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An Agricultural Law Research Article

## **European Union Food Law Update**

by

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# EUROPEAN UNION FOOD LAW UPDATE

*Nicole Coutrelis\**

## I. PUBLISHED REGULATIONS

### A. *Food Hygiene*

On December 22, 2005, the European Commission published several regulations supplementing and implementing the provisions of the new food hygiene rules adopted in April 2004, which overhauled previous hygiene legislation in the European Union (E.U.)<sup>1</sup> (so called “Hygiene Package”). The new hygiene rules consisted of the following:

- Regulation (EC) No. 2073/2005/EC “on microbiological criteria for foodstuffs;”<sup>2</sup>
- Regulation (EC) No. 2074/2005/EC “laying down implementing measures for certain products under Regulation (EC) No. 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No. 854/2004 of the European Parliament and of the Council and Regulation (EC) No. 882/2004 of the European Parliament and of the Council, derogating from Regulation

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1. Directive 852/2004 of the European Parliament and Council “on the hygiene of foodstuffs,” 2004 O.J. (L 139) 1 (EC); Regulation 853/2004/EC of the European Parliament and Council “laying down specific hygiene rules on the hygiene of foodstuffs,” 2004 O.J. (L 139) 55; Regulation 854/2004/EC of European Parliament and Council “laying down specific rules for the organization of official controls on products of animal origin intended for human consumption,” 2004 O.J. (L 155) 206; and Regulation 882/2004/EC of European Parliament and Council “on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare,” 2004 O.J. (L 165) 1 (EC).

2. Commission Regulation 2073/2005, 2005 O.J. (L 338) 1 (EC).

(EC) No. 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004,”<sup>3</sup>

- Regulation (EC) No. 2075/2005/EC “laying down specific rules on official controls for *Trichinella* in meat;”<sup>4</sup> and
- Regulation (EC) No. 2076/2005/EC “laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004.”<sup>5</sup>

These four new hygiene regulations adopted in 2004 will be effective in all the Member States on January 1, 2006, except for some provisions of Regulation 2074/2005/EC (Chapters II and III of Annex V, dealing with harmonized structures of national websites and with the presentation of lists of approved premises), which shall apply beginning January 1, 2007.<sup>6</sup> Despite providing an effective date for some of the rules, Regulation 2076/2005/EC provides a transitional period until December 31, 2009 for some of the new hygiene rules.<sup>7</sup>

At the end of 2005, in order to assist food business operators and Member States with the implementation of the new food hygiene legislation, the Health and Consumer Protection Directorate-General of the Commission published three guidance documents. The first document published was the Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the Hazard Analysis and Critical Control Point (HACCP) principles in certain food businesses.<sup>8</sup> Following the HACCP Guidance document, a second document was provided, the Guidance document on the implementation of certain provisions of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.<sup>9</sup> Finally, the Commission published its final

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3. Commission Regulation 2074/2005, 2005 O.J. (L 338) 27 (EC).

4. Commission Regulation 2075/2005, 2005 O.J. (L 338) 60 (EC).

5. Commission Regulation 2076/2005, 2005 O.J. (L 338) 83 (EC).

6. Commission Regulation 2074/2005, art. 10, 2005 O.J. (L 338) 27 (EC).

7. Commission Regulation 2076/2005, art. 1, 2005 O.J. (L 338) 83 (EC).

8. See Europa, Guidance Document—Implementation of Procedures Based on the HACCP Principles, and Facilitation of the Implementation of the HACCP Principles in Certain Food Businesses, *available at* [http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance\\_doc\\_haccp\\_en.pdf](http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf)

9. See Europa, Guidance document on the implementation of certain provisions of Regulation (EC) 852/2004 on the hygiene of foodstuffs, *available at* [http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance\\_doc\\_852-2004\\_en.pdf](http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf).

guidance document, the Guidance document on the implementation of certain provisions of Regulation (EC) 853/2004 on the hygiene of food of animal origin.<sup>10</sup>

### B. Organic Farming

On August 6, 2005, the Commission published Regulation No. 1294/2005/EC “amending Annex I to Council Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.”<sup>11</sup> This directive provides for an extension of the transitional period during which the use of conventional feedingstuffs may be authorized for the production of animal products derived from organic farming.<sup>12</sup>

On September 28, 2005, the Council published Regulation No. 1567/2005/EC “amending Regulation (EEC) No. 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.”<sup>13</sup> Pursuant to Regulation 2092/91 (Article 11(6)(a)),<sup>14</sup> a transitional measure allows Member States to grant derogations for imports from third countries of products that have been produced with equivalent rules to those provided in Regulation 2092/91.<sup>15</sup> This transitional measure has been extended until December 31, 2006. The Commission is considering replacing the current national derogations with a new permanent system; yet, this replacement will take some time.

