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Beyond Nutrition and Organic Labels—30 Years of Experience With Intervening in Food Labels

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Abstract

Consumers are increasingly interested in farming methods and the nutritional quality of food. Manufacturers, in turn, are adding more information to food labels. In 1990, Congress passed two watershed laws on food labeling, one requiring nutrition labels to be included on most processed foods and the other requiring organic foods to meet a national uniform standard. This report examines the economic issues involved in five labels for which the Federal Government has played different roles in securing the information and making it transparent to consumers. In addition to the nutrition and organic labels, the report scrutinizes three other labels—one advertising foods made without genetically engineered ingredients, another advertising products made from animals raised without antibiotics, and the Federal country-of-origin label, which is now required for fresh and frozen fruits and vegetables, some nuts, fish and shellfish, ginseng, and certain meats. As interest grows in process-based and other types of food labeling, findings from these five case studies illustrate the economic effects and tradeoffs in setting product standards, verifying claims, and enforcing truthfulness.

Keywords: food labels, credence attributes, asymmetric information, product differentiation, nutrition labels, organic labels, raised without antibiotics labels, country-of-origin labels, non-genetically engineered labels.

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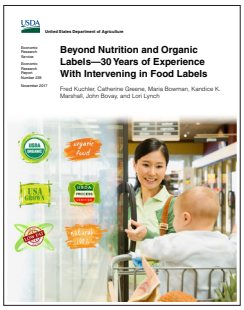

Beyond Nutrition and Organic Labels—30 Years of Experience With Intervening in Food Labels

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What Is the Issue?

Food labels can give consumers valuable information that they cannot verify for themselves. However, labels can also mislead consumers since food suppliers may voluntarily offer only information that increases demand for their products. In addition, consumers may not understand label claims, and instead of facilitating economic activity, labels may increase inefficiency in the marketplace. Food label claims have proliferated over the past three decades. Some of these additions have been federally mandated and some have been voluntary. Some may be certified or verified by the Government or by private-sector entities.

This paper includes five case studies from the past 30 years that highlight roles the Federal Government has played in food labels and the informational strengths and weaknesses of various labels. These case studies include the implementation of Federal standards for the "Nutrition Facts" label (mandatory for many foods), the USDA Organic seal, the voluntary labeling of food as made without genetically engineered ingredients, the voluntary labeling of meat and poultry products as raised without antibiotics (RWA), and the labeling of the federally defined country of origin of the product (COOL), which is mandatory for some food products. The case studies reveal the outcomes and implications of different interventions.

What Did the Study Find?

This report's main findings include:

- The Federal Government has developed uniform standards for disclosure and claims about some product attributes, and doing so led to labels that are credible and truthful. However, there are tradeoffs to consider.
  - The history of nutrition and organic labeling shows that creating a single, national standard can be a slow process, lasting many years.
  - Food manufacturers often compete on the basis of the product attributes they offer, and they work to make consumers aware of differences. In those cases, mandating label information may not make consumers better informed as they can already deduce everything they want to know about products, labeled or not.
  - Government standards for labeling some food product attributes have been rigidly defined, making alternative definitions illegal. This can discourage innovation and experimentation in marketing and product development.
- Once a single, mandatory, federally set standard is achieved, it does not automatically result in improved consumer understanding.

ERS is a primary source of economic research and analysis from the U.S. Department of Agriculture, providing timely information on economic and policy issues related to agriculture, food, the environment, and rural America.

- The Nutrition Labeling and Education Act led to the inclusion of the Nutrition Facts label on most food packages—nutrition information that most consumers treat as credible and truthful, but that many ignore.
- Consumers sometimes confuse Government standards with other standards. For example, the USDA Organic seal is often confused with other label claims, such as "natural" or "raised without antibiotics" that have fewer and/or lower standards and lower production costs.
- The mandatory country-of-origin label gives consumers complete information about the origin of products covered, but no information at all about product quality. Nonetheless, some consumers automatically equate domestic production with higher quality—an assumption that may or may not be correct.

- Where there is no single, national standard for a food attribute and food suppliers develop product definitions and standards, label information may not be consistent and may mislead consumers. These labels may not be truthful or understandable.
  - USDA approval of RWA claims gave credibility to competing labels. However, evidence reveals that, because private firms independently defined what the claim meant, the label has not ensured that consumers understood differences in products.
- Enforcement choices the Government makes will have consequences for market efficiency.
  - Enforcement activities range widely among labeling programs. USDA has an active program to ensure the appropriate use of the USDA Organic seal, but has limited resources to enforce animal-raising claims.
  - Private organizations have been the chief impetus for penalizing violations of RWA standards. To see the law enforced, these groups have filed lawsuits and gone to court.
- Positive environmental effects of labeling alternatively produced foods are limited by market size.
  - Some consumers look to food labels to identify greater attention to environmental stewardship. However, the market share of many alternatively labeled foods (such as "USDA Organic" meat products) is still small, and these labels offer limited ability to reduce negative environmental effects.
- Effects on interstate trade, but also international trade, have been both positive and negative.
  - Setting a national organic standard ended variance among State standards. This gave the organic sector more access to interstate and international markets, increasing sales.
  - The World Trade Organization (WTO) found that COOL acted as a barrier to trade in meat. Some analysts found that net effects of COOL were negative, and there was no market failure problem to address.
- Government and third parties compete to educate consumers about food product attributes.
  - There are many ways beyond food labels to communicate information about food attributes to consumers—Quick Response codes (matrix barcodes scanned by smartphones, leading to a manufacturer's website or a message), apps on phones, websites, list-serves, books, and magazines. These sources may access more indepth information, but have few controls to ensure truthfulness. They likely compete for consumers' attention with information that is federally regulated.

How Was the Study Conducted?

ERS researchers analyzed the successes and failures of five recent experiences in U.S. food labeling and have included summaries of current Federal activity in food labeling to put the case studies in context. They also examined major developments in providing food attribute information to assess the future of food labels.

Beyond Nutrition and Organic Labels—30 Years of Experience With Intervening in Food Labels

Introduction

To help consumers to make informed food choices, the law requires some retail packaging information. For example, a package of frozen breakfast sausage will indicate the product name; list the ingredients; specify the food supplier's name and place of business; list the net contents; and provide the inspection legend and USDA establishment number, a safe handling statement, safe handling instructions, and nutrition facts information. In addition, some information is provided voluntarily by food manufacturers. Labels may contain additional information deemed useful to consumers such as *Sell By, Best if Used By,* or *Use By* date. Package labels might also include marketing claims such as *all natural* or allergy attributes such as *gluten free*. All this information at the point of purchase likely affects the decision to buy or not.

As long as the labels are credible, truthful, and understandable, consumers learn about product attributes. Through label claims, consumers may sort what is offered and find what they desire. Likewise, food producers—by providing information about their products at the point of purchase—can differentiate their products from others. If they supply nutritional characteristics or observe production practices that consumers want, their sales will increase or they will be able to charge higher prices. Label information can enable markets to coordinate production of foods that match consumers' preferences.[1]

Sometimes, however, label information may fail to inform consumers, particularly when it is untruthful, confusing, or not credible. Four types of information failure can occur.

- ***Information might be missing***. Companies have an incentive to reveal their positive but not negative product attributes via labels. Even so, the absence of information is not always a problem for consumers. As long as some products advertise positive attributes, consumers can deduce that the absence of information on other products means something negative. Missing information is especially a problem when all the products consumers think of as substitutable share the same negative attribute. No company will have an incentive to reveal information

[1] Competition among firms enhances consumers' ability to deduce relatively complete information about products (Ippolito and Mathios, 1990a). For example, the producer of a food product low in fat might voluntarily advertise that fact. A competitor with a similar product low in both fat and sodium would have an incentive to advertise its product's two desirable attributes. Consumers would then be suspicious of products that failed to make both claims. This competitive disclosure, which Ippolito and Mathios named the "unfolding" theory, results in explicit claims for all positive aspects of products and allows consumers to make inferences about foods without claims.

Dranove and Jin (2010) explained that this unraveling of information—voluntary full disclosure of product quality—occurs because the firm with the best quality product has a financial incentive to distinguish itself from all the lower quality firms. Namely, the rational consumers will infer nondisclosure as having the lowest quality. The highest quality firm is likely to disclose quality as long as there is a zero-cost way to do so verifiably. Then, the next highest quality firm will have the same incentive to disclose. The process continues until all but the lowest quality is revealed.

that would help consumers deduce the presence of negative attributes. (See chapter "Private-Sector Labeling for Products Made Without Genetically Engineered Ingredients," p. 37)

- ***Information may appear credible to consumers, but could be misleading, untruthful, or subject to misunderstanding***.[2] If labels deceive or mislead consumers, consumers may purchase products that do not fill their needs. If consumers base their purchases on mistaken beliefs, they have wasted their money. (See chapter "Private-Sector Labeling for Livestock and Poultry Raised Without Antibiotics" p. 37.)
- ***Besides veracity, labels must provide the right amount of understandable information for consumers to find what they want***. Too little information means consumers cannot sufficiently differentiate products. Too much or too technical information may overload consumers. If the information offered is too difficult to process, consumers may not find what they prefer within their time constraints. (See chapters "Nutrition Labeling Under the Nutrition Labeling and Education Act of 1990" p. 18, "Organic Labeling Under the Organic Foods Production Act of 1990" p. 27, and "Country-of-Origin Labeling Under Title X of the Farm Security Act of 2002" p. 54.)
- ***Many food label claims describe attributes consumers find difficult or impossible to verify.*** Consumers cannot observe or test organic, local, or sustainably produced claims; for that reason, they might be skeptical about such claims and unwilling to pay the price premium such attributes command. In effect, asymmetric information—where sellers know more about product attributes than buyers and buyers are unable to verify sellers' claims—may result in consumers being unable to trust that products satisfy their altruistic concerns related to production practices such as environmental stewardship (Akerlof, 1970). (See subchapter "Federal Organic Program Facilitated Organic Imports and Exports," p. 35)

To compensate for such market deficits, private-sector organizations and the Federal Government have tried to assist food buyers and sellers with labels that provide useful and reliable information that consumers believe and understand, letting them make rational, informed choices. Can such involvement make markets for attributes consumers cannot verify operate just like markets for attributes they can?

This report examines some label claims and changes in label claims begun since 1990[3] and the lessons these choices reveal. Can past experience with labels help successfully guide future Federal decisions about whether to be involved with food labeling?

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[2] The long history of manufacturers' deliberate attempts to use label information and advertising to mislead consumers has been a major influence on the development of Federal regulations. In the second half of the 19th Century, aggressively marketed over-the-counter medications known as patent medicines were falsely promoted as cure-alls and not actually patented, although their ingredients were proprietary company secrets, undisclosed to consumers (Smithsonian National Museum of American History, no date). Manufacturers were pioneers in advertising, soliciting through the mail, providing free samples, carrying out national newspaper campaigns, creating outdoor signage, and offering testimonials. Their creativity led to many of their trademarks (not the secret formulas, which apparently had no value) being sold to larger manufacturers. Efficacy did not have to be proven, and doctors did not control access. Manufacturers made any therapeutic claim for their products that they wished. Dangerous levels of alcohol, opium, and other narcotics were not revealed to consumers. Exposés of misleading information and unsafe products are credited with promoting the first Pure Food and Drug Act of 1906. That is, regulators were concerned that problems with patent medicines would carry over to food. The law did not forbid the use of alcohol or opiates, but did require disclosure. Following the disclosure requirement, patent medicine sales declined precipitously (Baker, no date).

[3] Federal food label policy saw big changes in 1990 as Congress passed both The Nutrition Labeling and Education Act and the Organic Food Production Act.

Golan et al. (2001 and 2000) have recognized that Federal intervention in food labeling aims to achieve many goals: improving human health and safety, mitigating environmental hazards, averting international trade disputes, or supporting domestic agricultural and food manufacturing industries. They argue that mandatory food-labeling requirements work best in alleviating problems of asymmetric information but not as well in redressing environmental or other spillover effects associated with food production and consumption. Theory also suggests that the appropriate role for Government in labeling depends on the type of information involved and the level/distribution of the costs and benefits of providing that information. Golan et al. traced the economic theory behind food labeling and presented five case studies in which the Government had intervened in labeling or planned to: nutrition labels, dolphin-safe tuna labels, organic labels, country-of-origin labels, and labels for foods not containing genetically engineered (GE) ingredients. In the early 2000s, both mandatory nutrition labels and the voluntary USDA Organic seal were relatively new; the full set of effects had not been revealed. In the Golan et al. studies, both country-of-origin labeling and non-GE labeling were voluntary; effects were speculative. Given many years of real-world experience with mandatory and voluntary labels, the effects of Federal intervention can be seen. (See appendix table 1 for a review of major U.S. food-labeling legislation over the last century.)

Where Do Problems Occur?

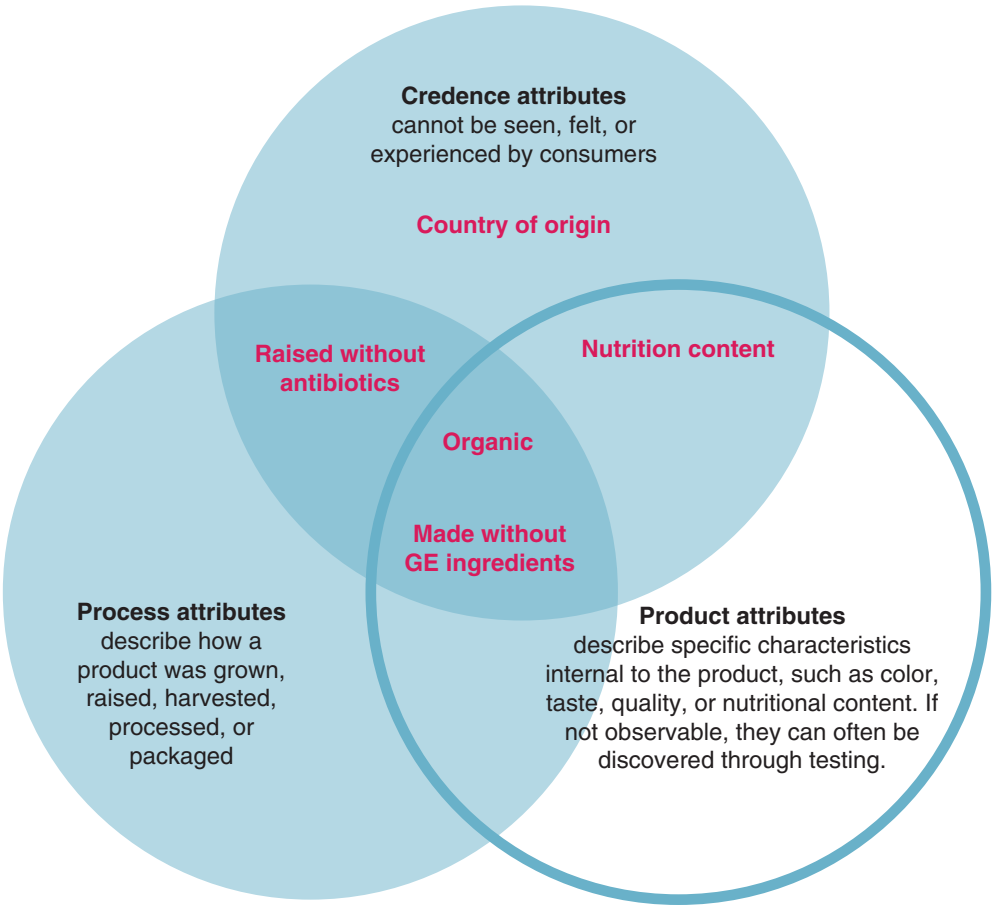
Food attributes can be classified to show that label issues are not all alike; communicating the presence or absence of attributes poses an array of information problems. Using two classification schemes, both demand and production issues can be covered.

Attributes have been grouped into three types: search, experience, and credence attributes (Nelson, 1970; Darby and Karni, 1973). *Search attributes* are those that the consumer knows about prior to purchase, such as whether a fruit is a banana or an apple; or the cheese is white or yellow. *Experience attributes* are those the consumer learns about by using or eating a product; these might include whether a steak is tender, or whether an apple is tart or sweet. Finally, *credence attributes* are those that the consumer cannot verify by looking at, buying, or eating/using the product.

Just as an attribute can be determined to be a search, experience, or credence attribute, attributes can also be differentiated as a *product* attribute, a *process* attribute, both *product/processed,* or *neither.* Process attributes deal with how a product was grown, raised, harvested, processed, or packaged. Many process attributes are unobservable credence attributes. Some may be discovered or verified through testing. Product attributes, on the other hand, are internal to the product, such as color, taste, quality, or nutritional content. Food can have both process and product attributes; some process attributes result in observable differences in the product. Examples of these types of attributes might be particular ways of processing a product, such as coarse-ground cornmeal or dried apples. Process and product attributes may raise different problems for goods whose sales rely on credence attributes.

The two classifications of attributes as *search/experience/credence* and *process/product/both/neither* yield a mix of outcomes for the labels examined in this report (fig. 1). All five labels identify credence attributes, but they raise distinct economic and policy issues as they fall into four groups. These include labeling process-based credence attributes (e.g., "raised without antibiotics" labels), product-based credence attributes (e.g., nutrition labels), credence attributes that are both product and process based (organic, made without GE ingredients), and labeling an attribute that does not fit neatly into either category (country of origin).

Figure 1
Product and process attribute classifications overlap with search/experience/credence attribute classifications, but are not identical



Note: GE = genetically engineered.

Source: USDA, Economic Research Service.

There is not much ambiguity in labels for search attributes, so most are recognized as credible, truthful, and understandable. Because consumers cannot confirm experience attributes until they have purchased, eaten, or used the product, a firm could deliberately make misleading claims on the product label such as "this steak is tender." In this case, an information asymmetry exists—the supplier knows more about the product or how it was produced than the consumer does. Still, labels can serve to direct consumers to their most preferred product attributes. With repeat purchases, consumers can assess the truthfulness and the reliability of label claims, and this updated information can influence their future purchase decisions. In this way, suppliers develop a reputation. Insofar as consumers can rely on their own assessments of truthfulness when making purchase decisions, they give suppliers a financial incentive to label truthfully.

With experience goods, by building a reputation, firms can sometimes overcome consumers' reluctance to pay for attributes that are not immediately observable. When a firm invests in building its brand or reputation, it stands to lose if consumers find its label claim untruthful. Consumers who believe a firm's claim is false may take their business elsewhere (Klein and Leffler, 1981). Beyond brands and reputations, explicit warranties that protect consumers against particular types of product failure can overcome consumers' reluctance to pay for quality that is not immediately observable (Grossman, 1981).

When it comes to credence attributes, market outcomes are less certain. As with experience attributes, an information asymmetry exists in which the producer knows more about a product than the consumers. But with credence attributes, the consumer cannot verify the label claim through buying, using, or eating the food. In many cases, even an extraordinarily motivated consumer could not evaluate the credibility of the claim. For example, in the case of animal-raising claims such as "humanely raised," the consumer may gain information about the claim by visiting the farm, but may not have the knowledge or experience to judge whether the claim is credible or accurate. In cases like these, a brand may be difficult to build. If consumers have no way to be sure about the presence or absence of the claimed attribute—the quality is never observable—the penalty that might be imposed on brand-building firms would be difficult to enforce. And a warranty does not offer much value to the consumer if nothing is observable. If consumers are skeptical about claims they cannot verify, their skepticism is likely to reduce their willingness to pay, and as mentioned earlier, markets for attributes may vanish.

Not surprisingly, consumers do not always understand credence or process-based labels, particularly those related to sustainability or growing/raising claims. For example, the *natural* claim might be misinterpreted. (See box "Issues With the 'Natural' Claim.")

Multi-attribute claims may also confuse consumers. For example "organic" encompasses multiple attributes. But some consumers do not realize that the organic claim signals "raised without antibiotics" (RWA) and "non-genetically engineered" (non-GE). They look for other labels to indicate these attributes. Conversely, some consumers think single-attribute label claims mean more than the single claim. For example, organic chicken is RWA, but *natural* chicken is not always RWA. "Natural" is a single attribute claim that consumers can believe implies multiple attributes (Oberholtzer et al., 2006). Consumer preferences and willingness to pay for a particular attribute or product can change in response to the number and combination of attributes labeled on a product, as well as in response to the introduction of new product labels (Gao and Schroeder, 2009; Lusk, 2013).

Consumer demand is growing for goods with credence attributes, particularly those that relate to environmental sustainability, animal welfare, and how food is grown (McFadden, 2013). More and more, segments of consumers care about whether food is organically grown, sustainably produced, locally grown, humanely raised, or raised without antibiotics or hormones.[4] Some of this demand may be driven by altruism or by concern about environmental externalities. For example, some consumers may be concerned that ordinary food choices have negative environmental impacts; or, specialized foods might be considered environmentally benign or beneficial. In other cases, demand arises because consumers believe that certain foods are healthier for them to eat. Table 1 offers a partial list of credence attribute claims that can be found on food packaging, representing a wide range of interests.

[4] Producers and consumers have many different views of what sustainable agriculture means. While there is no one single definition, the 1990 Farm Bill defines sustainable agriculture as a system of plant and animal agriculture that does the following: (1) satisfies human needs for food and fiber; (2) enhances environmental quality and the natural resource base; (3) uses nonrenewable and on-farm resources efficiently and, where appropriate, uses biological cycles and controls; (4) sustains economic viability of farms; and (5) enhances quality of life for farmers and society.

Issues With the "Natural" Claim

The USDA Food Safety and Inspection Service (FSIS), which regulates meat, poultry, egg products, and catfish, allows food manufacturing companies to use the term *natural* on product labels if the product contains no artificial ingredient or added color and is only minimally processed (USDA, FSIS, 2008).[5] The policy of the U.S. Food and Drug Administration (FDA), which regulates most other food products, is similar, although the FDA website notes explicitly that *natural* is not intended to address pesticide use and other production practices or irradiation and other food processing methods (FDA, 2016d):

> Although the FDA has not engaged in rulemaking to establish a formal definition for the term "natural," we do have a longstanding policy concerning the use of "natural" in human food labeling. The FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. However, this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA also did not consider whether the term "natural" should describe any nutritional or other health benefit.

Despite partial agreement between USDA and FDA on the current definition of *natural*, and an FSIS requirement that *natural* claims be accompanied by a definition, such as "no artificial ingredients; minimally processed," many consumers interpret *natural* as meaning something else. A number of economic studies using consumer surveys and experimental studies suggest that consumer confusion about the natural claims is widespread (Gifford and Bernard, 2010; Onken et al., 2011; Butler and Vossler, 2017; McFadden and Huffman, 2017). A 2015 survey[6] found that 64 percent of consumers surveyed believed that *natural* meant that no artificial growth hormones were used, 59 percent believed that it meant that animals were fed feed that did not contain genetically engineered ingredients, and 57 percent believed that it meant that no antibiotics or other drugs were used (Consumer Reports, 2015). This discrepancy between the definition for *natural* and the consumer perception about the meaning of the term led USDA, Agricultural Marketing Service (AMS) to develop and subsequently withdraw a standard for *naturally raised*.

In response to requests by three Federal district court judges and petitions by firms and citizens groups such as Hormel Foods, Consumers Union, and others, FDA and FSIS have recently solicited public comments on the definition of *natural* (FDA, 2014b; FDA, 2016d; USDA, FSIS, 2008). In both processes, outcomes are still pending.

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[5] Minimal processing means that the product was processed in a manner that does not fundamentally alter the product.

[6] Consumer Reports® described its survey as a nationally representative sample of 1,005 adult U.S. residents selected by means of random-digit dialing, weighted so that respondents were demographically and geographically representative of the U.S. population.

Table 1

Examples of common label claims about food production and processing methods

Label	Major crop production requirements	Major animal production requirements	Major food manufacturing requirements	Commonly labeled products	Third-party verification
Food label claims with U.S. Government standards					
USDA Organic	– Exclude synthetic pesticides, fertilizers – Exclude GE inputs – Exclude sewage sludge – Build soil organic matter – Rotate crops – Enhance biodiversity	– Exclude antibiotics, hormones, and GE inputs – Require pasture for grazing (ruminants) – Require outdoor access (poultry) – Do not cage – Use organic feed only	– Have no artificial flavors, colors – Use minimal processing – Exclude GE inputs – Prevent organic and conventional mixing – Include only USDA-approved inputs	– Produce – Dairy, meat, and eggs – Packaged food – Beverages	USDA regulation mandates annual inspection and certification by USDA-accredited certifiers
Other food label claims					
Grassfed	NA	– Feed grass and forage only after weaning	NA	– Animal products	Many products have third-party verification from private groups
Humanely raised	NA	– No consistent requirements across labels	NA	– Animal products	Many products have third-party verification from USDA or private groups
Locally grown[1,2]	NA	NA	NA	– Produce – Dairy, meat, and eggs	Some grocers display signage on farm location, and some markets are farmer-only—but most products not third-party verified
Natural	NA	NA	– No artificial ingredients added during processing – Minimize processing (meat products only)	– Produce – Dairy, meat, and eggs – Packaged food	Most products not third-party verified
Non-GE	– Exclude GE inputs	– Exclude GE inputs	– Exclude GE inputs	– Produce – Dairy, meat, and eggs – Packaged food	Many products have third-party verification from private groups or USDA
Raised cage free	NA	– Egg-laying hens not caged	NA	– Eggs	Many products have third-party verification from USDA or private groups
Raised without antibiotics/No antibiotics ever	NA	– Exclude all antibiotics	NA	– Animal products	Many products have third-party verification from USDA or private groups

Note: GE = genetically engineered.

