

July 17, 2001

Via Messenger

FSIS Docket No. 98-005P
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102-Annex
300 12th Street, SW
Washington, DC 20250-3700

**Re: Nutrition Labeling of Ground or Chopped Meat and Poultry Products
and Single-Ingredient Products; Docket No. 98-005P**

Dear Sir or Madam,

The Food Marketing Institute (FMI) is pleased to respond to the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service's (FSIS's) request for comments on the FSIS proposal regarding nutrition labeling for raw, single-ingredient meat and poultry products. 66 Fed. Reg. 4970 (Jan. 18, 2001). FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of \$300 billion, which accounts for more than three-quarters of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets.

I. EXECUTIVE SUMMARY

FMI and FMI's members strongly support providing consumers with nutrition information. Indeed, FMI, in conjunction with our partners in the meat and poultry production chain, used data generated by USDA to develop the Nutri-Facts consumer nutrition information program in 1985. Nutri-Facts brochures and posters continue to provide point-of-purchase nutrition information to consumers on meat and poultry products, as well as produce and seafood, and have been used by our members and other

food retailers for nearly two decades. We believe, and our surveys show, that the majority of consumers use the nutrition information now provided at retail, which includes brochures, posters, and product labels.

Accordingly, we urge FSIS not to abandon the current program for nutrition labeling, but to add the proposed provision that will officially allow retailers to continue to label ground meat and poultry products with statements of percentage fat and lean content. Consumers rely heavily on the percent fat/percent lean statements with which many retailers have voluntarily labeled ground products for years. We strongly endorse USDA's proposal to add a regulation in this regard.

In our opinion, and based on the available data, the voluntary nutrition labeling program provides a sound means of offering consumers with one source of information regarding the nutrition content of meat and poultry products. Many of our members have high quality programs for providing health and nutrition information to consumers on foods generally and for meat and poultry in particular. Indeed, the lowest estimates show that more than half of all retailers currently participate in the voluntary program, including many smaller, independent retailers that are exempt from participation under the regulations. Moreover, even the most conservative data show that retailers now provide nutrition information for nearly two-thirds (63%) of meat and poultry products on a volume-weighted basis. We commend those retailers who are meeting or exceeding the standards in the current voluntary nutrition labeling program, but recognize that mandatory regulations are likely to limit the number of products that retailers will be able to provide for consumers. Therefore, we strongly urge USDA to maintain the voluntary program, rather than imposing a mandatory system.

Although we believe in the integrity and value of the Nutri-Facts program currently in place, we also recognize that improvement is always possible. Toward that end, we would be pleased to work with USDA to develop updated information for the voluntary program that is more "consumer-friendly," and to reach out to the industry to encourage even higher participation in the voluntary program. With the recent formation of our new Independent Operator Division and the addition of all of the domestic stores that are part of the 4,000 store Independent Grocers Alliance (IGA) to our membership in June of this year, we are well-positioned to reach all segments of the retail food industry to promote participation in the voluntary nutrition labeling program.

II. BACKGROUND

A. Legal Authority

The Federal Meat Inspection Act and the Poultry Products Inspection Act (the Acts) broadly prohibit the misbranding of meat and poultry products. 21 U.S.C. § 601,

§ 610(d); 21 U.S.C. § 451, § 450.¹ Products will be considered misbranded under the Acts if the labeling that accompanies the products is false or misleading in any way. 21 U.S.C. §§ 453(h)(1), 601(n).

In 1991, USDA proposed nutrition labeling regulations for meat and poultry products. 56 Fed. Reg. 60302 (Nov. 27, 1991). FSIS stated that it had the statutory authority to require nutrition labeling based on the Secretary's determination that meat and poultry products, *other than single-ingredient, raw products*, would be misbranded in the absence of such information.² 56 Fed. Reg. at 60305. Final rules were promulgated in 1993 in which USDA simply reiterated the determination made in the preamble to the proposed rule that the Department possessed sufficient statutory authority; no further analysis, rationale, or support was provided.³ 58 Fed. Reg. 632, 637 (Jan. 6, 1993).

B. Current Nutrition Labeling Regulations

Generally, the current regulations require all packages of multi-ingredient and heat-processed meat and poultry products to bear on-pack nutrition labels. 9 CFR, Part 317, Subpart B; 9 CFR, Part 381, Subpart Y.⁴ The regulations specify the information that must be included and its location and format. See, e.g., 9 CFR § 317.309. The regulations include several exemptions, including one for small businesses because the Department determined that nutrition labeling would create an undue economic hardship, as well as a disincentive to develop more nutritious food products. See 9 CFR § 317.400; 58 Fed. Reg. at 638.

Although the regulations require on-pack nutrition labels for most multi-ingredient, heat-processed products, the current mandatory requirements do not apply to

¹ FMIA and PPIA are substantially similar in their statutory construction. Accordingly, for simplicity, our comments primarily cite only the FMIA provisions.

² The entire analysis of the Department's authority in the preamble to the proposed rule follows:
FSIS has determined that it has statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient raw products, would be misbranded in the absence of such information on the label, under section 1(n) of the Federal Meat Inspection Act and section 4(h) of the Poultry Products Inspection Act.

56 Fed. Reg. at 60305.

³ FSIS's complete analysis of its statutory authority in the preamble to the final rule follows:

In the proposed rule, FSIS stated that it had statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient, raw products, would be misbranded in the absence of such information under section 1(n) of the Federal Meat Inspection Act and section 4(h) of the Poultry Products Inspection Act.

58 Fed. Reg. at 637.

⁴ The nutrition labeling Part of the poultry regulations is substantially similar to the meat nutrition labeling regulations. Accordingly, for simplicity, we primarily cite only the meat regulations in these comments.

single-ingredient, uncooked meat and poultry products. 9 CFR § 317.345. As noted above, USDA determined during the rulemaking process that the absence of nutrition labeling would not render these products misbranded. The stated basis was the Agency's determination that consumers had reasonable expectations as to the nutritional qualities of these products because their nutrient value had not been modified through various stages of preparation. 58 Fed. Reg. at 637. In the preamble to the proposed rule, FSIS also noted that nutrition information for single-ingredient, raw products was available to consumers through a variety of resources, and specifically cited the Extension Service, grocery stores, and trade associations as examples. 56 Fed. Reg. at 60306.

In place of mandatory nutrition labels, FSIS promulgated regulations for a program of voluntary nutrition labeling for fresh, single-ingredient products. 9 CFR § 345. Under the current program, retailers may choose to provide nutrition information either on labels that are applied directly to the products or through point-of-purchase materials, such as signs, brochures, notebooks, or leaflets presented in close proximity to the food. 9 CFR § 317.345(a)(2). FSIS intended the information to be provided for the major cuts of meat and poultry products, which are identified in Sections 317.344 and 381.445 of the nutrition labeling regulations.

Although FSIS expressly recognized that the Agency "[did] not have a statutory mandate" to do so,⁵ FSIS also promulgated a regulation under which the Agency would determine whether "significant participation" in the voluntary program was achieved by retailers. 9 CFR § 317.343. FSIS stated that it would evaluate significant participation by conducting surveys of a representative sample of companies allocated by type and size every two years beginning in May 1995. *Id.* at § 317.343(c), (e). FSIS "will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated" are providing the correct information on at least 90 percent of the major, single-ingredient, raw products that are identified by the Agency and carried by the retailer. If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect. 9 CFR § 317.343(e)(1).

If not, the regulation states that FSIS will conduct rulemaking to require nutrition labeling on those products that are covered by the voluntary program. 9 CFR § 317.343(e)(2). The preamble to the 1993 final rule further explains the Agency's approach:

If the Agency determines during any evaluation of its voluntary guidelines that significant participation does not exist, the Agency will initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling on single-ingredient, raw meat and poultry products.

58 Fed. Reg. at 640.

⁵ 58 Fed. Reg. at 640.

C. Surveys Conducted by USDA

USDA conducted three surveys in an attempt to measure retailer participation in the voluntary nutrition labeling program.⁶

The first survey was conducted in June 1995.⁷ Researchers surveyed 1,988 stores for the presence of nutrition information, either in “old” or “new” format posters, brochures, or other point-of-purchase information or in labels affixed to packages of meat and poultry products. Eighty-three percent of the stores surveyed were large stores (defined as annual sales of more than \$2,000,000); the remaining seventeen percent of the stores were defined as “small” for purposes of the survey. The “large” store category was further subdivided between chains (four or more stores under common ownership) and independents (less than four stores under common ownership); large chains constituted 62.2 percent of the overall survey population.

The researchers concluded that 72.2 percent of large stores (chains and independents combined) and 38.6 percent of small stores provided either old or new nutrition information; overall, nutrition information was located in 66.5 percent of stores. On a volume-weighted basis,⁸ the overall rate of compliance was 72.2 percent.

The second survey, conducted in December 1996, surveyed 2000 stores for the presence of only “new” format nutrition information.⁹ Eighty-two percent of stores surveyed were large stores and eighteen percent were small stores; large chains constituted 66 percent of the overall survey population. In contrast to the 1995 Survey, no information on labels affixed to products appears to have been recorded.

The 1996 Survey reports a large store compliance rate of 61.7 percent and an overall “store count” compliance rate of 57.7 percent. The overall volume-weighted compliance rate was reported as 60.9 percent.

⁶ As discussed more fully below, FMI has significant concerns with the way in which the studies were conducted. We submitted a Freedom of Information Act (FOIA) request to USDA to obtain information to address some of these concerns, however, the Agency declined to provide us with the information we requested.

⁷ USDA, “Nutritional Labeling/Safe Handling Information Study: Raw Meat and Poultry” (Sept. 29, 1995) (hereinafter 1995 Survey).

