Jessica Ellsworth

Food and Drug Law

Winter Term 2001
Professor Peter Hutt

The History of Organic Food Regulation

I. Introduction

From its beginnings on individual unregulated farms to its growth through local and regional networks, and finally now to the establishment of a national standard, organic foods have traveled an amazing path over the last thirty years. The growth has been continuous, driven by increasing ecological concerns, and, importantly, heightened consumer demand. As fast as growers and processors have put products on the market, consumers have put them into their shopping carts. As time has demonstrated, the popularity of organic foods is a pattern that is here to stay, not some kind of passing fad. According to a Kellogg Foundation poll, people who buy organic food at least once a week “defy demographic definition.”¹ At the same time, organic farming has exploded into “one of the hottest megatrends in U.S. agribusiness.”²

This paper explores the growth in organic food regulation that has accompanied the corresponding growth in the overall organic food business.

II. The Organic Food Industry

The variety of organic foods and food products available today is extensive and growing. Well established

markets exist for organically produced grains, fruits, vegetables, nuts, and herbs, and newer organic foods such as dairy products (milk, yogurt, butter, cheese, and ice cream), wine made with organic grapes, maple syrup, cereal, oil, tomato sauce, and imported coffee and tea are increasingly accessible for consumers.  

Although meat and poultry could not be sold as organic until the National Organic Program (NOP) was implemented, now that the NOP has been established, a large market is expected for these products as well as organic feed and forage markets. Organic products are sold in fresh, frozen, and processed form.

Domestic sales of organic foods have increased by over 20% every year since 1990. The accessibility of organic products to consumers is rapidly expanding in all sectors of the market. The organic food niche has become significant enough that large conventional-food companies have been buying up smaller organic companies. For example, General Mills owns Cascadian Farm and Muir Glen Tomatoes, Heinz owns Earth's Best Baby Food, and J. M. Smucker sells Santa Cruz and Knudsen juices.

Earlier this year, Dole Food company, the world’s largest producer and marketer of fruit and vegetables, expanded into the organic sector beginning an organic banana line. The majority of retail organic sales occur in natural products stores, such as the fast-growing Texas-based Whole Foods and Colorado-based Wild Oats chain markets, but organic sales in conventional grocery stores and other mass-market outlets are also on the rise. Distributors who specialize in organic foods and buy directly from farmers supply most of these domestic outlets.

---

4See id.
5See id.
7See Burros, supra note 6.
8See David Longtin and David Lineback, Keep eyes open if you go organic, USA Today, January 24, 2001, at 11A.
10See Vaupel, supra note 3, at 139.
to the domestic growth, the market for exporting organic food to Europe and the Pacific Rim is strong and steadily increasing for organic grains, dried fruits, and nuts.\footnote{11}

Consumers provide multiple reasons for their purchases of organic food including a belief that it is more nutritious, that it is safer, and that it is of higher quality. Some consumers also claim to buy organic food because it is easier on the environment. In one recent survey, 56% of consumers indicated a belief that organic foods are more nutritious, 47% think they are fresher, and 36% claimed they taste better.\footnote{12} The results of another study found 68% of consumers perceive organic food to be safer than conventional food and 71% of consumers indicated the ecologically-sound nature of the food contributed to their interest in purchasing it.\footnote{13} Organic producers, in fact, often advertise themselves on this last point, using their environmental scheme as an opportunity for “green marketing.”\footnote{14} Organic food, however, have never been advanced by any legislature as healthier or better food; rather, regulation centers on the production process.\footnote{15}

Thus, as this section indicates, “the [federal] regulations come at a time of soaring popularity for organic foods.”\footnote{16} While just six years ago in 1995, fresh and processed organic foods sales topped $2.8 billion,\footnote{17} last year domestic sales of organic products totaled an estimated $7.8 billion.\footnote{18} As sales increase, the number of organic farmers and producers is also swelling rapidly. Washington state, for example, began an organic food program in 1988 with 63 organic farms producing $2.5 million of organic food. Twelve years later,  

\footnote{11}{See Vaupel, supra note 3, at 139. But it is important to note that even as overseas sales of organic foods have grown, American exporters have struggled in the overseas market because the potential importers did not want to deal with 44 different state and private organic certifying agencies that operated in the United States. See Burros, supra note 6.}
\footnote{13}{See Murphy, supra note 1 (citing a study that found that 68% of consumers perceived organic food as safer than conventional food, while 71% of consumers were very interested in ecologically-sound foods).}
\footnote{14}{See Amaditz, supra note 12, at 554 n.177.}
\footnote{15}{See infra notes 70-72 and accompanying text; see also Amaditz, supra note 12, at 554 (suggesting that if the consumers are being led astray by organic labeling, then the FDA might opt to restrict organic labeling claims for misleading consumers or concealing material facts in these areas).}
\footnote{16}{Burros, supra note 6.}
\footnote{17}{See Vaupel, supra note 3, at 138.}
the state houses 522 farms, 98 processors, and 111 handlers of organic food, which cumulatively represent a $100 million industry and include $15 million in organic products exported to Japan.\footnote{See Victor Ostrowidzki, \emph{State Almost in Line with Agriculture’s Organic Food Rules}, Seattle Post-Intelligencer, December 23, 2000, at B4.} On the other coast, Maine has seen a growth from twelve organic farms in 1972, to 190 in 1999, and to 240 in 2000, a 26 percent increase in the past year alone!\footnote{See Tess Nacelewicz, \emph{New Organic Rules Level Playing Field}, Portland Press Herald; January 2, 2001, at 1A.}

