INSIDE

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IN FUTURE ISSUES

Supreme Court denies Chevron *deference to statutory interpretations in agency opinion letters and similar formats*

In its May 1, 2000, decision in *Christensen v. Harris County*, 120 S. Ct. 1655 (2000), the United States Supreme Court ruled that statutory interpretations made by agencies in pronouncements that do not have the force of law, such as opinion letters, policy statements, agency manuals, and enforcement guidelines, are not entitled to "*Chevron* deference." Instead, "*Skidmore* deference" applies. *Skidmore* deference, whose namesake is the Court's decision in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), is less forceful than *Chevron* deference for it compels the federal courts to defer to agency interpretations of statutes only to the extent that the interpretations have the "power to persuade." *See* 1 Kenneth Culp Davis & Richard J. Pierce, Jr., *Administrative Law* § 6.3 (3rd ed. 1994) [hereinafter Davis & Pierce]. The decision is significant for agricultural lawyers because many federal agencies, including the USDA, render interpretations of the statutes they administer in formats that do not have the force of law.

"Chevron deference" takes its name from the Court's decision sixteen years ago in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). In that decision the Court held that when the federal courts are faced with an ambiguous statute, the courts must defer to an agency's regulation containing a reasonable interpretation of the statute. In essence, *Chevron* deference analysis potentially presents two questions. The first question is whether the statute at issue is ambiguous. If the statute is not ambiguous in that it speaks directly to the question at issue, then the statute must be applied. If, on the other hand, the statute is ambiguous, the court must defer to the agency's regulatory interpretation of the statute if the interpretation is reasonable. The second question, therefore, is whether the agency's interpretation is reasonable. *See id*. at 842-43.

If a court reaches the second question, the odds favor the agency. A recent study found that courts of appeals' decisions citing *Chevron* upheld the agency interpretation seventy-three percent of the time. Michael Herz, *Judicial Review in* Developments in Administrative Law and Regulatory Practice 1998-1999, 52 n.26 (Jeffrey

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Risks in asking for adequate assurance of performance

The U.S. Court of Appeals for the Eighth Circuit on May 11, 2000 issued a decision denying the appeal of several Iowa cooperatives that challenged jury instructions related to the question of adequate assurance on hedge-to-arrive (HTA) contracts.

While an Iowa federal district court found that the HTA contracts were cash forward contracts not subject to the federal Commodity Exchange Act, a jury granted nominal damages to a producer on a remaining claim for breach of contract and denied the cooperatives' claims for damages against the producer.

The appellate court outlined the letter sent by the Farmers Cooperative of Ledyard to the producer, which was entitled "Demand for Adequate Assurance of Performance." The letter, among other things, "stated its concern surrounding the substantial sums the Elevator had committed to covering margins under the Flex Hedge Contracts….[The Elevator] stated that various market and non-market conditions and developments created reasonable grounds for insecurity with respect to [the producer] and others who held Flex Hedge Contracts with the Elevator. Because of such insecurity, [the Elevator] demanded that [the producer] provide the Elevator with adequate written assurances of his intent to perform under the Flex

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S. Lubbers, ed. 2000) (citing Orin S. Kerr, *Shedding Light on* Chevron*: An Empirical Study of the* Chevron *Doctrine in the U.S. Courts of Appeals*, 15 Yale J. Reg. 1 (1998)). Thus, "[i]n general, one of two things happen in a *Chevron* case: either the court concludes that the statute contains the answer, in which case the agency's interpretation becomes irrelevant, or it determines that the statute does not, in which case the agency's interpretation becomes, for all intents and purposes, dispositive." *Id*. at 52.

In *Chevron*, the agency's interpretation of the statute was contained in a legislative rule; that is, it was found in a rule that had been duly promulgated under the rulemaking procedures prescribed in the Administrative Procedure Act. As recently as in the 1999 Supplement to their treatise, Professors Davis and Pierce noted that the Court had been "unable or unwilling" to say whether *Chevron* deference should be accorded to nonlegislative rules such as interpretive rules. Davis & Pierce, *supra*, at § 3.5 (Supp. 1999). They also observed that "[s]ome might argue that the uncertainty and conflicting authority [in the lower courts] on this issue are not particularly important because agency interpretive rules are at least entitled to *Skidmore* deference." *Id*. They further noted, however, that "[i]n many cases ... the difference between *Chevron* deference and *Skidmore* deference is outcome determinative." *Id*.

In *Christensen v. Harris County*, the Court became either able or willing to answer the question that Professors Davis and Pierce had noted as remaining unanswered: whether agency pronouncements contained in formats other than a legislative rule are subject to *Chevron* deference. In response to a claim that a Department of Labor opinion letter that expressed the agency's interpretation of a provision of the Fair Labor Standards Act was entitled to *Chevron* deference, the Court in *Christensen* held that *Chevron* deference did not apply. *Christensen*, 120 S. Ct. at 1662-63. Specifically, the Court ruled:

> Here...we confront an interpretation contained in an opinion letter, not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking. Interpretations such as those in opinion letters–like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law–do not warrant *Chevron*-style deference. Instead, interpretations contained in formats such as opinion letters are "entitled to respect" under our decision in *Skidmore v. Swift & Co.*..., but only to the extent that those interpretations have the "power to persuade...."