On November 25, 2005, the Commission published Regulation No. 1916/2005/EC “amending Annex II to Council Regulation (EEC) 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.”<sup>16</sup> This amendment contains a list of vitamins, pro-vitamins and chemically well-defined substances having a similar effect which are authorized in organic farming.<sup>17</sup>

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10. See Europa, Guidance document—Implementation of Certain Provisions of Regulation (EC) No. 853/2004 on the Hygiene of Food of Animal Origin, *available at* [http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance\\_doc\\_853-2004\\_en.pdf](http://ec.europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf).

11. Commission Regulation 1294/2005, 2005 O.J. (L 205) 16 (EC).

12. Commission Regulation 1294/2005, whereas (3), 2005 O.J. (L 305) 16 (EC).

13. Council Regulation 1567/2005, 2005 O.J. (L 252) 1 (EC).

14. Council Regulation 2092/91, art. 11(6)(a), 1991 O.J. (L 198) 1, 1-15 (EC).

15. Council Regulation 1567/2005, whereas (1), 2005 O.J. (L 252) 1 (EC).

16. Council Regulation 1916/2005, 2005 O.J. (L 307) 10 (EC).

17. Council Regulation 1916/2005, annex, 2005 O.J. (L 307) 11 (EC).

### C. Food Contact Materials

On November 19, 2005, the European Commission published Directive 2005/79/EC “amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food.”<sup>18</sup> Among other things, this directive modifies the list of monomers which may be used in the manufacturing of plastic materials and articles intended to come in contact with food.<sup>19</sup> It also provides for additions to the list of additives which may be used in the manufacture of plastic materials and articles.<sup>20</sup> Directive 2005/79 is to be implemented into national law by Member States by November 19, 2006.<sup>21</sup> Importation into the E.U. and manufacturing of plastic materials and articles not complying with the new requirements will be forbidden after November 19, 2007.<sup>22</sup>

During the second half of 2005, the Commission updated several documents relating to legislation on food contact materials, including a list of E.U. and Member States’ measures on food contact materials and a consolidated list of monomers as well as additives appearing in the directives on plastics for food applications.<sup>23</sup>

### D. Food Allergens

On October 4, 2005, the Commission published Directive 2005/63/EC “correcting Directive 2005/26/EC concerning the list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council.”<sup>24</sup> Pursuant to Directive 2005/63/EC, carotenoids which were mistakenly omitted from the list in the annex to Directive 2005/26/EC of substances not considered to be a risk for allergic people were thereby added.<sup>25</sup>

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18. Commission Directive 2005/79, 2005 O.J. (L 302) 35 (EC).

19. Commission Directive 2005/79, whereas (1), 2005 O.J. (L 302) 35 (EC).

20. Commission Directive 2005/79, whereas (2), 2005 O.J. (L 302) 35 (EC).

21. Directive 2005/79, art. 3, 2005 O.J. (L 302) 36 (EC).

22. *Id.*

23. European Commission, Health & Consumer Protection Directorate-General, Food Contact Materials: Substances Listed in E.U. Directives on Plastic in Contact with Food, available at [http://ec.europa.eu.int/comm/food/food/chemicalsafety/foodcontact/eu\\_substances\\_en.pdf](http://ec.europa.eu.int/comm/food/food/chemicalsafety/foodcontact/eu_substances_en.pdf)