\section*{III: The System of State Regulation, 1973-1990}

In 1973, Oregon passed the first state law regulating organic food, and in doing so, it provided the impetus for other states to subsequently enact legislation relating to organic food products.\footnote{See OR. Rev. Stat. § 616 (1999) (Organic Food Regulation).} From then through the 1980s, the organic industry waged an internal struggle to define organically grown food, to standardize permissible production methods, and to establish record-keeping requirements, labeling procedures and enforcement methods.\footnote{See Gordon G. Bones, \emph{State and Federal Organic Food Certification Laws: Coming of Age?}, 68 N.D. L. Rev. 405, 407 (1992); see also Vaupel, \emph{supra} note 3, at 141-145.} Nevertheless, substantial differences arose across the country in state organic farming regulation as to the permissible materials for use in production, the length of time required for a transition to organic acreage, and the allowable production practices.\footnote{See Vaupel, \emph{supra} note 3, at 145-147; see also, e.g., Bones, \emph{supra} note 22, at 410-425 (outlining the differences between the Texas and California organic food statutes in the areas of defining organically grown and handled food, setting soil and crop management standards, outlining livestock, dairy and egg production and handling standards, setting testing and inspection standards, certification requirements, record keeping requirements, labeling requirements, transition to organic, enforcement provisions, and funding mechanisms).} As an example, Colorado required organic products to be certified and organic producers to obtain a license under one set of state guidelines; Maryland required organic producers, processors, distributors, and retailers to obtain a permit under another set of guidelines, and Iowa merely required organic producers to provide vendors with a sworn statement of compliance.\footnote{See Vaupel, \emph{supra} note 3, at 142.}
By 1990, there were 22 states with organic food regulations falling into three broad categories: three states chose to operate their own organic certification programs,25 four states opted to contract with an independent certification organization,26 and fifteen states defined organic food and production techniques but did not provide any government oversight of certification.27 Because certification was not mandatory, organic producers, handlers, processors, and distributors in these 15 states had to affiliate themselves with an independent certification association in order to be able to claim or advertise any organic certification status. The degree of state oversight of these associations differed significantly throughout the nation,28 and accordingly so did the degree of difficulty of marketing food products from each state as organic.29 Importantly, the twenty-eight remaining states lacked any organic food statutes, meaning producers and marketers there could continue to make inconsistent or capricious organic claims.30 As one state void of any rules for organic food reported, buying organics in the absence of regulation involved guesswork and led many consumers to shy away from buying organic because of confusing labels.31

As the organic food industry continued to struggle in its effort to self-regulate and develop a consensus across the states for production and certification standards, the industry finally in the late 1980s resorted to petitioning the United States Congress asking Congress to draft legislation that would conclusively de-

28 See Bones, supra note 22, at 407; see also Lanthrop, supra note 6, at 892-93 (discussing the same three types of categories).
29 See Amaditz, supra note 12, at 539.
30 See id.
fine “organic.” In making this request, the organic food industry was no different than the rest of the food industry which had seen the benefit of national uniformity in food safety and labeling as early as the 1960s. When Congress looked into the issue, it found the current system of organic food regulation confused consumers, contained multiple inconsistencies, and demonstrated a need for federal action. In summary:

The resulting patchwork of state regulation encouraged inconsistency in organic food labeling, engendered confusion among consumers, and played havoc with interstate commerce in organics. Organic farmers and food processors faced both the burden of labeling food to meet conflicting standards and the possibility that food deemed organic in their home state would not qualify as organic across the state border. Food retailers and distributors were concerned about the authenticity of organic items under the varied state laws; consequently, they were reluctant to purchase organic foods, and fewer organics made it to the grocers' shelves. Even when organic foods did make it to the supermarket, consumers were left to decipher a confusing array of private and State labels. Food that was labeled “organic” could have contained anywhere from twenty to 100% organically-grown ingredients, making it difficult for even the most sophisticated consumer to know what the term “organic” really meant. False and deliberately misleading labels exacerbated consumer uncertainty and created a sea of counterfeit and pseudo-organic products. As a result, some consumers and food merchandisers doubted the veracity of legitimate organic producers’ claims and hesitated to buy their products....

In 1989, the infamous Alar pesticide scare appeared in the national press. As the Environmental Protection Agency (EPA) banned the chemical in the wake of public outrage over the exposure of children to pesticides, organic producers experienced a welcome and renewed consumer preference for “grown without” foods.... Consumers wanted organic foods, and few analysts doubted that the market would continue to grow.

Congress’ concern with false and misleading labeling in the organic food market was further magnified by concern that the higher prices charged for organic food products provided an incentive for companies to make questionable organic claims in order to increase profits. Federal regulation of organic labeling could serve two important functions that state government regulation alone could not. First, national standards could ease consumer confusion and ensure consumers received consistent and uniform information about

---

33 See Lanthrop, supra note 6, at 903. See also Charles D. Nyberg, The Need for Uniformity in Food Labeling, 40 Food Drug Cosm. L.J. 229, 230 (1985) (noting that “[u]niformity in law governing food labeling is a constant and continuing goal of food producers, processors, and the organizations that represent them”).
34 See Rick Franzen, Will GATT Take a Bite Out of the Organic Food Production Act of 1990, 7 Minn. J. Global Trade 399, 402 (1998) (noting the incentive to mislabel food as organic comes from the ability to charge higher prices for organic foods due to the higher cost of organic production and from a demand that exceeds supply).
organic foods, and second, it could promote fair trade practices in organic food marketing that would serve to protect interstate commerce.  

