Journal of Food Law & Policy

Volume 6 | Number 2 Article 9

2010

European Union Food Law Update

Emilie H. Leibovitch

EUROPEAN UNION FOOD LAW UPDATE

*Emilie H. Leibovitch**

I. INTRODUCTION

This EU Food Law Update will focus on the recent developments in the areas of genetically modified organisms, novel foods, feed safety, transmissible spongiform encephalopathy, salmonella and food borne diseases, food additives, organic farming, food contact materials, and labeling.

II. GENETICALLY MODIFIED ORGANISMS

On July 13, 2010, the Commission issued a Communication proposing that Member States be able to allow, restrict, or ban the cultivation of genetically modified organisms in their entire territory or in part of their territory.[1] Up until now, Member States wanting to forbid the cultivation of GMOs could do so based on the safeguard clause of article 23 of Directive 2001/18/EC or based on the emergency measures laid out in article 34 of Regulation (EC) No 1829/2003. The European Food Safety Authority (EFSA), however, has not always deemed this ban scientifically justified. Because the Commission feels that the reasons for wanting to ban the cultivation of GMOs are diverse (e.g., national policies, biodiversity, nature conservation objectives, etc.), they should be taken into account. As a result, the Commission suggests that Member States should be able to set conditions under which GMO cultivation could be banned. These conditions would be in addition to those already set

* Emilie H. Leibovitch is a US-licensed attorney working on EU/US/international food law issues in her law firm in Brussels, Belgium. She also teaches American Civil Procedure and International Arbitration at the University of Metz, France.

1. *Commission Communication on the Freedom For Member States to Decide on the Cultivation of Genetically Modified Crops*, at 7, COM (2010) 380 final (July 13, 2010), *available at* http://ec.europa.eu/food/food/biotechnology/docs/communication_en.pdf.

at European level, and would have to respect the principles of non-discrimination between national and non-national products and of the free circulation of goods. The Commission submitted a proposal to the European Parliament and the Council, and discussions are thus now at their beginning stages.

On July 28, 2010, the European Commission issued six decisions authorizing the import of six genetically modified maize lines: two from Monsanto (MON88017xMON810, MON89034xNK603),[2] two from Pioneer (1507x59122, 59122x1507xNK603),[3] and two from Syngenta (Bt11xGA21, Bt11).[4] These six GMOs can be used as food, food ingredients, feed, and "products other than food and feed containing or consisting of [these maize lines] for the same uses as any other maize with the exception of cultivation."[5]

In May 2010, several environmental associations expressed an intention to file a complaint to the European Court of Justice against the European Commission over the latter's decision to authorize the genetically modified potato Amflora for cultivation in the European Union.[6] According to the associations, the Commission violated the Directive on the deliberate release into the environment of genetically modified organisms,[7] which prohibits to some extent the approval of genetically modified plants that contain antibiotic-resistance markers. The Commission had reached this decision following confirmation of EFSA's previous finding that "according to information currently available, adverse effects on human health and the environment resulting from the transfer of the two antibiotic resistance marker genes, nptII and aadA, from GM plants to bacteria, associated with use of GM plants, are unlikely."[8] In September 2010, Austria and Luxembourg indicated their intention to join the associations in the lawsuit.

---

2. Commission Decision 2010/429, 2010 O.J. (L 201) 46 (EU); Commission Decision 2010/420, 2010 O.J. (L 197) 15 (EU).

3. Commission Decision 2010/432, 2010 O.J. (L 202) 11 (EU); Commission Decision 2010/428, 2010 O.J. (L 201) 41 (EU).

4. Commission Decision 2010/426, 2010 O.J. (L 199) 36 (EU); Commission Decision 2010/419, 2010 O.J. (L 197) 11 (EU).

5. *See supra* notes 2-4.

6. Environmental Associations: Lawsuit Against Amflora in the European Court of Justice, GMO COMPASS (May 11, 2010), *available at* http://www.gmo-compass.org/eng/news/511.eu_environmental_associations_lawsuit_against_amflora.html.

