

The National Agricultural
Law Center



University of Arkansas School of Law

NatAgLaw@uark.edu ☎ (479) 575-7646

An Agricultural Law Research Article

**Organic Diaries Dodge A Bullet with
the Rescission of New USDA
Guidance and Directives**

by

Nicholas A. Heike

Originally published in DRAKE JOURNAL OF AGRICULTURAL LAW
10 DRAKE J. AGRIC. L. 567 (2005)

www.NationalAgLawCenter.org

ORGANIC DAIRIES DODGE A BULLET WITH THE RESCISSION OF NEW USDA GUIDANCE AND DIRECTIVES

Nicholas A. Heike

I.	Introduction.....	567
II.	The National Organic Program (NOP).....	568
III.	Labeling Issues.....	569
IV.	How is “Organic” Defined for Labels?.....	570
V.	Controversy Looms Over rbST Treated Milk.....	571
VI.	Where Does the Controversy Stem?.....	572
VII.	Problems with Conforming to Labeling Requirements.....	573
VIII.	Consumer Concern over Labeling Requirements.....	574
IX.	How Do the New Interpretations Tie In?.....	576
X.	Why Were the Directives Rescinded?.....	578
XI.	Conclusion.....	582

I. INTRODUCTION

According to the United States Department of Agriculture (“USDA”), organic farming has become one of the fastest growing divisions of United States agriculture during the last decade.¹ “[More and more] producers are turning to certified organic farming systems as a potential way to lower input costs, decrease reliance on nonrenewable resources, capture high-value markets and premium prices, and boost farm income.”² Organic farmers use ecologically based practices, including biological pest management, and “virtually exclude the use of synthetic chemicals in crop production and prohibit the use of antibiotics and hormones in livestock production.”³

The fight between organic and inorganic dairy producers rages on with recent interpretations of the laws governing the National Organic Program

1. USDA, Economic Research Service: *Organic Farming and Marketing*, <http://www.ers.usda.gov/Briefing/Organic/> (last visited Oct. 31, 2005).

2. *Id.*

3. *Id.*

("NOP") by the USDA.⁴ In April 2004, the USDA attempted to "expand the use of antibiotics and hormones in organic dairy cows."⁵ Before these new standards were proposed by the USDA, cows that had been treated with nearly any kind of antibiotic or hormone would not be allowed back into the herd to produce organic milk.⁶ However, if these new standards are implemented, cows or calves that receive such treatment may return to the herd one year after their last treatment.⁷ Organic dairy producers who strictly followed earlier interpretations of the NOP feel cheated that antibiotics may be used and the products can remain being labeled as organic.⁸ Though the interpretations have been rescinded for further investigation and discussion, it is possible they will be reinstated.⁹ Due to the irreparable harm these new directives would cause to the quality-driven standards of the organic dairy community, the interpretations should not be placed back on the books.

The effects these new interpretations will have on the organic community will be extensive.¹⁰ Essentially, cows that have been treated with hormones, such as the controversial Recombinant Bovine Somatotropin ("rbST"), would be allowed to be converted into an organic herd, so long as twelve months have passed since their last treatment.¹¹ The basic goal of the NOP, the protection of the integrity of the organic label, and the new interpretations show little adherence to that goal and will lead "to the erosion of consumer confidence that forms the very foundation of the organic industry."¹²

II. THE NATIONAL ORGANIC PROGRAM (NOP)

In 1990, Congress passed the Organic Foods Production Act (OFPA) which required the USDA to set nationwide standards for "organically produced

4. See Marian Burros, *Organic Standards Change Again*, SUN-SENTINEL, June 17, 2004, at 5.

5. Carol Ness, *Organic Food Fight: Outcry Over Rule Changes that Allow More Pesticides, Hormones*, S. F. CHRON., May 22, 2004, at A1.

6. See *id.*

7. See *id.*

8. See *id.*

9. See Eco-labels, *USDA Verbally Agrees that Interpretations Made in Directives Should Not Stand* (Oct. 2004), <http://www.eco-labels.org/featurePrint.cfm?FeatureID=8>.

10. See Press Release, Organic Trade Ass'n, *Organic Trade Association Strongly Objects to National Organic Program's April 2004 Guidance Documents and Directive* [hereinafter Press Release], (May 26, 2004), http://www.ota.com/pics/documents/FactSheet_All.pdf.

11. See Nat'l Organic Program ("NOP"), *Guidance Statement* [hereinafter NOP, *Guidance Statement*] (April 13, 2004), available at <http://www.organicconsumers.org/organic/usdaantibioticsdirective.pdf>.