⁸ The researchers calculated compliance rates on both a “store count” and an “all commodity volume” (ACV) basis. According to the report, the ACV data are “weighted estimates that represent annual store sales volumes and reflect the percent of the market serviced.” 1995 Survey at 5. Thus, ACV data “approximates [sic] more representatively than Store Count the percent of the population exposed to the nutrition labeling information.” Id.

⁹ USDA, “Nutrition Labeling/ Safe Handling Information Study: Raw Meat and Poultry” (Dec. 1996) (hereinafter 1996 Survey).

The most recent survey was conducted in October, 1999.¹⁰ Of the 2,000 stores that were surveyed, eighty-one percent were large stores, while the remaining were small stores. The percentage of the survey represented by large chains fell to 63 percent in the 1999 Survey. No information on nutrition labels was reported in the 1999 Survey. The report, which had a margin of error of +/- 4 percent, found that 65.5 percent of large chains offered nutrition information. Overall, the researchers calculated a 54.8 percent compliance rate on a “store” basis and a 62.8 percent compliance rate on a volume-weighted basis.

D. Proposed Mandatory Program

On January 18, 2001 FSIS proposed to amend the current nutrition labeling regulations. 66 Fed. Reg. 4970 (Jan. 18, 2001). The proposal has three essential elements: (1) mandatory nutrition labeling for major, uncooked, single-ingredient, whole cuts of meat or poultry; (2) mandatory on-pack nutrition labels for all ground or chopped products; and (3) optional statements of percentage lean and fat content for ground products. The proposal also includes specific exemptions. Each of these provisions is discussed below.

1. Proposed Mandatory Nutrition Labeling for Whole Cuts

a. Requirements

USDA intends to make the guidelines currently in place for the voluntary nutrition labeling program mandatory for the uncooked, single ingredient, whole cuts of meat and poultry that are currently covered by the voluntary program. 66 Fed. Reg. at 4973. Under the proposal, retailers would be required to provide nutrition information for the whole cuts of fresh products identified by FSIS in Sections 317.344 and 381.444, either through on-pack labels or point-of-purchase information. Proposed 9 CFR § 317.300(a); 381.400(a).

Proposed Section 317.345 sets forth the requirements that would apply to information provided through point-of-purchase materials, such as signs, brochures, notebooks or leaflets placed in close proximity to the food. The proposed regulation would allow the information to be presented in the simplified format described in proposed Section 317.309(f), although point-of-purchase materials would not be required to comply with any of the format requirements of the regulations. Proposed 9 CFR § 317.345(a)(3)(ii).

¹⁰ USDA, “Nutrition Labeling/Safe Handling Information Study: Raw Meat and Poultry” (Oct. 1999) (hereinafter 1999 Survey).

If information is provided through on-pack labels, it must comply with all provisions of Section 317.309, with some minor variations. For example, the information may be declared on either an “as packaged” or “as consumed” basis; unlike processed products, if declared on an “as consumed” basis, the “as packaged” information will not also be required. Moreover, the number of servings per container will not be required because these products are offered to consumers on a random-weight basis and the number of servings is not currently required on random weight products. 66 Fed. Reg. at 4974.

Nutrient data for the labels may be obtained from USDA’s National Nutrient Data Bank or from composite data that reflect different quality grades of beef or other variables affecting nutrient content. Proposed 9 CFR § 317.345(e). Nutrition information that is based on the USDA data will not be subject to Agency compliance reviews, unless a nutrition claim is made on the basis of the representative data base values. Proposed 9 CFR § 317.345(f). Retailers may also use data bases that they believe reflect the nutrient content of single-ingredient, raw products, however, such labels would be subject to compliance procedures. Proposed 9 CFR § 317.345(g).

b. Rationale

To support the proposal for mandatory nutrition labeling for major cuts of single-ingredient, uncooked meat and poultry products, FSIS stated that, without nutrition information, consumers are not able to assess the nutrient content for the major cuts and, thus, cannot make educated choices about these products based on nutrition information. 66 Fed. Reg. at 4973-74. As a result, “FSIS believes that the lack of this information on the labeling of the major cuts causes the labeling to be misleading.” 66 Fed. Reg. at 4974. Without the nutrition information for the major cuts of single-ingredient, raw products that would be provided if significant participation in the voluntary program existed, the Agency has tentatively concluded that these products are misbranded under the Acts. *Id.*

FSIS is proposing to allow the nutrition information for these products to continue to be provided on point-of-purchase materials because, the Agency asserts, “consumers have reasonable expectations as to the nutrient content of these products.” 66 Fed. Reg. at 4974. In addition, FSIS states that the nutrient content of a given major cut is relatively uniform across the market and whole cuts are not formulated. 66 Fed. Reg. at 4974. As a result, FSIS theorizes that nutrition information should be “relatively easy” to prepare and for consumers to use on point-of-purchase materials. *Id.*

2. Proposed Mandatory On-Pack Labels for Ground Products

a. Requirements

FSIS has proposed to require that all ground or chopped products and hamburger, with or without added seasonings, bear nutrition labels that appear directly on the package, unless an exemption applies. Proposed 9 CFR § 317.301. Products that would be covered by the regulation include raw hamburger, ground beef, ground beef patties, ground chicken, ground turkey, ground chicken patties, ground pork, and ground lamb. Nutrition information would be required to be provided on an “as packaged” basis for ground products, although producers could choose to add “as consumed” information as well, if clear preparation and cooking instructions were also included. Proposed 9 CFR § 317.309(b)(3).

FSIS proposes to verify compliance with the nutrition label regulations through a field monitoring and verification program. 66 Fed. Reg. at 4980. Specifically, FSIS intends to sample and conduct nutrient analyses of ground or chopped products in conjunction with the Agency’s current *Escherichia coli* O157:H7 testing program to verify compliance with nutrition labeling requirements, even if nutrition labeling is based on the most current representative data base values contained in USDA’s National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference and there are no claims on the labeling. See 66 Fed. Reg. at 4980.

For ground or chopped products that are labeled with nutrition information at official establishments, FSIS program employees will collect samples for nutrient analysis at the establishments. 66 Fed. Reg. at 4980. However, if the product is further processed at retail, FSIS will sample at retail instead. *Id.*

b. Rationale

In support of the proposal to require nutrition labels for ground products, FSIS states the following. First, the Agency claims that consumers cannot easily see the fat in ground or chopped products and, therefore, consumers do not have a basis upon which to compare the levels of fat in these products to fat levels in other products. 66 Fed. Reg. at 4975.

Second, FSIS believes that ground products are highly formulated, with fat percentages varying by only two percentage points around the average fat percentage. 66 Fed. Reg. at 4976. The Agency cites this information as proof that ground product “can be and is precisely formulated and within the control of the producer.” *Id.* Furthermore, according to FSIS, many ground beef producers use quality control programs to control the fat content of product, which is verified through regular sampling and testing. *Id.* FSIS notes that there are numerous formulations of ground or chopped products and concludes that “it would be difficult for producers or retailers to develop point-of-purchase materials that would address all the different formulations that would exist for these products.” *Id.* at 4977

Third, FSIS reports that the nutrient profile of ground products varies depending on their formulation. Specifically, with respect to beef and pork, some producers (other than retailers) use meat from advanced meat recovery (AMR) systems and low temperature rendering in ground or chopped beef products. *Id.* at 4976. For poultry products, FSIS notes that the source of the product (e.g., skin, light meat, dark meat) will affect the fat content and nutritional profile of the resulting ground product.

FSIS concludes that the variation in the fat and nutrient content of different ground or chopped products, their “formulated nature,” and the fact that the fat content of these products cannot be readily assessed visually makes it difficult for consumers to have reasonable expectations as to the nutritional quality of these products. *Id.* at 4977. In the absence of reasonable consumer expectations, USDA assumes that labels on ground products will be misleading to consumers unless they include nutrition information. *Id.*

3. Percentage Lean/Fat Statements

FSIS proposes to amend its regulations to expressly allow the use of percentage statements for lean and fat content on the labels of ground products. Proposed 9 CFR § 317.362(f). Specifically, the proposed regulations would permit labels of ground or chopped products to bear a statement of the lean percentage of the product, provided that a statement of the fat percentage was contiguous to the lean statement and the lettering appeared in the same color, size, type and on the same color background as the lean percentage statement. *Id.* Label statements of this type would be permitted regardless of whether the product meets the criteria for “low fat,” as defined in Section 317.362(b)(2).

Proposed Section 317.362(f) would codify the informal FSIS policy allowing percent fat/percent lean statements that has been applied by retailers and relied upon by consumers for nearly a decade.¹¹ In the preamble, FSIS notes that lean percentage statements provide “a quick, simple, accurate means of comparing all ground or chopped meat and poultry products.” 66 Fed. Reg. at 4981.

4. Proposed Exemptions

a. Small Business Exemption

FSIS has proposed to amend the small business exemption from the nutrition labeling regulations to clarify that ground or chopped products produced by a single retail store or multi-retail store operation could qualify for the small business exemption.

¹¹ See 59 Fed. Reg. 26916 (May 24, 1994) (proposal to amend regulations to permit percentage labeling for lean and fat content); 59 Fed. Reg. 39941 (Aug. 5, 1994) (notice of extension of compliance date for nutrition labeling as it applies to ground beef and hamburger until Agency completes rulemaking on proposal to allow percent fat/percent lean statements).

Proposed 9 CFR § 317.400(a)(1). To qualify for the exemption under the proposed amendment, the retail facility (either a single retail store or a multi-store operation) must employ a total of fewer than 500 employees and produce no more than 100,000 pounds per year of the product that qualifies the establishment for an exemption. 66 Fed. Reg. at 4978.