7. Council and Parliament Directive 2001/18, 2001 O.J. (L 106) 1 (EC).

8. Press Release, European Food Safety Comm'n, EFSA Evaluates Antibiotic Resistance Marker Genes in GM Plants (June 11, 2009), *available at* http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902569389.htm.

III. NOVEL FOODS

Following the March issuance of the Council Common Position on the Commission Proposal for a Regulation on Novel Foods,[9] the Parliament's Environment, Public Health and Food Safety Committee had MEP Kartika Liotard (the Netherlands) prepare a draft report. The Council and the Parliament share the view that clones and their offspring should not be regulated by the Novel Foods Regulation, but the Council is afraid that not having them regulated in a legal text, such as the Novel Foods Regulation for now, would generate legal uncertainties. The Parliament vehemently opposes the inclusion of cloning in this Regulation because it sees this as opening the door to a sentiment of tolerance over cloning, which could in turn yield its future presence on the EU market. The Parliament would rather have a separate law on cloning, while the Council would prefer to include cloning in the Novel Foods Regulation and have the Commission issue a report on the matter within a year of the Regulation's adoption and make a legislative proposal should it be needed. In its Common Position, the Council agreed to include food from the first generation of clones' offspring in the definition of novel food; this means that these food products would be subject to the marketing authorization procedure prior to being placed on the market. It is worth noting that the Council and the Commission are not in total agreement either. The Commission does not agree with the Council's position because it opposes the inclusion of food from clones' offspring within the scope of the Novel Foods Regulation.[10] The current definition of novel food includes all foods derived from animals obtained by new reproductive techniques (such as cloning), but not the food derived from animals obtained by conventional reproductive techniques. The Commission thus does not see a proper justification for the inclusion of food from clones' offspring since they are obtained through conventional breeding tech-

9. Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, 11261/2/09 REV 2, 2008/0002 (COD), Mar. 5, 2010, *available at* http://register.consilium.europa.eu/pdf/en/09/st11/st11261-re02.en09.pdf.

10. *Commission Communication to the European Parliament concerning the position of the Council on the adoption of a Regulation of the European Parliament and of the Council on novels foods, amending Commission Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001*, COM (2010) 124 final (Mar. 24, 2010), *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0124:FIN:EN:PDF.

niques.[11] The Commission therefore suggests maintaining "the legal status quo for the food produced with new breeding techniques such as cloning and to prepare the foreseen report by the end of the year."[12]

With respect to nanotechnologies, the Parliament had requested a legal definition of nanomaterials and their mandatory labeling. The Council, in its Common Position, indicated that the labeling should be set on a case-by-case basis in the authorization decision, but included a definition of "engineered nanomaterials."

In July 2010, the Parliament adopted a position in Second Reading.[13] The Parliament wants to exclude foods derived from cloned animals and their offspring from the scope of the Regulation and wants the Commission to issue a legislative proposal on foods derived from cloned animals and their descendants within six months before the application of the Regulation. Given the incompatibility between the positions of the Parliament and the Council, the Novel Foods Regulation is now going to leave the process of co-decision and go through conciliation. The conciliation is a negotiation process in the form of a three-way discussion between representatives of the Council, representatives of the European Parliament, and the Commissioner of the unit responsible for the proposal. The participants then report to their group. With the Commission playing a role of mediator, the parties try to draft a compromise - also called a joint text - which then must be submitted to each branch for approval according to each branch's rules: the Council's delegation must approve the joint text by a qualified majority while the Parliament's delegation can approve the joint text only by a simple majority.[14] Parties must approve a joint text within six weeks of the first meeting of the Conciliation Committee, with a possibility to extend that time period to eight weeks.[15] Once the joint text is approved, the Parliament and the Council sign it, the text is published in the Official Journal, and the procedure ends. Should one of the

11. *Id.*

12. *Id.*

13. European Parliament legislative resolution of 7 July 2010 on the Council position at first reading for adopting a regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001, July 7, 2010, *available at* http://www.europarl.europa.eu/oeil/file.jsp?id=5583302.

