Food, Farming, and Sustainability

Readings in Agricultural Law

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crops, other countries adopt genetic engineering technology, and more GE traits are incorporated into existing and new crops.

The higher costs associated with GE seeds are not always offset financially by lower production costs or higher yields, the report notes. For example, farmers in areas with fewer weed and pest problems may not have as much improvement in terms of reducing crop losses. Even so, studies show that farmers value the greater flexibility in pesticide spraying that GE crops provide and the increased safety for workers from less exposure to harmful pesticides.

The economic effects of GE crops on farmers who grow organic and conventional crops also need further study, the report says. For instance, organic farmers are profiting by marketing their crops as free of GE traits, but their crops' value could be jeopardized if genes from GE crops flow to non-GE varieties through cross-pollination or seed mingling.

Farmers have not been adversely affected by the proprietary terms involved in patent-protected GE seeds, the report says. However, some farmers have expressed concern that consolidation of the U.S. seed market will make it harder to purchase conventional seeds or those that have only specific GE traits. With the exception of the issue of seed industry consolidation, the effects of GE crops on other social factors of farming—such as labor dynamics, farm structure, or community viability—have largely been overlooked, the report says. More research is needed on the range of effects GE crops have on all farmers, including those who don't grow GE crops or farmers with less access to credit. Studies also should examine impacts on industries that rely on GE products, such as the livestock industry.

Research institutions should receive government support to develop GE traits that could deliver valuable public benefits but provide little market incentive for the private sector to develop. Examples include plants that decrease the likelihood of off-farm water pollution or plants that are resilient to changing climate conditions. Intellectual property that has been patented in developing major crops should be made available for these purposes whenever possible.

D. The Labeling of Genetically Engineered Food Products

1. General Principles

The FDA has consistently affirmed its adherence to the principle that genetically engineered products should be regulated only according to the specific features of the product and not the process by which the product was created. Under this principle, many genetically engineered products have been approved as food products. Indeed, it is estimated that 70% of all processed U.S. foods are likely to contain some genetically engineered ingredients, due primarily to the high incidence of genetically modified corn and soybeans.

However, the widespread consumption of genetically engineered products does not necessarily mean that there the same widespread level of consumer support for genetic

engineering. The FDA has long expressed the concern that consumers have unfounded fears about genetic engineering, despite FDA's approval of them.

These two factors support FDA's opposition to any special labeling of food containing genetically engineered ingredients or produced with the aid of genetically engineered products. FDA's concern about consumer fear also explains FDA's hesitancy to allow the voluntary labeling of products as not containing genetically engineered ingredients. FDA has often stated that labeling a food as developed without genetic engineering implies that such food is superior, and as such is misleading to the consumer. Restricting the labeling of foods in this way has proven more controversial than FDA's decision to not requiring the labeling of genetically engineered foods.

FDA's policy is explained in the following Industry Guidance. This document was released in January 2001 and noticed in the Federal Register at 66 Fed. Reg. 4839 (Jan. 18, 2001). It has never been made final nor withdrawn. It represents current FDA labeling policy.

Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance

January 2001

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

This draft guidance represents FDA's current thinking on voluntary labeling of foods indicating whether foods have or have not been developed using bioengineering. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA's Good Guidance Practices (65 FR 56468, September 19, 2000).

BACKGROUND

In the Federal Register of May 29, 1992 (57 FR 22984), FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy). The 1992 policy applies to foods developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology (which is often referred to as "genetic engineering" or "biotechnology"). This guidance document refers to foods derived from plant varieties that are developed using rDNA technology as "bioengineered foods." In addition, because the Federal Food Drug, and Cosmetic Act (the act) defines food as articles used for food or drink for man or other animals, this guidance document applies to animal feeds as well as to human foods. The 1992 policy provides guidance to industry on scientific and regulatory issues related to bioengineered foods and solicited written comments from interested persons. The policy includes guidance on questions to be answered by developers of foods from new plant varieties, to ensure that the new products are safe and comply with applicable legal requirements. It also encourages continuation of the general practice of the food industry to consult with the agency about the safety of new foods, e.g., bioengineered foods.

