS, COM (2007) 469 final [hereinafter REPORT].
52. Council Regulation 183/2005, art. 8, 2005 O.J. (L 35) 1, 6.
53. *See* REPORT, *supra* note 51, at 6.

year public debate on the various options.[54] Further analysis of the cost and impact of financial guarantees should follow, after which the Commission will finally consider the need for a legislative proposal to be made.

V. Transmissible Spongiform Encephalopathy

In 2006 and 2007, the Commission published a number of regulations relating to transmissible spongiform encephalopathy (TSE), and more particularly relating to bovine spongiform encephalopathy (BSE). On February 14, 2006, the Commission published Commission Regulation 253/2006/EC, amending Regulation 999/2001 of the European Parliament and of the Council with regard to rapid tests and TSE eradication measures on small ruminants.[55]

On February 24, 2006, Commission Regulation 339/2006/EC amended Annex XI to Regulation 999/2001/EC of the European Parliament and of the Council, providing "the rules for importation of live bovine animals and products of bovine, ovine and caprine origin."[56] It deleted Brazil, Botswana, Chile, El Salvador, Namibia, Nicaragua, and Swaziland from the list of countries exempted from certain TSE-related trade conditions for live bovine animals and products of bovine, ovine and caprine origin.[57]

On March 31, 2006, Commission Regulation 546/2006/EC implemented Regulation 999/2001/EC of the European Parliament and of the Council with regard to national control programs for scrapie and "additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation 1874/2003/EC."[58]

On April 10, 2006, Commission Regulation 657/2006/EC amended Regulation 999/2001/EC of the European Parliament and of the Council with regard to "the United Kingdom and repealing Council Decision 98/256/EC and Decisions 98/351/EC and 1999/514/EC."[59] This regulation lifted the embargo on the United Kingdom on "live cattle and products derived from cattle slaughtered in the United Kingdom" that "are liable to enter the food or

54. *Id.* at 2.
55. Commission Regulation 253/2006, 2006 O.J. (L 44) 9.
56. Commission Regulation 339/2006, 2006 O.J. (L 55) 5.
57. Regulation 339/2006, at 5.
58. Commission Regulation 546/2006, 2006 O.J. (L 94) 28.
59. Commission Regulation 657/2006, 2006 O.J. (L 116) 9.

feed chain" or that are "destined for use in cosmetics or medical or pharmaceutical products."[60]

On May 4, 2006, Commission Regulation 688/2006/EC amended Annexes III and XI to Regulation (EC) 999/2001/EC of the European Parliament and the Council with regard "to the monitoring of transmissible spongiform encephalopathies and specified risk material of bovine animals in Sweden."[61] On July 7, 2006, the Commission published Commission Regulation 1041/2006/EC amending Annex III to Regulation (EC) 999/2001/EC of the European Parliament and the Council "as regards monitoring of transmissible spongiform encephalopathies in ovine animals."[62] In December 2006, Regulation 1923/2006/EC of the European Parliament and the Council amended Regulation 999/2001/EC "laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies."[63] The amendments dealt with the categorization of countries, specified risk materials, TSE surveillance, and import conditions.

In 2007, all the regulations relating to TSE so far have amended Regulation 999/2001/EC of the European Parliament and the Council. Regulation 999/2001 is the main legislation setting the standards for "the prevention, control and eradication of certain transmissible spongiform encephalopathies."[64] On June 25, 2007, Commission Regulation 722/2007/EC amended Annexes II, V, VI, VIII, IX and XI to Regulation 999/2001/EC that provide "rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies."[65] On June 26, 2007, Commission Regulation 727/2007/EC amended Annexes I, III, VII, and X to Regulation 999/2001 by modifying the eradication measures and monitoring for ovine and caprine animals.[66] On October 30, 2007, Commission Regulation 1275/2007/EC amended Annex IX to Regulation 999/2001 on import conditions for products of animal origin from bovine, ovine and caprine animals.[67] Finally, on December 4, 2007, Commission Regulation 1428/2007/EC amended Annex VII to Regulation 999/2001 by allowing a possibility to delay the

