

# The National Agricultural Law Center



A research project from The National Center for Agricultural Law Research and Information  
University of Arkansas • [NatAgLaw@uark.edu](mailto:NatAgLaw@uark.edu) • (479) 575-7646  
[www.NationalAgLawCenter.org](http://www.NationalAgLawCenter.org)

---

An Agricultural Law Research Article

## **European Union Food Law Update**

by

Nicole Coutrelis

June 2006

Originally published in the Journal of Food Law & Policy  
2 J. FOOD L. & POL'Y 493 (2006)

## EUROPEAN UNION FOOD LAW UPDATE

**Nicole Coutrelis**

Attorney at Law  
Coutrelis & Associates  
Brussels, Belgium and Paris, France

### I. PUBLISHED REGULATIONS

#### A. *Food Allergen Labeling: New Allergen Exemptions List*

On November 10, 2003, the European Parliament and Council Directive 2003/89/EC amended Directive 2000/13/EC.<sup>1</sup> Directive 2000/13/EC of the European Parliament and Council of March 20, 2000 “on the approximation of the laws of the Member States relating to the [labeling], presentation and advertising of foodstuffs”<sup>2</sup> requires food manufacturers to indicate twelve potentially allergic ingredients and their derivatives on food packaging.<sup>3</sup> The allergen substances are listed in the Annex IIIa to the Directive.<sup>4</sup> These new food allergen labeling requirements became effective on November 25, 2005.<sup>5</sup>

However, Directive 2000/13/EC provided that the Commission may provisionally exclude certain ingredients or products of those ingredients from the allergen list if they are not likely to be a risk for allergic peoples.<sup>6</sup> In March 2005, the European Parliament and Council published Directive 2005/26/EC “establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC.”<sup>7</sup> Pursuant to Directive 2005/26/EC, eight substances derived from

- 
1. Council Directive 2003/89, 2003 O.J. (L 308) 15 (EC).
  2. Council Directive 2000/13, 2000 O.J. (L 109) 29 (EC).
  3. Council Directive 2003/89, art. 1(a), at 16-17.
  4. Directive 2003/89, ann. IIIa, at 18.
  5. Directive 2003/89, art. 2(1), at 17-18.
  6. See Directive 2003/89, art. 1(e), at 17.
  7. Council Directive 2005/26, ann., 2005 O.J. (L 75) 33, 34 (EC).

those listed in Annex IIIa shall be excluded from this Annex when used in specific conditions.<sup>8</sup> The Directive allows for such exclusion until November 25, 2007.<sup>9</sup> Member States have until September 21, 2005, at the latest, to publish the regulations necessary to comply with the exemption list.<sup>10</sup> The new provisions will be effective after November 25, 2005.

According to the minutes of its meeting held on June 23, 2005, the Standing Committee on the Food Chain and Animal Health discussed and approved by a wide majority a draft of informal guidelines.<sup>11</sup> These guidelines were compiled by the Commission and representatives of Member States to interpret the provisions set out in Article 6, paragraph 10 of Directive 2000/13/EC as amended by Directive 2003/89/EC.<sup>12</sup>

### *B. Feed Hygiene*

On February 8, 2005, the European Parliament and Council published Regulation 183/2005/EC “laying down requirements for feed hygiene.”<sup>13</sup> This regulation will be effective in all Member States on January 1, 2006.<sup>14</sup> Its objective is to strengthen feed safety at all stages as feed traceability is an essential component in ensuring such safety.<sup>15</sup>

Regulation 183/2005/EC replaced Council Directive 95/69/EC that went into effect December 22, 1995.<sup>16</sup> Regulation 95/69/EC “[laid] down the conditions and arrangements for approving and

---

8. For example, wheat-based glucose syrups including dextrose are provisionally excluded as a product derived of cereals containing gluten. See Directive 2005/26, ann., at 34.

9. Directive 2005/26, art. 1, at 33.

10. Directive 2005/26, art. 2(1), at 33.

11. See Standing Committee on the Food Chain and Animal Health, *Summary Record of Meeting 23rd June 2005*, at 2, available at [http://europa.eu.int/comm/food/committees/regulatory/scfcah/general\\_food/summary16\\_en.pdf](http://europa.eu.int/comm/food/committees/regulatory/scfcah/general_food/summary16_en.pdf).

12. See Europa, *Guidelines Relating to Article 6 Paragraph 10 of Directive 2000/13/EC as Amended by Directive 2003/84/EC*, available at [http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/guidelines\\_6\\_10.pdf](http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf).

13. Commission Regulation 183/2005, 2005 O.J. (L 35) 1.

14. Regulation 183/2005, art. 34, at 12.

15. Regulation 183/2005, whereas 6, at 1.

16. See Regulation 183/2005, art. 33, at 12.

registering certain establishments and intermediaries operating in the animal feed sector and [amending] Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC.”<sup>17</sup> These amended directives provide for the approval and registration of feed businesses involved in the manufacture, use, or marketing of certain feed additives.<sup>18</sup> Regulation 183/2005/EC extends approval and registration for most all feed businesses.<sup>19</sup> Regulation 183/2005/EC also introduced Hazard Analysis and Critical Control Point (HACCP) principles for the feed business operators other than at the level of primary production.<sup>20</sup> Regulation 183/2005/EC completes the “hygiene package” published on April 29, 2004. The “hygiene package” consisted of the following four regulations:

- Regulation 852/2004/EC of the European Parliament and Council “on the hygiene of foodstuffs;”<sup>21</sup>
- Regulation 853/2004/EC of the European Parliament and Council “laying down specific hygiene rules for food of animal origin;”<sup>22</sup>
- Regulation 854/2004/EC of European Parliament and Council “laying down specific rules for the organi[z]ation of official controls on products of animal origin intended for human consumption;”<sup>23</sup> 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 rules.”<sup>24</sup>

