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Reexamining the Labeling for Biotechnology in Foods: The Species Connection

by

Margaret Gilhooley

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Margaret Gilhooley*

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* Professor, Seton Hall Law School; J.D., Columbia Law School. I appreciate the help of my research assistant Joan Karn and library assistance from Jeanne O'Connor.

I. INTRODUCTION

The Food and Drug Administration (FDA) recognizes that, in theory, through biotechnology "essentially any trait whose gene has been identified can be introduced into virtually any plant . . . ."[1] These genes may potentially be isolated from microbial, animal or plant sources.[2] The major uses of biotechnology to date in foods have involved agronomic uses that enhance yield or protect crops from pests or weeds. Some of these have involved gene transfers from the same source, such as the use of a recombinant version of a cow hormone to

1. Statement of Policy: Foods Derived from New Plant Varieties; Notice, 57 Fed. Reg. 22,984, 22986 (May 29, 1992) [hereinafter Statement of Policy].
2. *See id.*

increase milk production. Widespread crop protection uses involve the transfer of a bacterial pesticide gene to corn and a gene to enable soybeans to survive spraying with an herbicide.[3]

More novel uses of biotechnology are pending in addition to those that are theoretically possible. Some involve transfers from different plants to affect the taste and nutritional characteristics of the food itself. Golden Rice, for example, produces Vitamin A derived from a gene from a daffodil gene.[4] Sweet potatoes may be modified to contain amino acids.[5] In the past, field tests were even conducted on the transfer of fish genes to a tomato to provide protection from frost damage.[6] Biotechnology may also be used in animals in new ways, including to enhance the growth of salmon in fish farms.[7] FDA has stated that as a result of increased knowledge of the genome, biotechnology is "likely" to be used "to an increasingly greater extent" by plant breeders, and in some cases the products may present "more complex safety and regulatory issues."[8]

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3. *See* JORGE FERNANDEZ-CORNEJO & WILLIAM D. MCBRIDE, ECONOMIC RESEARCH SERVICE/USDA, ADOPTION OF BIOENGINEERED CROPS 4 (2002), *available at* http://www.ers.usda.gov/publications/aer810 (reporting that herbicide-tolerant soy and corn use reached 68% and 8-9% respectively, of crop acreage in 2001. Insect-resistant corn use reached 26% in 1999 and fell to 19% in 2000-01); *infra* Section IV.C.
4. *See* Raymond Formanek, Jr., *Proposed Rules Issued for Bioengineered Foods*, FDA CONSUMER, Mar-Apr. 2001, *available at* http://www.fda.gov/FDA/features/2001/201_food.html (citing development of rice by inserting genes from soil bacterium and two gene from a daffodil).
5. *See generally* Karen A. Goldman, *Labeling of Genetically Modified Goods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 718-19 (2000) (describing examples of the "'second generation'" genetically engineered foods).
6. *See* Statement of Policy, 57 Fed. Reg. at 22,986. Even though the plant has not been developed, the labeling of the food is relevant here to explore the issues on a theoretical level. For identification of field tests by public institutions on gene transfers from animals to plants for drug or food-related purposes, see Richard Caplan & Ellen Hickey, *Weird Science, The Brave New World of Genetic Engineering* (U.S. Public Interest Research Group 2000). A number are related to pest-protection and agronomic uses, such as tests on a transfer of a chicken gene to apples to resist fire blight, and a cow gene to sugarcane to develop a plant resistant to a disease-causing bacteria.
7. NATIONAL RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS 8 (National Academies Press 2002) (describing gene transfers presumably from the same animal to lower cholesterol in eggs, or to increase yield by cloning productive animals) [hereinafter NAS ANIMAL BIOTECHNOLOGY]. *See also* Associated Press, *New Type Pigs in the Future: Genetic Engineering Could Develop Porkers With Special Milk Traits*, ROCKY MOUNTAIN NEWS, Apr, 14, 1996, at 32A, *cited in* Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically-Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1219 n.21 (1998).
8. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 and 592) [hereinafter Premarket Notice]. The development of rice modified to express pro-vitamin A was cited as an example of "more complicated compositional changes being made

FDA has not required any special labeling on foods about the mere process of using biotechnology. Under its policy, labeling is needed, apart from safety risks, only if the resulting food differs in a "meaningful or uniform way" or "differs" in a way that the traditional name no longer applies.[9] The agency looks to is whether there are organoleptic differences in determining if there is a "material fact" that needs to be disclosed in the name.[10] The agency's position has been upheld in court challenges in cases.[11] Moreover, the effort by the state of Vermont to mandate disclosures about the use of cow growth hormone developed through biotechnology, based on consumer interest, was found to lack a substantial government interest and to be an unconstitutional form of compelled speech.[12] The agency, though, permits voluntary labeling that bioengineering has not been used when it does not misleadingly suggest a difference in safety.[13]

This Article examines whether the transfer of a gene from a different species should affect the need for labeling of the food. The complexities in developing a labeling framework are also explored. The best case for additional labeling is when a gene has been transferred from a different plant or animal species to a food to affect its taste or nutrition. Will it be sufficient that a new food identifies its new quality features, or should the name and labeling in some way indicate that the food has a gene from a different plant? One format explored here would be a specific reference to a plant as a source of a trait. If rice contained a sucrose gene, for example, the labeling would reflect that the food is "rice with a plant sweetener." Another format is to include the term "enhanced" in the name, by referring to "rice enhanced a with plant sweetener." With time and consumer familiarity, the enhanced term might become a shorthand way to indicate the addition of genes to a food of genes from another edible plant. When a gene from an animal or fish source is transferred to a plant, though,

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to food," ones involving multiple genes, that could be connected with "unintended changes." *Id.* at 4710.

Recently companies have been dropping projects involving the use of biotechnology to develop new crops because of the cost of obtaining agency approval and consumer resistance. See Narrow Path for new Biotech Crops, New York Times, C2 (May 20, 2004).

9. *See* Statement of Policy, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

10. *See* Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

11. *See* discussion *infra* Section III.B.

12. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

13. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001). *See infra* note 155; *Frankenstein Foods or Flavor Savors? Regulating Agriculture Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 301-03, 310-13 (2000) (discussing voluntary labeling and trust) [hereinafter Frankenstein Foods].

the labeling should indicate specifically that an animal or fish gene has been transferred.

The justification for the labeling explored here is the need to prevent deception about important changes that affect consumer's understanding of the identity of the food. If consumers do not expect foods to contain genes from a different species, a disclosure may be needed under an early Supreme Court case, *United States v. Ninety Five Barrels of More or Less Alleged Apple Cider Vinegar*.[14] The Court found a food to be mislabeled when a change was made in a constituent of the food, a change that did not affect the food's taste but which made the food differ from the popular and general understanding of "what [the food] really is."[15] The application of the deception theory to gene transfers from different species involves a generous but fair reading of this landmark precedent. The rationale is also different from the argument based simply on "consumer interest" about the mere use of biotechnology found wanting in the past litigation.[16]

The theory that underlies this paper, tied as it is to the need for labeling when a gene transfer makes a food "different," raises the complication of determining what makes a food "different." Gene transfers have occurred in plants for centuries through traditional plant breeding, with its modern extensions, with no labeling changes ordinarily needed.[17] Still, determining "difference" for purposes of labeling warrants consideration of whether a "wide cross" with a distant ancestor, made feasible in practice through biotechnology, should be considered the same as transfers using other extended techniques.

While the starting focus of this Article relates to gene transfers from a different species to affect the taste and nutrition characteristics of a food, the implications of the agronomic uses of biotechnology need to be recognized. The pesticide uses of biotechnology can involve gene transfers from different species, such as the transfer of a soil bacteria gene to corn. Plant pesticides could, in theory, be transferred to a different plant as a means to control pests. If consumers are deceived, absent disclosure, about transfers from a different species to affect a food's taste or nutrition, should the principle apply to agronomic uses? Special difficulties arise, though, in labeling agronomic uses, since the crops are often shipped as commodities. Chemical pesticides also have a special exemption from labeling as a chemical preservative, an exemption that may affect FDA's willingness, and its ability, to require labeling for the biotech pest protectors. Labeling solely the biotechnology use could provide an incentive for use of

14. 265 U.S. 438 (1924).
15. *Id.* at 443.
16. *See* discussion *infra* Part III.
17. *See* discussion *infra* subsection IV.A.2; Statement of Policy, 57 Fed. Reg. 22,984, 22984 (May 29, 1992).

chemical pesticides. While there is no fully satisfactory solution, a suitable approach would be a label disclosure that a food contains a "crop protector," whenever any type of pesticide or herbicide is used, but without a specification of the type.[18] The labeling would leave it to consumers to obtain more information from the seller of the food.

Lastly, the Article considers a new use of biotechnology, one that has a species connection, not because it involves a transfer from a different species but because the food developed through the process could alter the natural species. Notably, FDA is considering a request to allow a salmon growth hormone gene to be transferred to farm-raised salmon to enhance growth, but the use raises environmental concerns because of the potential impact on the wild salmon when some of the larger transgenic salmon escape. A report by the National Academy of Sciences found the environmental risk from transgenic fish to be the most important "science-based" concern.[19] Clearly, the key regulatory questions relate to whether the use should be permitted in light of this potential impact. This involves issues about the agency's authority to regulate environmental risk and the measures that might be taken to reduce the risk of escape. The other question noted here is whether labeling disclosures are appropriate, assuming the new use is permitted, to alert consumers of a consequence they would not expect, that consumption of the bioengineered form of the food could fundamentally change the natural unmodified form of the species. That labeling might indicate that measures have been required to minimize the risk that the enhanced salmon will escape and alter the wild salmon through interbreeding. That labeling is appropriate when the scope of the risk has important uncertainties that need further monitoring. The labeling would permit consumers to be involved in seeking alternatives to reduce the risk, including encouraging fish farm operators to be vigilant and to develop improved methods. Such an approach would give consumers an expanded role in risk decisionmaking. When the use of a food by consumers has a potential for a major change in the species itself, notice to consumers should be considered in developing an appropriate response. While the paper explores the legal rationale for requiring labeling under the existing law for this and the other recommendations, legislative action should also be considered.

Importantly, this Article does not deal with the debate about the safety of biotechnology for the existing uses or novel ones, an impor-

18. However, a more specific designation would be needed if the agronomic use involved the transfer of an animal or fish gene to a plant. *See* discussion *infra* subsection IV.A.2.