IV: The Organic Food Protection Act of 1990

In 1990, Congress passed the Organic Food Protection Act (OFPA) to serve three stated goals: (1) to “establish national standards governing the marketing of... organically produced products;” (2) to “assure consumers that organically produced products meet a consistent standard;” and (3) to “facilitate interstate commerce in fresh and processed food that is organically produced.” OFPA itself, however, did not define the term “organic.” Instead, the actual meaning of “organic” under the OFPA was left open for the United States Department of Agriculture (USDA) to establish in a future regulation. In order to accomplish its goals, however, the OFPA provided three specific guidelines for the USDA to follow in writing the regulation. First, to be organic, foods must be produced and handled without the use of synthetic chemicals. Second, the foods must not be produced on land that had had any prohibited substances, including synthetic chemicals, applied during the immediately preceding three years. Third, the foods must be produced and handled in compliance with an organic plan agreed to by the producer, the handler, and a certifying agent.

The USDA accepted the challenge of determining the details of federal organic regulation in accordance with the three guidelines. OFPA mandated that the USDA include in its regulation a list of synthetic

---

36 See Lanthrop, supra note 6, at 885-886, 892.
38 In fact, “Congress’ reluctance to define organic is apparent in the legislative history, where the lawmakers noted that ‘[o]rganically produced food defies simple definition.’” Amaditz, supra note 12, at 541 (citing S. Rep. No. 357, reprinted in U.S.C.C.A.N. at 4946.)
chemicals approved for use in organic production as well as a maximum allowable pesticide residues for organic produce. In order to assist the USDA in developing the regulation, OFPA provided that a National Organic Standard Board (NOSB) would be assembled to serve as an advisory board. The NOSB advisors were to be comprised of four organic farmers, two organic handlers, one retailer of organic products, three environmentalists, two consumer interest advocates, one scientist and one certifying agent. A fifteenth board membership, representing certifying agents was left open, to be appointed once the standards were in place. The board’s major function would be to provide recommendations to USDA on what substances, such as pesticides and fertilizers, should be permitted for use in organic operations. In making determinations of what the acceptable substance list should include, the act requires the NOSB to consider possible adverse human and environmental effects.

Like all of the prior state regulations, the OFPA standards themselves are formulated in terms of processing and production methods used, rather than end product quality. The OFPA requires all products labeled organic be produced on certified organic farms and handled solely by certified organic operations, with the determination of certifier accreditation to be made by the USDA regulation. The OFPA left room for the certifier to be either a private certifying agent or a state certification program. In addition, the OFPA exempted small farmers, or those with less than $5000 annual gross sales, in organic produce from having to comply with the national regulations.

The goal of Congress is enacting the OFPA was not total federal preemption. Congress wanted the OFPA


\[42\] See 7 U.S.C. §6518; Franzen, supra note 33, at 404.


\[44\] See Vaupel, supra note 3, at 142 (citing from 7 U.S.C. §§ 6502(3), 6503(b), 6503(d), 6505(d), 6506(a), 6514, 6519(d).

\[45\] See S. Rep. No. 357, reprinted in U.S.C.C.A.N. at 4942, 4948 (discussing the reasons why states may desire different or more stringent certification regulations, including health concerns and different regional production practices).
to provide a uniform federal certification law, which would partially pre-empt current state law but leave
equal flexibility to allow individual states to continue achieving their own interests.\footnote{46} In reality, OFPA
reflects Congressional ambivalence about the extent of desirable federal regulation. On one side, Congress
realized most organic production expertise is at the grass-roots level and that states need to address specific
local and regional needs, thus counseling against federal intrusion, but on the other side, continuing to allow
differing state standards would disrupt the interstate commerce and uniformity goals the act was designed
to serve.\footnote{47} The result is that OFPA prohibits the use of “organic” on any label not meeting the federal
standard, but it allows states to have their own label approved by USDA, which can then accompany the
federal label. The state standard must be as strict or stricter than the federal standard.\footnote{48}

OFPA does not exempt organic food from other existing federal food safety statutes, but it does grant the
USDA, instead of the Food and Drug Administration (FDA), primary federal authority for regulation and
enforcement of organic food certification and labeling.\footnote{49} Even though Congress granted the USDA complete
authority over organic food labeling, the FDA retains jurisdiction over all other labeling aspects of these
foods because many organic foods fall within the definition of food in the Food Drug and Cosmetic Act
(FDCA).\footnote{50} In addition, OFPA does not supersede the USDA’s authority over meat and poultry\footnote{51} or the
Environmental Protection Agency’s (EPA’s) authority of insecticides and pesticides.\footnote{52}

