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European Union Food Law Update

Emilie H. Lieibovitch

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I. INTRODUCTION

In June 2009, citizens of the European Union elected a new European Parliament. Some Members of the European Parliament (MEPs) were reelected while some were not. The majority party is the EPP, the Group of the European People's Party, and the Group of the Progressive Alliance of Socialists & Democrats has the second majority of the seats. The elections were still governed by the Treaty of Nice, since up until very recently, the future of the Treaty of Lisbon was still uncertain. The Treaty of Lisbon was up until now rejected by a few Member States, who, by their reluctance to sign, prevented it from taking effect throughout the entire union. At the end of October 2009, the Czech Republic signed the Treaty, which makes ratification increasingly probable.

The elections at Parliament level have slowed down the legislative process. In several cases, the policymakers decided to wait for the new elected officials to continue negotiations or the process of enactments of legislation. That is why this update is shorter than usual.

The following is an overview of the recent developments that have taken place in the areas of genetically-modified organisms, novel foods, feed safety, transmissible spongiform encephalopathy, food additives, food contact materials, food quality, food labeling, and nutrition/health claims.

II. GENETICALLY MODIFIED ORGANISMS

In April 2009, Germany banned the cultivation of MON810 Bt maize in Germany with immediate effect, relying on the safeguard clause of article 23 of Directive 2001/18/EC on the deliberate re-

lease into the environment of genetically modified organisms.[1] Article 23 allows a Member State to "provisionally restrict or prohibit the use and/or sale" of a GMO on its territory" if it has enough scientific information that gives this Member States "detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment."[2] Since the scientific GMO Panel of EFSA held that there is no new scientific-based evidence to justify a national ban on MON810, Monsanto had announced it might take legal action against the ban. Monsanto filed an appeal but it was rejected by the administrative court in Brunswick on the ground that the safeguard clause does not require new scientific evidence of an absolute risk to be presented.[3] Rather, evidence giving reasonable grounds to believe a risk might exist is enough.

In September, following a series of notifications received through the Rapid Alert System for Food and Feed (RASFF), the European Commission ordered Member States to remove from the shelves food products derived from unauthorized genetically modified linseed and coming from Canada.[4] The flax comes from Canada and is not authorised in the EU. In September, a total of eight notifications were received by the European Rapid Alert System for Food and Feed (RASFF). Canada has suspended shipments of linseed to the EU for now.

III. NOVEL FOODS

The debate over novel foods, and especially over whether cloned food should be included in the new Novel Foods Regulation, has intensified. At Council level, Member States disagreed on whether offspring of cloned animals should be excluded from the

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* Emilie H. Leibovitch is a member of the Arkansas Bar and the District of Columbia Bar, and is an associate member of the Brussels Bar. She practices international law and U.S. law at her law office located in Brussels, Belgium.

1. GMO Compass, *Germany: Minister Aigner bans MON810 Bt maize*, April. 14, 2009, http://www.gmo-compass.org/eng/news/432.docu.html (last visited Jan. 8, 2010); Directive 2001/18/EC, article 23, 2001 O.J. (L 106) 1, 13.

2. Directive 2001/18/EC, article 23, 2001 O.J. (L 106) 1, 13.

3. GMO Compass, *German court's initial ruling: Cultivation ban of genetically-modified MON810 maize upheld*, May 5, 2009, http://www.gmo-compass.org/eng/news/440.docu.html (last visited Jan. 8, 2010).

4. GMO Compass, *GM linseed: Products being taken off the market*, Oct. 1, 2009, http://www.gmo-compass.org/ eng/news/467.docu.html (last visited Jan. 8, 2010).

regulation altogether or whether they should be covered over several generations. Some Member States also supported the European Parliament's position that cloned food should not be dealt with in the Novel Foods Regulation and should instead be addressed in a separate piece of legislation. In June 2009, the Council adopted a political agreement on the draft novel food regulation.[5] The Council clarified the definition of novel food and the scope of the regulation and agreed that the new regulation explicitly applies to food produced from cloned animals, and that the regulation covers food from the offspring of cloned animals. In addition, the Council "invites the Commission to report on all aspects of food from cloned animals and their offspring within one year after the entry into force of the regulation and to submit, if appropriate, a proposal for a specific legislation on this topic."[6] Following this agreement, which differs from the Commission's initial proposal, the proposal on a novel foods regulation went back to the European Parliament for a second reading. After the European Parliamentary elections, the Environment, Public Health and Food Safety Committee confirmed that MEP Kartika Liotard would remain rapporteur for the Novel Foods Proposal.

With respect to nanotechnology, the Council and the Parliament might disagree on whether food products resulting from nanotechnology should be labeled or not. The Parliament is requesting such a labeling while Member States are still undecided on the issue.