19. NAS ANIMAL BIOTECHNOLOGY, *supra* note 7.

tant matter that has received analysis elsewhere.[20] Environmental issues are also not the primary focus, apart from the potential for an impact on the unmodified species, a risk that may occur with the transgenic salmon.[21] The aim is to explore the extent to which labeling can be justified to prevent deception, assuming that the biotech food uses meet regulatory safety and environmental standards.[22] The paper also examines labeling policies under U.S. law, and does not seek to compare the policies that European countries have developed with respect to Genetically Modified (GM) Foods. The U.S. has, though, instituted a proceeding in the World Trade Organization against the European Union about its moratorium on genetically modified commodities.[23] The labeling policies in Europe have an impor-

20. For illuminating analysis of the safety issues, see Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J. L. REF. 403, 489 (2002) (suggesting a more precautionary approach on safety and criticizing FDA's reliance on "substantial equivalence" as the test when new uses of biotechnology require additional testing), and National Academy of Sciences, Genetically Modified Pest-Protected Plants 6, 7–10 (National Academies Press (2000)) [hereinafter NAS Pest Protected] (reporting that transgenic and conventional methods "have the potential to produce organisms of high or low risk" and the properties, not the process, should be the focus of risk assessments, and recommending ways to improve the health and related data). *Compare* Dan L. Burk, The Milk Free Zone: Federal and Local Interests in Regulating Recombinant bST, 22 COLUM. J. ENVTL. LAW 227 (1997) (defending scientific soundness of use in milk production and examining "socioscientific" disputes). The transfers from different species can make the safety assessments more complicated, as suggested in Premarket Notice Concerning Bioengineered Foods. *See* 66 Fed. Reg. 4706 (proposed Jan. 18, 2001).

21. Environmental issues are discussed, in regard to genetically engineered salmon, and are suggested as an additional ground for labeling. *See* discussion *infra* Section IV.D.

22. Of course, it is true that if any labeling is provided about the use of biotechnology to prevent deception, consumers may decide not to use the food for other reasons including unsubstantiated ones. That complication can arise with respect to other required labeling, such as ingredient labeling, but it is not a basis for dispensing with labeling disclosures that are needed.

23. *See* David Leonhardt, *Talks Collapse on U.S. Efforts to Open Europe to Biotech Foods, Washington to Urge World Trade Group to Act*, N.Y. TIMES, June 20, 2003, at A1 (noting that the U.S. negotiators viewed the E.U. effort as protectionist since the technology is made by U.S. companies); John W. Boscariol & Orlando E. Silva, *Genetically Modified Organisms at Center of Major WTO Dispute* THE LAWYERS WEEKLY 23 (Mar. 26, 2004); Frankenstein Foods, *supra* note 13. For background on the WTO procedures and on an earlier dispute between the U.S. and the E.U. about the use of hormones in beef, see Joanne Scott, *On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO*, in THE EU, THE WTO AND THE NAFTA, TOWARDS A COMMON LAW OF INTERNATIONAL TRADE 125 (2000).

The European Union has recently allowed the sale of corn developed through biotechnology, accompanied by labeling, but the change is not expected to stop the U.S. from pursing its proceeding with the WTO. *EU Moves to Soften Its Stance on Biotech Corn*, WALL ST. J., INTERNATIONAL WORLD WATCH, May 20, 1994 (available at 2004 WL-WSJ 56929710).

tant impact in the ability of U.S. producers to sell modified foods.[24] The pendency of the dispute with Europe may lead to some greater interest in understanding the U.S. labeling policy and how it applies to novel types of food, the topic here.

To pursue the analysis, Part II will provide background on FDA regulatory authority with respect to the safety of biotechnology when used in developing new plant varieties or in animal drugs that promote growth and yield. The discussion will also outline the regulatory responsibilities of the Environmental Protection Agency (EPA) with respect to pesticide and herbicide uses. FDA's authority to require consumer labeling on foods will be described, along with the basis for the agency's policy of providing labeling about the use of biotechnology in limited circumstances.

Part III examines the legal challenges that sought, unsuccessfully, to require FDA to mandate additional labeling. The constitutional challenge that invalidated Vermont's effort to require labeling about biotechnology in milk production will also be considered. The discussion will then consider the deception theory as the basis for reflecting in the labeling of a food when there are gene transfers from different species. That theory has a different premise from the consumer interest found to be insufficient in the prior cases.

Part IV explores the type of labeling that might be adopted under the deception theory for the novel uses of food biotechnology with a species connection. The examination covers labeling of foods with genes from different species to achieve quality or nutritional effects, the special issues for pest-protected uses, and the appropriateness of labeling transgenic salmon with respect to the potential of altering the wild form of the species.

Part V concludes with some general observations on the need for labeling of foods with genes from different species and the role of consumers in making choices. Better labeling is needed to ensure that consumers do not perceive food as being something different than they believed it to be.

A note is appropriate on the terminology used here. FDA has referred to foods as being "bioengineered," and in Europe foods are referred to as genetically modified organisms (GMO). The National Academy of Science referred to biotechnology, in the case of animal drugs, a term that is also used for pharmaceuticals and in the press for stock market reports. This paper generally refers to biotechnology because it may be the term most familiar to the public, but the other terms are also used in context.

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24. *See* McGarity, *supra* note 20, at 502.

II. REGULATORY FRAMEWORK FOR BIOTECHNOLOGY IN FOODS

The authority to regulate the use of biotechnology uses in food is divided. Discussed first is FDA's safety authority with respect to new plant varieties and animal drugs for growth promotion. EPA's authority with respect to pesticides will be noted before turning to an elaboration of FDA's position on consumer labeling about biotechnology.

A. FDA Safety Authority with Respect to New Plant Varieties

1. FDA Basis for Safety Regulation: The 1992 Policy Statement

FDA's authority over food safety extends to new plants, even those developed by traditional plant breeding methods such as hybridization. New substances added to foods need approval in advance from the agency in the form of a regulation authorizing the "food additive," unless the substance is Generally Recognized As Safe (GRAS).[25] FDA ordinarily regards new plant varieties developed through traditional plant breeding and its extensions as GRAS and, thus, as excluded from being food additives that need prior approval

In a 1992 Policy Statement, FDA applied a similar approach to new plant varieties developed through biotechnology. A gene added through biotechnology was considered an "added" substance in the food.[26] The addition would not be considered to be a food additive for which pre-market approval was needed, though, simply because the transfer occurred through bioengineering. In determining whether the substance was recognized as safe, the agency would look instead at the transferred material and its expression products.[27] When the substances produced in the food is "already present in the food at generally comparable levels," the agency believed there was "unlikely to be a safety question sufficient to call into question the presumed GRAS status of such naturally occurring substances."[28] FDA identified transfers from known toxicants, activation of silent pathways, and allergencity as having a potential for concern, but also considered measures such as field testing practices as relevant in showing

25. Statement of Policy, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992). As a GRAS substance, the food would fall outside the definition of a food additive. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(s), 348 (2003). If an unexpected safety problem occurred during use, FDA would take court or other action under its basic authority over deleterious substance added to a food under 21 U.S.C. §342(a) (2000). *See* Statement of Policy, 57 Fed. Reg. at 22,989. A "public hearing" is available with respect to objections to the issuance of regulations for food additives. 21 U.S.C. § 348(f) (2000).

26. *See* Statement of Policy, 57 Fed. Reg. at 22,990.

27. *Id.*

28. *Id.*

safety.[29] There have been critics, though, of the "substantial equivalence" approach used by FDA and other agencies to determine that a bioengineered variety is as safe as the unmodified form.[30] FDA also stated that developers of new bioengineered varieties "should" consult with FDA before use of the product, a practice that the industry is believed to have followed.[31]

2. *Emergent Uses and FDA's 2001 Proposal for Pre-Market Notice*

In 2001, FDA reported that most uses of biotechnology in foods involved agronomic uses that increase yield,[32] but that the use of biotechnology is increasing as a means to affect a food's nutrition, flavor, or preservation.[33] The agency noted that some field trials underway involved changes intended "to modify the food itself,"[34] and were ones "more likely" to raise regulatory issues.[35] Moreover, an increasing number of substances being tested for introduction into food are ones "that cannot be introduced by traditional breeding," and create a "greater likelihood" that the change is so significant that pre-market approval for safety is needed.[36] As a result, FDA proposed to mandate consultation with FDA about the regulatory issues that can arise with respect to new biotechnology uses and the need for pre-market approval.[37]

That proposal illustrates a tension with respect to the regulatory framework for GRAS determinations. If foods are GRAS, the producer has been considered legally entitled to market the food, subject to the risk that the agency will take enforcement action to have a court resolve the dispute about GRAS status.[38] The proposal, though, would require notification rather than simply letting producers to take the

29. *Id.* at 22,987.
30. *See* McGarity, *supra* note 20, at 432-38.
31. *Id.* at 22,991; Premarket Notice, 66 Fed. Reg. 4706, 4710 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592).
32. *Id.* at 4711. FDA identified these as including "herbicide resistance, insect and virus resistance, delayed ripening or softening, male sterility, or fertility restorer and high phosphorus availability." *Id.* at 4712.
33. Statement of Policy, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).
34. Premarket Notice, 66 Fed. Reg. at 4711. These included modification of protein quality, increased carotenoid solids, altered fiber, and increased fruit sweetness. *Id.* at 4712.
35. *Id.* at 4711.
36. *See id.* at 4709. See Panel Sees No Unique Risk From Genetic Engineering, New York Times, A13 ((July 26, 2004) (reporting the findings of a penal of the National Academy of Sciences that bioengineered foods do not pose risks that cannot arise with conventional breeding, but recommending post-market surveillance for some changes that may have possible adverse health effects).
37. *See id.* at 4712-13.
38. *See* Statement of Policy, 57 Fed. Reg. at 22,989.

litigation risk. The agency has not issued a final rule, but the voluntary cooperation of the industry is likely to lead to continued advance consultation with the agency. The supporting field tests, and comments on the testing, are also in practice made public on the FDA home page, increasing the transparency of the process for the public and the scientific community.[39] The most notable aspect of the proposal in this setting, though, rests with the agency's projection that the emerging uses may have differences from earlier ones. These developments may have implications for labeling as well as GRAS determinations.