Id. (citations omitted).

Though the question may now have an answer, the Court did not speak in unison. The Court's opinion was written by Justice Thomas, who was joined by Chief Justice Rehnquist and Justices O'Conner, Kennedy, and Souter. Justice Scalia dissented as to the holding that the opinion letter was entitled only to *Skidmore* deference. Characterizing *Skidmore* deference as an "anachronism," Justice Scalia opined that, "[w]hile *Chevron* in fact involved an interpretive regulation, the rationale of that case was not limited to that context...." *Id*. at 1664 (Scalia, J., dissenting). Justice Breyer, in a separate dissent joined by Justice Ginsberg, took issue with Justice Scalia's characterization of *Skidmore* as an "anachronism," but he expressed the view that Justice Scalia may have been right in according the opinion letter *Chevron* deference. Justice Breyer maintained that "to the extent there may be circumstances in which *Chevron*-type deference is inapplicable–e.g., where one has doubt that Congress actually intended to delegate interpretive authority to the agency (an "ambiguity" that *Chevron* does not presumptively leave to agency resolution)–I believe that *Skidmore* nonetheless retains legal vitality." *Id*. at 1668 (Breyer, J., dissenting).

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VOL. 16, NO. 6, WHOLE NO. 187 May 1999

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Hedge Contracts."

The letter from the Farmers Cooperative of Ledyard included a detailed list of items it would consider as adequate. Included in the list was a demand for "payment in full of all commissions and margins previously paid by the Coop on your behalf and all other costs incurred by the Coop pursuant to the Contracts." Farmers Cooperative of Buffalo Center sent a similar letter to the same producer.

The jury instructions given by the district judge on the issue of adequate assurance provided that:

> You are instructed that it is unlawful to enter into a contract for the purchase or sale of commodity futures unless the transaction is conducted on or is subject to the rules of the Chicago Board of Trade or other designated contract market. Therefore, if you find that a demand for assurances constituted a demand to enter into a purchase or sale of commodity futures that was not on or subject to the rules of a designated contract market (i.e., it constituted a demand for an 'off-exchange transaction'), you may find that such a demand was unlawful and unreasonable....

The three-judge appellate panel rejected the cooperatives' claims that they were prejudiced by the jury instructions and found that "as a whole, they fairly and adequately stated the law applicable to the dispute." Finally, the appellate court said "a miscarriage of justice did not occur."

Parties to contracts certainly can be justified in asking for "adequate assurances of performance" under a variety of circumstances. The facts of this case, however, offer a vivid example of the dangers of doing it incorrectly. The decision [James Larson v. Farmers Cooperative Elevator of Buffalo Center, Iowa, et al.] can be found on the internet at http://www.ca8/uscourts.gov/opndir/00/05/992954P.pdf.

–David C. Barrett, Jr., National Grain and Feed Association, Washington, D.C.

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www.fda.gov/fdac/features/2000/100_bio.html>.

[5] In addition to federal regulation, agencies of each of the fifty states may regulate the use of biotechnology products within the particular state, under either independent state laws (for example, a state seed certification law) or authority delegated by a federal agency. Michael J. Malinowski, BIOTECHNOLOGY, LAW, BUSINESS, AND REGULATION § 11.06[A] (1999).

[6] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

[7] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23303 (June 26, 1986). The dual goals of promoting health and safety and promoting the U.S. biotech industry are readily apparent when one reads the Proposed Coordinated Framework. Proposal for a Coordinated Framework for Regulation of Biotechnology; Notice, 49 Fed. Reg. 50856 (December 31, 1984). Also, see *United States Regulatory Oversight in Biotechnology* (visited October 26, 1999) <http://www.aphis.usda.gov/biotech/OECD/usregs.htm>.

[8] Michael J. Malinowski, *Biotechnology, Law, Business, and Regulation* § 11.06[A], at p. 11-87 (1999). Also see Chart I in the Coordinated Framework, 51 Fed. Reg. 23302, 23304 (June 26, 1986) and *U.S. Regulatory Oversight of Biotechnology* (visited Feb. 15, 2000) <http://www.aphis.usda.gov/biotech/OECD/usregs.htm>.

[9] 21 U.S.C.A. § 303 (West 1999).

[10] 21 U.S.C.A. § 331 (West 1999).

[11] 21 U.S.C.A. § 342(a) (West 1999). Food is also adulterated if it contains an unsafe pesticide chemical residue, i.e., a residue exceeding a tolerance or exemption established by the Administator of the Environmental Protection Agency. 21 U.S.C.A. § 346a (West 1999).