14. Treaty on the Functioning of the European Union, May 9, 2008, 2008 O.J. (C 115) 47, 174-175.

15. *Id.*, art. 294(10) at 174.

institutions fail to give approval within the six- (or eight-) week time limit, the act is deemed not to have been adopted, and the procedure ends.[16]

IV. FEED SAFETY

In March 2010, Commission Regulation (EU) No 242/2010 creating the catalogue of feed materials was published.[17] This catalogue was requested by Article 24 of Regulation (EC) No 767/2009 on the placing on the market and the use of feed; feed producers are to list their feed materials in a common catalogue to provide information to feed users.[18] This Catalogue will then be updated regularly. In addition to that, article 24(6) provides that "[t]he person who, for the first time [as of September 1, 2010] places on the market a feed material that is not listed in the Catalogue shall immediately notify its use [in an Internet register set up and managed by the representatives of the European feed business sectors]."[19] This register was created on September 1, 2010.[20] This is meant to satisfy the transparency principle and to make the information on the composition of new feed materials readily available to customers.

V. TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

On July 16, 2010, the Commission published a Communication to the European Parliament and the Council on the TSE Road Map 2, which is a strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015.[21] This document follows the first TSE Road Map issued in 2005,[22] and identifies six areas where changes could be made with respect to the present TSE measures.[23]

---

16. *Id.*, art. 294(13)-(14) at 175.

17. Commission Regulation 242/2010, 2010 O.J. (L 77) 17 (EU).

18. Council Regulation 767/2009, art. 24, 2009 O.J. (L 229) 1, 13 (EC).

19. *Id.*, art. 24(6) at 14.

20. Press Release, European Feed Mfr. Fed'n, Information to Feed Material Suppliers (Aug. 31, 2010), *available at* http://www.fefac.org/file.pdf?FileID=30926.

21. *Commission Communication on the TSE Road Map 2: A Strategy Paper on Transmissible Spongiform Encephalopathies for 2010-2015*, COM (2010) 384 final (July 16, 2010), *available at* http://www.fsai.ie/uploadedfiles/legislation/FSAI_-_Legislation/2010/07_jul2010/EU_Communication_TSE.pdf.

22. *Commission Communication on the TSE Roadmap*, COM (2005) 322 final (July 15, 2005), *available at* http://ec.europa.eu/food/food/biosafety/tse_bse/dg_sanco_en.htm.

23. Press Release, Europa, Following Achievements of 1st Roadmap, Commission Outlines Future Steps Regarding BSE/TSE in the TSE Roadmap 2 (July 16,

The TSE Road Map 2 suggests that the European list of Specified Risk Materials be aligned with the international standards of the World Organization for Animal Health (Specified Risk Materials are tissues of ruminant animals that may contain BSE infectivity).[24] The document also recommends that a tolerance level of processed animal proteins be set. Processed animal proteins are defined as "animal proteins derived from animal by-products and which have been treated so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including pet food, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, colostrum, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and eggproducts, tricalcium phosphate and collagen."[25] Moreover, it calls for the removal of provisions that ban the use of certain processed animal proteins for non-ruminants (pigs, poultry and fish) without, however, removing the prohibition on intra-species recycling.[26] Other proposals are to increase the testing age limits to improve monitoring, and to make scrapie eradication measures in line with the latest scientific information (and thus adapt the measures if scientific data confirms the noncontagious character of atypical scrapie).[27] It also encourages the testing of live animals, should ante-mortem tests become available, and stopping the systematic cohort culling of cattle as long as they test BSE-negative before entering the food chain, since no animals have tested BSE-positive in 2009.