24. Commission Directive 2005/63, 2005 O.J. (L 258) 3 (EC).

25. Commission Directive 2005/63, whereas (3), 2005 O.J. (L 258) 3 (EC).

### E. Genetically Modified Organisms (GMOs)

On August 10, 2005, the Commission published Decision 2005/608 “concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line MON 863) genetically modified for resistance to corn rootworm.”<sup>26</sup> Pursuant to this decision, Monsanto has been authorized for ten years to place the genetically modified maize MON 863 on the market for import and processing as animal feed; however, the decision does not cover food or cultivation. MON 863 is the second maize to be authorized following the implementation of Directive 2001/18/EC “on the deliberate release of genetically organisms into the environment.”<sup>27</sup>

The Commission authorized the placing on the market of the genetically modified oilseed rape known as GT73 for import and processing during a period of ten years on August 31, 2005, following an application submitted by Monsanto.<sup>28</sup> This market placement is the third GMO product to be approved under Directive 2001/18.<sup>29</sup>

On November 3, 2005, the Commission authorized the genetically modified maize 1507 to be placed on the market for use in animal feed.<sup>30</sup> Maize 1507 is the fourth product to be authorized following the effective date for Directive 2001/18/EC.<sup>31</sup>

### F. Novel Foods

On July 29, 2005, the Commission also published Decision 2005/580/EC “authori[z]ing the placing on the market of isomaltulose as a novel food or novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council.”<sup>32</sup>

In contrast, however, on same day the Commission published Decision 2005/580/EC “refusing the placing on the market of be-

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26. Commission Decision 2005/608, 2005 O.J. (L 207) 17 (EC).

27. Commission Directive 2001/18, 2001 O.J. (L 106) 1 (EC).

28. Press Release, GMOs : Commission Authorizes Import of GM oilseed rape for Use in Animal Feed, (IP/05/1077), Aug. 31, 2005, available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1077&format=HTML&aged=0&language=EN&guiLanguage=en>.

29. *Id.*

30. Commission Decision 2005/772/EC, 2005 O.J. (L 291) 42 (EC).

31. Environment for Europeans, *Striking the Right Balance on GMOs*, Jan. 2006, available at [http://ec.europa.eu/environment/news/efe/22/article\\_3606\\_en.htm](http://ec.europa.eu/environment/news/efe/22/article_3606_en.htm).

32. Commission Decision 2005/581, 2005 O.J. (L 199) 90 (EC).

taine as a novel food or novel food ingredient under Regulation (EC) No. 258/97 of the European Parliament and of the Council.”<sup>33</sup> Such a decision is based upon the opinion of the European Food Safety Authority (EFSA), according to which the safety of betaine for the intended use has not been established.

### *G. BSE Legislation*

On August 6, 2005, the Commission published Regulation 1292/2005 “amending Annex IV to Regulation (EC) 999/2001 of the European Parliament and of the Council as regards animal nutrition.”<sup>34</sup> Regulation 999/2001 is the framework legislation addressing the control and eradication of BSE and transmissible spongiform encephalopathies.<sup>35</sup> Regulation 1292/2005 is to apply from September 1, 2005.<sup>36</sup>

On December 3, 2005, the Commission also published Regulation No. 1974/2005 “amending Annexes X and XI to Regulation (EC) No. 999/2001 of the European Parliament and of the Council as regards national reference laboratories and specified risk material”<sup>37</sup>

### *H. Pesticides Residues*

The Commission published Directive 2005/48 on August 24, 2005, “amending Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC as regards maximum residue levels for certain pesticides in and on cereals and certain products of animal and plant origin.”<sup>38</sup>

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33. Commission Decision 2005/580, 2005 O.J. (L 199) 89 (EC).

34. Commission Regulation 1292/2005, 2005 O.J. (L 205) 3 (EC).

35. Commission Regulation 999/2001, 2001 O.J. (L 147) 1, art. 1, (EC).

36. Commission Regulation 1292/2005, 2005 O.J. (L 205) 3, art. 2 (EC)

37. Commission Regulation, 1974/2005, 2005 O.J. (L 317) 4 (EC).

38. Commission Directive 2005/48, 2005 O.J. (L 219) 29 (EC).

## II. PENDING DRAFT REGULATIONS

### A. *Organic Farming*

On December 21, 2005, the Commission adopted proposals<sup>39</sup> for Council Regulations on organic production and labelling of organic products, amending Regulation (EEC) No. 2092/91<sup>40</sup> on organic production of agricultural products and indications referring thereto in agricultural products and foodstuffs. This proposal was aimed at entirely revising the current rules for production, labeling, control, and import of organic foodstuffs and hence replace Regulation (EEC) No. 2092/91.<sup>41</sup> According to the Commission proposal, the new rules would be effective as of January 1, 2009, except for the provisions on import which are to be effective beginning January 1, 2007.<sup>42</sup> The import provisions have an early implementation date since the current rules for import are due to expire on December 31, 2006 pursuant to Regulation No. 1567/2005/EC amending Regulation No. 2092/91.<sup>43</sup>