12. Press Release, *supra* note 10.

agricultural products to assure consumers that agricultural products marketed as organic meet consistent, uniform standards.”¹³ Both the OFPA and the NOP require that agricultural products holding an organic label must have been derived from state or USDA certified farms.¹⁴ The NOP, which was composed by the USDA in December of 2000, was created to “facilitate domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards.”¹⁵ The program sets out numerous guidelines as to the production and handling of organic products as well as listing substances, such as antibiotics and hormones that are either approved or prohibited from use in organic production.¹⁶

The market for organically produced foods has been growing at a rapid rate. The sales in this market have risen approximately twenty percent each year.¹⁷ This growth is due largely to the organic industry’s pledge to not use genetically modified (“GM”) ingredients.¹⁸ With such a steady increase in this market, it is that much more important to protect it from the invasion of GM supplements and ingredients. The regulations set forth in the NOP are designed to fill the loopholes in consumer awareness regarding products that may not qualify to be organic and to set uniform standards for all producers.¹⁹

III. LABELING ISSUES

Among the NOP’s standards for substances that can be used for production and handling of organic products are the standards for organic labeling.²⁰ The controversy over labeling is one of the main arguments brought forth by the campaign in favor of keeping the USDA’s interpretations from taking effect.²¹ When combined with the Federal Food, Drug, and Cosmetic Act (“FDCA”), the

13. USDA, *The National Organic Program: Background Information* [hereinafter USDA, *Background Information*], <http://www.ams.usda.gov/nop/FactSheets/Backgrounder.html> (last visited Oct. 31, 2005); see also Organic Certification, 3 U.S.C. § 6501 (2000).

14. See USDA, *Background Information*, *supra* note 13.

15. NOP, 65 Fed. Reg. 80, 548 (Dec. 21, 2000).

16. See NOP, 7 C.F.R. § 205 (2005).

17. Kathleen Hart, *An Introduction to Genetically Modified Foods*, 10 RICH. J.L. & TECH. 6, ¶16 (2004).

18. *Id.*

19. See generally NOP, 7 C.F.R. at § 205.

20. USDA, *Background Information*, *supra* note 13.

21. See Burros, *supra* note 4, at 5 (The Consumers Union and NOSB believe the interpretations will “significantly undermine the integrity of the organic label for consumers, farmers and certifiers”).

labeling provisions can be quite strict.²² “Under section 403(a) of the Act, a food is misbranded if statements on its label or in its labeling are false or misleading in any particular.”²³ Because organic dairy producers take pride in their high standards of not allowing any foreign substances into their herd, the interpretations would tarnish the pure image of those producers. In effect, consumers could never be certain that a quart of milk labeled as organic is truly organic.²⁴

The labeling problems are still a controversy whether or not the new interpretations are accepted into law. Some states have tried to implement legislation to require dairy producers to declare on their labels whether certain antibiotics or hormones had been used.²⁵ For instance, in *International Dairy Foods Ass’n v. Amestoy*, the state of Vermont attempted to force dairy producers to declare whether their products were derived from cattle injected with the controversial hormone rbST, a synthetic hormone used to increase milk production in cows.²⁶ Vermont argued that the consumer has a right to know what components are in the products they purchase.²⁷ The court ruled, however, that forcing dairy producers to make such declarations violates producers’ First Amendment constitutional right not to speak.²⁸ The dairy industry has proven to be quite successful in thwarting these labeling attacks under the First Amendment.²⁹

IV. HOW IS “ORGANIC” DEFINED FOR LABELS?

The standards set forth in the NOP tried to remedy these labeling problems by setting standards that must be followed in order to label a dairy product as “100 percent organic,” “organic,” or “made with organic ingredients.”³⁰ Obvi-

22. See generally Dep’t of Health and Human Services, 59 Fed. Reg. 6279, 6280 (Feb. 17, 1994).

23. *Id.*

24. See Ness, *supra* note 5, at A1 (“[M]any organic labels say ‘no antibiotics, no hormones,’ and consumers expect that to mean the milk comes from cows raised without such drugs...”).

25. See *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996).

26. See *id.* at 69; see also Andrew J. Nicholas, *As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods*, 15 LOY. CONSUMER L. REV. 277, 295 (2003).

27. See *Int’l Dairy Foods Ass’n v. Amestoy*, 898 F. Supp. 246, 249, 252 (D. Vt. 1995); see also Sarah L. Kirby, *Genetically Modified Foods: More Reasons to Label Than Not*, 6 DRAKE J. AGRIC. L. 351, 356 (2001).

28. See *Amestoy*, 92 F.3d at 72; see also Nicholas, *supra* note 26, at 295-96.

29. See Kirby, *supra* note 27, at 355 (“The First Amendment has proven to be a successful defense so far for GM companies challenging state imposed labeling requirements”).