This document will serve as a basis for discussions for the Council, the Parliament and other stakeholders on how the EU should address TSE within the next five years. Potential proposals may emerge as a result of these discussions.

VI. SALMONELLA AND FOODBORNE DISEASES

On April 29, 2010, a Commission Regulation was published in the Official Journal.[28] Commission Regulation (EU) No 365/2010

2010), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/957&format=HTML&aged=0&language=EN&guiLanguage=en.

24. *See Commission Staff Working Document Accompanying the Communication from the Commission to the European Parliament and the Council on the TSE Roadmap 2*, SEC (2010) 899 final (July 16, 2010), *available at* http://ec.europa.eu/food/food/biosafety/tse_bse/docs/CSWD_Road_Map_TSE-DTS_en.pdf.

25. *Id.* at 5.

26. *Id.*

27. *Id.*

28. Commission Regulation 365/2010, 2010 O.J. (L 107) 9 (EU).

amends Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[29] with respect to enterobacteriaceae in pasteurized milk and other pasteurized liquid dairy products, and listeria monocytogenes in food grade salt. This regulation changes the analytical reference method for enterobacteriaceae in pasteurized milk and other pasteurized liquid dairy products, and food grade salt was added in the list of ready-to-eat foods for which it is not required to undertake regular testing for listeria.[30]

VII. FOOD ADDITIVES

In May 2010, the European Parliament vetoed the European Commission's proposal to authorize thrombin, also called "meat glue," as a food additive.[31] Members of the European Parliament were of the opinion that the larger surface area of meat and the cold bonding process that is used to reconstitute meat products create a risk of bacterial infection.[32] Currently, Member States can decide to authorize thrombin as a processing aid in food products. However, additives are regulated at an EU level and additives can only be used if they benefit consumers and do not mislead them.[33] Here, the Parliament felt that since thrombin permits separate pieces of meat to bind to produce a single meat product, the risk of misleading consumers was clear.[34] The Parliament was also not convinced by the prohibition against the use of thrombin in meat products served in restaurants or other public establishments serving food, saying that such a prohibition would still not prevent some establishments from using thrombin and thus did not provide adequate protection against the misleading of consumers.[35]

---

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

30. Commission Regulation 365/2010, *supra* note 26, at 12.

31. *See* Resolution of 19 May 2010 on the Draft Commission Directive Amending the Annexes to European Parliament and Council Directive 95/2/EC on Food Additives Other Than Colours and Sweeteners and Repealing Decision 2004/374/EC, EUR. PARL. DOC. P7_TA (2010) 0182 (2010), *available at* http://www.europarl.europa.eu/sides/getDoc.do? pubRef=-//EP//TEXT+TA+P7-TA-2010-0182+0+DOC+XML+V0//EN&language=EN [hereinafter EP Resolution on thrombin]; Press Release, European Parliament, MEPs Veto "meat glue" Authorisation (May 19, 2010), *available at* http://www.europarl.europa.eu/news/expert/infopress_page/067-74644-137-05-21-911-20100517IPR74643-17-05-2010-2010-false/default_en.htm.

32. *Id.*

33. *Id.*

34. EP Resolution on thrombin, *supra* note 31.

35. *Id.*

VIII. ORGANIC FARMING

On July 1, 2010, the obligation to display the new EU "Euroleaf" organic logo on prepackaged food produced within the European Union came into force.[36] When displayed on processed products, the logo certifies that at least 95% of the agricultural ingredients are organic.[37] The logo is accompanied with the code number of the control body and the place where the agricultural raw materials that compose the product were farmed.[38] For the place of farming, operators have a choice between "EU Agriculture" (for agricultural raw material farmed in the EU), "non-EU Agriculture" (for agricultural raw material farmed in third countries), and "EU/non-EU Agriculture" (for products where part of the agricultural raw materials has been farmed in the EU and part of it was farmed in a third country).[39] A two-year transition period was put in place.