60. Regulation 657/2006.
61. Commission Regulation 688/2006, 2006 O.J. (L 120) 10.
62. Commission Regulation 1041/2006, 2006 O.J. (L 187) 10.
63. Council Regulation 1923/2006, 2006 O.J. (L 404) 1.
64. Council Regulation 999/2001, 2001 O.J. (L 147) 1.
65. Commission Regulation 722/2007, 2007 O.J. (L 164) 7.
66. Commission Regulation 727/2007, 2007 O.J. (L 165) 8.
67. Commission Regulation 1275/2007, 2007 O.J. (L 284) 8.

destruction of animals in TSE affected flocks for five breeding years.[68]

VI. Salmonella and Foodborne Diseases

A number of measures have been taken between 2006 and 2008 concerning the monitoring, prevention, and eradication of foodborne diseases. In order to obtain information on antimicrobial resistance that is comparable between Member States and in time, the Commission adopted Commission Decision 2007/407/EC of 12 June 2007 on a harmonized monitoring of antimicrobial resistance in *Salmonella* in poultry and pigs.[69] Moreover, two Commission Decisions called for financial contribution from the Community toward two surveys to be conducted in Member States in 2008 to collect data. One survey is to be carried out on "the prevalence and antimicrobial resistance of *Campylobacter* spp. in broiler flocks and on the prevalence of *Campylobacter* spp. and *Salmonella* spp. in broiler carcasses to be carried out in the Member States."[70] Another survey is to be conducted "on the prevalence of *Salmonella* spp. and Methicillin-resistant *Staphylococcus aureus* in herds of breeding pigs."[71]

On August 1, 2006, the Commission published Commission Regulation 1177/2006/EC to implement Regulation 2160/2003/EC of the European Parliament and Council with regard to the use of specific control methods required as a part of the framework of the national programs to control *Salmonella* in poultry.[72] On October 23, 2007, the Commission issued Regulation 1237/2007/EC amending Regulation (EC) 2160/2003 of the European Parliament and Council and Commission Decision 2006/696/EC, with regard to "the placing on the market of eggs from *Salmonella* infected flocks of laying hens."[73] Moreover, Commission Decision 2007/594/EC of August 29, 2007 amended Annex IV to Council Directive 90/539/EEC "as regards model veterinary certificates for intra-Community trade in poultry and hatching eggs to take account of certain public health requirements."[74] On December 11, 2007, the Commission published Commission Decision 2007/842/EC con-

68. Commission Regulation 1428/2007, 2007 O.J. (L 317) 61.
69. Commission Decision 2007/407, 2007 O.J. (L 153) 26.
70. Commission Decision 2007/516, 2007 O.J. (L 190) 25.
71. Commission Decision 2008/55, 2008 O.J. (L 14) 10.
72. Commission Regulation 1177/2006, 2006 O.J. (L 212) 3.
73. Commission Regulation 1237/2007, 2007 O.J. (L 280) 5.
74. Commission Decision 2007/594, 2007 O.J. (L 227) 33.

cerning the "approval of *Salmonella* control programs in breeding flocks of *Gallus gallus* in certain third countries, in accordance with Regulation 2160/2003/EC of the European Parliament and of the Council and amending Decision 2006/696/EC, concerning certain public health requirements at import of poultry and hatching eggs."[75] Regarding breeding flocks of *Gallus gallus*, the Commission approved almost all Member States' national programs (except for Luxembourg and Malta) for the control of *Salmonella* in breeding flocks of *Gallus gallus*.[76]

As for laying hens, the Commission adopted Commission Regulation 1168/2006/EC implementing Regulation 2160/2003/EC, which concerned the Community target for the reducing the prevalence of some *Salmonella* serotypes in *Gallus gallus* laying hens, and amending Regulation 1003/2005/EC.[77] The Commission also approved practically all Member States' national programs (with the exception of Malta) for the control of *Salmonella* in flocks of laying hens of *Gallus gallus*.[78]

As far as broilers are concerned, the Commission passed Commission Regulation 646/2007/EC implementing Regulation (EC) 2160/2003 of the European Parliament and Council regarding "a Community target for the reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* in broilers" and repealing Regulation (EC) 1091/2005.[79] Commission Decision 2005/6346/EC provided for "a financial contribution by the Community towards a baseline survey on the prevalence of *Salmonella* spp. in broiler flocks of *Gallus gallus* to be carried out in the Member States."[80] The study was conducted by the European Food Safety Authority's (EFSA) Task Force on Zoonoses Data Collection, and the results were published in the EFSA Journal.[81]

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75. Commission Decision 2007/843, 2007 O.J. (L 332) 81.

