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Labeling Genetically Engineered Food in the United States: Suggestions for a New Approach

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Abstract: The Federal Food, Drug, and Cosmetic Act (FFDCA) provides that a food is misbranded if the label accompanying the product is false or misleading in any particular. Congress provided minimal guidance to assist the FDA in making these determinations. When challenged, courts have granted substantial deference to FDA’s various interpretations of what constitute a material fact. However, when confronted with the regulatory question of whether or how to label products derived from genetically engineered (GE) crops, the FDA adopted a narrow reading of the statute that focused on changes in the product itself, rather than the act of genetic engineering. Only those GE products that possessed characteristics significantly different from their conventional counterparts would require labels. This “process *versus* product” distinction in food labels lies at the heart of the FDA’s resistance to repeated calls for mandatory labeling of foods derived from genetic engineering. Consumer interest in GE food, according to the agency, is not a material fact to trigger mandatory labeling under the statute. In contrast to its approach to GE labels, the agency has long required (since 1966) process-based labels for foods treated with irradiation. As recently as 1986, the FDA affirmed that materiality of information under its misbranding analysis is not limited to product safety or even the abstract worth of the information, but whether consumers view the information as important and whether the omission of a labeling statement would mislead the consumer. Accordingly, mere consumer interest can give rise to a mandatory labeling regime under the FFDCA. In the irradiation context, whole foods and single-ingredient products treated with irradiation must bear a label indicating the process. The irradiation of components in a multi-ingredient food product, however, need not bear a label. This distinction between processed, multi-ingredient and whole or single-ingredient foods provides a potential pathway for the agency to revise its approach to mandatory GE labeling. Exempting highly processed, multi-ingredient foods from a labeling regime would minimize traceability and

segregation-generated disruptions in the commodity supply chain, thereby minimizing potential compliance costs, while also empowering consumers to express their preferences for non-GE whole and single-ingredient food products.

Keywords: genetic engineering; labeling; biotechnology; food; regulation; first amendment; FDA; GRAS; irradiation

Abbreviations

FDA: Food and Drug Administration; USDA: United States Department of Agriculture; GE: genetically engineered; FFDCA: Federal Food, Drug, and Cosmetic Act; GRAS: Generally Recognized as Safe; rBST: Recombinant Bovine Somatotropin; ANPR: Advanced Notice of Proposed Rulemaking.

1. Introduction

At the federal level, regulatory decisions regarding the labeling of products intended for food and feed fall under the purview of the Food and Drug Administration (FDA). This includes mandatory disclosures such as nutrition information, as well as the wide and growing array of optional labeling communications such as health claims, nutrient content claims and, more recently, GM-free claims. FDA jurisdiction in this area arises from the Federal Food, Drug, and Cosmetic Act's (FFDCA) prohibition against the introduction into interstate commerce of misbranded food [1]. As a general rule, a food is misbranded if the labeling accompanying the product is "false or misleading in any particular" [2]. This, of course, begs the question of what is a "particular" with respect to a food item.

Congress provided minimal guidance to assist the FDA in determining whether the label on an allegedly misbranded item is misleading [3]. The general definitions section of the FFDCA states that an assessment of an allegedly misleading label should take into account not only the "representations made or suggested by" the labels text/graphics, but also "the extent to which the labeling ... fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article..." [4] This applies to not only what the label affirmatively states, but also what it fails to disclose when viewed within the context of the affirmative label statements [5].

This rather vague statutory definition, surprisingly, has generated little litigation. Perhaps this is due to the FDA's history of cooperation with the regulated industry [6] and perception as an impartial arbitrator.¹ Moreover, when challenged, courts have unanimously affirmed FDA's various interpretations of what constitutes a "material fact" with respect to labels associated with specific food products.² As a matter of administrative law, this perfect track record is not surprising given the

¹ Although public confidence in the FDA has fallen over the past few years, the public has higher confidence in the agency relative to business interests to manage risks associated with new technologies [7,8].

² For example in *United States v. Ninety-Five Barrels More or Less Apple Cider Vinegar*, the court affirmed the agency's finding that vinegar made from dehydrated, as opposed to fresh apples is a material fact requiring a labeling statement [9]. Similarly, in *United States v. An Article of Food Labeled Nuclomin*, the court affirmed the agency's finding that the label on a dietary supplement was "misleading," despite no dispute that the actual label was 100% accurate [10], and in

substantial deference courts generally afford agency interpretations of statutes [3], especially when the statutory section at issue is vague or capable of alternative interpretations [13]. The statutory term “false or misleading in any particular” certainly qualifies as a statement susceptible to reasonable differences in interpretation and thus warranting significant deference by reviewing courts [3].