[12] 21 U.S.C.A. § 333 (West 1999). The criminal penalties cannot exceed three years in prison and a $10,000 fine.

[13] 21 U.S.C.A. § 342(a) (West 1999).

[14] 21 U.S.C.A. § 348(a)(2) (West 1999).

[15] 21 U.S.C.A. § 321(s) (West 1999). Food additives used prior to 1958 can also be "generally recognized as safe" because of the experience based on their common use in food.

[16] 21 U.S.C.A. § 331(a) and (b) (West 1999).

[17] 21 U.S.C.A. § 343(a) (West 1999).

[18] 21 U.S.C.A. § 371(a) (West 1999).

[19] *See* 21 U.S.C.A. § 346a. The quoted language comes from § 346a(b)(2)(a)(ii). The EPA has addressed the issue of tolerances for pesticides produced by *Bt* corn, for example. In the case of MON 810, the EPA concluded that no tolerance was necessary and exempted the active ingredient. See Pesticide Fact Sheet (visited Feb. 14, 2000). <http://www.epa.gov/docs/fedrgstr/EPA-PEST/1997/September/Day-10/cry.htm>.

[20] To reduce regulatory burden, FDA exercises minimal oversight of products that are Generally Recognized as Safe (GRAS). Such foods are subject to FDA's section 402 broad post-market authority to remove unsafe foods from the marketplace, but exempt from the far more rigorous and resource demanding pre-market review of section 409 (unsafe food additives.

[21] FDA looked explicitly at both food and feed use of products containing the "antibiotic marker gene" introduced into the Flvr Savr tomoto by genetic engineering, both for the likelihood of inactivation of therapeutic antibiotics (the gene did not inhibit the use of existing antibiotics in people) and for the potential of genetic flow to microorganisms (nor did it contribute substantially to bacteria developing resistence). FDA concluded that the gene was safe. See FDA's review document at <http://vm.cfsan.fda.gov/~dms/OPA-ARMG.HTML#1> (Visited September 23, 1999.)

[22] Because the objective of most modifications is to effect some kind of change in composition no matter how small, one could argue that a genetically engineering food cannot be exactly equivalent. This is largly the argument of those who question the safety of any GM food. In practice, there is an iterative consultation process between developers and FDA through which it is decided by mutual consensus whether pre-market approval should or should not be required. FDA provides guidance to the developer on a case-by-case basis. Personal communications from Dr. Bruce Chassy, Professor and Head, Department of Food Science and Human Nutrition, UIUC.

[23] Statement of Policy, Foods Derived From New Plant Varieties, 57 Fed. Reg. 22983 (1992).

[24] The concept of substantial equivalence as applied to GM foods was first used in an OECD publication, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles," 1993, available at <http://www.oecd.org//dsti/sti/s_t/biotech/prod/MODERN.pdf>, accessed October 10, 1999. It is a report of a group of 60 experts from 19 countries, nominated by their governments. An October 7, 1999, article in *Nature*, challenging the validity of using substantial equivalence to evaluate the safety of GM foods has drawn quick rebuttals. See <http://www.biotechknowledge.com/showlib_us.php3?2167>, accessed October 10, 1999.

[25] *See* Statement of Policy, Foods Derived From New Plant Varieties, 57 Fed. Reg. 22983 (1992).

[27] U.S. Food and Drug Administration, Foods Derived from New Plant Varieties Derived through Recombinant DNA Technology-Final Consultations under FDA's 1992 Policy (visited January 31, 2000) <http://vm.cfsan.fda.gov/~lrd/biocon.html>.

[28] David A. Kessler, Michael R. Taylor, James H. Maryanski, Eric L. Flamm, Linda S. Kahl, *The Safety of Foods Developed by Biotechnology*, 256 Science 1747, 1749 (1992).

[29] FDA did not require special labeling for the Flavr Savr tomoto because the new tomato was not significantly different from the range of commercial varieties referred to by that name. However, Calgene (the developer of the Flavr Savr tomoato) decided to provide special labeling, including point-of-sale information, to inform consumers that the new tomato has been developed through genetic engineering.

[30] The agency has not required labeling for other methods of plant breeding such as chemical- or radiation-induced mutagenesis, somaclonal variation, or cell culture. For example, there is no requirement to label hybrid sweet corn because it was developed through cross-hybridization.

[31] See, e.g., Greenpeace, *The Sound of Unsound Science: EPA and EU Regulation of Bt Crops and Effects on Non-Target Insects* (visited May 16, 2000). <http://www.greenpeace.org/~geneng/>.

[32] See Food and Drug Administration, *Bioengineered Foods* (visited May 16, 2000). <http://www.fda.gov/oc/biotech/default.htm>.