76. Commission Decision 2006/759, 2006 O.J. (L 311) 46; Commission Decision 2007/873, 2007 O.J. (L 344) 45; Commission Decision 2007/874, 2007 O.J. (L 344) 46; Commission Decision 2007/849, 2007 O.J. (L 333) 85.

77. Commission Regulation 1168/2006, 2006 O.J. (L 211) 4.

78. Commission Decision 2007/848, 2007 O.J. (L 333) 83).

79. Commission Regulation 646/2007, 2007 O.J. (L 151) 21.

80. Commission Decision 2005/636, 2005 O.J. (L 228) 14.

81. *Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of Salmonella in holdings of broiler flocks of Gallus gallus, Part A*, 98 EFSA J. 1 (2007); *Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of Salmonella in holdings of broiler flocks of Gallus gallus, Part B*, 101 EFSA J. 1 (2007).

The Commission also launched one-year studies in 2006 to estimate the prevalence of *Salmonella* spp. in flocks of turkeys and in herds of fattening pigs across the EU.[82] In December 2007, the Commission called for another one-year survey to study the prevalence of *Salmonella* spp. and Methicillin-resistant *Staphylococcus aureus* in herds of breeding pigs in the Member States.[83]

In addition, every year the Commission adopts a decision on the Community's cofinancing of national programs for the eradication and monitoring of animal diseases, or certain TSEs, and for the prevention of zoonoses.[84] Furthermore, in May 2006, six Community Reference Laboratories were designated to coordinate the work of the National Reference Laboratories and to assist the Commission in detecting and monitoring biological hazards in food.[85]

VII. Organic Farming

Council Regulation (EC) 834/2007 of June 28, 2007, "on organic production and labeling of organic products," repealed Regulation (EEC) 2092/91.[86] It aims at simplifying and harmonizing rules on organic production and labeling. The regulation introduces a new permanent import regime that allows third countries to export to the EU market under the same or equivalent conditions as EU producers[87] and provides for more consistent controls. It renders the use of the EU organic logo mandatory, although national or private logos can also accompany it.[88] Organic logos can be used only if at least 95% of the ingredients are organic.[89] Moreover, non-organic products that contain organic ingredients may label such ingredients as organic only on the ingredients list. Genetically-modified organisms are still prohibited in organic foods, and the limit of 0.9% for

82. Commission Decision 2006/662, 2006 O.J. (L 272) 22; Commission Decision 2006/668, 2006 O.J. (L 275) 51.

83. Commission Decision 2008/55, 2008 O.J. (L 14) 10.

84. *See, e.g.*, Commission Decision 2005/873, 2005 O.J. (L 322) 21; Commission Decision 2006/875, 2006 O.J. (L 337) 46; Commission Decision 2007/872, 2007 O.J. (L 344) 44.

85. Commission Regulation 776/2006, 2006 O.J. (L 136) 3.

86. Council Regulation 834/2007, 2007 O.J. (L 189) 1.

87. Council Regulation 834/2007, art. 32, 2007 O.J. (L 189) 1, 19.

88. Regulation 834/2007, art. 25, at 17.

89. Regulation 834/2007, art. 23, at 16.

the accidental presence of authorized GMOs is now expressed.[90] The regulation does not prohibit stricter private standards.[91]

VIII. Maximum Residues Limits

New developments occurred in the areas of contaminant residue and pesticide residue legislation.

A. Contaminant Residues

Commission Regulation (EC) 1881/2006 set maximum residue levels for certain food contaminants.[92] This Regulation took effect on March 1, 2007, and replaced Commission Regulation (EC) 466/2001. The contaminants subject to maximum residues levels are: nitrate, mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T'-2 and HT-2-toxin), metals (lead, cadmium, mercury, inorganic tin), 3-MCPD, dioxins and PCBs, and polycyclic aromatic hydrocarbons (benzo(a)pyrene).[93]