In contrast, FSIS is proposing to amend the small business exemption to exclude the labeling requirements associated with major cuts of single-ingredient, raw products. Thus, all retailers, regardless of their size or resources, would be required to provide nutrition labeling for whole cuts and subject to penalties for failure to do so. As a basis, the Agency states only that, "FSIS intends to make point-of-purchase materials available over the Internet free of charge." 66 Fed. Reg. at 4974.

b. Multi-Ingredient Products Prepared at Retail

FSIS is proposing that the current exemptions from nutrition labeling for multi-ingredient or ready-to-eat products packaged or portioned at retail would not apply to ground or chopped products, unless another exemption, such as the small business exemption applies. 66 Fed. Reg. at 4975, 4979. The current exemption is based on the understanding that meat and poultry products prepared at retail constitute an insignificant proportion of the diet. 66 Fed. Reg. at 4978, citing 58 Fed. Reg. at 639. In contrast, FSIS believes that a significant amount of ground beef is processed at retail. Accordingly, the Agency has proposed not to allow ground or chopped products to qualify for the current exemption for multi-ingredient or ready-to-eat products. *Id.*

II. COMMENTS

A. FMI Supports FSIS's Proposal To Authorize Use of Percentage Fat and Lean Statements

FSIS has proposed to allow statements that describe the lean and fat percentage of ground or chopped products to appear on the labels of those products, provided that the lettering and color requirements described above are met. Proposed 9 CFR § 317.362(f). Our research¹² indicates that consumers understand this information and continue to rely on it in making their purchasing decisions. Accordingly, we support USDA's proposal and urge the Agency to promulgate the regulation that will provide retailers with a voluntary means of providing consumers with the information that they use regarding their ground products.

¹² FMI participated in research concerning nutrition labeling. A summary is enclosed for your information.

1. Consumers Rely On and Understand Percentage Fat/Lean Statements and Will Not Be Misled by Them

Percent fat/percent lean statements provide a simple and easy method for consumers to compare the fat content in ground products. Consumers rely on percent fat/percent lean statements in choosing ground products, particularly ground beef.¹³ When asked for their recall – unaided by the surveyor – of wording on labels of ground beef that they buy, thirty-four percent of respondents identified a particular cut of meat (*e.g.*, sirloin, chuck). Twenty-three percent cited information regarding percent fat or percent lean content of the product. Wirthlin Worldwide, “Public Understanding of Ground Beef Labeling” at 10-11 (March 2001) (hereinafter “Wirthlin Study”).

In the preamble, FSIS asked whether percentage fat/lean statements will mislead consumers in any way. 66 Fed. Reg. at 4981. Our research indicates that consumers understand the meaning of percentage content statements and are not misled by them.

Specifically, in the Wirthlin study, consumers were asked what a label that said “percent lean” and “percent fat” meant to them. Wirthlin study at 14-15. By far the most popular response (40%) was fat percentage or fat content. An additional one-quarter (24%) of respondents interpreted the phrase to refer to the percentage of meat in the product. Thus, nearly two-thirds of respondents understood that the phrase referred to the fat and meat content of the product. Moreover, when read a list of leanness designators ranging from 70% lean to 93% lean, three-quarters of respondents (76%) were able to correctly identify that “93% lean” ground beef has the lowest fat content. Wirthlin Study at 13-14. Accordingly, consumers understand percentage fat/lean statements and will not be misled by them.¹⁴

2. Replacing Percentage Fat and Lean Statements with “Reduced Fat” Labeling Will Confuse Consumers

FSIS states that a private group has petitioned the Agency to authorize “reduced fat” labeling instead of percentage fat/lean statements. FMI does not support the approach of comparative labeling suggested by the petitioner because it would penalize retailers who offer only the leanest products and do not offer those with higher fat contents.

¹³ A study conducted as early as 1994 showed that shoppers prefer labels describing the cut of beef along with a “percent lean/percent fat” statement. Specifically, four out of ten shoppers preferred labels with full descriptions, *e.g.*, “Ground Beef 70% lean/30% fat;” thirty percent of shoppers preferred “Ground Beef, 70% lean.” Ground Beef Nomenclature and Knowledge Survey (March 1994).

¹⁴ In the preamble, FSIS asked whether the statement should be required to appear in either “percent lean/percent fat” or “percent fat/percent lean” format. USDA should not mandate either format. Consumers understand the information regardless of the order in which it is presented.

For example, many retailers sell regular ground beef (70% lean). However, the retailers that have cultivated the highly health conscious segment of the market offer only those ground meat products that have a lean content of 80 percent or more. If USDA adopted a comparative claim approach, consumers would be misled and the retailer that has been offering lower fat products would be penalized because the basis for comparison would be a different and much leaner product. Specifically, in a store that offers 70% lean product, an 85% lean product would bear a "50% reduced fat" label; however, in a store that offers product with no more fat than 20% fat, the same 85% lean product would be labeled "25% reduced fat." Thus, the comparative claims approach would be an incentive for retailers to offer products with the highest fat levels so that the retailers could make the strongest comparative claims. We further expect that "reduced fat" labeling would be confusing to consumers who understand and have come to rely on the percentage fat and lean statements that are currently in use.

3. FSIS Should Specify Tolerance for Percentage Content Statements Comparable to Tolerance Allowed for Nutrient Value Variations

Retailers use good manufacturing practices (gmp's) to produce ground beef products that have specific, different levels of fat content and to label them accordingly. The nutrition label regulations and the preamble to the final rule include a tolerance for discrepancies up to 20 percent between the labeled value and the analyzed value for the nutrient information that must be provided on nutrition labels. 9 CFR § 317.309(h); 58 Fed. Reg. at 660-61. Although percentage fat/lean statements are considered claims rather than declarations of nutrient value, we believe it is appropriate to recognize a tolerance for percent lean/fat statements, as well.

The meat and poultry products that are the basis of ground products are natural products that will have natural variability of fat content. Even with the exercise of a sound gmp program, some variability in fat/lean content of the source material is inevitable. Accordingly, we recommend that the final rule include recognition of the variation by providing for a tolerance that can be applied for compliance verification and enforcement purposes.

B. Mandatory Labeling Regulations for Major Cuts of Raw, Single-Ingredient Meat and Poultry Products Are Unsupported by Statutory Authority, Unnecessary To Prevent Misbranding, and Unjustified by FSIS's Surveys

1. The Acts Do Not Impose Statutory Mandate on or Provide Sufficient Authority for FSIS To Promulgate Mandatory Nutrition Labeling Regulations for Uncooked, Single-Ingredient Meat and Poultry Products

As noted above, the meat and poultry Acts prohibit the performance of any act that would cause meat or poultry products to be adulterated or misbranded. Products will be misbranded under the Acts if their labeling is false or misleading in any particular. The Acts do not, however, direct USDA to promulgate nutrition labeling regulations, or give the Agency sufficient authority to mandate nutrition labeling for fresh, single ingredient meat and poultry products.

In determining the scope of USDA's authority under the meat and poultry Acts, it is useful to consider the authority provided to the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act (FD&C Act) to regulate foods other than those covered by the meat and poultry Acts. 21 USC, §§ 301, et seq. Specifically, and similarly to the meat and poultry Acts, the FD&C Act broadly prohibits the adulteration or misbranding of food and food will be considered misbranded under the FD&C Act if its labeling is false or misleading in any particular. 21 USC §§ 331(a), 343(a)(1).

In contrast to the general authorities set forth in the meat and poultry Acts, the FD&C Act also includes specific provisions regarding nutrition labeling; these were added in 1990 when Congress amended the FD&C Act by passing the Nutrition Labeling and Education Act (P.L. 101-535) (NLEA). Most relevant to the present inquiry, the NLEA amended the FD&C Act provision defining "misbranded food" to add a new paragraph that specifically states that food regulated under the FD&C Act will be misbranded if its label or labeling fails to bear the nutrition information specified in the NLEA. 21 USC § 343(q). The NLEA further directs the Department of Health and Human Services and (by extension FDA) to issue proposed and then final regulations within specific time periods to establish a comprehensive nutrition labeling program for the non-meat and non-poultry foods regulated by FDA. See PL 101-535, Sec. 2(b).

Two important conclusions may be drawn from the foregoing comparison of the primary statutes that regulate the food supply and, in many respects, are quite similar. First, Congress has not directed USDA to promulgate nutrition labeling regulations for meat and poultry products. The legislature considered and debated the issue of nutrition labeling, the information that should be provided to consumers, and how best that purpose might be accomplished. Congress then chose to amend only the FD&C Act to require HHS and FDA to promulgate nutrition labeling regulations for foods regulated by FDA; Congress did not amend the meat and poultry Acts in the same manner. Accordingly, USDA does not have a Congressional mandate to issue nutrition labeling regulations for meat and poultry products.

Second, unamended by a legislative vehicle comparable to the NLEA, the meat and poultry Acts do not give USDA the statutory authority to mandate nutrition labeling

for raw, single-ingredient meat and poultry products.¹⁵ When Congress decided that nutrition labeling was important for food products other than meat and poultry, the legislature considered the FD&C Act and concluded that “there is no requirement that nutrition information be required.” House Report No. 538, 101st Cong. at 8, *reprinted in* 1990 U.S. Code Cong. Admin. News 3336, 3338. Indeed, the stated purpose of the NLEA is “to clarify and strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods.” *Id.* at 7, *reprinted in* USCCAN at 3337.