When confronted with the regulatory question of whether or how to label products derived from genetically engineered (GE) ingredients, the FDA adopted a narrow interpretation of the statute that limited the agency discretion to require labeling only relating to changes in the product itself, rather than the act of genetic engineering [14]. Only those GE products that possessed characteristics significantly different from their conventional (non-GE) counterparts (e.g., nutritional changes; potential allergens) would require labeling. The FDA announced this labeling strategy concurrently with its regulatory determination that products produced via genetic engineering generally are substantially the same as their conventional counterparts. The result was the creation of a policy exempting most GE food products from disclosing the production process. This “process *versus* product” distinction in food labels lies at the heart of the FDA’s resistance to repeated calls by consumers and NGOs for mandatory labeling of foods derived from genetic engineering, as well as its hesitancy to support voluntary GM-free labeling initiatives.³

The FDA’s 1992 no-label determination, however, has not been the last word in the GE labeling debate within the United States. Some individual states have advanced mandatory labeling regimes through direct appeals to voters (*i.e.*, ballot initiatives), as well as more traditional legislative avenues. At each stage, significant debate has centered on the ability of the state operating within the federal system to require, or in one case, prohibit, GE labeling schemes on food products. This issue raises unique questions of overlapping regulatory authority and constitutional allocations of power between the state and federal government. Moreover, to the extent labels facilitate market-based participatory democracy [17], the GE-label debate provides important insight into current governing approaches in the United States.

In Section 2, this article will analyze the federal approach to GE labeling in the United States. Particular attention will focus on the historical development of the current rule as well as the FDA’s cautious support for voluntary, GE-Free labels. Section 3 will explore state-level GE labeling measures along with constitutional challenges brought by opponents to labeling rules. In Section 4, this article analyzes the FDA’s approach to another process-based labeling scheme—food irradiation. Section 5 concludes with a call for federal re-engagement in the GE labeling debate, modeled on the government’s long-established approach to irradiation labels for non-processed food products. The current irradiation labeling requirement does not extend to processed foods (multi-ingredient

Alliance for Bio-Integrity, the court affirmed an agency policy statement that process of genetic engineering is not a material fact [3]. A second district court reached the same conclusion in *Stauber v. Shalala*, when it affirmed the agency’s decision to not require labeling of dairy products derived from cows treated with rbST [11]. But in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) the court rejected FDA’s argument on First Amendment grounds that health claims that lack significant scientific agreement are inherently misleading and cannot be cured via use of a disclaimer [12].

³ For example, the *Genetically Engineered Food Right to Know Act* garnered 58 co-sponsors in the 106th Congress, but failed to advance beyond the committee stage. Similar bills failed in the 107th through the 110th Congress. [15]. In 2011, the FDA acknowledged that most of the comments received by the agency requested mandatory labeling of foods produced with genetic engineering [16].

products). In contrast, most calls for biotech labeling include labeling of ingredients in processed foods. This approach presents significant scoping and traceability challenges as the primary GE crops in the United States—corn and soybeans—are present in innumerable processed food products. In contrast, a targeted labeling requirement applicable only to whole (single ingredient) foods directly consumed by consumers (e.g., GE sweet corn, tomatoes, apples), would vastly simplify the traceability and labeling requirements for most commodity-based supply chains. The proposed labeling requirement limited to whole foods would also provide more meaningful information to consumers, as it would identify those products altered by the technology that are consumed directly, rather than the more insignificant and ubiquitous components of a multi-ingredient product (e.g., the trace amounts of high fructose corn syrup derived from GE corn added to a frozen dinner).

2. Development of GE Food Labeling Rules by the Federal Government

The *Coordinated Framework for Regulation of Biotechnology* [18] outlined FDA's intention to apply existing statutory authority to regulate foods derived from GE plants in the same manner as conventionally-produced food products. Much has been written about the FDA's subsequent regulatory approach to the safety of genetically engineered foods as specified in the agency's 1992 *Statement of Policy: Foods Derived from New Plant Varieties* [14,19–21]. Accordingly, only a brief summary follows.

In its Statement of Policy, the FDA acknowledged that it possessed two statutory routes to assert jurisdiction over the safety of foods derived from new plant varieties: an added substance that may be injurious to health, or the premarket approval requirement for food additives [14]. The “added substance” authority is the primary means used by FDA for the post-market regulation of the presence of contaminants in conventional whole foods [14]. In contrast to the reactionary nature of its “added substance” authority, agency regulation via the “food additive” section of the statute requires, in most instances, FDA's pre-market review and approval of the added substance. Under this regulatory paradigm, food processors must receive FDA approval prior to marketing a product containing a food additive.⁴ One exception to this pre-market review procedure is the statutory carve out from the definition of a food additive—substances generally recognized as safe (GRAS) [22].⁵ The statute provides that GRAS substances are not technically “food additives,” and thus need not traverse the FDA approval process prior to marketing.

The FDA's 1992 Statement of Policy outlined the agency's position with respect to these two jurisdictional issues—treatment of genetic modification under the “added substance” framework and the food additive regime. Noting that the legal burden of marketing safe food rested on the novel food producer seeking to introduce or use genetic engineering, the agency stated that the post-market

⁴ Section 402(a)(2)(c) of the FFDCFA, 21 U.S.C. § 342(a)(2)(c) deems a food adulterated “if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title,” which subsequently provides that a food additive is unsafe unless approved by the agency for a particular use.

⁵ The Federal Food, Drug, and Cosmetic Act defines a food additive as “any substance the intended use of which results ... in its becoming a component or otherwise affecting the characteristics of any food ... if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety ... to be safe under the conditions of its intended use...”

regulation of novel plant varieties derived from genetic engineering would follow the current regulatory regime for new plants modified via traditional methods [14]. In sum, an *ex post* regulatory approach whereby the agency would pursue any food safety violations via post-market enforcement authority [14]. The FDA acknowledged that the producer could engage the agency on a voluntary basis for informal consultations regarding safety of the “added substance” resulting from genetic engineering, but such consultations would not be a mandatory step in pre-commercial activities [14].