B. Pesticide Residues

The most important change in pesticide residue legislation is the publication, on March 1, 2008, of Annexes II-IV to Regulation 396/2005.[94] These changes will take effect on September 1, 2008.[95] Annex II contains the EU maximum residue limits already established by the directives on specific food groups. Annex III sets temporary EU maximum residue limits for active substances for which inclusion in Annex I to Council Directive 91/414/EEC has not yet been decided. Annex IV lists the substances exempted from maximum residue limits. Until the regulation is in force, Member States can set provisional national maximum residue limits via the current legislation, although those limits will only remain valid until the new legislation becomes effective. Annexes II and III can still be amended until September 1, 2008. Substances that have not been submitted to the Committee by March will be subject to the new

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90. Regulation 834/2007, art. 9, at 8; Council Regulation 1830/2003, art. 7, 2003 O.J. (L 268) 24, 27 (EC).
91. Regulation 834/2007, art. 1, at 4.
92. Commission Regulation 1881/2006, 2008 O.J. (L 364) 5.
93. Regulation 1881/2006, at 15-22.
94. Commission Regulation 149/2008, 2008 O.J. (L 58) 1.
95. Regulation 149/2008, art. 2, at 2.

regulation under which, when considering whether to authorize a substance, Member States can decide whether a new maximum residue level (MRL) is necessary or whether an existing MRL (detailed in Annexes II or III) should be modified. For a routine MRL, with the comitology procedure and the SPS notification, the process will take approximately one year for the new MRLs to be adopted.

IX. Food Contact Materials

On December 22, 2006, the European Commission published Commission Regulation 2023/2006 laying down the rules on good manufacturing practices (GMP) for "materials and articles intended to come into contact with food" listed in Annex I to Regulation (EC) 1935/2004.[96] Later, several specific directives were adopted. On April 2, 2007, the Commission issued Commission Directive 2007/19/EC to amend Directive 2002/72/EC "relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs."[97] On that same day, the Commission published Commission Regulation 372/2007/EC "laying down transitional migration limits for plasticizers in gaskets in lids intended to come into contact with foods."[98] This Regulation was to apply until Directive 2007/19/EC's entry into force. On June 29, 2007, the Commission published Commission Directive 2007/42/EC "relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs."[99] On March 6, 2008, the Commission issued Commission Directive 2008/39/EC amending Directive No. 2002/72/EC relating to plastic materials and articles intended to come into contact with food.[100]

X. Food Improvement Agents Package

On July 28, 2006, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council establish-

96. Commission Regulation 2023/2006, art. 1, 2006 O.J. (L 384) 75.
97. Commission Directive 2007/19, 2007 O.J. (L 97) 50.
98. Commission Regulation 372/2007, 2007 O.J. (L 92) 9; Corrigendum to Regulation 372/2007, 2007 O.J. (L 92) 3 (EC).
99. Commission Directive 2007/42, 2007 O.J. (L 172) 71.
100. Commission Directive 2008/39, 2008 O.J. (L 63) 6.

ing a common authorization procedure for food additives, food enzymes and food flavorings,[101] as well as separate proposals of regulation of food additives,[102] food enzymes,[103] and food flavorings and certain food ingredients with flavoring properties for use in and on foods.[104] These proposals were meant to harmonize EU legislation is these areas and clarify current legislation in order to simplify approval procedures for these three food groups. Before these proposals, food enzymes were governed by national legislation within Member States, whereas food additives and flavorings were already covered by EU legislation.

The European Parliament delivered its first-reading opinion on July 10, 2007, introducing amendments to the Commission proposal.[105] On March 10, 2008, the Council issued a Common Position on the adoption of three separate regulations of the European Parliament and of the Council on food additives,[106] food enzymes,[107] and

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101. *Proposal for a regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings*, COM (2006) 423 final (July 28, 2006), *available at* http://ec.europa.eu/food/food/chemicalsafety/additives/com2006_423_en.pdf.

102. *Proposal for a regulation of the European Parliament and of the Council on food additives*, COM (2006) 428 final (July 28, 2006), *available at* http://ec.europa.eu/food/food/chemicalsafety/additives/com2006_428_en.pdf.

103. *Proposal for a Regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC*, COM (2006) 425 final (July 28, 2008), *available at* http://ec.europa.eu/food/food/chemicalsafety/additives/com2006_425_en.pdf.

104. *Proposal for a regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1576/89, Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC*, COM (2006) 427 final (July 28, 2008), *available at* http://ec.europa.eu/food/food/chemicalsafety/additives/com2006_427_en.pdf.