[33] See, e.g., National Research Council, Genetically Modified Pest-Protected Plants: Science and Regulation, at Chapter 4: Strengths and Weaknesses of the Current Regulatory Framework, p. 143-180 (2000). This publication is available from National Academy Press and is on the Internet (visited May 16, 2000) at <http://books.nap.edu/catalog/9795.html>.

[34] Id.

[35] The White House Office of the Press Secretary, *Clinton Administration Agencies Announce Food and Agricultural Biotechnology Initiatives: Strengthening Science Based Regulation and Consumer Access to Information* (visited May 9, 2000). <http://www.pub.whitehouse.gov/uri-res/I2R?urn:pdi://oma.eop.gov.us/2000/5/4/10.text.1>. This FACT SHEET can be accessed through the web site for White House Electronic Documents, <http://www.pub.whitehouse.gov/WH/Publications/html/Publications.html>, and searching for Fact Shhets issued May 3, 2000). *See also*, Food and Drug Administration, *FDA to Strengthen Premarket Review of Bioengineered Foods* (visited May 16, 2000) <http://www.fda.gov/bbs/topics/NEWS/NEW00726.html>.

Regulating foods derived from genetically engineered crops

by Donald L. Uchtmann

Genetic engineering offers much promise.[1] Perceived benefits arising from its application to agriculture and the food industry include:

- Cheaper and more abundant food
- New foods of higher quality and greater utility for the consumer
- Reduced food production costs for the farmer
- Reduced use of chemical pesticides and the accompanying reduction in environmental degradation
- Job creation, especially in countries at the leading edge of biotechnology research and commercialization
- Staving off a world food crisis potentially arising from world population increases.

Associated with these perceived benefits is an array of risks[2] and societal concerns including:

- Known food safety, agricultural, or environmental risks, e.g., allergies, a new bacteria resistant to antibiotics, or a new "super" weed
- Unknown food safety, agricultural, or environmental hazards
- Concerns about biotechnology's impact on the structure of agriculture and the number of "family" farms
- Concerns about biotechnology's impact on corporate mergers and the accompanying concentration of economic power
- Ethical and religious concerns, about patenting genes and about both *using* a technology to move genes among organisms which do not naturally mate and *repressing* a technology that offers the potential for significant humanitarian benefits.

The opportunity to glean significant benefits from genetic engineering, coupled with some risks and societal concerns, causes genetic engineering and its products to be both controversial and subject to governmental regulation.[3] This article focuses on the federal regulatory scheme intended to assure that foods derived from genetically engineered plants are just as safe to consumers as other foods consumed in the United States.[4] The foundation for that regulatory scheme is found in the Federal Food, Drug, and Cosmetic Act (FDCA) and two significant public policy statements, all three of which are described below.

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Genetic engineering and food-safety: key federal policies and statutes

The 1986 Coordinated Framework for the regulation of biotechnology

Biotechnology products, including foods derived from genetically engineered crops, are regulated pursuant to a coordinated framework announced in 1986 by the White House Office of Science and Technology Policy. Relying on existing federal laws, the coordinated framework assigns lead regulatory responsibility to one federal agency for each category of product use.[5] For example, the Food and Drug Administration (within the Department of Health and Human Services) is the lead regulatory agency for genetically engineered products in the category of "food and food additives" even though the Food Safety and Inspection Service (within the Department of Agriculture) has jurisdiction over meat and poultry products. Where agency responsibilities or authorities adjoin or overlap under existing laws, the coordinated framework sets out principles for coordinated and cooperative reviews.[6]

Some background: In the mid-1980's numerous federal agencies had already amassed considerable experience regulating agricultural, pharmaceutical, and other products developed by traditional genetic manipulation techniques such as selective breeding. In the spring of 1984 the Reagan Administration formed an interagency working group to consider the adequacy of the existing regulatory framework as the basis for regulating new products of biotechnology. This working group "sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry."[7] The working group published Notice of its Proposal for a Coordinated Framework in December, 1984, and announced its regulatory policy in June, 1986. Present in both the 1984 and 1986 Notices is the working group's conclusion that existing laws as currently administered by existing agencies would adequately meet the regulatory needs for products of the newer biotechnologies, for the most part.

Under the Coordinated Framework, selected categories of products potentially produced by biotechnology processes and the specific agencies given primary responsibility for approving their commercial use under existing laws are:[8]

- *plants, seeds, plant pests, and certain genetically engineered organisms containing genetic material from plant pests:* regulated by the **Animal and Plant Health Inspection Service (APHIS)** of the US Department of Agriculture.
- *pesticides and other toxic substances*: regulated by the **US Environmental Protection Agency (EPA)**.
- *food additives and food:* regulated by the **Food and Drug Administration (FDA)** of the U.S. Department of Health and Human Services (FDA actually regulates all food other than meat and poultry products, the Food Safety Inspection Service of USDA has jurisdiction for domestic livestock and poultry products, and EPA sets "tolerances" for pesticide residues in food; but FDA is the lead agency for all food and food additives).