The agency adopted a more nuanced approach with respect to regulation of genetic engineering as a food additive. The insertion of DNA into a plant variety intended for food could fall under the definition of a food additive [22]. To avoid the tedious (from an industry perspective) pre-market approval procedure of traditional food additives, the FDA promulgated an opinion that the minor variations of molecular structure resulting from genetic engineering would be substantially equivalent to the plant’s conventionally developed counterpart [14].⁶ Because of the substantial equivalence to the preceding plant variety, the changes resulting from genetic engineering ordinarily would not alter the GRAS status of the new plant and, therefore, not warrant formal premarket review and approval by FDA under the food additives provision of the FFDCA. The agency, once again, stressed that ultimate responsibility (and thus potential regulatory liability) for assuring safe food rests with the food producer, and any questions regarding GRAS status should trigger voluntary consultation with the agency.⁷

The substantial equivalence/GRAS conclusion reached in the food safety context substantially informed the agency’s approach toward labeling food derived from genetically modified plants. The FDA’s Statement of Policy limited the materiality analysis of the FFDCA [4] to differences from the food’s “traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted” [14]. In light of the GRAS finding from a safety-perspective, the agency concluded that GE foods did not differ from conventional products in “any meaningful or uniform way” or presented “any different or greater safety concern[s]” [14]. Accordingly, the absence of a label indicating genetic engineering would not rise to the level of misbranding for failure to “reveal facts material.”⁸ Four years later, as part of the FDA’s Education/Compliance Program for genetically engineered foods, the agency proffered a third justification for its decision to reject mandatory labeling—the consumer’s desire to know does not require disclosure of items under the FFDCA [27]. Once again, a statement by the FDA outside of the

⁶ The FDA noted that “With respect to transferred genetic material (nucleic acids), [it] does not anticipate that transferred genetic material would itself be subject to food additive regulation. Nucleic acids are present in the cells of every living organism... and do not raise a safety concern as a component of food.” [14].

⁷ In 1996, the agency released guidance for consultation procedures [23]. In 2001, the agency proposed (but has yet to finalize) a rule requiring premarket notice of foods derived from genetically engineered plants [24]. Although not a rule, the agency recommends developers of novel foods consult the agency [25]. The FDA publishes a list of completed voluntary FDA consultations on genetically engineered foods [26].

⁸ The FDA in 2001 published a guidance document that specifically identified four instances in which labeling is necessary to avoid misbranding charges: (1) a genetically engineered food “is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food”; (2) there is an issue relating to how the new food is used or the consequences of its use; (3) there is a significantly different nutritional composition; or (4) the new food includes an allergen not typically associated with the traditional food. [17].

procedural requirements embedded in notice and comment rulemaking. This interpretation of consumer desire alone not “requiring” disclosure, however, does not foreclose the possibility of the agency at some point in the future from taking consumer sentiment into account during its evaluation of materiality.

FDA’s refusal to mandate labeling of products derived from genetic engineering has survived two court challenges [3,11]. In both court cases, the result hinged on the broad discretion afforded the agency’s factual determination that any difference in characteristics between the challenged product and the conventionally produced counterpart were immaterial. Consumer demand for labels, absent some other factor, was an insufficient basis upon which to mandate a labeling statement [11]. In dicta, the court in *Stauber* went so far as to claim it would be “misbranding” to label a product as different if, in fact, the product characteristics did not differ in any significant way, even if consumers misperceived the products as different [11]. This rather strict reading of the agency’s statutory authority by the district court, however, overlooks the agency’s history of including consumer demand in its labeling analysis and the deference courts should grant the agency’s statutory interpretation of “material fact” to include additional factors. On the other hand, the FDA has been reluctant to encourage product labeling claiming the absence of GE ingredients.

The FDA’s approach to labeling milk products derived from animals treated with the GE hormone Recombinant Bovine Somatotropin (commonly referred to as rBST) is illustrative of the FDA’s cautious approach to GE-free labeling regimes. Approved by the FDA in 1993 [28], rBST continues to engender significant controversy. The FDA asserts that milk from animals injected with rBST show no significant differences when compared to that of untreated animals [29–31]. However, some argue that the studies relied upon by the FDA in approving use of the hormone were not sufficient and that, regardless of the hormone’s safety, consumers have a right to know which products are derived from rBST-injected cows [29]. Seeking to capitalize on this potential market, some farmers that do not to use rBST have attempted to market their milk-products with labels claiming to be free of the GE hormone [32].

Although the FFDCA grants the FDA jurisdiction to regulate product labeling, the agency’s interim guidelines noted that it has no authority to require disclosure when it determines that there is no significant impact from use of the hormone [32]. Additionally, the FDA stated that milk labeling should primarily be a state concern, with the FDA’s findings used as guidance in developing state/local rules [32]. The agency did specify that producers may voluntarily label their products concerning the absence or presence of rBST treatment, so long as all statements are truthful and not misleading [32]. While the FDA made clear that it would not mandate rBST labeling, it left open for debate what falls under “truthful and not misleading” [1].