### B. *Labeling: Health Claims*

In December 2005, the Council adopted a Common Position on the Proposal for a Regulation on the use of nutrition and health claims made on foods, which was issued by the Commission in July 2003.<sup>44</sup> Among the large number of amendments proposed by the European Parliament, the Council rejected two controversial ones. First, the Council chose to reject the provision regarding the substitution of the authorization procedure for health claims proposed by the Commission by a simple notification procedure. A second provision was rejected involving the deletion of nutrient profiles for

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39. See Proposal for a Council Regulation on Organic Production and Labeling of Organic Products, COM(2005) 671 final, available at [http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005\\_0671en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0671en01.pdf).

40. Council Regulation 2092/91, 1991 O.J. (L 198) 1, 1-15 (EEC).

41. See Proposal for a Council Regulation on Organic Production and Labeling of Organic Products, COM(2005) 671 final at 3, available at [http://europa.eu.int/eurlex/lex/LexUriServ/site/en/com/2005/com2005\\_0671en01.pdf](http://europa.eu.int/eurlex/lex/LexUriServ/site/en/com/2005/com2005_0671en01.pdf).

42. *Id.* at 8.

43. *Id.*

44. See Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Food, COM(2003) 424 final, available at [http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003\\_0424en01.pdf](http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0424en01.pdf).

foods. This new text has been forwarded to the European Parliament for its second reading, which is expected to take place no sooner than May 2006. Members of the Parliament can submit amendments until February 15, 2006.<sup>45</sup>

### C. Food Fortification with Vitamins and Minerals

In December 2005, the Council also adopted a Common Position concerning the Proposal for regulation of the addition of vitamins, minerals and other substances to foods, which was issued by the Commission in November 2003.<sup>46</sup> Such a proposal has been sent to the European Parliament for its second reading, which is expected to take place at the same time as the nutrition and health claims proposal in May 2006.

Until recently, this matter has not been harmonized in the E.U. According to the proposed text, supplementation of food for ordinary consumption would be authorized—under certain conditions—all over the E.U.<sup>47</sup> The authorized substances would be identical to those already authorized for food supplements in Directive 2002/46.<sup>48</sup>

### D. Food Additives

In October 2005, the European Parliament adopted the Proposal for a Directive with amendments,<sup>49</sup> amending Directive 95/2/EC on food additives other than colours and sweeteners<sup>50</sup> and Directive 94/35/EC on sweeteners for use in foodstuffs,<sup>51</sup> which was issued by the Commission in the light of recent scientific develop-

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45. See EurActiv, *Nutrition and Health Claims Made on Foods*, May 9, 2006, <http://www.euractiv.com/en/health/nutrition-health-claims-foods/article-133154>.

46. European Commission, Proposal for a Regulation of the European Parliament and of the Council on the Addition of Vitamins and Minerals and of Certain Other Substances in Foods, COM(2003) 671 final, available at [http://ec.europa.eu/comm/food/fs/sfp/df/df\\_ff\\_reg1\\_en.pdf](http://ec.europa.eu/comm/food/fs/sfp/df/df_ff_reg1_en.pdf).

47. *Id.* at 12-13.

48. *Id.*

49. 2004/0237 (COD), Proposal for a 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 Sweeteners for Use in Foodstuffs, available at <http://www.food.gov.uk/multimedia/pdfs/com2004650.pdf>.

50. European Parliament and Council Directive 95/2/EC, 1995 O.J. (L 61) 1, 1-40.

51. European Parliament and Council Directive 94/35/EC, 1994 O.J. (L 237) 3, 3-12.

ments in October 2004. Among other matters, the draft directive amends the conditions surrounding the use of nitrates and nitrites in foodstuffs, following a judgment of the European Court of Justice (ECJ) of March 20, 2003.<sup>52</sup> In this judgment, a Danish regulation was upheld, which was stricter than the E.U. directive regarding the use of those additives.<sup>53</sup> The proposal as amended by the Parliament was forwarded to the Council for adoption.