30. See NOP, 7 C.F.R. § 205.301 (2005); 7 U.S.C. § 6501 (2004); see also Nicholas, *supra* note 26, at 288 (stating the four categories a food must fall into in order to receive an organic label).

ously, to label a product as "100 percent organic," it must contain only 100 percent organically produced ingredients.³¹ A product can be labeled as "organic" if the organically produced ingredients make up 95 percent or more of the product.³² The remaining percentage, however, that does not qualify must be "organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List" in the NOP.³³ Finally, products labeled as made with organic ingredients "must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements."³⁴

These labels are strictly required, not only by the NOP, but also by the OFPA.³⁵ Fines up to \$10,000 may be imposed upon those not complying with these labeling standards.³⁶ Such stiff penalties encourage compliance with the standards and subsequently allow consumers to feel more at ease knowing that the contents of the products they are buying are truthfully listed.³⁷ Though these regulations upon the labeling of organic products are supposed to allow consumers to feel informed about their products, there are still certain products, such as milk containing rbST, that are not obligated to disclose hormone-treatment.³⁸ Controversy over such dairy products will continue for some time. Meanwhile, organic milk sales are growing rapidly.³⁹

V. CONTROVERSY LOOMS OVER rbST TREATED MILK

Even though organic milk has slowly become more popular, hormone treated milk has become more widespread than ever.⁴⁰ At least one third of this country's dairy herd has been injected with hormones that stimulate milk production.⁴¹ This number is most likely greater since many dairy farms pool their

31. See NOP, 7 C.F.R. at § 205.301(a); see 7 U.S.C. at § 6501; see also Nicholas, *supra* note 26, at 288.

32. See NOP, 7 C.F.R. at § 205.301(b); see 7 U.S.C. at § 6501; see also Nicholas, *supra* note 26, at 288.

33. See NOP, 7 C.F.R. at § 205.301(b); see also Nicholas, *supra* note 26, at 288.

34. See NOP, 7 C.F.R. at § 205.301(c).

35. See Organic Foods Production Act of 1990 ("OFPA"), §2120, 7 U.S.C. § 6519 (2000); Nicholas, *supra* note 26, at 287-88.

36. See 7 U.S.C. at § 6519; see also Nicholas, *supra* note 26, at 288.

37. See Hart, *supra* note 17, at ¶16.

38. See Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996); see also Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995).

39. Hart, *supra* note 17, at ¶16.

40. *Id.*

41. *Id.*

cows' milk, mixing both treated and untreated milk.⁴² With such a widespread use of the hormone, and few labeling regulations, there is little wonder why this area is in such dispute.

The synthetic hormone rbST is the "first genetically engineered product approved and used in livestock food production."⁴³ This hormone was synthesized using the naturally occurring protein bovine somatotropin ("bST") as a model, which is a natural hormone cows possess to produce milk.⁴⁴ According to one of the leading manufacturers of rbST, "[t]he use of supplemental bST by dairy farmers, both large and small, generally increases milk production by 10 to 15 percent using the same number of cows."⁴⁵ However, "[n]o milk is 'bST-free,' because all milk contains a low concentration of bST, regardless of whether a cow receives extra rbST as a drug."⁴⁶ There is also no solid proof, in terms of quality, taste, or safety, that milk derived from cows treated with rbST is any different from those untreated.⁴⁷ The FDA had approved the use of rbST in dairy cattle "despite considerable criticism and safety concerns from scientists, economists, farmers, and environmental groups."⁴⁸

VI. WHERE DOES THE CONTROVERSY STEM?

Because there is no proven difference between milk treated with rbST and that without, the FDA decided that special labeling would not be required.⁴⁹ The FDA did not require dairy products to be labeled as treated because consumers could be misled into thinking that such products are unsafe or different from those not treated.⁵⁰ The FDA has allowed voluntary labeling of goods produced

42. See *id.*

43. Terence J. Centner & Kyle W. Lathrop, *Labeling rbST-Derived Milk Products: State Responses to Federal Law*, 45 U. KAN. L. REV. 511, 511 (1997).

44. See *id.* at 511-12; see also Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have not Been Treated with Recombinant Bovine Somatotropin [hereinafter Interim Guidance], 59 Fed. Reg. 6279 (1994); Inst. of Food Sci. & Tech., *Bovine Somatotropin (bST)* (Sept. 1999), http://www.monsantodairy.com/about/human_safety/ifst_rbst1.html.

45. Inst. of Food Sci. & Tech., *About Posilac*, <http://www.monsantodairy.com/about/index.html> (last visited Nov. 7, 2005).

46. Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 729 (Spring 2000).

47. See Centner, *supra* note 43, at 520 ("The evidence presented at these [FDA] hearings demonstrated no differences between the composition or quality of milk between untreated and rbST-treated cows); see also Goldman, *supra* note 46, at 729.

48. Nicholas, *supra* note 26, at 290.

49. See Goldman, *supra* note 46, at 730; see also Interim Guidance, *supra* note 44, at 6280 (stating that using the label "bST-free" would be misleading).

50. See Goldman, *supra* note 46, at 730.

using rbST as long as such labels were “truthful and not misleading.”⁵¹ The FDA stated that:

[L]abeling may be misleading if it fails to disclose facts that are material in light of representations made about a product or facts that are material with respect to the consequences that may result from use of the product. Thus, certain labeling statements about the use of rbST may be misleading unless they are accompanied by additional information.⁵²

Therefore, if a product is labeled “rbST free,” someone may get the impression that products produced using rbST are different compositionally rather than in the manner in which they are produced.⁵³

In effect, the FDA has a difficult time finding an appropriate label for rbST-produced products because any label has a tendency to mislead in some way.⁵⁴ For that reason, the FDA would like additional information provided on the labels in an attempt to prevent misleading consumers.⁵⁵ Such additional information may include a statement that clearly and truthfully informs consumers that the product is not made using rbST yet it is no different compositionally.