In the 1992 policy, FDA also addresses the labeling of foods derived from new plant varieties, including plants developed by bioengineering. The 1992 policy does not estab-

lish special labeling requirements for bioengineered foods as a class of foods. The policy states that FDA has no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

To fully understand the agency's mandate and authority in requiring labeling of foods, one must refer to the Federal Food, Drug, and Cosmetic Act (the act) to determine the extent to which the agency is charged with governing labeling of foods. Section 403 governs the labeling of foods. Under section 403(a)(1), a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act provides additional guidance on how labeling may be misleading. It states that labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. While the legislative history of section 201(n) contains little discussion of the word "material," there is precedent to guide the agency in its decision regarding whether information on a food is in fact material. Historically, the agency has generally interpreted the scope of the materiality concept to mean information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: 1) pose special health or environmental risks (e.g., warning statement on protein products used in very low calorie diets); 2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).

Although the 1992 policy does not require special labeling for bioengineered foods, the agency advised in that policy that labeling requirements that apply to foods in general also apply to foods produced using biotechnology. Section 403(i) of the act requires that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, under section 201(n), the label of the food must reveal all material facts about the food. Thus:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.
- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

In the Federal Register of April 28, 1993 (58 FR 25837), the agency requested data and information on certain labeling issues that had arisen from the labeling guidance in the 1992 policy. In 1999, the agency announced that it would hold three public meetings (64 FR 57470; October 25, 1999). The purpose of those meetings was for the agency to share

its current approach and experience over the previous five years regarding bioengineered foods, to solicit views on whether FDA's policies should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. The agency received more than 50,000 written comments about its policy regarding safety and labeling of bioengineered foods. The theme related to labeling in those comments and the testimony at the meetings was that there are very strongly held but divergent views as to whether bioengineered foods should be required to bear special labeling. However, there was general agreement that providing more information to consumers about bioengineered foods would be useful. A number of comments supported the need for guidance from FDA regarding appropriate ways that industry could voluntarily provide information on a food label about bioengineering.

FDA has reviewed information in the comments received in response to the 1992 policy and the 1993 information request as well as the comments from the 1999 meetings. Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food. However, these comments did not provide data or other information regarding consequences to consumers from eating the foods or any other basis for FDA to find under section 201(n) of the act that such a disclosure was a material fact. Many of the comments expressed concern about possible long term consequences from consuming bioengineered foods, but they did not contend that any of the bioengineered foods already on the market have adverse health effects. The comments were mainly expressions of concern about the unknown. The agency is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act. FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods.

The agency is providing the following guidance to assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients. While the use of bioengineering is not a material fact, many consumers are interested in the information, and some manufacturers may want to respond to this consumer desire. The guidance was developed using information from the comments and from focus groups, as well as other resources, and is intended to help ensure that labeling is truthful and not misleading.

GUIDANCE

In determining whether a food is misbranded, FDA would review label statements about the use of bioengineering to develop a food or its ingredients under sections 403(a) and 201(n) of the act. 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. Under section 201(n), both the presence and the absence of information are relevant to whether labeling is misleading. That is, labeling 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. In determining whether a statement that a food is or is not genetically engineered is misleading under sections 201(n) and 403(a) of the act, the agency will take into account the entire label and labeling.

Statements about foods developed using bioengineering

FDA recognizes that some manufacturers may want to use informative statements on labels and in labeling of bioengineered foods or foods that contain ingredients produced

from bioengineered foods. The following are examples of some statements that might be used. The discussion accompanying each example is intended to provide guidance as to how similar statements can be made without being misleading.

- "Genetically engineered" or "This product contains cornmeal that was produced using biotechnology."

The information that the food was bioengineered is optional and this kind of simple statement is not likely to be misleading. However, focus group data indicate that consumers would prefer label statements that disclose and explain the goal of the technology (why it was used or what it does for/to the food). Consumers also expressed some preference for the term "biotechnology" over such terms as "genetic modification" and "genetic engineering."

- "This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat."

This example includes both required and optional information. As discussed above in the background section, when a food differs from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference. Because this soybean oil contains more oleic acid than traditional soybean oil, the term "soybean oil" no longer adequately describes the nature of the food. Under section 403(i) of the act, a phrase like "high oleic acid" would be required to appear as part of the name of the food to describe its basic nature. The statement that the soybeans were developed using biotechnology is optional. So is the statement that the reason for the change in the soybeans was to reduce saturated fat.