B. FDA Safety Regulation for Animal Biotechnology: Growth and Yield Promotion[40]

FDA also regulates the administration of biotech products used on food-producing animals under its authority over animal drugs that are used to affect the structure and function of the animal as well as those that are used to prevent or treat disease.[41] Pre-market approval is required for the license to use a new animal drug.[42] The transparency of the approval process is reduced, though, by the confidential status of submissions.[43] One of the earliest forms of biotechnology approved by FDA involved the use a recombinant form of a hormone naturally produced in small amounts by cows to stimulate milk production. The biotech version of a hormone found in cows, rBST, enabled injections to induce further production for commercial use.[44] FDA's approval of rBST without requiring labeling set the stage for some of the court challenges discussed below. The use of growth hormones for farm-raised salmon also involves the use of an animal drug to affect the salmon and necessitates FDA pre-market approval. The environmental issues raised by the effort to obtain approval will be discussed in Section IV.D.

C. Pest and Crop Protection Uses of Biotechnology

A major category of biotechnology used in food involves a gene transfer into a plant that provides protection for the food from insects during growth. The Environmental Protection Agency (EPA) regu-

39. Frankenstein Foods, *supra* note 13, at 274-75.
40. For general background on animal raising, even apart from the use of biotech products, *see* Michael Pollan, *This Steer's Life*, NEW YORK TIMES MAGAZINE, Mar. 31, 2002, at 44.
41. 21 U.S.C. § 355 (2003).
42. 21 U.S.C. § 360(b) (2000). Procedurally, the matter approval involves a formal adjudication, since the applicant is entitled to a hearing by statute.
43. *Future Fish, Issues on the Science and Regulation of Transgenic Fish* [PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY] 52 (2002) [hereinafter Future Fish].
44. *See* Burk, *supra* note 20, at 230-31.

lates the safety of all pest control products, both chemical and biotech, under its authority over "chemical pesticides,"[45] including those used in foods. EPA now designates the biotechnology form of pest protection, not as a "Plant Pesticide," as it previously had done, but as "Plant-Incorporated Protectants."[46] FDA recognizes that EPA addresses under its authority "the food safety issues associated with the pesticide."[47] FDA enforces the EPA tolerances for pesticide in foods. The Department of Agriculture has a separate, but debated, responsibility to ensure that farmers meet restrictions set by EPA to guard against the development of pesticide resistant species as the result of new biotech pesticides.[48]

EPA has found several pest-protectants to be safe for use in plants, through licensing approval or exemptions, including the use of *Bacillus thuringiensis (Bt)* in soybeans.[49] Obtaining approvals for a new chemical pesticide often costs substantially more than obtaining permission for use of a transgenic pest-protected plant, making transgenic plants more attractive.[50] EPA also regulates herbicides and herbicide-resistant plants including those used for food.[51] The category includes Roundup Ready soybeans that have a gene that makes it possible for farmers to spray the crop with the herbicide Roundup to control weeds without harming the soybeans.[52]

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45. *See* Federal Environmental Pesticide Control Act, 7 U.S.C. §136-136y (1982); United States Environmental Protection Agency, *EPA's Regulation of Biotechnology for Use in Pest Management* (2003), *available at* http://www.epa.gov/pesticides/biopesticides/reg_of_biotech/eparegofbiotech.htm. For analysis of legal framework and implementation, see McGarity, *supra* note 20, at 464-73. For analysis of the scientific issues, see NAS Pest-Protected, *supra* note 20, at 33.

46. Regulations Under the Federal Insecticide, Fungicide and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 40 C.F.R. pt. 174 (2004).

47. Statement of Policy, 57 Fed. Reg. 22,984, 23,005 (May 29, 1992).

48. *See* Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L. J. 297, 307, 320 (2002) (criticizing divided responsibilities and recommending a single regulatory authority), and Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WILLIAM & MARY L. REV. 2167, 2249 (2004) (proposing a new regulatory framework that would assign regulatory authority based upon each agency's regulatory expertise, a change that would leave FDA responsible for direct health risks from bioengineered food and drug products, but make EPA responsible for environmental risks).

49. *See* Goldman, *supra* note 5, at 747-55.

50. NAS Pest-Protected, *supra* note 20, at 224.

51. *See* Goldman, *supra* note 5, at 751. This paper treats the herbicide uses in the same way as the pest-protected uses without distinguishing them.

52. *See* J. Madeleine Nash, *Grains of Hope*, TIME MAGAZINE, July 31, 2000, at 38.

D. FDA's Policy Statement on Labeling of Biotechnology in Foods

FDA has statutory authority with respect to consumer labeling for whole foods. FDA maintains that labeling about the use of biotechnology in foods is not normally needed, a position that relies again on the "substantial equivalence" of foods developed through biotechnology to foods using traditional methods.[53]

1. Material Omissions and Process

FDA has the authority to prevent misleading statements in foods,[54] and in doing so "may" take into account "material" omissions with respect to the statements about the food or the consequences of use.[55] The FDA position has been that the method of developing a plant through bioengineering or other plant breeding methods is not "normally" a "material" fact that needs disclosure to prevent a food label from being misleading.[56] FDA did not call for any special labeling of new plant varieties merely because of the use of biotechnology. The agency explained that it:

> [H]as not considered the methods used in the development of a new plant variety (such as hybridization, chemical or radiation-induced mutagenesis, protoplast fusion, embryo rescue, somaclonal variation, or any other method) to be material information . . . . and [the methods] would not usually be required to be disclosed in labeling for the food.[57]

Biotechnology was simply an extension "at the molecular level of traditional methods."[58] Since there is no showing that foods using the new methods differ "in any meaningful or uniform way," from other foods, or that the resulting foods present any "different or greater safety concern," the method would not be material information needing disclosure.[59] Disclosure would be required, though, if there was a need for labeling because of a safety risk such as allergenicity. Under the policy, FDA did not find labeling to be needed for the "FlavR SavR" tomato, one of the earliest marketed foods produced through bioengineering, and one with an added gene derived from a tomato to retard ripening during shipping as a way to prevent spoilage.[60]

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53. *See* McGarity, *supra* note 20, at 459.
54. 21 U.S.C. §343 (2003).
55. *Id.* at § 321(n) (2003).
56. Statement of Policy, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.* at 22,985; Goldman, *supra* note 5, at 735-36 (citing FDA Press Release, at 736). FDA accepted the GRAS status of an enzyme, chymosin, produced through biotechnology, without requiring labeling. *See* Direct Food Substances Affirmed as Generally Recognized as Safe; Rennet (animal-derived) and chymosin preparation (fermentation-deprived), 21 C.F.R. 184.1685 (2004) (recognizing the safety in

2. Food Names and Ingredient Labeling

Foods are also required to bear their common or usual name, and ingredient labeling,[61] requirements that also serve the core goal of preventing deception. Under FDA regulations, the name used for the ingredient used in the labeling ordinarily is specific, and not a collective or generic reference to the function, such as "sweetener" or "dough conditioner," a specificity that can help consumers in avoiding substances to which they are allergic.[62]

FDA found that it would require a change in the name of the food developed through biotechnology if the food "differs" from its traditional counterpart "such that the common or usual name no longer applies" or if consumers must be alerted to a "safety or usage issue."[63] While the test may seem conclusory, the context indicates the limited circumstances in which a change in a name would be needed. FDA did not believe that the mere use of biotechnology affected the name of the food in a way that required disclosure. Moreover, in an example used by the agency, FDA seemed unconcerned about the need for the name of a food to reflect that there has been a transfer from a different plant. FDA stated that if a peanut protein were transferred to a tomato, this would constitute a material fact that had to be disclosed to prevent deception because of the need to alert consumers allergic to peanuts, even if the "basic taste and texture" of the tomato remained the same.[64] While the focus may have been on the need for labeling to avoid risks from allergencity, the implication seems to be that, apart from safety risks and a change in taste, no other labeling disclosure would be needed.

III. STATUTORY AND CONSTITUTIONAL LIMITS ON BIOTECHNOLOGY LABELING: LITIGATION AND THE DECEPTION RATIONALE

The FDA policy has survived court challenges to date, and a Vermont statute that required labeling for milk with a growth hormone produced through biotechnology was struck down on constitutional grounds. The cases, however, primarily dealt with the inadequacies of

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making cheese or an enzyme derived from calf stomachs or from fermentation of the gene for the enzyme). Since the fermented enzyme came from a gene found in calves, and was used in making cheese, a dairy product, it does not involve a gene transfer between species.

61. 21 U.S.C. §343(i) (2003).

62. 21 CFR § 101.4; PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 81 (2d ed. 1991) (reporting the agency's caution about allowing widespread declaration of alternative ingredients in labeling since it may be a disadvantage to consumers with allergies).

63. *See* Statement of Policy, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

64. *Id.*

consumer demand or mere "consumer curiosity" to necessitate labeling. These decisions will be explored before considering the consumer deception rationale for labeling when gene transfers are made from different plants that affect the quality or nutritional value of the finished food, or have other significant differences.

A. Litigation on FDA's Statutory Authority and Policy

1. Litigation on Recombinant BST in Milk

FDA had found that labeling of recombinant BST (rBST) in milk was not required since it produced "no significant effect on the overall composition of milk" or its organoleptic properties and was not needed merely because there was an increase in somatic cell counts.[65] In *Stauber v. Shalala*, the FDA position was challenged on the grounds that there was a consumer demand for labeling. The court rejected that consumer demand as a basis for disclosure when "the product does not differ in any significant way from what it purports to be."[66] Moreover, the transfer was for an agronomic use, and involved a transfer from the same species, involving as it did use in cows of a hormone produced by cows.

2. Litigation on General FDA Policy Statement on Labeling

In *Alliance for Bio-Integrity v. Shalala,* a citizen group challenged FDA's failure to require labeling about the use of genetic engineering in foods on the grounds that widespread consumer demand for labeling represented a "material" change that had to be disclosed.[67] The court, though, viewed the materiality of consumer demand as a matter left by Congress to the agency's reasonable discretion, but the court also questioned whether that factor could ever provide the "sole" justification for labeling. Materiality is also not an independent basis for requiring disclosures, but is, instead, relevant to the extent that a omission is deceptive to consumers.[68]

The case also dealt with the need for disclosures about gene transfers from different species in the context of whether the constitutional protections for religion required disclosures of the presence in plants of pork or beef genes. The court upheld the agency policy in not requiring these particular disclosures because the position was a neutral one of general applicability.[69] The case for labeling of gene

65. *See* Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).
66. *Id.* at 1193.
67. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 178 (D.D.C. 2000).
68. *Id.* at 178; 21 U.S.C. § 321 (n) (2003).
69. *See Alliance,* 116 F. Supp. at 180-81. In addition, disclosure was not needed based on the Religious Freedom Restoration Act 42 U.S.C. §§ 2000bb-2000bb-4 (2003), since voluntary labeling was an available alternative.

transfers from different species explored below looks to a broader rationale based on consumer deception generally. The court also upheld other aspects of FDA policy, finding that the agency's determination that gene additions to food made through biotechnology were presumptively GRAS was within the agency's reasonable discretion.

