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United States Food Law Update

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UNITED STATES FOOD LAW UPDATE

*Michael Tingey Roberts and Margie Alsbrook**

I. INTRODUCTION

This update summarizes some of the significant changes and developments in food law over the first half of 2006. Not every change in food law is included; instead, this update provides a starting point for scholars, practitioners, food industry members, and policymakers determined to understand the shaping of food law in modern society. Tracing the development of food law through these updates, which appear in each issue of the *Journal of Food Law & Policy*, also provides historical context for the development of significant food law issues over time. New developments in state law, while certainly important and deserving in attention, are beyond the scope of this summary.

II. RECENT FEDERAL REGULATIONS

A. *USDA Final Rule to Revise National Organic Program Regulations*

In June 2006, the United States Department of Agriculture (USDA) published a final rule¹ that revises the National Organic Program (NOP) regulations to comply with the final court order in

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1. National Organic Program—Revisions to Livestock Standards Based on Court Order (*Harvey v. Johanns*) and 2005 Amendment to the Organic Food Production Act (OFPA), 71 Fed. Reg. 32803 (June 7, 2006) (to be codified at 7 C.F.R. pt. 205).

*Harvey v. Johanns*² lawsuit and with the 2005 amendments to the Organic Foods Production Act of 1990 (the Act or OFPA).³

1. Background

OFPA establishes national standards governing the marketing of food products that qualify for the “organic” USDA label.⁴ To bear USDA’s “organic” seal, a food product must be at least ninety-five percent organic⁵ and produced and handled without the use of synthetic substances in accordance with an organic plan agreed to by an accredited certifying agent and by the producer and handler of the food product.⁶ Synthetic substances that are exceptions to this general prohibition against such use are to be listed on a National List following notice and comment and are subject to review.⁷

Harvey held that certain provisions in the National Organic Program Final Rule⁸ contravened OFPA.⁹ The First Circuit first held that the final rule allowing a converting herd to be fed a diet of only eighty percent organic feed for a period of nine months for newly converting herds violated the OFPA provision requiring all organic dairy animals to receive organic feed for twelve months prior to sale of milk or milk products.¹⁰ The First Circuit next held that the Final Rule allowing the listing of synthetics for use in the handling of products labeled organic contravened the OFPA provision that bars synthetics in processed foods.¹¹ The First Circuit also remanded for declaratory judgment as to whether the Final Rule establishes a blanket exemption to the National List requirements for non-

2. See 396 F.3d 28 (1st Cir. 2005).

3. See Agriculture, Rural Development, Food And Drug Administration, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-97, § 724, 119 Stat. 2153 (2005), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ097.109.

4. Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. § 6501 (Supp. 2005).

5. 7 C.F.R. § 205.301(a)(2005).

6. OFPA § 6504 (Supp. 2005). Food labeled “100% organic” cannot contain non-organic ingredients or processing aids. 7 C.F.R. § 205.301(a); 7 C.F.R. § 205.303.

7. OFPA §§ 6517(a), (d), (e); 6518(k), (l), (m) (Supp. 2005).

8. 7 C.F.R. pt. 205 (2005).

9. 396 F.3d at 32.

10. *Id.* at 44; see also Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. § 6509(e)(2) (Supp. 2005); 7 C.F.R. § 205.236(a) (2005).

11. *Harvey*, 396 F.3d at 40; see also OFPA § 6509(e)(2) (Supp. 2005); 7 C.F.R. §§ 205.600(b) (2005).

organic products that are not commercially available.¹² The First Circuit directs that such a blanket exemption would controvert the OFPA requirements for the National List.¹³