[1] Definitions of a locally grown product vary and may specify maximum miles to market, such as 100 miles, or production within same region, State, or county.

[2] U.S. law requires many food products to display their country of origin.

Source: Compiled by USDA, Economic Research Service.

Newer marketing methods and information platforms could make marketing credence attributes easier, if consumers believe the claims, or more difficult (simply confusing consumers), if they do not believe the claims. Industry trade associations and consumer advocacy groups are developing smartphone apps (software applications that may be used on smart phones or tablets) to educate consumers about food product attributes, and retail grocery stores and food service/restaurant chains are developing requirements that their suppliers must meet. These requirements are multiple credence attributes. The presence of the attributes, such as Whole Foods' "Responsibly Grown" rating system, is often communicated to consumers through point-of-purchase advertising or information on the company's website. (See box "Smartphone Apps and Other New Information Platforms for Food Attributes.")

Smartphone Apps and Other New Information Platforms for Food Attributes

One outcome of the digital revolution has been the advent of smartphone apps and other information platforms sponsored by industry groups and consumer advocacy associations that offer details about the healthfulness and environmental attributes of various food products. These groups often use rankings or indexes that encompass multiple food attributes. Although these rankings or indices may be easier for consumers to understand while shopping, what the index or ranking means and how it was computed is not always disclosed. Firms or groups may develop rankings and indices with the aim of promoting their own products.

Restaurants, wholesalers, and retailers have also begun to make claims regarding process-based characteristics related to the sourcing of their products. A number of stores (e.g., Costco) and restaurants (e.g., Chick-fil-A, Chipotle, Bon Appetit Management Co., and McDonald's) have declared a commitment to sourcing only meat products grown without antibiotics by a certain date. Fiorillo (2016) identifies 19 major retailers (e.g., Walmart, Target, Sysco, Sodexo, and Safeway) and restaurants (e.g., McDonald's and Darden/Red Lobster) that have made commitments to sourcing sustainable seafood. These companies use third-party verification groups to ensure they are sourcing traceable and sustainably produced seafood and fish products. These sourcing claims may have issues with credibility as well, as Fiorillo (2016) finds that many companies have made some progress but few have reached the announced commitments.

In principle, these sourcing commitments can accomplish several things. First, companies take on the burden of discovering and verifying that products have the desired attributes. This process may leverage economies of scale to decrease search costs for consumers. Second, if these attributes and commitments are well publicized, then consumers know where they can purchase products with desired attributes, again decreasing their search costs.

For the companies, these commitments may have a "halo" effect, leading consumers to infer that all the company's products have similar positive attributes even if the business itself makes no other claims. These commitments also may lead consumers to make inappropriate inferences about the products themselves, a "magic bullet" effect. For example, when meat is labeled "raised without antibiotics," consumers may perceive that animals are treated more humanely

—continued

Smartphone Apps and Other New Information Platforms for Food Attributes—continued

(even if that is not true). In addition, consumers may take a negative view of companies that do not make these commitments.

These sourcing commitments can be seen as a top-down approach—i.e., companies translate consumers' demands and seek suppliers who can fulfill them, rather than stocking a variety of products with different attributes and allowing consumers to select what they would like. The former process decreases consumer choice. In addition, these sourcing commitments face criticism for what they do not include and/or for a lack of measurable standards (Hardcastle, 2014). Schemes like sourcing commitments decrease search costs for consumers but shift the burden of proof to an entity that may have a conflict of interest.

In addition to apps and sourcing commitments, information about process-based characteristics is dispersed by personalities or groups through websites or social media. For example, one group publicizes issues to followers to encourage petitions and other actions to create change in the food industry—such as labeling genetically engineered (GE) products or changing ingredients in certain products. These recommendations may reduce retail demand for products from companies that may or may not be guilty of doing anything wrong. As consumer demand changes in response to these influences, companies may respond by re-formulating products or changing production practices. These personalities and their information are also largely unverified and unpoliced.

If the absence of a label claim implies a negative attribute, growers may require multiple verifications to market their goods, and marketing could become more expensive. Higher costs will decrease the value of a label unless the market returns a higher price premium. Many organic processors have sought non-GE labels, some under pressure from retailers, even though the USDA Organic seal means they did not use GE ingredients. Private labels, such as Whole Foods' "Responsibly Grown" rating system and label, increase costs for many growers. In fact, organic growers raised this concern about the "Responsibly Grown" ranking label, as well as about the index quality and Whole Foods' conflict of interest in developing the rating.

How Can Government Target Missing Information and Information Asymmetry?—Limitations and Possibilities

Problems of information asymmetry or missing information might be solved or mitigated by requiring manufacturers to supply the information that consumers lack. Mandatory label requirements can arise through legislation, executive decisions, or via the courts. But Government has not mandated that information be provided in all cases in which it is held asymmetrically or is missing. A proposal to make some information mandatory, deciding that consumers have a right to know the details of product manufacturing, can be judged—like most public policies—on whether it does more good than harm.

In order for the Government to justify intervening and mandating labels of credence attributes, Sunstein (2017) finds that a market failure must be present—that is, private sellers are not providing the information that would normally be expected. Second, for mandatory labels to correct a market failure, the benefits of such labels must exceed the costs. The fact that some consumers prefer that information be provided—that certain attributes be labeled—is not enough to justify mandating labels. The collective or public willingness to pay for an attribute label must exceed the costs of providing those labels.

For example, food suppliers may be happy to provide consumers with information on positive attributes but less enthusiastic about labeling negative attributes. If all suppliers have to provide the same types of information, fairness reigns, and if sales decline as a result of the disclosures, companies have the option of changing a product's formulation to improve its nutritional content.

Production and Consumption Externalities

But there are other ways markets might fail to solve information problems. That is, there might still be cases where private production or consumption decisions diverge from the socially optimal levels of production or consumption of food products. For example, when negative externalities exist in the production or consumption of food products, the private firm or consumer does not pay the full cost of their production or consumption decisions. In these cases—where companies and consumers may not make decisions that consider the greater well-being of the environment or the public—food labels might yield positive net benefits.

Examples of potential positive externalities include more open space, conserved natural landscapes, and wildlife habitat. Examples of potential negative externalities include more soil erosion and runoff of agricultural fertilizer and more pesticide pollution in water.

Food labeling might draw a distinction for consumers between foods produced from agricultural production methods that result in negative externalities and foods produced using more benign methods. Food labels can create a choice so that consumers who want to support particular methods can do so, although not even mandatory labels will compel any producer to follow such production methods. If few producers follow the methods deemed sustainable, then most food will still be produced without meeting this test of sustainability (Golan et al., 2001 and 2000). Therefore, neither a mandatory nor a voluntary label may have much effect on the environmental externalities

of concern; a Government regulation on production methods, taxes, or other policy tools may have more effect.

Choices Have To Be Made To Support Labels

Market outcomes of various labels can be compared and contrasted based on what was done via (1) standard setting or product definition; (2) monitoring and verification; and (3) enforcement. Implicitly or explicitly, choices will be made about each of the activities. Each of these requires two choices:

- Should the activity be conducted by public and/or private-sector entities?
- What should be done?

If market mechanisms have not solved the information problem, either the private sector or the public sector can step in to help. Involvement of both the Government and third parties has taken many forms.[7] And different mixes of public- and private-sector activities are feasible. That leaves many alternative ways to organize a label claim.

1. The private sector can be responsible for everything. That is, a for-profit company (first party) or a nonprofit group (nongovernmental organization (NGO); third party) can set standards for a food attribute. (See, for example, the chapters in this report on non-GE labels and RWA.) Companies and NGOs can set up competing standards (identical, similar, or distinct).
2. At the other extreme, the public sector can be responsible for everything. In the case of the Nutrition Facts label, the Government made labels mandatory for most processed foods. The Government set the standards and format with which information should be conveyed and provided some enforcement of the labels. Similarly, country-of-origin labeling is mandatory for some foods.
3. A mix of public and private is always possible. For example, the USDA National Organic Program (NOP) sets standards. It also accredits other organizations, mostly State governments and NGOs, as certifiers. NOP relies on those organizations for certification of farms and food manufacturers as meeting the organic standards.
4. Federal regulatory agencies can directly enforce the use of labels through reviews, fines, and recalls of products. Enforcement via judicial solutions can be accomplished regardless of whether other responsibilities for labels are in the public or private sectors.

Labeling and Standard Setting

Establishing a label claim that will be credible, truthful, and understandable requires developing a standard or a product definition as an agreed method or meaning.[8] When people share the same expectations about a product or service, the information asymmetry problem diminishes.

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[7] We define the parties involved in a transaction as follows:
- First party – The manufacturer and/or supplier.
- Second party – The purchaser and/or user.
- Third party – An independent party with no vested interest in the transaction between the first and second party.

[8] Federal regulations associate the term "standard" with specific legal requirements. Here, our focus is on information problems that limit exchange among individuals, and thus our usage of the term is the more common and conventional, meaning "level of quality or attainment."

Without standards, label claims may fail to signal actual differences in product quality. For example, if no commonly agreed on definition of genetic engineering (GE) or of the acceptable GE content threshold exists, then producers and marketers can label nearly anything as "non-GE."[9] If consumers mistakenly believe all the standards are alike, then the supplier with the least difficult/least costly standard to meet will have a financial advantage over the competitors. In that case, the higher standards might not be provided in the market even if some consumers are willing to pay for products meeting those standards.[10]

The main difficulty in achieving a product definition or standard is reaching agreement: doing so requires making some tradeoffs. For example, consider the case of labeling food made without GE ingredients. First, everyone must agree on the definition of GE—i.e., what types of plant changes are "breeding" and which are GE? Next, market participants must agree on a threshold for GE content. If everyone (consumers and producers) agreed that food with 0.9 percent GE content or less could qualify for a label of "made without genetically engineered ingredients," then consumer confusion may exist but not due to inconsistencies with the definition. If different certifiers all use the same standard, the various labels will convey the same information to consumers. Each label will be sufficient to categorize food as containing GE ingredients or not. Of course, some consumers may not agree with the standard—they may prefer that the allowable threshold is zero—that the product is completely free of any trace of genetic engineering ingredients. Without common ground, universally agreed-on standards will be impossible and similar label claims will mean different things.

If consumers and firms cannot agree on the meaning of labels of credence attributes, or if various firms each have their own definitions or private standards, the Federal Government may change market outcomes by intervening, setting standards, and mandating that certain (usually, well defined) information be provided on a label. The Government can set product standards or definitions that must be followed if certain terms are used but will not always mandate that all manufacturers relay this information. For example, FDA requires that anything labeled "mayonnaise" contain a minimum of 65 percent vegetable oil by weight. Products that resemble mayonnaise but have less fat cannot be called mayonnaise. Although the Federal Government can standardize label information, it does so at the cost of ruling out competing standards or different product attributes. That is, one definition exists for all products regardless of the variation in preferences. The unseen cost to consumers is a market with less variety and less innovation. Reaching agreement can also be time consuming, which can limit responses to changes in consumer demand.

Product standards have been set by individual firms, industry groups, and a wide variety of third parties, including nonprofits, retailers, and the public sector. In effect, transactions may involve more individuals and organizations than just the buyers and sellers. (Table 1 gives examples of some common process-based and product-based claims and whether claims have third-party verification.)

When private-sector firms create standards, they expect to recover the cost of their efforts from their sales and price premiums. In the public sector, general tax revenues are usually used to finance standard setting. For example, USDA, Grain Inspection, Packers and Stockyards Administration's

[9] Foods containing genetically engineered ingredients are sometimes described as containing "genetically modified organisms (GMO)." Here, we use "genetically engineered" or GE unless referring to words on a specific food label.

[10] Having many suppliers make the same credence-attribute claim but with differing standards or definitions may not be problematic as long as consumers are aware that the claims mean different things. Then, the market might be judged as offering differentiated products and satisfying the various needs of consumers, with no need to agree.

user fees cover only testing costs, not the costs for development of standards and testing methods (MacDonald et al., 1999).

Monitoring, Testing, and Verification

The Federal Government can establish whether label claims need public sector or private sector confirmation, and can verify directly or qualify third-party organizations to do so. Users can pay fees for verification services. Once a standard is in place, someone has to judge whether those standards have been met. Testing and verification are easier for some attributes than for others. For example, plant-based products are grown with or without GE seeds. In this case, testing the final product can verify which products satisfy the criteria.[11]

When no scientific test exists to test for the presence of an attribute, for example a process-based credence attribute, auditors need to collect information to verify the presence or absence of an attribute. In the case of the USDA Organic seal, auditors visit farms and food manufacturing plants looking for evidence that pesticides were not used, as well as conduct random pesticide residue testing of products. Label claims for country of origin or locally produced might require auditors to follow the chain-of-custody paperwork for the product. Purchase records for seed might indicate whether non-GE seeds were sown. Products must retain these attributes through the entire supply chain—growing and processing. Advances in information technology have allowed for sophisticated inventory management systems, but verifying a credence attribute is an additional cost.

In some cases, third-party verification can fail to deliver on its promises.[12] Like any business, these firms need to be paid for their work. Third-party verification is usually financed by the sellers seeking verification. Therefore, the third-party verifier has a financial incentive to support the seller's interests rather than the buyer's, especially if sellers can shop for verifiers that best support the label claims. Such arrangements can reduce the third-party verifier's objectivity. Enforcement can have varying frequency and penalties.

The Government may be more objective than third-party verification companies that compete with each other for clients. It may be in the public interest for Government to certify or verify label claims. Even if the Government is paid directly by the sellers obtaining services and the Government competes with private verification companies, the overall public interest might be enhanced. In some cases (such as with USDA, FSIS inspection of meat), Government verification of a credence attribute, such as meat wholesomeness, may be justified from a public health perspective, even if a Government agency is the only verification body and the public finances the inspections through taxes.

Every time a firm wants to confirm a label claim, it has to consider whether it will certify its own products or acquire verification from someone else. Credibility, too, can be considered an input into production. Investing in a brand name and ensuring products routinely meet quality claims is one way to build credibility. But this may be a slow process as consumers must repeatedly sample a product and see that their expectations were met. And with credence goods, the mechanism for ensuring that consumers received what they expected is unclear. The Federal Government can

[11] Testing must be done before any cooking or refining because highly processing the product destroys its genetic identity.

[12] See Rosenthal and Kunreuther (2010) for a retrospective look at four examples of third-party certification in other industries, most of which failed.

confirm a label claim, which will likely bring credibility quickly as long as the Government has no conflict of interest. That is, a Government stamp of approval may convince consumers that the claim has merit when they might otherwise be skeptical.

Enforcement

Enforcement of an established standard or definition may deter firms whose products do not meet the standard or definition from using a related label or from listing product claims for the standard. Firms can be forced to remove their claims—either relabeling the product or doing a recall. Other types of enforcement actions are also possible. Just as with standard setting and verification, many types of entities can be responsible for enforcing label claims. The public sector is responsible for enforcing many credence standards regarding safety, nutrition, and quality. FDA and FSIS are also responsible for enforcing a universal standard that labels are truthful and not misleading, and they engage in various activities to this end. For example, FSIS requires that many label claims undergo a pre-approval process, and both FDA and FSIS periodically audit label claims. FSIS recently solicited comments on animal-raising label claims.

USDA, AMS shares responsibility for enforcing the U.S. Organic standard with the USDA-accredited private certifiers. The certifiers ensure that certified operations meet the standard and may take enforcement actions up to and including suspension or revocation of the operation's certification if they do not. AMS also fields complaints made directly to it by consumers or other firms and takes the appropriate enforcement actions.

For standards that are verified by a private-sector third party, the third party can enforce the standards. For example, Non-GMO Project routinely tests non-GE grain for the presence and levels of GE grain in shipments for both verification and enforcement purposes.

If the Government or a private-sector entity finds that products do not meet a standard, enforcement activities can take multiple forms. Enforcers can:

- Request or require a label or claim to be removed
- Withhold inspection services, effectively stalling product entry into the marketplace (e.g., FSIS can withhold inspection of meat and poultry slaughter and processing to enforce food safety requirements)
- Request or require that a product be recalled from the marketplace
- Impose civil penalties (e.g., fines)
- Impose criminal penalties

Besides these formal enforcement mechanisms, other types of de facto enforcement-related activities can occur, including:

- If a firm or consumer believes a label claim does not meet a standard or warrants investigation, the firm or person can submit complaints to Government agencies or third-party certifiers.

- If a firm believes that a label claim has harmed its business through false advertising, it can file suits against other firms, in accordance with the Lanham Act sections 1116 and 1125 (Bowman et al., 2016).[13]
- If a consumer or advocacy group believes a label claim to be misleading, the person or group can sue firms (Humane Society of the United States, 2014).
- Consumers and third parties can organize boycotts of the company's products.
- If a consumer believes a label claim to be misleading, s/he may seek out alternative brands. By walking away from untrustworthy standards or claims, consumers exact a financial penalty.

[13] The Lanham Act is the primary Federal trademark statute in the United States. The Act prohibits trademark infringement, trademark dilution, and false advertising.

A Retrospective View of Labeling Initiatives for Healthy Food and Agricultural Stewardship

U.S. food policy has evolved over the last century from an early focus on meat safety and commodity inspection to more expansive goals for educating consumers on food and nutrition and facilitating movement of organic and other healthy foods into the mainstream. Consumers have been instrumental in achieving these changes over the last century. Their reaction to *The Jungle* (Sinclair, 1906), on conditions in meat-packing plants, led to USDA's routine meat inspections. Similarly, their reaction to *Silent Spring* (Carson, 1962), on the detrimental impacts of indiscriminate pesticide use, led to heightened interest in farming practices as well as the creation of the U.S. Environmental Protection Agency (USDA, FSIS, 2015c; Lewis, 1985).

Food-labeling requirements in most of the early laws—such as the 1906 Federal Meat Inspection Act and the 1924 Agricultural Products Inspection and Grading Act—were based on color, size, and other measurable *product-based food attributes*. In 1990, Congress passed groundbreaking legislation, the Nutrition Labeling and Education Act, which substantially expanded food labeling requirements by requiring standardized "Nutrition Facts" labels on most food products. The Act also authorized food labeling for health claims that have strong empirical evidence linking food consumption to reduction in disease risk.

Congress also passed another significant food labeling law in 1990, the Organic Foods Production Act, which required USDA to set uniform national standards for organic agriculture. In contrast with earlier food labeling standards, USDA's national organic standards are characterized mostly by *process-based food attributes*—the practices and materials used in farming and food handling. The USDA Organic seal and standards encompass everything from soil health, farm-level biodiversity, and pasture for ruminants to prohibitions on the use of genetic engineering, antibiotics, hormones, and most synthetic pesticides, fertilizers, and food processing aids.

Although organic is still the only process-based food claim with Federal standards, USDA has begun providing verification services to firms that want to advertise their own process-based standards. For meat and poultry labeling, USDA requires firms to submit some label claims for pre-approval—whether claims are verified or not—and provides definitions for many terms that may be part of a label claim. Firms are mostly using label claims that represent a single production attribute, such as "raised without antibiotics" or produced without genetic engineering (non-GE).

Another type of food label claim that has emerged in recent years—for geographic origin—indicates where the product was grown but generally does not describe either product attributes or the practices used to produce the product. Many firms that use this label do so voluntarily. For example, farmers and retailers will advertise that their fruits and vegetables were grown locally—i.e., in the same State where they are being marketed—or within a certain distance of that market. In 2002 and 2008, Congress passed legislation mandating that food imports carry a geographic country-of-origin label (COOL). (See appendix for a description of the USDA and FDA programs that administer quality verification services and other food safety and labeling programs.)

In the next set of chapters, we examine five of the food label claims that have changed or emerged since 1990:

- Nutrition Facts—complex set of attributes (nutrition); U.S. standards; public-sector enforcement
- USDA Organic—many process attributes; U.S. standards; certification required; public-sector enforcement with civil penalties and criminal prosecution
- Raised without antibiotics (RWA)—one process attribute; industry standards (meet USDA definitions); verification optional; limited enforcement
- Non-genetically modified (non-GE)—one process attribute; industry standards; verification optional (but frequently used); limited enforcement
- COOL—no product/process attributes; U.S. standards; mandatory for selected commodities; public-sector enforcement.

For each of these labels, we examine the market failure that is addressed, how the public or private standards were developed, the use of third-party verification, whether the label is policed, and whether penalties exist for noncompliance. We also examine the producer and consumer responses to these labels and how well each label meets basic goals for credibility, truthfulness, and understandability.

Nutrition Labeling Under the Nutrition Labeling and Education Act of 1990

The Nutrition Labeling and Education Act of 1990 (NLEA) aimed to improve Americans' diets by standardizing information about nutrient content on the back of almost every food package in the form of the Nutrition Facts label.[14] The regulations required to implement the statute amounted to one of the biggest changes in the history of food label policy. Regulations required the Nutrition Facts label on about 90 percent of processed food sold in the United States (Wilkening et al., no date). NLEA also allowed food manufacturers to make some front-of-package health and nutrition claims, while controlling what could be claimed about each food. For a summary of the demand for label information and market failure leading to NLEA, as well as consumer and industry responses since, see box "Major Themes of the Nutrition Labeling Under the Nutrition Labeling and Education Act of 1990 (NLEA)."

Before NLEA, it was well known that Americans' diets were low quality. The 1988 Surgeon General's report (U.S. DHHS, 1988), as well as preceding issues of *Dietary Guidelines for Americans* (both based on existing nutrition research), pointed out American consumers' poor diet quality and the negative effects on health. At that time, the nutrition information on food labels was limited and provided inconsistently, or missing altogether. Before NLEA, packaged foods were required to include the name of the food, net quantity, a list of ingredients, and the name and address of the manufacturer. Only those foods that made a nutrition claim or were nutritionally fortified with vitamins, minerals, or protein were required to display nutrition information (Greenberg, 1990). When nutrition information was offered, it included serving size, number of servings, calories, macronutrients, and recommended daily allowances (RDA) of seven micronutrients.

This information was opaque to many consumers as the quantitative measures were listed in units such as grams, milligrams, international units, and retinol equivalents (Kessler et al., 2003). In effect, even when there was nutrition information on packages, many consumers found it difficult to interpret.

The stated objectives of NLEA were to reduce consumer confusion about labels, help consumers make better food choices, and encourage innovation by giving manufacturers an incentive to improve the nutrition profiles of foods (FDA, 2014a). FDA issued final regulations for NLEA on January 6, 1993, and the rule became effective May 8, 1994 (FDA, 2014a). Proponents of NLEA and the supporting regulations argued that if consumers were given understandable and credible information about food, they would choose healthier diets. Doing so would provide a financial incentive for food manufacturers to offer more healthy products, making it easier for consumers to choose healthy foods (Zarkin et al., 1993).

[14] Initially, the panel was called the Nutrition Facts panel. The current convention is to refer to it as the Nutrition Facts label, and this paper will maintain that convention.

Major Themes of the Nutrition Labeling Under the Nutrition Labeling and Education Act of 1990 (NLEA)

Demand for label/information: Proponents of NLEA and the implementing regulations argued that American consumers' diets were generally unhealthy and that if consumers were given understandable and credible information about food, they would choose healthier diets. Such choices would give food manufacturers a financial incentive to offer more healthy products, making it easier for consumers to choose healthy foods.

Market failure: Before NLEA, the nutrition information on food labels was limited and provided inconsistently, or missing altogether. Where there was nutrition information on packages, many consumers found it difficult to interpret.

Consumer response: Even with NLEA in place, food manufacturers have tried alternate and simpler forms for recommending food choices, indicating that the standardized information is too complex for many consumers.

Industry response: The obvious change attributable to NLEA is the profusion of front-of-package health- and nutrition-related claims. Foods were reformulated to use the new ability to make front-of-package claims. Evidence that foods became healthier overall is ambiguous.

Standard Setting—Nutrition Facts Labels

With NLEA, FDA designed a panel of information that is required to appear on the back of food packaging. (See box "NLEA: Standard Setting, Verification, and Enforcement.") As implemented, each Nutrition Facts label was required to indicate serving size and the servings per container.[15,16] Nutrient declarations include calories and calories from fat (both in terms of amount per serving). Total fat and trans fat (as of 2006, see Rahkovsky et al., 2012) were required. Conditionally, saturated fat, polyunsaturated fat, and monounsaturated fat were required, depending on levels of total fat and whether the label specifically included claims about fat and cholesterol levels. Cholesterol, sodium, and protein were required, and potassium was voluntary unless the label includes a claim about potassium. Carbohydrates and dietary fiber were required, and more detail was required if claims about the components (e.g., soluble fiber) were also made. Except for protein, a percent of recommended daily allowance (RDA) had to be included for each nutrient where RDAs or daily reference values had been established (FDA, 2014a). Amounts of vitamins A and C along with calcium and iron were required. NLEA also specified the ordering of optional vitamins and minerals. The Nutrition Facts label includes a chart providing threshold guidance for total fat, saturated fat, cholesterol, sodium, total carbohydrates, and dietary fiber for 2,000- and 2,500-calorie diets.