B. Constitutional Challenge to State-Mandated Labeling for rBST in Milk

The Second Circuit also rejected a Vermont effort to require labeling of rBST milk, but did so relying on the constitutional protections for commercial speech. The statutory requirement compelling speech was permissible only if it served a substantial government interest. The court read Vermont's basis as aimed merely at satisfying consumer demand, the consumer right-to-know, and "consumer curiosity," grounds insufficient to be a substantial government interest.[70] Consumer interest was insufficient to require "the functional equivalent" of a warning when a production method had no 'discernible" impact on the final product.[71]

Given the court's constitutional basis, the decision limits Congress' authority as well as that of federal agencies. What is important to note, though, is the narrow grounds of the decision with the court rejecting mere consumer demand as a sufficient basis for compelled disclosures, a rationale that does address consumer deception as a rationale. Again, the decision related to the use of rBST is a hormone normally found in cows, and did not present the more complex issues that arise with gene transfers to a food to affect its quality and nutrition that come from a different plant or animal.

C. Deception Theory for Labeling

1. Deception and Food Constituents Changed by the Process

The Supreme Court's 1924 decision in *United States v. Ninety Five Barrels of More or Less Alleged Apple Cider Vinegar* is often seen as establishing that no disclosure is needed about the process of manufacture of a food. The Court indeed stated "[w]hen considered independently of the product, the method of manufacture is not material."[72] On the other hand the Court found that the statute's concern with preventing deception extended to "food, and the ingredients and substances contained therein" with the aim "to enable purchasers

70. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996). *See generally* Burk, *supra* note 20, at 275-317 (analyzing the dormant commerce clause, and preemption as preferable constitutional basis for faulting the state scheme).

71. *Amestoy,* 92 F.3d at 73.

72. 265 U.S. 438, 445 (1924).

to buy food for what it really is."[73] To determine what the food is, the Court looked to how the food is "popularly and generally known."[74] The facts of the case illuminate the Court's tough standard for when changes alter the identity of a food.

The process involved in the case was an earlier instance of food preservation, one accomplished by evaporating most of the liquid from apple cider and reconstituting it later with water, after the apple season ended, to make cider vinegar, sold as "Apple Cider Vinegar." The Court found the name misleading since reconstituting the apples with water meant it was not "the identical thing," as cider made with fresh apples, the food consumers would understand the product to be.[75] The reconstituted cider was "not the identical product" even though it was "like or similar" to it in appearance and taste.[76]

The court below had maintained that the process of evaporation was like the mechanical separation of cream thorough a centrifuge, and similarly needed no disclosure.[77] The Court saw it differently, though, apparently because the process went beyond a mechanical change to one that affected the content of the food in a way that differed from consumer understanding of the food. Moreover, no safety issue was found with the food, and the only objection was related to the potential for deception. The Court left it to the producer to come up with a new name that would not deceive by ambiguity or indirection.[78] Thus, the Court did not use simply an organoleptic standard in judging whether the name for the food was misleading, even though that is a key test used by FDA to determine whether there is a "material fact"[79] that needs to be disclosed for bioengineered foods.

Biotechnology affects a food at a genetic level not in terms of a major constituent, as occurred in the*Ninety Five Barrels* case. Nor are consumers familiar with biotechnology. Nonetheless, the important question is whether the consumer would understand a food to be different, and not what they thought it to be, if the food incorporated a gene from a different plant without a disclosure. An expansive reading of the case permits that possibility, but its validity needs to be tested against the implications of the test, a matter best considered, as discussed below, in light of the examples of the changes that may be made in foods and the type of labeling that might be provided. Of

73. *Id.* at 443-44.
74. *Id.* at 444.
75. *Id.*
76. *Id.* at 443.
77. Ninety Five Barrels of More or Less Alleged Apple Cider Vinegar v. United States, 289 F. 181, 187 (6th Cir. 1923).
78. *Ninety Five Barrels*, 265 U.S. at 443-45.
79. The material fact test is in 21 U.S.C. §321(n) (2000), a provision enacted later, but one that is best seen as an elaboration, rather than a change of the core test for deception articulated by the Court in *Ninety Five Barrels.*

course, courts often defer to the agency's judgment with respect to what changes are material.[80] Nonetheless, a failure to provide for any disclosure for important transfers from different plant not only can exceed the bounds of the agency's reasonable discretion but also be inconsistent with providing a name that is consistent with the consumer's understanding of what the food is.

IV. FRAMEWORK AND RATIONALE FOR ADDITIONAL LABELING

The preceding discussion identified the potential legal theory for labeling biotechnology modifications of food. This Part will consider the need for labeling of bioengineered foods to prevent deception, beginning with genetic modifications that introduce genes from different plants to develop new plant varieties for nutrition or quality reasons. If some type of labeling is needed for plants with genes from different plants, consideration is needed of the test for what makes a plant different, including whether wide crosses beyond the reach of hybridization should be considered to represent a different plant species.

The analysis also focuses on the discussion of the labeling needed for foods that are found in packaged foods. Many of the foods discussed, though, are also sold as raw agricultural commodities. The labeling in retail stores presents special difficulties, and might involve the need for store signs or bin cards. The agency has had to develop a format to facilitate the provision of nutrition information about produce in retail stores, and this could provide a model for other information about produce.[81] While these practical aspects would need more exploration if disclosures were considered necessary, the aim here is to consider the underlying question, whether any disclosures are appropriate.

A. Labeling for Gene Transfers from Different Species in New Plant Varieties

1. Need and Labeling Format

When a food contains a gene from a different plant, it provides the best case for finding that a disclosure of the different makeup is needed. The theory, derived from *Ninety Five Barrels*, would be that the addition of a gene from a different plant makes the food different from the popular understanding of what "it really is." The public would not expect a melon to contain a pineapple gene, a tomato plant

80. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.C. Cir. 2000); Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 1227 (1984).

81. *See* 21 U.S.C. § 343(q)(4) (2000) (providing for issuance of guidelines on voluntary nutrition labeling by retailers on raw agricultural commodities and raw fish and for regulations if substantial compliance does not occur).

a potato gene, or a strawberry a sucrose or fish gene. Moreover, the food and its ingredients are to bear "common or usual" names that are not deceptive, names that are typically specific.[82]

The emergence of new biotech varieties, to provide flavor or nutritional benefits, serves to illustrate the issues that can arise concerning what exactly makes a name adequate. Is it enough that the disclosure indicates the distinctive characteristic that the new plant has, or should it reflect that the change has been brought about by the incorporation of a gene from a different plant?

The development of Golden Rice can provide an illustration of how new plant varieties developed through biotechnology should be labeled, assuming that the food were to be sold as a packaged food in this country, rather than solely for use in developing countries. The rice has a gene from a daffodil that provides both a golden color and betacarotene that is a source of Vitamin A, an addition that has an important nutritional benefit especially in the developing world.[83]

FDA expects the common or usual name of food to be changed to reflect material changes, and so the would need a disclosure of the nutritional benefit, presumably by stating the name as "rice with betacarotene."[84] This name, though, would not indicate that the rice obtains the betacarotene from a different plant. More disclosure would be needed though if consumers do not expect a food to contain a gene from a different plant.

What is important is that the name reflects that the source is from a different plant, and to achieve this, the name might be "Rice with plant betacarotene."[85] FDA has used the term "plants" in recognizing a qualified health claims for Plant Sterol/Stanol Esters, thus providing an example of the use of the generic term "plant" in labeling.[86]

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82. *Supra* note 60.

83. Nash, *supra* note 52, at 38, 40 (reporting genes are from daffodils and erwinia uredovoro bacteria). Golden rice was developed at the Swiss Federal Institute of Technology, with funding provided by the Rockefeller Foundation. Several pharmaceutical and agribiotech companies, including Monsanto, provided free licenses for the intellectual property rights used in the development of the rice. *See* Ingo Potrykus, *The 'Golden Rice' Tale*, *at* http://www.biotech-info.net/GR_tale.html (Oct. 23, 2000). Golden Rice is undergoing further research, with expected completion in 2005. *See* http://www.syngenta.com/en/social_responsibility/position.aspx.

84. The name should not be "rice", with "betacarotene" listed separately in the name or ingredient statement, since the betacarotene is not added separately. Instead the name needs to indicate that the food contains the betacarotene.

85. Arguably, the disclosure should refer to the specific plant source when the source is not an edible one, which could lead to a name such as rice with daffodil-derived betacarotene. Nonetheless, the specific reference may be confusing in suggesting that the food has other characteristics associated with the specific plant.

86. *See* Health Claims: Plant Sterol/ Stanol Esters and Risk of Coronary Heart Disease, 21 C.F.R. § 101.83 (2004). Plant sterol esters include those made from edi-

Another alternative in developing names is to use "enhanced" as part of identifying the name of the added plant source. Thus, the name for the rice might be "rice enhanced with plant betacarotene." The "enhanced" term is useful in suggesting a change both in the makeup of the food and in its effects. This enhanced designation could also become a recognized shorthand way to indicate that an ingredient has features that come from a different plant. Over time, for example, consumers may be familiar enough with the "plant-enhanced" or "enhanced" term that it might be used at the end of the ingredient statement with an asterisk to other ingredients that have such a change.[87]

The potential for development of new foods with genes from different plants to obtain flavor characteristics also illustrates the potential for consumer confusion if the new name only reflects its flavor characteristics. The efforts to develop sweeter melons[88] provides a vehicle for exploring the issue given the theoretical possibility for an unlimited range of biotechnology transfers of genes whose traits have been identified.[89] Suppose for example that a sweet gene, perhaps one from a pineapple or from corn, gave a cantaloupe, not a distinct taste, but the flavor and the sweetness of the best cantaloupes.[90] Should the melon have to indicate that it had a non-melon gene? Indeed, will any disclosure be needed about its enhanced flavor characteristics.[91] The key test (apart from nutrition and safety) that FDA has looked to in determining whether gene transfer produces a "material change" that has to be disclosed is the effect on the taste characteristics of the

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ble foods and those made by esterifying byproducts of the Kraft paper pulping process with food grade fatty acids. *Id.* at § 101.83(c)(2)(ii)(B)(1).