105. Opinion of the European Parliament of July 10, 2007, 2006/0143 (COD) (not yet published in the Official Journal).

106. *Common position adopted by the Council on 10 March 2008, with a view to the adoption of a regulation of the European Parliament and of the Council on food additives*, 2006/145 (COD), *available at* http://register.consilium.europa.eu/pdf/en/07/st16/st16675-re02.en07.pdf.

107. *Common position adopted by the Council on 10 March 2008 with a view to the adoption of a regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) 258/97*, 2006/0144 (COD), *available at* http://register.consilium.europa.eu/pdf/en/07/st16/st16676-re01.en07.pdf.

food flavorings,[108] and on the adoption of a regulation on a common authorization procedure for all three.[109] Those are aimed at harmonizing evaluation procedures in accordance with the farm to fork concept,[110] in order to provide a high level of consumer protection while ensuring free circulation in the EU's internal market. The proposals went back to the Parliament for a second reading, and in July 2008, the Parliament adopted the amended text. The Council now needs to adopt it as well, before it can be officially published.

XI. Food Supplements and Addition of Vitamins and Minerals

The list of permitted vitamin or mineral preparations that can be added for specific nutritional purposes in food supplements found in Directive 2002/46/EC,[111] which sets harmonized rules for the labeling of food supplements and introduces specific rules on vitamins and minerals in food supplements, was amended by Commission Directive 2006/37/EC to include additional substances.[112]

Regulation 1925/2006/EC of the European Parliament and of the Council of December 20, 2006, on the addition of vitamins, minerals, and certain other substances to foods, aims at "ensuring the effective functioning of the internal market" while guaranteeing consumer protection.[113] The regulation harmonizes the various Member States' provisions that relate to the addition of vitamins and minerals to foods.[114]

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108. *Common Position adopted by the Council on 10 March 2008 with a view to the adoption of a regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulations (EEC) 1576/89 and (EEC) 1601/91, Regulation (EC) 2232/96 and Directive 2000/13/EC*, 2006/1047 (COD), *available at* http://register.consilium.europa.eu/pdf/en/07/st16/st16677-re03.en07.pdf.

109. *Common Position adopted by the Council on 10 March 2008 with a view to the adoption of a regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings*, 2006/0143 (COD), *available at* http://register.consilium.europa.eu/pdf/en/07/st16/st16673-re02.en07.pdf.

110. *Id*. at 2.

111. Council Directive 2002/46, 2002 O.J. (L 183) 51.

112. Commission Directive 2006/37, 2006 O.J. (L 94) 32.

113. Council Regulation 1925/2006, 2006 O.J. (L 404) 26.

114. Regulation 1925/2006, at 26.

XII. Labeling, Nutrition, and Obesity

Since last update, significant changes have occurred in the area of labeling and nutrition. The evolution of nutrition policy in the EU in the last few years is perhaps one of the most drastic changes in EU food law.

A. Labeling Proposal

On January 30, 2008, the European Commission adopted a proposal on the provision of food information to consumers.[115] This proposal combines Directive 2000/13/EC of the European Parliament and of the Council on the labeling, presentation and advertising of foodstuffs and Council Directive 90/496/EC on nutrition labeling for foodstuffs. It proposes to combine different labeling rules in one text since it covers several issues including nutrition labeling, country of origin labeling, and voluntary food information, and is meant to simplify the regulatory framework.[116] Among other things, the proposal suggests minimum font sizes on labels, and for mandatory declaration of specific nutrients such as the energy value, the amount of fat energy value, the amounts of fat, saturated fatty acids, carbohydrates with specific reference to sugars, and salt.[117] Currently, under the present Directive, nutrition labeling is voluntary, but becomes mandatory if a nutrition claim is made on the label.[118]

The Commission is also working on revision of technical issues of the EU nutrition labeling directive.[119] The issues that are to be revised concern the list of vitamins and minerals, their recommended daily allowances and significant amounts, as well as the definition of dietary fiber and tolerances for nutrient values declared on labels.[120]

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115. *Proposal for a regulation of the European Parliament and of the Council on the provision of food information to consumers*, COM (2008) 40 final (Jan. 30, 2008), *available at* http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/proposal_regulation_ep_council.pdf.

116. *Id.*

117. *Id.* art. 14, at 30; art. 29, at 36.