In response to the First Circuit's decision in *Harvey v. Johanns*, Congress approved a rider to the 2006 agriculture appropriations that amended OFPA.¹⁴ The rider allowed organic dairy animals to be fed "transitional" organic feed during all of the twelve months of the conversion year.¹⁵ This change in essence would allow milk to be sold as organic as soon as the land qualifies as organic.¹⁶ The rider did not allow, however, the twenty-percent conventional feed as did the final rule reversed by *Harvey*.¹⁷ Next, the rider reverses *Harvey's* holding of no synthetic ingredients in handling by amending OFPA to remove prohibitions on synthetic ingredients in post-handling, provided that they are listed on the National List.¹⁸ Finally, the rider amends OFPA to permit the USDA Secretary to develop emergency procedures to designate for the National List agricultural products not commercially available in organic form for a maximum one year period.¹⁹

2. Final Rule Provisions

Effective June 9, 2007, the final rule revises eliminates the twenty-percent feed provision whereby dairy producers will no longer be able to use twenty percent non-organic feed during the first nine months of whole herd conversion from conventional to organic production.²⁰ The final rule allows crops and forage from land included in the organic dairy system plan of a dairy farm that is in its third year of organic management to be fed to the converting animals.²¹ Finally, the final rule clarifies that non-organically produced products listed in 7 C.F.R. § 205.606 may be used as ingredi-

12. *Harvey*, 396 F.3d at 36.

13. *Id.*

14. See OFPA §§ 6501-6522 (Supp. 2005), as amended through Pub. L. No. 109-97, § 724, 119 Stat. 2153 (2005),).

15. OFPA § 6509(e)(2)(B) (2005) (as amended).

16. See *id.*

17. See *id.*

18. See Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. § 6510(a)(a) and § 6517(c)(B)(iii) (2005) (as amended).

19. OFPA 7 U.S.C. § 6517(d)(6) (2005) (as amended).

20. National Organic Program, *supra* note 2 at 32,804.

21. *Id.*

ents in or on processed products labeled as “organic” only when such organic products are not commercially available.²²

B. FSIS Announces Salmonella Reduction Initiative

In February 2006, the Food Safety & Inspection Service (FSIS) announced an initiative targeting the reduction of salmonella in meat and poultry products.²³ The plan is modeled after the agency’s previous initiative to reduce the presence of *E.coli* 0157:H7 in beef²⁴ and is based on the Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) system that was first implemented in 1996.²⁵ The initiative focuses on high-risk meat plants and production facilities and emphasizes quicker turn-around time for testing, as well as a shift from testing carcasses in groups to testing carcasses individually.²⁶ FSIS will also publish salmonella testing data quarterly on its Website.²⁷ FSIS had initially planned to report individual test results on their Website or make them available via a Freedom of Information (FOIA) request, but after the comment period decided instead on quarterly reporting.²⁸

C. FSIS Allows Prepared Poultry from China to Return to U.S.

FSIS announced in April 2006 a final rule allowing processed poultry products prepared in China to be imported to the United States.²⁹ The rule only applies, however, to chicken products made with chicken that was raised and slaughtered in the U.S. and proc-

22. *Id.*

23. *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection, 71 Fed. Reg. 9,772 (Feb. 27, 2006).

24. See Press Release, USDA Food Safety & Inspection Service, FSIS Announces Initiative to Reduce Salmonella in Meat, Poultry (Feb. 23, 2006), available at http://www.fsis.usda.gov/News_&_Events/NR_022306_01/index.asp.

25. Pathogen Reduction Hazard Analysis and Critical Control Point (PR/HACCP) System, 61 Fed. Reg. 38,806 (July 25, 1996) (to be codified at 9 C.F.R. pt. 310.25(b)(1), 381.94 (b)(1)).

26. See FSIS Announces Initiative to Reduce Salmonella, *supra* note 24.

27. See e.g., USDA, FSIS, Quarterly Progress Report on *Salmonella* Testing of Selected Raw Meat and Poultry Products; Preliminary Results, April – June, 2006, http://www.fsis.usda.gov/Science/Q2_2006_Salmonella_Testing/index.asp (last visited Feb. 16, 2007).