87. The development of names for the new biotech varieties could follow the model FDA has used in the past in naming a food that was at the time unfamiliar to consumers. In the case of canola oil for example, FDA used the technical chemical name and in parenthesis the shorter canola name that the industry preferred to use. After several years, FDA allowed use of only canola as the name. HUTT & MERRILL, *supra* note 62, at 78.

88. *See* David Barboza, *You Asked for it, You Got It: The Pint-Size Watermelon*, N.Y. TIMES, Jun. 15, 2003, at A1 (describing development without the use of biotechnology of a new form of watermelon through processes that have developed orange bell peppers, and broccolini, a cross between Chinese kale and broccoli, and also reporting efforts to offer "sweeter cantaloupes; smaller, better-tasting tomatoes; and firmer peppers, some through conventional breeding methods and others through genetic engineering").

89. Statement of Policy, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992).

90. Since this flavor is all too rarely found, the example illustrates the benefits of biotechnology; however, the question is not its benefits, but rather when it makes a difference that needs disclosure.

91. FDA did not require labeling about the flavor advantage of FlavR SavR tomatoes even when the company had proposed to do so, but the change came from a gene from the same plant. *See* Calgene, Inc.; Availability of Letter Concluding Consultation, 59 Fed. Reg. 26,647 (May 23, 1994).

food, not the source of the change.[92] If organoleptic characteristics are the test for significant differences, the comparison may be made to the best of the unmodified melons, a result that might lead to no disclosure.[93] Moreover, if the melon were simply labeled as having "better flavor," the statement would not indicate that the source was from a gene from an entirely different plant.

An analogy can also be made to the addition of a corn sweetener to another food, something that would have to be listed in the ingredient statement as a high-fructose corn sweetener. When a corn sweetener is added to a food indirectly through a gene transfer, the sweetening effect should be disclosed, presumably by stating that the food is sweetened, but the source should also be disclosed, by stating that the food is a plant-enhanced variety, or with sufficient familiarity as an enhanced variety.[94]

2. *Wide Crosses as Different*

Whether a food is different is often straightforward under the popular understanding of the food: a peach is not a melon, and a tomato is not a potato. FDA has, though, an expansive test for traditional plant breeding. It includes not only hybridization through pollination, but other methods such as "chemical or radiation-induced mutagenesis, protoplast fusions [and], Embryo rescue."[95] These more extended techniques permit "wide crosses" to "different species" and "more distant wild relatives."[96]

As FDA has explained, "[t]he most commonly used breeding method is a 'narrow cross', which is hybridization between varieties of the same species. Hybridization between related species or genera that cannot be cross-fertilized is a 'wide cross' . . . . [These] are performed relatively infrequently because of technical and logistical diffi-

92. J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L. J. 105, 111 (2000).

93. It may lead to a continuing evolution of the identification of the food's characteristics. When dealing with new varieties the organoleptic test can be uncertain and not adequately informative.

94. The enhanced variety designation is appropriate when a new form of fruit is created such as a peach-flavored melon that combines two distinct foods possible only thorough biotechnology, as compared with a name that only indicates a flavor difference, or ambiguously suggests special quality such as peachy melon. However, if the name is clear that it combines different foods, such as a "Peach-Melon," the alternative enhanced variety designation would not be essential. As a result the enhanced variety designation would not be an invariable proxy for the use of biotechnology. But if the aim is to ensure that consumers understand when a food has genes from a different plant, the name itself can do that by indicating the different plant sources clearly.

95. Statement of Policy, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992).

96. *Id.* at 22,986. See NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 20-21 for a summary of techniques.

culties."[97] Biotechnology may increase transfers with these related species. If a gene transfer with a different plant needs some special labeling indication, the determination whether a wide cross is a different plant becomes more important.

Wide crosses can be viewed as different because of the factor noted by the FDA: They cannot be cross-fertilized. Indeed, the FDA characterizes as the "same species" only those that were possible through narrow crosses or hybridization.[98] The scientific way to determine what a species is relates to the capacity for interbreeding, and for wide crosses interbreeding is not possible.[99]

Some may believe that consumer understanding is not helpful in determining whether a "wide cross" makes a food different from what it "really is," on the grounds that consumers do not understand plant breeding and frequently disapprove even of hybridized plants made from conventional techniques.[100] Hybridization though is more likely to be familiar to the public than advanced forms of plant breeding such as radiation-induced mutagenesis. Moreover, the test reflects a scientific basis for identifying species.

If the wide crosses are appropriately regarded as from a different plant, a designation such as "enhanced plant variety" would be needed when a wide cross is made through biotechnology. As a result, if a cantaloupe obtained a flavor gene from a watermelon, a designation like this would be needed, even if the two fruits are distant relatives but ones that could not be cross-fertilized. Other names are, of course possible, so long as they are informative and not confusing and reflect that the plant has a new component from the ordinary species. For example, the new variety might be designed as a "wide cross," or, with time, as an "enhanced variety."

a. Existing Wide Crosses

On the other hand, wide crosses might not be thought to be a different food, since there has been a continuing modification of foods through gene transfers in various ways. Apparently a number of existing foods are the result of wide crosses made through extended methods of plant breeding without any use of biotechnology. Thus,

> "wide crosses" across species, and even across genera, [have] made use of tissue culture techniques to produce genetic combinations that could not occur in nature. The products of these techniques, including widely used varieties of

97. Premarket Notice, 66 Fed. Reg. 4706, 4710 (proposed Jan. 18, 2001).
98. *See id.*
99. D. PETER SNUSTAD ET AL., PRINCIPLES OF GENETICS 745-46 (1997).
100. Beales, *supra* note 92, at 110. The consumer understanding might also be tested not simply in terms of approval of hybridization, but by whether a plant becomes different if it has genes from a different species or from an ancestral plant with which it could not be cross-pollinated.

> tomato, potato, corn, oats, sugar beets, wheat and rice, have been in use for decades . . . .[101]

Still, making wide crosses through these extended techniques create important practical difficulties that limit new forms. As FDA has noted, wide crosses "are useful for expanding the range of genetic source material that can be introduced into food crops, but are performed relatively infrequently because of technical and logistical difficulties."[102] Biotechnology makes possible as a practical matter crosses with distant related species that may have been theoretical but not commercially viable. Biotechnology should be regarded as transferring genes from a different plant when they involve wide crosses not in commercial use.[103] If that is not done, gene transfers through biotechnology between a cabbage and mustard plant, its distant ancestor, might be regarded as not involving different plants, and not needing any special identification.[104]

3. *Varieties for Which Labeling Distinction Not Needed*

Under this approach, no special labeling would be needed for plant varieties developed through biotechnology that transfer genes from one type of a plant to another within the species for which narrow crosses are possible. No designation would be needed if biotechnology techniques make possible a more efficient transfer of genes that could be made with traditional plant breeding through hybridization for that plant species. Biotechnology that transferred genes possible only with wide crosses would need to be designated, unless perhaps it mirrored what is already done in plants that are already commercially grown. To have a realistic benchmark for what makes a plant differ-

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101. *Id.* at 106. *See* discussion *supra* note 88 for the development of broccolini. *See also* Food Labeling; Foods Derived from New Plant Varieties, 58 Fed. Reg. 25,837, 25,840 (Apr. 28, 1993) (stating that "most commercially produced tomatoes have introduced genetic traits derived from related weedy species.")

EPA regards "wide crosses" as part of the definition of conventional plant breeding for purposes of plant pesticides. *See* 40 C.F.R. pt. 174.3 (2003); Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,795 (July 19, 2001).

102. Premarket Notice, 66 Fed. Reg. at 4710.

103. The existing wide crosses in use at this point should be accepted or grandfathered as within the plant type because of its acceptance in practice. New plant varieties that represent wide crosses that are developed without biotechnology would need a name that adequately indicated that it combined different plant forms. For example, if broccoli and cabbages represent wide crosses, a new hybrid version combining them and called Broccage would have a name adequate to indicate the different plant sources. If the name were ambiguous, a designation of "advanced variety" would be appropriate to avoid confusing consumers who associate the enhanced variety term especially with the use of biotechnology.

104. *See* Beales, *supra* note 92, at 105 (describing relationship between cabbages and mustard plants).

ent, cross-fertilization provides the surest test, extended if at all only to reflect the wide crosses developed through extended methods that were sufficiently viable to come into general use.[105]

4. Transfers from Animal Species: The Need for Labeling

Specific labeling of the source of a gene is needed when there are major differences in the species involved. Theoretically, a gene from a flounder might be used in a tomato or strawberries to provide protection from frost.[106] Some might find any labeling unnecessary, regarding it as only the use of a process that needs no disclosure when the taste of the food is not altered.[107]

However, this gene transfer involves the introduction into a plant of a fish gene, something that not only crosses a species line, but the flora/fauna biological categories. The difference simply seems too great, and one that should be considered misleading unless disclosed because it differs so basically from the consumer understanding of what a food is. If a change were made, for example, to affect a food's crunchiness, a designation should be made under the policy discussed above that reflects the non-plant, such as "fish-enhanced crunch."

Complications arise, though, when an animal/plant gene transfer involves an agronomic use. The field test that occurred with a flounder gene was to protect the tomato from frost, not specifically to affect the flavor of the finished food. This use might be thought to be like pesticide and growth promotion uses for which labeling is not provided. Even if no additional labeling is considered necessary for these other forms of agronomic uses, when the transfer involves a transfer of an animal/fish gene to a plant (or to a different animal or fish) the change affects consumer understanding of the food in a way that needs disclosure. Thus, even if the use is considered agronomic, the labeling should indicate the presence of a flounder gene in a plant, perhaps in the ingredient statement as "fish-enhanced crop protector."

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105. New forms of corn are being developed, through "conventional means," that have a gene for Vitamin A that comes from other varieties of corn. Whether these new forms would need special labeling under this proposal would be affected by whether they reflect wide crosses or narrow crosses. *See* Andrew Pollack, *Grant Aims at More Healthful Crops*, N.Y. TIMES, Oct. 21, 2003, at F7.