---

17. Council Directive 95/69, 1995 O.J. (L 332) 15-32 (EC).

18. Directive 95/69, arts. 4 & 5, at 15-32.

19. Council Regulation 183/2005, arts. 4 & 5, at 5-6.

20. Regulation 183/2005, art. 6, at 6.

21. Council Regulation 852/2004, 2004 O.J. (L 139) 1 (EC).

22. Council Regulation 853/2004, 2004 O.J. (L 139) 55 (EC).

23. Council Regulation 854/2004, 2004 O.J. (L 139) 206 (EC).

24. Council Regulation 882/2004, 2004 O.J. (L 165) 1 (EC).

### *C. Food Contaminants*

On January 28, 2005, the European Commission published Regulation 123/2005/EC “amending Regulation 466/2001/EC as regards ochratoxin A.”<sup>25</sup> According to Regulation 466/2001/EC,<sup>26</sup> the provisions regarding ochratoxin A were to be reviewed to take into account the presence of such contaminant in some foodstuffs<sup>27</sup> (such as cereals, wine, roasted coffee, etc.).<sup>28</sup> On January 26, 2005, Directive 2005/5/EC was published “amending Directive 2002/26/EC as regards sampling methods and methods of analysis for the official control of the levels of ochratoxin A in certain foodstuffs.”<sup>29</sup>

On February 8, 2005, the European Commission published Regulation 208/2005/EC of February 4, 2005 “amending Regulation 466/2001/EC as regards polycyclic aromatic hydrocarbons.”<sup>30</sup> This regulation went into effect for all Member States on April 1, 2005.<sup>31</sup>

In its December 4, 2002 opinion, the Scientific Committee on Food reached the conclusion that some polycyclic aromatic hydrocarbons (PAH) are genotoxic carcinogens.<sup>32</sup> To prevent PAH contamination of foods, maximum levels for benzo(a)pyrene have been set in Regulation 208/2005/EC.<sup>33</sup> The European Commission also published Directive 2005/10/EC “laying down the sampling methods and the methods of analysis for the official control of the levels of benzo(a)pyrene in foodstuffs.”<sup>34</sup> In addition, on February 8, 2005, the Commission published Recommendation

---

25. Commission Regulation 123/2005, 2005 O.J. (L 25) 3 (EC).

26. Regulation 466/2001 set maximum levels for contamination in foodstuffs. See Regulation 466/2001, 2001 O.J. (L 77) 1 (EC).

27. Commission Regulation 123/2005, 2005 O.J. (L 25) at 3-5.

28. Regulation 466/2001, ann. I, at 6.

29. Commission Directive 2005/5, 2005 O.J. (L 27) 38-40 (EC).

30. Commission Regulation 208/2005, 2005 O.J. (L 34) 3 (EC).

31. Regulation 208/2005, art. 2, at 4.

32. Regulation 208/2005, whereas 3, at 3.

33. Regulation 208/2005, whereas 6, at 3.

34. Commission Directive 2005/10, 2005 O.J. (L 34) 15-20 (EC).

2005/108/EC “on the further investigation into levels of polycyclic aromatic hydrocarbons in certain foods.”<sup>35</sup>

#### *D. Feed Contaminants*

On January 29, 2005, in order to have analytical results reported and interpreted in a uniform way, the Commission published Directive 2005/7/EC “amending Directive 2002/70/EC establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs.”<sup>36</sup> On the same date, the Commission also published Directive 2005/8/EC of January 28, 2005 “amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed.”<sup>37</sup>

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

On March 5, 2005, the European Commission published Decision 2005/174/EC “establishing guidance notes supplementing part B of Annex II to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.”<sup>38</sup> This decision provides guidance to Member States for assessing the safety of the contained use of genetically modified micro-organisms.

On April 21, 2005, the Commission published Decision 2005/317/EC “on emergency measures regarding the non-authori[z]ed genetically modified organism Bt10 in maize products.”<sup>39</sup> This decision imposed controls on imports of genetically modified corn gluten feed and brewers grain from the United States.<sup>40</sup> Such controls were imposed after the unauthorized Bt10 maize had been accidentally found in some batches.<sup>41</sup>

---

35. Commission Recommendation 2005/108, 2005 O.J. (L 34) 43-45 (EC).

36. Commission Directive 2005/7, whereas 3, 2005 O.J. (L 27) 41 (EC).

37. Commission Directive 2005/8, 2005 O.J. (L 27) 44-45 (EC).

38. Commission Decision 2005/174, 2005 O.J. (L 59) 20-26 (EC).

39. Commission Decision 2005/317, 2005 O.J. (L 101) 14-16 (EC).

40. Decision 2005/317, art. 1, at 15.

41. Decision 2005/317, whereas 2, at 14.

## II. PENDING DRAFT REGULATIONS

### A. Hygiene: Draft Community Guidance on HACCP Flexibility and Draft Regulation on HACCP

Article 5 of Regulation 852/2004/EC<sup>42</sup> “on the hygiene of foodstuffs” was amended requiring food business operators to implement and to maintain a permanent procedure based upon HACCP principles.<sup>43</sup> The concept allows HACCP principles to be implemented with appropriate flexibility.

On May 25, 2005, the European Commission issued an updated Draft Guidance document “on the implementation of HACCP as mentioned in Article 5 of Regulation 852/2004/EC on the hygiene of foodstuffs.”<sup>44</sup> The aim of the Draft Guidance is to offer assistance on the flexible application of the HACCP principles in order to ensure a harmonized approach in all Member States.<sup>45</sup>

On May 25, 2005, the Commission also reissued an updated version of the Draft Guidance document on the implementation of HACCP principles in food businesses.<sup>46</sup> It has yet to be decided whether these documents will be finalized in the form of a guidance document or a Commission decision. During a June 2005 meeting of the Standing Committee on the Food Chain and Animal Health, the Commission agreed, upon the advice offered from some delegations, to merge both documents into a single one.<sup>47</sup> Member States expressed their general satisfaction with the drafts and were asked to send any further comments as soon as possible.<sup>48</sup> The Commission is planning to have this document finalized before the end of 2005.<sup>49</sup>

---

42. Council Regulation 852/2004, art. 5, 2004 O.J. (L 139) 1, 15 (EC).

43. Council Regulation 854/2004, 2004 O.J. (L226) 83, 87 (EC).

44. SANCO/1515/2005, *Draft Guidance Document on the Facilitation and of the Implementation of the HACCP Principles in Food Businesses*, at 4, available at <http://www.food.gov.uk/multimedia/pdfs/sanco15152005.pdf>.