118. Council Directive 90/496, 1990 O.J. (L 276) 40.

119. Commission of the European Communities, Working Document: Commission Directive amending Directive 90/496/EEC of the Council as regards recommended daily allowances, energy conversion factors and definitions (Jan. 11, 2008).

120. *See id.*

B. Health and Nutrition Claims

Regulation 1924/2006/EC on nutrition and health claims made on foods was adopted in December 2006,[121] and took effect on July 1, 2007. It provides that in order for foods to bear nutrition or health claims, the Commission should first establish nutrient profiles with which certain foods or certain food groups should comply.[122] Therefore, the EFSA was mandated to assist the Commission in establishing a nutrient profile system, by issuing a scientific opinion on nutrient profiles and providing additional guidance on the setting of these profiles. The regulation specifically states that the setting of nutrient profiles should take into account the dietary role and importance of food groups and their contributions of nutrients to the overall diet of the population.[123] The opinion was adopted on January 31, 2008 and gives general scientific recommendations. The EFSA's Panel on Dietetic Products, Nutrition and Allergies recommends that "the choice of nutrients to be included in nutrient profiles should be driven by their public health importance for EU populations."[124] It adds that "[t]hese nutrients include saturated fatty acids, sodium, dietary fiber and unsaturated fatty acids, intakes of which generally do not comply with nutrient intake recommendations in many Member States."[125] In addition to this opinion, the EFSA is developing a representative food composition database that will allow the testing of any proposed profiling scheme.

Previously in December 2007, the Commission's Standing Committee on Food Chain and Animal Health adopted a guidance document on the implementation of Regulation 1924/2006.[126] This document is not legally binding, and is merely meant to provide assistance in understanding and correctly applying the regulation.

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121. Corrigendum to Council Regulation 1924/2006, 2007 O.J. (L12) 3 (EC).
122. Corrigendum to Regulation 1924/2006, art. 4, at 8.
123. Corrigendum to Regulation 1924/2006, art. 4, at 8.
124. *The Setting of Nutrient Profiles for Foods Bearing Nutrition and Health Claims Pursuant to Article 4 of the Regulation (EC) No 1924/2006, Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies*, 644 EFSA J. 1, 2 (2008), *available at* http://www.efsa.europa.eu/EFSA/Scientific_Opinion/nda_op_ej644_nutrient%20profiles_en,2.pdf.
125. *Id.*
126. *Guidance on the Implementation of Regulation No. 1924/2006 on Nutrition and Health Claims Made on Foods, Conclusions of the Standing Committee on the Food Chain and Animal Health* (Dec. 14, 2007), *available at* http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf.

C. Other Labeling Changes

1. Foods for Infants and Young Children and Foods for Special Medical Purposes

On December 22, 2006, the Commission published Commission Directive 2006/141/EC, which establishes compositional and labeling requirements for infant formula and follow-on formula intended for use by infants in good health in the Community.[127] The Directive also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes, which addresses marketing, information and the responsibilities of health authorities.[128] Pending the transposition of Directive 2006/141/EC into national legislations, Commission Regulation 2006/1609/EC of October 27, 2006, provides for the temporary marketing of infant formula "based on hydrolysates of whey protein derived from cows' milk protein."[129]

Furthermore, Commission Directive 2006/125/EC of December 5, 2006 on "processed cereal-based foods and baby foods for infants and young children" replaced Commission Directive 96/5/EC, which had addressed the same issues.[130] Directive 2006/125/EC sets the standards on the composition and labeling of processed-cereal based foods and other baby foods, and it contains specific rules on pesticides residues in processed cereal-based baby foods and baby foods; it notably requires that baby foods contain levels of pesticides no greater than 0.01 mg/kg except for certain pesticides which have specific maximum levels provided in the Annex IV, and also requires that certain toxic pesticides not be used in the production of processed cereal-based baby foods and baby foods.[131]

Commission Directive 2006/141/EC also amended Commission Directive 1999/21/EC of March 25, 1999, on dietary foods for special medical purposes, which sets standards for the composition and labeling of foods that are "specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision."[132]

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127. Commission Directive 2006/141, 2006 O.J. (L 401) 1.
128. Directive 2006/141, art. 1, at 4.
129. Commission Regulation 1609/2006, 2006 O.J. (L 299) 9.
130. Commission Directive 2006/125, 2006 O.J. (L 339) 16.
131. Directive 2006/125, at 16.
132. Commission Directive 1999/21, art. 1, 1999 O.J. (L 91) 29, 30.