- "These tomatoes were genetically engineered to improve texture."

In this example, the change in texture is a difference that may have to be described on the label. If the texture improvement makes a significant difference in the finished product, sections 201(n) and 403(a)(1) of the act would require disclosure of the difference for the consumer. However, the statement must not be misleading. The phrase "to improve texture" could be misleading if the texture difference is not noticeable to the consumer. For example, if a manufacturer wanted to describe a difference in a food that the consumer would not notice when purchasing or consuming the product, the manufacturer should phrase the statements so that the consumer can understand the significance of the difference. If the change in the tomatoes was intended to facilitate processing but did not make a noticeable difference in the processed consumer product, a phrase like "to improve texture for processing" rather than "to improve texture" should be used to ensure that the consumer is not misled. The statement that the tomatoes were genetically engineered is optional.

- "Some of our growers plant tomato seeds that were developed through biotechnology to increase crop yield."

The entire statement in this example is optional information. The fact that there was increased yield does not affect the characteristics of the food and is therefore not necessary on the label to adequately describe the food for the consumer. A phrase like "to increase yield" should only be included where there is substantiation that there is in fact the stated difference.

Where a benefit from a bioengineered ingredient in a multi-ingredient food is described, the statement should be worded so that it addresses the ingredient and not the food as a whole; for example, "This product contains high oleic acid soybean oil from soybeans produced through biotechnology to decrease the level of saturated fat." In ad-

dition, the amount of the bioengineered ingredient in the food may be relevant to whether the statement is misleading. This would apply especially where the bioengineered difference is a nutritional improvement. For example, it would likely be misleading to make a statement about a nutritionally improved ingredient on a food that contains only a small amount of the ingredient, such that the food's overall nutritional quality would not be significantly improved.

FDA reminds manufacturers that the optional terms that describe an ingredient of a multi-ingredient food as bioengineered should not be used in the ingredient list of the multi-ingredient food. Section 403(i)(2) of the act requires each ingredient to be declared in the ingredient statement by its common or usual name. Thus, any terms not part of the name of the ingredient are not permitted in the ingredient statement. In addition, 21 CFR 101.2(e) requires that the ingredient list and certain other mandatory information appear in one place without other intervening material. FDA has long interpreted any optional description of ingredients in the ingredient statement to be intervening material that violates this regulation.

Statements about foods that are not bioengineered or that do not contain ingredients produced from bioengineered foods

Terms that are frequently mentioned in discussions about labeling foods with respect to bioengineering include "GMO free" and "GM free." "GMO" is an acronym for "genetically modified organism" and "GM" means "genetically modified." Consumer focus group data indicate that consumers do not understand the acronyms "GMO" and " GM" and prefer label statements with spelled out words that mean bioengineering.

Terms like "not genetically modified" and "GMO free," that include the word "modified" are not technically accurate unless they are clearly in a context that refers to bioengineering technology. "Genetic modification" means the alteration of the genotype of a plant using any technique, new or traditional. "Modification" has a broad context that means the alteration in the composition of food that results from adding, deleting, or changing hereditary traits, irrespective of the method. Modifications may be minor, such as a single mutation that affects one gene, or major alterations of genetic material that affect many genes. Most, if not all, cultivated food crops have been genetically modified. Data indicate that consumers do not have a good understanding that essentially all food crops have been genetically modified and that bioengineering technology is only one of a number of technologies used to genetically modify crops. Thus, while it is accurate to say that a bioengineered food was "genetically modified," it likely would be inaccurate to state that a food that had not been produced using biotechnology was "not genetically modified" without clearly providing a context so that the consumer can understand that the statement applies to bioengineering.

The term "GMO free" may be misleading on most foods, because most foods do not contain organisms (seeds and foods like yogurt that contain microorganisms are exceptions). It would likely be misleading to suggest that a food that ordinarily would not contain entire "organisms" is "organism free."