[15] Foods exempt from the regulations include those sold by small businesses, restaurants, and food service vendors. Other exemptions include ready-to-eat foods, donated foods, coffee beans, tea, and food colors and flavors that have no nutritional significance.

[16] Labeling continues to be voluntary for raw fruits, vegetables, and seafood. In 2010, FSIS required a Nutrition Facts label on raw meat and poultry products (USDA, FSIS, 2010).

NLEA: Standard Setting, Verification, and Enforcement

Nutrition Facts Label

Who sets the standard?
The nutrients listed on the Nutrition Facts label were set by law. FDA made recommendations for daily intake of nutrients and for defining serving sizes for all foods.

Who verifies the standard?
FDA does not pre-authorize labels, so manufacturers are responsible for making sure that what they list on the Nutrition Facts label is true. Manufacturers will either have to test or consult literature or accepted databases for their analysis, then they will have to have records of the analysis. They do not have to submit anything to FDA, but FDA will have access to the records if requested. FDA district offices do some random sampling of products and test some nutrients subject to Association of Official Analytical Chemists' methods. Also, FDA does some directed sampling, usually based on consumer or competitor complaints, but sometimes through other investigations that point to labeled nutrient levels being unlikely to be correct.

Who enforces the standard?
When FDA has evidence that information on the Nutrition Facts label is incorrect, it usually begins with a warning letter to the manufacturer.

Health- and Nutrition-Related Claims

Who sets the standard?
FDA authorizes health claims based on review of the scientific literature, generally as a result of a petition, and determines whether the substance/disease relationship is well established. FDA permits the use of label claims that characterize the level of nutrient in a food if the claims have been authorized by FDA and are made in accordance with FDA's authorizing regulations. FDA does not pre-approve labels, so once a claim is approved for one manufacturer to use, all can use it. Claims decisions are now made through notice and comment rulemaking. Nutrient content claims and health claims have been made through regulation and through reliance on authoritative statements.

Who verifies the standard?
Manufacturers do not have to submit anything to FDA to support claims, but FDA will have access to the records if requested. FDA has to agree that label statements are in fact authoritative and not simply what a food manufacturer wants to put on its label. Health claims where scientific evidence is limited also may sometimes be approved as qualified health claims, through FDA's enforcement discretion.

Who enforces the standard?
False claims are provably so, and scientific evidence may be sufficient. However, it is harder to prove that misleading claims are misleading, because proof depends on demonstrating what is commonly understood by a claim's wording. Enforcement discretion used to allow qualified health claims sometimes puts the FDA in a difficult position because it is open to First Amendment considerations.

Beyond NLEA—Food Label Changes Yet To Come

The nutrients listed on the Nutrition Facts label were set by law. For food manufacturers to be able to calculate the amount of each nutrient per serving, FDA has to define serving sizes. This is an ongoing activity as new foods enter the food supply and some old foods that initially did not require serving sizes now do. For example, ice now requires a serving size because a manufacturer wanted to use a no-sodium claim on bags of ice. For the claim to be shown as valid and compared across different brands, the label needed to display the Nutrition Facts label and a serving size.

All the elements of the Nutrition Facts label reflect choices FDA had to make about whose needs should be addressed. Recommendations for some nutrients depend on daily caloric intake. But recommended caloric intake depends on age and gender. Vitamin and mineral requirements also vary with age and gender and raise similar questions about whose intake should serve as the base. FDA had to choose whether to present information tailored to the most vulnerable population or to an average consumer. New research results and changing nutritional needs complicated the decision as RDAs have shifted over time.

For multiple reasons, it was not immediately obvious how the information gap should be filled. Tastes and preferences vary by cultural norms and geographic region. Also, consumers' abilities to process information varies. Under these conditions, how does one best construct a limited set of statements that both fit on a food package and fill information gaps for consumers who have varying information needs? The attempt to do so has occupied FDA for decades. Several years prior to NLEA, FDA recognized that legislation like NLEA was likely and began working to deliver the implementing regulations. It recently announced a major revision (FDA, 2016b). On June 13, 2017, FDA announced its intention to extend the compliance date for the Nutrition Facts label final rules (FDA, 2016a, updated June 19, 2017).

Defining serving sizes for all foods, conducting research to define RDAs for all the missing values, deciding the type of consumer for which recommendations would be written, and figuring out how to communicate recommendations was not the end of FDA's work. More than 20 years after the first label became mandatory, FDA is in the process of refining the information contained in the label, with the stated goal of helping "people make informed decisions about the foods they eat and feed their families" (FDA, 2016a). The new label will highlight "calories" and "servings," and serving sizes have been revised to more closely reflect amounts of food that people currently eat—variables that have changed since 1993. Added sugars will be identified. Dual columns will indicate per-serving and per-package information. RDAs will be updated. Information on vitamin D and potassium (nutrients that research has shown many people are not getting enough of) will be required, and information on vitamins A and C will not, as deficiencies of these are rare. Information on calories from fat will be removed because research shows the types of fat are more important to health than the amounts.

Menu Labeling

Other changes in the way Americans eat have diluted the effect of nutrient-content labels. Food consumed away from home has steadily increased in importance in Americans' diets at least since 1929 (USDA, ERS, 2015). In 2014, the share of food expenditures in full-service and fast-food restaurants reached 43.7 percent, up from 35.8 percent in 1990. Some fast-food chains voluntarily provide nutrition information on their websites, but often nutrition information is not readily avail-

able to consumers as they are making food choices. While NLEA increased information available to consumers when they prepare food at home, initially it did not make any demands on food consumed away from home. The increasingly incomplete dietary coverage of NLEA could be limiting the positive influence information might have on diet quality and health.

That possibility may be soon reduced. Gregory et al. (2014) noted that a number of States, counties, and municipalities have implemented (or soon will implement) menu-labeling policies designed to provide consumers with nutrition information at the point of purchase. The Patient Protection and Affordable Care Act (2010) seeks to set a uniform national standard for menu labels, superseding State and local provisions under the final Federal rule developed by FDA. The rule requires all restaurants and fast-food establishments with 20 or more locations to post the number of calories contained in each menu item. Information about fat, saturated fat, cholesterol, sodium, total carbohydrates, sugars, fiber, and protein would have to be available in writing on request.

Health- and Nutrition-Related Claims Changed Food Marketing

Regulations state which nutrient-content claims are allowed and under what circumstances such claims can be used. NLEA also provided for the possibility of health claims—science-based statements of disease-risk reduction from foods and dietary supplements (Schneeman, 2010). Before NLEA, such a claim would have been treated as if it were a drug claim; FDA policy essentially banned health claims on foods (Ippolito and Mathios, 1990b; Hutt, 1986).

Martinez (2013) tracked trends in new product introductions in the United States with voluntary health- and nutrition-related claims.[17] He found that the percentage of new products with at least one claim trended downward, from 34.6 percent in 1989 to 25.2 percent in 2001. This result was consistent with a previous study of products at a representative superstore. Caswell et al. (2003) found that the percentage of products with voluntary health and nutrient content claims fell by 5 percentage points from 1992 (before NLEA) to 1999 (after implementation). That is, food manufacturers making label claims may have dropped the claims because the claims did not meet the new NLEA requirements.

However, Martinez's calculations showed that the number of claims per product increased from 2.0 claims in 1989 to 2.2 in 2001, suggesting that competition between food suppliers is helping to inform consumers about nutrition (see footnote 1). In effect, consumers will be well-informed about the nutrition and health dimensions of food products. NLEA may have contributed to the unfolding process by providing a credible means of promoting the health and nutritional attributes of foods.

[17] FDA categorizes health- and nutrition-related claims into nutrient content claims, health claims, qualified health claims, and structure/function claims (FDA, 2009). Nutrient-content claims characterize the level of a nutrient found in a food, such as "low fat." Health claims characterize the presence or absence of a nutrient linked to a disease or condition. For example, a label intended to highlight a food's calcium content could say "Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis." FDA may allow such claims when there is a scientific consensus. Where there is not a consensus, FDA may allow a qualified health claim. For example, FDA may allow the following claim about the benefits of psyllium husk. "Psyllium husk may reduce the risk of type 2 diabetes, although the FDA has concluded that there is very little scientific evidence for this claim." Structure/function claims have historically appeared on food labels. The Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory requirements for using structure/function claims. Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones" (FDA, 2014a).

The number of new products carrying at least one health- and nutrition-related claim began climbing after 2001, and 43.1 percent carried such claims in 2010. The growth in claims reflects increases in claims related to calories, vitamins/minerals, whole grain, fiber, and sugar.

It is not surprising that health- and nutrition-related claims have become widely used by food manufacturers. Ippolito and Mathios (1990a) examined results of one food manufacturer's insistence on using a health claim despite FDA's proscription and found that numerous other firms followed. Teisl and Levy (1997) reported results of retail food demands shifting with the provision of shelf-label nutrition information.

Profit-maximizing food manufacturers would incur the costs of making health- and nutrition-related claims on their packages only if they believed that they were providing information consumers wanted and would favorably change their purchase patterns. The fact that so many products carried these claims suggests that consumers valued the information. Manufacturers wanted to experiment, offering new products and using new marketing methods.

Even so, some consumers' preferences must have gone unsatisfied. There are benefits to tightly controlling which claims food manufacturers may print on labels: When the science behind a claim is unambiguous, deliberately misleading claims can be all but eliminated. Label claims will be more truthful. Of course, this means that some claims that will eventually be proven true will not be allowed immediately; some consumers will not be able to benefit from those health claims. In effect, when regulators opt for label claims to be scientifically proven, product diversification is lower than it otherwise would be. Many products that would have been successfully marketed will not be marketed.

Consumer Confusion Persists Over Nutrient Content

Rahkovsky et al. (2013) pointed to survey data indicating that shoppers' use of the Nutrition Facts label is limited and that consumers struggle to understand it. The idea that a listing of nutrient quantities in a food might be too complex (credible and truthful, but not understandable) for many consumers to use led to the development of summary measures, and some pre-date NLEA. Sweden's Keyhole and Australia and New Zealand's Tick (check mark) were introduced in 1989. The American Heart Association developed its Heart Check label in 1995. These labels indicate healthier options within food groups with a front-of-package symbol or logo. Beginning in 2004, food manufacturers began developing labels that displayed nutritional information in a more simplified and prominent way than the Nutrition Facts label. For example, General Mills developed the "Goodness Corner" label, a system based on the FDA's regulations for nutrient content. Indirectly, they were recommending the labeled products as healthful for the consumer. However, they did not label all products—just those that met the designated criteria so consumers would have to infer a negative recommendation. PepsiCo developed "Smart Spot," a system indicating products containing targeted nutrients. Again, products were not labeled if they did not satisfy the criteria. Other notable examples of such summary measure labels include the Guiding Stars Program™, NuVal™, Traffic Light, and Facts Up Front (Institute of Medicine, 2010).

The Hannaford supermarket chain in 2006 initiated its Guiding Stars Program™. Foods were given one to three star ratings based on the nutritional value of the food, where three stars were the best. Hannaford convened a scientific advisory panel to create the ratings, which evaluated the nutrient content of foods using nutrition data displayed in the Nutrition Facts label. Shelf tabs identified

foods that were awarded stars. Foods at the low end of the ratings were not awarded a star, which consumers were left to infer indicated a low nutrition rating. Rahkovsky et al. (2013) studied effects on breakfast cereal demand and found that the stars shifted demand toward more nutritious cereals and away from less nutritious cereals.

The market's many alternative measures that are offered to help guide consumers' food choices suggest that the Nutrition Facts label is too complex for many consumers. However, while the summary measures solve the confusion problem posed by detailed lists of nutrients, they raise new issues. The food manufacturers' labels apply only to products they produce, and as such, confront consumers with a multitude of labels when shopping. And the manufacturers' labels have not all followed the same criteria. Because these labels focus on positive recommendations, manufacturers' less healthful products are unrated, leaving it to consumers to make the correct inference. Food retailers can use the same labeling system for all labeled products within their store, allowing consumers to compare between products. However, retailers also focus on providing positive information, leaving consumers to infer that labels that do not list positive qualities signify less healthful products. Many food manufacturers agreed to use the common Smart Choices "better for you" logo on their products to overcome the inconsistency problem. However, almost immediately after the logo's introduction in 2009, nutritionists, consumer groups, and the media criticized it, citing sugar-sweetened cereals as examples of foods receiving the label recommendation. The Smart Choices label ceased to operate later that year pending the outcome of an FDA investigation and regulation development.

Despite the effort involved in making more information available to consumers, small dietary changes (at most) are the only evidence of results. The *Dietary Guidelines for Americans* released in 1990 pointed to Americans' poor diet quality as the cause of many chronic diseases.

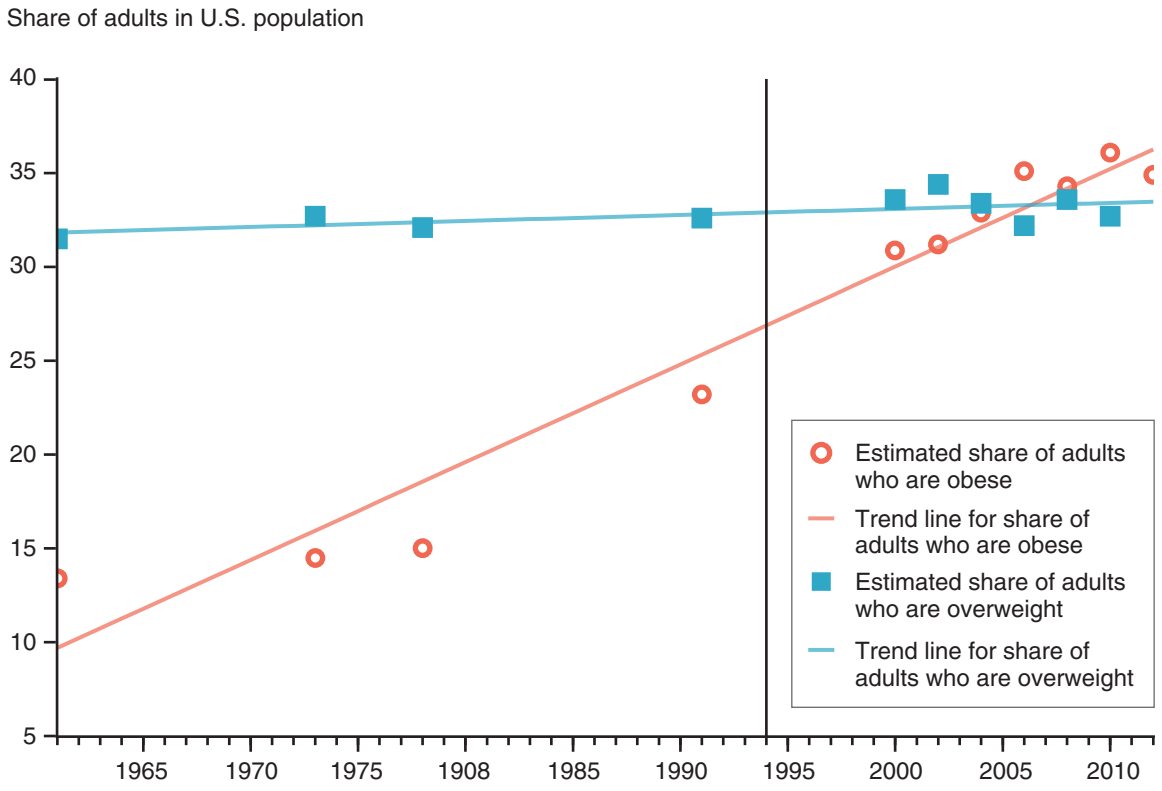
> Many American diets have too many calories and too much fat (especially saturated fat), cholesterol, and sodium. They also have too little complex carbohydrates and fiber. Such diets are one cause of American's high rates of obesity and of certain diseases—heart disease, high blood pressure, stroke, diabetes, and some forms of cancer.

The *Dietary Guidelines for Americans* released in 2015 made a similar statement.

> About half of all American adults—117 million individuals—have one or more preventable chronic diseases, many of which are related to poor quality eating patterns and physical inactivity. These include cardiovascular disease, high blood pressure, type 2 diabetes, some cancers, and poor bone health. More than two-thirds of adults and nearly one-third of children and youth are overweight or obese. These high rates of overweight and obesity and chronic disease have persisted for more than two decades and come not only with increased health risks, but also at high cost.

In historical context, it would have been remarkable if NLEA had made an obvious improvement in diet and health. The incidence of overweight and obesity was increasing long before Congress passed NLEA. NLEA began in the middle of the long-term trends toward higher overweight and obesity rates (fig. 2).

Figure 2.
Trend lines for obese and overweight U.S. adult population shares



Note: Overweight and obesity were estimated for identically defined, age-adjusted adult populations for all years. Vertical line at 1994 indicates initation of the Nutrition Labeling and Education Act of 1990
Source: Earliest results were drawn from the National Health Examination Survey (1960-62), and all succeeding rates were drawn from the National Health and Nutrition Examination Survey. See Fryar et al. (2012) and Ogden et al. (2014)

Many explanations for the rise in obesity have been offered. Cutler et al. (2003) argued that it was increased food access and lack of self-control—an increase in calorie intake. Posner and Philipson (2011) argued that it was the result of the technological change and a decrease in calorie expenditures—sedentary jobs that increasingly demand mental acuity rather than strong backs. Regardless of the explanation, Americans have been on a long-term trend toward overweight and obesity.

Overall, research on the relationship between food label use, particularly as implemented under NLEA, and dietary and health outcomes remains limited (Institute of Medicine, 2003; Pappalardo, 2001). Variyam (2008) described the empirical studies that found benefits associated with NLEA. These included findings that new labels helped consumers acquire, use, and comprehend more nutrition information; reduced the prevalence of potentially misleading claims; and enhanced unfolding (per the unfolding theory—see foonote 1). Several studies asked how labels influenced dietary intake. Among these, most relied on self-reported label use and did not account for self-selection bias. But few studies evaluated NLEA's effect on dietary intakes, and those that did mostly suffered from self-selection bias.

Variyam (2008) found that mandatory label information can be credited with increasing fiber and iron intake. These have public health significance because fiber is under-consumed by most adults,

and increased iron intake is especially beneficial for premenopausal women. Failing to account for self-selection generally leads to overestimating label effects on nutrient intake, as Variyam found no evidence that label use was associated with a reduction in fat, saturated fat, or cholesterol intake. These were important drivers of forecasted benefits.

Todd and Variyam (2008) examined consumers' use of nutrition labels before and after NLEA was implemented (1995/96 and 2005/06). They found that a majority of consumers used such information, but use had declined. The decline was especially large for adults younger than 30 years old.

Teisl et al. (2001) argued that we might judge mandatory labeling a success even without observing any improvements in consumers' health. Consumers might use the extra information provided by labels to choose more palatable diets that leave overall diet quality unchanged.

Despite the potential benefits, Moorman et al. (2012), in examining the nutritional quality of foods being offered, found some unintended consequences of NLEA. Nutrition improved for some foods: in new brands, brands in low-health categories, and brands in small-portion categories. In the existing, principal product lines, taste improved but nutrition declined. Apparently, for the largest shares of manufactured foods, Moorman et al. (2012) found consumers placed more importance on taste and price than on nutrition and believed that healthier foods were not tasty. Consumers might use mandatory information to avoid healthier foods.

Focusing on the relation between obesity and label use, Variyam and Cawley (2006) relied on label use questions on the National Health Interview Survey before and after NLEA to link label use to obesity. They found that the probability of obesity among non-Hispanic White females who were label users was significantly lower than it would have been in the absence of labels. The total monetary benefit of NLEA—due to lower mortality, reduced medical expenditures, declining absenteeism at work, and increased productivity—was estimated to be about $166 billion (1991 dollars). This exceeds FDA's estimate of NLEA benefits. However, Williams et al. (2016) argued that over time it has become clear that the relationships among labeling, behavior, and health are more complex than was previously assumed—it is still uncertain whether NLEA yielded positive net benefits.

Summary and Conclusions

NLEA addressed a complex problem—providing nutrition information about desired levels of macro- and micro-nutrients to a population with diverse needs and diverse food preferences—and sought to do so using a small amount of food package space. Deciding what belonged on the label demanded new research. Even with additional research, there was reason to think NLEA would have limited success in improving Americans' diets and health. Demographic changes brought changing information needs, and regulations are not flexible tools. NLEA was initiated and revised in a period in which consumers' diets were demonstrably poor and overweight and obesity were increasing, possibly from easier food access or increasingly sedentary work. Food was increasingly consumed away from home where there were no labels. In effect, NLEA faced strong forces that made it difficult to achieve improvements in diets and health.

One outcome of the digital revolution has been the advent of numerous new information platforms, offering details about the healthfulness of foods and diet advice. These compete with information on food packaging for consumers' attention. There are not many regulatory constraints on the content of the new information platforms. The outcome of this development has not yet been revealed, but it opens the possibility of mandatory labels losing the influence they have.

Organic Labeling Under the Organic Foods Production Act of 1990

The long history and comprehensive standards associated with the USDA Organic seal used on food packaging, along with its widespread use worldwide,[18] distinguishes organic labels from other, mostly single-attribute, process-based labels that have emerged in recent years. Organic agriculture developed early in the 20th century as an alternative to conventional production systems that depend on synthetic chemical inputs. Organic systems place more emphasis on soil quality, nutrient cycling, and plant health (Heckman, 2006). By the late 1960s, "a new generation of environmentally conscious consumers—Baby Boomers—were coming of age and demanding foods produced without chemicals" (Mergentime, 1994). Avoidance of the chemicals used in conventional production is still a major reason that consumers buy organic products (Hughner et al., 2007). For a summary of the demand for information, consumer confusion, and market failure leading to the national organic standard and the industry response since the standard was implemented, see box "Major Themes—USDA National Organic Regulations and Seal."

The practices used in organic production are associated with various environmental benefits, including reduced pesticide residues in food and water, reduced nutrient pollution, improved soil tilth and organic matter, lower energy use, carbon sequestration, and enhanced biodiversity (Reganold and Wachter, 2016). Many of these benefits were recognized in USDA's 1980 landmark study on organic farming systems (USDA, 1980).

The first Federal legislation on organic agriculture was introduced in 1972, and the Organic Foods Production Act of 1990 (OFPA) was passed nearly two decades later. OFPA directed USDA to set national standards for organic production and processing and create the National Organic Program (NOP) to provide regulatory oversight. The wide range of production and processing attributes covered under NOP standards encompass everything from agricultural soil health, farm-level biodiversity, and pasture for ruminants to prohibitions on the use of genetic engineering, antibiotics, hormones, and most synthetic pesticides, fertilizers, and food processing aids.

USDA's national organic standards required third-party certification to label products or practices as organic, strengthened enforcement activities to thwart consumer fraud, and improved producer access to domestic and international markets. The labeling standards have also facilitated development and implementation of USDA organic provisions and programs in risk management, conservation, research, and technical assistance.

Major Themes—USDA National Organic Regulations and Seal

Demand for label/information. Consumers' demand for organic comes both from concerns that chemical and other residues in conventionally produced foods will compromise their own health, as well as from more altruistic motivations that organic production will benefit environmental quality broadly.

—continued

[18] In 2014, data on organic acreage was available from 172 countries showing an estimated 108 million acres of land managed under organic production systems (Willer and Lernoud, 2016).

Major Themes—USDA National Organic Regulations and Seal—continued

Consumer confusion. The National Organic Standard, commonly known as the USDA organic regulations, covers a wide variety of environmental stewardship issues. Consumers are largely unaware of what organic covers and are unaware of what competing labels cover. While food labeled as organic must be certified as meeting the standard and suppliers face penalties for misleading consumers, food labeled as natural, for example, is not well defined or certified to a standard. Food labeled as local sometimes competes with organic because many consumers imagine local to be organic or because they want to support local farmers even if they are not organic. Single-attribute labels like non-GE compete even though organic prohibits GE ingredients. Price premiums for local, non-GE, and other single-attribute products are also typically less than those for organic products.

Market and Government failure. At retail, consumers cannot distinguish organic from conventionally produced food without labels identifying organic as such. Prior to implementation of USDA organic regulations, organic standards were developed by mostly by State governments and private-sector nonprofits. Varying standards became problematic for labeling multi-ingredient processed foods. Enforcement was negligible. Lack of a national standard was argued to impede international trade.

Industry response. Organic production has increased rapidly since the national standard was implemented, with industry analysts saying U.S. organic food sales grew over 15 percent annually during the 1990s and 2000s, prior to the downturn in the U.S. economy in 2008, and have generally exceeded 10 percent since. However, consumer confusion is creating conditions in which ill-defined labels and single-attribute labels can compete with the USDA Organic seal.