106. *See* Statement of Policy, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992) (noting that "[r]ecombinant DNA techniques involve the isolation and subsequent introduction of discrete DNA segments containing the gene(s) of interest into recipient (host) plants. The DNA segments can come from any organism (microbial, animal, or plant)").

107. Labeling has been seen as unnecessary because some genes found in animals are also present in plants and the animal gene may be the most convenient source of a protein that is also found in plants. Beales, *supra* note 92, at 110. The resulting plant behaves like a plant and does not acquire animal-like characteristics. *Id.*

This labeling would also indirectly benefit consumers who have special labeling interests. Some consumers are vegetarian and may find unacceptable the presence of a non-vegetable constituent even in the form of a gene, which only expresses agronomic characteristics useful for growth. This type of labeling suggested here would indicate the presence of an animal gene in plants on the grounds that it is needed in view of the general consumer expectations about the vegetable nature of a plant. The labeling may also be of interest to those with religious objections to consuming beef or pork constituents. A court has rejected the constitutional or statutory necessity for providing special labeling solely to meet religious preferences.[108] The rationale for the labeling suggested here is broader and rests on the need to prevent misleading the general consumer who does not expect meat or fish derived substances to be in a plant unless disclosed.[109]

B. Plant Biotechnology for Pesticide Use and Labeling

As already discussed, many examples of biotechnology in plants relate not to food quality but to pest protection. Corn and soybeans contain biotech plant-incorporated protectants, which leads to the presence of biotech gene transfers in many processed foods.[110] The case for providing any labeling on foods about pesticide uses, chemical or biotech, faces serious obstacles. These obstacles relate to the deception connection, the relevance of labeling exemptions for chemical pesticides, and constitutional restraints and practical difficulties. Before discussing the difficulties, the impact of developments in biotechnology need to be noted. The discussion also seeks to identify options that can address some of the labeling hurdles.

1. Impact of Biotechnology on Need for Labeling

The absence of labeling on the biotech pesticides may become more problematic, if labeling were to be provided, as suggested here, for quality changes in foods made through gene transfers from different plants. If a tomato were developed with a potato gene to achieve a quality effect, the tomato would have to be designated in some way to indicate the addition such as "plant-enhanced," under the scheme sug-

108. Alliance for Bio-Interity v. Shalala, 116 F. Supp. 2d 166, 179-80 (D.C. Cir. 2000) (holding that the right to free exercise of religion is not violated by government allowing unlabeled genetically engineered foods on the market).

109. *Id.* The special restriction on consumer labeling for pesticides as chemical preservatives, discussed *supra* in Part II, should not preclude this disclosure. The statute was aimed at protecting the use of chemical pesticides, not animal sources. Even if the exemption is read to cover pest protectants made through biotechnology, that policy should not go so far as to encompass animal sources used in plants.

110. CORNEJO, *supra* note 3.

gested above. No such designation is made now, if the tomato had a potato gene to protect against insects. Additions made through biotechnology for agronomic purposes are different from the chemical pesticide uses that are made through separate appreciation in the field. Instead the change occurs at the genetic level in the seed before the seed is planted and occurs through a similar process whether the change is for an agronomic purpose or for a food's quality or nutrition. Consumers may believe labeling about the presence of a plant from a different species in a food, will cover all additions to the food, including those for agronomic uses for pest control as well as quality. If they did so and relied on the absence of the labeling as indicating there were no additions from other plant sources, they could be misled.

The potential for confusion could be alleviated if consumers understood that the special labeling does not apply to agronomic uses, but that distinction may not be clear to many. Moreover, if no labeling appears on agronomic uses, it will heighten the importance of the classification of a use as an agronomic, and whether they encompass dual uses or other forms of farm use such as frost protection.[111]

2. Form for General Labeling

An approach to the labeling conundrum explored here would be for Congress to require any plant using chemical or biotech pesticides or herbicides to be labeled at the end of the ingredient statement as "Crop Protectors" or "Enhanced and Other Crop Protectors" with the enhanced term being an indicator that a transfer from different species was made to the food crop. The disclosure would be for any pesticide functional use and would not specify the means used.[112] The general labeling would state the positive effect of the use, and might not encounter the resistance that there may be to the "chemical" designation. But the statement would alert consumers in some way that the agronomic uses introduce residues or a different substance into an ingredient to kill plant pests. If consumers do not expect foods to contain genes from different plants, or chemical residues, for agronomic purposes, this statement helps to guard against deception. Moreover, the consumer would then be able to seek more information from the food manufacturer about more specific type of pest or crop protector

111. For example, the FlavR SavR tomato, discussed *supra* at note 91, used a gene transfer to delay ripening and spoilage during shipping. Perhaps some might characterize that as a pest-related use or preservative use when the gene came from a different plant.

112. The disclosure would be broad enough to cover Bt sprays used in organic agriculture, but organic foods could have labeling that crop protectors meet the standards for organic foods. *See* Bratspies, *supra* note 48, for organic use, and 7 C.F.R. § 205.602 (2004) for absence of Bt sprays from non-synthetic substances prohibited from use in organic agriculture.

used. This can create a market incentive for more voluntary labeling.[113]

C. Objections to Labeling and Assessment

1. *Absence of Deception*

Some may see no risk of deception since consumers do not expect foods to be pesticide-free and would recognize, with reflection, that agronomic practices are not a matter of labeling. The long history of the absence of pesticide labeling would be seen as dispelling any notion of consumer deception on this matter.

2. *Insufficiency of General Labeling*

On the other hand, some may find the general labeling as too innocuous and uninformative for consumers. Some may favor instead discrete labeling that specifically identifies foods that use biotechnology.[114]

3. *Limits on FDA's Authority, and Labeling Exemption for Pesticide Chemicals*

FDA is precluded by statute from requiring pre-harvest agronomic uses of chemical pesticides to be labeled as "chemical preservatives," an exemption that arguably may carry over to the biotech pest protectors. Consequently a Congressional authorization of labeling for pesticide uses would be important in establishing the agency's authority and in avoiding litigation. Moreover the history of the exemption illustrates the practical and policy issues involved.

a. History

Foods are required to declare the presence of chemical preservatives.[115] In the 1950s, FDA sought to require labeling on store display bins stating that the food bore a "chemical preservative" when foods had pesticide chemicals applied after harvest. FDA believed that consumers are "entitled to know" and "want to know" whether a food contains a preservative.[116] FDA also believed that pesticides applied

113. *See infra* note 155 for FDA policy on voluntary labeling, and Section IV.D. on environmental aspects that arguably might influence consumer decisions. For a means for consumers to obtain more information, 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. 156 (2003).

114. McGarity, *supra* note 20, at 502-03.

115. 21 U.S.C. § 343(k) (2000).

116. Goldman, *supra* note 5, at 741 (citing Chemical Preservatives: Hearings on H.R. 9521 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce, 85th Cong. 2d Sess. 118 (1958) (statement of John L. Harvey, Deputy

after harvest, but not before, were ingredients to the food subject to ingredient labeling absent an exemption.[117] However, Congress objected because of practical factors and the risk of "buyer resistance," and in 1960 made "chemical preservative" labeling inapplicable to pesticide chemicals used before harvest.[118] Moreover, labeling about the use of pesticides after harvest was limited to a disclosure on the shipping container (as an aid to agency enforcement of tolerance levels), and would not cover display in the store.[119] While FDA "in principle" still believed in the need for labeling, the agency accepted the legislative compromise recognizing the enforcement difficulties at the federal level and the prospects for prolonged litigation.[120]

b. Wider Applicability of Policy?

The objections to labeling for use of pesticide chemicals have been seen as ones that strongly resemble the dispute over the labeling of genetically-modified foods.[121] The industry emphasized the practical problems in providing labeling about pesticides, including the cost involved of segregating foods for labeling, and the difficulty of determining when commingled foods had been treated. Furthermore, since the same pesticide may be used before harvest and after harvest, the industry maintained successfully that they should be treated the same way for labeling with none provided to consumers for either use.[122]

Since plant-incorporated pest protectants, the ones produced by biotechnology, are regulated by EPA as "pesticide chemicals," the same preclusion of labeling has been seen as appropriate for biotech

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Commissioner of Food and Drugs, FDA, Dept. of Health, Education, and Welfare)).

117. Letter from Acting Secretary Elliot Richardson to Senator Lester Hill (Sept. 11, printed in S. Rept. 1548, 86th Cong. 2d Sess. 5 at 6 (1960)) [hereinafter Richardson Letter]. The agency rationale was that when pesticides are applied after harvest, the fruit or vegetable "being no longer in its natural state, is a 'fabricated food' and the chemical is an 'ingredient.'" *Id.* This rationale for ingredient labeling would not apply to pesticides used before harvest. Interestingly, FDA regards bioengineered foods as containing an "added" substance for food safety purposes, if not for ingredient labeling. Statement of Policy, 57 Fed. Reg. 22,984 (May 29, 1992).

118. 21 U.S.C. § 343(k) (2000) now exempts from labeling as a chemical preservative "a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil." The agency also had authority to establish safety levels for pesticides, which reduced the need for labeling. H.R. Rep. No. 85-2119, at 6 (1958).

119. The disclosure can now be required on shipping containers of foods for which pesticide chemicals have been applied after harvest, but not while on the containers held for sale in stores. 21 U.S.C. §343(l) (2000).

120. Richardson Letter, *supra* note 117.

121. Goldman, *supra* note 5, at 742.

122. *Id.* at 743.

products as well as chemical ones.[123] The history could also be read as confirming the soundness of FDA's position that the process of manufacture is not relevant for labeling purposes at least for pest-related agronomic uses. Indeed, FDA maintains that the "labeling prohibition pertaining to postharvest pesticides applies to preharvest pesticides since the same type of labeling problems would be encountered."[124] In view of the problems, the agency stated, in 1991, that it was "not prepared to seek statutory authority to require pesticide labeling at this time."[125]

Perhaps one can read the Congressional limits narrowly as limited to chemical pesticides, and solely concerning labeling about the presence of a "chemical preservative," a term especially likely to draw consumer resistance. Any reading, though, which led to labeling solely for biotech pesticides has the consequence of putting them at a disadvantage and may confuse consumers if they think unlabeled foods contain no pesticides. Moreover, any such interpretation would likely be one that the court viewed as committed to agency discretion, and an expansive approach by the agency seems doubtful.[126] Consequently, any change in labeling for biotech pest protection is likely to have to come from Congress. In developing a legislative proposal, it will be important to be mindful of the practical objections and compliance problems that influenced Congress and the agency in the past.[127]

4. Assessment of General Labeling Approach

The type of general labeling outlined above has some advantages in dealing with the practical obstacles that have been concerns for Congress and others. Agricultural crops like corn and soybean are shipped as commodities, which makes specific disclosures about pesticide use difficult, but which may not necessarily rule out more general labeling. There is no burden of segregating crops when all have to bear the same labeling. Since virtually all crops use some type of pesticide, the designation would presumptively be needed for all and could appear in the same way for all. Still, implementing such an ap-

123. *Id.* at 740.