28. See *Salmonella* Verification Sample Result Reporting, 71 Fed. Reg. at 9,776-77.

29. Press Release, USDA Food Safety & Inspection Service, China Added to List of Countries Eligible to Export Processed Poultry to the U.S. (April 20, 2006) (available at http://www.fsis.usda.gov/News_&_Events/NR_042006_01/index.asp).

essed in China, and does not allow the importation of chicken raised in China to the United States.³⁰ Additionally, chicken processed in Chinese facilities must be processed separately from chicken intended for domestic use and may be subject to additional inspections upon its return to the U.S.³¹

D. FSIS Publishes Rule Raising Sodium Allowances for "Healthy" Meats

In January 2006, FSIS announced an interim final rule for determining the meaning of the word "healthy" on meat labeling.³² Focusing on sodium content, the rule limits individual meat products claiming to be "healthy" to 480 mg of sodium and "meal-type" meat products to 600 mg of sodium.³³ This new rule extinguishes the agency's previous, scaled system which, although having lower sodium requirements, was disfavored by industry.³⁴ The FDA published a similar rule in 2005.³⁵

III. RECENT ADMINISTRATIVE GUIDELINES

A. FDA Releases Guidelines for Whole Grain Labels

In February 2006, FDA published its "Guidance for Industry and FDA Staff: Whole Grain Label Statements."³⁶ Claims that products contain whole grains have been allowed for quite some time,³⁷ provided the claims are not false or misleading under the relevant

30. *See id.*

31. *See id.*

32. Food Labeling; Nutrient Content Claims, Definition of the Term: "Healthy," 71 Fed. Reg. 1,683 (Jan. 11, 2006) (to be codified at 9 C.F.R. pt. 317, 381).

33. *Id.*

34. *See id.* (giving a history of the sodium requirements under the "healthy" rule and citations to various rules that the agency has implemented over the years); *see also* Peter Barton Hutt et al., *Group Wants Sodium Rules for "Healthy" Foods Lifted*, 15 GUIDE TO U.S. FOOD LABELING L. 2 (April 2006) (reporting that The Salt Institute was one of the groups advocating for the change in the "healthy" rule).

35. FDA, Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term "Healthy", 70 Fed. Reg. 56,828 (Sept. 29, 2005), available at <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/05-19511.htm>

36. FDA, Guidance for Industry and FDA Staff: Whole Grain Label Statements, 71 Fed. Reg. 8,597 (Feb. 17, 2006) available at <http://www.cfsan.fda.gov/~dms/flragui.html>.

37. *See, Id.* (citing 21 C.F.R. 102.5(b) (2006), 21 C.F.R. 101.13(i) (2006)).

section of the federal Food, Drug & Cosmetics Act.³⁸ When the 2005 federal food pyramid recommended consumption of three or more ounces of whole grains on a daily basis,³⁹ the number of products that claimed to contain whole grains in the marketplace increased significantly.⁴⁰ This increase caused confusion as both industry and consumers struggled to distinguish between foods containing true whole grains and refined-grain food products that were less nutritious.⁴¹

The new FDA guidance clarifies what constitutes a whole grain for packaging and labeling. The guidance states that cereal grains such as amaranth, barley, buckwheat, bulgur, corn (including popcorn), millet, quinoa, rice, rye, oats, sorghum, teff, triticale, wheat, and wild rice would be considered whole grains and most likely qualify to make whole grain claims on labels.⁴² This definition of whole grains was supported and endorsed by the Whole Grains Council and other industry groups.⁴³ Other products that contained refined flour or are made with whole wheat flour, such as pizza crusts, depending on the process for creating the flour and which parts of the grain are allowed into the final product may not be able to make the whole grain claim.⁴⁴

38. Federal Food, Drug & Cosmetics Act, 21 U.S.C. § 343(a) (2006).

39. See, e.g., U.S. DEP'T OF HEALTH AND HUMAN SERV., U.S. DEP'T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS 2005, available at www.healthierus.gov/dietaryguidelines/.