For example, accompanying the statement ‘from cows not treated with rbST’ with the statement that ‘No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows’ would put the claim in proper context.⁵⁶ The FDA further stated that “[p]roper context could also be achieved by conveying the firm’s reasons (other than safety or quality) for choosing not to use milk from cows treated with rbST, as long as the label is truthful and nonmisleading.”⁵⁷

VII. PROBLEMS WITH CONFORMING TO LABELING REQUIREMENTS

Due to the fine line between an acceptable label and one considered misleading, the organic producers have a difficult time determining how to comply with the USDA’s guidelines. Much of this difficulty comes from the extra costs in the labeling process.⁵⁸ The cost of labeling products can be substantial.⁵⁹ For

51. *Id.*; see also Interim Guidance, *supra* note 44, at 6280 (stating “a food is misbranded if statements on its label are false or misleading...”).

52. Interim Guidance, *supra* note 44, at 6280.

53. *See id.*

54. *See id.*

55. *See id.*

56. *Id.*

57. *Id.*; see generally Centner, *supra* note 43, at 520-24.

58. *See, e.g.,* Int’l Dairy Foods Ass’n v. Amestoy, 898 F. Supp. 246, 250 (D. Vt. 1995) (stating manufacturers are worried about the costs of labeling and consumers may react negatively

example, FDA estimated that nutrition labeling would cost food processors \$1.4 billion to \$2.3 billion over 20 years.⁶⁰

Other problems arise when each state implements separate guidelines governing the process of labeling within their borders.⁶¹ With separate standards for each state, milk producers find it difficult to market their products in each state due, in part, to the extra costs in altering their labels for each.⁶² For example, Minnesota permits “dairy products to be labeled as farmer-certified rBGH-free on the condition that the processors have affidavits from product producers guaranteeing that no rbST has been used.”⁶³ Wisconsin has implemented similar rules.⁶⁴ Wisconsin, however, requires compliance with several guidelines that are stricter than Minnesota and other states, in regards to what statements can and must be made on dairy product labels.⁶⁵ When requirements between states, especially neighboring states in this instance, differ in such material ways, it is that much more difficult for producers to efficiently market their products in multiple states.⁶⁶ Needless to say, the labeling obstacles confronting dairy producers that do not use rbST make out-of-state sales and production problematic and almost not worth doing.⁶⁷

VIII. CONSUMER CONCERN OVER LABELING REQUIREMENTS

Despite all of the concerns regarding labeling requirements placed on the producers of dairy products and other organic products in general, consumers

toward labels with information on rbST), *rev'd*, 92 F.3d 67 (2d Cir. 1996); *see also* Centner, *supra* note 43, at 550-51.

59. *See* Paula Kurtzweil, *Good Reading for Good Eating*, 27 FDA CONSUMER 4, 13 (1993).

60. *Id.*

61. *See* Centner, *supra* note 43, at 543 (noting that “[d]ue to the contrasting state provisions. . . producers, processors, and handlers who wish to label products as being from cows not treated with rbST may have difficulties in marketing milk and milk products in more than one state”).

62. *Id.* at 543-44.

63. *Id.* at 544; *see also* MINN. DEPT. OF AGRIC., DAIRY DIV., Office Memorandum, *Minnesota BST Labeling Guidance*, at 1 (May 17, 1994); MINN. STAT. ANN. § 32.75 (West 1996).

64. Centner, *supra* note 43, at 543-44; WIS. STAT. ANN. § 97.25(3) (West 2000).

65. *See* WIS. ADMIN. CODE [ATCP] § 83.02(3) (2005) (prohibiting rBST-free labels without the required statements stipulated in the code).

66. *See* Centner, *supra* note 43, at 545 (discussing the difficulty for dairy products to be sold in multiple states due to “patchwork regulation” in labeling laws).

67. *See id.*

also have a lot to say regarding their own safety and rights.⁶⁸ Some of the largest concerns raised by consumers are whether organic foods are actually safer and more nutritious than those genetically modified.⁶⁹ There is no solid scientific evidence that organic foods are any more safe or nutritious than those that are genetically modified.⁷⁰ However, even absent such proof, many consumers still want to know the source and composition of the foods they eat.⁷¹

Despite the outcry from the health-conscious population, little has been done on either the state or federal levels to require food producers to disclose facts regarding the presence of genetically modified ingredients.⁷² One reason the FDA is reluctant to require labeling for much of the food industry is the lack of evidence showing that genetically modified foods are materially different from traditional organic foods.⁷³ There are “four exceptions to this general policy which could bring [the FDA] to require special labeling of GMOs.”⁷⁴ The first exception is applied “when a food is ‘significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food.’”⁷⁵ “The second exception applies when ‘an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use.’”⁷⁶ The FDA’s third exception is applied “when a ‘bioengineered food has significantly different nutritional property,’ and then ‘its label must reflect the difference.’”⁷⁷ Finally, the fourth exception is applied when “‘a new food includes an allergen that consumers would not expect to be present based on the name of the food,’ and then ‘the presence of that allergen must be disclosed on

68. See Melissa Healy, *Behind the Organic Label: As the Industry Grows, Skeptics Are Challenging the Health Claims*, L.A. TIMES, Sept. 6, 2004, at F1 (stating consumers are starting to ask questions about the superiority of organic food).