\footnote{46}{See Lanthrop, \textit{supra} note 6, at 894.}
\footnote{47}{See Amaditz, \textit{supra} note 12, at 543.}
\footnote{48}{See 7 U.S.C. § 6507(a)-(b). See \textit{infra} notes 91-99 and accompanying text.}
\footnote{49}{To exercise this authority, however, the USDA is required to consult the FDA about labeling processed foods and to
determine if substances on the National List harm human health or the environment. See Bones, \textit{supra} note 22, at 440.}
\footnote{50}{See 21 U.S.C. §§ 301 et seq. (2000). The Federal FDCA defines food as “(1) articles used as food or drink for man or
other animals, (2) chewing gum, and (3) articles used for components for any such article.” 21 U.S.C. § 321(f). Organic foods
fall under this broad definition and accordingly may be regulated by FDA. One commentator has criticized the OFPA labeling
system, arguing that that “[t]he inefficiency of this system is obvious. For a bag of organic celery, FDA would review the
label to ensure that its requirements are met, including those relating to nutrition information, manufacturer data, quantity
and weight, food additives, pesticide residues, artificial flavoring and coloring, chemical preservatives, and prominence of label
information. Meanwhile, USDA would review the same bag of celery to ensure that it complies with OFPA standards. This
overlap is unnecessary and wasteful. Moreover, it creates potential conflict between OFPA and FDA labeling requirements.”
See Amaditz, \textit{supra} note 12, at 553 (citations omitted).}
\footnote{51}{This USDA authority arises under the Federal Meat Inspection Act, 21 U.S.C. §§ 601 et seq., the Poultry Products Inspection
\footnote{52}{This EPA authority arises under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136 et seq.}
purports to establish national standards for the marketing of organic foods, the Federal Trade Commission (FTC) will presumably continue to exercise authority over food advertising. As a result, the OFPA is but another layer of law with which the organic producer, processor, and handler must comply.


The NOSB moved slowly, not issuing its first recommendations until 1994, but between 1994-1996, the NOSB produced a plethora of recommendations on every aspect of the organic food regulation being promulgated. Although non-binding on USDA, many viewed the proposals as likely to be incorporated into the finished proposed rule for two reasons: (1) the NOSB spent considerable time and resources developing its recommendations as per Congress’ specific charge that the NOSB play an advisory role to USDA in developing the regulation, and (2) cooperation between NOSB and USDA staff was reportedly high, with some recommendations even being co-authored by USDA employees and NOSB members. Once the NOSB finished its recommendations, USDA was set to propose a rule in the Federal Register for comment from the industry.

In spite of this alleged spirit of cooperation, USDA was immediately faced with immense opposition and staggering public outcry to its first attempt at a proposed regulation in 1997. The standard for “organic” under this USDA proposal endorsed such controversial production techniques as irradiation, genetic modification, and sewer sludge fertilization. Organic farmers and consumer advocacy groups “howled” at the USDA’s

53 See Amaditz, supra note 12, at 544.
57 See Amaditz, supra note 12, at 547 n.123.
proposal, finding the proposed rules were wholly inconsistent with current organic practices.\(^{59}\) The industry complained about every facet of the rule, from the fact it permitted synthetic pesticides and irradiation to be used to kill bacteria on food\(^{60}\) to the fact that beef fed up to twenty percent non-organic food could carry the “certified organic” label.\(^{61}\) In large part, complaints centered on the fact that the Secretary of Agriculture had ignored many of the NOSB proposals.\(^{62}\) Overall, USDA received 275,603 comments during the public comment period - more than one comment for every minute of the period!\(^{63}\) In the face of such public outrage, the USDA felt no choice but to withdraw its proposal.

After considerable redrafting, USDA issued a revised proposal three years later in March 2000. This proposal still inspired much controversy. In particular, debate surrounded such aspects of the proposed standards as (1) a product which was made with only 50% organic ingredients could be labeled “made with organic [ingredient(s)],” well below the 70% standard in the European Union,\(^{64}\) (2) no provision required all ingredients in a product labeled organic be organic even if the ingredients were available in organic form, (3) no provision allowed manufacturers to state the exact percentage of organic ingredients on the principal display panel, (4) wine made with organic grapes could not be labeled “organic” if it was produced with sulfur dioxide, (5) the residue testing standard for determining a ceiling pesticide residue level above which a product cannot be sold as organic was linked to a still underdeveloped national mean program, and (6) the USDA organic

---

\(^{59}\) Editorial: Truth in Food Labeling, Atlanta Constitution, December 27, 2000 at A18; Green, supra note 18.

\(^{60}\) See Organic Groups’ Outcry Compels USDA to Delay Action on Labeling Rules, Minneapolis Star-Trib., February 7, 1998, at 10A.

\(^{61}\) See Franzen, supra note 33, at 404.

\(^{62}\) See Organic Groups’ Outcry Compels USDA to Delay Action on Labeling Rules, supra note 60; see also Kirsten S. Beaudoin, On Tonight’s Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century, 83 Marq. L. Rev. 237, 268-69 (1999) (arguing as of 1998, OFPA appears to be a “dismal failure” in part because “[t]he official advisory board in charge of making recommendations, the National Organic Standards Board (NOSB), has seen their policy proposals disregarded by the agency at every turn”).


\(^{64}\) In general, the US and the EU have generally comparable rules over what is organic, so the discrepancy between the standards would be exacerbated by this differential. See Brandon Mitchner, U.S. Sets Standards for ‘Organic’ Foods In Move to End a Hedgepodge of Rules, The Wall Street Journal, December 27, 2000, available at 2000 WL-WSJ 26621061 (noting the only major difference between the two is the certification process, which remains decentralized in Europe but is now in the hands of federal inspectors in the US).
seal was allegedly confusing. In total, the agency received an additional 40,774 comments on these and other nuances of the rule.

After reviewing those comments, USDA made substantial changes to certain aspects of the March 2000 proposal. These changes were intended to enhance market incentives for organic products, provide better information for consumers, provide greater flexibility for organic farmers, and incorporate industry standard practices. The USDA issued its Final Rule on December 21, 2000. Many of these changes will be discussed in the context of the December 2000 rule below. The final rule went into effect February 20, 2001, and will be fully implemented eighteen months from then. In other words, every farmer, livestock producer, handler, processor who wants to market products as organic has a maximum of eighteen months to comply. This section will outline the various provisions of the Final Rule with which these operations will be quickly moving to comply.