On that same day, the new rules on organic aquaculture production of fish, shellfish and seaweed came into force.[40] The Regulation sets EU-wide criteria for production and stocking.[41] It specifically requires the separation of organic and non-organic production units.[42] Specific stocking densities are set for particular species. It also specifies that organic feed and fish meal coming from sustainable fisheries should be used for feeding purposes.[43] The countries that are the most active producers of foodstuffs coming from organic aquaculture are the UK, Ireland, Hungary, Greece and France.[44] The top species produced in such a way is salmon.[45]

---

36. *Logo and Labeling*, EUROPA.EU, http://ec.europa.eu/agriculture/organic/consumer-confidence/logo-labelling_en (last visited Sept. 29, 2010).

37. European Comm'n on Agric. and Rural Dev., Questions & Answers, ORGANICFARMING.EU (Mar. 30, 2010), *available at* http://ec.europa.eu/agriculture/organic/files/eu-policy/logo/FAQ_logo_en.pdf; *see also Logo and Labeling*, EUROPA.EU, http://ec.europa.eu/agriculture/organic/consumer-confidence/logo-labelling_en (last visited Sept. 29, 2010).

38. *Id.*

39. *Id.*

40. Commission Regulation 710/2009, 2009 O.J. (L 204) 15 (EC).

41. *Id.*

42. *Id.*

43. *Id.*

44. Press Release, European Commission, New organic aquaculture rules a route to a more sustainable and profitable future for aquaculture (June 30, 2010), *available at* http://ec.europa.eu/fisheries/news_and_events/press_releases/300610/index_en.htm.

45. *Id.*

IX. FOOD CONTACT MATERIALS

Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intending to come into contact with foodstuffs allows bisphenol A to be used in food contact materials in the European Union.[46] The European Food Safety Authority (EFSA) is working on an extensive opinion on bisphenol A. The full opinion is expected to be adopted in September 2010.[47] Bisphenol A has been subject to scientific analysis for several years now. Back in 2006, EFSA set a Tolerable Daily Intake of 0.05 milligram/kg body weight, an estimate of the quantity of bisphenol A that can be consumed over a lifetime without any noticeable risk.[48] A 2008 opinion confirmed this level after conducting a study on the difference between infants and adults in the ability to eliminate bisphenol A from their body.[49] Following a study published in the Journal of the America Medical Association in September 2008,[50] the European Commission asked EFSA to evaluate the study's conclusion that there was a link between raised levels of urinary bisphenol A and increased occurrences of serious medical conditions such as cardiovascular diseases and diabetes.[51] EFSA found that the study did not sufficiently prove such a link and the Agency decided not to question its established Tolerable Daily Intake.[52] Between October 2009 and March 2010, following a study commissioned by the American Chemistry Council undertaken as a result of the introduction of a Canadian law aimed at banning the use of bisphenol A in baby feeding bottles, the Commission asked EFSA to evaluate the importance of this

46. Commission Directive 2002/72, 2002 O.J. (L 220) 18 (EC).

47. *See* Letter from Catherine Geslain-Lanéelle, Exec. Dir., European Food Safety Auth., to Paola Testori Coggi, Dir. Gen., Health and Consumer Prot. Directorate Gen., European Comm'n (July 8, 2010), *available at* http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00864.

48. *Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a Request From the Commission Related to 2,2-BIS(4-HYDROXYPHENYL)PROPANE (Bisphenol A)*, 428 THE EFSA J. 1, 46 (2006).

49. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) on a Request From the Commission on the Toxicokinetics of Bisphenol A, 759 THE EFSA J. 1, 1-10 (2008).

50. Iain A. Lang et al., *Association of Urinary Bisphenol A Concentration With Medical Disorders and Laboratory Abnormalities in Adults*, 300(11) J. AM. MED. ASS'N 1303, 1303-1310 (2008).