USDA Organic Regulations Built on Decades of State and Private Progress

Private organizations, mostly nonprofits, began developing certification standards in the early 1970s as a way to support organic farming and thwart organic fraud. One of the first organizations to offer third-party certification, California Certified Organic Farmers, formed in 1973 and is still the largest provider of certification services. Three States—Oregon, Massachusetts, and Maine—also passed legislation on organic agriculture in the 1970s. The Massachusetts organic labeling law defined organically grown food as "natural food which has not been subjected to pesticides or artificial fertilizers, hormones, or antibiotics" and established a State registration program (Anton, 1992). Maine's legislation established standards for foods labeled or advertised as organic, organically grown, and biologically grown.

By the time the U.S. Congress passed OFPA in 1990, over half the States had established legislation on organic labeling, and nearly half had set State standards. Most of these States made third-party certification voluntary, but required compliance with the production standards outlined in State law (Anton, 1992). Several dozen private, nonprofit groups were providing third-party certification services to well-defined standards by the early 1990s, and a dozen States administered their own organic certification programs.

These State and private initiatives resulted in a fairly robust system of certification with many areas of overlapping standards, particularly for crop production, but small differences caused disagreements among certifying agents over whose standards to apply to multi-ingredient organic processed products. Also, in the absence of a national standard, the high information and search costs for foreign buyers to determine the compatibility of standards may have discouraged purchases of U.S. organic products.

Although Congress passed both OFPA and the Nutrition Labeling and Education in 1990, numerous stakeholder groups played an active role in USDA's rule-making process, and finalizing organic regulations took three times longer than finalizing nutrition regulations. The first USDA proposed rule was published in 1997 and included the possibility of using GE and other materials and practices. These proposed materials and practices conflicted with OFPA requirements, as well as existing international organic standards, and were opposed by nearly all organic consumers, producers, and manufacturers (Hagedorn, 1998). The 1997 proposed rule garnered a record number of mostly negative responses, and USDA withdrew this proposal.

USDA published a second proposed rule in March 2000 to mostly positive response and published the final rule setting national organic standards and establishing NOP in 2000 (USDA, AMS, 2000). The standards cover every aspect of agricultural production and food processing and reflect many environmental and human health concerns. (See box "USDA's National Organic Program—Production and Processing Standards.") USDA's organic regulations are largely process based—focusing on the methods, practices, and substances that are used. The final rule did include one major product-based standard—a tolerance level for accidental pesticide residues, set at a maximum of 5 percent of the EPA tolerance level for conventional crops.

USDA's National Organic Program—Production and Processing Standards

Who sets the standard?

U.S. organic standards were set by law in 1990. In 2000, USDA published the final organic rule implementing the law. USDA organic regulations define organic production as the use of cultural, biological, and mechanical practices that support cycling of on-farm resources, promote ecological balance, and conserve biodiversity. Conventional producers must avoid using prohibited materials for a 3-year transition period prior to selling crops labeled as organic.

Who verifies the standard?

The law mandates that all but the smallest operations (earning $5,000 or less in annual organic sales) be certified by a USDA-accredited certifier in order to label or advertise their products—or their practices—as organic. Organic operations that qualify for this exemption are still required to meet all the other Federal organic standards under NOP.

Who enforces the standard?

USDA, AMS shares responsibility for enforcing the USDA Organic standard with the USDA-accredited private certifiers. The certifiers ensure that certified operations meet the standard and may take enforcement actions up to and including suspension or revocation of the operation's certification if they do not. AMS also fields complaints made directly to the agency by consumers or other firms. Organic operations that falsely sell or label a product as organic are subject to civil penalties of up to $11,000 per violation.

—continued

USDA's National Organic Program—Production and Processing Standards—continued

Major requirements of the U.S. organic standard include:

Organic Cropping Systems

Avoid synthetic pesticides and fertilizers—most synthetic chemicals are prohibited, and exceptions must be included on the NOP's National List of Allowed and Prohibited Substances.[19] Avoid genetic engineering (GE)—recombinant DNA and other GE technologies are prohibited.

Avoid ionizing radiation—which is prohibited.

Avoid sewage sludge—which may contain heavy metals and is prohibited.

Build soil quality—with practices such as adding animal or green manures and compost.

Conserve soil—with practices such as cover cropping, mulching, and conservation tillage.

Practice crop rotation—which is required to help manage pests and disease, build soil organic matter, prevent soil erosion, and increase farm biodiversity.

Organic Livestock Systems

Avoid antibiotics and growth hormones—which are prohibited.

Accommodate natural nutritional and behavioral requirements—including access to pasture for cattle, sheep, and other ruminants during the grazing season.

Provide organic feed—all feed, pasture, and forage (and plant-based bedding) must be organic.

Source livestock raised organically for the last third of gestation—birds for poultry and egg production must be raised organically beginning the second day of life.

Vaccinate livestock—and use other disease-preventive techniques.

Organic Processors and Handlers

Prevent mixing—of organic and conventional products.

Manage pests in facilities—with preventive techniques and approved substances, which may not come in contact with organic products.

Organic Labeling Requirements Cover Raw, Fresh, and Processed Products

Four categories—depend on organic content:

"100-percent organic" label—only organic ingredients, excluding water and salt.

"Organic" label—at least 95 percent organic ingredients.

"Made with organic ingredients" label—at least 70 percent organic ingredients.

Listing organic ingredients in ingredients panel only—if the product is composed of less than 70 percent organic ingredients.

The USDA Organic seal is approved for "100-percent organic" and "Organic."

[19] Criteria for evaluating substances in organic systems include: (1) potential for detrimental interactions with other materials used; (2) toxicity and persistence in the environment; (3) probability of environmental contamination during manufacture, use, or disposal; (4) effects on human health; (4) effects on the agroecosystem, soil organisms, crops, and livestock; (5) alternative practices and materials available; (6) compatibility with sustainable agriculture.

Although genetic engineering was prohibited[20] and GE avoidance practices were required, a GE tolerance level was not set. USDA did not believe there was sufficient consensus to establish a GE tolerance level when the rules were finalized in 2000. However, organic food manufacturers and retailers have sought additional assurance in recent years that organic foods do not contain GE material, and many have set tolerance levels. Most adhere to a 0.9-percent tolerance level used in the European Union and by the Non-GMO Project and other non-GE testing and verification programs that have emerged in the United States during the last decade (Greene et al., 2016). (See box, "USDA's National Organic Program—Production and Processing Standards.)

Mandatory Third-Party Certification for Use of Organic Label Claim

USDA's final organic rule requires all but the smallest operations (earning $5,000 or less in annual organic sales) to be certified by a USDA-accredited certifier in order to label or advertise their products—or their practices—as organic. Organic operations that qualify for this exemption are still required to meet all the other Federal organic standards under NOP. All certified organic crop and livestock producers and food processors and other handlers must submit an organic system plan to their certifier annually for review. This plan describes the practices that the operation will use to comply with the regulations, including pest and nutrient practices, use of approved substances used during the growing or handling process, recordkeeping systems, and barriers that prevent commingling with nonorganic products. Organic operations must also be inspected at least once a year to maintain certification. The USDA-accredited certifier is responsible for ensuring that the operation complies with all organic standards.

Certification Fees May Influence Organic Market Structure

Certification represents an additional, ongoing expense in certified organic farming systems and may be a hurdle for some farmers, particularly small-scale farmers. The Federal Government initiated a national program to subsidize the cost of organic certification as part of the 2008 Farm Act, and the 2014 Farm Act expanded 2014-18 funding for this program to $57.5 million, more than doubling funding levels under the 2008 Farm Act.

The recent increase in funding for the organic certification cost-share program may help attract small-scale producers in particular, since the cap is high enough to cover a majority of the certification fees for smaller operations. Organic producers and handlers are eligible to receive reimbursements for up to 75 percent of certification costs each year up to a maximum of $750 for each type of operation—crop, livestock, wild crop, and handling—that they have certified. According to data from a national USDA survey in 2008, U.S. farmers reported that the average cost of organic certification was $1,264 per farm (Greene, 2014). However, average organic certification costs increased to about $1,517 per farm in 2015, and more producers may now reach the reimbursable limit before 75 percent of their certification costs are covered. Also, fewer than half of the respondents to USDA's national organic producer survey in 2015 reported enrollment in the certification cost-share program, and USDA has expanded outreach about this program.

[20] Recombinant DNA and other GE processes that genetically modify organisms or influence their growth in ways that are not possible under natural conditions or processes are excluded. Organic farmers and handlers are completely prohibited from using products engineered by cell fusion, microencapsulation, macroencapsulation, and recombinant DNA technology, including gene deletion, gene doubling, introduction of a foreign gene, or changing the positions of genes.

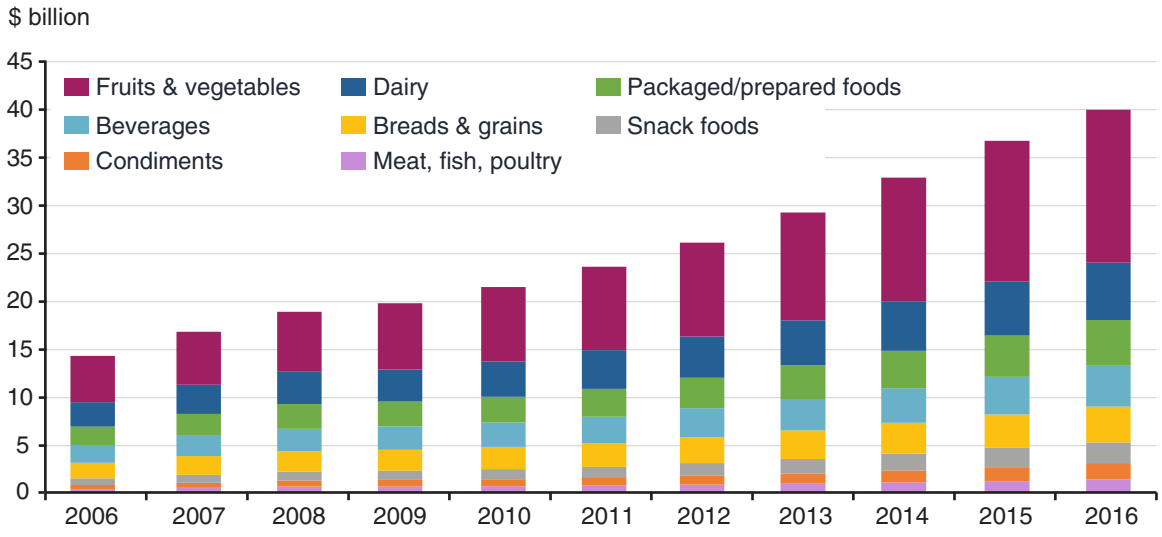
Many small-scale farmers were also concerned that publication of organic regulations would entice more large-scale farmers into the market, crowding out their market niche for organic products. Grow and Greene (2009) examined the certification patterns in the U.S. organic sector, and concluded that NOP had not substantially affected the proportion of small-scale farmers. Findings from USDA's more recent national organic producer surveys also show that the proportion of small-scale producers has remained stable.

Consumer Sales Expanded Rapidly With the "USDA Organic" Label

USDA expected that the rigorous organic regulations, mandatory certification, annual inspections, and strong measures to deter fraud would enhance consumer assurance and help expand the U.S. organic market. Producer access to domestic and international markets was also expected to improve by harmonizing the various State and private organic standards in the United States and by establishing organic equivalency agreements with other countries.

Consumer demand for organic food increased quickly during the period after national organic regulations were established, triggered in part by the development and success of USDA's organic regulatory program and label (Kiesel and Villas-Boas, 2007; Molyneaux, 2007; Batte et al., 2007). According to industry sources, U.S. organic food sales grew over 15 percent annually during the 1990s and 2000s, prior to the downturn in the U.S. economy in 2008, and has generally exceeded 10 percent since (fig. 3). U.S. organic food sales were estimated to have reached over $40 billion in 2016 (Nutrition Business Journal, 2017) and now account for over 5 percent of total at-home U.S. food sales. According to the Organic Trade Association, U.S. sales of organic personal care products, linens, and other nonfood products were an estimated $3.9 billion in 2016.

Figure 3
U.S. organic food retail sales, 2006-16—Fruits and vegetables are still top category



Source: USDA, Economic Research Service using data from Nutrition Business Journal, 2017.

Fruits and vegetables accounted for an estimated 40 percent of total U.S. organic retail food sales in 2016 and were still the top-selling organic category (Nutrition Business Journal, 2017). Organic dairy came in second, with about 15 percent of total U.S. organic sales, followed by prepared and

packaged foods (12 percent), beverages (11 percent), breads and grains (9 percent), snack foods (5 percent), condiments (4 percent), and meat, fish, and poultry (3 percent).

Domestic production has expanded, although not as much as consumer demand. Fruit and vegetable growers and producers in other high-value, market-driven crop sectors have adopted organic management systems much more widely than producers of other crops. Over 10 percent of U.S. vegetable acreage for carrots and lettuce and about 5 percent of fruit acreage was under organic management in 2011, compared with less than 0.3 percent of U.S. corn and soybeans. In the livestock sector, organic dairy cows accounted for nearly 3 percent of the total, compared with only 0.3 percent of the beef cows.

Prior to the USDA organic regulations, organic labeling for crops and meat was handled differently by different regulatory agencies. Food crops and nonmeat animal products (eggs and dairy products) were regulated by the FDA and were allowed to carry an organic label throughout the 1990s. In contrast, meat and poultry, which were (and still are) regulated by USDA, were not allowed to carry an organic label until the national standards were nearly completed in 2000 (Greene, 2001). Organic meat and poultry markets still lag those for crops and dairy partly because of the long delay in approving an organic label for those products. One reason is that consumer loyalty may have built around other beef labels that organic producers developed in the 1990s prior to the USDA Organic seal.

New Process-Based Labels Compete for Organic Consumers

This rapid growth highlights other challenges still to be overcome in the organic sector. As consumer demand for organic products has widened, organic retail sales have spread far beyond the natural food store niche in urban areas and college towns and into big-box stores across the country. While new producers have emerged to help meet demand, the supply of domestic organic feed grains appears to be price-inelastic, temporarily limiting growth in the overall organic production sector since the mid-2000s (Greene et al., 2009). Public and private initiatives have recently emerged to provide investment incentives, conversion assistance, and other mechanisms that encourage more domestic grain production.

The USDA Organic seal represents strict Federal regulatory standards for a large set of environmental attributes. Products that meet Federal standards offer a mix of attributes that is not well understood by many consumers. This confusion has been exploited in the market, with many products now labeled with one or more of the attributes of organic. For example, many single-attribute labels—declaring that pesticides, GE ingredients, antibiotics, or hormones were not used or that pasture and humane practices were used—advertise attributes that are included in the Federal organic standard. The incentive to offer such products is the possibility of collecting a price premium while avoiding the cost of meeting all the requirements of organic food.

Benefits derived from the organic seal may be attenuated from complementary labels, too, such as the "local" label. Even though the local label is not associated with any production or processing practices, it may be emerging as the most trusted label by consumers (Hartman Group, 2014). According to a recent ERS report, 7.8 percent of U.S. farms sold food through local food marketing channels in 2012, including direct-to-consumer marketing channels such as farmers markets and intermediated markets, such as restaurants and schools (Low et al., 2015). Although the local label denotes that the product was grown nearby, the allowed distance varies substantially depending

on the buyer and may be 400 miles or more. Even though consumers often think of direct market producers as organic producers, only about 10 percent are also organic. Recent ERS analysis of the production practices used by farmers that market directly to consumers and those that do not shows that their practices are similar (Low et al., 2015).

Another rapidly growing single-attribute label, Non-GMO Project Verified, verifies one of the attributes of the USDA Organic seal. The Non-GMO Project reported that products worth $19 billion in annual sales were verified under its protocol in 2016. All organic products must be produced without the use of GE, so having organic products labeled as Non-GMO Project Verified might be seen as redundant. Yet, over half of Non-GMO Project Verified products are already certified organic (see fig. 4). Many processors and retailers have required organic producers to obtain verification from the Non-GMO Project, partly because many consumers are unaware that organic certification already provides non-GE verification. Under the National Bioengineered Food Disclosure Standard that was signed into law on July 29, 2016, USDA was directed to deem organic certification sufficient to make a non-GE claim.

The "natural" label also competes with the USDA Organic seal, despite the ambiguity of this label claim for most food products. USDA defines natural meat products as minimally processed products that do not have added color or artificial ingredients (practices used during livestock production are not addressed), and FDA has not developed a definition of the term on other food products. According to industry sources, organic sales as a percentage of total organic and natural sales increased from 46 percent in 2002—the year that USDA implemented national standards and the USDA Organic seal—to 52 percent in 2007, but the organic share has remained relatively flat since then (Nutrition Business Journal, 2015).

Some consumers may be substituting purchases of the less expensive products with various single-attribute products because they care more about those single attributes than about the additional organic attributes, or because they may fail to differentiate between a single-attribute product and an organic product. Survey and experimental research suggests that many U.S. consumers do not understand the difference between organic and natural claims on food packaging (Gifford and Bernard, 2010; Onken et al., 2011; Butler and Vossler, 2017; McFadden and Huffman, 2017).

The Federal Government *directly* supports environmental stewardship on farms through a variety of initiatives, including programs that help producers adopt conservation practices. Further, farms receive *indirect* Government support in the form of programs to facilitate organic and other food labels. Although labels enable consumers who value lower pesticide residues on food, biodiversity, water quality, and other environmental services to pay for these services via organic purchases, environmental services are still public goods—a situation that gives some of those who value these services an opportunity to "free ride." That is, some who purchase only conventionally produced foods benefit by others' organic food purchases.

Federal Organic Program Closed Gaps in Regional Enforcement

Before the USDA National Organic Program was implemented, there were significant enforcement gaps of fraudulent organic claims at the State level. Under NOP, all farming and handling operations prepare an annual organic system plan showing how the operation will comply with the organic regulations and undergo an annual third-party inspection. Certifying agents review the organic system plans, conduct annual onsite inspections, and have the authority to conduct investi-

gations and initiate suspension or revocation actions, as well as to report violations of the standards to USDA. Certifying agents also conduct residue testing to determine if the preventive practices documented by farmers and handlers in their organic system plans are adequate to avoid contact with substances, such as prohibited pesticides, antibiotics, and GE ingredients.

Organic operations that falsely sell or label a product as organic are subject to civil penalties of up to $11,000 per violation, and USDA has taken disciplinary action against thousands of operations and levied millions of dollars in civil penalties. USDA's FY 2015 organic compliance and enforcement report shows 549 incoming complaints and 390 completed complaints, issuing cease and desist and other compliance orders (USDA, AMS, 2016e). USDA also levied nearly $1.9 million in civil penalties during FY 2015. USDA has used criminal prosecution in cases involving large-scale fraud (McEvoy, 2012).

The 2014 Farm Act included several new provisions to strengthen enforcement of organic regulations and also expanded authorized annual funding for NOP to $15 million, a substantial increase from previous funding levels. NOP was authorized at $5 million in the 2008 Farm Act, increasing to $11 million in 2012. In 2015, NOP launched an updated version of its database of organic farms, food manufacturers, and other organic operations. The new version, called the Organic Integrity Database, is updated routinely and provides a way for the organic industry and consumers to verify that products with the USDA Organic seal are certified organic. In addition to listing the operations that are currently certified organic, the database also lists operations that have surrendered their organic certification or have had their certification revoked or suspended.

Federal Organic Program Facilitated Organic Imports and Exports

USDA has streamlined trade in organic products with multiple foreign governments since 2002 to help open international markets. These trade partnerships—organic equivalency arrangements with Canada, the European Union (EU), and several other countries—allow U.S. organic products to be sold as organic in these countries without maintaining certification to multiple standards. The value of U.S. organic trade has generally been increasing since 2011 when the United States began tracking some of the organic products that are imported and exported. U.S. organic exports were over half a billion dollars in 2015.

U.S. organic imports must also meet USDA's regulatory standards for organic production and handling or meet an equivalent international standard. The most commonly used method for authorizing foreign organic products to be imported to the United States is to obtain organic certification from a USDA-accredited certifier. USDA has accredited certifying agents—mostly nonprofits and governmental groups (including U.S. based groups)—in over 150 countries worldwide. The other method is by obtaining certification to an equivalent international standard under an organic trade partnership with United States.

The value of tracked U.S. organic imports exceeded $1.6 billion in 2015. Top U.S. organic imports that are tracked include bananas, coffee, olive oil, and mangos, which the United States does not produce in large quantities, as well as wine and feed grains (Greene, 2014). Imported organic soybeans currently account for more of U.S. organic supplies than do domestically grown soybeans, and imports of other organic feed grains are rising rapidly (Greene et al., 2016). Consumer interest in organic agriculture has historically been associated with shortening food supply chains (Mergantime, 1994; Kuepper, 2010), and a number of firms are initiating efforts to build domestic supply of feed grains. Also, many of the environmental benefits associated with organic production accrue in the countries where they are produced, not where they are consumed.

Summary and Conclusions

The Organic Foods Production Act of 1990 established a National Organic Standards Board (NOSB) that represents producer, consumer, environmental, and other stakeholder groups appointed by USDA to offer advice on inputs and other aspects of organic agriculture. NOSB has also provided recommendations for USDA's organic rulemaking activities since 2000. For example, in June 2010, USDA published new rules that substantially tightened the pasture requirements for livestock. USDA is also in the late stages of rulemaking to tighten requirements on avian and mammalian living conditions, and to add requirements for several potential organic products—including honey and fish—that were not included in 2000.

Clearly, the organic industry has grown while using the label. Will such growth continue? Partly because of consumer confusion and the price premiums of organic products, single-attribute process-based labels have levered consumers away from the USDA Organic seal. In the 2002 Farm Act, Congress established the first USDA grant program to support research on organic production systems, which could help to lower organic production costs. Mandatory funding has been nearly trendless for a decade and was set at $20 million per year in the 2014 Farm Act.

Consumer education efforts on the meaning of the USDA Organic seal have already started expanding among industry groups, as well as inside USDA, where over 30,000 USDA employees, have taken USDA's "Organic Literacy" class in recent years. USDA has also widened the offerings of risk management, conservation, and other programs to improve their accessibility for organic producers. And in 2014, Congress authorized the potential for an organic research and promotion order, which if developed, could also play a role in consumer education. Internationally, the USDA Organic seal is also increasingly in competition with other sustainability labels, and the Research Institute of Organic Agriculture and the International Trade Centre have research underway to examine the performance of these other standards (Willer and Lernoud, 2015).

Private-Sector Labeling for Livestock and Poultry Raised Without Antibiotics

Antibiotics have historically been used in livestock production to prevent disease, treat and control disease, and promote growth. Antibiotics can be administered in ovo (in the egg, pre-hatch), via feed or water, or through injection, spray, or other forms of direct administration. These are clear benefits of antibiotic use in livestock and poultry production, but antibiotic use can also lead to resistance (Brown and Layton, 1996; McEwen and Fedorka-Cray, 2002; Marshall and Levy, 2011; The White House, 2015).[21] When bacteria become resistant to antibiotics, they can make human and animal infections more difficult and costly to treat (Prescott, 2000; Laxminarayan and Malani, 2007; Roberts et al., 2009; CDC, 2013; CDC, 2014).[22] Several different classes of antibiotics are used in livestock production, some of which are important to human medicine (e.g., aminoglycosides), and others that are not used in humans and have not been shown to contribute to resistance to antibiotics important to human medicine (e.g., ionophores) (National Research Council, 1999; McEwen and Fedorka-Cray, 2002; Jones and Ricke, 2003; Sneeringer et al., 2015).

In the early 2000s, the absence of Federal regulatory action spurred consumer advocacy and research groups, such as the Union of Concerned Scientists, the Pew Charitable Trusts, and Center for Science in the Public Interest, to publicize the risks of antibiotic use in animal agriculture and lobby for Federal policy change. Some media sources were running similar headlines (Lieberman and Wootan, 1998; Dobb, 2000; Mellon et al., 2001). As consumers became concerned about the issue in the mid-2000s, a market opportunity arose for firms attuned to the growing domestic demand for RWA meat and poultry products (Oberholtzer et al., 2006; Crandall et al., 2009; Consumer Reports, 2012; Peacock, 2013; Greene and Oberholtzer, 2007).[23] Although RWA pork and beef comprise a small portion of the market, chicken that is RWA was approximately 16 percent of the value of the market (less, by volume) in 2015 (approximately 3-percent organic chicken and 13-percent RWA) (Trotter, 2016; Wyatt and Ramsey, 2016). For information on the demand for RWA label information, consumer response, market/industry failure, and industry response, see box "Major Themes—'Raised Without Antibiotics' Labels."

Major Themes—"Raised Without Antibiotics" Labels

Demand for label/information. Consumer demand for meat and poultry products that are raised without antibiotics (RWA) is growing because of concerns about antibiotic residues in food and the contribution of antibiotic use in animals to the development of antibiotic resistance. Because onfarm antibiotic use is a process-based, credence attribute that is not observable when a consumer buys meat or poultry in the grocery store, a label is one way for a producer or company to communicate whether its product is RWA.

—continued

[21] Models of antibiotic effectiveness have treated it as a common property resource that is overexploited. Some model it as a renewable resource; others contend that it is exhaustible/nonrenewable due to the slow development of new antibiotics (Brown and Layton, 1996; Laxminarayan and Brown, 2001).