45. *Id.*

46. SANCO/2655/2004 Rev. 7, *Draft Guidance Document on the Implementation of HACCP as Mentioned in Article 5 of Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs*, available at <http://www.food.gov.uk/multimedia/pdfs/sanco26552004rev7.pdf>.

47. SANCO-E.2(05)D/521175, *Summary Record of the Standing Committee on the Food Chain and Animal Health Held in Brussels on 21-22 June 2005*, at 6-7, available at [http://europa.eu.int/comm/food/committees/regulatory/scfcah/controls\\_imports/summary44\\_en.pdf](http://europa.eu.int/comm/food/committees/regulatory/scfcah/controls_imports/summary44_en.pdf).

48. *See id.*

49. *See id.*

## *B. Labeling: Health Claims*

On June 3, 2005, European Union (E.U.) Health Ministers reached a political agreement on the proposal for regulation on the use of nutrition and health claims made on foods.<sup>50</sup> On May 26, 2005, the European Parliament held its first reading vote on the Commission's proposal and recommended several amendments.<sup>51</sup> The Commission accepted a number of these amendments but rejected the deletion of Article 4 on nutrient profiles. The article related to the amounts of fat, sugar, and salt a food may or may not contain in order to be allowed to bear health-related claims. The Commission also rejected the amendments replacing the authorization procedure for health claims with a notification procedure.<sup>52</sup> In June 2005, the Health Council accepted Article 4 as drafted by the Commission as well as the authorization procedure.<sup>53</sup>

A common position is expected to be published by the Council in the coming months. The Health Claims Regulation will then undergo a second reading by the European Parliament and Council. A common regulation is expected to eventually be adopted in early 2006.

## *C. Addition of Vitamins and Minerals and of Certain Other Substances to Foods (So-called Fortification)*

As of today, national rules in the E.U. vary widely concerning addition of vitamins or minerals to foodstuffs. In November 2003, the European Commission issued a "proposal for regulation of the addition of vitamins, minerals and other substances to foods."<sup>54</sup> The aim of the proposed regulation was to regulate the voluntary addition of vitamins and minerals to foods in order to promote the free circulation of such foods in the E.U. while providing a high level of protection for consumers. The proposed regulation included positive lists of vitamins and minerals which may be added to food. It

---

50. Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods, COM (2003) 424 final, *available at* [http://europa.eu.int/comm/food/fs/fl/fl07\\_en.pdf](http://europa.eu.int/comm/food/fs/fl/fl07_en.pdf).

51. See Press Release, European Commission, Commissioner Kyprianou Welcomes Council Agreement on Health Claims (June 3, 2005), *available at* <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/668&format=HTML&aged=0&language=EN&guiLanguage=en>.

52. See *id.*

53. See *id.*

54. Proposal for a Regulation of the European Parliament and of the Council on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods, COM (2003) 671 final, *available at* [http://europa.eu.int/comm/food/food/labellingnutrition/vitamins/df\\_ff\\_reg1\\_en.pdf](http://europa.eu.int/comm/food/food/labellingnutrition/vitamins/df_ff_reg1_en.pdf).

also recommended daily intakes of specific substances. The proposed regulation provided a basis for restricting or prohibiting the addition of other substances to food.<sup>55</sup>

At the end of May 2005, the European Parliament welcomed the proposed regulation in its first reading. The proposed regulation is to be adopted jointly by the European Parliament and the Council of Ministers under the co-decision procedure.<sup>56</sup> The Council has considered the amendments offered by the Parliament but some areas of disagreement exist between the two institutions.

Even though the Council reached a political agreement on the proposed regulation and agreed to the content of its common position, the Council is not expected to send the latter back to the Parliament for a second reading until at least the end of 2005 due to legal and linguistic editing of the text. Once the Parliament receives the Council's common position, it will have three months to either approve the Council's common position and adopt the regulation or forward further amendments to the proposal to the Council and the Commission.<sup>57</sup>

#### *D. Draft Proposals for New E.U. Regulation on Food Additives and Enzymes*

Following the meeting of the European Commission's Working Group on Food Additives held at the end of February 2005, the European Commission issued a revised version of a draft proposal for a Regulation on food additives authorized for use in foodstuffs intended for human consumption.<sup>58</sup> The Working Group also issued a draft proposal for a new regulation on enzymes used or intended for use in foods.<sup>59</sup>

---

55. See Press Release, European Commission, Commission Proposes Common Rules for Adding Vitamins and Minerals to Foods (Nov. 10, 2003), *available at* <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/1516&format=HTML&aged=0&language=EN&guiLanguage=en>.

56. See *id.*

57. See *EU Decision-making*, *available at* <http://www.ecosa.org/csi/ecosa2003.nsf/asw/EU%20info-European%20Community-EU%20Decision-making>.

58. See Food Law News, *Additives—Draft Proposals for New EU Regulations on Food Additives and Enzymes*, Mar. 11, 2005, *available at* <http://www.foodlaw.rdg.ac.uk/news/eu-05021.htm> [hereinafter *Additive and Enzyme Proposals*].