Example: New *Bt* corn varieties (plants genetically engineered to produce a protein toxic to European Corn Borer) have fallen under the regulatory jurisdiction of all three agencies–USDA, EPA, and FDA. For a particular line of *Bt* corn to be commercially grown in the United States, it needed to be approved by USDA-APHIS (e.g., a petition for "nonregulated status" needed to be approved), which would consider whether the plant would be a "plant pest" and would prepare an environmental assessment. The USDA approval is intended to assure that the crop would not be harmful to agriculture considering both its benefits (effective control of European Corn Borer) and its shortcomings (possibly speeding the development of *Bt*-resistant pests). Because *Bt* corn plants contain their own toxic protein, it was also regulated by EPA, which has responsibility to assure the safety of pesticides. Since the *Bt* corn is intended to be fed to livestock, processed into corn syrup (a sweetener) for use in soft drinks, or made into corn flakes, FDA also had regulatory jurisdiction. To summarize: A company bringing a particular variety of *Bt* corn to the marketplace needed to approach USDA, EPA, and FDA and meet all their regulatory requirements: USDA would determine that it was safe to grow, EPA that it was safe for the environment, and FDA that it was as safe to eat as other foods (although FDA would not automatically review and formally approve the product before it entered the marketplace). Not all genetically engineered crops would

fall within the jurisdiction of all three agencies, but *Bt* corn is one that does.

The 1938 Federal Food, Drug, and Cosmetic Act

Regarding the safety of all food, including food developed from biotechnology, the key legislation is the 1938 Federal Food, Drug, and Cosmetic Act.[9] The following provisions of the Act, as amended, are especially significant:

- Act § 402. Adulterated Foods. Summary: The adulteration of food and the introduction into interstate commerce of adulterated food is prohibited by the Act.[10] Foods are deemed adulterated, for example, if they contain any poisonous or deleterious substance in a quantity that ordinarily renders the food injurious to health.[11] The Act provides criminal sanctions for violation of its prohibited acts,[12] and perhaps more significantly, by criminalizing conduct, the Act provides a foundation for civil liability. Section 402 is also the statutory basis of FDA's "*post-market*" authority to remove food from the market that has been found, through experience or otherwise, to be unsafe.
- Act § 409. (Unsafe) Food Additives. Summary: The addition of an "unsafe" food additive to food, or the introduction into interstate commerce of food with an "unsafe" food additive, is prohibited.[13] Food additives are "unsafe" unless, for example, the additive and its use are in conformity with a federal regulation prescribing the conditions for safe use.[14] Substances that are "generally recognized as safe" (GRAS) by scientists are excluded from the definition of "food additives" and, therefore, cannot be a § 409 (Unsafe) Food Additive.[15] Importantly, § 409 is the basis for FDA's only "*pre-market*" approval requirements for genetically engineered food or any other food.
- Act § 343. Misbranded Food. Summary: The misbranding of food or introducing misbranded food into interstate commerce is prohibited.[16] Foods are misbranded if, for example, the label is false or misleading.[17]
- Act § 701. Regulations and Hearings. General authority to promulgate regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act is delegated to the Secretary of Health and Human Services (the "departmental home" for FDA).[18]
- Act § 408a. Pesticide Tolerances. Summary: Foods containing "unsafe" levels of pesticide residues are brought within the meaning of § 402 Adulterated Foods, thus making their sale unlawful. Unsafe levels of residues include those exceeding the "tolerances" established by EPA. The Administrator of EPA is given the authority to issue regulations that establish, modify, or revoke tolerances for particular pesticide residues. Such tolerances must be "safe," meaning generally that "there is a reasonable certainty that no harm will result from aggregate exposure ...."[19]

Whole foods, such as fruits, vegetables, and grains, generally are not subject to pre-market approval under Act § 409 (Food Additives) because such foods are generally recognized as safe (GRAS).[20] But should a genetically engineered whole food be subject to strict pre-market review and approval by FDA? FDA gained insight into this question when it chose to conduct a pre-market extensive review of the Flavr Savr tomato, utilizing an evaluation process open to public comments and a decision process open to public scrutiny.[21] The rationale for the pre-market extensive review was the uncertainty about whether the genetically engineered Flavr Savr tomato was "substantially equivalent" to existing tomatoes, which are recognized as safe. If it was not substantially equivalent to existing tomatoes, its transgenic food components would be a "food additive" (i.e. not GRAS) and the food would be required to undergo pre-market review and approval under § 409.[22] FDA's conclusion was that the Flavr Savr tomato was "substantially equivalent" to its non-genetically engineered tomato counterparts. More importantly, the experience gained in the Flavr Savr considerations contributed to the development of FDA's 1992 Policy Statement regarding foods derived from new plant varieties.