There is potential for the term "free" in a claim for absence of bioengineering to be inaccurate. Consumers assume that "free" of bioengineered material means that "zero" bioengineered material is present. Because of the potential for adventitious presence of bioengineered material, it may be necessary to conclude that the accuracy of the term "free" can only be ensured when there is a definition or threshold above which the term could not be used. FDA does not have information with which to establish a threshold level of

bioengineered constituents or ingredients in foods for the statement "free of bioengineered material." FDA recognizes that there are analytical methods capable of detecting low levels of some bioengineered materials in some foods, but a threshold would require methods to test for a wide range of genetic changes at very low levels in a wide variety of foods. Such test methods are not available at this time. The agency suggests that the term "free" either not be used in bioengineering label statements or that it be in a context that makes clear that a zero level of bioengineered material is not implied. However, statements that the food or its ingredients, as appropriate, was not developed using bioengineering would avoid or minimize such implications.

For example,

- "We do not use ingredients that were produced using biotechnology";
- "This oil is made from soybeans that were not genetically engineered"; or
- "Our tomato growers do not plant seeds developed using biotechnology."

A statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled. FDA has concluded that the use or absence of use of bioengineering in the production of a food or ingredient does not, in and of itself, mean that there is a material difference in the food. Therefore, a label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not bioengineered would be misleading. The agency will evaluate the entire label and labeling in determining whether a label statement is in a context that implies that the food is superior.

In addition, a statement that an ingredient was not bioengineered could be misleading if there is another ingredient in the food that was bioengineered. The claim must not misrepresent the absence of bioengineered material. For example, on a product made largely of bioengineered corn flour and a small amount of soybean oil, a claim that the product "does not include genetically engineered soybean oil" could be misleading. Even if the statement is true, it is likely to be misleading if consumers believe that the entire product or a larger portion of it than is actually the case is free of bioengineered material. It may be necessary to carefully qualify the statement in order to ensure that consumers understand its significance.

Further, a statement may be misleading if it suggests that a food or ingredient itself is not bioengineered, when there are no marketed bioengineered varieties of that category of foods or ingredients. For example, it would be misleading to state "not produced through biotechnology" on the label of green beans, when there are no marketed bioengineered green beans. To not be misleading, the claim should be in a context that applies to the food type instead of the individual manufacturer's product. For example, the statement "green beans are not produced using biotechnology" would not imply that this manufacturer's product is different from other green beans.

Substantiation of label statements

A manufacturer who claims that a food or its ingredients, including foods such as raw agricultural commodities, is not bioengineered should be able to substantiate that the claim is truthful and not misleading. Validated testing, if available, is the most reliable way to identify bioengineered foods or food ingredients. For many foods, however, particularly for highly processed foods such as oils, it may be difficult to differentiate by validated analytical methods between bioengineered foods and food ingredients and those obtained using traditional breeding methods. Where tests have been validated and shown to be reliable they may be used. However, if validated test methods are not available or

reliable because of the way foods are produced or processed, it may be important to document the source of such foods differently. Also, special handling may be appropriate to maintain segregation of bioengineered and nonbioengineered foods. In addition, manufacturers should consider appropriate recordkeeping to document the segregation procedures to ensure that the food's labeling is not false or misleading. In some situations, certifications or affidavits from farmers, processors, and others in the food production and distribution chain may be adequate to document that foods are obtained from the use of traditional methods. A statement that a food is "free" of bioengineered material may be difficult to substantiate without testing. Because appropriately validated testing methods are not currently available for many foods, it is likely that it would be easier to document handling practices and procedures to substantiate a claim about how the food was processed than to substantiate a "free" claim.

FDA has been asked about the ability of organic foods to bear label statements to the effect that the food (or its ingredients) was not produced using biotechnology. On December 21, 2000, the Agriculture Marketing Service of the U.S. Department of Agriculture (USDA) published final regulations on procedures for organic food production (National Organic Program final rule; 65 FR 80548). That final rule requires that all but the smallest organic operations be certified by a USDA accredited agent and lays out the requirements for organic food production. Among those requirements is that products or ingredients identified as organic must not be produced using biotechnology methods. The national organic standards would provide for adequate segregation of the food throughout distribution to assure that non-organic foods do not become mixed with organic foods. The agency believes that the practices and record keeping that substantiate the "certified organic" statement would be sufficient to substantiate a claim that a food was not produced using bioengineering.