59. See *id.*

The Commission's first proposal on food additives aimed to provide for a single E.U. regulation intended to replace Council Directive 89/107/EEC<sup>60</sup> of the Council "on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption" (the food additives framework Directive).<sup>61</sup> The hope was that this single regulation would eventually replace and repeal European Parliament and Council Directive 95/2/EC<sup>62</sup> "on food additives other than [colors] and sweeteners," European Parliament and Council Directive 94/35/EC "on sweeteners for use in foodstuffs,"<sup>63</sup> and European Parliament and Council Directive 94/36/EC "on [colors] for use in foodstuffs."<sup>64</sup>

The Commission's second proposal on food enzymes consisted of an E.U. regulation to control uses of enzymes in foods. Currently, some enzymes used as additives are regulated under Directive 95/2/EC,<sup>65</sup> whereas controls on other enzymes used as processing aids are not harmonized across the E.U. but rather are subject to different national measures in each Member State.<sup>66</sup> The Commission's proposal would harmonize the regulation of enzymes at the Community level. The new regulation on food enzymes would require dossiers of safety and technical information on each enzyme prior to their approval on the market.<sup>67</sup> Furthermore, it would call for enzymes to go through a reauthorization process every ten years<sup>68</sup>—a rule which is likely to be imposed on additives. According to the Commission, the two proposals on food additives and food enzymes, which are only working documents as of today, are expected to be formally published before the end of 2005.<sup>69</sup>

---

60. Council Directive 89/107, 1989 O.J. (L 40) 27-33 (EEC).

61. See Additive and Enzyme Proposals, *supra* note 58.

62. Council Directive 95/2, 1995 O.J. (L 61) 1 (EC).

63. Council Directive 94/35, 1994 O.J. (L 237) 3 (EC).

64. Council Directive 94/36, 1994 O.J. (L 237) 13 (EC).

65. Council Directive 95/2, 1995 O.J. (L 61) 1 (EC).

66. See Additive and Enzyme Proposals, *supra* note 58.

67. See *id.*

68. See *id.*

69. *Id.*

### *E. Proposal on Food Flavorings*

As of today, the E.U. does not have a positive list for flavoring substances. Instead, a register exists of more than 2,500 substances.<sup>70</sup> According to European Parliament and Council Regulation 2232/96/EC “laying down a Community procedure for [flavoring] substances used or intended for use in or on foodstuffs,”<sup>71</sup> all substances listed in the register of flavoring substances are required to undergo a safety evaluation. Once this procedure is completed, a positive list of flavoring substances authorized for use on or in foods in the E.U. is to be adopted.<sup>72</sup>

In February 2005, the European Food Safety Authority (EFSA) adopted three additional opinions regarding flavoring group evaluations.<sup>73</sup> It had already published two opinions in November 2004.<sup>74</sup> Initially, the positive list of flavoring substances was due for completion in July 2005. According to the latest estimates of the Commission, however, the evaluation process will not be completed and a positive list adopted until July 2007.<sup>75</sup>

---

70. Beveragedaily.com, *Health Risk for Flavour List Needs New Data, says EFSA Panel*, Aug. 7, 2005, at <http://www.beveragedaily.com/news/ng.asp?n=61173-flavours-positive-list> (last visited Jan. 3, 2006).

71. Council Regulation 2232/96, 1996 O.J. (L 299) 1.

72. Regulation 2232/96, art. 5, at 3.

73. EFSA, *Opinion of the Scientific on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a Request from the Commission Related to Flavouring Group Evaluation 7 (FGE.07)*, 164 E.F.S.A. J. 1-63 (2004), available at [http://www.efsa.eu.int/science/afc/afc\\_opinions/813/afc\\_opinionflav\\_ej164final\\_en1.pdf](http://www.efsa.eu.int/science/afc/afc_opinions/813/afc_opinionflav_ej164final_en1.pdf); EFSA, *Opinion of the Scientific on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a Request from the Commission Related to Flavouring Group Evaluation 9 (FGE.09)*, 165 E.F.S.A. J. 1-51 (2004), available at [http://www.efsa.eu.int/science/afc/afc\\_opinions/814/afc\\_opinionflav\\_ej165\\_en1.pdf](http://www.efsa.eu.int/science/afc/afc_opinions/814/afc_opinionflav_ej165_en1.pdf); EFSA, *Opinion of the Scientific on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a Request from the Commission Related to Flavouring Group Evaluation 11 (FGE.11)*, 166 E.F.S.A. J. 1-44 (2004), available at [http://www.efsa.eu.int/science/afc/afc\\_opinions/815/afc\\_opinionflav\\_ej166\\_en1.pdf](http://www.efsa.eu.int/science/afc/afc_opinions/815/afc_opinionflav_ej166_en1.pdf).

74. EFSA, *Opinion of the Scientific 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/671/afc\\_opinion18\\_ej107\\_flavourings\\_group3\\_en1.pdf](http://www.efsa.eu.int/science/afc/afc_opinions/671/afc_opinion18_ej107_flavourings_group3_en1.pdf); EFSA, *Opinion of the Scientific on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a Request from the Commission Related to Flavouring Group Evaluation 6 (FGE.06)*, 108 E.F.S.A. J. 1-69 (2004), available at [http://www.efsa.eu.int/science/afc/afc\\_opinions/672/afc\\_opinion19\\_ej108\\_flavourings\\_group6\\_en1.pdf](http://www.efsa.eu.int/science/afc/afc_opinions/672/afc_opinion19_ej108_flavourings_group6_en1.pdf).

75. See Food Law News, FSA Letter, *FLAVOURINGS—Commission Working Group on Flavourings—1st March 2005*, Mar. 14, 2005, available at <http://www.Foodlaw.rdg.ac.uk/news/eu-05022.htm>.

As far as the reform is concerned stemming from Council Directive 88/388/EEC “on the approximation of the laws of the Member States relating to [flavorings] for use in foodstuffs and to source materials for their production,”<sup>76</sup> no major event happened during the first half of 2005. The Commission Working Group only met to discuss the draft document of July 2004.