2. Dietetic foods

Commission Directive 2006/34/EC amended Commission Directive 2001/15/EC of February 15, 2001, "on substances that may be added for specific nutritional purposes in foods for particular nutritional uses,"[133] in order to include additional substances to the Annex.[134]

D. Obesity

Obesity has become a significant issue in the European Union, and policy makers want to take action against the "obesity epidemic." After the publication of the European Commission's Green Paper in 2005,[135] the Commission issued a White Paper on that same issue,[136] in which the Commission recognized obesity as being an important issue and set forth the three factors that must be taken into consideration in drafting any nutrition policy aimed at obesity.[137] First, individuals are ultimately responsible for their lifestyles, and those of their children, although the environment does play a role and influences their behavior.[138] Second, only well-informed consumers can make reasonable decisions.[139] Finally, both the complementarity and integration of the different relevant policy areas and of the different levels of action must be promoted in order to get the best possible response.[140] The Commission also outlined four essential aspects to the actions to be taken: any action's goal should be to "address the root causes of the health related risks"; the actions are to work at all levels of government and across government policy areas; private actors (including the food industry and schools) must be involved in the action; and finally, the actions taken need to be monitored so as to be as well-adapted as possible to new and evolving circumstances.[141] Thus, the Commission rec-

133. Commission Directive 2001/15, 2001 O.J. (L 52) 19, 20.
134. Commission Directive 2006/34, 2006 O.J. (L 83) 14.
135. COMMISSION GREEN PAPER, PROMOTING HEALTHY DIETS AND PHYSICAL ACTIVITY: A EUROPEAN DIMENSION FOR THE PREVENTION OF OVERWEIGHT, OBESITY AND CHRONIC DISEASES, COM (2005) 637 final (Dec. 8, 2005).
136. COMMISSION WHITE PAPER, A STRATEGY FOR EUROPE ON NUTRITION, OVERWEIGHT AND OBESITY RELATED HEALTH ISSUES, COM (2007) 279 final (May 30, 2007).
137. *Id*. at 3.
138. *Id*.
139. *Id*.
140. *Id*.
141. *Id*. at 3-4.

ommended that partnerships be created at both EU and local levels.[142] It also stressed the need for consistent policy across the EU and that policy would make consumers be better informed about what they buy and eat, and the importance of making healthy options available, encouraging physical activity, focusing primarily on the groups the most vulnerable to obesity (children and people in low socio-economic groups), developing scientific research to substantiate the various policies, and developing monitoring systems.[143]

After the Commission's adoption of this White Paper, the European Parliament's Environment, Public Health and Food Safety Committee, which must issue a non-legislative report on it, mandated Rapporteur Adriana Poli Bortone to write a draft report on the issue. Poli Bortone's report was published last December and the Committee will vote on it in April 2008.[144] Poli Bortone's Draft Report stresses the need to focus on children as an important part of the fight against obesity.[145] It notably suggests that schools take a more active role in this area by encouraging physical activity, promoting nutritional education, and providing healthier meal options to students. Poli Bortone also calls for a ban on the sale, sponsorship, and advertising of products high in sugar, salt, and fat in schools, and for restrictions on the volume of commercials for unhealthy foods specially aimed at children and the proposed limitations on the time slots in which these commercials could air. This report's strict proposals have drawn heavy criticism on the part of the industry as well as on the part of Members of the European Parliament.

XIII. Conclusion

EU Food Law is in constant evolution. By the time this article is published, additional decisions regarding the aforementioned topics will have been reached. Out of all these regulatory developments, one thing is sure—EU lawmakers are striving for as much uniformity and consistency as possible. Although this trend does not affect all areas yet, it is shaping today's biggest EU food law issues. Further developments in these and other areas will continue to be followed in later updates.

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142. *Id.* at 5.
143. *Id.* at 5-9.
144. Adriana Poli Bortone, Comm. On the Envt., Pub. Health and Food Safety, Draft Report on the White Paper on Nutrition-, Overweight- and Obesity-related Health Issues, 2007/2285(INI) (Dec. 19, 2007).
145. *See id.*