### *E. Aquaculture Products*

On August 23, 2005, the Commission issued a proposal for a Council Directive “on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.”<sup>54</sup> The proposal’s objective was to update and to simplify the existing provisions of Directives 91/67/EEC, 93/53/EEC and 95/70/EC.<sup>55</sup>

## III. CASE LAW: JUDGMENTS ISSUED

### *A. Food Supplements*

On July 12, 2005, following the submission of request for a preliminary ruling, the European Court of Justice (ECJ)<sup>56</sup> confirmed the validity of the European Parliament and Council Directive 2002/46/EC “on the approximation of the laws of the Member States relating to food supplements.”<sup>57</sup> The validity of the legislation implementing the Food Supplements Directive, which partially har-

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52. 2004/0237 (COD), Proposal for a 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 Sweeteners for Use in Foodstuffs, at 2, available at <http://www.food.gov.uk/multimedia/pdfs/com2004650.pdf>.

53. Case C-300, Kingdom of Den. v. Comm’n. of European Communities, 2003 ECJ CELEX LEXIS 66 (March 20, 2003).

54. See Proposal for a Council Directive on Animal Health Requirements for Aquaculture Animals and Products Thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals, COM(2005) 362 final, available at [http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005\\_0362en01.pdf](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0362en01.pdf).

55. *Id.* at 2.

56. Joined Cases C-154/04, Alliance for Natural Health & Nutri-Link Ltd. v. Sec’y of State Health and C-155/04 Nat’l Ass’n of Health Stores and Health Food Mnr. Ltd. v. Sec’y of State Health, Nat’l Assembly for Wales, 2005 ECJ CELEX LEXIS 327 (July 12, 2005).

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

monized the rules in the European Union (E.U.) governing the marketing of food supplements from August 1, 2005, had been challenged in the United Kingdom (UK) by a European association of manufacturers, wholesalers, distributors, retailers, and consumers of food supplements and a small specialist distributor and retailer of food supplements in the United Kingdom.<sup>58</sup> The claimants argued that the new Food Supplements legislation did not improve the conditions for the establishment and functioning of the single market and some provisions were contrary to the principle of the free movements of goods.<sup>59</sup>

The ECJ confirmed the internal market base of such directive, i.e. Article 95 of the EC Treaty.<sup>60</sup> It also upheld the positive lists of vitamins and minerals that may be used in the manufacture of these products. As a result, some substances which are currently authorized for sale in the UK will be forbidden after a transitional period, but the Court ruled that such a consequence was to be accepted in order to have a single market in this sector.<sup>61</sup>

Also, on September 8, 2005, following an action brought by the European Commission against France on the basis of the infringement procedure provided by Article 226 of the EC Treaty, the ECJ declared that by failing to transpose the Food Supplements Directive 2002/46/EC, the French Republic has failed to fulfil its obligations under that directive.<sup>62</sup> The period prescribed for the transposition of the directive into national law expired on July 31, 2003.<sup>63</sup> Indeed, the French process was very slow because France took this opportunity to review its entire legislation on food supplements, not only regarding vitamins and minerals as provided for in the Directive, but also regarding all substances, including herbal supplements.

### B. Residues

Pursuant to the judgment rendered on July 12, 2005, the ECJ did not confirm the judgment of the Court of First Instance pursu-

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58. *See Alliance for Natural Health*, 2005 ECJ CELEX LEXIS 327.

59. *Id.*

60. *Id.*

61. *Id.*

62. Case C-57/05, *Commission of the European Communities v. French Republic*, available at <http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs>  
&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-57%2F05&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100.