*F. Proposal for a Recast Commission Directive on Infant Formulae and Follow-on Formulae*

On February 2005, the Commission’s Directorate General for Health and Consumer Affairs made available a recast version of a working document for a proposal for the amendment of Commission Directive 91/321/EEC<sup>77</sup> on infant formulae and follow-on formulae called the “Working Draft Commission Directive .././EC of [...] on infant formulae and follow-on formulae.”<sup>78</sup> A first working document had already been circulated in April 2004. The changes proposed in the new document took into account the discussions at the international level within the Codex Alimentarius as well as the latest scientific advice on the essential composition of infant formulae and follow-on formulae.

---

76. Council Directive 88/388, 1988 O.J. (L 184) 61 (EEC).

77. Commission Directive 91/321, 1991 O.J. (L 175) 35 (EEC).

78. SANCO D4/HL/mm/D440180 Rev.2, *Working Document Draft Commission Directive .././EC of [...] on Infant Formulae and Follow-on Formulae*, available at [http://europa.eu.int/comm/food/consultations/working\\_doc\\_draft\\_en.pdf](http://europa.eu.int/comm/food/consultations/working_doc_draft_en.pdf).

### III. CASE LAW

#### A. Judgments Issued

##### 1. Definitions of Foods and Medicines

Following the submission of request for a preliminary ruling on June 9, 2005,<sup>79</sup> the European Court of Justice (ECJ) delivered its judgment on several cases addressing the issue of classification of products as foodstuffs or medicinal products for the purposes of being marketed in Germany. The classification of products sold in the Netherlands as food supplements (consequently as foodstuffs) was at stake in these cases.

Pursuant to German food law, the Dutch companies that were considering selling their products in Germany tried without success to obtain from the national authorities a general application approving the marketing of their product in their country.<sup>80</sup> One of the reasons the German authorities refused to approve marketing was because the products were medicines and not foodstuffs. Consequently, the Dutch companies have decided to bring an action against the German authorities.<sup>81</sup>

Among the main questions covered in this judgment, the ECJ confirmed<sup>82</sup> its earlier jurisprudence regarding the classification of products; however, such confirmation offered little or no additional guidance. The ECJ first confirmed that only the provisions of Community law specific to medicinal products apply to a product which satisfies both the conditions for classification as a foodstuff and the conditions for classification as a medicinal product.<sup>83</sup>

---

79. Joined Cases C-211/03, C-299/03, and C-316/03 – C-318/03, HLH Warenvertriebs GmbH v. Federal Republic of Germany, *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-211%2F03&datefs=&date&datefe=&nomusuel=&domaine=&mots=&resmax=100>

80. *Id.*

81. *Id.*

82. Case C-227/82, Van Bennekom, 1983 E.C.R. 3883 (1983).

83. Joined Cases C-211/03, C-299/03, and C-316/03 – C-318/03, HLH Warenvertriebs GmbH v. Federal Republic of Germany, *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-211%2F03&datefs=&date&datefe=&nomusuel=&domaine=&mots=&resmax=100>

The ECJ also confirmed<sup>84</sup> that it is up to the Member States to determine the status of the product on a case-by-case basis and that the pharmacological properties of a product are the factor upon which the authorities of a Member State must ascertain whether it, for the purposes of Directive 2001/83/EC, may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.<sup>85</sup> The ECJ held that the health risk a product possesses is an autonomous factor that must also be taken into consideration when classifying the product as medicinal.<sup>86</sup> In its judgment, the ECJ also admitted that differences between Member States may still exist in the classification of products as medicinal products or as foodstuffs.<sup>87</sup>

Another important point is the ECJ's confirmation of the fundamental principle of free movement of goods.<sup>88</sup> To the extent that Directive 2001/83/EC harmonizes the procedures for the production, distribution, and use of medicinal products, the ECJ held that Member States are no longer allowed to adopt national measures which restrict the free movement of goods on the basis of Article 30, in particular on grounds of the protection of human health.<sup>89</sup>

Finally, with respect to the powers of EFSA, the ECJ held that a national court cannot refer questions on the classification of products to EFSA.<sup>90</sup> However, an opinion delivered by EFSA may constitute evidence that that court should take into consideration in the context of that dispute.<sup>91</sup>

---

84. *Id.*

85. Council Directive 2001/83, art. 1(2), 2001 O.J. (L 311) 67, 71 (EC); Joined Cases C-211/03, C-299/03, and C-316/03 – C-318/03, *HLH Warenvertriebs GmbH v. Federal Republic of Germany*, 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-211%2F03&datefs=&date&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

86. Joined Cases C-211/03, C-299/03, and C-316/03 – C-318/03, *HLH Warenvertriebs GmbH v. Federal Republic of Germany*, 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-211%2F03&datefs=&date&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

## 2. Use of Name “Tocai” for Certain Italian Wines

“Tocai” is a vine variety which is traditionally grown in the Italian region of Friuli-Venezia Giulia.<sup>92</sup> In 1993, the European Community and Hungary signed an agreement on the reciprocal protection and control of the names of wines. In order to protect the Hungarian geographical indication “Tokaj,” the parties agreed to prohibit the use of the name “Tocai” until March 31, 2007.<sup>93</sup> The applicants sought to annul the Italian law that implemented the agreement.

In its judgment of May 12, 2005,<sup>94</sup> the ECJ noted that as opposed to “Tokaj,” “Tokai” did not constitute a geographical indication within the meaning of the EC-Hungary Agreement on wines. Because it does not exclude any reasonable method of marketing Italian wines, the ECJ also held that the prohibition does not constitute a deprivation of possession for the purposes of the European Convention on Human Rights.<sup>95</sup> The ECJ reached the conclusion that the prohibition of the use of the name “Tocai” in Italy was valid.<sup>96</sup>

### *B. Adventitious Presence of GMOs in Infant Foods*

Pursuant to Council Regulation 1139/98/EC “concerning the compulsory indication on the [labeling] of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC,”<sup>97</sup> all genetically modified food must be labeled to show

---

91. Joined Cases C-211/03, C-299/03, and C-316/03 – C-318/03, HLH Warenvertriebs GmbH v. Federal Republic of Germany, *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-211%2F03&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

92. See Tom Cannavan, *The Wines of Villa Russiz, Friuli*, May 2005, *at* <http://www.wine-pages.com/organise/russiz.htm> (last visited Jan. 15, 2006).