FDA's 1992 policy statement: foods derived from new plant varieties

FDA's 1992 policy statement clarified FDA's legal and regulatory framework for foods derived from new plant varieties, including new varieties developed through genetic engineering. It established a "standard of care" for the developers of new crop varieties regarding the testing necessary to assure that foods arising from the new plant varieties would be as safe as other foods. It provided guidance as to when a new plant variety would trigger the pre-market approval requirements of § 409. And it provided guidance to producers regarding when they should voluntarily consult with FDA regarding various issues. Under this framework, foods derived from genetically engineered crop varieties are regulated using an approach identical in principle to that applied to foods derived from conventionally developed new varieties.[23]

Under FDA's 1992 policy the safety of food and its regulatory status (is pre-market approval required or not?) depends on specific characteristics of the food and its intended use, irrespective of the method by which the plant variety was developed. In other words:

- if a new plant variety (for example, a new *Bt* variety of corn) is intended to be used as a food, the safety of that new variety is generally determined by examining the likely presence of toxicants or allergens in the food and any changes in nutritional value;
- the mere presence of trans-genetic material (nucleic acids) in the food does not trigger the pre-market FDA review and approval required by section 409 (the *genetic material* is GRAS);
- but if the new genetic material *expresses* itself in the food as a new protein, carbohydrate, fatty acid, oil, or other substance that *differs significantly* from those currently found in existing foods, then (a) the food is not substantially equivalent[24] to foods already on the market, (b) the "new" proteins, etc., will not be GRAS, and (c) the food with "new" proteins, etc., is subject to the pre-market review and approval requirements of § 409 (unsafe food additives).

For example, if the genes in a new plant variety express themselves in food as a *novel* protein sweetener, that sweetener would trigger the submission of a § 409 food additive petition by the company and mandatory pre-market approval by FDA. But the mere presence of recombinant DNA in the food, by itself, would not trigger the pre-market approval apparatus.[25]

A company could easily have questions about food from its new plant variety. For example, is the food substantially equivalent to existing foods and thereby generally recognized as safe (GRAS)? Or is pre-market approval required? The 1992 policy statement provided guidance on when the company should voluntarily consult with FDA on scientific issues, the design of appropriate test protocols, whether a food additive petition under § 409 would be required, and the requirements for labeling. Although the consultations are technically voluntary, they have become part of the standard of care expected of industry and are relevant in determining civil liability in cases involving unsafe food. As a practical matter, the voluntary consultations are tantamount to being mandatory.[26] A list of completed consultations can be found on the World Wide Web.[27] A helpful explanation of when a company should consult with FDA, and a decision diagram showing the critical points when consultation should occur, can be found in a 1992 issue of Science.[28]

FDA's 1992 policy also addressed labeling of foods derived from new plant

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varieties, including plants developed by genetic engineering. The FDCA defines the information that must be disclosed in labeling. The Act also requires that all labeling be truthful and not misleading, but it does not require disclosure in labeling of information solely on the basis of consumer desire to know.

FDA requires special labeling if the composition of the GM food differs significantly from its conventional counterpart. For example, if a food contains a major new sweetener as a result of genetic modification, a new common name or other labeling may be required.[29] Similarly, if a new food contains a protein derived from a food that commonly causes allergic reactions (and the developer cannot demonstrate that the protein is not an allergen), labeling would be necessary to alert sensitive consumers. Regarding the need to label a food just because it is from a genetically engineered plant variety, FDA does not require foods produced from GM crops to be specially labeled.[30] FDA's rationale is that it has no basis to distinguish genetically engineered foods as a class from foods developed through other methods of plant breeding.

Genetic engineering and food-safety: some key regulatory issues

The use of foods derived from genetic engineering has been controversial.[31] In the United States, the FDA has addressed this controversy by holding a series of public meetings in late 1999 titled "Biotechnology in the Year 2000 and Beyond." These meetings, held in Chicago, Washington, D.C., and Oakland, have served as a forum for the airing of views from experts and lay citizens regarding the current regulation of foods derived from genetically modified plants. A sampling of these issues appears below and transcripts from these meetings can be obtained from the FDA's internet site.[32]

New technology and a patchwork of old laws: does the patchwork of older legislation provide an adequate statutory basis for the regulation of new risks associated with products at the cutting edge of technological innovation? The Coordinated Framework relies on a patchwork of laws such as the 1938 Federal Food, Drug, and Cosmetic Act as the statutory basis for biotechnology regulation. Critics argue that these laws were not enacted to regulate biotechnology and have been stretched beyond their original regulatory intent. Others argue that the laws are sufficient to identify the broad agricultural, environmental, and food-safety concerns related to biotechnology and to assign regulatory oversight to appropriate agencies, and that the laws have been amended as necessary to fix outdated provisions. Furthermore, the broad concepts present in the laws provide flexibility to agencies as they promulgate rules and regulations which are the heart of the regulatory effort.