63. *Id.*

ant to which the European Commission has unlawfully failed to act in regard to the establishment of maximum residue limits for veterinary medicinal products<sup>64</sup> pursuant to Council Regulation 2377/90/EEC “laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.”<sup>65</sup>

At stake in this Court decision was the use of a veterinary product containing progesterone marketed by Pfizer and CEVA Santé Animale.<sup>66</sup> In 1993, CEVA had submitted an application to the Commission for the establishment of maximum residue limits for progesterone in cattle and horses.<sup>67</sup> The Commission did not take any action before January 2000 because of divergent scientific data on the risks with progesterone. In July 2001, the Commission adopted a draft regulation amending Regulation 2377/90/EEC classifying progesterone in Annex I of such regulation (i.e. the list of substances for which maximum residue limits are defined).<sup>68</sup>

In November 2000, CEVA and Pfizer brought proceedings before the Court of First Instance arguing that the Commission had failed to take necessary measures for the classification of progesterone in Annex II to Regulation 2377/90 (i.e. the list of substances for which no maximum residue limit is defined), and as a consequence failed to comply with its obligations under Community law.<sup>69</sup> On February 26, 2003, the Court of First Instance ruled that the Commission’s inaction between January 2000 and July 2001 amounted to a breach of the principle of sound administration capable of giving rise to liability of the Community.<sup>70</sup>

On appeal, the ECJ overruled the judgment of the Court of First Instance, stating that the Commission must be given sufficient discretion to allow it to determine on a fully informed basis in order to protect public health.<sup>71</sup>

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64. Case C-198/03, *Comm’n v. CEVA Santé Animale SA and Pfizer Enterprises Sàrl*, 2005 ECJ CELEX LEXIS 737 (July 12, 2005).

65. Council Regulation 2377/90, 1990 O.J. (L 224) 1, 1-8 (EC).

66. *See CEVA Santé Animale SA and Pfizer Enterprises Sàrl*, 2005 ECJ CELEX LEXIS 737.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Joined Cases T-344/00 and T-345/00, CEVA Santé animale SA and Pharmacia Enters. SA v. Comm’n*, 2003 ECJ CELEX LEXIS 40 (Feb. 26, 2003).

71. Case C-198/03, *Comm’n v. CEVA Santé Animale SA and Pfizer Enterprises Sàrl*, 2005 ECJ CELEX LEXIS 737 (July 12, 2005).

### C. Use of Name "Feta" (Protected Designation of Origin)

On October 25, 2005, the ECJ upheld the name "Feta" for the cheese produced in Greece as a protected designation of origin (PDO),<sup>72</sup> hereby dismissing the actions brought both by Germany and Denmark against the registration of the name "Feta" as a PDO by Commission Regulation 1829/2002/EC "amending the Annex to Regulation (EC) No. 1107/96 with regard to the name 'Feta,'" the word "Feta" was inserted in the list of PDOs.<sup>73</sup>

In order to benefit from a PDO, a name such as "Feta" must refer to an agricultural product or a foodstuff from a defined geographical environment with specific natural and human factors, capable of conferring on that product or foodstuff its specific characteristics.<sup>74</sup> Additionally, the name cannot have become generic if the product is to be classified as a PDO.<sup>75</sup>

Using these guidelines, the ECJ reached the conclusion that the word "Feta" has not become generic.<sup>76</sup> This ruling puts an end to a longstanding dispute, opposing many non-Greek cheese producers, particularly in France, Germany, and Denmark. Finally, Greece has succeeded in obtaining that, within the E.U., the name "Feta" be allowed only to Greek cheese.<sup>77</sup>

### D. Hygiene

On November 24, 2005, following the submission of request for a preliminary ruling, the ECJ held that Austria is entitled, on grounds of public health protection, to prohibit the sale of unwrapped chewing gum products from automatic vending machines.<sup>78</sup> Pursuant to Austrian law, it is forbidden to sell sugar confectionery

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72. Joined Cases C-465/02 and C-466/02, Federal Republic of Germany and Kingdom of Den. v. Comm'n, *available at* <http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-466/02&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

73. Commission Regulation 1829/2002, art. 1(1), 2002 O.J. (L 277) 10, 14 (EC).

74. Commission Regulation 1829/2002, whereas (35), 2002 O.J. (L 277) 10, 14 (EC).

75. Commission Regulation 1829/2002, whereas (30), 2002 O.J. (L 277) 10, 14 (EC).

76. Commission Regulation 1829/2002, whereas (29), 2002 O.J. (L 277) 10, 14 (EC).

77. Commission Regulation 1829/2002, art. 1(1), 2002 O.J. (L 277) 10, 14 (EC).

78. Case C-366/04, Georg Schwarz v. Bürgermeister der Landeshauptstadt Salzburg, 2005 ECJ CELEX LEXIS 511 (June 28, 2005).