69. See *id.*

70. See *id.*

71. See Emily Robertson, *Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 1, 156-57 (2003) (stating “people feel that they should have access to all information relevant to make informed decisions that comply with their personal and political beliefs. Specifically, some consumers believe they have a right-to-know whether they are purchasing genetically modified food. . .”).

72. See *id.* at 157-58 (stating “consumer advocate groups have tried, although unsuccessfully, to get the government of both the federal and state levels to mandate GMO disclosure”).

73. See *id.* at 160 (discussing a 1992 FDA policy statement).

74. Robertson, *supra* note 71, at 160; see also CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* [hereinafter FDA, *Guidance*] (Jan. 2001), available at <http://www.cfsan.fda.gov/~dms/biolabgu.html>.

75. Robertson, *supra* note 71, at 160; FDA, *Guidance*, *supra* note 74.

76. Robertson, *supra* note 71, at 160; FDA, *Guidance*, *supra* note 74.

77. Robertson, *supra* note 71, at 160; FDA, *Guidance*, *supra* note 74.

the label.”⁷⁸ Therefore, only if the genetically modified ingredient or food product falls within these four exceptions, which is not often, will the FDA require labeling that alerts the consumer of its presence.⁷⁹

Though the FDA has these required labeling guidelines in place, there is controversy as to when a food or ingredient is materially different and requires labeling.⁸⁰ Some consumers feel the line of materiality should be drawn when any change to the original food’s composition is made.⁸¹ This feeling is due to the changes that are made to the composition of many foods that the FDA may not deem material but may be material in the eyes of a consumer.⁸²

IX. HOW DO THE NEW INTERPRETATIONS TIE IN?

With such a steady increase in the amount of organic products being produced and purchased in the United States, maintaining the quality and integrity of those products is crucial to keep the organic industry thriving.⁸³ The new interpretations of the NOP have posed a serious threat to what the organic agriculture community had strived so hard to achieve throughout past years.⁸⁴ These directives undermined the whole scope of the NOP and attempted to tear down the walls that it had built so strongly since its existence.⁸⁵

The guidance statements and directives the USDA released, in a nutshell, “require[d] organic certifiers to certify farms that use unknown ingredients in pesticides, including materials of toxicological concern, and guidance statements that allow antibiotic use in cows that produce organic milk and artificial pre-

78. Robertson, *supra* note 71, at 160; FDA, *Guidance*, *supra* note 74.

79. See Robertson, *supra* note 71, at 160; see also FDA, *Guidance*, *supra* note 74.

80. See Robertson, *supra* note 71, at 159 (stating that “[w]hether genetic engineering constitutes a ‘material’ change to food has become the focus of a legal controversy”).

81. See *id.* at 168 (stating consumer advocate groups argue GMDs are materially different based on a hybrid of genetic material).

82. See Paul S. Naik, *Biotechnology Through the Eyes of an Opponent: The Resistance of Activist Jeremy Rifkin*, 5 VA. J.L. & TECH. 5, ¶118 (2000) (stating unprecedented genetic combinations are appearing in foods such as tomatoes, tobacco, and fish that should be deemed material but do not require labeling).

83. See Letter from Katherine T. DiMatteo, Executive Dir., Organic Trade Ass’n, to Ann M. Veneman, Sec’y, U.S. Dep’t of Agric. [hereinafter DiMatteo Letter] (May 17, 2004), available at <http://www.ota.com/pics/documents/Venemanltrhd.pdf>.

84. See Organic Trade Ass’n, *Victory for the Organic Industry! Secretary Veneman Directs AMS to Rescind all Four Documents* (July 23, 2004), <http://www.ota.com/response.html> (stating “there is no reason why now – when the sales of organic products are increasing overwhelmingly – the NOP should work at cross-purposes with the trade leading to the erosion of consumer confidence that forms the very foundation of the organic industry”).