Toward this end, Congress amended the statutory standard for “misbranded” foods to include foods with labeling that fails to provide specific nutrition information. P.L. 101-535, Sec. 2(a), codified at 21 USC § 343(q). If Congress had concluded that FDA had sufficient authority under the general provisions of the FD&C Act, (which are comparable to those in the meat and poultry Acts), Congress could simply have directed the Agency to promulgate regulations regarding nutrition labeling under the Agency’s duty to prohibit “false and misleading” labeling.

Thus, Congress apparently concluded that the general authorities in the pre-NLEA FD&C Act did not provide a sufficient statutory basis upon which to promulgate nutrition labeling regulations and amended the FD&C Act to give FDA the necessary authority. Likewise, the general authorities in the meat and poultry Acts do not provide a sufficient basis to promulgate nutrition labeling regulations for uncooked, single-ingredient meat and poultry products. If Congress had wanted to require nutrition labeling for meat and poultry products, Congress would have amended the meat and poultry Acts either through the NLEA or a comparable vehicle to provide USDA with a mandate and authority similar to that granted to FDA.

2. Fresh, Single-Ingredient Meat and Poultry Products Are Not Misbranded without Nutrition Labeling

Even if we assume, *arguendo*, that the general authorities of the Acts provide a sufficient legal basis upon which to promulgate nutrition labeling regulations for some meat and poultry products, uncooked, single-ingredient meat and poultry products are not misbranded in the absence of nutrition labeling.

In the preamble to the proposed nutrition labeling regulations, FSIS repeatedly distinguishes uncooked, single-ingredient products from prepared products. Indeed, FSIS refers to the Secretary’s determination “that meat and poultry products *other than single-ingredient raw products*, would be misbranded in the absence of” nutrition labeling when justifying its decision to promulgate regulations for prepared products. 56 Fed. Reg. at 60305 (emphasis added). Clearly, if USDA had determined that single-ingredient raw products were misbranded without nutrition labeling, the Agency would have included

¹⁵ Whether or not the Agency has the authority to issue nutrition labeling regulations for processed meat and poultry products is beyond the scope of the present inquiry.

these products in the provisions of the mandatory program when it promulgated regulations in 1993.

FSIS's 1993 determination that the absence of nutrition labeling information would not render these products misbranded appears to be based on two factual determinations: (1) consumers had a reasonable expectation as to the nutritional qualities of these products because their nutrient value had not been modified through various stages of preparation and (2) nutrition information for these products was available to consumers through other means "such as the Extension Service, grocery stores, and trade associations." See 58 Fed. Reg. at 637; 56 Fed. Reg. at 60306. FSIS did not provide any measure of either consumer expectations regarding the nutrient value of products or of the nutrition information available to consumers at the time.

Despite FSIS's protestations to the contrary in the preamble to the instant proposal, the rationale offered for concluding that uncooked, single-ingredient meat and poultry products are not misbranded without nutrition labeling information is just as valid today. That is, the instant FSIS preamble provides no basis to believe that consumers have any less of a reasonable expectation as to the nutritional qualities of these products.¹⁶ Similarly, USDA has not provided any information to support the relative claim that less information is available today than was available in 1993. Indeed, with the advent of the Internet, we would posit that consumers have *more* sources of information available to them today than they did in 1993.¹⁷

In the preamble to the current proposal, FSIS adds the following rationale:

[W]ithout nutrition information, consumers cannot assess the nutrient content of the major cuts and thus cannot make educated choices about these products. FSIS believes that the lack of this information on the labeling renders the labeling misleading [and, therefore, misbranded].

¹⁶ Indeed, in its attempts to distinguish whole cuts from ground products later in the preamble, the Agency repeatedly asserts that consumers have a reasonable expectation of the nutrition profile of whole products, but not ground products. If consumers already have "reasonable expectations as to the nutritional qualities of these products," consumers are not being misled without mandatory nutrition labeling.

¹⁷ Today, 64 percent of consumers have access to a personal computer with Internet access. FMI, "Trends in the United States: Consumer Attitudes & the Supermarket" at Table 44 (2001). Indeed, in the Wirthlin Worldwide survey that we conducted, consumers cited at least sixteen different sources of nutrition information in response to an unprompted question. These included the following: package label, signs in meat department, butcher, Internet, magazines, newspapers, television, radio, cookbook, textbooks, doctor, and friends or family. Moreover, many retailers today provide percentage fat and lean statements on labels of ground products, thereby providing consumers with information on the nutrition fact that they care most about.

66 Fed. Reg. at 4973. In the absence of the nutrition information that would have been available if significant participation in the voluntary program had been achieved,¹⁸ FSIS concludes that fresh, whole cuts are misbranded unless they have nutrition labeling.

The Agency's reasoning here suffers from the same failure noted above: FSIS has made no showing that there is any less information available to consumers today than there was in 1993. FSIS states above that without nutrition *information* (not even labeling) consumers cannot assess their meat products. However, consumers have many sources of nutrition information beyond labeling, therefore, its absence on the labeling cannot render the labeling misleading or the product misbranded.¹⁹ Even FSIS's claims that less than sixty percent of retailers provide nutrition labeling is an insufficient basis to conclude that less nutrition information is available today since FSIS has provided no data on the level of availability or retailer participation in 1991 or 1993.

The preamble notes that a petitioner has asked USDA to require nutrition labeling for all fresh meat and poultry products so that they would be consistent with FDA's regulations. See, e.g., 66 Fed. Reg. at 4981. However, the law upon which FDA's regulations are based clearly treats fresh, unprocessed commodities (in this case, fruits, vegetables, and seafood) differently from all other foods. 21 USC § 343(q)(4). Thus, consistency with FDA's regulations and, more importantly, the FD&C Act, would mitigate in favor of the continued voluntary program for fresh meat and poultry products. Moreover, industry estimates indicate that there are over 3,000 whole muscle cuts of beef alone. Obtaining data for all possible cuts would pose substantial logistical difficulties for retailers.

3. Retailers Have Achieved "Significant Participation" in Nutrition Labeling Program, So Voluntary Nutrition Program Should Remain in Effect

USDA's regulations state that, "[I]f significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect." 9 CFR § 317.343(e)(1). The regulations further elaborate on a showing that will satisfy the "significant participation" standard.

¹⁸ FMI's concerns with respect to the design, conduct, and conclusions of the surveys that USDA relies upon to conclude that "significant participation" has not been reached are discussed below.

¹⁹ Indeed, as much of the data for uncooked, single-ingredient meat and poultry products is generated by USDA, the Agency can post the information on its website and publicize its availability. Under NLEA, HHS is directed by Congress to "carry out activities which [sic] educate consumers about the availability of nutrition information in the label or labeling of food." PL 101-535, Sec. 2(c)(1). USDA might conduct a similar educational campaign to raise awareness regarding the nutrition information that is currently available.

Specifically, Section 317.343(d) states that, “FSIS *will find* that significant participation by food retailers exists if at least sixty percent of all companies that are evaluated are participating in accordance with the guidelines.” 9 CFR § 317.343(d) (emphasis added). A retailer will be participating in accordance with the guidelines if it provides nutrition labeling information for at least ninety percent of the major cuts that the retailer sells, provided that the nutrition label or labeling conforms to the regulatory standards. 9 CFR § 317.343(b). In order to determine whether “significant participation” is achieved, USDA’s regulations state that the Agency “will evaluate significant participation of the voluntary program every 2 years beginning in May 1995” by surveying a representative sample of companies allocated by type and size. 9 CFR § 317.343(c), (e).

Toward this end, USDA hired a research firm to conduct three surveys of retailer participation in the voluntary nutrition labeling program. According to USDA, the first study, which was conducted in September, 1995, showed that 66.5 percent of stores surveyed provided either “old” or “new” format nutrition information. In the December, 1996 study, the research group found that 57.7 percent of stores surveyed provided “new” nutrition information. According to the most recent survey, 54.8 percent of stores surveyed provide “new” nutrition information.

Even if we assume for purposes of discussion here that the surveys were properly conducted and that the results are an accurate reflection of retailer participation and the composition of the marketplace (assumptions that are disputed below), the regulations are sufficiently flexible to allow USDA discretion in determining whether the survey results establish that retailers have met the “significant participation” standard. In particular, the regulations mandate that the voluntary program must continue if significant participation is found and require the Agency to find significant participation if 60 percent of retailers are providing information on 90 percent of products carried. However, the regulations do not preclude the Agency from finding “significant participation” on another basis.²⁰

Specifically, if we assume that USDA has the authority to promulgate these regulations in the first place, the Agency also has the authority to decide that any meaningful level constitutes “significant” participation. “Significant” is defined as “having meaning” or being “important.” Webster’s II New College Dictionary at 1027 (1995). Thus, even a result less than a majority might be deemed “significant.”

Furthermore, given current consumer shopping patterns and the state of the retail food industry today, the more important means of evaluating consumer exposure to nutrition information is not the number of physical stores that have provided the information, but the volume of product sold by stores that carry the information. The suggestion that “significant participation” is properly determined by looking at the

²⁰ Indeed, given the minimal justification in the preamble, the sixty percent standard might even be considered arbitrary and capricious.

number of stores arises from the provision added to the FD&C Act by the NLEA in 1990, which requires FDA's regulations to find that, "there is not substantial compliance if *a significant number* of retailers have [sic] failed to comply with the guidelines." 21 USC § 343(q)(4)(B)(ii) (emphasis added).

As the Agency is undoubtedly aware, and as discussed more fully below, significant changes have occurred in the composition of the retail food industry since the NLEA was enacted in 1990. Specifically, the number and ownership of stores have changed to an extent not reflected in the survey samples. New formats, such as supercenters and warehouses, that account for a significant volume of retail food sales have emerged in the past decade. Sales of all products, including meat and poultry, have shifted to these formats and to other stores that would fall within the "large chain" category described by USDA.