VI: The Final Rule Unveiled, December 2000

On December 21, 2000, Secretary of Agriculture Dan Glickman released what he called the world’s strongest and most comprehensive organic food standard in the world. At the news conference where the rule was announced, he reported that the final rule established a uniform, federal standard that was a win for farmers and consumers alike: “For farmers, the standards create clear guidelines for how to take advantage of the exploding demand for organic products. For consumers, the organic standards offer another choice in the

---


Those who want to buy organic can do so with the confidence of knowing exactly what it is that they’re buying.\textsuperscript{69}

Glickman, however, was careful to emphasize that an organic label is not an indication the food is any safer than other foods. He commented that “[t]he organic label is a marketing tool. It is something that I think consumers want. It is not a statement by the government about food safety. Nor is ‘organic’ a value judgment by the government about nutrition or quality.”\textsuperscript{70} His clarification on this point accords with Congress’ understanding when it passed OFPA. Congress had carefully focused the legislation on methods of production precisely in order to avoid linking organic food and health benefits.\textsuperscript{71} Glickman’s statement is also consistent with the fact there is no accepted scientific evidence that organic food is compositionally different from conventionally produced food, even though many consumers and farmer may continue to believe it is better for them.\textsuperscript{72}

The Final Rule is set up in seven subparts: (A) Definitions, (B) Applicability, (C) Organic Crop, Wild Crop, Livestock, and Handling Requirements, (D) Labels, Labeling and Market Information, (E) Certification, (F) Accreditation of Certifying Agents, and (G) Administrative: The National List of Allowed and Prohibited Substances; State Organic Programs; Fees; Compliance; Inspection and Testing, Reporting, and Exclusion from Sale; Adverse Action Appeal Process; Miscellaneous. The final standard occupies over 100 pages in the federal register, and is detailed and complicated. This section discusses provides a basic overview of the

\textsuperscript{69}Butler, \textit{supra} note 61.
\textsuperscript{70}Id.
\textsuperscript{71}See S. Rep. No. 357, \textit{reprinted} in 1990 U.S.C.C.A.N. at 4946-47 (“This legislation does not attempt to make scientific judgments about whether organically produced food is more healthful, nutritious, or flavorful than conventionally produced food.... The Committee contends that organically produced food is food produced using certain defined materials and production methods.”).
standard, highlighting specific components that were particularly significant, controversial, or interesting. Since Subpart A consists solely of definitions, it will only be discussed as the definition of terms impacts other provisions of the rule.

Subpart B provides an overview of what the NOP governs and how it applies, addressing uses of the term organic, recordkeeping requirements, and ingredients in organic production and handling. Any operation intending to sell, label, or represent its agricultural products as organic (the first three categories discussed in Subsection D, infra) must comply with the certification requirements in the rule. During the eighteen month implementation period, the NOP will provide specific standards for certain production categories that have unique requirements and will need further regulations applied to them, such as mushrooms, aquatic species, culinary herbs, and pet food. As an addition to the proposed rule, this subsection also now establishes a civil penalty for violation that is set at a maximum of $10,000 per violation.

Subpart C establishes the production and handling requirements for certification. Under the final rule, each crop, wild crop, livestock, or handling operation which requires certification must submit an organic system plan to its certifying agent in order to determine that all applicable requirements are being met. This mandated organic system plan has six parts: (1) a description of practices and procedures used by that operation, (2) a list of each substance used, and whether that substance is characterized as a production or handling input, (3) an explanation of monitoring techniques, (4) an explanation of the recordkeeping system, (5) a description of the management practices and physical barriers established to prevent commingling of organic and non-organic products, and (6) additional information deemed necessary by the certifying agent to evaluate site-specific conditions relevant for compliance with regulations. This subpart outlines specific standards for growing organic crops, including crop rotation, and raising organic livestock, including feed and

pasture provisions, as well as standards for handling the products of the two and for preventing commingling of organic and nonorganics. In a notable difference from the 1997 proposal, the handling standards in the final rule prohibit ionizing radiation, ingredients produced using excluded methods, and volatile synthetic solvents, and it includes synthetic substances approved on the National List of Allowed and Prohibited Substances (National List). This result followed extensive comments on the issue, focused on the need to incorporate industry standard practices.

Subpart D contains the labeling requirements. These labeling requirements, intended to ensure consistency in labeling to aid consumers and to prevent labeling abuses, apply both to fresh, raw products and to processed foods that contain organic ingredients. The subpart additionally includes specific labeling requirements for organically produced livestock feed, for containers used in shipping and storing organic products, for denoting organic bulk products in market information at the point of retail sale. Subpart D establishes what and how organic terms and references can and cannot be displayed on an organic food product’s principal display panel, information panel, ingredient statement, or other package panel. Consistent with the fact that the rule requires all farm and processing operations that grow and process organic foods to be certified by a USDA-accredited agent, see discussion of Subpart E, infra, the rule requires the name and address of that certifying agent to be displayed on the information panel. In addition, any product labeled as organic must identify each organically produced ingredient in the ingredient statement on the information panel. The final rule contains no restrictions on the use of other truthful labeling claims such as “no drugs or growth hormones used,” “free range,” or “sustainably harvested.” The labeling requirement subpart retains the OFPA restriction that the NOP rule does not, and is not intended to, supersede other Federal labeling requirements and regulations. For example, FDA regulation of the placement of information on food and food product packages, the USDA regulations for meat, poultry, and egg products, the FTC and ATF reg-

ulations still apply.