85. See Press Release, *supra* note 10.

servatives in livestock feed supplements.”⁸⁶ Each of these issues has the potential to damage the organic industry. The effects that would have resulted from the guidance statements regarding the use of antibiotics in organic milk production could have been devastating.⁸⁷ Allowing the use of antibiotics and hormones in cattle, though under strict regulation, while allowing the milk produced to be labeled as organic would be damaging to the organic industry in a number of ways.⁸⁸ Most importantly, the trust and confidence that consumers have maintained in products labeled as organic would weaken.⁸⁹ These guidance statements will also diminish the integrity of the NOP, which places strict standards on keeping products as purely organic as possible.⁹⁰

There are a number of reasons why consumers would begin to lose faith in the NOP if such directives were implemented.⁹¹ Foremost, consumers would not truly know whether the products they are consuming are purely organic.⁹² “This weakened standard causes consumer confusion because of contradictions with organic dairy product claims regarding antibiotic and synthetic growth hormone use.”⁹³ In other words, dairy farmers that subject their cattle to antibiotics or synthetic growth hormones would still be able to label milk from those animals as organic, up to twelve months from the animal’s last dosage of either substance.⁹⁴ Because the labels would have remained the same regardless of whether the animals used to produce the products were treated with foreign substances, consumers could not be guaranteed that the products they purchase come from a truly organic source.⁹⁵ “[M]any organic labels say ‘no antibiotics, no hormones,’ and consumers expect that to mean the milk comes from cows raised without

86. *Id.*

87. See The Indep. Organic Inspectors Ass’n, *On the NOP Guidance and Directive Documents* [hereinafter NOP Directive], 13 THE INSPECTORS’ REP. 2, 11 (2004), available at <http://www.ioia.net/images/TIRArchive/V13n2part1.pdf>.

88. See Elaine Lipson, *USDA Directives May Jeopardize Organic Label*, THE NAT. FOODS MERCHANDISER (May 14, 2004), available at <http://www.naturalfoodsmerchandise.com/ASP/articleDisplay.asp?strArticleId=996&strSite=NFM Site&Screen=HOME>.

89. See *id.*; see also Ness, *supra* note 5, at A1 (stating “it could have the effect of weakening consumer confidence in the organic label”).

90. See Ness, *supra* note 5, at A1 (“The interpretations represent major changes that could threaten the integrity of the program...”).

91. See Press Release, *supra* note 10.

92. See *id.*

93. *Id.*

94. See *id.*

95. See Ness, *supra* note 5, at A1 (“it could have the effect of weakening consumer confidence in the organic label”); see also Eco-Labels, *USDA Verbally Agrees that Interpretations Made in Directives Should Not Stand* (Oct. 2004), <http://www.eco-labels.org/feature.cfm?FeatureID=8>.

such drugs....”⁹⁶ “If the [NOP] loses the confidence of the consumers and producers it was created to serve, it will fail.”⁹⁷

X. WHY WERE THE DIRECTIVES RESCINDED?

Despite the widespread public and industry outcry over the damage that could have been caused by the interpretations, there were other technical reasons for the directives not staying on the books.⁹⁸ One of the main arguments from the opposition to these directives was the fact that the USDA did not consult the National Organic Standards Board (“NOSB”), stakeholders in the organic trade, or the public before issuing the guidance statements.⁹⁹ Also, the language of the directives clearly contradicted the language of the NOP statute.¹⁰⁰

Not giving the NOSB, or the public in general, an opportunity to comment on the passage of the directives sparked much controversy among opposition to the action.¹⁰¹ The mission of the NOSB “is to assist the Secretary [of Agriculture] in developing standards for substances to be used in organic production. The NOSB also advises the Secretary on other aspects of implementing the national organic program.”¹⁰² The NOSB did not have any forewarning as to the issuance of the directives.¹⁰³ The board’s vice chairperson at the time, James Riddle, stated that “[t]he board was totally caught by surprise.”¹⁰⁴ Upon learning of the directives, Riddle and the NOSB immediately wrote to demand the directive’s rescission.¹⁰⁵ “The NOSB expressed its concern by concluding its 3-day meeting with the following statement; ‘The NOSB expresses its strong opposition to and concern with the National Organic Programs’ issuance of significant policy directive without consultation with or advance notice to the NOSB.’”¹⁰⁶

96. See Ness, *supra* note 5, at A1.

97. Letter from Steering Committee of the Organic Committee to Anne Veneman, Secretary, U.S. Department of Agriculture [hereinafter Veneman Letter] (June 22, 2004) available at http://www.rafiusa.org/whatsnew/Organicdirectives_letter.html.

98. See Press Release, *supra* note 10.

99. See *id.*

100. See *id.*

101. See Burros, *supra* note 4, at 5 (Some view the lack of consulting the public as “unbelievable and outrageous, far beyond anything they’ve done in the past”).