From a regulatory perspective, “false” labels generally are easier to identify than “misleading” labels. For example, it would be false for any milk producer to claim that its product is “BST-free” or “hormone-free,” as BST is a naturally occurring hormone present in all milk producing cows. Indeed, FDA has issued warning letters to various firms attempting to market dairy products as “Hormone Free” [33,34]. Claiming that milk is “rBST-free,” however, may be true, but, according to the FDA, potentially misleading. From the agency’s interpretation of scientific capabilities at the time of its decision, there is no way to differentiate analytically between naturally occurring BST and rBST in milk products [29]. Moreover, the FDA is unaware of any measurable compositional difference from

cows receiving supplemental rBST and cows that do not [29]. Accordingly, in its interim guidelines, the FDA noted that claiming a product is free of the hormone rBST may imply a compositional difference between the conventional milk product and milk from animals treated with rBST—a claim the FDA regards as false⁹. The agency specified language that may avoid potential confusion, citing the following as an example of a truthful and not misleading label: This milk is “‘from cows not treated with rBST’ accompanied with the qualifying statement that ‘No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows’” [29]. While the FDA’s guidance at least outlines one potential lawful approach to distinguish milk products, as agency guidance (as opposed to a regulation) it remains non-binding and opens the door for states to struggle with their own rBST labeling rules.

3. State Level GE Labeling Regimes and Legal Challenges

In 1994, Vermont enacted a statute mandating the labeling of dairy products derived from rBST injected cows [35]. In response, the International Dairy Foods Association (IDFA), among others, sought to enjoin enforcement, claiming that product labels are a form of speech protected by the First Amendment and the statute requiring a label violated dairy producers’ First Amendment right not to speak [36].

The trial court denied IDFA’s request for a preliminary injunction [37]. On appeal, the Second Circuit Court of Appeals reversed. The Court held that the dairy producers and retailers had a First Amendment right not to speak (*i.e.*, attach a label to a product) unless the state could establish a substantial interest for labeling rBST derived products. Vermont argued that its statute supported a “strong consumer interest and the public’s ‘right to know.’” The court, however, held that mere consumer curiosity in the production process of an item cannot meet the test of a “substantial state interest” sufficient to restrict First Amendment rights. Pointing to the FDA’s research and the inability of scientists to distinguish between end-products produced with or without use of rBST, the Court held in favor of the challenger, IDFA, and enjoined enforcement of Vermont’s mandatory labeling statute.

The Court’s opinion included a vigorous dissent asserting that the state interest was not limited to consumer curiosity, but also substantive concerns regarding rBST’s impact on the health of humans and cows, the financial sustainability of small farms, and general concerns regarding the manipulation of nature via genetic engineering. The proper question, in the dissent’s view, is whether the Constitution prohibits government from mandating disclosure of truthful, relevant information to promote informed consumer choice.

Although the Second Circuit opinion certainly leaves open the possibility that mandatory labeling could pass constitutional muster if the state advanced a more substantive interest, a generalized interest in satisfying consumer curiosity appears to be a losing argument for states attempting to mandate labeling of otherwise scientifically indistinguishable products. Rather, the court relegated process-based labeling decisions to market forces, opining that “those consumers interested in such information

⁹ The FDA notes that “[t]here is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not” [29].

should exercise the power of their purses by buying products from manufacturers who voluntarily reveal [the absence of rBST use].

Another state, Ohio, embarked on an rBST labeling journey similar to Vermont's earlier attempt, but seeking to accomplish the opposite result—restrict dairy producers' ability to label their products as produced without the use of rBST. In February 2008, the Ohio Department of Agriculture issued rules [38] reinterpreting existing Ohio statutes for food labels [39] and the sale of dairy products [40]. The order, purporting to combat the “mislabeling of dairy products” and to create uniformity in dairy labeling across the state, declared “rBST-free” or “No Artificial Hormones” label claims false and misleading [41,42].

The International Dairy Foods Association (“IDFA”), the lead plaintiff in the Vermont litigation discussed above, immediately filed a complaint seeking a declaration that the Ohio rules violated, *inter alia*, the First and Fourteenth Amendments, as well as the Commerce Clause [43]. The IDFA argued that the Ohio statute unconstitutionally silences dairy producers and prevents consumers from receiving accurate information—in this case information about the lack of use of the GE hormones [43]. In *International Dairy Foods Association v. Boggs*, the Sixth Circuit Court of Appeals upheld IDFA's challenge to the labeling ban [44]. In sum, the Court held that Ohio's rule banning composition claims such as “rBST free” was more extensive than necessary to accomplish the state's interest in preventing consumer deception [44]. When read together, the litigation surrounding the Vermont and Ohio rBST labeling statutes illustrate the tension between the First Amendment's protections of speech and the state's interest in regulating process-based food labels to meet constituent demand (whether it is consumers in Vermont or milk producers in Ohio).