40. See, e.g., Karen Fernau, *Whole Grains Grow Popular*, ARIZ. REPUBLIC, Mar. 1, 2006, available at <http://www.azcentral.com/arizonarepublic/news/articles/0301grains01.html>; Elizabeth Lee, *Sorting Out the Chaff in Grain Claims: A Few Servings of Advice Can Help Decipher Guidelines*, ATLANTA J. & CONST., Feb. 16, 2006, at F1.

41. See *id.*

42. Guidance for Industry, *supra* note 15.

43. See Press Release, Whole Grains Council, Statement from Oldways and the Whole Grains Council on FDA Whole Grains Review (Feb. 15, 2006) (available at <http://www.wholegrainscouncil.org/PR060215FDA.html>).

44. See, e.g., Guidance for Industry, *supra* note 36; see also Press Release, FDA, FDA Provides Guidance on Whole Grain for Manufacturers (Feb. 15, 2006) (available at <http://www.fda.gov/bbs/topics/news/2006/NEW01317.html>); Oregon State University, Linus Pauling Institute, Anatomy of a Whole Grain, <http://lpi.oregonstate.edu/infocenter/foods/grains/anatomy.html> (last visited Feb. 16, 2007).

*B. USDA Sets Timeline for Implementation of
National Animal ID System*

In April 2006, USDA announced its timeline for implementing its National Animal ID System (NAIS).⁴⁵ The NAIS is designed to coordinate the efforts of federal agencies, state agencies, interested companies and industry groups, and anyone else who has an involvement in the storage and transport of animals.⁴⁶ It is anticipated that in the event of an animal disease outbreak NAIS will allow for rapid tracing, location, and subsequent treatment or destruction of infected or exposed animals.⁴⁷

Implementation of the NAIS involves three stages: first, identifying and registering premises that house animals, second, tagging each animal with an AIN tag, and third, testing and implementing a database that will hold detailed information about the animals, their origins, and their locations.⁴⁸ The third step has generated considerable controversy over APHIS' decision to make control of the database private and over what type of information will be available to government officials and the public.⁴⁹ Concerns over confidentiality and liability amongst producers have stirred resistance to NAIS.⁵⁰

The proposed timeline for the implementation of NAIS calls for the system to be operational by 2007 and for full producer par-

45. Press Release, USDA, Johanns Releases National Animal Identification System Implementation Plan (Apr. 6, 2006) (available at http://www.usda.gov/wps/portal/lut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2006/04/0120.xml).

46. USDA APHIS, "National Animal Identification System: Overview," http://www.aphis.usda.gov/lpa/pubs/fsheet_fa_notice/fs_ahnaidtrack.html (last visited Feb. 16, 2007) ("Currently, working groups comprised of industry and government representatives are developing plans for cattle, swine, sheep, goats, horses, poultry, bison, deer, elk, llamas, and alpacas."). Even animals that are only used for recreation or competition purposes will need to be identified under the NAIS. See USDA APHIS, "National Animal Identification System: Questions & Answers," http://www.aphis.usda.gov/lpa/pubs/fsheet_fa_notice/faq_ahuids.html (last visited Feb. 16, 2007).

47. USDA APHIS, "National Animal Identification System: Goal and Vision," http://www.aphis.usda.gov/lpa/pubs/fsheet_fa_notice/fs_ahnaispln.html (last visited Feb. 16, 2007).

48. See NAIS Overview, *supra* note 46.

49. See, e.g., Amy K. Guerra, Comment, *Agricultural Accountability: The National Animal Identification Plan, Confidentiality and the Freedom of Information Act*, 15 SAN JOAQUIN AGRIC. L. REV. 213 (2006); John Dobberstein, *Government Outlines New Animal ID Program*, TULSA WORLD, April 7, 2006, at E1.