93. The Budapest Sun Online, *Tocai Appeal Rejected*, Apr. 4, 2005, *at* [http://www.budapestsun.com/full\\_story.asp?ArticleID=%7B625254FEC03F4878A333A988418A50C3%7D&From=Business](http://www.budapestsun.com/full_story.asp?ArticleID=%7B625254FEC03F4878A333A988418A50C3%7D&From=Business) (last visited Jan. 15, 2006).

94. Case C-347/03, Regione Autonoma Friuli-Venezia Giulia and ERSA v. Ministero delle Politiche Agricole e Forestali, *available at* [http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c\\_182/c\\_18220050723en00080009.pdf](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_182/c_18220050723en00080009.pdf).

95. *Id.*

96. *Id.*

97. Council Regulation 1139/98, 1998 O.J. (L 159) 4. This Regulation is now repealed and replaced by Council Regulation 1829/2003/EC of September 22, 2003 “on genetically modified food and feed.” Council Regulation 1829/2003, 2003 O.J. (L 268) 1, 19.

that it contains or was produced from GMOs. An exemption from this labeling requirement exists with respect for the adventitious or technically unavoidable presence up to a limit of one percent (now 0.9%).<sup>98</sup>

Before the National Administrative Court, an Italian consumer association successfully challenged the one percent labeling exemption prescribed by Italian legislation to infant formulae.<sup>99</sup> Upon appeal by the Italian Ministry of Public Health, the question was referred to the ECJ.<sup>100</sup> In its judgment of May 26, 2005, the ECJ ruled that the labeling exemption for one percent (now 0.9%) applied to all foods, including infant formulae, and could not be called into question on the basis of the precautionary principle.<sup>101</sup>

### *C. Conclusions of Advocate General*

#### 1. Registration of the Name “Feta” as a Protected Designation of Origin

On May 10, 2005, Advocate General Ruiz Jarabo delivered his opinion<sup>102</sup> in two cases pertaining to the name “Feta”<sup>103</sup> in reference to cheese. He proposed that the ECJ should dismiss the actions brought both by Germany and Denmark against the registration of the name “Feta” as a Protected Designation of Origin (PDO). In his view, “Feta” meets the requirements of a PDO because it describes a cheese originating from a substantial part of Greece whose characteristics are derived

---

98. Regulation 1829/2003, art. 12(2), at 11.

99. See Philip Bentley, *Key Developments—Consumer Protection: Trade in Genetically Modified Agricultural Commodities*, June 3, 2005, at 2, available at <http://www.mwe.com/info/news/bb060305.pdf>.

100. *Id.*

101. Case C-132/03, *Ministero della Salute v. Coordinamento delle associazioni per la difesa dell’ambiente e dei diritti degli utenti e dei consumatori (Codacons), Federconsumatori*, available at [http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c\\_271/c\\_27120051029en00020003.pdf](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_271/c_27120051029en00020003.pdf).

102. *Joined Cases C-465/02, Federal Republic of Germany v. Commission of the European Communities; and Case C-466/02, Kingdom of Denmark v. Commission of the European Communities*, available at [http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c\\_055/c\\_05520030308en00110011.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_055/c_05520030308en00110011.pdf).

103. *Joined Cases C-465/02, Federal Republic of Germany v. Commission of the European Communities; and Case C-466/02, Kingdom of Denmark v. Commission of the European Communities*, available at [http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c\\_055/c\\_05520030308en00110011.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_055/c_05520030308en00110011.pdf).

from its geographical environment and its production, processing, and preparation are carried out in a geographically defined area.<sup>104</sup>

By Commission Regulation 1829/2002/EC “amending the Annex to Regulation 1107/96 with regard to the name ‘Feta,’” the word “feta” was inserted in the list of PDOs.<sup>105</sup> In his opinion, the Advocate General considers the name “Feta” not to be generic because it is associated with a specific foodstuff.<sup>106</sup> Yet, the Advocate General reached the conclusion that the word “Feta” meets the requirements to be regarded as a traditional name, which can be assimilated to a designation of origin, and, therefore deserves protection throughout the E.U.<sup>107</sup>

## 2. Labeling Requirements for Animal Feed

On April 7, 2005, Advocate General Antonio Tizzano delivered his opinion in several cases<sup>108</sup> addressing the validity and interpretation of the European Parliament and of Council Directive 2002/2/EC.<sup>109</sup> Directive 2002/2/EC was adopted with a view to provide adequate safeguards for public health in the event of food-related crises.<sup>110</sup> The Directive was prompted due to the fact that the former

---

104. Joined Cases C-465/02, Federal Republic of Germany v. Commission of the European Communities; and Case C-466/02, Kingdom of Denmark v. Commission of the European Communities, *available at* [http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c\\_055/c\\_05520030308en00110011.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_055/c_05520030308en00110011.pdf).

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

106. The Advocate General considers “Feta” to refer to cheese produced in a large area of Greece using sheep’s milk or a mixture of sheep’s milk and goat’s milk, formed by the natural and artisan process of coagulation at normal pressure. See Joined Cases C-465/02, Federal Republic of Germany v. Commission of the European Communities; and Case C-466/02, Kingdom of Denmark v. Commission of the European Communities, *available at* [http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c\\_055/c\\_05520030308en00110011.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_055/c_05520030308en00110011.pdf).

107. Joined Cases C-465/02, Federal Republic of Germany v. Commission of the European Communities; and Case C-466/02, Kingdom of Denmark v. Commission of the European Communities, *available at* [http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c\\_055/c\\_05520030308en00110011.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/c_055/c_05520030308en00110011.pdf).