Moreover, regardless of the composition of the retail food industry, consumers shop at multiple stores and often choose to purchase different items at different locations.²¹ Thus, consumers are likely to have access to nutrition information through at least one of the multiple stores at which they shop. Moreover, nine percent of respondents indicated that they make food purchases from stores other than their primary store for better quality meats. Trends 2001 at Table 24. Thus, consumers exercise care in the purchase of their meat and poultry products, and are willing to make an extra effort to ensure the quality of the product.²²

Given the change in the industry and consumer shopping patterns, it is more appropriate for USDA to evaluate "significant participation" by considering the volume-weighted percentage at which nutrition information was provided. In the first survey, which was designed to include both "old" and "new" information, nutrition labeling information was provided on a volume-weighted basis 72.2 percent of the time; however, "new" information was provided on a volume-weighted basis 59.1 percent of the time. Since then, the volume-weighted basis at which nutrition information has been provided has steadily increased to 60.9% in 1996 and 62.6% in 1999.²³

²¹ Consumers average 2.2 trips to the grocery store each week; more than three-quarters (77%) of shoppers visit two or more stores per month and more than 40 percent visit three or more stores per month. Trends 2001 at Table 21. In contrast, in 1996, the earliest year for which we have this statistic, nearly half (46%) of respondents said that they shopped at their primary grocery store every time. Trends 1996 at Table 25.

²² Consumers today find and utilize nutrition information at their grocery stores. Sixty-seven percent of consumers said that their primary grocery store provides nutrition and health information; 57 percent of shoppers said that they use this information at least once per month. Trends 2001 at Tables 15-16.

²³ These figures implicitly rely on USDA's view of the retail marketplace, which, as discussed more fully below, we do not believe is accurate; even higher percentages of compliance would be reflected if the surveys had relied on samples that accurately reflected today's retail food industry and omitted the stores that are excluded under the small business exemption.

In the absence of a statutory mandate to determine “significant participation” by one particular method and given the flexibility in the language of the nutrition labeling regulations on this issue, USDA has the discretion to determine “significant compliance” by a method that is more appropriate than the one outlined in the regulations. In light of the significant changes in the previous decade in the retail food industry, and the methods available for consumers to obtain nutrition information (including supermarket websites), consumer purchasing patterns, the volume-weighted average basis is clearly the most appropriate method to determine whether “significant participation” has been achieved. Accordingly, we urge USDA to adopt this approach, to conclude that “significant participation” has been achieved, and to retain the current voluntary nutrition labeling regulations.

4. Surveys Conducted Do Not Provide Proper or Reliable Basis To Determine Significant Participation of Retail Food Industry

Upon review of the survey reports, FMI had concerns regarding the manner in which the studies were conducted and the effect on the integrity and validity of the studies. In an attempt to obtain information to address some of these, we filed a Freedom of Information Act (FOIA) request with the Agency on February 22, 2001 seeking the following information:

Any and all data and assessments gathered or generated by any USDA officials or contractors, including National Retail Tracking Index or Retail Diagnostics Incorporated (RDI), that were used in the preparation of the “US Department of Agriculture Nutrition Labeling/Safe Handling Information Studies” for raw meat and poultry that were issued in September, 1995, December, 1996, and October, 1999. Our request generally includes the forms and other raw data gathered by the inspectors when they visited each location. We already have copies of the reports themselves; we are specifically interested in the survey results that were tabulated to produce the reports. We also request copies of all training materials provided for or given to the individuals who visited stores and all information related to the manner in which the stores visited were selected.

On March 28, the Agency responded that they were searching for the information that we had requested. On May 15, the Agency denied our request stating that the information we requested was “not in the possession of the government nor were copies maintained by the Agency” and that USDA had no records beyond the information in the published reports regarding the manner in which stores were sampled.

- a. Surveys Were Not or May Not Have Been Conducted in Accordance with FSIS Regulations

We have several concerns with the way in which the surveys were conducted. First, FSIS's regulations affirmatively state that the surveys will be conducted every two years beginning in May 1995. Although the first survey was conducted in June, 1995 (and reported in September 1995), the second survey was conducted only eighteen months later, in December 1996. The third survey was conducted in October 1999, nearly three years after the second survey. The difference in survey intervals is contrary to USDA's regulations and, thus, the surveys should not be used as a basis for determining "significant participation."

Second, the preamble to the final rule states that the survey sample "shall cover all chain companies and a representative sample of independent companies." 63 Fed. Reg. at 640; see also 61 Fed. Reg. at 60307. Although the introduction to the survey results describes the numbers of stores in each of three categories (large chain, large independent, small independent) that were sampled, it does not state whether every chain company was included. Moreover, several new retail food formats have emerged over the past decade. These include the supercenter and wholesale club stores that now represent a significant proportion of the retail food market. Despite the significant role that these formats play in the retail food industry, they are often overlooked when those less familiar with the industry consider its composition. Thus, we would not be surprised if the survey failed to include them, although their exclusion would have seriously biased the results and precluded it from being the "representative sample" of retailers envisioned by Section 317.343(c).²⁴

Similarly, we question the basis upon which the Agency decided to apportion the samples among large chains, large independents, and small independents. No information was provided on this issue and our request for information was denied. However, the percentages on their face do not square with our experience in the industry. For example, USDA assumed that large chains comprised 66 percent of stores in 1996, but only 63 percent of stores in 1999. Trends in the industry suggest that the proportion of stores owned by large chains would have increased from 1996 to 1999.

Third, neither the 1996 nor the 1999 surveys report on nutrition information that was applied in label form directly to the package. In 1995, more than 25 percent of stores used labels to convey nutrition information. See 1995 Survey at Table 11. The introduction to the 1996 study states that labels affixed to packages were only recorded if the primary forms (poster, panel, pamphlet, brochure or notebook) were not present, however, the category type is not included in the results. See 1996 Survey, Table 12. The introduction to the most recent survey notes that nutrition labels are one way to establish compliance with the voluntary program and yet nowhere does information on the rate of nutrition label usage appear. We know that several of our larger members offer "case ready" beef and poultry products that are pre-packaged by the processor with

²⁴ If the Agency had responded to our FOIA request, we would have had this information so that we would have been in a better position to understand the types of stores that USDA included in the study.

nutrition labels attached. As this information does not seem to have been captured by the surveys, we are concerned that the surveys do not accurately reflect the nutrition information currently provided by retailers.²⁵

Fourth, we are concerned that the sampling may not have properly reflected the full standard set forth in Section 317.343. Specifically, the regulation states that a retailer will be deemed to be participating at a significant level if the retailer provides nutrition information for at least 90 percent of the major cuts of uncooked, single ingredient products *that the retailer carries*. Thus, retailers are not responsible for providing nutrition information for non-major cuts that they carry or for major cuts that they do not carry.

In the section of the introduction to the 1999 Survey that discusses methods of compliance, the report states that the presence of an “FMI ‘new’ format vehicle” would document automatic compliance with the standard. The presence of the “generic vehicle” would also be sufficient, except if: “the generic vehicle failed to include all 45 major meat/poultry items” or if the generic vehicle was in three or more parts and one was missing. See 1999 Survey at 8. Although the standard only requires retailers to offer labeling on products that the retailer sells, the description in the report sounds as if the field representative would deem the store non-compliant if information on less than all 45 items was presented, regardless of the number of products offered by the retailer. For example, a retailer that carried only twenty of the major cuts of meat and poultry would be in compliance if labeling was available for eighteen of those, even if no information was provided for the other twenty-seven cuts listed in Section 317.344. Without the information we requested under FOIA, we are concerned that the survey applied an improper standard.

Fifth, we suspect that the survey included stores that are properly exempt from the nutrition labeling guidelines. Specifically, Section 317.400(a) broadly states that meat and poultry products produced by small businesses “are exempt from nutrition labeling;” the language clearly encompasses both mandatory and voluntary nutrition labeling. The fact that FSIS is proposing to disallow the small business exemption for whole cuts under the proposed mandatory program is further evidence that the exemption now applies to nutrition labeling and small retailers. Clearly, USDA believes that the language of the current regulation encompasses retailers, because the only proposed change in this regard is to specify that the term “single-plant facility” *includes* single retail stores and the phrase “multi-plant company/firm” *includes* multi-retail store operations. If the Agency did not interpret the terms to include retailers already, FSIS would have proposed broader amendatory language to achieve the goal of adding them to the regulation.

²⁵ Although not necessarily labeling, *per se*, we note that some retailers offer nutrition information on their websites. The surveys underrepresent the quantity of nutrition information available to consumers to the extent that the surveys do not capture this vehicle.

We suspect that many of the small independent stores that USDA surveyed with annual sales between \$500,000 and \$2,000,000 also have fewer than 500 employees and produce less than 100,000 pounds of each product annually, the litmus tests for the small business exemption.²⁶ See 9 CFR § 317.400(a)(1)(ii)(C). Accordingly, these retailers qualify for the small business exemption and are, therefore, exempt from nutrition labeling under Section 317.400. As a result, these stores should not be included in the surveys. Including exempt stores skews the results downward; therefore, the results do not accurately reflect the level of participation envisioned by the regulations.

b. Concerns Regarding Integrity of Study

In addition to the issues noted above, we are concerned with the way in which the study was conducted. Specifically, the studies rely exclusively on data gathered by an unknown number of surveyors who were responsible for accurately evaluating the information available in 2000 supermarkets across 48 states. Accordingly, the instructions provided to and the oversight of the survey takers is essential to the validity and integrity of the survey results. For this reason, we requested information from USDA through FOIA; unfortunately, the Agency chose not to provide us with any of the information that we requested.