Subpart D contains four categories of foods that can indicate some degree of their “organic” nature on the label. First, on one end, a product in which every ingredient, including processing aids, is organic can use the phrase “100 percent organic” on the label. A product that contains at least 95 percent organic contents by weight will be labeled “organic,” as long as nothing in the remaining five percent can be produced using excluded methods, sewage sludge, or ionizing radiation. The phrase “made with organic [specified ingredients or food group(s)]” can be used on a product whose contents are 70-95 percent organic. Finally, for products that are between 1-70 percent organic, the word “organic” cannot appear on the front of the package label but the product may list organic items on the ingredients panel. The idea is that the higher the organic content of a product, the more prominently its organic nature can be displayed. The third and fourth categories may not display the USDA organic seal, but any certified operation producing “100% organic” or “organic” products may use the official USDA organic seal. The regulations explain in detail exactly how to calculate the organic percentage to facilitate processors and handlers ability to determine into which labeling category a particular food product falls. At least some commentators and Consumer Reports, however, have questioned whether the fine gradations of this multi-tiered labeling scheme will be comprehensible to the general public consumer.

Some of the most consequential changes to the overall regulation occurred in Subpart D during the revisions

---

76 The rule clarifies once again at this point that the certification is for the process of production, not the end product quality. See 65 Fed. Reg. at 80587.

77 See Table 1 (Prohibited Production and Handling Practices for Labeling Categories), 65 Fed. Reg. at 80578, and Table 2 (Labeling Consumer Product Packages), 65 Fed. Reg. at 80580, explain the use of these labels.

78 See Appendix A for a picture of the seal.

79 See Consumer Reports Online, “A New Organic Food Label,” <http://www.consumerreports.org/Special/ConsumerInterest/Reports/0103org0.html>; Amaditz, supra note 12, at 551 (criticizing a multi-tiered organic labeling hierarchy as “liable to further cloud consumer perception because the fine distinctions between the tiers will not be apparent to the average shopper” and suggesting “a simple, prominent percentage statement could provide an easy answer to these concerns”). For a depiction of how USDA envisions the four categories working in practice, see National Organic Program, Organic Labeling Categories, <http://www.ams.usda.gov/nop/labelingphoto.htm>.
from the March 2000 proposal to December 2000 final rule.\textsuperscript{80} Primarily, in the final rule, the minimum content for “made with organic ” was 50 percent in the proposal and 70 percent in the final rule. All of the comments USDA received, including those from certifying agents, leading organic associations, the European Union, and other international commenters recommended raising the standard to 70 percent to make it consistent with international standards. Secondly, the final rule added a “commercially available” provision, which mandates that all products labeled “organic” (95-99 percent) must be using only nonorganic ingredients that are not commercially available in organic form. Another change was from the proposed rule’s prohibition on of a food group in the “made with organic ” category to the permissibility of a food group listing like “made with organic fruit” or “made with organic vegetables.” Additionally, in the final rule, the display of a product’s organic percentage is optional for “organic” (95-99 percent) and “made with organic ” (70-94 percent) products, whereas it was mandatory in the proposed rule. Also changed in the final rule, the term organic cannot be used in an agricultural product name when the term would be modifying an ingredient that is not organically produced. For example, a product cannot claim to be “organic chocolate ice cream” if the chocolate is not organically produced even if the ice cream is.\textsuperscript{81} USDA comments received indicated that to allow organic to be used in such a way would be misleading. Finally, the December 2000 rule revised the USDA seal to more clearly indicate the USDA is not the certifier, but merely accredits certifiers, and to appear as more of a “process” seal than a “quality” seal.

Subpart E contains the certification requirements, which shift certification to a mandatory requirement from its prior voluntary status in some states.\textsuperscript{82} Under the new standard, USDA will accredit state, private, and foreign organizations or persons to become “certifying agents.” Certifying agents will certify that

\begin{footnotes}
\textsuperscript{80}See 65 Fed. Reg. at 80576-83.
\textsuperscript{81}Following this same logic, wine produced with sulfur dioxide can be labeled “made with organic grapes,” but not organic wine under the final rule. See 65 Fed. Reg. at 80578.
\textsuperscript{82}See 65 Fed. Reg. 80588-97, 80649-51; see, e.g., Nacelewicz, supra note 20 (describing this change for the state of Maine).
\end{footnotes}
production and handling practices meet the national standards. Every operation or portion of an operations
that produces or handles agricultural products intended to be sold, labeled, or represented as “100 percent
organic,” “organic,” or “made with organic ___” needs to be certified. The rule provides a few exceptions to
the certification rule. Farmers and handlers producing less than $5,000 a year in gross organic agricultural
income are exempt from the certification requirements, although they must still comply with the labeling
requirements, organic production requirements, and handling requirements in the NOP that are applicable to
its type of operation.\textsuperscript{83} Likewise, some other handlers do not need to be certified: those which do not process
or repackage products, those which only handle products with less than 70 percent organic ingredients, and
those which are retail food establishments (restaurants, delica
tessens, bakeries, grocery stores) that process
or prepare raw and ready-to-eat food labeled organic.\textsuperscript{84}