[22] For example, bacteria from poultry products have been linked to urinary tract infections, and antibiotic-resistant bacteria may make these more difficult to treat (Manges et al., 2007; George and Manges, 2010; Tavernise, 2013).

[23] Global demand for chicken that is RWA is also strong, especially in Europe where countries have restricted growth-promotion and disease-prevention uses of antibiotics in livestock (Johnson, 2011).

Major Themes—"Raised Without Antibiotics" Labels—continued

Consumer response. Consumers are largely unable to distinguish between different antibiotic use claims, and for the most part do not understand the complex relationship between antibiotic use, animal health, and antibiotic resistance.

Market and Government failure. When firms introduce voluntary label claims, an absence of standard setting or regulation about which claims can be used and what they mean may lead to diverse label claims with inconsistent meanings. Thus, in the face of diverse antibiotic-use claims (including the false and misleading claim discussed in the box, "Perdue and Tyson Label Their Chicken As Raised Without Antibiotics"), consumers are confused about what these claims mean, and the labels may not be credible or understandable to consumers.

Industry response. The presence of information asymmetries in the absence of verification may allow firms to charge a price premium without actually addressing the RWA "credence attribute," thereby undermining the truthfulness and credibility of a claim. Penalties for using misleading and/or false label claims may not dissuade firms from pursuing this path if the payoffs for introducing label claims are sufficiently high.

Standards, Definitions, and Requirements—"Raised Without Antibiotics" and Other Antibiotic-Use Claims

Several agencies within USDA, including FSIS and AMS, have developed definitions or requirements, in various forms, for what "raised without antibiotics" and variations on that claim mean. In addition, AMS' National Organic Program sets standards for antibiotic use in organic meat and poultry products.

FSIS Requirements for Antibiotic-Use Labeling

FSIS oversees the use of almost all labels for meat and poultry products including voluntary, process-based label claims, such as RWA claims. (See appendix—U.S. Food Safety and Labeling Programs.) For most animal-raising claims, FSIS does not establish standards or definitions. Instead, it allows firms to develop their own standards for label claims and submit them to FSIS for approval with supporting documentation. As a result, different antibiotics claims proliferated on meat and poultry products during the last 15 years.

FSIS was forced to clarify its definitions and requirements for RWA in 2008 and 2009 when two major poultry producers sought approval for their RWA claims. (See box "Perdue and Tyson Label Their Chicken As Raised Without Antibiotics.") The events of 2008 and 2009 prompted FSIS to clarify—for animal products bearing RWA label claims—that the animals must be raised without any antibiotics from birth to slaughter, including in broiler chicken eggs (USDA, FSIS, 2008; Vilsack, 2012).

These FSIS requirements hold for label claims that assert "raised without antibiotics," "no antibiotics added," or "no antibiotics ever." However, FSIS has also approved other antibiotics-related claims such as "responsible use of antibiotics," "no antibiotics used for growth promotion," and "antibiotics only used in the treatment or prevention of illness" when they are included as part of a firm's approved USDA Process Verified Program (PVP).

Perdue and Tyson Label Their Chicken as Raised Without Antibiotics

In the fall of 2007, Perdue filed a trademark registration for "Purely All-Natural Harvestland," indicating that it was preparing to market a new RWA brand of poultry and developed a voluntary RWA label claim that FSIS approved. Shortly after, Tyson asked FSIS to approve an RWA label claim for its chicken products. In the absence of standard criteria, Tyson defined RWA differently than Perdue did, to include the continued use in feed of ionophores (an animal-only class of antibiotics not shown to contribute to the development of resistance to antibiotics important for human medicine), and omitted the fact that the company injected eggs with an antibiotic that is important to human medicine. FSIS subsequently approved this application.

FSIS quickly required that Tyson remove the original claim and then approved a qualified label claim, "Raised without antibiotics that impact resistance in humans."

Competitors resorted to the courts to address their concerns, claiming a violation of the Lanham Act (see footnote 13), and the courts enjoined Tyson to stop all advertising with both label variations. FSIS followed by instructing Tyson to remove all RWA label claims. Even so, variants of Tyson's RWA label claims persisted for over a year, and court testimony suggests that the company was able to raise its prices while its competitors suffered financial harm. (See Bowman et al. (2016) for more details.)

AMS Definitions and Programs Related to Antibiotics

In 2009, AMS developed the "Never Ever 3" (NE3) Program for livestock producers:

> The NE3 program was developed in 2009 as a bundled marketing claim and associated verification program to address a market need for livestock whose products would qualify for marketing claims of: 1. No Antibiotics administered; 2. No Hormones administered; and 3. No Animal By-products fed at any point in the animal's life. (USDA, AMS, 2015b)

However, the NE3 program requirements stated that producers could use ionophores, an animal-only antibiotic class that does not contribute to resistance issues for human medicine, for specific purposes and still meet the NE3 standards. Thus, the NE3 definition for "no antibiotics administered" and the FSIS requirements for RWA or "no antibiotics administered" were different. In 2015 and 2016, AMS rescinded the NE3 program (as well as the "naturally raised" and "grass fed" marketing claim standards), stating that the development of these process-based animal-raising standards exceeded AMS's statutory authority to define and regulate marketing claims in commerce—such as those related to organic production, product origin, and method-of-production—for certain commodities sold at retailers, as defined. General marketing claims associated with products such as those from livestock are regulated by sister agencies within the Federal Government.

Currently, firms can make claims about antibiotic use (effectively define their own standards) and include them as part of their USDA Process Verified Program. These claims are then verified and audited by AMS (see Appendix box, "The USDA Agricultural Marketing Service's Process Verified Program"), but AMS does not create definitions or standards for these claims.

AMS National Organic Program Standards

The USDA National Organic Program has a clear standard for antibiotic use in organic livestock, which is certified and audited. For both organic beef and organic pork products, the organic standard requires no antibiotic use from birth to slaughter. The organic standard specifies that poultry can be certified organic if birds were raised organic from the second day of life (Fanatico, 2008; USDA, AMS, 2013b). The organic standard for poultry, then, differs slightly from FSIS requirements for RWA and other labels that imply no antibiotic use.

Inconsistencies on Antibiotic Use in Federal Requirements, Definitions, and Standards

FSIS currently requires that both RWA and "no antibiotics administered" mean that meat and poultry products must never have been administered any antibiotics (including ionophores) from birth to slaughter. However, FSIS also approves other antibiotics claims that are qualified or allow for some antibiotic use, especially if included as part of a firm's Process Verified Program. As mentioned previously, until 2015, the FSIS requirement for RWA and the AMS "Never Ever 3" standard were inconsistent. Currently, neither FSIS nor AMS has an official standard related to antibiotic use, though FSIS recently provided additional guidance on the types of information that should be submitted to support antibiotic use and other animal-raising claims (USDA, FSIS, 2016). The organic standard certifies that beef and pork producers use no antibiotics, but poultry producers are allowed to purchase day-old chicks from conventional hatcheries that may have administered antibiotics on the first day of life.

These differences in Federal requirements and standards with respect to antibiotic use, combined with an ability for producers to define their own standards, may have contributed to confusion in the food and agriculture industries about what the requirements were to put forward an RWA label claim. Or, alternately, the industries may have perceived that Federal regulators and policymakers disagreed about what RWA or other label claims meant, which may have led them to believe that misleading label claims might go unnoticed.

Would a preemptive Federal standard have reduced the incentives for introducing false or misleading labels? If FSIS had preemptively developed an RWA standard, this would have ensured that RWA claims meant the same thing for all firms and might have also reduced the degree of consumer confusion about antibiotics-related label claims as they proliferated in the marketplace. However, early standard setting can also be costly and inefficient. In order for FSIS to define a standard, it must undertake a lengthy process that includes public comment, input from stakeholders, and coordination with other Government agencies.[24] The industry wants to move fast when it perceives changing consumer demands, and consumers are often reluctant to wait for the Government to produce the products with attributes they demand.

Pros and Cons of Voluntary Labeling for RWA

If voluntary RWA claims were truthful, credible, and understandable, consumers could choose among conventional meat and poultry and RWA meat and poultry, with no information asymmetries. But, what we see in this case study is that voluntary label claims where firms define their own

[24] Based on interviews with FSIS.

standards do not always meet these standards. This reality calls into question under what circumstances process-based, voluntary label claims are able to improve market efficiency and resolve information asymmetries. Is mandatory labeling an improvement in this case? The United States has rarely implemented mandatory labels that do not directly relate to food safety or nutrition, with the exception of country-of-origin labeling for selected products, which was recently repealed for beef and pork. (See chapter "Country-of-Origin Labeling for Beef and Pork Under Title X of the Farm Security Act of 2002.") Mandatory labeling can have a welfare cost to both producers and consumers, especially relative to an alternative where voluntary label claims are truthful, credible, and understandable (Lusk and Marette, 2010; Lusk and Marette, 2012).

In addition to the information asymmetry inherent to RWA label claims, there is also a potential production externality: antibiotic use contributes to the development of antibiotic resistance. Thus, even in the case of functioning product labels, we cannot assume that consumer and producer choices and voluntary labeling will result in the socially optimal level of antibiotic use in livestock production, information asymmetries aside.

Consumers' Confusion About Antibiotic Use and Resistance

This case study suggests that at least some consumer confusion might result because food manufacturers' voluntary label claims are not credible and because the standards for RWA claims have historically contradicted one another. However, several other issues may be at play that undermine economic assumptions about consumer decisionmaking—primarily, the assumption that consumers have complete and well-defined preferences. What if, for example, consumers do not have well-defined preferences about antibiotic use on farms or do not understand the issue or information provided to them via a label claim? Would truthful and credible label claims be enough to ensure a functioning market for chicken that is RWA? If we examine the issue a bit more, we may find other reasons that consumers are confused.

Antibiotic Use and Resistance Are Complex Issues

Consumers may or may not understand how antibiotic use relates to the development of antibiotic resistance and how this use might affect human health. In fact, many consumers assume that the primary benefit of consuming RWA meat or poultry—rather than preventing antibiotic resistant bacteria—is avoiding consuming antibiotic residues (trace amounts of antibiotics) in their food (Caswell, 1998; McInturff et al., 2011):

> Most moms will assume they are eating the antibiotics in the food and that is the causal process. Some continue to believe this even after reviewing literature that explains the issue is really about transmission of resistant bacteria. (McInturff et al., 2011).

FDA establishes tolerances for antibiotic residues in meat and poultry products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b), and FSIS administers the U.S. National Residue Program under the Federal Meat Inspection Act (21 U.S.C. § 601) and the Poultry Products Inspection Act (21 U.S.C. § 453). This means that meat and poultry are regularly tested for residues, and meat and poultry products (RWA and non-RWA) are safe for human consumption. Still, research

suggests that consumers buy RWA products because they believe the products are healthier and safer for them to eat (despite inconclusive scientific evidence).[25]

Nonetheless, when consumers purchase RWA meat or poultry, they may contribute to a public benefit: reduced antibiotic use in livestock might decrease the magnitude of antibiotic resistance or stem its increase (McEwen and Fedorka-Cray, 2002; Marshall and Levy, 2011; The White House, 2015). Whether consumers' willingness to pay for RWA products arises from this public benefit depends on how much information they have and how altruistic they are (Lusk et al., 2006; Lusk, 2013).

In the cases of consumers who buy RWA products because they believe such products are safer or healthier (or are less likely to contain antibiotic residues), these consumers may experience a welfare loss by paying more than they need to for the desired characteristic (though they may unknowingly contribute to reducing the externality of antibiotic resistance, which can increase social welfare). In general, consumers can only make decisions based on their perception of quality (not actual quality), which results in a "cost of ignorance" when perceived quality and actual quality are not the same (Foster and Just, 1989).

Information Overload

Even if information about process-based characteristics on labels is truthful and credible, it can be too much information for consumers to process (Lohr, 1998; Lusk, 2013). Consumers might also perceive similar items or label claims as being equivalent. In 2012, the Consumers Union discovered 24 different antibiotics-related label claims on grocery store shelves, not all of which were approved by USDA, and several of which the Consumers Union deemed "confusing" (Consumers Union, 2012).[26]

Not only does this happen with RWA label claims, but also, consumers may be confused or ambivalent about what attributes are included as part of different labels (especially multi-attribute labels such as "natural" or "organic"). For example, organic chicken is RWA from the second day of life, but "natural" chicken is not necessarily RWA (Oberholtzer et al., 2006; Crandall et al., 2009; Harbaugh et al., 2011; McFadden, 2013; Consumer Reports, 2014).[27]

Consumers have a number of tools available for them to learn about the meaning of different antibiotics labels, as well as to associate particular antibiotic use practices with specific firms or product labels. Nonprofit advocacy groups—such as the Environmental Working Group, Consumers Union, and U.S. Public Interest Research Groups—compile resources to help consumers differentiate

[25] There is some research that compares prevalence of antibiotic-resistant bacteria on different types of meat and poultry products, and some papers suggest that animals raised without antibiotics and their meat (including organic meat and poultry) may harbor fewer antibiotic-resistant bacteria, though there may be a tradeoff with overall bacterial load (Cui et al., 2005; Price et al., 2005; Miranda et al., 2008; Sapkota et al., 2011; Kilonzo-Nthenge et al., 2015).

[26] Label claims not approved by USDA were "No antibiotic growth promotants," "Antibiotic free," and "No antibiotic residues," and label claims that confused consumers regarding antibiotic use were "Natural" and "No antibiotics* as verified by 120-day affidavit."

[27] Another complication—in theory and in practice—is that consumer preferences and willingness to pay for a particular attribute or a product in general can change depending on how many other product attributes are labeled, what combination of attributes are labeled on a product, and in response to the introduction of new product labels. This finding challenges the assumption that consumer demand for a product or labeled attribute is independent of the existence of other products or labels (Gao and Schroeder, 2009; Lusk, 2013).

between different antibiotic use labels. Some of these groups also produce apps for mobile phones to help consumers decode labels in the grocery store. One such example is Consumer Reports' Eco-Label app. However, these sources of information may not always be correct, consistent, or up to date with new labels or relevant Federal requirements. Consumers who are willing to put in additional time can get information about antibiotic use practices from individual companies' websites and from the USDA Process Verified Program (PVP) website (for firms that have a PVP). Although it is not always easy to tell what companies produced a product since meat and poultry products are often sold under store-branded product lines, consumers can also use the establishment number on packaged meat and poultry to trace their products back to the processing plant and supplier.

Verification for Antibiotics Label Claims

Many firms have chosen to seek third-party verification for their antibiotics label claims. Entities that verify and certify such claims include the USDA Process Verified Program (PVP), the Global Animal Partnership, and Certified Humane. (For more information on verification and enforcement, see box "Raised Without Antibiotics Label Claims: Standard Setting, Verification, and Enforcement.") For example, both Perdue and Tyson now employ third-party veriification through the USDA PVP to differentiate some product lines with respect to antibiotic use practices. Becoming certified organic also constitutes a third-party antibiotic use verification.

Raised Without Antibiotics Label Claims: Standard Setting, Verification, and Enforcement

Who sets the standard?

USDA, Food Safety and Inspection Service (FSIS) now has a more clearly defined requirement for handling raised-without-antibiotics (RWA) label claims. It requires that no antibiotics are used from birth to slaughter of an animal (including in broiler chicken eggs). But, in general (and for antibiotics claims other than RWA), firms are allowed to develop their own standards for antibiotic-use label claims as long as they provided documentation to FSIS to support their claim.

Who verifies the standard?

Firms provide supporting documentation to FSIS (as mentioned above), but in many cases, there is no additional verification that firms are abiding by the standard. Though some firms choose to have additional verification of their antibiotic-use claims, for example through the USDA, Agricultural Marketing Service's Process Verified Program, verification is not required.

Who enforces the standard?

If FSIS discovers that firms are being untruthful or misleading, it has the authority to rescind product labels. In addition, firms have taken the issue to court to determine whether false and misleading labeling and advertising adversely affected their businesses.

Source: Compiled by USDA, Economic Research Service.

Perhaps partly because of the confusion around requirements for antibiotics labeling, FSIS has even considered requiring third-party certification for animal-raising claims such as RWA. In October 2008, FSIS published a Federal Register Notice entitled "Product Labeling: Use of the Animal Raising Claims in the Labeling of Meat and Poultry Products" stating that the agency would hold

a public meeting and solicit public comments as it considered revising the procedure for approving labels with animal-raising claims (USDA, FSIS, 2008). At this public meeting, FSIS described the challenges of the label approval process, including information asymmetries between the producer and FSIS and ambiguously defined standards for animal-raising claims, which could result in similar label claims with different meanings (Poretta, 2008).[28] FSIS suggested that third-party certification could be one tool to verify animal-raising claims, but no official action toward FSIS's requiring third-party certification resulted from the public meetings or comment process.

Possibilities for Enforcement of RWA Label Claims

The primary role of FSIS (see appendix, "U.S. Food Safety and Labeling Programs") is to "protect consumers from misbranded and economically adulterated meat, poultry, and egg products which ensure that all labels are truthful and not misleading" (USDA, FSIS, 2015b). To ensure that RWA label claims are truthful and not misleading, FSIS has a prior label approval process in place through which the agency reviews a firm's documentation of its label claim before it can be used. However, the Tyson RWA case (see box "Perdue and Tyson Label Their Chicken as Raised Without Antibiotics" on page 39) is an example that shows that misleading claims can still occur.

When FSIS finds that a label is not truthful or may be misleading, the agency can rescind the label (see appendix table 1 "Major U.S. Regulatory Statutes and Food-Labeling Activities"). In the Tyson and Perdue example, FSIS rescinded Tyson's label claims and eventually requested that the company remove all claims, but the most direct costs to Tyson were legal costs and court fees associated with competitors' court cases and settlement costs in a related consumer case. FSIS did eventually require Tyson to remove its claims, but there is no evidence Tyson faced any additional penalties. Although FSIS can withhold inspection services and can require a company to correct or change labels on a misbranded product (and stop the product from leaving the plant if the company does not comply), FSIS does not issue financial penalties to companies for labeling violations. It is unclear how the costs to Tyson would have changed if FSIS had directly penalized Tyson, but the penalties for misleading consumers would need to be large relative to the potential gains, and swift and certain in order to have an effect.[29]

The Tyson and Perdue case suggests that *de facto* enforcement via the judicial system may play an important role in weeding out untruthful or misleading label claims—court cases filed by competitors and by consumers were essential to revealing the misleading label claim, forcing action on the part of FSIS, and leading to eventual financial repercussions for Tyson (through a consumer class action lawsuit).

[28] "Because FSIS does not regulate food animal production, the agency may not always have all the relevant information necessary to properly evaluate the animal-raising practices described in a producer's animal production protocol" (Poretta, 2008, p. 10).

"Animal producers and certifying entities may have different views on the specific animal-raising practices that qualify a product to bear a given animal-raising claim on its label. Thus, the same animal-raising claim may reflect different animal-raising practices, depending on how an animal producer or certifying entity defines the basis for the claim" (Poretta, 2008, p. 11).

[29] See Kirchhoff (2000) for a discussion of how "greenwash" can be an optimal strategy for a firm if there is a short-term profit, and the most likely future outcome is having to remove the claim and charge a lower price. (This changes if there is a probability of a fine or a penalty imposed by consumers, depending upon the magnitude of each.)

Possible Effects of Antibiotic Use on U.S. Trade

The RWA label claim has not presented any significant trade issues. However, the use of antibiotics in livestock in the United States and the regulation of such use in the United States and in other countries has been discussed as a trade issue. In particular, the United States has at least considered whether restrictions on antibiotic use—in countries such as New Zealand, the EU, or South Korea—could have implications for U.S. trade (Johnson, 2011). Sneeringer et al. (2015) summarize that restrictions on antibiotic use in the United States have the potential to increase prices of U.S. meat and poultry, thereby making products more expensive to export—but also have the potential to increase demand in countries where antibiotic use is a concern. Therefore, it is plausible that, in countries where there are more stringent restrictions on antibiotic use, there is increased demand for RWA products—or, that the increased cost of RWA products make them less cost competitive for export, depending on the market in question.

Summary and Conclusions

The RWA and other antibiotic label claims are voluntary, process-based claims that are often made about meat and poultry products. FSIS is responsible for making sure that the claims are truthful and not misleading, but the agency does not develop standards for, audit, verify, or certify animal-raising claims. Though there are some third parties that verify and certify the claims, the claims can be used without either verification, which affects their credibility. When use of the claim first proliferated, Government agencies, firms, and organizations had diverse requirements and definitions for what it meant to be "raised without antibiotics," which led to untruthful or misleading claims and a lack of understanding by consumers. Requirements and definitions have begun to converge on the meaning of RWA, but it is not clear whether this consensus has made the label claim more understandable to consumers, given that other (truthful) antibiotics claims that relate to antibiotic use are also allowed. Many firms now use third-party verification as a tool to make their antibiotics claims more credible. Despite these changes, there is still the potential that firms will introduce untruthful claims to the marketplace, since RWA and other antibiotic use claims can be voluntary and do not need to be certified or verified.

"Non-GMO Project Verified" and Other Voluntary Label Claims for Non-GE Products

Genetically engineered (GE) crops are widely used in the United States to produce animal feed and processed foods and food ingredients, such as breakfast cereals, snack foods, sugar, starch, and oils. Most U.S. corn, soybeans, and sugar beets are grown with herbicide-resistant GE seed varieties, and GE varieties of several fruits and vegetables, including apples and potatoes, have recently been commercialized. Consumer demand in the longstanding market for organically grown food (which excludes GE seed and material) continues to expand, and a market for conventionally grown foods produced without GE seeds has also developed. For information on the demand for GE label information, consumer response, market/industry failure, and industry response. (See box "Major Themes—Non-GE Labels.")

The most prevalent voluntary label that firms use to communicate that their products are non-GE is the "Non-GMO Project Verified" label. The Non-GMO Project, which was started by two cooperative grocery stores (one in the United States and one in Canada) in 2005, certifies as non-GE more than 39,000 products (about 3 percent of total products), worth over $19 billion annually. The Non-GMO Project (hereafter, NGP) sets standards for the use of its label, which reads "Non-GMO Project Verified," and bears the image of a butterfly (Non-GMO Project, 2016a). (See box "Non-GMO Project: Standards, Verification, and Enforcement.")

NGP Verified products must meet a threshold of no more than about 0.9 percent GE content, by weight, which is similar to the EU's threshold for mandatory labeling of processed foods made with GE ingredients.[30] According to Non-GMO Project Verified, to verify that non-GE ingredients are used, traceability and segregation of inputs are also required. Inputs and crops for which GE varieties are available—including alfalfa, canola, corn (except popcorn), cotton, papaya, soy, sugar beets, apples, potatoes, squash, animal-derived ingredients, and a host of production and processing inputs—are on NGP's "risk list." For products where at-risk ingredients make up at least 5 percent of the product's dry finished weight, NGP verification requires testing of either the ingredients or the finished product.[31]

[30] The details are more nuanced, as NGP standards vary slightly by product and ingredient, and typically rely on testing ingredients or feed grains for GE presence because it may be difficult to detect GE presence in finished products.

[31] "Minor" at-risk ingredients—those that make up 0.6 percent to 4.9 percent of the product's dry finished weight—are exempt from testing only if they are organic. In the Federal organic standard, USDA explicitly excluded the use of recombinant DNA and other processes that genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes (USDA, AMS, 2000). Although USDA did not set a tolerance level for the unintended presence of GE material in organic food, most retailers adhere to the 0.9-percent tolerance level. Further, any detection of GE material in organic food could trigger an investigation by the certifying agent to determine if a violation has occurred.

All ingredients present at less than 0.5 percent are exempt from testing, except for several types of processing inputs, including products of synthetic biology, viable microbes, functional enzymes, and ingredients that are direct products of GE microorganisms and are not in purified form. If any of these latter ingredients are used, the product cannot qualify for the NGP Verified label. If testing these minor organic and major ingredients reveals that more than 0.9 percent of the product is formulated from GE ingredients, it cannot be certified by the NGP technical administrators and will not be eligible for the NGP Verified label.

Major Themes—Non-GE Labels

Demand for label/information. Some consumers want to avoid consuming food made with GE ingredients. Some food manufacturers and marketers have voluntarily labeled their products as non-GE as a way to differentiate their products.

Consumer response. With the proliferation of Non-GMO Project Verified labels, consumers who want to avoid buying products with GE ingredients have much better access to alternative products. However, lack of consumer understanding about GE and about labels presents economic issues—for example, consumers may believe that products labeled as non-GE are inherently safer; they may not understand that some products are labeled as non-GE even though there is no GE crop variety available; and they may not understand that all certified organic products are non-GE.[32]

Market and Government failure. Unless a mandatory label for food made with GE ingredients is in place, or unless food products are labeled non-GE, non-GMO, or with similar claims, consumers cannot be sure whether food products are made with GE ingredients.

Industry response. More than 39,000 products now bear the Non-GMO Project Verified label, up from around 2,000 at the beginning of 2012. Many verified products are made from crops that do not have GE varieties available for commercial use, indicating that some producers have found the label profitable where the information is true but could not be otherwise. AMS also certifies companies' non-GE claims through its Process Verified Program. To date, AMS has verified five different companies' non-GE claims. (See appendix box, "The USDA Agricultural Marketing Service's Process Verified Program.")