Regulating the product, not the process: should GM foods be subject to a separate regulatory scheme because they are derived from a genetic engineering process, or should they be regulated like all other foods where the focus is on the characteristics of the product? Consistent with the Coordinated Framework, FDA currently focuses on the characteristics of the food product, not the fact that it may have been produced from a plant produced from the process of genetic engineering, in determining how it is regulated. For example, foods derived from *Bt* corn or Roundup Ready soybeans are not subject to a separate, mandatory regulatory scheme. However, they are subject to a voluntary consultation process. Critics argue that the process of creating plants through genetic engineering makes GM foods inherently different, creates inherently different risks, and should be subject to a strict regulatory scheme applied to all foods derived from genetically engineered plants.

Pre-market approval and substantial equivalence: should all foods derived from genetically modified plants be subject to mandatory pre-market approval, even food thought to be "substantially equivalent" to its non-GM counterpart? Most foods have not been tested and approved by FDA before coming to market. Under current laws and regulations, the only foods subject to FDA pre-market approval (FDCA, § 409 - Food Additives) are foods containing added substances. Under its 1992 policy statement, FDA does not generally require pre-market approval for genetically modified foods – it views the GM food as GRAS unless there is a significant difference in its proteins, carbohydrates, etc., compared to the food's non-GM counterpart. Only if there are significant differences, is pre-market approval required. To date, most of the GM foods reviewed by FDA under its voluntary consultation procedures have not been viewed as significantly different, so most GM foods have not been formally reviewed and approved by FDA before entering the market. Critics argue that no GM foods are exactly equivalent to their non-GM counterparts; therefore, all should be subject to the existing pre-market approval requirements applying to food additives.

Voluntary consultations: should the voluntary consultative procedure described in FDA's 1992 Policy Statement be made mandatory? Although technically voluntary, the threat of civil liability makes the consultations tantamount to mandatory in the eyes of the companies. And FDA believes all companies that have brought genetically engineered foods to market so far have participated in the voluntary consultations. The results of those consultations are available to consumers under the Freedom of Information Act, and FDA has asked the public for advice about how it might make the consultation data available in a more user-friendly manner. Critics argue that the voluntary nature of the consultation, on its face, erodes consumer confidence and, in a procedural sense, does not provide the kind of "sunshine" on the decision-making process that a mandatory consultative process would provide.

Labeling and allergies: by not labeling all genetically engineered foods, is FDA putting the public at greater risk of ingesting a new allergen and suffering an allergic reaction? FDA does not believe that a GM food is any more likely to cause an allergic reaction than a non-GM food. It notes that about ninety percent of all food allergies in the U.S. are caused by cow's milk, eggs, fish and shellfish, tree nuts, wheat, and legumes (especially peanuts and soybeans). Under existing policy, companies must generally tell consumers on the food label when the food contains a gene from one of these common allergy causing foods. FDA also indicates it has no scientific evidence to indicate that any of the new proteins introduced into food by GM foods will cause allergies. And, in the unlikely circumstance that the GM food does cause allergic reactions, FDA can exercise its post-market authority to remove the food from stores, just as it would with unsafe foods resulting from other remote risks. Critics argue that a new protein in a GM food could theoretically be a new allergen and there is no known test that can assure it is not; therefore, consumers who wish to choose non-GM foods as a way of avoiding a "new allergen" risk cannot tell which foods might be genetically engineered.

Consumer choice and labeling: should genetically engineered foods be labeled to allow consumers to choose? The issue is more complex than it would first appear. Should foods containing some threshold of GM ingredients be subject to mandatory labeling or should the labeling policy simply allow (as it currently allows) the food industry to segregate, label as "GM Free," and supply foods that are below an established threshold for GM free? How do we best use the limited amount of "label space" available? How do you label genetically engineered foods without misleading the public?

Getting maximum bang for the regulatory buck: if FDA were given new funding to improve the safety of food, would it make sense to invest those new dollars in combating the risks of genetically engineered food or combating other food safety risks? Microbial spoilage and food contaminants (substances like lead or diox-

ins) probably pose much greater risks to the safety of the food supply than genetic engineering. In light of this, should new funds be invested in new programs to combat food spoilage and contamination, or in expanding FDA's capacity to conduct pre-market reviews and approvals of all foods derived from genetically engineered foods?

Narrow regulatory mandates: do the narrow statutory mandates to agencies prevent them from considering ethical and religious dimensions of biotech-related issues? The regulatory jurisdiction of FDA, for example, is statutorily focused on food safety and labeling issues. FDA has no statutory authority to ban GM foods because of ethical or religious-based concerns about genetic engineering. Some who hold such views believe the statutes should empower the agencies to look beyond their current scope of authority. Others believe that such ethical and religious views are entirely proper as a basis for individual actions, e.g., consumer boycotts. They argue, however, that agencies should not be enforcers of ethics or religion because such a role would raise the issues of "whose ethics" and "whose religion;" instead, such issues should be deferred to the political arena, subject to constitutional limits on the role of government and protections of individual freedoms. It should be noted that the narrow mandates of biotech regulators and the current labeling void for genetically engineered foods creates a dilemma for those who object to biotechnology on religious or ethical grounds. They are either forced to recast their objections as concerns about health and environmental risks (if they are to have any impact on agency rule-making), or they must resort to public protests and civil disobedience (if they are to otherwise "live" their beliefs). If it were possible, through some resolution of the labeling issue, to empower these people to "live" their beliefs through consumer choice, such a resolution might bring greater clarity to the arguments about health and environmental risks and defuse some of the public protests about genetically engineered foods.