or similar products in vending machines if the products have not been wrapped.<sup>79</sup>

In an action brought in Austria stemming from unwrapped chewing gum in vending machines, Schwarz lodged an appeal arguing that the Austrian legislation was not compatible with Council Directive 93/43/EEC “on the hygiene of foodstuffs”<sup>80</sup> and the free movements of goods (Articles 28 and 30 of EC Treaty).<sup>81</sup> In this case, the ECJ held that the packaging of confectionery products marketed in vending machines has not been harmonized by Directive 93/43.<sup>82</sup> As a result, national measures in this field must, therefore, be assessed in regard to the EC Treaty provisions relating to the free movement of goods.

The ECJ then stated that Austrian provisions at stake constitute a measure having equivalent effect to quantitative restrictions to importations within the meaning of Article 28 EC.<sup>83</sup> Pursuant to consistent case law, which has held national rules which hinders the free movement of goods is not necessarily contrary to Community law if it may be justified by one of the public-interest grounds set out in Article 30 EC or by one of the mandatory requirements laid down by the Court’s case-law where the national rules are applicable without distinction, the ECJ reached the conclusion that such a prohibition constitutes an adequate and proportionate measure for the protection of public health.<sup>84</sup>

#### *E. Genetically Modified Organisms (GMOs)*

On October 5, 2005, the E.U. Court of First Instance<sup>85</sup> dismissed the actions for an annulment brought by the region of Upper Austria and Austria against the Commission Decision 2003/653/EC of 2 September 2003 “relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty.”<sup>86</sup>

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79. *Id.*

80. Council Directive 93/43/EEC, 1993 O.J. (L 175) 1 (EC).

81. *Schwarz*, 2005 ECJ CELEX LEXIS 511.

82. *Id.*

83. *Id.*

84. *Id.*

85. Joined Cases T-366/03 and T-235/04, *Land Oberösterreich and Austria v. Comm’n*, 2005 ECJ CELEX LEXIS 454.

86. Commission Decision 2003/653/EC, 2003 O.J. (L 230) 34, 34-43 (EC).

In accordance with Article 95(5) of the EC Treaty, Austria proposed a regulation banning the use of genetically modified organisms in the region of Upper Austria, in derogation to the provisions of the European Parliament and of Council Directive 2001/18/EC “on the deliberate release into the environment of genetically modified organisms.”<sup>87</sup> The Commission adopted such a decision thereby rejecting the Austrian proposed legislation because the latter had failed to provide new scientific evidence or demonstrate that a specific problem existed in that region.<sup>88</sup> The Court confirmed the Commission decision.<sup>89</sup>

#### IV. OTHER RELEVANT NEWS

##### A. Regulations Entered Into Application

On November 25, 2005, the new allergen labeling requirements, introduced by Directive 89/2003/EC<sup>90</sup> amending Directive 2000/13/EC, became effective.

##### B. Unofficial Documents and Announcements

###### 1. Food Additives

After the release of the results of the study on the artificial sweetener aspartame during the summer of 2005, the Italian scientific Ramazzini Institute published the completed study in November 2005 in the journal, *Environmental Health Perspectives*.<sup>91</sup> Following this controversial study, the EFSA asked the Director of the Institute to provide full research data so that a complete risk assess-

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87. Regulation 2001/18/EC, 2001 O.J. (L 106) 1 (EC).

88. *Land Oberösterreich*, 2005 ECJ CELEX LEXIS 454.

89. *Id.*

90. See FoodQualitynews.com, Anthony Fletcher, *EU Strengthens Allergen Labeling*, Nov. 30, 2005, at <http://www.foodqualitynews.com/news/ng.asp?id=64224-eu-directive-label>.