Non-GMO Project: Standards, Verification, and Enforcement

Who sets the standard?
The Non-GMO Project (NGP), a nonprofit organization, sets a voluntary standard for GE content in fruits and vegetables, processed food ingredients, and animal feeds that have GE varieties.

Who verifies the standard?
International Organization for Standardization (ISO) 17025-accredited laboratories that apply to NGP may be approved by NGP to test ingredients and foods for compliance with the NGP's standards. As of May 24, 2016, nine U.S. laboratories, six in Germany, and one each in Australia, Brazil, Bulgaria, India, and Sweden were approved by NGP.

Who enforces the standard?
If testing reveals that products verified under the program are not in conformance with NGP's standards, producers are given a certain timeframe within which to correct the problem. Annual reverification is required.

[32] In this report, the term "non-GE" does not refer to a total absence of GE material in a product, but instead to products that may contain a small amount of GE material, with tolerances often set at 0.9 percent and sometimes as high as 5 percent for the unintended presence of GE traits (Organic Trade Association, no date).

In addition to NGP, foods and food products that are certified as organic by USDA's National Organic Program meet a set of standards that prohibits all use of GE technology in organic food production and processing. Producers must also maintain a buffer zone around fields where organic crops are grown and document all actions taken to prevent GE contamination in their Organic System Plan (OSP). While the USDA Organic seal does not include language regarding the specific attributes represented by the seal, well-informed consumers may realize that all organic products are non-GE.

In 2015, AMS began verifying products as non-GE through its USDA Process Verified Program (PVP). (See appendix, "U.S. Food Safety and Labeling Programs.") Because the PVP allows firms to develop their own standards, individual firms' standards with respect to their non-GE label claims can vary. Several companies—including a vegetable processor, a grain handler, and a poultry producer—have begun using the USDA PVP to verify use of non-GE ingredients (USDA, AMS, 2016a). In addition to the USDA PVP, a few other private organizations have announced third-party standards for certifying products as non-GE, including NSF International's Non-GMO True North verification program.

What Do Consumers Understand About Non-GE Labels?

The NGP standards and verification program makes information more available to consumers about non-GE food products, but the label still does not resolve all issues of consumer confusion. For example, the NGP Verified label is on some products listing only ingredients for which no GE versions yet exist, such as peanut butter made from 100-percent peanuts and juice made from 100-percent grapes. NGP Verified labels on such products may lead consumers to conclude, incorrectly, that competitors' products not bearing NGP Verified labels are GE. On the other hand, many consumers do not keep track of the specific commodities that are produced with genetic engineering, and this segment of consumers may want broader labeling of GE products.

Some products bear non-GE label claims that are not verified by any third-party organization. Interestingly, some non-GE labels without third-party verification provide more information than the NGP Verified label, such as footnotes indicating "not a product of genetic engineering" and "like all types of these ingredients, not genetically engineered." In addition, some companies provide information to supplement the NGP label. For example, Whole Foods Market's 365 Everyday Value® Organic brand contains the following statement on some products: "365 Everyday Value® products are formulated to avoid genetically engineered ingredients. U.S. law does not allow the use of genetically engineered ingredients or seed in products labeled as organic." Statements like these provide consumers with more context about what the non-GE label claims signify, but may also lead to information overload.

Besides being confused about the details of the NGP standards and about differences between the NGP's non-GE standard and USDA's comprehensive multi-attribute organic standards, consumers may also not understand basic concepts about the methods used to genetically engineer food. By labeling foods as non-GE (whether NGP Verified or not), food manufacturers and marketers hope to capture a larger share of the market with an implicit claim that GE content is an attribute to be avoided.

Under the current system of voluntary labels, consumers have difficulty understanding the difference between the various claims. Although FDA and USDA are not responsible for making sure

consumers understand voluntary labels, they do have a legal mandate to ensure that voluntary product label claims are truthful and not misleading. Given that some products bear NGP Verified and other non-GE label claims even when GE versions of the crops do not exist, these labels may be misleading for some consumers, but still welcomed by others who do not know which crops have GE versions but only care that a product is non-GE.

In addition to buying products with the NGP logo, USDA Organic seal, and other non-GE label claims, consumers have another option to ensure that their food is non-GE. Consumers may buy fresh and unprocessed commodities for which GE varieties do not exist and processed foods that do not contain ingredients that have GE versions. However, this option requires substantial effort on the consumer's part to learn about GE food varieties, so third-party verified non-GE claims improve consumer access to information about non-GE foods.

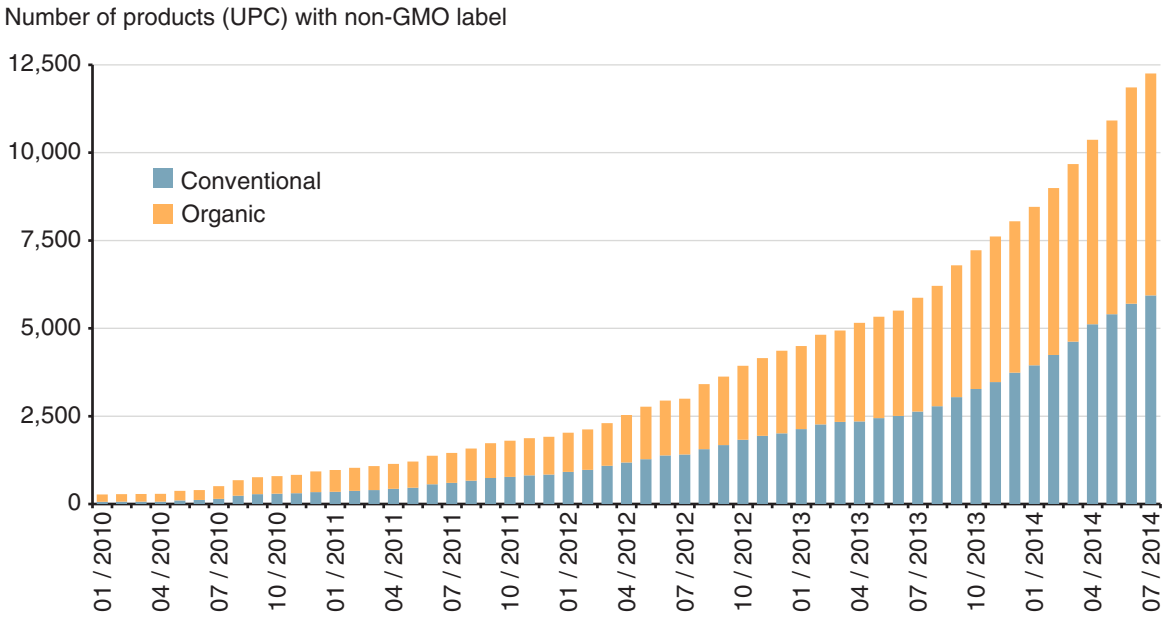
Voluntary Non-GE Labels, Marketing, and Provision of Information

Consumers who desire to avoid consuming GE foods can rely on the USDA Organic seal and other voluntary labels indicating the absence of GE ingredients. Marketers may be able to increase demand by actively marketing their products as non-GE, if those claims are accurate and credible.

Certain retailers and restaurants have also pledged to avoid using GE inputs, although such claims may not be as forceful without third-party certification to the USDA Organic standards or verification to NGP requirements. Many food retailers are seeking NGP verification and the NGP Verified butterfly seal for both organic and conventionally grown products, even though informed consumers understand that USDA Organic certification standards already include a complete prohibition on the use of genetic engineering. Organic producers seeking NGP verification may be doing so to cater to uninformed consumers who do not understand the USDA Organic requirements and want to avoid GE foods. Or, these producers may be seeking NGP verification in an effort to maintain competitiveness with rivals. Approximately half of the products bearing the NGP label are organic (fig. 4).

NGP has improved the quality of information available to consumers concerned about the GE content of their food. Under the unfolding theory (see footnote 1), consumers may make the inference that all food without the NGP Verified label is GE or contains GE ingredients; they can make inferences about labeled and unlabeled foods. However, the voluntary verification program does not completely solve the asymmetric and imperfect information problem, because some producers and marketers will not find it profitable to pursue the NGP Verified label, even if their products meet the requirements.

Figure 4
The number of products bearing Non-GMO Project labels increased rapidly, 2010-14



Note: UPC = universal product code. Data exclude brands owned by Whole Foods Market (365, Whole Foods Market, and Whole Pantry), which accounted for 608 Non-GMO Project verified products as of July 2014. As of August 2016, the Non-GMO Project label was on over 39,000 products (Non-GMO Project, 2016b).

Source: USDA, Economic Research Service analysis based on data from Non-GMO Project Verified.

Verification of Voluntary Non-GE Label Claims

The NGP has authorized four technical administrators (TAs) to determine if products comply with the NGP standards. Companies seeking the NGP Verified label for one of their products first select and hire a TA for verification and have ingredients or final products tested by one of 20 NGP-approved laboratories around the world. To meet conditions for NGP approval, labs must be accredited by ISO 17025, a general set of standards for testing and calibration labs issued by the International Organization for Standardization. In addition to fees paid to the laboratory and the TA, companies must pay an administrative fee of $50 per product to NGP. Upon completion of the NGP licensing agreement, manufacturers undertake testing with the TA. The product verification license must be renewed annually, and companies must pay the associated fees to the laboratory and the TA (Non-GMO Project, 2016c).

The third parties responsible for verifying compliance with the NGP standard—the TAs and the laboratories—provide assurance that the standards are being evaluated in an objective way. In contrast, if NGP, the standard setter, also evaluated compliance with the standard, a conflict of interest would appear to exist.

In contrast to NGP, which verifies products according to a uniform standard, USDA's Process Verified Program verifies companies' marketing claims via a scheduled auditing of their supply chains and manufacturing processes. Companies that go through the PVP can add a label to their packages consisting of an image of a shield and reading "USDA Process Verified." See appendix,

"U.S. Food Safety and Labeling Programs," for additional information on USDA's Process Verified Program.

Costs to Producers of Non-GE Verification

To obtain NGP verification, producers must incur several types of costs. The four TAs each have their own schedule of fees, which depends on number of products (i.e., a volume discount), onsite facility inspection requirements, and whether ingredients on the risk list are used.[33] If the current formulation of products is such that the final product contains more than 0.9 percent GE content by weight, producers that hope to obtain NGP verification must incur costs to change their inputs, their suppliers, or practice better segregation techniques.

For verification of non-GE claims under USDA's Process Verified Program, AMS charges user fees according to a schedule established in 7 CFR Part 62 and AMS's annual notice of fees (USDA, AMS, 2016c). Nonconformances may trigger additional audits of corrective actions taken and associated additional fees.

Costs to Producers and Manufacturers of Voluntary Versus Mandatory Labeling

An alternative to voluntary labeling of non-GE foods is mandatory labeling of foods that do contain GE ingredients, and a form of GE labeling will soon be mandatory under Federal law. (See box, "Recent Developments in State and Federal Labeling Policy for GE Products.") Existing mandatory GE labeling policies, such as those in Europe, Australia, Brazil, Russia, and China, are intended to address the same asymmetric information problem as voluntary non-GE labels. However, the two types of labeling/disclosure have different economic implications because mandatory disclosure of GE content imposes costs on different firms and informs consumers about the (potential) *presence* of GE ingredients or products, instead of their *absence.* In addition, the burden of proof in terms of testing and verification is different for GE labels than for non-GE labels: in essence, under mandatory GE labeling, food products are assumed to be GE unless proven otherwise, as they are required to carry labels disclosing the possibility that they may contain GE material. On the other hand, under a system of voluntary non-GE labels, no food manufacturers are required to use labels, whether they produce food with or without GE material.

Evidence from an economic experiment demonstrates that labels can induce consumers to change their preferences for non-GE and GE food (Liaukonyte et al., 2013). Consumers presented with labels reading "contains X" (where X is one of several ingredients and processes including genetically modified ingredients) were willing to pay a premium for a similar product without that label. The effect was mitigated if additional information about the benefits of the ingredient or process was presented. The study also found an asymmetric effect, in that consumers were willing to pay a premium for food with labels indicating "free of X" only if presented with negative information on that ingredient or process.

[33] The schedules of fees are available at NGP's website. As of November 14, 2016, the standard fees paid to a TA to verify a single high-risk product ranged from $650 to $3,490. To verify 10 high-risk products and ingredients, the standard fees ranged from $2,000 to $3,490. The TAs offer bulk and other discounts, and most charge different rates for non-high-risk products.

Recent Developments in State and Federal Labeling Policy for GE Products

By 2016, over 30 States had proposed legislation that would require mandatory labeling of products containing GE ingredients for certain product categories. Four States passed such laws, and on July 1, 2016, the first State-level mandatory GE labeling law went into effect in Vermont.

In response to this trend toward State-level mandatory GE labeling policies and the potential economic implications of having a patchwork of varying policies, on July 29, 2016, President Barack Obama signed a bill, the National Bioengineered Food Disclosure Standard (NBFDS), which requires the U.S. Secretary of Agriculture to establish a Federal mandatory disclosure standard for GE foods within 2 years. The NBFDS preempts States from establishing their own mandatory GE labeling laws and requires that USDA establish a threshold for how much GE material can be in a food product in order for it to be considered GE. It establishes a "disclosure" as a text label, symbol, or electronic or digital link (for example, a quick response (QR) code) that would take the consumer to the required information, though it also mandates more research on whether these disclosures provide consumers with enough information. Animal products and products containing animal products as the predominant ingredients are exempted from the NBFDS, as are small food manufacturers.

Some firms, such as Campbell and General Mills, had already made commitments to add GE disclosure statements to their product labels—for distribution nationally—in response to the Vermont law, while others took a wait-and-see approach (Gasparro and Bunge, 2016). A few companies, including Vermont Fresh Pasta and Freedom Foods LLC, reformulated their products to remove GE ingredients and avoid the label requirement. After the Federal law was passed, Campbell reconfirmed its commitment to a disclosure statement on the food label, while General Mills has reconsidered the use of an on-package disclosure statement.

USDA is required to enforce the law; the penalties, however, will not include fines or recalls. The States cannot establish their own unique requirements related to labeling of GE food. States may choose to adopt the language of the Federal law into their State laws and determine different enforcement strategies based solely on the Federal statute. However, any State-level requirements for disclosure will mirror identically the Federal disclosure requirement.

Proponents of mandatory GE labeling typically claim that (1) consumers have a right to know whether the foods they purchase were produced using genetic engineering and (2) mandated labels would enhance the range of choices available to consumers. These arguments are only relevant, however, if labels are effective: if they provide information that is credible, truthful, and understandable to their users. Because the information conveyed via QR codes requires the use of smartphone applications and broadband Internet access, QR codes might not provide ready access to understandable information about the GE content of food. A recent AMS study (USDA, AMS, 2017) found that over three-quarters of all Americans own a smartphone, and most live in areas with sufficient broadband access to scan a digital link, but many consumers experience technical challenges using specific software applications for scanning digital links.

It remains to be seen how the new law will be implemented and how it will affect business and consumer behavior. However, because the new GE disclosure standard will likely provide different information from voluntary labeling of non-GE foods, the demand for the voluntary non-GE label will likely persist in order for consumers to be able to identify and purchase foods that are verified not to contain GE ingredients.

The new Federal law does not define non-GE and similar claims. However, FDA issued a nonbinding guidance document several years ago that advises manufacturers on how to develop non-GE label claims (FDA, 2015).

What Possibilities for Enforcement Are Available for Voluntary Non-GE Labels?

If nonconformities are detected during the NGP Verified program application or renewal process, they must be corrected in order to achieve or maintain compliance with the NGP Standard (Non-GMO Project, 2016d). The NGP Standard also describes the necessary timing of corrective action if major nonconformities are discovered between annual review cycles. Minor nonconformities must be corrected before the next annual renewal. It appears that products are rarely removed from the NGP Verified product list, which may be because manufacturers with detected nonconformities can easily change the sourcing of their ingredients to achieve compliance.

Under the PVP, AMS must conduct a second "surveillance" audit within 6 months of the original onsite audit to ensure that practices are implemented and records maintained in accordance with the claims made on the label. Approved programs must be audited annually, and in addition, AMS may conduct more frequent audits when numerous minor nonconformances or a major nonconformance are identified during an audit. Companies must undertake corrective action when nonconformances occur; nonconforming inputs must be excluded from use in manufacturing PVP products, and nonconforming final products may not be marketed with the PVP label. If a company has nonconformances that affect the integrity of the program or the products cannot be corrected, then the company will be withdrawn from the PVP, which disallows the continued use of the PVP shield, and removed from the Official Listing of Approved USDA Process Verified Programs.

NGP-Verified Label Has Minimal Effect on Exports

The NGP-verified label is a registered trademark in the United States and Canada and cannot be used in other countries. Dozens of countries around the world require mandatory labels for many foods containing GE ingredients. The tolerances for these labels are usually 0.9 percent of the product, by weight, which is similar but not identical to the NGP standard. Thus, going through the NGP verification process is not likely to present any advantage for manufacturers, in terms of the export market (outside the United States and Canada).

Summary and Conclusions

Some consumers seek information about whether food contains ingredients made using genetic engineering. In the absence of mandatory GE labels, voluntary labels claiming that foods are non-GE have emerged as a market solution over the last decade. According to Non-GMO Project Verified, by August 2016, manufacturers of some 39,000 products had undergone third-party verification of conformance with this standard. Other manufacturers have used USDA's Project Verified Program to substantiate claims. These third-party verified, voluntary claims represent an improvement in terms of information provided—although the compact labels conceal the complexity of the standard they represent, and survey evidence indicates that consumers are poorly informed about GE. Use of these voluntary non-GE labels is likely to continue increasing in response to consumer demand and because producers see that label claim as adding value to their products.

Country-of-Origin Labeling for Beef and Pork Under Title X of the Farm Security Act of 2002

Country of Origin Labeling (COOL) is a labeling law that was originally mandated by Congress in the 2002 and 2008 Farm Bills. It amended[34] the Agricultural Marketing Act of 1946[35] to require retailers (primarily grocery stores and supermarkets) to notify their customers about the country of origin of certain foods, including muscle cut and ground meats (beef, veal, pork, lamb, goat, and chicken); wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng. Previously, the Tariff Act of 1930[36] required country-of-origin labels, but exempted products that would be "economically prohibitive" to label. For example, before 2002, individual apples did not need to be labeled with country of origin, but a carton of apples coming from a foreign country required a country-of-origin label on the carton. For more information on demand for label/information, consumer response, market/Government failure, and industry response regarding COOL, see box "Major Themes—Country of Origin Labeling."

Major Themes—Country of Origin Labeling (COOL)

Demand for label/information on beef and pork products. The demand for the label was primarily from farmers and ranchers hoping to increase demand for domestic products. Some proponents also argued that consumers had a right to know about the geographic origin of their purchases, decreasing information asymmetry.

Consumer response. COOL was supposed to be used by consumers as a source of information—a food-labeling program that would only allow identification of a product's country of origin by stage of production. However, many consumers used COOL as an indication of quality or food safety. Because they expected COOL to cover these latter attributes, which it did not, they misunderstood the label and paid for an attribute that they were not receiving.

Market and Government failure. The purpose behind COOL was to address asymmetric information for consumers, related to where their food was sourced and processed.

Industry response. A major cattle-raising organization supported COOL. However, other parts of the pork and beef supply chain were unsupportive of COOL because of the additional costs imposed on producers and suppliers, across borders, and in various stages of production. Other industries, namely poultry producers, have enjoyed the benefits of COOL because their production line is vertically integrated, with very little movement of the product in different stages of production.

COOL was rolled out over a period of time, with mandatory COOL going into effect for all covered commodities on March 16, 2009. After international legal challenges to the rule, the COOL regulations were amended effective May 23, 2013, to require muscle cuts of meat derived from animals slaughtered in the United States to list the country in which production steps (born, raised, and

[34] 7 U.S.C. §§ 1638-1638d.

[35] 7 U.S.C. §§ 1621-1638d.

[36] 19 U.S.C. §§ 1301-1683g.

slaughtered) occurred. For example, the updated label might read, "Born in Country X, Raised in Country Y, Slaughtered in Country Z." On December 18, 2015, an omnibus spending bill repealed the mandatory COOL requirements for muscle cuts of beef and pork and for ground beef and pork. Canada and Mexico had challenged COOL using the WTO's dispute settlement process, and WTO ruled that COOL practice, particularly for muscle cut meats (beef and pork), discriminated against imported livestock. Canada and Mexico appeared to be ready to retaliate, raising tariffs on goods imported from the United States into Canada and Mexico. (For details of the trade dispute, see Greene (2015).)

Here, our focus is largely on beef and pork, even though COOL covers many other commodities. Examining effects of labels on beef and pork is an appropriate focus of attention here; the aim is to learn from history, and the history of COOL for beef and pork now appears to be complete given that USDA ended its enforcement of COOL for these commodities in 2015. Of course, historical effects of labels on beef and pork cannot be considered to indicate current effects on all other commodities. For producers who sourced internationally, the costs of COOL for beef and pork required segregating animals and meat products, recordkeeping throughout animals' lives, and marketing meat products. In contrast, for vegetables, simply packing them in shipping containers bearing origin information was usually sufficient to satisfy COOL requirements.[37] Recognizing these differences among covered commodities, we focus attention on beef and pork because the higher costs revealed the factors that influenced the level and distribution of producer and consumer benefits derived from COOL.

This case study provides background on standards and enforcement for mandatory COOL, arguments for and against COOL, and information regarding the costs and benefits to producers and consumers since COOL took effect, with a focus on (now-repealed) COOL for beef and pork.

COOL Standards Set by Farm Bills

Prior to COOL, country-of-origin labels appeared voluntarily on some food and agricultural products. Champagne from France and Parmigiano-Reggiano and Prosciutto de Parma from Italy are products associated not just with particular countries, but also with specific regions and prescribed production processes. When producers voluntarily label products with the country of origin, they may do so because they anticipate consumers will pay a premium for these products—e.g., coffee grown in Kenya. Consumers may treat identity preservation as a sign of quality (Lusk et al., 2006).

In contrast, the mandatory COOL is not designed to signal quality per se (USDA, AMS, 2013a). More precisely, "while some U.S. producers may hope to receive benefits from the COOL program for products of U.S. origin, the purpose of the COOL program is to provide consumers with origin information" (USDA, AMS, 2009). In 2003, a representative of the American Farm Bureau Federation testified before Congress in support of mandatory COOL, promoting COOL as a program that would allow consumers to choose between foreign and U.S. products and give U.S. producers the opportunity "to promote the excellent products they take great pride in producing" (Farm Bureau, 2003). In this case, COOL was not designed to promote quality, but only to distinguish where the product was produced.

[37] The Tariff Act of 1930 required containers of fruits and vegetables (rather than single items) to be labeled with country of origin. In its initial stages, mandatory COOL would have imposed additional costs in these industries. The final rule for COOL made recordkeeping in these industries less of a burden, lowering the anticipated costs associated with mandatory COOL (VanSickle, 2008).

COOL is similar to the USDA Organic label standards (set in the 1990 Farm Act) in that the original "standards" were set by Farm Acts (2002 and 2008), rather than wholly by a Federal department or agency. These standards have been revised to provide more information (country or countries of production), as well as remove some products from the COOL regulations (beef and pork). The original purpose of COOL was to provide consumers with additional information about the origins of their food choices (USDA, AMS, 2013a), but these standards were adopted only by the United States and not necessarily by other countries. The effect on meat suppliers of meeting COOL requirements when they comingled domestic and imported products was quite large because the same animal can be born, raised, and slaughtered in three different countries, and products that move between facilities and producers incurred a much larger burden in terms of paperwork, tracking, and verification (fig. 5). Producers that have a vertically integrated production process (poultry producers, for example) were able to benefit from COOL by marketing their products as "Product of U.S.A." without additional production costs besides the physical label.

FSIS regulates the labeling of meat and poultry products and reviews voluntary label claims related to geography and regional or location-specific styles. These types of claims include geographic logos or flags and State endorsement programs, and must be approved by FSIS' Labeling and Program Delivery Staff (LPDS) prior to entering the market (USDA, FSIS, 2015a). In contrast, country-of-origin statements, which are more generic than the other regional claims, can be "generically approved" by the LPDS—and do not require prior approval before entering commerce—as long as the label complies with all regulatory requirements and the statement is truthful and not misleading. In the case of COOL, all supporting documentation also needs to be kept with the labeling record (USDA, FSIS, 2015a). Mandatory country-of-origin labels differ from the geographic claims in that they require producers to track the locations of birth, raising, and slaughter for a variety of products, rather than just making regional claims—for example, Idaho potatoes, Florida oranges, or Georgia Vidalia onions. Because many livestock products are made from animals born in one country and then transported across a border for finishing and slaughter, COOL is more complicated—and requires more segregation and traceability—for meat products than for nonmeat products.

Also, processed foods do not require COOL—e.g., teriyaki-flavored pork loin or roasted peanuts. However, some of these items might require COOL under the Tariff Act.[38] Additionally, State, regional, or locality label designations are acceptable in lieu of COOL for domestic and imported perishable agricultural commodities, macadamia nuts, peanuts, pecans, and ginseng. However, these locality designations must be nationally distinct.[39]

Because the Federal Government mandated and oversees COOL and administers consequences for mislabeling or not providing the proper paperwork, the label is likely to be perceived as credible. For more information, see box "Standard Setting, Verification, and Enforcement: Country-of-Origin Labels.