102. National Organic Standards Board Homepage, <http://www.ams.usda.gov/nosb/> (last visited Nov. 7, 2005).

103. See Press Release, *supra* note 10.

104. Ness, *supra* note 5, at A1.

105. *Id.*

106. NOP Directive, *supra* note 87.

The USDA did not believe it was required to consult the NOSB or to seek public comment on the issuance of the directives.¹⁰⁷ Opposition surprised the USDA's deputy administrator, Barbara Robinson, who is in charge of the NOP.¹⁰⁸ Some of the opposition felt that "they were not clarifications of existing regulations but new policy."¹⁰⁹ Robinson believed the "department is not creating new rules but establishing the limits of existing regulations..., so it is not required to seek public comment or to consult with the National Organic Standards Board."¹¹⁰ However, some believe the lack of consultation with others violated administrative law.¹¹¹ For instance, Jean Halloran, director for the Consumer Policy Institute of Consumers Union, believes that "the law prohibits such changes unless they are recommended by the standards board and have been subjected to public comment."¹¹²

The law that governs such actions is the Administrative Procedures Act.¹¹³ According to this act:

"[T]he agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose."¹¹⁴

However, also within this rule is an exemption for interpretations of rules and regulations:

Except when notice or hearing is required by statute, this subsection does not apply—(A) to *interpretative* rules, general statements of policy, or rules of agency organization, procedure, or practice; or (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.¹¹⁵

107. See Burros, *supra* note 4, at 5 (Barbara Robinson, deputy administrator of Agricultural Marketing Services, which is in charge of the [NOP], says the "department is not creating new rules but establishing the limits of existing regulations..., so it is not required to seek public comment...).

108. See *id.*; see also Ness, *supra* note 5, at A1.

109. NOP Directive, *supra* note 87, at 10; accord Ness, *supra* note 5, at A1.

110. Burros, *supra* note 4, at 5; see also Veneman Letter, *supra* note 97.

111. See Burros, *supra* note 4, at 5.

112. *Id.*

113. 5 U.S.C. § 553 (2003).

114. *Id.* at § 553(c).

115. *Id.* at § 553(b) (emphasis added).

The guidance statements released by the USDA have been construed as interpretations, clarifications, and directives with the force of law.¹¹⁶ Barbara Robinson herself said that “these are not interpretations.”¹¹⁷ If the person in charge of the NOP believes these are not interpretations, then they would not fall under one of the exceptions in the Administrative Procedures Act.¹¹⁸ In other words, the directives would need to be subject to public comment before the USDA could implement them.¹¹⁹ Robinson was, in effect, contradicting herself when she stated that she did not believe the public needed to be consulted while at the same time stating they were not interpretations of the rules.¹²⁰ However these statements are defined, the public, as well as the NOSB, was distraught that they were not included in the decision-making processes involved with issuing these statements.¹²¹

Other than the lack of consultation with the NOSB or the public, the new directives had problems with the NOP statute itself. For instance, the new antibiotic policy somewhat “contradicts the NOP regulation, section 205.238.c.1, which states, “The producer of an organic livestock operation must not sell, label or represent as organic any animal or edible product derived from *any* animal treated with antibiotics.””¹²² Another section to the NOP states that “livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching.”¹²³ The former section is a bit more lenient on the ability to label milk as organic, which is why the USDA chose it instead of section 205.236(a).¹²⁴ In essence, the USDA found that milk is not considered an edible product derived from an animal as pertaining to section 205.238.¹²⁵ However, it is consistent with the conversion for dairy animals. As long as conversion is allowed, there is no way to restrict management of the dairy animals prior to conversion. It’s the regulation itself that is inconsistent.¹²⁶

116. See Lipson, *supra* note 88 (“All of these [directives] are what is in the regulations and what is enforceable in a court of law”); see also Ness, *supra* note 5, at A1 (“The statements simply say what is enforceable under the existing regulation and statute and what is not”).

117. Lipson, *supra* note 88.

118. See 5 U.S.C. at § 553.

119. See *id.* at § 553(c).

120. See Lipson, *supra* note 88.

121. See *id.*

122. See Press Release, *supra* note 10 (emphasis added); see also NOP Directive, *supra* note 87, at 11.

123. NOP, 7 C.F.R. § 205.236(a) (2005).

124. See NOP Directive, *supra* note 87, at 11.

125. *Id.*

126. *Id.* at 11, 26.

The main problem with allowing dairy cattle to be treated with antibiotics and eventually return to the herd is that it “promotes the continuous introduction of conventionally raised dairy cows into organic dairy herds.”¹²⁷ Therefore, these directives indicated “anything that happens before the transition period is essentially ‘erased’ with regard to production of organic milk.”¹²⁸ In other words, all treatments, such as antibiotics or hormones, will be negated and forgotten about after a year has passed.¹²⁹ These directives are therefore “in conflict with existing organic regulations which require dairy replacement cows to be raised as organic from the last third of gestation.”¹³⁰ Essentially, a pregnant cow must be fed with 100 percent organic feed and must stay antibiotic and hormone-free for about the last ninety days of its pregnancy.¹³¹ Taking such action would ensure the calf is born fully organic, allowing its products to be immediately labeled as organic, be it meat or milk.¹³²

Whenever a herd is converted, however, producers must raise all dairy animals from the last third of gestation in accordance with applicable standards set forth in the OFPA and the final rule. The prefatory comments state that the conversion provision cannot be used routinely to bring nonorganically raised animals into an organic operation. It is a one-time opportunity for producers working with a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.¹³³