Despite these legal setbacks, the voters in the state of Washington are moving forward with a state-level labeling regime for all products produced with genetic engineering. Initiative I-522, titled the *People's Right to Know Genetically Engineered Food Act* [45], would require labeling of food products (including dietary supplements) that contain GE ingredients. The Initiative is similar to California's Proposition 37, which failed in November 2012, in that it seeks to mandate labeling of foods, including raw agricultural products, processed foods, seed and seed stock offered for retail sale that have been or may have been, entirely or partially produced with genetic engineering. Similarly, the Illinois legislature is considering a *Genetically Engineered Food Labeling Act* [46] that would require labeling of food products that contain more than .09% of ingredients (by weight) of genetically engineered materials. Although these measures are unlikely to pass the legislature, they are clear indications that the state-level battle over labeling food produced via use of genetic engineering continues after the legal uproars in Ohio and Vermont.

4. Mandatory Labeling of Production Processes: The Case of Food Irradiation

Food processing employs a variety of preservation methods, including additives, fumigants, growth regulators and temperature controls such as sterilization, pasteurization and refrigeration. Food irradiation—the treatment of food with ionizing radiation—may supplement or even substitute for conventional preservation methods [47]. Specifically, irradiation can extend shelf life by delaying the ripening of fresh produce and reducing concentrations of microorganisms. Other potentially positive changes resulting from irradiation include reduced rehydration time for dehydrated vegetables,

increased yield of fruit juices and tenderized meat products. On the other hand, the irradiation process produces results undesirable to some consumers, as even small changes can affect the flavor or texture of the food product. The irradiation process also precipitates a chemical reaction in food, which results in the production of a novel chemical substance known as radiolytic products. Finally, some consumers, despite its history of safe use, wish to avoid irradiated products due to health concerns [47].

The 1958 Food Additives Amendment to the FFDCA included “foods treated with radiation” on the list of additives requiring pre-market agency approval prior to entering interstate commerce [48]. In 1963, the FDA approved the first use of irradiation on a food product (canned bacon), and in the next three years approved irradiation treatment on several additional products, including wheat flour, potatoes and potable water. In 1966, the FDA Commissioner proposed that food treated with radiation should have that fact declared on the product’s label at the retail level [49]. Specifically, the proposed rule would require the phrase “[p]rocessed by ionizing radiation” or “[t]reated by ionizing radiation” on the food label.

The agency received a total of nine comments in response to its labeling proposal [50]. Six of the nine comments objected to the term “ionizing radiation” on the grounds that consumers would confuse the term with nuclear radiation and suggested instead the term “ionizing energy.” In addition, objectors suggested replacing the term “processed by” and “treated by” with more positive terms such as “sterilized by” or “pasteurized by.” The agency rejected the term “ionizing energy” as consumers associated the term “energy” with capacity of the food to provide nutritional energy rather than a production process. The agency also rejected the terms “pasteurize” and “sterilize” as an undesirable departure from the commonly accepted usages of these terms. Accordingly, with little fanfare, the agency implemented its first labeling requirement for irradiated foods in 1966, as neither the Washington Post nor the New York Times bothered to report on this development.

4.1. First Attempts to Repeal Irradiation Labels for the Retail Market

In 1981, the FDA’s Bureau of Foods’ Irradiated Food Committee issued a report on the safety of irradiated foods and outlined a course of action for future agency regulation [51]. A corresponding notice in the Federal Register provided an advance notice of proposed rulemaking (ANPR) and requested comments relating to the existing labeling requirements for food treated by irradiation technologies. Three years later, in 1984, the agency addressed the public comments and proposed the elimination of labeling statements at the retail level for food products treated with irradiation [52].

Comments received in support of the ANPR (*i.e.*, seeking repeal of the current mandatory labeling scheme) noted that because irradiation is a “process,” not an “additive,” irradiation is not an ingredient of food and does not require identification on the label as an “ingredient.” Although the agency agreed that irradiation is not an “ingredient” and thus does not require labeling as such, the agency refused to acknowledge a statutory exemption for indicating all “processes” on food labels. To illustrate this point, the agency identified pasteurized and homogenized milk as examples of existing processes that require disclosure on product labels. Other process-based labels include 100% orange juice made from concentrate [53], potato chips made from dehydrated potatoes [54], onion rings made from dried

and/or diced onions [55], fish sticks comprised of minced fish [56], and fried claims from minced claims¹⁰ [57].

Instead, the FDA framed the issue with respect to the labeling of a particular process as one of “materiality” and the potential to mislead consumers [52]. The specific test is whether the absence of a label indicating a processing technique would fail to convey “material information” that could have the effect of misleading consumers. Based on this interpretation, the agency concluded that information about irradiation processes is not material and therefore need not be present on the label of retail foods [52].

In stark contrast to historically limited public responses to proposed rules relating to food irradiation, the FDA received over 2,500 comments specifically addressing the proposal to eliminate mandatory labeling or irradiation [58]. More than eighty percent of these comments urged maintaining the labeling requirement to “prevent consumer deception” [58]. The remaining comments opposed any type of retail labeling (*i.e.*, supported the proposed rule). In response to this outpouring of consumer opposition, the FDA changed course and issued a revised labeling rule that maintained mandatory labeling of food products treated with irradiation [59].