References

1. Levy, A.S., Derby, B.M., "Report on Consumer Focus Groups on Biotechnology", Consumer Studies Team, Center for Food Safety and Nutrition, Food and Drug Administration, Washington, D.C., 2000.

Notes

1. The United States and a number of its trading partners have long disagreed about the labeling of genetically engineered ingredients in food products. This issue was debated at the May 2010 meeting of the Codex Alimentarius Commission's Committee on Food Labeling. The Codex Alimentarius commission was established by the Food & Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations. It is charged with developing international food standards to serve as a model for countries seeking to improve their food safety and quality standards and to serve as an export standard for trading nations. The Committee on Food Labeling proposed to allow different countries to adopt different positions for labeling genetically engineered foods, consistent with its current guidance. The U.S. through the USDA and the FDA, argued that allowing countries the option of mandatory labeling would suggest that genetically engineered foods were somehow different from other foods.

It was reported that the U.S. position was opposed by most countries, with only Mexico, Argentina, and Costa Rica supporting it. Moreover, 80 food, farm, and consumer

organizations including the Consumers Union, the Organic Trade Association, the Union of Concerned Scientists, and the Center for Food Safety sent a letter to FDA and USDA officials objecting to the U.S. position, arguing that it "could potentially create problems for food producers in the U.S. who want to indicate that their products contain no GE ingredients, including organic food, where genetic engineering is a prohibited method." They argued that it was inconsistent to oppose mandatory labeling as misleading when voluntary labeling in the U.S. is allowed and not considered misleading.

An agreement was not reached at the meeting.

2. Case Study: Bovine Somatotropin

Bovine somatotropin (bST), sometimes called bovine growth hormone or BGH, is a naturally occurring hormone produced in cattle. In the early 1990s, Monsanto used recombinant DNA technology to synthesize bST in large quantities, and in 1994 gained approval to market it as Prosilac, a cattle drug to be used to increase milk production.

The use of rbST has been controversial for a variety of reasons. Given the importance of milk as a staple food, particularly for children, the notion that extra hormones were being given to dairy cows raised concerns about the human health consequences. While most studies have refuted these concerns, they persist in the minds of many consumers.

Animal welfare concerns have been persistent and documented. The extra productivity comes at a health cost to the dairy cow, with studies indicating an increased incidence of mastitis, increased lameness, diminished body condition, and a shortened production life. Animal welfare concerns led to a ban on the use of rbST in Canada, Australia, New Zealand, much of Europe.

Opponents of rbST also raise their support of small family farm operations as another reason to oppose the use of the hormone. They argue that its use, most common and most profitable in the largest dairies, has resulted in the displacement of many of the smaller dairy operations. Over-production of milk is often cited as a factor in the financial problems of the dairy industry, although consumers benefit from reduced milk prices.

From its initial approval of rbST, the FDA has been unwavering in its approval. It has been steadfast in asserting that there is no human health risk associated with its use and that any animal welfare issues are insignificant. The impact of rbST on the dairy industry is a factor that is clearly outside of FDA's jurisdiction or concern.

With respect to the labeling of milk produced from cows who received rbST, consistent with its policy with respect to genetically engineered products, the FDA required no special labeling. It found "no measurable compositional difference between milk from cows that receive rbST and those that do not."

At least one state saw the issue differently. In 1994, Vermont enacted a statute requiring that "[i]f rBST has been used in the production of milk or a milk product for retail sale in the state, the retail milk or milk product shall be labeled as such." The International Dairy Foods Association sued, arguing that the statute was unconstitutional. The Second Circuit Court of Appeals agreed, holding that the statute violated the plaintiff's First Amendment rights. *International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996).

The more controversial issue, however, has been efforts to restrict the voluntary labeling of milk produced without the use of rbST. The right or lack thereof of dairies and

food processors to voluntarily label their food as "rbST-free" has spawned a variety of legal issues on both the state and federal levels.

The FDA's position on rbST labeling is set forth in an Interim Guidance published in the Federal Register in 1994. 59 Fed. Reg. 6279 (Notice) (Feb. 10, 1994). The following excerpt explains FDA's guidance.

Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin

Appropriate Labeling Statements

At the Federal level, statements about rbST in the labeling of food shipped in interstate commerce would be reviewed under sections 403(a) and 201(n) of the act. 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. Under section 201(n), both the presence and the absence of information are relevant to whether labeling is misleading. That is, labeling 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. This guidance is based on the use of the false or misleading standard in the Federal law, which is incorporated in many States' food and drug laws. States may also have additional authorities that are relevant in regulating such claims.

Because of the presence of natural bST in milk, no milk is "bST-free," and a "bST-free" labeling statement would be false. Also, FDA is concerned that the term "rbST free" may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as "from cows not treated with rbST" or in other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.

FDA believes such misleading implications could best be avoided by the use of accompanying information that puts the statement in a proper context. Proper context could be achieved in a number of different ways. 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. Proper 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. . . .

Notes

1. Oakhurst Dairy in Maine claims to be the first major U.S. dairy to reject the use of rbST in the production of its milk. Oakhurst included the following label on its milk cartons: "Farmers' Pledge: No Artificial Growth Hormone Used."

Monsanto sued Oakhurst in 2003, alleging that the label was misleading under the Food, Drug and Cosmetic Act and in violation of FDA standards. Oakhurst, capitalizing

on its status as a family-owned independent dairy up against a multinational corporation, held firm. The case generated a good deal of publicity and eventually settled. Oakhurst retained the right to put its Farmers' Pledge on its milk label but added a disclaimer: "FDA states: No significant difference in milk from cows treated with artificial growth hormone."

2. As a result of consumer demand, milk produced without rbST and labeled in a similar fashion is widely available, with most major supermarkets offering at least one brand. Nevertheless, some in the industry still seek to restrict the ability of dairies to segregate and label their milk in this manner. Missouri, Pennsylvania, and Ohio have all had recent laws proposed that would prohibit milk producers and processors from using labels that state the milk was produced from cows not treated with rbST.

3. The National Organic Standards prohibit the use of rbST in the production of milk that is labeled organic, as all "animal drugs, including hormones, to promote growth" are prohibited. 7 C.F.R. §205.237. Legal scholar Dean Jim Chen explores potential conflicts between the FDA's labeling policies and the National Organic Standards with respect to genetically modified foods in the article, *Beyond Food and Evil*, 56 DUKE L.J. 1581 (2007).

4. Monsanto sold its POSILAC Brand Dairy Product and Related Business to Elanco Animal Health, a division of Eli Lilly and Company in August 2008.

E. International Trade and Genetically Engineered Products

Tadlock Cowan & Geoffrey S. Becker
Agricultural Biotechnology: Background and Recent Issues
Congressional Research Report RL-32809
Feb. 13, 2009

* * *

The U.S. approach to biotechnology regulation contrasts with that of many major trading partners. For example, the European Union (EU), Japan, South Korea, New Zealand, and Australia either have or are establishing separate mandatory labeling requirements for products containing genetically modified ingredients; in many of these countries, consumer and official attitudes toward GE foods are more skeptical. Differing regulatory approaches have arisen at least partly because widely accepted international standards continue to evolve. Incidents, such as those discussed below, have been disrupted U.S. exports and contributed to trade tensions.

GE Rice

Although several GE varieties of rice have been approved for commercial use ("deregulated," in regulatory parlance), none have been marketed, although they have been planted on test plots in the United States. In August 2006, the Secretary of Agriculture announced that "trace amounts" of an unapproved variety of GE rice had been found in samples of the 2005 crop of U.S. long grain rice. The Secretary and other USDA officials sought to reassure the rice trade and consumers that the findings posed no human health, food safety, or environmental concerns.

D. The Labeling of Genetically Engineered Food Products

1. General Principles

Edit to Notes pages 608-609

Add the following new note on page 609:

2. Over the last couple of years several bills and ballot initiatives requiring the labeling of genetically engineered foods have been introduced. Several have been defeated including the California Right to Know Genetically Engineered Food Act Proposition 37, which was on the November 6, 2012 ballot in California as an initiated state statute. The California initiative would have required:

> Labeling on raw or processed food offered for sale to consumers if made from plants or animals with genetic material changed in specified ways. Prohibits labeling or advertising such food as "natural." Exempts foods that are: certified organic; unintentionally produced with genetically engineered material; made from animals fed or injected with genetically engineered material but not genetically engineered themselves; processed with or containing only small amounts of genetically engineered ingredients; administered for treatment of medical conditions; sold for immediate consumption such as in a restaurant; or alcoholic beverages.