However, meat from the offspring born to a conventional cow, even if the mother was fed organically for the last third of her gestation, can never be labeled as organic.¹³⁴ The directives allow a non-organic cow to birth an organic calf and permit the mother to be treated with any drug, as long as it is not in the last third of her gestation period.¹³⁵

127. Press Release, *supra* note 10.

128. NOP Directive, *supra* note 87, at 11.

129. *See id.*

130. Press Release, *supra* note 10.

131. *See* NOP, *Guidance Statement*, *supra* note 11; *see also* Cent. Mo. Univ. of Mo. Extension, *Twenty Ways to Wean More Pounds of Beef*, 5 AG CONNECTION 10 (1999), available at <http://outreach.missouri.edu/agconnection/newsletters/is-99-10.htm> (“The cow’s gestation period averages 282 days but ranges from 278 to 292 days”).

132. *See* NOP, *Guidance Statement*, *supra* note 11.

133. Harrison M. Pittman, *A Legal Guide to the National Organic Program*, THE NAT’L AGRICULTURAL LAW CTR. 20 (Mar. 2004), available at http://nationalaglawcenter.org/assets/articles/pittman_organicprogram.pdf (citation omitted).

134. *See* NOP, *Guidance Statement*, *supra* note 11.

135. *See id.*

XI. CONCLUSION

The organic industry was built and thrives on the principle of consistent, uniform standards for agricultural products.¹³⁶ When that principle is threatened by the government entity created to protect it, the industry's delicate structure can crumble rapidly. Consumers of organic produce and dairy products expect the producers they buy from to meet all strict standards required by the NOP and the USDA.¹³⁷ Consumers should see the USDA stamp on the label and know the product is free from all nonorganic treatment and that it was produced under accepted organic management practices. A loss of consumer trust and confidence in the organic industry will bring the whole program back to square one, requiring it to rebuild and restructure its standards to regain that confidence.

The interpretations and directives released by the USDA would do nothing more than tear down what has taken so long to build. Allowing for cows to be treated with hormones and antibiotics, and later allowing them to be labeled as organic, goes against the organic agricultural industry's position.¹³⁸ However, the strong voice of those adversely affected by these interpretations came through with overwhelming volume.¹³⁹ These people were unwilling to allow the interpretations to hit the books without being consulted on their substance and predicted effect.¹⁴⁰ The vast number of letters addressed to Secretary of Agriculture, Ann Veneman, that flooded in is a strong indicator of how the organic public reacted to the USDA's announcement.¹⁴¹ The organic industry has grown to be such a large part of agriculture in the United States.¹⁴² It is time for it to be taken more seriously and given more weight when decisions are made concerning its

136. See generally NOP, 7 C.F.R. § 205.236(a) (2005).

137. See Laura Everage, *An Update on Organics*, 25 GOURMET RETAILER 3, 99-101 (2004).

138. See NOP, 7 C.F.R. at § 205.236(a).

139. See DiMatteo Letter, *supra* note 83; see also Letter from R. David Pittle, Sr. Vice President, Technical Policy, Consumers Union, et. al, to Anne Veneman, Sec., U.S. Dept. of Agric. Concerning Organic Directives [hereinafter Pittle, Sr. Letter] (May 5, 2004), available at http://www.consumersunion.org/pub/core_food_safety/001216.html; Letter from Michael Sligh, Co-Chair, Organic Committee, National Campaign for Sustainable Agriculture, et. al., to Anne Veneman, Sec., U.S. Dept. of Agric. Concerning Organic Directives [hereinafter Sligh Letter] (June 22, 2004), http://www.rafiusa.org/whatsnew/Organicdirectives_letter.html.

140. See DiMatteo Letter, *supra* note 83; see also Pittle, Sr. Letter, *supra* note 139; Sligh Letter, *supra* note 139.

141. See DiMatteo Letter, *supra* note 83; see also Pittle, Sr. Letter, *supra* note 139; Veneman Letter, *supra* note 97.

142. See Everage, *supra* note 137, at 99 ("The organic food segment is breaking all the records. Boasting annual sales of nearly \$6.6 billion and growth rates of at least 20 percent annually throughout the 1990's, it is one of the fastest growing in the food industry and industry analysts predict it will not slow down").

regulation and operation. It seems the USDA learned a valuable lesson in April 2004. The organic industry does not merely consist of the farmers and producers, but the consumers play just as large of a role in its success. When all of these voices are combined in defense of their livelihoods, the organic community is essentially sending its own guidance statement to the USDA, stating that the organic industry's strict standards are taken very seriously and should not be altered without the consultation and consent of all affected.¹⁴³ Although the interpretations and directives have been taken off the books, there remains the chance that similar actions will be taken by the USDA, but it is unlikely they will be taken without prior approval from all those affected.

143. See DiMatteo Letter, *supra* note 83; see also Pittle, Sr. Letter, *supra* note 139; Veneman Letter, *supra* note 97.