Conclusions and recent developments

How healthy is the food-safety regulatory scheme

How healthy is the regulatory scheme for genetically engineered food? There is considerable evidence that the regulatory system's vital signs are surprisingly healthy.[33] The system has appropriate checks and balances, overall responsibility is shared between governmental and private entities, and decision making generally takes place "in the sunlight" of public scrutiny. It provides opportunities for the public and scientific experts to be heard, and for both the regulated (the researchers and companies) and the intended beneficiaries of regulation (the consumer and the public) to fully participate. It generally operates in a manner that instills public confidence. It is dynamic and undoubtedly will continue to evolve. It has been tested by controversial issues in the past and has managed to evolve and adapt successfully to changing scientific discoveries and political realities. It is difficult to imagine that a truly erroneous regulatory decision regarding biotechnology would be made, or stand very long if it were made. Either consumers, scientists, the public at large, the courts, the legislature, or the increasingly important international community would find a way to effectively intervene.

Can biotech-related food-safety regulation be improved?

Our system of regulating biotechnology is not a perfect system.[34] We should continue to evaluate both the regulatory system and its specific regulatory actions. And we should continue to work diligently to identify where improvements can be made. For example, regarding the system of biotech regulation, should there be some rearrangement or consolidation in the agency roles outlined in the Coordinated Framework? Does the system strike the appropriate balance between formal governmental regulation and the less formal regulation of consumer choice exercised through the marketplace? Has the system struck the correct balance between our society's insatiable desire for safety and its insatiable demand for innovation and new products, such as those resulting from genetic engineering? To what extent should our domestic regulatory scheme be in harmony with the schemes of trading partners or defer to international trading rules?

Regarding specific agency actions, can FDA find some resolution of the labeling issue (perhaps some guidance for voluntary labeling as was developed for organic foods)? Should FDA make its 1992 voluntary consultation procedures mandatory? Can the food testing and risk analysis data developed in those consultations be more readily available to consumers who want that information, perhaps through "Food Safety Assessments" that would be available on the internet and functionally analogous to the Environmental Assessments of agency actions required by the National Environmental Policy Act? Are there other approaches to these and other issues that would better serve the public interest?

In a Press Release issued May 3, 2000, the White House announced plans to strengthen science-based regulation of biotechnology and consumer access to information.[35] More specifically, the plans call for the following steps regarding food safety:

- The Food and Drug Administration (FDA) will take steps to ensure that it is informed at least 120 days before new agricultural biotechnology crops or products are introduced into the food supply and will propose that submitted information and the agency's conclusion be made available to the public.
- The U.S. Deptartment of Agriculture (USDA), FDA, and the Environmental Protection Agency (EPA) will support an expanded program of competitively awarded, peer-reviewed research focusing on current and future safety issues.
- FDA will develop guidelines for voluntary efforts to label food products under their authority as containing or not containing bioengineered ingredients in a truthful and straightforward manner, consistent with the requirements of the Federal Food, Drug, and Cosmetic Act.
- USDA, FDA, EPA, and the State Department will enhance domestic and foreign public education and outreach activities to improve understanding of the nature and strength of our regulatory process.

On their face, these initiatives seem to be a reasoned response intended to improve a regulatory scheme that is currently serving U.S. consumers quite well. But the details will be important, and they have yet to be developed.

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[1] *See, e.g.*, Food and Drug Administration, *Genetic Engineering: Fast Forwarding To Future Foods* (article revised February 1998 and visited May 16, 2000). <http://www.fda.gov/bbs/topics/CONSUMER/geneng.html>.

[2] *See* Gerald C. Nelson *et al*, *The Economics and Politics of Genetically Modified Organisms in Agriculture: Implications for WTO 2000*, at 32 (1999) (Bulletin 809, November 1999, Office of Research, College of ACES, U. of Illinois at Urbana-Champaign).

[3] For an excellent, brief discussion of the contemporary setting of biotechnology, science, government regulation, and public concern, see the *Preface* to National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation (2000)*. This publication is available from National Academy Press and is on the Internet (visited May 16, 2000) at <http://books.nap.edu/catalog/9795.html>.

[4] Regarding the safety of bioengineered foods generally, see U.S. Food and Drug Admin., *Are Bioengineered Foods Safe?*, DA Consumer Magazine Jan.-Feb. 2000 (visited Jan. 31, 2000). < http://

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