For example, we were interested in the following: Were field representatives told to walk in and look in the meat and poultry departments? Or did they look throughout the store to see if the information was available?²⁷ How were field representatives compensated? Were they paid by the number of stores that they surveyed? How many stores were the samplers responsible for surveying each day? Did the firm perform any quality control to ensure that the survey takers accurately recorded the nutrition information in the stores? All of this information is essential to the integrity of the surveys and the validity of the results.

We find it astonishing that the Agency does not have access to the training materials that were provided to the survey takers. (FSIS certainly had access to the “contract requirements” in which the introduction to the 1999 survey said that the researchers were “trained.” See 1999 Survey at 6.) This lack of knowledge suggests a

²⁶ One survey of the food industry that FMI conducts annually indicates that nearly all stores with annual sales up to \$10 million have fewer than 500 employees. FMI, “The Food Marketing Industry Speaks: 2001” (Detailed Tabulations) at 3-2 (2001). Although this statistic does not reflect the amount of different types of products produced by these stores, it certainly suggests that some, if not all, of the “small stores” included in the survey (which were defined as having sales between \$500,000 and \$2,000,000) are properly considered exempt from nutrition labeling.

²⁷ The results of the 1995 Survey include the location at which the information was found in the store, e.g., meat department, customer service, rebate island, checkout, other. See 1995 Survey at Table 14. Neither the 1996 nor the 1999 Surveys includes this information. As the regulations do not specify the location of the information in the store, any of these locations should be a basis for compliance. If the 1996 and 1999 Surveys failed to check other areas of the store, they applied a different standard from the one used in 1995 and provided for in the regulation.

lack of control over the study that undermines FSIS's ability to use and rely upon the study as a reasonable or credible basis for a rulemaking of this magnitude and importance.

C. Requiring On-Pack Nutrition Labels for Ground Products Is Unsupported by Acts and Poor Policy Because It May Obscure Products and Reduce Variety of Ground Products Available to Consumers

In addition to the concerns expressed above regarding FSIS's general authority to mandate nutrition labeling for uncooked, single-ingredient meat and poultry products as a class, we have the following concerns related specifically to the proposal to mandate on-pack nutrition labels for ground products.

1. Ground Products Are Not "Misleading" To Consumers in the Absence of On-Pack Nutrition Labels

As discussed more fully above, USDA is proposing to require all ground meat and poultry products to bear on-pack nutrition labels similar to those provided for processed meat and poultry products. USDA has tentatively concluded that ground products without nutrition labels are misbranded because consumers do not have "a reasonable expectation of the nutritional quality of these products." 66 Fed. Reg. at 4977. USDA rests its tentative conclusion on the following three reasons:

- The use of meat from advanced meat recovery (AMR) systems changes the nutritional profile of the product;
- The fat content is difficult to assess visually; and
- The fat content can be controlled by the producer.

66 Fed. Reg. at 4975-77. As discussed more fully below, USDA's analysis of the facts and subsequent conclusion are erroneous.

a. Presence of AMR Does Not Change Nutrient Profile in a Manner that Would "Mislead" Consumers within the Meaning of the Acts

USDA asserts that producers sometimes use meat from AMR and low temperature rendering in ground or chopped beef products. As USDA notes, these products are "considered beef and can be used in ground or chopped meat products" in accordance with USDA's regulations. 66 Fed. Reg. at 4975. Indeed, FSIS, through chemical composition tests and nutritional analysis has determined that AMR is the same as meat and, as such, does not need to be identified or labeled. According to USDA, producers use these products at no more than to10 percent in ground beef to achieve specific lean contents. 66 Fed. Reg. at 4976.

The Agency claims, however, that the presence of AMR affects the nutrient content of ground products to the extent that consumers cannot have a reasonable expectation of the nutritional quality of the products. In support of this assertion, the Agency provides the following statistics:²⁸

	<u>Cholesterol</u>	<u>Iron</u>	<u>Calcium</u>
Regular Ground Beef	85 mg	1.7 mg	8 mg
Ground Beef with 10% AMR	86.7 mg	2.09 mg	18.7 mg
Ground Beef with 10% AMR	88 mg	1.81 mg	18.0 mg

66 Fed. Reg. at 4976. Although the level of cholesterol is slightly elevated (2-3%) in the products with AMR, we suspect that the increase is within the level of variability that naturally occurs in meat products.²⁹ Thus, although the data cited by USDA might generate compliance discrepancies for ground beef nutrition labels if such labels were required, *the change in nutrient levels that may result from the use of AMR in some ground beef products does not rise to the statutory standard of “misleading” consumers – most of whom do not know whether ground beef contains 1.7 mg or 2.09 mg of iron – in a manner that would render the product misbranded in the absence of an on-pack nutrition label.*

b. Any Difficulty Consumers Experience Visually Assessing Ground Products for Fat Content Is Offset by Availability of Information

²⁸ USDA also provided statistics on the levels of cholesterol, iron and calcium found in studies that were conducted on beef samples comprised entirely of AMR; however, as AMR is used at no more than 10 percent of commercially available ground products, only the relevant data are reproduced here. See 66 Fed. Reg. at 4976.

²⁹ The increase in iron is just slightly above the Agency’s 20 percent tolerance policy, but, since the studies were not performed in a compliance context, no additional information is available here on historical levels and sources, etc, that would shed light on whether the difference accords with good manufacturing practices. The fact that the nutrient level will vary to a degree that is significant for enforcement purposes with the level of AMR added by the producer before the product is shipped to retailers is another reason, however, that retailers are concerned that it will be exceptionally difficult to ensure the accuracy of ground beef labels at retail.

See, e.g., 58 Fed. Reg. at 660 (regarding compliance parameters and tolerance levels, USDA recognized that “wide variation [of nutrient levels] can be introduced due to natural variability of nutrients in foods and that some nutrients do change over the course of product shelf life.”)

USDA also argues that fat levels are difficult for consumers to assess visually in ground products. Consumers, however, use a wide variety of means to assess the fat level in ground products. In addition to appearance or color, surveyed consumers say that they rely on the information currently provided in the meat department or on the package, including the percentage fat/lean statements that appear on many ground products. Consumers clearly understand the percentage lean/fat statements: in response to an open-ended question regarding the meaning of these statements, nearly two-thirds (63%) of respondents identified the statement as referring to the percentage of fat or meat in the product. More than three-quarters (76%) of respondents understood that products labeled “93% lean” had less fat than products identified with statements that ranged from “70% lean” to “90% lean.”

Nonetheless, despite the availability and high understanding of this information, 45 percent of consumers choose ground beef based on price and 23 percent choose ground beef based on cut; 9 percent of consumers identified fat content as the reason for choosing their ground beef product. Thus, to the extent consumers want it, information is available to them to assess the fat content of ground products and, therefore, consumers are not misled because they cannot visually assess the fat content of ground products.³⁰

c. Degree of Producer Control Over Fat Content in Ground Products Is Irrelevant To Determination of Whether Absence of Nutrition Label Renders Product “Misbranded” under Acts

The third argument that USDA uses to justify its conclusion that ground products are misbranded in the absence of on-pack nutrition labels is the degree of control that FSIS alleges that producers have over the fat levels in products. With all due respect to the Agency, the level of control exercised by the producer is wholly irrelevant to whether or not the absence of a nutrition label is “misleading” to consumers in a manner prohibited by the meat and poultry Acts. Throughout the preamble, USDA ties its “misleading” argument to whether or not consumers have a reasonable expectation regarding the nutrient profile of the product. The fact that producers attempt to control the fat level to respond to consumers’ desires for leaner levels of ground product has no impact on consumers’ expectations regarding nutrient levels.

³⁰ Indeed, requiring the addition of another label on the product package will further hinder consumers from assessing products visually. Consumers are interested in seeing the product for more than just fat content; they are interested in a variety of quality factors, including, color, appearance, degree of grind, and freshness.

In response to a question posed to our members as to whether the label could be affixed to the bottom of the package, our members advised that the uneven surface of the overwrap on the bottom of the package and the seepage that occurs from some packages would render this approach impractical. Moreover, fewer consumers would be aware of the information if it was on the bottom of the package.

Accordingly, whether or not producers exercise “precise” control over fat levels, the issue is irrelevant to the inquiry of whether or not consumers are misled within the meaning of the Acts in the absence of nutrition labels on ground products.

2. Requirement for On-Pack Nutrition Labels for Ground Products May Reduce Varieties of Ground Products Available to Consumers

In addition to the legal arguments cited above, USDA argues, in effect, that on-pack nutrition labels for ground products are important from a policy perspective. Specifically, the Agency reiterates the arguments made by a petitioner that, without on-pack nutrition information, consumers will not have information on the levels of fat per serving of ground beef or the levels of saturated fats, calories or protein in the product. 66 Fed. Reg. at 4977. Moreover, the lack of information on the label will, according to the Agency, prevent consumers from comparing meat products on a “fat per serving” basis. *Id.* at 4977. The Agency tentatively concludes that this information is important because “nutrition information is integral to consumer purchase decisions because use of this information may result in prevention of health problems and reduction of health risks for some consumers.” *Id.* at 4977.

a. Information on “Fat per Serving” Available on Current Nutrition Labeling Posters in Manner that Facilitates Comparison among All Meat and Poultry Products

Without on-pack nutrition labels, consumers will have the same sources of nutrition information for ground products that consumers have for whole cuts, including nutrition labeling on posters that are displayed by many retailers. If the nutrition labeling includes the different varieties of ground products, consumers would actually have an easier means of comparing the nutritional profiles of different meat and poultry products.