To become certified under Subpart E, the applicant must submit an organic plan to an accredited certifying
agent. The information that must be included in this plan is outlined in the discussion of Subpart C,
\textit{supra}. The certifying agent will review the application, conduct an on-site inspection of the operation at
a time when the inspector can observe the practices used and talk to someone knowledgeable about the
operation. If the combination of an on-site inspection and the organic plan demonstrates that the applicant
is complying with the relevant standards and requirements, the certifying agent will issue a certification
certificate. Such certification will then remain in effect until terminated, either voluntarily or through the
enforcement process. While remaining certified, each certified operation will submit to an annual inspection
and provide an annual update to the certifying agent in advance of the inspection. Certifying agents must be
notified by a producer immediately of any changes affecting an operation’s compliance with the regulations,
such as application of a prohibited pesticide to a field. Furthermore, once certified, applicants will have to

\textsuperscript{83}See 65 Fed. Reg. at 80552.
\textsuperscript{84}See National Organic Program Certification, \texttt{<http://www.ams.usda.gov/nop/facts/certification.htm>}.
keep accurate post-certification records for five years concerning the production, harvesting, and handling of agricultural products that are to be sold as organic. In addition to the annual inspection, Subpart E allows USDA or a certifying agent to conduct unannounced inspections at any time to enforce the regulations adequately. These unannounced inspections may include residue tests if there is reason to believe there may be contamination by prohibited substances.

Subpart F outlines the accreditation of certifying agents. Both state and private agencies can be accredited as certifying agents for domestic or foreign organic production and handling operations. The NOP accreditation process is designed to “facilitate national and international acceptance of U.S. organically produced agricultural commodities.” Accreditation lasts for five years, and the application process requires demonstrated expertise in organic production and handling techniques, ability to implement the organic certification program, and ability to comply with a State Organic Program (SOP) if it exits under Subpart G. An application to be an accredited certifier must specify procedures to be used for certifying operations, ensuring compliance, and complying with recordkeeping. Subpart F also contains a potentially problematic restrictive conflict of interest clause. Under this clause, certifiers are prohibited from giving advice or providing consultancy services to applicants for certification because of impartiality and objectivity concerns. Many private certifiers commented vehemently, but unsuccessfully, against this provision, arguing the requirement places an undue burden on membership based private certifiers. Certifying agents, like those certified, will be subject to an on-site visit and must submit an annual business report.

Subpart G has three components of primary importance: the National List, the SOP requirements, and the residue testing standard. The National List is a list based on NOSB recommendations to USDA in a
“dynamic process” of additions and deletions on an annual basis.\(^88\) Although a premise of organic farming is the fundamental principal that synthetic chemicals should not be used in the production or handling of organic food products, the National List is the procedural mechanism for establishing exceptions where necessary. Synthetic chemicals may be allowed in production or handling of organic products if they are determined safe for human consumption, are necessary to the production or handling of the product, and have no commercially available natural substitutes. Each substance that is on the list will be periodically reviewed to determine when it should be removed as no longer necessary or as having a commercially available alternative.\(^89\) The first National List can be found in the final rule.\(^90\) So far, the NOSB has received petitions for to review sixteen additional synthetic substances for potential inclusion next year: four have been found unacceptable, five have been approved, and there are seven others still under review.\(^91\) This list however, does not override FDA authority to issue regulations for the safe use of substances in food production and processing or USDA authority to determine efficacy and suitability regarding meat, poultry and egg product production and processing. Controversy and tension are likely to arise when this list is issued and each time it is updated.

The second component deals with SOP requirements.\(^92\) Under this rule, a state may have a SOP, but the state must get the approval of the USDA Secretary. The SOP can be more restrictive than the NOP only if such additional stringency can be justified based on specific environmental conditions or specific practices particular to the state which necessitates such action. The SOP must still be demonstrably consistent with the purposes of the NOP. The SOP provision is controversial because it acts as both a floor and a

\(^{88}\)See 65 Fed. Reg. at 80612.  
\(^{89}\)See 7 U.S.C. § 6517.  
\(^{90}\)See 65 Fed. Reg. at 80656-58.  
\(^{92}\)In states that do choose not to get a SOP approved, USDA will administer and enforce the requirements of the NOP. USDA will monitor any State, private, and foreign certifying agents operating within the State to assure compliance with the national program. See National Organic Program: State Organic Programs, <http://www.ams.usda.gov/nop/facts/states.htm>.
ceiling, even though when Congress passed OFPA, the goal was not total federal preemption.\textsuperscript{93} Because of the emphasis on national uniformity, OFPA did require that state standards be at least as strict as OFPA requirements, but it also allowed the state standards to be higher.\textsuperscript{94} Instead, the final rule avoids the potentially discriminatory situation that could have arisen under the OFPA if state labels carry a perception of having requirements that produce superior quality food compared to those labeled by the USDA: such state labels could have frustrated the very purposes of the OFPA.\textsuperscript{95} The final rule represents a shift away from a USDA obligation to approve any “reasonable” plan that meets the OFPA requirements, including one with additional state requirements and more restrictive state standards.\textsuperscript{96}

In 1990, Congress appeared ambivalent over the extent of allowable and desired state regulation, acknowledging organic production expertise exists largely at the local level as does knowledge of specific regional needs, but also recognizing the danger of restrictive state standards for interstate commerce and the overarching goal of uniformity.\textsuperscript{97} In contrast, a state can only have more restrictive requirements than the NOP under the final rule if those requirements are found to be necessary in light of a particular environmental condition or unique production or handling practice in the state or a particular area of the state. For instance, a state may request approval of additional restrictions to protect a sensitive watershed.\textsuperscript{98} Furthermore, a state cannot use its own organic seal to indicate a higher standard of organic than the national USDA standard.