91. See Morando Soffritti, et al., First Experimental Demonstration of the Multi-potential Carcinogenic Effects of Aspartame Administered in the Feed to Sprague-Dawley Rats, 114 ENVIRONMENTAL HEALTH PERSPECTIVES 379 (March 2006), available at <http://www.ehponline.org/members/2005/8711/8711.pdf>.

ment could be administered within three to five months after the reception of the requested information.<sup>92</sup>

Based upon the study carried on rats, the Ramazzini Institute has been claiming that aspartame is a multi-potential carcinogenic agent, even at a daily dose of twenty milligrams/kilograms of body-weight.<sup>93</sup>

## 2. Feed Additives

On December 16, 2005, the Commission updated the Community Register of Feed Additives in accordance with Article 17 of Regulation (EC) 1831/2003 on additives for use in animal nutrition,<sup>94</sup> which has only informative purposes.

## 3. Nutrition Policy

On December 8, 2005, the Commission adopted a Green Paper “Promoting healthy diets and physical activity—a European dimension for the prevention of overweight, obesity and chronic diseases”<sup>95</sup> and launched a public consultation on how to reduce obesity levels and the prevalence of associated chronic diseases in the E.U.<sup>96</sup>

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92. See Press Release, EFSA, New Research Data on the Sweetener Aspartame to be Considered by EFSA’s Scientific Experts (July 14, 2005), [http://www.efsa.eu.int/press\\_room/press\\_release/1038/pr\\_aspartame\\_en1.pdf](http://www.efsa.eu.int/press_room/press_release/1038/pr_aspartame_en1.pdf).

93. See Soffritti, *supra* note 91.

94. See European Commission, Community Register of Feed Additives Pursuant to Regulation (EC) No 1831/2003, *available at* [http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/comm\\_register\\_19122005.pdf](http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/comm_register_19122005.pdf).

95. Promoting Healthy Diets and Physical Activity: a European Dimension for the Prevention of Overweight, Obesity and Chronic Diseases (Green Paper), COM (2005) 637 final (Aug. 12, 2005), *available at* [http://europa.eu.int/comm/health/ph\\_determinants/life\\_style/nutrition/documents/nutrition\\_gp\\_en.pdf](http://europa.eu.int/comm/health/ph_determinants/life_style/nutrition/documents/nutrition_gp_en.pdf).

96. See European Commission’s Health and Consumer Protection DG, *EU Launches Debate on how to Tackle Obesity*, Dec. 2005, [http://ec.europa.eu/comm/dgs/health\\_consumer/consumervoice/cv\\_122005\\_en.pdf](http://ec.europa.eu/comm/dgs/health_consumer/consumervoice/cv_122005_en.pdf).

#### 4. BSE in UK

In July 2005, the Commission adopted a reflection paper, the TSE Roadmap,<sup>97</sup> providing an outline of possible modifications to EU measures on BSE in light of the new developments (less cases of BSE reported, ...).<sup>98</sup> In September 2005, the Commission's Food and Veterinary Office published a favorable report regarding the situation in the UK after the ban on the export of live cattle and all cattle products from the UK subsequent to the BSE crisis in 1996.<sup>99</sup> Based upon the report, the possible lifting of the ban on British cattle could be discussed with Member States.

#### 5. Wines

On September 14, 2005, the E.U. and the United States reached a first-phase agreement regarding the protection of E.U. wine designations and access of European wines to the American market.<sup>100</sup> They also agreed to initiate the negotiations of a second-phase agreement ninety days after the entry into force of the first agreement.<sup>101</sup>

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97. European Commission, The TSE Roadmap, COM (2005) 322 final (July 15, 2005), *available at* [http://ec.europa.eu/comm/food/food/biosafety/bse/roadmap\\_en.pdf](http://ec.europa.eu/comm/food/food/biosafety/bse/roadmap_en.pdf).

98. Press Release, European Commission, Questions and Answers on TSE Roadmap (July 15, 2005), *available at* <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/263&format=HTML&aged=0&language=EN>.

99. Press Release, European Commission, BSE: Prospects for lifting current restrictions on the trade of cattle and beef from the UK (Sept. 28, 2005), *available at* <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/05/342&format=HTML&aged=0&language=EN>.

100. European Commission, United States Barriers to Trade and Investment, March 2006, at 26, 70, [http://trade-info.cec.eu.int/doclib/docs/2006/march/tradoc\\_127632.pdf](http://trade-info.cec.eu.int/doclib/docs/2006/march/tradoc_127632.pdf).

101. *Id.* at 70.