IV. FEED SAFETY

Regulation (EC) No 767/2009 of 13 July 2009 on the placing on the market and use of feed was published in the Official Journal on September 1, 2009.[7] This new text amends Regulation (EC) No 1831/2003 (on additives for use in animal nutrition) and repeals Council Directive 79/373/EEC (on on the marketing of compound feedingstuffs), Commission Directive 80/511/EEC (authorizing, in

5. Council of the European Union, Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX, Political Agreement, June 17, 2009, *available at* http://register.consilium.europa.eu/pdf/en/09/st10/st10754.en09.pdf; Press release, *Council agrees on new rules for novel foods*, Council of the European Union, June 22, 2009, *available at* http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/misc/108678.pdf.

6. Press release, *Council agrees on new rules for novel foods*, supra note 5.

7. Regulation (EC) No 767/2009, 2009 O.J. (L 229) 1.

certain cases, the marketing of compound feedingstuffs in unsealed packages or containers), Council Directives 82/471/EEC (concerning certain products used in animal nutrition), 83/228/EEC (on the fixing of guidelines for the assessment of certain products used in animal nutrition), 93/74/EEC (on feedingstuffs intended for particular nutritional purposes), 93/113/EC (concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition) and 96/25/EC (on the circulation of feed materials) and Commission Decision 2004/217/EC (adopting a list of materials whose circulation or use for animal nutrition purposes is prohibited).

The labeling rules for feed are now aligned with those for food designed for human consumption. Nutrition claims are allowed if they are "objective, verifiable by the competent authorities[,] understandable [by the feed user]" and scientifically based, and health claims are prohibited except for the case of coccidiostats and histomonostats.[8] In addition, the regulation provides for the creation of an EU Catalogue of feed materials, where feed producers are to list their feed materials in a common catalogue to provide information to feed users.[9] Moreover, the new Regulation calls for the Commission to encourage the development of Community Codes of good labeling practice for pet food and for compound feed for food producing animals.[10]

V. TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

This year's EU Veterinary Week saw the announcement by Health Commission Androulla Vassiliou of a consultation on a future EU Animal Health Law.[11] This law would aim at providing a "single, clearer regulatory framework for all EU animal health legislation and . . . a coherent basis for all future EU actions concerning animal health."[12]

On September 28, 2009, the Commission issued Decision No 2009/719/EC authorizing some Member States to revise their an-

8. *Id.* art. 13, at 10.

9. *Id.* art. 24, at 13.

10. *Id.* art. 25, at 14.

11. Press release, *Androulla Vassiliou Member of the European Commission, responsible for Health "Animals + Humans = One Health" Opening Speech at the EU Veterinary Week Conference in Brussels, 28 September 2009, available at* http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/09/415&format= HTML &aged=&language=EN&guiLanguage=en .

12. *Id.*

nual BSE monitoring programmes.[13] Following an EFSA scientific opinion concluding that in Slovenia, less than one BSE case would be missed every year in some Member States if the age of the bovine animals subject to the monitoring was increased from 24 months to 48 months,[14] the Commission decided to authorize some Member States to monitor animals that are over 48 months instead of 24 months.

VI. RAPID ALERTS

On 16 July 2009, European Commissioner for Health Androulla Vassiliou launched the Rapid Alert System for Food and Feed (RASFF) Portal website, composed of an electronic database of RASFF notifications.[15] This database allows RASFF members to post notifications according to a number of criteria, and make this information readily available to the general public. RASFF notifications can be either market notifications or border rejections. A market notification refers to a notification sent when a risk is detected in a feed or food product placed on the market, while a border rejection helps to inform the public when a product is refused entry in the geographical zone of the network. Market notifications can either be alert notifications (sent when a rapid action on the part of members is required: when a food or feed presenting a serious health risk is on the market, such a notification is sent in order for RASFF members to determine whether the product in question is on their market and take the required rapid action) or information notifications (sent when there is a risk about a food or feed product placed on the market, but no rapid action is required on the part of the other members either because the product has not reached, is no longer present on, these members' market, or because the nature of the risk for some reason does not require rapid action). In addition, any food or feed safety information that is deemed interesting to the control authorities is communicated in the database as news. The notifications are also divided in three product type categories: food, feed, and food contact materials. The

13. Commission Decision 2009/179/EC, 2009 O.J. (L 236) 35.

14. Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on the updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States. *The EFSA Journal* (2009) 1059, 1-40.

15. European Commission, RASFF Portal - online searchable database http://ec.europa.eu/food/food/rapidalert/ rasff_portal_database_en.htm (last visited Jan. 8, 2010).

network is composed of the EU Member States as well as those of the European Free Trade Association (EFTA), which thus adds Iceland, Liechtenstein, Norway and Switzerland to the list of countries involved in RASFF.