\textsuperscript{93}See S. Rep. N. 357, \textit{reprinted in} U.S.C.C.A.N. 4948 (discussing the reasons why states may desire different or more stringent certification regulations, including health concerns and different regional production practices); see also Lanthrop, \textit{supra} note 6, at 894 (arguing Congress passed OFPA to provide a uniform federal certification law that partially pre-empts current state laws, but arguably provides enough flexibility to allow the states to continue to serve their own interests.) For a discussion of the theories of federal preemption under OFPA, see Lanthrop, \textit{supra} note 6, at 898-902.

\textsuperscript{94}See 7 U.S.C.A. § 6507(b)(1). In particular, because this standard acts as a ceiling and does not allow private organic certification seals, it creates a problem for areas like maple syrup where USDA has not yet issued rules, and is not planning to in the near future. See Maine Organic Farmers and Growers Association, “USDA Organic Standards Final,” \textlangle http://www.mofga.org/newsltr_0012.html#usda\textrangle.

\textsuperscript{95}See Franzen, \textit{supra} note 33, at 403 n.23; Amaditz, \textit{supra} note 12, at 556 (“The OFPA’s allowance for additional state restrictions on organic food labeling is potentially the most daunting obstacle to the goal of national uniformity.”)

\textsuperscript{96}See Amaditz, \textit{supra} note 12, at 543.

\textsuperscript{97}See id. (citing from the United States Code and the Senate Reports).

Many organic producers are upset about this provision of the final rule, feeling it limits their ability to exercise speech right to educate consumers about their products and will hurt the competitive edge of those who more stringently adhere to organic principles.\footnote{See, e.g., Frederic J. Frommer, \textit{Some Worry that New USDA Label Might Change Organic Farming}, The Bismarck Tribune, January 14, 2001, at 3C; Nacelewicz, supra note 20.} In fact, the Organic Consumers Association criticized the NOP on exactly this point.\footnote{See Organic Consumers Association, \textit{“Organic Certifier Denounces New USDA Standards,”} <http://www.purefood.org/Organic/denouncenop.cfm>.}

The third important component of Subsection G is the residue testing standard. Under the proposed rule, the NOP has required implementation of a newly developed Pesticide Data Program's estimated national mean as the compliance tool responsible for monitoring prohibited substances. In the final rule, this standard was replaced with a simpler one to administer: allowing five percent of the EPA tolerance standard. Those who supported this change argued the five percent rule would lead to consumer confidence. If an organic food is found to have greater than the five percent threshold, it cannot be sold or marketed as organic. This standard will be monitored by those implementing the SOPs and by accredited certifiers.

\textbf{VII. Conclusion: Reaction to the NOP Thus Far}

When USDA announced the final rule, the organic industry celebrated.\footnote{See, e.g., Organic Trade Association, \textit{“Final Rule Announced- Industry Celebrates,} <http://www.ota.com>; Organic and Natural News \textit{“USDA releases final organic rule,”} <http://www.organicandnaturalnews.com/articles/9c1organic.html>. But outside of the organic industry, however, there was less enthusiasm. The Grocery Manufacturers of America, for example, said it opposes many aspects of the organic rule and is concerned USDA should monitor to make sure consumers understand the new label does not mean they are buying a safer product. See Marc Kaufman, \textit{U.S. Sets ‘Organic’ Standard}, The Washington Post, December 21, 2000, at A1 (quoting Susan Ferenc, the Grocery Manufacturers of America Vice President for Science and Regulatory Policy).} The Organic Trade Association, a national organization representing organic growers, processors, certifiers, distributors, retailers and others in the organic products industry in North America, championed USDA’s efforts as strengthening consumer confidence in U.S. organic products domestically and internationally and achieving consistent standard and
labeling requirements: “No longer will there be questions concerning what ‘organic’ stands for, or whether
the process has been certified... National organic standards will protect the integrity of the organic guarantee,
and prohibit the use of irradiation, sewage sludge, or genetic engineering in anything labeled organic.”

The chief executor of a leading organic food company reported the final federal rule “is acceptable to our
industry and is consistent with what we have been doing.” The Organic Farming Research Foundation
thanked Secretary Glickman for a job well done. USDA received extensive praise: “The long wait for the
final rule was worthwhile... USDA has delivered a strict organic standard that is a great boost to the organic
industry. In no way is this final rule less than what the industry wanted.” Farmers and consumers were
also largely pleased with the final rule. As the California Certified Organic Farmers reported, “[t]he new
federal standards are a good working definition of organic production and are true to the organic philosophy
and approach that has gained the confidence of many consumers.”

As the organic market continues to flourish, and final NOP implementation occurs, the goals the industry
and Congress set out to accomplish over a decade appear to be on their way to fulfillment. The passage of
time will surely reveal hidden intricacies as well as new problems and new solutions. For the time being,
however, the decade long wait for the final regulation appears worth the time it took to create.

103 See Ostrowidzki, supra note 19 (quoting Gene Kahn, chief executive officer of Small Planet Foods, a leading organic food
compny that is a all-organic subsidiary of General Mills International).
105 See Burros, supra note 6 (quoting Organic Trade Association executive director Katherine Dimatteo).
106 See, e.g., Fernau, supra note 31; California Certified Organic Farmers Press Release, December 20, 2000,