In its stated reasoning to maintain the labeling requirement, the agency seemed to reverse course on its increasingly limited interpretation of the FFDCA and adopted an approach sensitive to consumer choice and implied representations. The agency acknowledged that the irradiation process may not change the exterior presentation of the food and, therefore, the failure to make a label statement regarding the treatments implies to consumers that the food is not processed [58]. Moreover, the FDA noted that “materiality” of information is not limited to product safety or even the abstract worth of the information, but on whether consumers view the information as important and whether the omission of a labeling statement would mislead the consumer. The large number of comments provided important evidence to the agency of the significance placed by consumers on the information conveyed by the irradiation labeling program. Based on this evidence, the FDA concluded that irradiation labeling was of material significance, and the failure to include such a label may mislead a consumer—the statutory trigger under 21 U.S.C. § 321(n) to require labels to avoid misbranding [58].

In retaining the labeling rule, the agency distinguished between first and second generation foods. The irradiation of one ingredient in a multiple-ingredient food (second generation food) is a different situation than irradiation of a whole food, single ingredient product (first generation), because multiple-ingredient food has obviously been processed [58]. The agency reasoned that “[c]onsumers would not expect [ingredients in processed foods] to look, smell, or taste the same as fresh or

¹⁰ Courts have upheld challenges to process-based labels. In *United States v. Ninety-Five Barrels More or Less Apple Cider Vinegar*, the U.S. Supreme Court interpreted the 1906 Pure Food and Drug Act’s prohibition against “misleading” product labels [9]. The Court noted the “plain and direct” wording of the statute that “condemn[s] every statement, design, and device, which may mislead or deceive.” [9]. Moreover, the Court observed that “it is not difficult to choose statements ... which will not deceive” and reasoned that statements that are ambiguous or liable to mislead should be interpreted as misleading under the act [9]. Accordingly, the Court supported the agency’s condemnation of the misbranded product labeled “Apple Cider Vinegar” that was made from dehydrated, rather than fresh apples. In reaching this result, the Court stated “[t]he misrepresentation was in respect of the vinegar itself, and did not relate to the method of production merely” [9]. Although vinegar from fresh versus dehydrated apples produced a similar product, the trial judge was able to discern a slight difference in the products [9].

unprocessed food, or have the same holding qualities” [58]. Accordingly, food products that contain an irradiated ingredient (second generation food) are exempt from the irradiation labeling rule.

4.2. *Contemporary Efforts to Reform Irradiation Labeling*¹¹

The Food and Drug Administration Modernization Act of 1997 included a relatively obscure amendment to the 1938 FFDCA. Specifically, the Act added Section 403(c) to the FFDCA, which prohibits FDA from imposing any requirement that the radiation disclosure statement be more prominent than the declaration of ingredients [61]. The accompanying Joint Statement, however, directed FDA to seek public comment on whether additional changes should be made to current irradiation labeling requirements [62]. In accordance with the Congressional directive, FDA issued a public notice on February 17, 1999 seeking suggestions for potential regulatory revisions [63]. In response to the notice, the agency received over 5,500 comments, the majority of which strongly supported the current labeling regime [64]. Although some comments did advocate substitution of terms such as “cold” or “electronic” “pasteurization” for “irradiation,” other comments noted that such terms would merely confuse consumers. The FDA confirmed this potential for consumer confusion during a series of public focus group meetings in 2001 [64].

The Farm Security and Rural Investment Act of 2002 renewed the “cold pasteurization” debate. The Act amended the FFDCA to include new criteria for the term “pasteurization” in food labels [65], and directed the FDA to establish an interim procedure for approving alternative labeling of irradiated foods (presumably “pasteurization”) while the agency solicited public comment on revised labeling regulations [65]. FDA subsequently issued a guidance document advising parties on the petition process for alternative labeling for irradiated foods [66]. The agency, however, did not receive any petitions requesting use of the alternative labeling option.

Finally, after almost 20 years of relative calm and cautious deliberation, on April 4, 2007, the FDA submitted yet another proposal for public comment suggesting three major revisions in the labeling regime for irradiated food products [67]. First, it would require labeling food as irradiated only if the treatment would cause a material change in the end food product [68]. Second, for those foods subject to irradiation labeling, the label must include specific language describing the material change caused by the irradiation [67]. The 1986 rule (the current rule) allows, but does not require, the manufacturer to include a statement on the label that explains the purpose of the treatment [68]. Because any mandatory label will be the result of a material change in the characteristics of the final food product, the proposed rule will require explicit language describing the material change in the food or its condition of use (e.g., “irradiated to inhibit sprouting”) [63]. Finally, the proposal would authorize, in certain circumstances, substitution of the current term “irradiated” with “pasteurized”—an argument lingering since the original labeling rule of 1966 [50] and revived in the 2002 Farm Bill amendment to the FFDCA [65].

As noted above, the FDA has clear statutory authority to mandate specific statements on food labels when the absence of such a declaration would fail to disclose material facts to the consumer [2,4]. But, the newly proposed rule would require labels only if the treatment would cause a material change in

¹¹ This section is adapted, in part, from the author’s prior work published in the *Journal of Food Law and Policy* [60].

the food—a nutritional, organoleptic, or functional alteration. FDA proposed that it would determine materiality on a case-by-case basis, as the same change could be of importance to the use or consumption of some foods, but not others—a determination likely to engender significant controversy [67]. In its proposal, the FDA stated that the primary result of irradiation—the control of foodborne pathogens—is immaterial, and thus not sufficient to trigger labeling [67]. Extending shelf-life may be another immaterial consequence of irradiation. The agency, however, noted that shelf-life extension would be subject to case-by-case evaluation, as lengthening the shelf-life for some products (e.g., spices) may be immaterial, but delaying the ripening of fruit such as bananas may be a material change due to the varying uses of the product (e.g., consumers may purchase bananas for a use dependent upon quick ripening and thus, the purpose of the product could be frustrated by an extended shelf-life) [67].