[38] For example, roasted peanuts, pecans, and macadamia nuts are considered processed food items under COOL and do not require country-of-origin labeling; however, under the Tariff Act, if the nuts are of "foreign origin," the country of origin must be indicated on the packaging. Similar instances exist for other food items.

[39] For example, Rio Grande Valley is not nationally distinct because the consumer cannot determine if the label is referring to the United States or Mexico. Additionally, "locally grown" does not designate a region, so it is not acceptable for COOL declaration. While established State marketing programs (e.g., Colorado Proud) can be used in place of COOL, they are not accepted on meat and ground meat, fish, or shellfish commodities.

Standard Setting, Verification, and Enforcement: Country-of-Origin Labels

Who sets the standard?

The initial "standards" were set in the 2002 and 2008 Farm Bills and later revised.

Who verifies the standards?

Verification is held by the retailers and comes from records and documents that retailers receive at the point of sale. For pre-labeled products, the label itself is considered sufficient information on which the retailer can rely to establish the product's origin and production method—no additional records or paperwork about the product are necessary. For products that are not pre-labeled, it may include bills of lading, invoices, and packing slips. Per the rule, any person involved in supplying a retailer with a covered commodity must make available to the purchaser all information regarding the countries of origin and methods of production. Records covering the immediate previous source and the immediate subsequent recipient must also be documented for up to 1 year after the date of the transaction. Any intermediate supplier that is found to be holding an incorrectly designated product will not be held in violation of the COOL standard if the intermediate supplier relied on information and documents from the initiating supplier (or other previous supplier)—under the condition that the intermediate supplier did not ignore information by which one could reasonably conclude the supplied documents verifying country of origin and production information were false.

Who enforces the standard?

USDA works with States that have enforcement infrastructure in place to conduct retail compliance reviews. When a retailer is notified of an upcoming review, it has 5 business days to make available to USDA all supporting documents and materials. For each violation, the law allows up to a $1,000 penalty for both retailers and suppliers. If a supplier or retailer is found out of compliance, it has 30 days to take necessary steps to comply. If the retailer or supplier has been found (1) not to have made a good faith effort to comply and (2) continues to violate the COOL statutes willfully, then after providing notice and a hearing, the supplier or retailer may be fined up to $1,000 for each violation. In addition to the enforcement provisions stated in the COOL statutes, statements regarding the product's origin and production must also conform to other existing Federal statutes. If the labeling is found to be in violation of any other statutes, penalties associated with existing statutes may also be levied. Because COOL is a retail labeling program, it does not address food safety. Given this limitation of COOL, imported and domestic food products must also meet the food safety standards of the U.S. Food and Drug Administration and the USDA Food Safety and Inspection Service.

Would COOL Occur Without Mandatory Labeling?

Why did the Government choose the route of mandatory COOL, rather than voluntary COOL—particularly for beef and pork? If producers believed that there was a strong enough interest in COOL, it is likely that they would have taken this route on their own, in order to capture price premiums associated with a "specialty product."

While proponents for mandatory COOL argued that the benefits would outweigh the costs, no producers implemented COOL voluntarily (Ikenson, 2004). In contrast, some producers have chosen to participate in the National Organic Program, where consumers have demonstrated a willingness to pay a price premium for organic products. In the past, (around 2000-03, prior to mandatory COOL implementation), a joint FSIS/AMS voluntary program allowed producers to have USDA certify that livestock, meat, and meat products (which were covered under the proposed COOL regulations) were eligible to be labeled with a U.S.-origin sticker, as long as the label was truthful and could be documented; however, no one participated in the program (USDA, AMS, 2003). If COOL was not occurring through a voluntary Government-provided program, it is likely that consumers were not actually interested in COOL, or that producers did not believe the return (through increased demand for particular products) on voluntary COOL investment was strong enough to cover the cost of labeling. On the other hand, if all producers do not provide voluntary COOL, and if consumers do not trust the voluntary labels that are provided, then benefits might occur only with mandatory COOL, avoiding asymmetric information that could occur in the market with misleading, *voluntary* COOL (Brester et al., 2004). With Government-regulated COOL, the label might be more credible and truthful than voluntary labels.

Awada and Yiannaka (2012) discussed the market effects of switching from no COOL to mandatory COOL, as well as from voluntary COOL to mandatory COOL. They found that a change from no COOL to mandatory COOL would generate welfare losses and gains, but the overall welfare effect was difficult to determine and depended on relative prices of products, consumer preferences, and strength of consumer demand for COOL. However, the researchers found that a change from *voluntary COOL* to mandatory COOL would only lead to welfare losses. Under voluntary COOL, in which all producers had the option of labeling their products with country of origin, only those producers who anticipated increased profits under COOL would incur the costs of paperwork, tracking, and labeling. When all producers are required to use COOL, many will incur costs without gaining sufficient revenue to offset those costs. And the evidence that consumers are interested in COOL—willing to pay a premium for products with COOL—was limited.

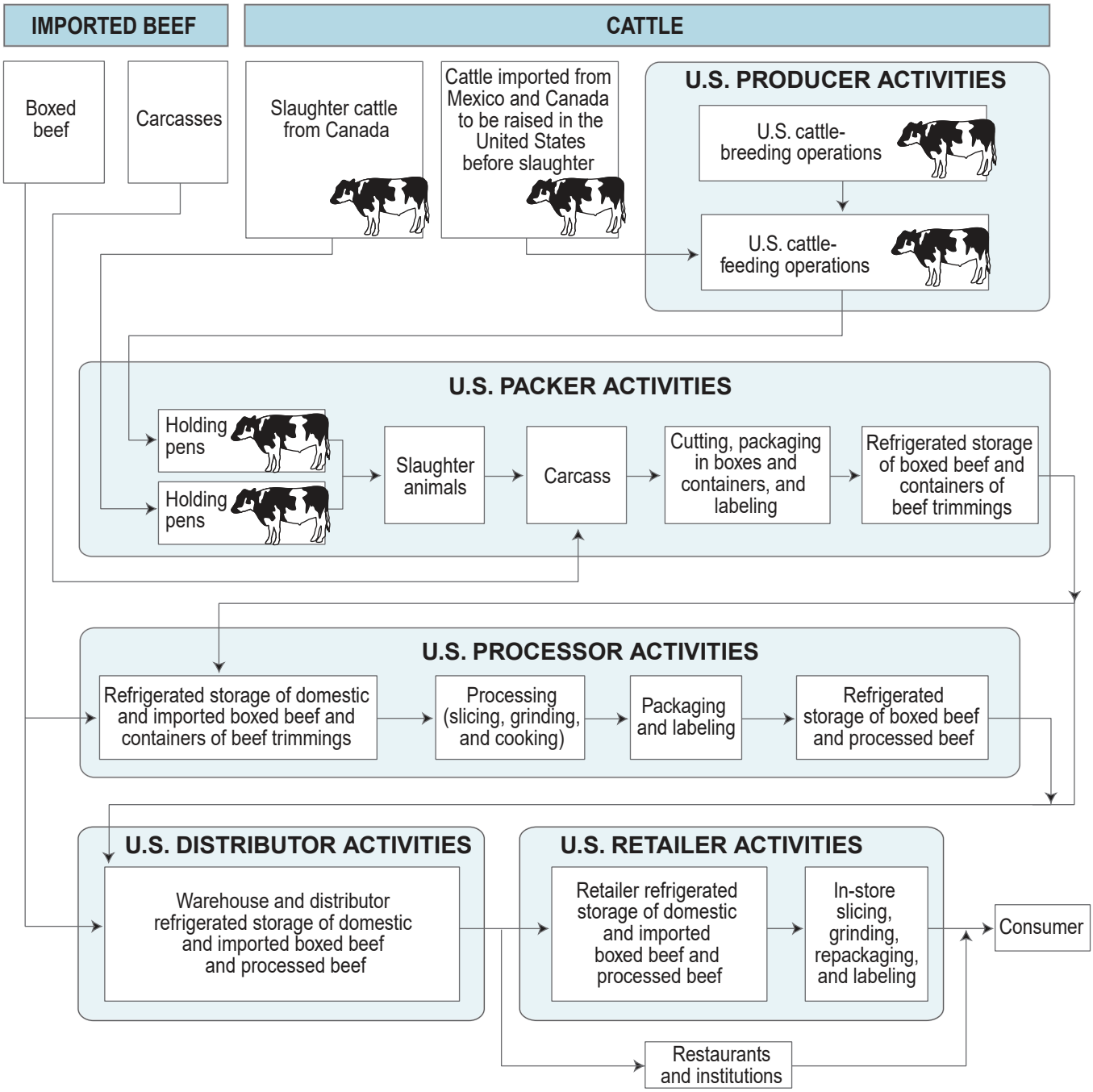
Kuchler et al. (2010) examined whether the implementation of COOL changed the demand for seafood, in particular, shrimp. At the time of their report, shrimp made up the largest amount of seafood consumption in the United States, and over 90 percent of the shrimp was imported. The researchers noted that seafood from Southeast Asia, especially shrimp, was associated with numerous food safety issues. With mandatory COOL, an information gap could be filled for consumers, and if consumers were worried about food safety issues, then the researchers expected to find a shift in demand away from imported shrimp that was attributable to mandatory COOL. They noted that a large shift in demand for shrimp might not provide a lot of information for other markets, but a lack of shifting demand for the shrimp market would suggest that consumers were not responding to—or interested in—COOL. Kuchler et al. (2010) found no evidence of a shift in demand; the absence of a shift suggested that COOL effects have been small at most.

Estimates of the Costs and Benefits of COOL

An early report on mandatory COOL from the U.S. General Accounting Office (GAO) (GAO, 2000) determined that mandatory COOL would require meatpackers to change their practices (fig. 5), which would in turn raise industry costs across the industry. However, the costs could only be estimated and remained largely uncertain. For example, the meat industry estimated an annual cost of $182 million for meatpackers and processors to maintain documents related to the country of origin for beef. The grocery industry estimated that grocers would incur annual costs of around $375

million for maintaining records, managing inventory, and labeling meats that they ground in stores. These additional costs would either be passed backward to suppliers in the form of lower revenue, or forward to consumers in the form of higher retail prices. The GAO report also estimated FSIS costs to enforce COOL for meat products to be over 10 percent of the agency's budget, more than $60 million per year.

Figure 5
Activities involved in bringing beef to consumers



Source: U.S. General Accountability Office, 2000.

In 2003, AMS found "little evidence that consumers are willing to pay a price premium for country-of-origin labeling …" (Brester et al., 2004, p. 50) and that "estimated benefits associated with this rule are likely to be negligible" (p. 49). However, most studies considered only labels with a single country of origin—not those with multiple points of origin, for example, "USA, Canada, and Mexico" (Taylor and Tonsor, 2013). Results from an experimental auction study in Logan, Utah, for traceability in red meat suggested that consumers would be willing to pay for these meat characteristics, and the magnitude of the results suggest that a profitable market exists for developing a system to monitor this characteristic (Dickinson and Bailey, 2002). However, this was a small study and was not verified in field trials. Additionally, the effect to the cost structure for producing and processing red meat—a major piece of market viability—was not introduced in this research.

Loureiro and Umberger (2003) found that consumers in three different Colorado cities in 2002 were willing to pay an average of 38 percent to 58 percent more for individual products labeled as "U.S. Certified Steak" and "U.S. Certified Hamburger." However, this study was conducted after public alarm over food in Japan and Europe, so it is possible that consumers were more concerned about their food sources at this point in time than during more regular times. The authors also noted, that post 9/11, respondents also may have experienced a more "positive or patriotic reaction toward a labeling policy which is intended to signal "U.S. Certified Beef."

Since the law's implementation, additional research has been done regarding the costs and benefits of mandatory COOL. In many of these studies, total costs have been estimated to be greater than total benefits, and the estimated consumer and producer surplus decreased after implementation. Most recently, the USDA Office of the Chief Economist Report to Congress on COOL (USDA, OCE, 2015) noted that while its research did not find a measurable increase in demand for beef or pork after mandatory COOL was introduced, USDA's regulatory proposals and impact studies often received a number of comments from the public, indicating that COOL was a topic of interest: "A consumer's right to know benefits those consumers who desire COOL information." However, the agency's analysis of a 10-year period following the 2009 COOL implementation on *all covered products* found that cost shifts associated with implementing COOL would amount to an estimated $212 million decrease in consumers' purchasing power in the 10th year.

On the cost side, COOL affected certain countries and industries more than others. Beef and pork products were especially affected, in part due to an increasingly global supply chain. For example, within North America, cattle and hogs may be born in one country, raised in another, and slaughtered in a third—this meant that increased traceability requirements were costly, especially for products where any stage of production was outside of the United States (Taylor and Tonsor, 2013; Moens and Leon, 2012; USDA, OCE, 2015; Pouliot and Sumner, 2014). In particular, U.S. feedlots and slaughter operations that process animals born in Canada or Mexico must, under COOL, segregate foreign-born animals from the domestic-born animals that constitute the bulk of production. The USDA analysis (USDA, OCE, 2015) simulated the implementation costs of the 2009 COOL legislation for the pork, beef, and poultry industry over a 10-year span. They found "economic welfare losses totaling a discounted net present value of $8.07 billion for the U.S. beef industry and $1.31 billion for the pork industry." In a retrospective econometric analysis, Pouliot and Sumner (2014) found that, in order to offset the costs of segregation, U.S. feedlot operators paid $3.30 to $8.82 per hundredweight (cwt) less for feeder cattle born in Canada than for U.S.-born cattle and that imports of fed cattle decreased. In contrast, the U.S. poultry industry was estimated to have an increase in economic welfare of $753 million. This is because poultry producers are vertically integrated (MacDonald, 2014; MacDonald, 2008)—most often, chicks are raised and slaughtered where they

are hatched. Poultry producers would be able to avoid the changes in production practices and documentation requirements.

To summarize, most research has determined that (1) mandatory COOL did not increase the consumer demand for products; (2) compliance costs for pork and beef producers increased substantially and were passed down the supply chain; and (3) poultry producers did not experience the same compliance costs associated with mandatory COOL.

How Did Consumers Use the Country-of-Origin Label?

The original purpose behind COOL was to provide consumers information about the source of the food they were purchasing—the countries that their food came from. However, some consumers have viewed COOL as an indicator of quality and safety (Wimberley et al., 2003; Umberger et al., 2003; Loureiro and Umberger, 2005; Lusk et al., 2006). While the mandatory COOL label might be truthful and credible, it is not necessarily understandable to the consumer.

When consumers view COOL as an indicator of quality, this leads to vertical product differentiation, or a ranking of labeled products, allowing perceived high-quality products—or in the case of COOL, U.S. products—to capture market share, even if all products have the same price (Awada and Yiannaka, 2012). Proponents of COOL for meat initially argued that COOL would provide U.S. producers with a competitive advantage in the marketplace because consumers believed U.S. products to be higher quality than imported meats. Consumer beliefs could lead to an increase in market share for U.S. products and potentially a price premium for domestic products (Umberger, 2004). However, this possible consumer interpretation of COOL is at odds with what was stated in the 2002 Farm Bill—namely, that COOL was a "food-labeling program that would only allow identification of a meat product's country of origin by stage of production" and did not include any food safety regulations or protocols associated with tracing the path of products.

If COOL is used as a source of information regarding country of origin, then the market would experience horizontal product differentiation, and all labeled products at the same price would experience positive market share (Awada and Yiannaka, 2012). Because COOL is a credence attribute, a COOL could provide additional information to consumers. Some consumers might use the label to make more environmentally friendly choices by choosing products that (they perceive to) have a smaller carbon footprint than imported foods (Krissoff et al., 2004; Kuchler et al., 2010).

Verification for COOL Claims

COOL verification is held by the retailers and comes from records and documents that retailers receive at the point of sale. (See box, "Standard Setting, Verification, and Enforcement: Country-of-Origin Labels" on page 56.) These may include bills of lading, invoices, and packing slips. For prelabeled products, the label itself is considered sufficient information on which the retailer can rely to establish the product's origin and production method—no additional records or paperwork about the product are necessary. With explicit rules regarding verification of COOL, the consumer can trust that the label is credible and truthful.

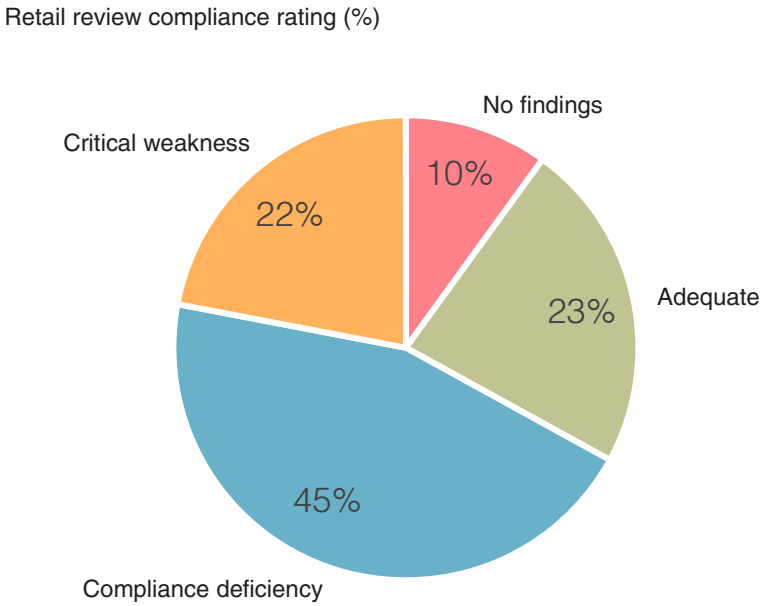
COOL Enforcement Steadily Increased After Implementation

USDA works with States that have enforcement infrastructure in place to conduct retail compliance reviews. When a retailer is notified of an upcoming review, it has 5 business days to make available to USDA all supporting documents and materials. For each violation, the law allows up to a $1,000 penalty for both retailers and suppliers. (See box "Standard Setting, Verification, and Enforcement: Country-of-Origin Labels" on page 56.)

In 2011, the USDA Office of the Inspector General determined that the enforcement of mandatory COOL was lacking (USDA, OIG, 2011). The review found a number of repeat retailer noncompliances, after having already been cited by AMS for noncompliance, primarily because AMS did not follow up with the offenders after the 30-day grace period. AMS had not issued any civil penalties from the time that the final rule went into effect in 2009.

However in fiscal year (FY) 2015, AMS reviewed a total of 1,055,966 COOL-covered commodities at retail. The AMS COOL Division conducted 3,062 retail surveillance reviews, with 2,252 of the reviews following up on FY 2014 compliance deficiencies (figs. 6 and 7). Out of a number of possible noncompliance violations—including illegible COOL, unacceptable regional designation, no production steps identified, or no record keeping—the most frequent noncompliance code was for not identifying a country of origin on the label (USDA, AMS, 2016d). This is the most common noncompliance code found in each fiscal year from the 2009 report to the 2015 report.

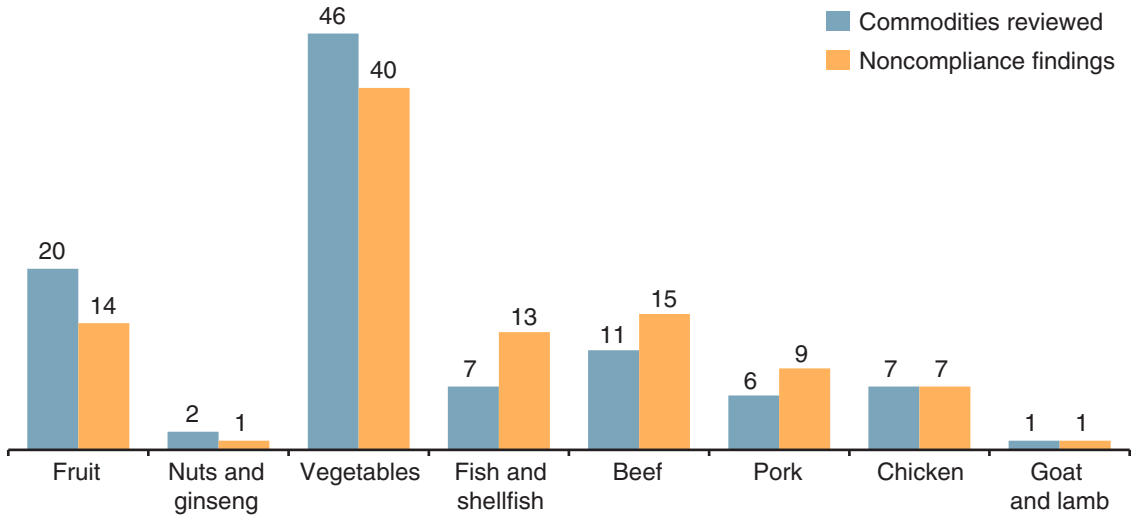
Figure 6
Percent of retailers by compliance rating



Note: No Findings = 0 noncompliance (NC) codes; Adequate = NC < 4 and NC as percent (%) of commodity count < 5%; Compliance Deficiency = NC ≥ 4 or NC as % of commodity count ≥ 5%; Critical weakness = NC >14 and NC as % of commodity count ≥ 5%.

Source: USDA, Agricultural Marketing Service's Country of Origin Labeling compliance data, fiscal year 2015 (February 2016).

Figure 7
All commodities reviewed versus noncompliance findings identified by commodity category (percent)



Note: The blue bars represent the share of the category in relation to the entire retail sales, while the orange bars represent the noncompliance of that category. For example, fruit was 20 percent of the retail sales, but 14 percent of fruit was found to be noncompliant.

Source: USDA, Agricultural Marketing Service's Country of Origin Labeling compliance data, fiscal year 2015 (February 2016).

Mandatory COOL Initiated a Dispute With Mexico and Canada

Mexico and Canada filed a dispute against the United States with the World Trade Organization (WTO) claiming the label decreased competitiveness between countries. COOL is still in place for all covered products, except muscle cuts of beef and pork, and ground beef and pork.

Summary and Conclusions

Mandatory COOL was first introduced in the 2002 Farm Bill, but was not fully enacted until 2009. The time sequence is an indication of how complicated a label can be, especially when spanning a variety of products, industries, and even countries. From COOL, we learned that there can be disagreements within an industry about whether a mandatory label is useful or too costly. However, consumers might find a mandatory, Government-regulated label to be more credible than a voluntary label with minimal oversight.

COOL is also an example of a confusing, easily misunderstood label. Although COOL's purpose is just to provide information about the origin of a product or where it was processed, consumers have often viewed it as something more—a symbol of quality or safety (Wimberley et al., 2003; Umberger et al., 2003; Loureiro and Umberger, 2005; Lusk et al., 2006). The confusion adds to knowledge asymmetry in the market—consumers pay for attributes that they are not necessarily receiving (better quality). In the case of COOL, mandatory labeling did not create a label that was more understandable than another option.

Finally, trade barriers can influence labels that occur (or do not occur) on packaging in the United States. Although there is merit to companies and industries wanting to promote U.S. products, as a member of the WTO, the United States agrees to promote competition across countries. If other countries experience U.S. labeling laws as a violation of WTO rules, then they can file a case.

It is unclear whether mandatory COOL improved consumer or producer welfare. The answer likely depends on the industry and the production process of particular goods. But, for products that cross national borders and have a number of steps in production, production costs rose because of mandatory COOL. While consumers seemed interested in knowing where their food came from, they also have tried to infer additional information about the *quality* of the product, which COOL was never intended to provide. Mandatory COOL exemplifies a food label that is truthful and credible but not necessarily understandable, and one that reached beyond the United States with its trade implications.

What Have We Learned From These Case Studies?

The public has become increasingly concerned about the healthfulness of food as well as externalities created by agricultural and food production. In response, food producers have added a lot of information about health and production methods on food packaging. However, much is still missing, and much of the information provided is unreliable. Label claims can lack credibility, truthfulness, and understandability, undermining consumers' ability to make informed food choices. This report examines whether food labeling answers consumers' health questions or ensures that foods are produced in ways they prefer. The report examines Government and private-sector roles in standard setting, verification, and enforcement, comparing and contrasting these aspects of the five labels—the Nutrition Labeling and Education Act (NLEA), the National Organic Program (NOP), Raised Without Antibiotics (RWA) label claims, Non-GMO Project Verified claims, and mandatory Country-of-Origin Labeling (COOL) (table 2). These comparisons are suggestive, indicating where similar outcomes might be expected by relying on the Government, private sector, or some combination of both Government and private sector. The report highlights the inherent tradeoffs in relying on private solutions or private solutions with public-sector involvement, as well as the unintended consequences of Government intervention.