108. Joined Cases C-453/03, The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency; Case C-11/04, Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others; Case C-12/04, Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others; and Case C-194/04, Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder, *available at* <http://curia.eu.int/jurispl/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

109. Council Directive 2002/2, 2002 O.J. (L 63) 23 (EC).

110. See Directive 2002/2, whereas 8, at 23.

system had proven to be inadequate for addressing the crises of bovine spongiform encephalopathy (BSE).<sup>111</sup>

Several manufacturers of feedingstuffs in the United Kingdom, Italy, and the Netherlands have brought proceedings before the national courts challenging the domestic regulations implementing Directive 2002/2/EC. In particular, the feed companies have challenged two new stringent obligations imposed upon them by Directive 2002/2/EC: (i) the obligation to provide detailed, quantitative information by weight of the feed materials used in the feedingstuffs on packaging with a margin of tolerance of fifteen percent (Article 1(4)); and (ii) the obligation to provide, at the request of customers, the exact percentages by weight of the ingredients used in the products (Article 1(1)(b)).<sup>112</sup> The national courts of those three Member States asked the ECJ to determine whether Article 1(4) and Article 1(1)(b) had been adopted on an incorrect legal basis and to ascertain whether those two obligations were compatible with the principle of proportionality, the fundamental right to property, the precautionary principle, the principle of non-discrimination, and the principle of the freedom to pursue a trade or profession.<sup>113</sup>

In his opinion, the Advocate General began by stressing the importance of public health within the Community system and the priority to which public health must be given over economic and commercial interests.<sup>114</sup> He also added that within an area such as common agricultural policy, the

---

111. Directive 2002/2, whereas 4, at 23.

112. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

113. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

114. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, available at <http://curia.eu.int/>

Community legislature enjoys broad discretion, and review by the ECJ must be limited to determining whether there are manifest defects.<sup>115</sup>

With respect to the validity of Article 1(4) and Article 1(1)(b) of Directive 2002/2/EC, the Advocate General stated that the first obligation of providing quantitative information in labeling is legitimate as it is necessary and adequate for safeguarding public health. Whereas traceability of feedingstuffs is guaranteed primarily by the indication of batch number on the packaging, the Advocate General opined that the quantitative information enables stock farmers and the authorities to speed up the traceability of a contaminated substance and makes it possible to take appropriate measures.<sup>116</sup> On the other hand, according to the Advocate General, the obligation to inform customers upon their request of exact quantities goes beyond what is required for safeguarding public health and is manifestly disproportionate. As a result, he proposed that the court should hold the second obligation invalid.<sup>117</sup>

---

[jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100](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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100).

115. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

116. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

117. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

The Advocate General also gave his opinion regarding two questions regarding the interpretation of Directive 2002/2/EC.<sup>118</sup> He first reached the conclusion that the obligation to indicate the feed materials used by their specific names is not conditioned upon a “positive list” of feed materials used in compound animal feedingstuffs. He stated that it should be left to the Member States to adopt the necessary measures for them to comply with the obligations set out in Directive 2002/2/EC.<sup>119</sup>

Finally, the Advocate General stated that administrative authorities of a Member State do not have the power to suspend the implementation of internal measures giving effect to Community provisions of disputed validity. Even in the case where a court of another Member State has already requested that the ECJ deliver a ruling on the validity of those provisions, authorities should not have such suspension powers. In the case of an administrative authority, there is no requirement to guarantee the coherence of the Community judicial system.<sup>120</sup>

In addition to the above-mentioned cases before the Court of Justice, a case is pending before the European First Court of Instance. The action was brought on September 8, 2003 by Juckem

---

118. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

119. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

120. Joined Cases C-453/03, *The Queen, on the application of ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; Case C-11/04, *Fratelli Martini & C. spa and Cargill srl v. Ministero delle Politiche Agricole e Forestali and Others*; Case C-12/04, *Ferrari Mangimi srl and Associazione nazionale tra i produttori di alimenti zootecnici v. Ministero delle Politiche Agricole e Forestali and Others*; and Case C-194/04, *Nederlandse Vereniging Diervoederindustrie Nevedi v. Produktschap Diervoeder*, 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-194%2F04&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

GmbH and Others against European Parliament and Council of the E.U.<sup>121</sup> The applicants claim compensation for the damage supposedly caused by Directive 2002/2/EC.

#### *D. Pending Cases*

On March 18, 2005, the European Commission decided to bring an action against Germany before the ECJ on two grounds. First, the Commission brought action regarding the consistent treatment of garlic preparations, such as capsules containing pure dried garlic powder, as medicines, even though they are lawfully marketed as foodstuffs in other Member States.<sup>122</sup> Secondly, action was brought over Germany's requirement that hospitals can only be supplied with medicines by pharmacies in the same city or district.<sup>123</sup>

Regarding the first issue, the Commission is of the opinion that the German practice constitutes a disproportionate and unnecessary obstacle to the free movement of goods and is therefore prohibited under Articles 28 and 30 of the EC Treaty.<sup>124</sup> Moreover, the German position seems to demonstrate an insufficient understanding of the distinction between food supplements and medicinal products in the context of current European legislation.

### IV. OTHER RELEVANT NEWS

#### *A. Regulations Entered Into Application*

January 1, 2005 was the effective date for some of the key provisions of the European Parliament and Council Regulation 178/2002/EC "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."<sup>125</sup> The traceability requirement affords food companies the ability to completely trace the flow

---

121. Case T-321/03, Juckem GmbH and Others v. European Parliament and Council of the European Union, *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=T-321%2F03&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

122. Case C-319/05, Commission v. Federal Republic of Germany, *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-319%2F05&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

123. *Id.*

124. *Id.*

125. Council Regulation 178/2002, 2002 O.J. (L 31) 1 (EC).

of goods throughout all stages of production, processing, and distribution.<sup>126</sup> The requirement is one of the significant new requirements which came into force during the beginning of 2005.<sup>127</sup>

## *B. Unofficial Documents and Announcements*

### 1. Food and Health

On March 15, 2005, the European Commission launched an action group called the “Platform on Diet Physical Activity and Health” to fight obesity in the E.U.<sup>128</sup> This platform is comprised of representatives of European institutions as well as organizations from business, civil society, and the public sector. Members of this platform are expected to propose action plans in order to promote healthier diets and to encourage people to participate in more physical activities.