51. *Scientific Opinion on Bisphenol A: Evaluation of a Study Investigating its Neurodevelopmental Toxicity, Review of Recent Scientific Literature on its Toxicity and Advice on the Danish Risk Assessment of Bisphenol A*, 8(9) THE EFSA J. 1829 (2010).

52. *Id.*

study and to look at any other new relevant scientific evidence.[53] Since March 2010, EFSA has been in the process of drafting its opinion on bisphenol A. The drafting process has taken longer than expected because EFSA was reviewing more than 800 publications. EFSA finally released its opinion on September 23, 2010.[54] The Panel concluded that they could not identify any new evidence that could lead them to a revision of the current Tolerable Daily Intake set by EFSA in 2006 and confirmed in 2008.[55] Because the panel recognized that some studies report an adverse effect on animals exposed to bisphenol A, the Panel will reconsider its conclusion should new data become available in the future that could indicate potential adverse effects on humans.[56]

X. LABELING

Following the June vote of the European Parliament on the Commission Proposal for a Regulation on the provision of food information to consumers, it is now the Council's turn to express its opinion on the piece of legislation as voted by the Parliament in a Common Position. At the time of publication, this position has not been released yet. Member States hold monthly meetings on this text, with the current Presidency of the Council (Belgium) making proposals.

XI. MISCELLANEOUS

In September 2010, the United Kingdom's Food Standards Agency, the UK governmental body whose mission is to protect the public's health and consumer interests in relation to food, underwent changes in terms of responsibilities for food labeling.[57] The responsibilities for food labeling were divided up between three departments.[58] The FSA will keep its responsibility for the food safety aspects of labeling. This encompasses

---

53. *Id.*

54. *Id.*

55. *Id.*

56. *Scientific Opinion on Bisphenol A: Evaluation of a Study Investigating its Neurodevelopmental Toxicity, Review of Recent Scientific Literature on its Toxicity and Advice on the Danish Risk Assessment of Bisphenol A*, 8(9) THE EFSA J. 1829 (2010).

57. Press Release, Food Standards Agency, Government Food Labelling Changes (Sept. 1, 2010), *available at* http://www.food.gov.uk/news/newsarchive/2010/sep/labelgov.

58. *Id.*

> expert scientific advice on the food safety aspects of date marking, assessment and labeling of ingredients/foods with food safety implications, food safety aspects of organic food and of foods controlled by compositional standards, treatments and conditions of use with food safety implications, GM and novel foods (including use of nanotechnology), animal feed, including Codex Intergovernmental Task Force on Animal Feeding, food safety incidents, including misleading labeling and food fraud with possible food safety implications, EU General Food Law regulation, including traceability of food and feed, [and] Codex Committees on Food Hygiene, Methods of Analysis and Sampling, Food Additives, Contaminants in Foods.[59]

The Department of Health will take over the nutritional labeling policy, such as "nutrition related aspects of the EU food information regulation, front of pack labeling, food for particular nutritional uses, infant formula and follow on formula, health and nutrition claims, food supplements, calorie information in catering establishments, [and] Codex Committee on Nutrition and Foods for Special Dietary Uses.[60] The Department for Environment, Food and Rural Affairs will oversee labeling relating to aspects other than food safety and nutrition, providing

> [the] general lead on food labeling legislation and relevant EU negotiations, lead on the EU Food Information proposal, country of origin labeling, food composition standards and labeling such as fruit juice and fruit nectars, jams and bottled water, technical advice on compositional standards for food without specific legislation, such as soft drinks and cereal products, fish labeling, use of marketing terms e.g. natural, fresh, clear labeling, vegan and vegetarian labeling, food authenticity program, Codex Committees for: Food Labeling, Processed Fruits and Vegetables, Fresh Fruits and Vegetables, Fats and Oils, Fish and Fishery Products, Europe, General Principles, [and] lead on Codex Alimentarius Commission, General Principles and Coordinating Committee for Europe.[61]

59. *Id.*
60. *Id.*
61. *Id.*