The 2007 proposal represented an unstated reversal of the agency’s long-settled determination that materiality is not limited to safety or physical changes in the food, but rather includes consumer perception. When justifying the 1986 rule that extended the mandatory labeling regime, the FDA explicitly acknowledged that “materiality” of information is not limited to product safety or even the abstract worth of the information, but on whether consumers view the information as important and whether the omission of a labeling statement would mislead the consumer.¹² In stark contrast to its 1986 position, the preamble to the agency’s 2007 proposal defines materiality as relating solely to the “characteristics of the food” [64]. This would include cases in which the absence of a label would lead consumers to assume that a processed food would have different nutritional, organoleptic or function properties from its unprocessed counterpart. With respect to irradiation, the agency reasoned that the physical changes in the food product will vary with the product and, therefore, must be determined on a case-by-case basis. This approach eviscerates from consideration of what the average consumer may view as a material characteristics of the food.

Recall, however, that the agency, in 1984, also proposed to eliminate labeling of all irradiated food [41]. In response to consumer reaction via the public comment process, the agency apparently changed its course and retained the rule. Perhaps the same will hold true if the agency, under a different presidential administration, ever takes final action on its now six-year-old proposal.

5. Reconciling Irradiation and Genetic Engineering: A Compromise Proposal for Labeling Processed Foods

In many respects, the FDA’s 2007 irradiation labeling proposal closely tracks the agency’s current “process *versus* product” labeling guidance distinction for foods derived from GE crops [14,17], and is consistent with the agency’s position that the regulatory status (*i.e.*, marketability) of foods is dependent upon the objective characteristics and intended use of the food, irrespective of the process by which the product is developed [14]. Under this line of reasoning, the FDA generally does not require labels to indicate a food derived from genetic engineering. But this rather rigid statutory approach focusing on the physical characteristics of a food product disregards the agency’s long-standing

¹² “Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer [58].”

view, at least with respect to irradiation, that consumer interest may give rise to a determination of materiality under the FFDCFA, and thus require a distinguishing label to prevent claims of misbranding.

An analysis of the political economy of the markets for irradiation and genetic engineering may help to explain the evolution for this difference in labeling policy, as well as illustrate a potential compromise position for GE labeling schemes based on the existing rules for labeling irradiated food. As more fully explained below, a GE labeling policy that applies only to whole or single-ingredient foods, as opposed to the more comprehensive approaches (*i.e.*, label even highly processed foods with any GE ingredients) advanced by some NGOs and the proposal before the state of Washington, may alleviate most of the cost concerns associated with comprehensive, mandatory GE labels—specifically the high cost of developing traceability and segregation systems in the commodity supply chain for the primary GE crops of corn and soybean that permeate many processed, multi-ingredient food products in the grocery store.

5.1. An Industry Perspective to Mandatory Labeling Regimes

Early advocates of irradiation technologies were public entities such as the Department of the Army's Quartermaster Research and Engineering Center and the U.S. Atomic Energy Commission, as well as a few large corporations (General Electric Co. and Westinghouse Electric Corp.). The public entities had little incentive to oppose mandatory labeling requirements. General Electric and Westinghouse Electric certainly had incentives to advance wide-spread adoption of the technology, and thus minimal labeling requirements, but also had a business model predicated on a wide array of industrial and consumer products. The irradiation business was outside their core business strategy and these companies had limited incentive to mount a vigorous opposition to mandatory labeling rules. Consumers, therefore, had a comparatively louder voice in debate. In addition, as discussed above, the irradiation labeling debate played out via relatively open notice and comment rulemaking, resulting in a transparent agency analysis and the eventual issuance of regulations.

In contrast to irradiation, the life science companies advancing genetic engineering technologies placed multi-million dollar "bets" on the commercial success of a few seed varieties supporting large-scale commodity agriculture. These private companies, especially in light of a restrictive regulatory regime in the large European Union market [69], absolutely needed an unrestricted domestic regulatory and consumer environment to encourage farmer adoption of the technology and capture an adequate return on their investment. Moreover, as part of a long-standing and highly-efficient commodity market, the interjection of a new traceability and labeling system designed to segregate GE crops from their conventional counterparts would have required, on a nationwide scale, production changes down to the farmer level. Altering the established supply chain, especially the infrastructure-intensive commodity-based grain handling system in the United States, would have been a difficult and costly proposition. Accordingly, there was a strong incentive by an organized group (the life science industry and the commodity grain-handling industry) to oppose a labeling system that would mandate identification of GE ingredients. Also, in contrast to the irradiation debate, the FDA deliberations on the labeling rule consisted of a few listening sessions and submission of comments resulting not in the promulgation of a regulation subject to notice and comment rulemaking, but rather an agency Statement

of Policy in 1992 and the release of Draft Guidance to Industry in 2001; relatively weak agency actions in comparison to irradiation regulations, but equally effective in advancing a policy objective.