124. Food Labeling: Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,611 (June 21, 1991).

125. *Id.*

126. In 1991, for example, the agency not only found it lacked the authority to require labeling for pesticide residues in foods, but also declined to seek a legislative change, citing the practical difficulties and enforcement problems in detecting residues. *See id.*

127. *See also* NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 118, Box 7.2 (noting the need to have verifiable methods of detection if labeling were to be required for the use of biotechnology).

proach may involve developing detection methods to ensure enforcement, and the recognition of an exemption for low-levels of use.[128]

A labeling requirement that applied only to biotech forms of pesticides could indirectly provide an advantage for use of chemical pesticides. The chemical pesticides have their own detriments for the environment,[129] and some believe the agronomic uses of biotechnology have environmental advantages.[130] The general labeling outlined above would apply to both types and not advantage either type. The labeling could either simply refer to crop protectors or to both types, by saying "enhanced or other crop protectors."

Overall, labeling that reflects when biotechnology introduces a new species into a food used for quality purposes but not agronomic purposes has a potential for consumer confusion that warrants reconsideration of the labeling about agronomic use. Developing an adequate response, however, presents considerable hurdles. While the general disclosures, suggested above has promise, further study is warranted of other alternatives.

In any case, if biotech pesticides are used solely, or in part, to preserve the finished food, a label declaration should be made. Chemical preservatives added to a processed food require a label declaration.[131] A comparable disclosure, with an appropriate name, is also needed when bioengineering permits an addition to a food that achieves a substantially equivalent preservative function. Indeed, this need for equivalent treatment provides an alternative explanation for the reason for disclosures of the use of irradiation in finished foods, a process that substitute for other form of adding a preservative to a food.[132]

128. *See id*; McGarity, *supra* note 20, at 502 (citing European Union exemption from its labeling requirements of foods with less than 1% of genetically-modified material).

129. *See* Goldman, *supra* note 5, at 760 (suggesting biotech pest protectors, while not perfect are "'examples of the approach'" Rachel Carsons advocated as an alternative to chemicals in dealing with disease resistance) (citing Bernard Dixon, *The Paradoxes of Genetically Modified Foods*, 318 BRIT. MED. J. 547, 548 (1999).

130. Jonathan Rauch, *Will Frankenfood Save the Planet*, ATLANTIC MONTHLY (Oct. 2003), *available at* http://tehatlantic.com/issues/2003/10/rauch.htm (noting advantages of salt-tolerant and no-till farming from biotech varieties).

131. 21 U.S.C. § 343(k) (2000).

132. *See* Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 Food & Drug L J. 301 (2000) (noting irradiation as a unique example of the disclosure of a process, and examining the extent to which changes in food composition or consumer safety concerns provide an explanation). Irradiation constitutes a food additive by law. 21 U.S.C. § 321(s) (2000).

D. Animal Biotechnology and Labeling

1. Growth Promotion and Emerging Uses

Animal biotechnology involves important uses, ones that could have labeling implications.[133] The emerging uses involve a range of novel issues, including the cloning of animals for food production.[134] The NAS Committee that evaluated the emerging uses found no "science-based" reason for labeling, but it recognized there might be "other reasons" that might provide a legitimate basis in public policy for requiring labeling."[135] The reasons included that "arguably . . .in the current climate surrounding biotechnology, the fact of genetic engineering is an aspect of the identity of the food."[136] Because the wider policy concerns were beyond the Committee's charge it did not make recommendations. An exploration of these issues is also beyond the reach of this paper. Instead the focus will be on the relevance of labeling with respect to the farm-raised salmon.

The farm-raising of salmon creates changes in the salmon, even apart from biotechnology, that can bear on labeling. Artificial colors have been added to the salmon, a practice which has been challenged as necessitating labeling about the addition of artificial color.[137] Farm-raising also affects the nutritional profile of the salmon. They are larger and have more fat and fewer Omega-3 fatty acids than wild salmon,[138] and they may have higher PCB levels, ones that can reflect higher contamination levels in Europe as compared to North and South America.[139] Perhaps some means to provide a disclosure about the nutritional difference should be considered.

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133. If consumers expected an animal's substance to come from what an animal eats without being enhanced by drugs, labeling of the food to indicate growth enhancement produced by the use of animal drugs may be needed. Comparable labeling would also be needed for antibiotics and other animal drugs that promote growth. The change would be so substantial, though, that Congressional action would be appropriate.

134. *See* NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 118 Box 7.2.

135. NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 118 Box 7.2.

136. *Id.* The other reasons included religious, ethical, right-to-know or preference reasons.

137. The farm-raised salmon have a greyish color, because of the absence of crustaceans in their diet. Marian Burros, *Issues of Purity and Pollution Leave Farmed Salmon Looking Less Rosy*, N.Y. TIMES, May 28, 2003, at F1. The growers, ever resourceful, have added artificial colors to achieve a better tint, a practice that led to a class action suit alleging that the failure to label the food as containing artificial colors violated federal law. *See* 21 U.S.C. §343(k). As a result stores are re-labeling the foods. If the fish were ever bioengineered to add a suitable color from a carrot gene or from a shrimp gene, it would create a nice maze of labeling issues.

138. Burros, *id.* at F1.

139. *Id*; Marian Burros, *Farmed Salmon is Said to Contain High PCB Levels*, N.Y. TIMES, Jul. 30, 2003, at F1 (describing report from Environmental Working Group, and noting that while the PCB levels do not exceed FDA guidelines, the

2. *Species Impact and Salmon*

a. *Scientific Issues*

The principal focus here is on the potential for animal biotechnology to impact the species as illustrated by a pending proposal that affects salmon. Biotechnology permits the addition of a gene to salmon that expresses a growth hormone and which allows development of a transgenic line to be used in farm-raised salmon.[140] In fish farming generally, some salmon escape from the pens and can breed with wild salmon. The very large salmon made possible by the growth hormone gene transfer creates an environmental risk that escaped salmon could interbreed with the wild salmon, altering the species.[141] Similar risks can occur with respect to other types of transgenic fish that are farm raised.

A National Academy of Sciences Committee that evaluated Animal Biotechnology for FDA found that sufficient "gaps still exist in our understanding of the key net fitness parameters to allow an assessment of the impact of [Genetically Engineered Atlantic salmon] into the wild."[142] Some of the lines of transgenic salmons in laboratories grew four to six times faster than non-transgenic salmon.[143] The Committee found there is an environmental concern that "cannot be dismissed" about whether the salmon and other transgenes could result in new evolutionary lines because "the magnitude of phenotypic change that is possible with transgenesis could exceed that of conventional breeding or natural mutations."[144] According to the report:

> At the heart of the issue is how species evolve. Domestication is widely believed to be the consequence of small incremental changes in trait value, and the ecologic niche of the animal is not changed if the phenotype of a mutant individual is only slightly changed. Expression of transgenes, however, could cause mega-mutations that instantaneously and substantially change the phenotype of the transgenic organism.[145]

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agency might reexamine the guidelines); *see also* Ronald A. Hites et al., *Global Assessments of Organic Contaminants in Farmed Salmon*, 303 Science 226, 229 (2004) (demonstrating "the importance of labeling salmon as farmed and identifying the country of origin.").

140. For a description, see NAS ANIMAL BIOTECHNOLOGY, *supra* 7, at 89-92.

141. *Id.* at 11; *see also* Kenneth R. Weiss, *It Came From the Gene Lab; Faster Growing Salmon?*, L.A. TIMES, May 14, 2003, at A1; Marian Burros, *Chefs Join Campaign Against Altered Fish*, N.Y. TIMES, Sept. 18, 2002, at F1.

142. NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 11. The Committee also noted transgenic salmon that grow faster because of a growth hormone could provide an environmental benefit by producing less waste. *Id.*

143. *Id.*

144. *Id.* at 79-80.

145. *Id.* at 80.

The environmental risks from animal biotechnology, in general, has been seen by the Committee as "the greatest science-based concern" with animal biotechnology.[146]

b. FDA's Statutory Authority with Respect to Environmental Impacts

FDA has the authority to regulate the genetic addition of a growth hormone to the salmon under its authority over animal drugs.[147] Important questions exist, though, about FDA's authority to regulate the transgenic fish based on an environmental impact, and about the agency's institutional capability to deal with the environmental questions.[148]

FDA, though, maintains that it has the authority to consider environmental effects.[149] On the other hand, the agency "has not taken an action in which it has identified an environmental effects not involving risks to human health as an influential consideration."[150] FDA, though, took an expansive view of the way in which safety risks are created when it banned the use of chlorofluorocarbon (CFCs) in FDA-regulated products, and required a warning as an interim measure.[151] The CFC's in the stratosphere depleted the ozone layer and increased the risk of skin cancer to humans. Thus the safety risk was not to the immediate user and came about indirectly.