For example, if a consumer were interested in lowering “fat per serving,” the nutrition labeling chart would provide an ideal means of comparison. The consumer could review the chart, determine which products had the appropriate level of fat, and then purchase those. Or, if the consumer was interested in comparing three or four particular products, she could find them in the chart and compare them on that basis rather than juggling the individual packages. Indeed, if the purpose is to facilitate comparison with whole cuts, for which no nutrition labels will be mandated, consumers will still in many cases need to refer to the nutrition labeling to get information on the whole cuts, even if the ground products are labeled.

As noted in the Executive Summary above, FMI has and will continue to work with USDA to develop Nutrition Facts materials that are even more “consumer-friendly” than the current materials. In conjunction, we can perform outreach to the industry,

including the independent operators,³¹ through our new Independent Operator division. Earlier this year, the Independent Grocers Alliance and all of the domestic independent stores represented by that organization became members of FMI. We will also continue our joint efforts with the National Grocers Association in this regard.

b. Required On-Pack Nutrition Labels May Reduce Varieties of Ground Products Currently Available to Consumers

In support of its argument to require on-pack nutrition labels, USDA recognizes the numerous formulations of ground or chopped products that are currently being provided to consumers, but then concludes that, “it would be difficult for producers or retailers to develop point-of-purchase materials that would address all the different formulations that exist for these products.” 66 Fed. Reg. at 4977. FMI agrees with the fact that retailers today offer consumers an unprecedented number and variety of ground or chopped products. However, USDA’s concern for the difficulty of producing point-of-purchase materials for all of these products is misplaced.

Clearly, if it is difficult – as USDA admits – to develop point-of-purchase materials for them, it will be *substantially more difficult* to develop and ensure the accuracy of complete, on-pack nutrition labels for the full panoply of ground products that are currently offered to consumers. As a result, many retailers, particularly smaller retailers, may be forced to eliminate some of the choices that are currently available to consumers. The expense associated with testing and verifying all of the nutrient values required for each nutrition label may force retailers to stock fewer varieties.

Moreover, a small, but important, segment of consumers request custom-ground products. That is, rather than selecting a package of pre-ground meat, they select a whole cut of meat and ask the butcher to grind it for them. Retailers will have no way of providing nutrition labels for these ground products, which will present significant difficulties for retailers who want to continue to serve their loyal customer base with the highest standards.

Therefore, the likely result of mandating on-pack nutrition labels for ground products may be a marked reduction in the choices of ground products available to consumers.

c. Required On-Pack Nutrition Labels May Hinder Consumers’ Ability To Inspect Product Visually

Furthermore, additional labels on the package may reduce consumers’ ability to inspect products visually. Under the current regulations, ground meat and poultry products must bear labels to provide information on the name of the product; the

³¹ “Independent Operators” operate up to ten stores. See FMI, “Supermarket Facts” (2000).

ingredients; the name and place of business of the manufacturer, packer, or distributor for whom the product is prepared; net quantity of contents; and an official inspection legend. 9 CFR § 317.2(c). In addition, products must bear safe handling instruction labels. Requiring the addition of nutrition labels may further obscure consumers' view of ground meat and poultry products.

D. Comments on Specific Provisions of Proposed Regulations

1. Enforcement

a. FSIS Should Add Mitigating Provision Comparable to NLEA

The meat and poultry Acts impose civil and criminal penalties for violations. Specifically, the FMIA provides for imprisonment of up to one year and fines of up to \$1,000 for each violation of any provision of the chapter for which no other penalty is provided. 21 USC § 676(a); 21 USC § 462. The statute authorizes the Secretary to treat minor violations more leniently by suitable written notice of warning if the public interest would be adequately served. 21 USC § 676(b); 21 USC § 462.

FMI is very concerned that, if USDA promulgates mandatory nutrition labeling regulations, retailers will be subject to substantial civil and criminal penalties. For example, if the poster that provides nutrition labeling information for the several hundred packages of whole cuts of uncooked, single ingredient meat and poultry products that a retailer has displayed for sale falls down or is otherwise ruined, the meat and poultry Acts could be interpreted to require one year of imprisonment and a \$1,000 fine for each of the hundreds of packages that are on display. Such a result would clearly be disproportionate to the offense, nonetheless, the potential for substantial penalties is of grave concern.

Knowing that the FD&C Act provides similar civil and criminal penalties to the meat and poultry Acts, this issue was not lost on Congress. To address this potential situation, the NLEA includes a provision requiring reasonable enforcement of the provisions related to raw agricultural commodities and raw fish; to wit:

No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

21 USC § 343(q)(4)(F). The legislative history explains that this provision prevents a grocer or other person who offers produce or fish for sale from being prosecuted for a minor violation of Section 403(q). House Report 101-538 at 15. It addresses the concern that the Secretary could theoretically prosecute a grocer for a violation of Section 403(q)(4) "simply on the basis of evidence that the grocer ran out of brochures or that a

sign complying with the section mysteriously disappeared.” House Report 101-538 at 15. Although the Energy and Commerce Committee, which authored the report, did not believe that FDA would prosecute “such a trivial violation,” the provision allows a defendant to avoid prosecution by demonstrating substantial compliance with the requirements of Section 403(q)(4). *Id.*

Clearly, the potential for substantial penalties and unfair enforcement would be present if USDA finalizes the mandatory nutrition labeling regulations for fresh, single ingredient meat and poultry products that are now under consideration. To address this situation, we urge you to codify the enforcement discretion provided in Section 676(b) and amend the final regulations to state that failure to display nutrition labeling would be a minor violation subject to suitable written notice of warning.

b. Retailers Should Be Allowed To Use USDA Data for On-Pack Nutrition Labels for Ground Products

In the preamble to the proposal, USDA states that the nutrition labels that would be required on ground products would be subject to the compliance procedures set forth for product sampling and nutrient analysis in Section 317.309(h) and Section 381.409(h). 66 Fed. Reg. at 4980. The Agency intends to sample and conduct nutrient analyses to verify compliance with the nutrition labeling requirements, even if nutrition labeling on these products is based on the most current representative data base values contained in USDA’s National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference (hereinafter collectively referred to as “USDA Data”) and there are no claims on the labeling. *Id.* USDA’s rationale is that FSIS program employees cannot visually assess whether nutrition information on the label of ground or chopped products accurately reflects the labeled products’ contents because, in most cases it is not possible to visually assess the level of fat in a ground product and the fat content, which, as the Agency notes, can vary considerably depending on the fat content of the product that is being ground. *Id.*

The approach discussed above reflects the Agency’s choice to treat ground products like processed products. We believe that FSIS should, instead, continue to treat ground products in the same manner as the rest of the single-ingredient, fresh products and allow products to be labeled with USDA Data values. Specifically, if the Agency insists on conducting compliance samples at retail, simpler and less expensive tests could be conducted to evaluate the product simply for fat content. Once that had been verified, products labeled with the corresponding USDA Data values should not be subject to any further compliance or enforcement, just as USDA intends to treat the remainder of the fresh, single-ingredient products,³² which, until this rulemaking, the Agency had always considered as part of the class of fresh single ingredient meat and poultry products.

³² See 66 Fed. Reg. at 4980 (FSIS does not intend to verify the accuracy of Handbook 8 data that are used on labels of whole cuts).

As USDA states, the USDA Data are derived by the Agency and, since the FSIS personnel can visually identify the whole muscle cut, there is no need for further compliance testing; USDA analysis of the fat content of ground products would serve a purpose comparable to the inspector's visual identification of the product cut or type, but the remaining compliance steps should remain the same, i.e., if USDA Data values are used on the labels, no further testing should be necessary.

2. Exemptions

a. Small Business Exemption Must Apply to Uncooked, Whole Cuts Carried by Small Retailers and Employ Phase-In Comparable to Current Regulations

The current regulations exempt small quantities of products that small businesses produce from nutrition labeling. To qualify, the business must employ fewer than 500 employees. From July 1994 to July 1995, the exemption applied to products that the business produced in quantities less than 250,000 pounds. During the following year of implementation, the exemption applied to products produced in quantities less than 175,000 pounds. Subsequently and currently, the exemption applies to products produced in quantities less than 100,000 pounds annually. 9 CFR § 317.400(a)(1). The preamble specifies that each food product is a formulation not including distinct flavors that do not significantly alter the nutritional profile of the product, sold in any size package in commerce. Thus, ground or chopped products formulated to have different levels of fat are considered different food products. 66 Fed. Reg. at 4978.

i. Whole Cuts

USDA has proposed not to apply the small business exemption to the major cuts of single-ingredient, raw meat and poultry products produced by small businesses. 66 Fed. Reg. at 4978. FSIS states that mandatory nutrition labeling will not impose an economic hardship for small businesses, including those that are retail stores, because "FSIS intends to make point-of-purchase materials available over the Internet free of charge." 66 Fed. Reg. at 4978. With all due respect to the Agency, this rationale shows an utter lack of understanding of the challenges faced by small businesses and the economic hardships that regulations impose upon them.

First, many small businesses do not have Internet access. For many, Internet access is a luxury that cannot be justified until the basic business necessities, e.g., cost of products, labor, real estate, etc., have been fully met.³³

³³ We at FMI are very aware of the situation; some of our smaller members still do not have electronic mail, which limits the way in which we distribute information to our membership.

Second, costs associated with nutrition labeling information exceed those associated with gathering the data. Those small retailers that have opted not to participate in the voluntary labeling program under the current small business exemption would need to find space to display the signs in the store.³⁴ Display space is at a premium in all stores and, in small stores, with even less space, requiring retailers to post nutrition labeling information is difficult and expensive with respect to the opportunity cost represented by the space. Moreover, personnel would need to be trained that the information must be displayed because failure to display might well lead to penalties.