This Act was defeated by a narrow margin of 51.41 percent to 48.59 percent. *See*, Statewide Summary by County for State Ballot Measures, Cal. Sec'y of State 100-02 (2012).

Millions of dollars have been spent to campaign and advertise against the labeling of genetically engineered food initiatives. For example, in Washington state, Monsanto contributed $5.4 million and the Grocery Manufacturers Association contributed roughly $11 million into fighting a ballot initiative for labeling genetically engineered foods. The initiative was defeated. *See,* Johnson and Gillam, Food Corporations Fight GMO Labeling Measure With Big Money, Huffington Post, (Jan. 23, 2014).

On June 25, 2013, Connecticut's Governor Dannel Malloy signed the first state law mandating the labeling of foods that contain genetically modified ingredients. However, this law will only go in to effect after four additional states, including one that borders Connecticut enacts similar mandatory labeling laws and any combination of northeastern states with a combined population of twenty million must pass similar mandatory labeling laws. *See*, Press Release, Dannel P. Malloy, Governor of Conn., Gov. Malloy and Legislative Leaders Announce Agreement on GMO Labeling Legislation (June 1, 2013), available at http://www.governor.ct.gov/malloy/cwp/view.asp?Q=525816&A=4010;%20Conn.%20Gen.%20Stat.%20%25C2%25A721a-92c(a)

On January 12, 2014, Maine Gov. Paul LePage signed a bill (L.D. 718) that will require labeling for foods containing genetically modified ingredients if at least five other states or a state with a population of at least 20 million passes similar legislation. Restaurants, alcoholic beverages and medical foods will be exempt from the labeling requirements. *See*, Reid Wilson, *Maine becomes second state to require GMO labels,* Washington Post, (January 10, 2014).

On May 8, 2014, Vermont lawmakers passed a bill (H.B. 112) requiring the mandatory labeling of foods made with genetically modified ingredients. The bill requires foods containing GM ingredients sold in retail outlets to be labeled as either "partially produced with genetic engineering," "produced with

genetic engineering," or "may be produced with genetic engineering." The legislation would also make it illegal to describe any food product containing GM ingredients as "natural" or "all natural." The legislation is expected to take effect July 1, 2016. *See*, Dana Ford and Lorenzo Ferrigno, *Vermont governor signs GMO food labeling into law* (May 8, 2014), CNN.com.

The Vermont GE Labeling Law has been constitutionally challenged by four food, beverage and business trade organizations, including the Grocery Manufactures Association. *Grocery Mfrs. Ass'n v. Sorrell*, No. 14-0117 (U.S. Dist. Ct., D. Vt., filed June 12, 2014). In April 2015, the district court judge denied a request for a preliminary injunction to suspend the law and also denied Vermont's motion to dismiss. A copy of the order is posted on the FFS Resources website. The plaintiffs appealed to the 2nd Circuit Court of Appeals, and an expedited appeal schedule has been set. Updates to the litigation can be found on the Vermont Attorney General's website at http://ago.vermont.gov/hot-topics/ge-food-litigation.php.

D. The Labeling of Genetically Engineered Food Products

2. Case Study: Bovine Somatotropin

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In 2008 Ohio enacted a state-wide ban prohibiting milk producers and processors from using labels stating "rbGH free," "rbST free," or "artificial hormone free" on dairy products produced by cows not treated with rbST. The International Dairy Foods Association and the Organic Trade Association filed suit and in 2010 the Sixth Circuit Court of Appeals struck down the law as unconstitutional, ruling the ban violated the milk producers and processors first amendment rights. See *International Diary Foods Ass'n v. Boggs*, 622 F.3d 628 (2010), available on the FFS Resources website.

E. International Trade and Genetically Engineered Products

The CRS report excerpted on pages 611-616 has been updated.

Tadlock Cowan, *Agricultural Biotechnology: Background and Recent Issues*, Cong. Res. Rep. No. RL-32809 (June 18, 2011). This report is posted on the FFS Resources website.