Several areas to be focused on include consumer information, marketing, and advertising on composition of foods, availability of healthy food options, portion sizes. Also, a Green Paper on the obesity issue is to be prepared by the European Commission probably before the end of 2005.<sup>129</sup> In 2006, the European Commission intends to prepare a communication.

---

126. Regulation 178/2002, art. 3(15), at 8.

127. The other provisions of Regulation 178/2002 came into force on 21 February 2002. Regulation 178/2002, art. 65, at 24.

128. See Press Release, European Commission, EU Platform for Action on Diet, Physical Activity and Health: Questions and Answers (Mar. 15, 2005), *available at* <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/91&format=HTML&aged=0&language=EN&guiLanguage=en>.

129. See Press Release, European Commission, Commission Launches Consultation on How to Promote Healthy Diets and Physical Activity (Dec. 8, 2005), *available at* <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1550&format=HTML&aged=0&language=en&guiLanguage=en>.

## 2. Hygiene

On June 29, 2005, the European Commission issued a useful guidance document on the new rules for hygiene of foodstuffs<sup>130</sup> (Regulation 852/2004/EC, Regulation 853/2004/EC and Regulation 854/2004/EC).<sup>131</sup>

## 3. Risk and Crises Management in Agriculture

On March 9, 2005, the European Commission has published a Communication on risk and crisis management in agriculture (Communication)<sup>132</sup> describing available crisis management tools to help farmers in the E.U. In this Communication, three options were presented to promote the development of crisis management tools at the E.U. level. Option 1 addresses the possibility of contributing to the payment of premiums to be paid by farmers, where they take insurance against natural disasters, extreme weather conditions or disease.<sup>133</sup> Option 2 encourages the development of mutual funds for agriculture by granting temporary and degressive support for the funds' administration.<sup>134</sup> Option 3 considers basic insurance coverage against income crises.<sup>135</sup> These crisis management options are to be assessed by the other European institutions.

## 4. General Food Law Guidelines

In March 2005, the European Commission published guidelines to facilitate the implementation of major requirements set in Regulation 178/2002/EC "laying down the general principles and

---

130. Directorate General of Health and Consumer Protection, *Guidance Document—Key Questions Related to Import Requirements and the New Rules on Food Hygiene and Official Food Controls*, available at [http://europa.eu.int/comm/food/international/trade/interpretation\\_imports.pdf](http://europa.eu.int/comm/food/international/trade/interpretation_imports.pdf).

131. Council Directive 852/2004, 2004 O.J. (L 139) 1 (EC); Directive 853/2004, 2004 O.J. (L 139) 55 (EC); Directive 854/2004, 2004 O.J. (L 155) 206.

132. Communication from Commission to the Council on Risk and Crisis Management in Agriculture, COM (2005) 74 final, available at [http://europa.eu.int/comm/agriculture/publi/communications/risk/com74\\_en.pdf](http://europa.eu.int/comm/agriculture/publi/communications/risk/com74_en.pdf).

133. *Id.* at 6-7.

134. *Id.* at 7-8.

135. *Id.* at 8. See Press Release, European Commission, Risk and Crisis Management in Agriculture: Commission Invites Council to Debate Options (Mar. 9, 2005), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/274&format=HTML&aged=0&language=EN&guiLanguage=en>.

requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.”<sup>136</sup> These guidelines were effective as of January 1, 2005.<sup>137</sup>

The specific requirements found in those guidelines included requirements applicable to imports and exports of food and feed products (Articles 11 and 12),<sup>138</sup> responsibilities of food and feed business operators (Article 17),<sup>139</sup> traceability of food and feed products (Article 18),<sup>140</sup> and withdrawal of unsafe food or feed products from the market and notification to the competent authorities (articles 19 and 20).<sup>141</sup> This guidance document was not considered authoritative as the ECJ remains the only body entitled to interpret the law.

## 5. European Food Safety Authority

In June 2005, EFSA, which was created by Regulation 178/2002/ EC primarily to conduct scientific risk assessment, moved to Parma, Italy.<sup>142</sup>

## 6. Standardization of Food Labels

In January 2005, the European Commission announced that it was considering reviewing the current E.U. legislation on food labeling to accomplish standardization of labeling across the E.U.<sup>143</sup> Currently, food labeling is regulated by Directive 2000/13/EC.<sup>144</sup> However, variations of this directive have been implemented by the Member States.

---

136. Council Regulation 178/2002, 2002 O.J. (L 31) 1 (EC).

137. Standing Committee on on the Food Chain and Animal Health, *Annotated EC Guidance on the Implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law*, 1-38, available at <http://www.food.gov.uk/multimedia/pdfs/gflreu1782002.pdf#page=1>.

138. *Id.* at 34-38.

139. *Id.* at 6-8.

140. *Id.* at 9-17.

141. *Id.* at 18-33.

142. See Press Release, EFSA, EFSA Today Inaugurates Its Official Seat in Parma (June 21, 2005), available at [http://www.efsa.eu.int/press\\_room/press\\_release/980/pr\\_inauguration\\_en1.pdf](http://www.efsa.eu.int/press_room/press_release/980/pr_inauguration_en1.pdf).

143. See Dairyreporter.com, *EU: Unified Version for Food Labels Across All States?*, Jan. 27, 2005, at <http://www.dairyreporter.com/news/ng.asp?id=57654-eu-unified-version> (last visited Jan. 15, 2006).

144. Council Directive 2000/13, 2000 O.J. (L 109) 29 (EC).