In determining whether to approve an animal drug, FDA considers not only the safety to humans but also the safety to animals, with the

146. *Id.* at 9.
147. *See* discussion *supra*, Part II.
148. NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 111, 113-15; *see also* Future Fish, *supra* note 43, at 47-49, 57; discussion *supra* Part II; FDA Questions and Answers about Transgenic Fish, *at* http://www.fda.gov/cvm/index/consumer/transgen.htm.
149. *Study Faults U.S. on Assessing Altered Fish*, N.Y. TIMES, Jan. 15, 2003 at A16 (citing FDA official that the agency requires environmental assessments on animal drugs and can seek input from other agencies). In the 1970s, a court found that the National Environmental Policy Act provides FDA with "supplementary authority" and permits FDA to base a decision upon environmental factors, when balanced against other relevant considerations. Envtl. Defense Fund, Inc. v. Mathews, 410 F. Supp. 336, 338 (D.D.C. 1976).
150. *See* HUTT & MERRILL, *supra* note 62, at 1311; Future Fish, *supra* note 43, at 48.
151. *See* 21 C.F.R. § 2.110 (1979) (ban citing the risks of increase in skin cancer and changes in the climate); 21 C.F.R. § 740.11 (1979) (warnings on cosmetics). FDA has since revised its regulation to provide that the labeling requirements are designated by the EPA, 21 C.F.R. 2.40.11 (2003). The agency also now uses its authority under the Clean Air Act for determining essential uses, but has stated that a nonessential product may still be considered adulterated or misbranded under the food and drug laws. Final Rule, Use of Ozone-Depleting Substances: Essential Use Determinations, 67 Fed. Reg. 48370, 48372 (2002). The author provided advice to the agency with respect to these regulations. The regulations were not challenged in court.

target animal being the focus.[152] Perhaps an expansive view of the safety risks to the animals could encompass the indirect harm to the wild form of the same species. Still, the questions raised about the scope of the agency's authority are important ones, and legislative action to provide clear authority would remove litigation risks that may arise if the industry had major objections to the agency action.

c. Role for Consumer Labeling

Assuming that FDA's statutory responsibilities reach these environmentally-caused effects, another question arises about the extent to which consumer labeling should play a role. Assume, for example that FDA approves the use of growth hormone, viewing the risk as limited when farm operators use safeguards to prevent escape. Still, according to the NAS Report many uncertainties remain, and continual monitoring may be appropriate.[153]

Given the uncertainty consumer labeling has a role. While there is no transfer of a gene from a different species, the transfer has an impact on the species itself. A disclosure can be viewed as needed to prevent deception since consumers would not expect that their consumption of a food like salmon to pose a risk that the wild form of the food would be altered. That disclosure might, for example, be in the form of a statement that requirements are in place to reduce and monitor the risk of escape of farm-raised salmon that could adversely affect the wild salmon.

Consumers are in a special position to evaluate the risks from transgenic salmon. The growth enhancement produced by biotechnology lowers the cost and increases the availability of a food that consumers desire for its health benefit and flavor. On the other hand, the enhanced salmon can pose a risk of environmental harm to the wild form, one that it may not be entirely possible to eliminate. The tradeoff in how to balance the risks and benefits is a difficult one, and one that should not necessarily be made solely at the regulatory level on an all-or-nothing decision when the extent of the risk depends upon practical developments. Consumers have their own responsibility to monitor how effectively the environmental risks are balanced against their personal interest in availability. Providing labeling about the effect of enhanced growth effects is one way to involve consumers in the choice. Some may decide to not use the salmon that poses the risk. Others may look for foods labeled as having extra safeguards against escape of the salmon that exceed any restrictions that are governmentally imposed. Consumers may take special interest in reports of vio-

152. Future Fish, *supra* note 43, at 48.

153. *See* NAS ANIMAL BIOTECHNOLOGY, *supra* note 7, at 115 (stating "uncertainties remain about the efficacy of various containment measures and what degree of efficacy is appropriate or acceptable in various circumstances").

lations of restrictions, an interest which may lead to better compliance. The labeling could create a market in developing new ways to minimize the risk.

Voluntary labeling by producers, though, is often seen as the appropriate alternative to mandated consumer labeling about the use of biotechnology.[154] On the other hand, if consumers do not know of the risk of species harm that may occur with transgenic salmon, they will not know of the significance of additional measures. If the labeling is provided it may lead to the provision of additional voluntary labeling to consumers as discussed above, but that labeling presents its own complications. FDA has provided guidance on voluntary disclosures, and while it objects to claims like "GM free," it accepts as appropriate statements like "We do not use ingredients that were produced using biotechnology."[155] The affirmative statements also need to avoid misleading implying safety risks from the use of biotech, but there can be tough questions about what is misleading, an issue that has led to private litigation.[156] While an appropriate format will need to be worked out, labeling remains an appropriate way to inform consumers when a particular use of biotechnology may alter the natural species of the food, and to permit them to seek alternatives to reduce the species risk.

3. Environmental Risks from Bt Pesticides in Crops

While the use of transgenic fish provides a dramatic example of a potential species impact, some pesticide uses of biotechnology may also present environmental risks to the traditional means of pest control. The gene transfer of the soil bacterium Bt to corn to control pests, for example, can erode the effectiveness of the use of Bt in organic agriculture as a temporary spray by contributing to pesticide resistance.[157] The EPA and the Department of Agriculture share re-

154. Beales, *supra* note 92, at 112-13.

155. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4,839, 4,840 (Jan. 18, 2001). *But see* McGarity, *supra* note 20, at 463-64 (discussing criticisms that the guidance could discourage voluntary statements).

156. *See* David Barboza, *Monsanto Sues Dairy in Maine Over Label's Remarks on Hormones*, N.Y. TIMES, Jul. 12, 2003, at C1 (describing lawsuit by Monsanto alleging that the dairy's milk carton labeling that there are no artificial growth hormones in the milk is deceptive and misleading); *Monsanto Co.: Oakland Dairy Settles Lawsuit over Growth Hormone Labeling*, WALL ST. J., Industrial Brief, Dec. 26, 2003, *available at* 2003 WL-WSJ 68131889 (reporting a settlement with confidential terms under which the label could state "No Artificial Growth Hormone Used," along with a message that FDA has found no significant difference in milk from growth hormones; the prior labeling did not include "used").

157. Rebecca Bratspies, *supra* note 48, at 307, 320 (describing transgenic Bt crops as presenting the dangers of a common pool risk, and as posing a real risk of the spread of resistance).

sponsibilities to ensure that farmers who use the biotech form of Bt maintain surrounding reserve areas of non-use to retard the development of Bt resistant pests.[158] The adequacy of the system and its monitoring have been criticized, and a recommendation has been made for a new regulatory framework with coordinated or central decision making.[159]

Whether consumer labeling can play any role in dealing with an environmental impact like that involving the use of Bt to control pests is problematic. There is no identifiable impact on a specific food, as there is with transgenic fish. Questions exist about FDA's authority to regulate environmental risks created by animal drugs, an area in which the agency has direct responsibility. The responsibility for the risks from pesticides is placed elsewhere. Of course, if consumer labeling for foods had a general disclosure about the use of "crop protectors," it may have some usefulness for consumers who want to take environmental considerations into account.

V. CONCLUSION

The development of new forms of foods from biotechnology has the potential to provide consumers with nutritional benefits they desire and more interesting and flavorful forms of food. On the other hand, the scope of the ability to make novel foods raises the specter that consumers may distrust the use of biotechnology in foods, and even regard some of them as "Frankenstein Foods," as European consumers have done.

The labeling for the new foods can be expected to reflect the quality and nutritional changes produced. However, when the change comes about through a transfer to a food of a gene from a different species, not possible through traditional plant hybridization, the change tests the understanding of what the food is. If consumers come to believe that foods have undisclosed "secret" genes from other plants, it could create a crisis of confidence like that created by the StarLink(R) incident, when corn intended only for use in animals was found in tacos.[160] The best approach to preventing consumer deception is to have the labeling reflect in some way when a common food contains a gene from a different species that affects its characteristics. The use of the designation "plant-enhanced" or "enhanced" is a way to do that, one that takes account of some of the practical problems of labeling.

158. *Id.* at 323-29.

159. *Id.* at 347-48; *see Editorial, Keeping Seeds Safe*, NEW YORK TIMES, Mar. 1, 2004, at A20 (commenting on the need for vigilance in protecting traditional seed stocks – the "genetic reservoir of plants on which humanity has depended for most of its history" – in light of a study finding contamination with genetically modified varieties in half the samples tested of traditional corn and soybean).

160. For information on StarLink, see McGarity, *supra* note 20, at 485-87.

When the transfer crosses the plant/animal biological line, the name should reflect with specificity the type of transfer involved.

Biotechnology can also involve transfers from different species for pest control or growth promotion. No consumer labeling has been provided for these agronomic uses, as a result of practical considerations and legal questions. Consumers could be confused, though, if the use of biotechnology is disclosed when a transfer from a different plant occurs for quality reasons, but not for pest control. Some reconsideration is needed about these different approaches to labeling, including requiring a label designation on foods grown with chemical or biotechnology pest protectors, indicating that "crop protectors" have been used. Legislative action should be considered if the agencies do not adapt the recommendations made here.

Biotechnology can have a species connection in another way, as illustrated by the development of farm-raised salmon with a gene for enhanced growth. The transgenic salmon may escape and interbreed with the wild salmon in a way that alters the species. A disclosure to consumers of this risk would make them aware of a larger harm that they would not expect. They could participate in making the balance between risks to the species and the health and economic benefits to the user that come from the expanded availability of the salmon.

Some may question Congress' or the agency's constitutional authority to require a disclosure about the impact on the wild species as a way to inform consumers and to involve them in reducing and monitoring the risk.[161] If the grounds for the labeling were only to satisfy consumer curiosity, the adequacy of the Government interest would be insufficient. The core basis, though, for all the labeling requirements explored here is the need to prevent consumer deception, an interest recognized as a substantial one that can justify the regulation of commercial speech.[162] A disclosure about gene transfers that leads indirectly to an alteration of the wild species can appropriately be seen as deceptive. A Congressional and regulatory judgment about the new ways that deception can occur through the emergence of biotechnol-

161. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d. Cir. 1996).

162. *See* Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 561-64 (1980) (holding First Amendment protects commercial speech if it is not misleading); Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 673 (1985) (holding that disclosure requirements do not infringe on an advertiser's First Amendment interests if "reasonably related to the State's interest in preventing deception of consumers."). Still, speech restrictions are not permitted if they are more extensive than necessary to achieve the government's interest, and an adequate showing would be needed that the direct regulatory restrictions to prevent release of the salmon were not themselves enough. Thompson v. Western. States Med. Ctr., 535 U.S. 357 (2002)

ogy, and the reasonableness of disclosures as a response, should be regarded as one that lies within the legislative judgment.[163]

The use of biotechnology in foods involves major challenges, including determining when changes affect the consumers' understanding about what a food is. Developing an appropriate means to label new foods under old principles warrants continued academic analysis. The important point is that adequate disclosures are needed to prevent deception and to permit the food industry to retain the confidence of consumers.

163. *See Thompson*, 535 U.S. at 389 (Breyer, J., dissenting) (opposing an overly rigid commercial speech test and recognizing Congressional role in health and safety issues).