VII. FOOD ADDITIVES

In August 2009, EFSA published the data requirements for the evaluation of food additive applications.[16] Pursuant to the new regulation, Regulation (EC) No 1333/2008 on food additives, food additives should be approved and used only if they fulfill the criteria laid down in it: food additives must for instance be safe when used, there must be a technological necessity for their use, and their use must not mislead the consumer.[17] According to the EFSA document, information should be provided on "the applicant and the application dossier (administrative data), the identity and characterisation of the additive (including the proposed specifications and analytical method), the manufacturing process, the stability, reaction and fate in foods to which the additive is added, the case of need and proposed uses, the existing authorisations and evaluations, the exposure assessment, and the biological and toxicological data."[18]

VIII. FOOD CONTACT MATERIALS

In May 2009, the Commission enacted Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.[19] This new regulation sets out additional requirements to Regulation (EC) No 1935/2004 (on materials and articles intended to come into contact with food) for active and intelligent materials and articles to guarantee their safe use; it also introduces an authorization scheme for substances that are used in food contact materials for active and intelligent functions.

16. Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food on data requirements for the evaluation of food additives applications following a request from the European Commission. The EFSA Journal (2009) 1188, 1-7 [hereinafter *EFSA Statement on Food Additives*].

17. Regulation (EC) No 1333/2008, art.6, 2008 O.J. (L 354) 16, 21.

18. *EFSA Statement on Food Additives*, supra note 16 at 4-5.

19. Commission Regulation (EC) No 450/2009, 2009 O.J. (L 135) 3.

IX. FOOD QUALITY

In May 2009, the Commission issued a Communication to the Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on agricultural product quality policy.[20] The document makes several suggestions, including a proposal to require labeling of the place where the product was produced, setting up a register of geographical indications, and creating good practice guidelines for the implementation of schemes linked to agricultural product quality. This communication represents the first formal step in the process leading toward a proposal for a regulation. MEP Giancarlo Scotta' (EFD, Italy) has been named rapporteur to issue the report for the European Parliament Agriculture and Rural Development (AGRI) Committee. Rapporteur Scotta' published his Draft Report on October 19, 2009.[21]

X. FOOD LABELING

Given that a vote on Rapporteur Renate Sommer's Draft Report on the Commission's Proposal on the Provision of Food Information to Consumers[22] had not taken place at Parliament level before the elections, Mrs. Sommer decided to wait for the new composition of the European Parliament Environment, Public Health and Food Safety (ENVI) Committee to rewrite her draft report. This second draft report is supposed to take into account the many amendments submitted by other Members of Parliament (MEPs), but at the time of writing of this article, the draft report in question has not been published yet. Chances are that Rapporteur Sommer will follow a line of reasoning similar to the one she used in her first draft report, but if she does take into account the variety of opinions of the other MEPs, differences might transpire in her new text.

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20. Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on agricultural product quality policy, May 28, 2009, COM (2009) 234 final, at 5, *available at* http://ec.europa.eu/agriculture/quality/policy/com2009_234_en.pdf.

21. European Parliament, Draft Report on Agricultural product quality policy: what strategy to follow?, Giancarlo Scotta', Oct. 19. 2009, (2009/2105(INI)), *available at* http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-430.362+01+DOC+PDF+V0//EN&language=EN.

22. Sommer Draft Report on the Proposal for a Regulation of the European Parliament and of the Council on the Provision of Food Information to Consumers, 2008/0028(COD) (Nov. 7, 2008), *available at* http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-415.015+01+DOC+PDF=V0//EN& language=EN [hereinafter *Sommer's Draft Report*].

XI. NUTRITION AND HEALTH CLAIMS

Nutrient profiles are still in interservice consultation, which is an internal consultation within the Commission, and it is very likely that the Commission will wait for the new College of Commissioners to continue addressing this matter. The new College of Commissioners was to take office in November 2009; however, given the uncertainties regarding the status of the Lisbon Treaty, discussions took place on whether to extend the current Commission's mandate until February 2010. However, with the recent turns of events, the delay might be shorter.

In addition, to this date, the European Food Safety Authority (EFSA) is still in the process of reviewing health claims falling under Article 13 of the EC Regulation on nutrition and health claims No 1924/2006. On October 1, 2009, EFSA issued a first series of opinions on 'general function' health claims, which are defined as "health claims other than those referring to the reduction of disease risk and to children development and health,"[23] and can refer to the role of a nutrient or substance in growth, the development and the functions of the body, psychological and behavioral functions, slimming and weight control or reduction of hunger, increase of satiety or reduction of available energy from the diet.[24] Out of the five hundred health claims submitted, only one third of them received a favorable evaluation because they were substantiated by sufficient scientific evidence.

23. Draft Briefing document for Member States and European Commission on Article 13.1 health claims list, EFSA's Scientific Panel on Dietetic Products, Nutrition and Allergies, at 1, *available at* http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/NDA_briefing_%20doc_Art_13_claims.pdf?ssbinary=true.

24. *Id.*