Table 2
Comparison of five food labels—who is involved, actions, and market outcomes

	Nutrition labeling	USDA oganic seal	Raised without antibiotics	Nongenetically engineered	Country-of-origin label for beef and pork
Mandatory or voluntary?	Mandatory	Voluntary	Voluntary	Voluntary	Mandatory but repealed in 2015
Who sets standards?	Government (FDA and USDA)	Government (USDA)	Private (firms' own or third-party standard), with some Government oversight	Private (firms' own or third-party standard), with some Government oversight	Government (USDA)
Demand for label information	Nutritionists, consumer advocates, and Government agencies	Consumers and producers (farmers and processors)	Consumers and producers	Consumers and retailers	Consumers and producers
Type of attribute	Credence and product	Credence, process, and product	Credence and process	Credence, process, and product	Credence
Externalities that might be addressed by labeling (beyond information asymmetries)	Health care costs of poor nutrition decisions	Environmental externalities, including those associated with pesticide and fertilizer use (among others)	Antibiotic resistance that impacts human health	Externalities associated with, for example, herbicide use inherent to herbicide-tolerant genetically engineered varieties	
Industry response	Shift to front-of-package claims to differentiate products	Production and sales of labeled products are increasing	Production and sales of labeled products are increasing	Production and sales of labeled products are increasing	Label costs for beef and pork have outweighed the benefits

—continued

Table 2
Comparison of five food labels—who is involved, actions, and market outcomes—continued

	Nutrition labeling	USDA Organic seal	Raised without antibiotics	Nongenetically engineered	Country-of-origin label for beef and pork
Consumer response	Many consumers find the information too complex to use	Some consumers may not be aware of all the attributes represented	Some consumers may be confused about the human health benefits	Some consumers may believe that the label means organic	Some consumers may believe that the label covers process attributes
Verification	None	Mandatory certification by a USDA-accredited certifier of all farmers and handlers	Not required; Voluntary verification through third parties	Not required; Voluntary verification through third parties	None
Enforcement	Government (FDA and USDA) enforcement of standard	Government (USDA) and USDA-accredited certifier enforcement of standard	Government responsible only for whether claim is "truthful and not misleading"	Government responsible only for whether claim is "truthful and not misleading"	Government (USDA) enforcement of standard

Source: Regulatory text is available on websites of the following agencies: USDA, Food Safety and Inspection Service; USDA, Agricultural Marketing Service; U.S. Food and Drug Administration; and the Federal Trade Commission.

The rationale for developing label standards, verification, and enforcement varied among the labels examined. NLEA represented a solution to consumers' missing information problem—labels did not offer enough information about the nutritional content of food. By requiring that most food products bear information on calories and nutrients, the Federal Government ensured consumers had information to enable them to make better food choices. Other labels began to highlight aspects of the food production process. Another conveyed the geographic origin of food products. These attributes—nearly impossible for consumers to confirm on their own—are identified by labels that involve Government to varying degrees. NLEA, COOL, and NOP originated in Federal law and Government regulation, although first two are mandatory and the last voluntary. RWA and NGP evolved from producers' and marketers' desires to differentiate products and satisfy consumers who were willing to pay higher prices for certain credence attributes. Both COOL and the new law for mandatory GE labels emphasize that consumers have a "right to know" the food attributes that the labels verify.

What Have We Learned From Examining the Operation of Markets for Labeled Foods?

Many of the credence attributes marketed to consumers are complex, and labels identifying such attributes have, so far, been unable to perfectly coordinate consumers' diverse preferences with food supply. If consumers found label information to be credible, if label information were truthful, and if consumers were able to fully understand the information, then labels would serve to coordinate production and distribution of the variety of foods marketed. Meeting these three conditions is sufficient for solving the coordination problem, but this is a high bar for label information. The Federal Government has been involved in labeling in many ways: standard setting and product definitions, verification, and enforcement. Each such involvement results in tradeoffs rather than in a solution.

Mandatory labels may include negative aspects of foods, but voluntary labels will not. Thus, voluntary labels rely on consumers to infer negative characteristics from the absence of a label claim on some products (when it is present on other similar products). Whereas the NLEA and COOL programs are mandatory, USDA Organic, non-GE, and RWA labels are voluntary—that is, farmers, food manufacturers, and retailers may choose to make these claims or not. When a label is voluntary, producers will undertake the costs of verifying product attributes only if they expect the process will lead to increased profit. In contrast, with a mandatory label, all food suppliers must reveal the same amount of information, some of which could reduce consumer demand for those products. Suppliers have to include negative information on the Nutrition Facts labels. For example, saturated fat has to be listed whether it is low or high, so that consumers concerned about saturated fat can choose products with low levels. Likewise, if a product is covered by COOL, suppliers have to say which country that product comes from, even if some consumers think the country has unacceptably low food safety standards.

For this reason, left to their own devices, food suppliers will offer only positive (and positively perceived) information. However, depending on what is mandated, mandatory labeling may or may not provide more complete information. Whether consumer knowledge is improved depends on how well consumers interpret label information and whether competition among food suppliers results in adequate "unfolding" (see footnote 1). Will consumers' skepticism about label claims and competition among food suppliers encourage food suppliers to voluntarily offer more information? Will consumers (correctly or incorrectly) infer that products without label claims are of lesser quality, and will labels (or their absence) allow consumers to identify all relevant attributes?

Unfolding tends to work least well when food suppliers know that consumers do not understand their label claims and have no incentive to correct misperceptions. If consumers imagine that a food has an attribute it does not, they pay a price premium and suppliers incur no cost by allowing consumers' misperception to remain: food attributes are not aligned with consumers' wants, but there is no corrective mechanism.

In the market for foods free of genetically engineered ingredients, misunderstanding about these attributes abounds—foods that could not be otherwise are advertised as "non-GE." Furthermore, although the labels equip consumers with additional knowledge, their misconceptions about genetic engineering may not lead to food choices that match underlying preferences for food safety.

Consumers may assume single-attribute claims cover multiple attributes the way the USDA Organic standard does. Verifying a single attribute is generally less costly than verifying the suite of attributes to satisfy the organic standard. Confusion between the USDA Organic standard and other standards implies that consumers regard the standards as the same, and suppliers that use any standard share the price premium, regardless of who actually verifies the desired attributes. USDA Organic product sales might have been larger without competition from single-attribute labels like "non-GE" and "Natural." In addition, some consumers want to see single-attribute claims, such as "non-GE," explicitly listed on organic products even though the organic standard covers this attribute.

Government standards improve label claims' credibility and truthfulness, but may delay market response to emerging consumer demand. When creating a standard, the Federal Government is likely to create a single, national standard—a slow and costly process, as demonstrated by the years devoted to bringing NLEA and NOP to force. In part, the time and money costs stem from the many stakeholders involved and the limited consensus about how to move forward (as in the cases of GE or non-GE label claims). These stakeholders may lobby to ensure the standard is aligned with

their interests (COOL). Another drawback to creating a single standard is that it constrains further product differentiation and experimentation with marketing methods. USDA Organic regulations mitigate this problem by including a standing standards committee that evaluates and recommends updates to the U.S. Secretary of Agriculture.

A mandatory standard is more likely than a voluntary one to lead to product reformulations that mitigate negative attributes or remove them altogether. On the other hand, voluntary standards set by private firms and nongovernmental organizations can respond quickly to consumers' desire for a new attribute, especially claims that represent a single attribute. Higher prices for differentiated products can stimulate producers to change their production practices to the ones consumers want or to reformulate their products to earn a price premium.

Federal intervention in standard setting or defining products may be a quick route to credibility and truthfulness. However, not even Federal intervention will ensure that consumers can make informed, rational choices. Because many consumers do not see a conflict of interest when the Federal Government develops label claims, the Government may bring credibility to label claims, thereby helping to create markets for differentiated products. Federal intervention in the USDA Organic seal ensured that all producers using the organic claim would meet a uniform standard, whereas the previous system involved dozens of differently defined claims. In effect, the Government defined what could be claimed about organic food, eliminating differences in meaning and definition. Similarly, the credibility of the mandatory COOL and nutrition labels is strong because the Government regulates these labels.

However, even labels with uniform and transparent standards (NLEA, NOP, and COOL) may be too complex to allow consumers to use them easily. The Nutrition Facts label contains information on nutrition that well-informed consumers may understand, but the relative healthfulness of monounsaturated and polyunsaturated fat is lost on many.[40] Similarly, the COOL regulation in place from 2009 to 2013 was contentious because it did not provide clearly worded information on the complex origins of meat products. The USDA Organic seal is still difficult for many consumers to understand because of the wide range of farming and food manufacturing practices that the standard encompasses.

Multiple standards for the same characteristic may increase consumer confusion. In some cases, the Federal Government controls label information but relies on private firms to set standards, and it allows standards to vary. Government-inspired credibility may not always make a label successful, and it does not ensure a label is understandable or truthful. When private firms or groups develop their own standards (such as RWA and Non-GE), they may respond to consumer demand but may also have an incentive to increase their sales by misleading consumers. When consumers misunderstand a complex product attribute and label information does not communicate differing standards, private firms can be anticipated to behave strategically to promote their own interests. They may also set label claim standards in such a way as to exclude others from the marketplace. The 2007-08 experience with RWA labels showed that USDA approval gave competing labels credibility, but largely left standard setting to the private sector, which resulted in multiple product standards but similar label claims. In the end, the early USDA approval did not ensure that the RWA labels were truthful or understandable in the short run. Empirical evidence indicated that consumers did not

[40] As health claims are also regulated under NLEA, this confusion persists. While a poly- or mono-unsaturated fat cooking oil is low in saturated fat, it cannot make a heart health claim because of the disqualifying level of total fat.

understand what they were buying. When poultry suppliers complained that their competitors' use of RWA was inappropriate, the courts arbitrating the dispute confirmed that some RWA labels were misleading. Subsequent USDA guidance has made RWA labels more truthful.

Enforcement choices the Government makes will have consequences for market efficiency. Because consumers themselves cannot verify most of these process-based attributes, the market often does not penalize private companies that mislead consumers as it may do with other labeling claim misrepresentations. In theory, the Federal legislative and rulemaking process could fill gaps in enforcement for misleading label claims. Currently, the types of enforcement methods used vary. FDA may send warning letters when food is improperly labeled or lacks a Nutrition Facts label. However, FDA has not been doing much testing and enforcement of food labels in recent years (GAO, 2008). USDA has an active program protecting the USDA Organic seal, fining producers for labeling food as organic when it fails to meet all the standards. Similarly, false claims about COOL meet financial penalties. Meanwhile, the Federal Government is not involved in enforcing compliance with non-GE standards, except with the relatively small number of firms that obtain non-GE verification through USDA.

USDA FSIS pre-approves labels but has limited enforcement resources. Often, consumer groups or competitors' complaints are the impetus to initiate an investigation. This process allocates some of the enforcement responsibility to the industry, which may have an incentive to punish competing companies and thus have a conflict of interest in asking for the USDA or the FDA to intervene. Alternatively, consumer groups or competitors could seek recourse from the judicial system, as in the case of RWA labels. In that case, consumer groups filed a class action lawsuit; competitors also filed a lawsuit claiming that the Lanham Act had been violated.

The power of label information to reduce the negative environmental effects of a particular product type depends on the size of its market. Two process-based label claims aim to reduce the negative environmental effects of agricultural production and food processing. Raising livestock without antibiotics reduces the likelihood that bacteria will develop resistance to antibiotics, so purchasing RWA meat has the benefit of reducing that risk. Similarly, the USDA Organic seal addresses antibiotic use in livestock and a suite of other environmental stewardship practices. However, although agriculture's negative environmental effects have been recognized for many years and label standards have sought to mitigate them, they still persist. So, while this market-oriented approach may encourage consumption decisions that incentivize producers to reduce environmental and health consequences, the labels' power to effect change is limited by the size of the markets they serve. In deciding whether mandatory or voluntary labeling makes sense, the Government may want to consider the size of the environmental benefit relative to cost of labeling, as well as the distribution of the benefits and costs. Alternatively, substantially reducing negative environmental effects might require other costly policies, like regulations on farm production methods.

Mandatory labeling may trigger trade complaints, and voluntary labeling may impede trade as well unless equivalency agreements can be negotiated. Mandatory labeling may trigger complaints from U.S. trade partners. In the case of mandatory COOL, Canada and Mexico argued that COOL was a barrier to livestock trade, and the World Trade Organization (WTO) agreed, ruling the mandatory COOL for beef and pork violated WTO agreements. The multiple organic standards early on were thought to impede interstate trading, as a group's definition and certification in one State might not be recognized in another State. Because the national organic standard ended such impediments, it allowed interstate commerce to prosper and also facilitated negotiations for interna-

tional trade in organic products that carried the NOP label. For the USDA Organic seal, USDA has streamlined equivalency agreements with Canada, the EU, and several other countries.

Efforts to educate consumers about food product attributes are limited. The labels examined in this report suggest that, so far, little investment has been made to clarify the claim information to consumers. Label claims alone cannot possibly elucidate for consumers the current variations of RWA claims, non-GE claims (including the Non-GMO Project Verified claim), the information included in the Nutrition Facts label, and the hundred pages of requirements for the USDA Organic seal. In response to the apparent consumer confusion, Government agencies, producer groups, and NGOs have begun providing informational videos and websites to help consumers understand. From both a marketing and informational perspective, using labels that are so complex or confusing that they require consumers to watch a video to understand them ignores the most basic reason for labels—informing consumers at the point of purchase.

The complicated requirements and fine print behind many labels are at odds with comprehension, and they illustrate the fundamental tradeoffs between presenting information that is simple and understandable versus nuanced and complex. One potential solution to this dilemma is the new technology that can now give consumers easy access to detailed information about processes and claims. Where a label's chief liability is lack of information, new information platforms may more fully convey product attributes and improve the label's truthfulness, relevance, and understandability. New information platforms including apps provide users with a large quantity of information while shopping or developing grocery lists. Food manufacturers have also suggested using QR codes as a way to convey more information to consumers about individual products (Fusaro, 2015).

Many consumer and environmental groups, retailers, and other organizations have developed apps that provide information to users on health and nutrition, social issues, and environment attributes. Some work on single issues, while others provide information on some combination of these attributes. A few apps assess the credibility of process-based labels themselves. Many share a mission to provide information that enables consumers to vote with their money—that is, these groups encourage consumers to purchase goods that represent their values and have the attributes they desire. However, although apps can include much more information than food labels can, apps (just like labels) must come from sources consumers trust. Apps are largely uncertified and unpoliced, which means they are of dubious quality.

There are fundamental tradeoffs in how information is presented to consumers. If it is presented simply, then important nuance or complexity may be missed. On the other hand, if standards and labels attempt to convey complexity, then consumers may just be confused. Policymakers and marketers will need to consider these tradeoffs in the future when developing new process-based labels.

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Appendix—U.S. Food Safety and Labeling Programs

Most U.S. food safety and labeling programs are administered by USDA, Food Safety and Inspection Service (FSIS), USDA; Agricultural Marketing Service (AMS); and the U.S. Food and Drug Administration (FDA) (appendix table 1).

Appendix table 1
Major U.S. regulatory statutes and food-labeling activities

Year	Statute	Regulatory agency	Products covered	Purpose /administrative authority
Food labeling for basic product attributes				
1906	Pure Food and Drug Act	FDA	All food, except most meat and poultry	• Prohibits interstate commerce in adulterated or misbranded food
1906	Federal Meat Inspection Act (FMIA)	USDA	Meat (excluding exotic species)	• Inspects products and prevents sale of adulterated or misbranded products
1914	Federal Trade Commission Act	FTC	All food	• Prohibits false and deceptive advertising
1924	Agricultural Products Inspection and Grading Act	USDA	Livestock and meat	• Sets U.S. grade standards based on measurable product attributes
1938	Federal Food, Drug and Cosmetic Act (FFDCA)	FDA, EPA	All food, except most meat and poultry	• Ensures that foods are pure and safe to eat; inspects factories (FDA) • Sets identity/quality standards (FDA) • Sets maximum pesticide residue levels in food (EPA)
1946	Agricultural Marketing Act (AMA)	USDA	Dairy, fruits, vegetables, meat, poultry, shell eggs	• Sets U.S. grade standards based on measurable attributes • Provides voluntary fee-for-service food inspection and other services
1957	Poultry Products Inspection Act (PPIA)	USDA	Poultry and products, except eggs	• Inspects products to prevent sale of adulterated or misbranded products
1966	Fair Packaging and Labeling Act (amends FFDCA)	FDA, FTC	All food products	• Inspects products to prevent sale of adulterated or misbranded products
1970	Egg Products Inspection Act (Amendments – 2012, 2013)	USDA, FDA	Shell eggs (FDA), egg products (USDA)	• Inspects products to prevent sale of adulterated or misbranded products
1990	Nutrition Labeling and Education Act (amends FFDCA)	FDA	Most food, except meat and poultry	• Requires nutrition labels on most foods regulated by FDA[1]
Food labeling for process-based attributes (e.g., sustainability or animal welfare)				
1906, 1938, 1957	FMIA FFDCA PPIA	USDA, FDA	Crops, livestock, eggs, and poultry	• USDA and FDA allow standards for process-based label claims set by firms or nonprofits • USDA and FDA allow voluntary claims that are truthful and not misleading • USDA requires pre-approval for some labels; FDA does not

—continued

Appendix table 1
Major U.S. regulatory statutes and food labeling activities—continued

Year	Statute	Regulatory agency	Products covered	Purpose /administrative authority
1990	National Organic Foods Production Act	USDA	All crops, livestock, eggs, poultry, and processed food	• Establishes U.S. process-based standards for organic production • All producers using USDA organic seal must meet U.S. standards
1995	Quality Systems Verification Programs (under AMA)	USDA	Crops, livestock, eggs, and poultry	• USDA offers verification services for private label claims[2]
Food labeling for geographic-origin indicators				
2002 2008	Amendments to AMA	USDA	Specialty crops and meat (except beef and pork)	• Country-of-origin labeling mandated for selected commodities

[1] USDA published the final rule in 2010 requiring nutrition labels on raw, chopped, and other meat and poultry products.

[2] USDA's Process Verified Program and other programs provide audit-based services to verify that firms are meeting their own process-based standards (on their use of antibiotics, animal-raising practices, and genetic engineering, for example).

Source: USDA, Food Safety and Inspection Service; USDA, Agricultural Marketing Service; and U.S. Food and Drug Administration.

USDA, FSIS Meat Safety and Labeling Programs

FSIS is responsible for ensuring that meat, poultry, and egg products are safe to eat and correctly labeled and packaged, under the statutory authority set in three laws: the Federal Meat Inspection Act (FMIA) in 1906, Poultry Products Inspection Act (1957), and Egg Products Inspection Act (1970). To prevent sale of adulterated or misbranded products, FSIS inspects meat and poultry processing plants and tests products for harmful substances such as drug residues, pesticides, and metals. FSIS also has authority to regulate labels on meat, poultry, and egg products, including label claims that inform consumers about production and processing practices (USDA, FSIS, 2007).

In contrast to products under FDA's purview, many label claims on meat and poultry products must be submitted to FSIS for review before they can be used on products (USDA, FSIS, 2007). All animal-raising and production claims, such as grass-fed or raised without antibiotics, are required to have prior label approval before products are marketed.

USDA, AMS Commodity Grades and Standards

AMS has many regulatory responsibilities, including development of quality grades and standards to encourage uniformity and consistency in commercial practices. Under the statutory authority provided in the Agricultural Products Inspection and Grading Act of 1924 and the Agricultural Marketing Act of 1946, AMS establishes U.S. grade standards for basic measurable quality attributes, such as color, freshness, tenderness, and the level of bruising and other visual defects (appendix figure 1).

Appendix figure 1
Two examples of USDA grading labels

The left is an example of a USDA Grade AA label for shell eggs, and the right is an example of a USDA Prime Grade label for beef.

AMS commodity grade standards have been in use on beef products since 1927 and dairy products since 1947. Grade standards have been used for eggs since the 1960s and have been used for poultry, fruits, and vegetables since the 1970s. AMS also sets grade standards for cotton and tobacco. Grading is voluntary and paid for by the firm that has a financial interest in the product and is conducted by a licensed Federal grader. Although grade marks are not always visible on product labels in the grocery store (particularly on fruits and vegetables), beef, lamb, chicken, turkey, butter, and eggs may bear visible grade marks—e.g., Grade AA or Grade A shell eggs, or USDA Prime, Choice, or Select Grade beef.

USDA, AMS National Organic Program

Under the Organic Foods Production Act of 1990, Congress required that USDA set uniform, national standards for organic food production and labeling and develop the National Organic Program (NOP) to administer and enforce the standards. In 2000, AMS published the final rule defining organic agriculture as an ecological production system and setting U.S. organic standards. The standards are process based, addressing the substances and practices permitted to be used in organic production and the processes that must be undertaken to protect natural resources and conserve biodiversity.

NOP accredits private, foreign, or State organizations to certify individual operations and facilities. The organic legislation also required the U.S. Secretary of Agriculture to appoint a National Organic Standards Board—made up of a rotating set of 15 representatives from producer, consumer, and other stakeholder groups—that continually reviews and recommends updates for the standards to NOP. The history of NOP and the successes and challenges associated with the USDA organic seal are discussed in a subsequent chapter.

USDA, AMS Auditing and Verification Services

In addition to developing grade standards for product quality and providing grading services, AMS also provides auditing and verification services to firms for processes and systems that are related to environmental management, food safety, animal welfare, and other farming and processing practices. In 1995, AMS published final rules establishing Quality Systems Verification Programs, which provide these services. These services are also paid for by the firm and are based on the standards of the International Organization for Standardization (ISO).[41]

[41] ISO is an independent, nongovernmental international organization with a membership of 161 national standards bodies (organizations that choose standards). "Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges."

One of the most popular AMS auditing and verification programs for user-defined labels is its 2005-implemented Process Verified Program (PVP), which audits dozens of companies with many claims about their use of antibiotics, animal-raising practices, genetic engineering, and other crop or livestock production practices. (See box "The USDA Agricultural Marketing Service's Process Verified Program" for more detail on how PVP works.)

The USDA Agricultural Marketing Service's Process Verified Program

The USDA Process Verified Program (PVP) is a fee-for-service program of the USDA Agricultural Marketing Service. The PVP verifies agricultural processes for firms, and firms with an approved PVP can use the USDA PVP shield on their product labels (appendix fig. 2).

A firm's program is supported by a documented management system and independently verified by an AMS auditor. "Process points" that comprise a PVP must be "verifiable, repeatable, auditable, feasible, and factual." AMS uses the ISO 9000 series standards to evaluate documentation and provide for consistent auditing.

To ensure transparency, the AMS website lists all approved firms with claims (and their standards) and lists plain-language definitions for all PVP claims. All products with the PVP shield also display the website URL.

A firm's steps to getting a PVP are as follows:

1. The firm decides what standards it wants to meet as part of its PVP. These can be international, industry-wide, or developed by the firm.
2. To present its standard to AMS, the firm documents its program through a quality management system and a quality manual that describe the firm's "process verified points," procedures, records, policies, objectives, and other components.
3. AMS auditors conduct a "desk audit," followed by a review of the firm's documentation by a Program Review Committee.
4. AMS conducts an onsite audit, which can involve multiple sites (e.g., farms and processing plants) and take up to a week (depending on the PVP's scope).
5. If the firm's PVP is approved, it can then use the USDA Process Verified shield on its product labels and marketing materials, such as brochures and websites.
6. A surveillance audit is conducted within the first 6 months after approval, and the firm must be re-audited annually after the first year.

Appendix figure 2
USDA PVP shield

Source: U.S. Department of Agriculture, Agricultural Marketing Service. Process Verified Program.

U.S. Food and Drug Administration Standards and Labeling for Food Safety and Nutrition

FDA food safety and labeling programs. Under the statutory authority set out in the Federal Food, Drug, and Cosmetic Act (FFDCA) in 1938 and the Fair Packaging and Labeling Act (1966), FDA is charged with ensuring that most foods—other than meat, poultry, and egg products—are not adulterated or misbranded and are safe to eat, healthy, and properly labeled. The FFDCA also authorized EPA to establish the maximum pesticide residue levels in food.

In contrast with USDA's prior-label approval process for meat and poultry products, FDA does not pre-authorize or pre-approve firms' labels. With respect to nutrition information, this means that firms must test their products or base compositional analysis on existing literature or databases. Firms maintain records of their analysis that must be available if FDA requests them. With respect to product health claims, FDA approves specific claims through a "Notice and Comment" rule-making process, which draws on authoritative statements from health organizations. If scientific evidence for a particular claim is limited, FDA sometimes approves "Qualified Health Claims."

Glossary of Abbreviated Terms

AMS – USDA Agricultural Marketing Service

APHIS – USDA Animal Plant and Health Inspection Service

COOL – Country-of-Origin Label

FDA – U.S. Food and Drug Administration

FSIS – USDA Food Safety and Inspection Service

GE – genetic engineering/genetically engineered

GMO – genetically modified organism

IFOAM – International Federation of Organic Agriculture Movements

LPDS – FSIS' Labeling and Program Delivery Staff

NE3 – Never Ever 3

NGP – The Non-GMO Project

NLEA – Nutrition Labeling and Education Act

NOP – USDA National Organic Program

OFPA – Organic Foods Production Act of 1990

OSP – Organic System Plan

PVP – USDA Process Verified Program

RWA – Raised Without Antibiotics

TA – Technical Administrator

USDA – U.S. Department of Agriculture

WTO – World Trade Organization