5.2. A Compromise Position: Mandatory GE Labeling for Whole (Non-Processed) Foods

Food processing/manufacturing interests also may have been willing to tolerate the irradiation labeling rule, as complete control of the irradiation process occurs at a relatively late stage in the food supply chain with little risk of an incorrect disclosure. In contrast, a comprehensive genetically engineered labeling system would require a farm-to-fork segregation system involving an undefined number of members in the supply chain extending from farmer to retailer. At each stage there is the potential for commingling or other segregation error and the resulting risk of an incorrect labeling statement at the retail level and potential liability for misbranding. Accordingly, the cost of industry compliance (including a risk premium) under a comprehensive genetically engineered labeling program would be much higher relative to the existing irradiation labeling regime applicable only to non-processed foods.

Perhaps a more important consideration, and source of potential compromise in the GE labeling debate, is to adopt the irradiation labeling regulatory treatment of processed, as opposed to whole or single-ingredient food products (e.g., a shelf-stable box of macaroni and cheese *versus* a fresh peach from the produce section of the retail store). The current irradiation labeling requirement does not extend to processed foods (multi-ingredient products). In contrast, most calls for biotech labeling would include labeling of ingredients in processed foods. Derivatives of two of the primary GE crops in the United States—corn and soybeans—are present in innumerable processed food products (e.g., high fructose corn syrup; soy lecithin). The potential scope of most mandatory GE labeling programs, therefore, would permeate almost the entire food supply chain, imposing significant costs and labeling risk on market participants. On the other hand, limiting a labeling requirement to only whole or single-ingredient foods (e.g., biotech sweet corn or tomatoes), as done in the irradiation context, would vastly simplify the potentially costly traceability and labeling requirements for the GE supply chain. A biotech labeling requirement limited to single-ingredient foods would also provide more meaningful information to consumers, as it would identify those products altered by the technology that are consumed directly by the individual, rather than the insignificant components of a multi-ingredient product that has already undergone extensive processing (e.g., the trace amounts of corn syrup added to a frozen dinner).

Given the extensive debate about genetic engineering, this is not the first, nor is it likely to be the last, on GE labeling. This approach, however, does take into account the feasibility of implementing a labeling scheme within the existing and highly efficient commodity supply chain. For example, Professor Gilhooley suggests an interesting bright-line rule for mandatory labeling of genetically engineered food products—the species connection [61]. From a consumer deception perspective, the transfer of genes from a different species would present a situation similar to the apple cider case at issue in *United States v. Ninety-Five Barrels Alleged Apple Cider Vinegar*, discussed *supra* [9]. An especially compelling argument for misleading labels would apply if the genetic manipulation not only crossed the species line, but flora/fauna biological categories, because the end product would differ at such a basic level from the reasonable consumer's understanding of what a food is [70]. But if this rule

is applied at the multi-ingredient level (*i.e.*, processed foods), Professor Gilhooley's proposal would trigger the extensive traceability and segregation costs discussed above. On the other hand, if applied only to whole or single-ingredient foods, a species-based trigger for labeling could provide a similar workable solution that provides meaningful information consumers.

As the FDA in the future undoubtedly will confront additional technologies with potentially controversial labeling issues (e.g., food products incorporating nanotechnology, synthetic biology), it should maintain, in addition to the core safety and organoleptic components, the agency's current ability to adopt a broad view of materiality, which may include consumer sentiment. Consistent with court precedent, this approach rejects the paternalistic tendencies of the current trend in FDA's labeling programs and facilitates market-based participatory democracy. This is beyond the simple "right to know" assertions raised and rejected by some courts [11,36]. As Professor Kysar observes, there is a confluence of citizen and market values into regulatory cost-benefit analysis [17]. Rather than measuring via traditional political activity the degree of citizen support for legislation/regulatory action to protect community goods (e.g., environment, worker rights, biodiversity, *etc.*), the public can, and some would argue primarily does, express its collective preference for certain environmental, fair labor or other process-based activities via participation in the private market (*i.e.*, purchase of goods with these desirable attributes) [17,71]. In sum, consumption replaces political engagement and the need for a regulatory program to achieve the attendant political demands. Translated to the food context, the process of purchasing food to eat is a political act¹³—advancing Wendell Berry's original statement that "eating is an agricultural act" [75].

This reliance on the market to demonstrate public preferences for community goods, however, relies on communications directed to the retail consumer—most notably product labels. Absent labels, consumers lack the ability to exercise their individual public preferences and, to the extent regulatory agencies defer labeling decisions of process-based characteristics to market forces, hinder the public's ability to engage in this evolving form of market-based participatory democracy. Agencies, therefore, rather than retreating further into the realm of cost-benefit analysis and strict statutory construction as overriding considerations for each labeling decision, should seek maximum discretion under their respective statutory authority to require labels in order to facilitate this new democratic process. A revised GE labeling regime for whole or single-ingredient food products falls within the FDA's statutory jurisdiction and would empower consumers to express their purchasing preferences.

Conflict of Interest

The author declares no conflict of interest.

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