50. See Michael Roberts and Doug O'Brien, *Animal Identification: Confidentiality of Information*, available at <http://lmic.info/memberspublic/animalID/fs05.pdf>; *Animal Identification: Liability Exposure and Risk Management*, available at <http://lmic.info/memberspublic/animalID/fs06.pdf>.

participation by 2009.⁵¹ Although participation will be voluntary in the beginning, this is highly controversial and there is a possibility that participation will eventually be mandated for certain animals or groups.⁵² Field trials of the system and its accompanying animal identification number (AIN) tags are currently being held by numerous states and Native American tribes, under the direction of USDA's Animal Plant Health Inspection Service (APHIS).⁵³

C. FDA Issues Guidance to Help Prevent Inadvertent Introduction of Allergens or Toxins into the Food and Feed Supply

In June 2006, FDA issued guidance on the early food safety evaluation of new non-pesticidal plant proteins.⁵⁴ The guidance recommends procedures for submitting the early food safety evaluation to FDA prior to when new proteins might inadvertently enter the food supply.⁵⁵ Where food safety concerns are not identified in the early evaluation and the same protein is introduced into a new plant species, the guidance provides that additional evaluation is unnecessary.⁵⁶ The guidance responds to FDA's recognition of rapid developments in genomics that will continue to lead to dramatic changes in the development and commercialization of new plant varieties.⁵⁷

51. See Johanns Releases National Animal Identification System Implementation Plan, *supra* note 45.

52. See APHIS Q&A, *supra* note 46; see also *Pork Industry to Implement Animal Identification System*, FOOD & DRINK WKLY., April 24, 2006, at 1 (reporting concerns that the NAIS will not be effective unless it is mandatory).

53. USDA APHIS, "National Animal Identification System: Questions & Answers," http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_ahuids.html (last visited Feb. 16, 2007); see also USDA APHIS, APHIS Factsheet: National Animal Identification System Animal Identification Number (AIN) Tags (Aug. 2006), http://www.aphis.usda.gov/publications/animal_health/content/printable_version/fs_NAIS_AIN_Tags_vs.pdf (last visited Feb. 16, 2007).

54. Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (June 2006), available at <http://www.cfsan.fda.gov/~dms/bioprgu2.html#intro>.

55. *Id.*

56. *Id.*

57. *Id.*

IV. ADDITIONAL DEVELOPMENTS

A. *Industry and Advocates Partner to Eliminate Soft Drinks in Schools*

In May 2006, an agreement was reached to end the sale of soft drinks in the nations' schools.⁵⁸ Participants in the agreement include industry giants Coca-Cola Co., Pepsi-Co., Inc. and Cadbury-Schweppes, PLC, who were convinced to participate in the plan by the Alliance for a Healthier Generation, an initiative of the American Heart Association and former U.S. President William "Bill" Clinton's Clinton Foundation.⁵⁹ The agreement limits beverage sales in most schools to water, low-fat milk, and unsweetened fruit juice with diet soda sales allowed at the high school level.⁶⁰ These changes are scheduled to be implemented by 2010 at the latest.⁶¹ Although some question the enforceability of the agreement, it has been viewed in the media as a coup in public health against childhood obesity.⁶²

58. See Samantha Gross, *Soda Distributors to End Most School Sales*, WASH. POST, May 3, 2006, at A1.

59. See *id.*

60. See *id.*

61. Press Release, William J. Clinton Foundation, *Question & Answer: School Beverage Policy Announcement*, May 3, 2006, available at <http://www.clintonfoundation.org/050306-nr-cf-hs-hk-usa-qa-question-and-answer-school-beverage-policy-announcement.htm>.

62. See Daniel DeNoon, *Soda Skip Schools: Soft-Drink Makers Join Childhood Obesity Fight, Won't Sell Sugary Sodas in Schools*, WEBMD MEDICAL NEWS, May 3, 2006, available at <http://www.webmd.com/content/article/121/114392.htm>.