Accordingly, requiring small businesses to display nutrition information, even information available from FSIS over the Internet, will impose undue economic hardship and significant burdens for small businesses. Therefore, we urge you not to exclude the nutrition labeling information relevant to whole cuts from the small business exemption.

ii. Poundage Phase-In

As noted above, the current regulation provided for a three-year phase-in of the small business exemption, based on quantity of product produced. 9 CFR § 317.400(a)(1). The proposal under consideration does not provide for a phase-in, but applies immediately only to products that are produced by small businesses in quantities less than 100,000 pounds annually. The small business exemption phase-in is as important to the proposed nutrition labeling regulations as it was for the original regulations. Therefore, the final regulation should be amended to add the same phase-in amounts for the small businesses that would be subject to the mandatory requirements if the regulations are finalized as proposed.

b. Exemption for Multi-Ingredient Products Prepared at Retail Store Should Apply to Ground or Chopped Products with or without Added Seasonings

The current regulations exempt multi-ingredient products, such as sausage, that are processed at a retail store or similar retail-type establishment from the nutrition labeling requirements, provided that no claims are made regarding the products. 9 CFR § 317.400(a)(7)(ii). The exemption is predicated on the fact that FSIS has historically provided for certain retail exemptions, which are based on the exemptions in the meat and poultry Acts. 58 Fed. Reg. at 639. Moreover, FSIS determined, “based on experience and on comments, that it would be impractical to enforce nutrition labeling requirements on products prepared or served at retail.” 58 Fed. Reg. at 639. Moreover, the Agency’s research showed that foods prepared and packaged at retail constituted an insignificant percentage of the average person’s diet. *Id.* at 639.

³⁴ As noted above, small retailers that meet the standard in the regulatory exemption are currently exempt from participation in the voluntary program. See Section II.B.4., *supra*.

FSIS has now proposed to exclude ground or chopped products with or without seasonings that are processed at retail from this basis for exemption from the nutrition labeling regulations. See 66 Fed. Reg. at 4978. The Agency relies on a 1996 study to conclude that a large proportion of ground products are ground or re-ground at retail and, therefore, consumers who purchase ground beef likely consume a significant amount of ground beef processed at retail. 66 Fed. Reg. at 4978-79. Moreover, USDA no longer believes that enforcement of nutrition labeling regulations at retail would be impractical because FSIS is already conducting testing for *Escherichia coli* O157:H7 at retail. Id. at 4979.

As discussed more fully above, nutrition information is available to consumers, and, therefore, USDA should not mandate nutrition labels for ground or chopped products in the first place. Nonetheless, should the Agency choose to mandate nutrition labels for ground products, we believe that the exemption remains appropriate for all products prepared at retail and should be expanded to clarify that it includes chopped products with or without seasonings.

The quantity of ground products actually prepared at retail still represents a small portion of the average diet. As proposed, the new amendment captures more than just hamburger; it would encompass products such as “Cajun hamburger patties” or “meatloaf,” which continue to represent a small proportion of the diet. Moreover, use of the 1996 study fails to take into account the growing trend in the past few years for retailers to shift to “case ready” meat products, particularly ground beef. These products are pre-packaged and labeled by the federal establishment and arrive at the store ready to be displayed for sale.³⁵

Moreover, the study cited by USDA indicates that ground and re-ground beef combined represents 81.3 percent of ground beef sold at retail. Most of this, however, is product that is re-ground from chubs at store level without the addition of meat by the retailer. Although we continue to believe that the exemption should be applicable to all such products, it is most critical for the products that retailers prepare by more than simple regrinding.

Specifically, butchers and retailers maximize the value of the primal cuts that they receive by incorporating “trim” – those portions of the meat beyond the whole cuts that are selected for sale from the primal cut – into beef that is ground at retail. Similarly, some retailers add a significant proportion (up to 15 percent) of whole, muscle cuts into the meat that is ground at store level. Although retailers can fairly readily measure the fat content of these products, establishing the exact nutrient profile in a timely manner would

³⁵ Some of our members, particularly small- or medium-sized, retailers have advised us that they perceive customer, labor, cost, and cold chain management challenges as obstacles to “case ready” products so that “case ready” is not an option available to all retailers.

be impossible; the mixtures and, hence, the nutrient profiles change, albeit slightly, on a daily basis depending on the specific cuts that are available and, by the time the complete analysis is performed and the results obtained, the meat would no longer be saleable. Accordingly, the exemption for products prepared at retail is essential for ground or chopped products if USDA promulgates regulations requiring nutrition labels on ground or chopped products.

Moreover, as noted above, a small, but important, segment of the consumer base requests custom-ground meats. That is, rather than purchasing pre-packaged ground products, they select one or more whole cuts of meat and ask the butcher to grind them. As the butcher would have no way of analyzing the nutrient content of the particular cut of meat that the customer selected, the product could not be sold with a nutrition label.

In light of the practical difficulties retailers would face if required to label ground or chop products prepared at retail with nutrition information, we urge USDA to amend the exemption so that the language clearly states that chopped products with or without added seasonings will be considered exempt under this provision.

3. USDA Should Provide for an 18-Month Implementation Period

The proposed regulation and accompanying preamble do not discuss the effective date that USDA would apply if the Agency decides to promulgate the final nutrition labeling regulations under consideration here. The effective date for the current nutrition labeling regulations was 18 months following the publication of the final rule. We urge FSIS to adopt an 18-month implementation period for the nutrition labeling regulations currently under consideration, if the Agency adopts them. The implementation period will be necessary to enable retailers to retrofit existing equipment or purchase new equipment to prepare the necessary nutrition labels. In addition, the implementation period will be necessary for USDA to complete its nutrition analyses so that all necessary USDA Data will be available.

4. Labels

We have the following comments regarding the labels that would be required for ground or chopped products if the proposal is finalized as written.

First, nutrition labels for ground products should be exempt from the type size requirement or else the labels will be too large. Alternatively, FSIS should allow us of the linear format label.³⁶

³⁶ As noted above, placing the label on the bottom of the package is impractical and would not serve the purpose for which it was intended.

Second, we understand that USDA has not yet generated all of the data necessary to implement the nutrition labeling requirements that would be imposed under the proposal. Specifically, we understand that the USDA Data are not current and that USDA is undertaking nutrient analyses of additional fat/lean combinations (e.g., 93/7, 90/10, 85/15) of ground beef. We recommend that USDA forestall promulgation or implementation of the regulations until all of the necessary information is available.

5. Estimates in Proposal Inaccurately Reflect Costs to Retailers

The preamble to the proposed rule includes assumptions and estimates the Agency made regarding the costs involved in the proposal. Some of these are inaccurate. For example, USDA assumed that 80 percent of retail establishments would not need to install new machines for stamping, printing or affixing nutrition labels for ground or chopped products because, they estimated, 96.7 percent of large chains have equipment to print safe handling labels that can be used to print nutrition labels. However, according to Hobart, the company that manufactures a large proportion of the scales used by retailers, 50 to 60 percent of supermarkets (15,000-18,000 retailers) would need to upgrade their current printers at a cost of \$3,000 to \$5,000 per store, which represents \$45 to \$75 million in costs to the retail industry. Moreover, 40 to 50 percent of supermarkets (12,000-15,000 retailers) would be required to replace their entire scale systems at store level, which Hobart estimates would cost \$54 to \$90 million.

Furthermore, retailers currently rely on fairly inexpensive tests to confirm the fat content of ground products labeled with percent fat/percent lean statements. These, however, will not be sufficient to ensure that the nutrient levels required on nutrition labels are accurate. Substantially more sophisticated and, therefore, substantially more expensive analytical equipment or laboratory testing will be needed to measure the nutrient profiles in ground products, which are likely to vary significantly in the context of USDA's compliance and enforcement standards.³⁷

III. CONCLUSION

As discussed more fully above, FMI and FMI members remain strongly committed to nutrition information for meat and poultry products. Accordingly, FMI would be pleased to continue to work with the Agency to develop improved materials for the voluntary nutrition labeling program and to engage in additional outreach efforts to the industry.

³⁷ See, also, Section II.C., supra, regarding impact of AMR added by producers on retailers' ability to judge nutrient profiles within the accuracy required by the nutrition label regulations.

We urge the Agency not to abandon the voluntary program, but to strengthen it by promulgating the proposed regulation to permit labeling of ground products with percentage fat and lean statements. We also recommend that USDA repeat the survey in a manner that fully and accurately reflects the composition of today's retail food industry, the variety of ways in which retailers provide nutrition information to consumers, and the way in which consumers purchase meat and poultry products.

Nonetheless, if the Agency decides to promulgate the proposed regulations in place of the voluntary program, we respectfully request the following amendments that are discussed more fully in our comments above:

- Redefine the "significant participation" standard to reflect the marketplace and the variety of vehicles retailers use to provide nutrition information to consumers;
- Clarify that USDA personnel would treat violations under the program proportionately;
- Permit reliance on USDA Data for nutrition labels on ground beef products to the same extent that the data would be permitted for whole muscle cuts;
- Retain the small business exemption for nutrition labeling;
- Include a phase-in for the small business exemption comparable to the phase-in permitted for the 1993 nutrition labeling regulations;
- Retain the exemption for multi-ingredient products prepared at retail, including ground products with or without seasonings; and
- Provide for an 18-month implementation period.

* * *

We appreciate the opportunity to provide our comments on FSIS's proposed amendments to the nutrition labeling regulations and urge you to consider them fully and on the record. If we can provide any further information, please do not hesitate to let us know.

Sincerely,

Tim Hammonds
President and CEO

Enclosure