

**A GUIDE TO FEDERAL FOOD LABELING  
REQUIREMENTS FOR MEAT, POULTRY, AND  
EGG PRODUCTS**

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## **DISCLAIMER**

**This Guide is designed as a user-friendly introduction to the basic food labeling requirements for meat, poultry, and egg products. It does not represent, nor should it be relied upon as, an official or binding statement by the Labeling and Consumer Protection Staff, LCPS), Office of Policy, Program, and Employee Development (OPPED), of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). Users should consider changes in FSIS regulations and policies arising after the Guide's publication date.**

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The impetus for the Guide was to create a user-friendly, comprehensive guide to assist food companies in the development of food labels that comply with the array of requirements policies. While not a substitute for careful review of the requirements referenced throughout, the Guide will provide the reader with a useful tool to identify and understand those requirements that shape the food label presented to consumers. Note: Guidance on egg product, labels can be found in Appendix A of this Guide.

Building from the expertise and experience of the Labeling and Consumer Protection Staff, OPPED, the Agency sought to utilize a contractor who would offer an understanding of the rules in practice. The reader benefits from the day-to-day learning's of those who are involved in the review and approval of labels and others who routinely assist companies in the application of the labeling rules.

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## **PREFACE**

The food label is important to food companies and consumers alike. A company's most direct (and sometimes only) way to communicate with the consumer is via the food label. For consumers, the food label contains a wealth of information, which allows for informed purchase decisions. The U.S. Department of Agriculture (USDA), by statute, is charged with assuring that meat and poultry products in interstate or foreign commerce, or that substantially affect such commerce, are wholesome, not adulterated, and properly marked, labeled and packaged. <sup>1</sup> Responsibility for the development and application of the labeling requirements applicable to meat and poultry products rests principally with USDA's Food Safety and Inspection Service (FSIS). <sup>2</sup> FSIS is charged with developing the labeling policy by which it is determined if a meat or poultry product is misbranded or adulterated. <sup>3</sup> FSIS food labeling regulations have evolved over the years, reflecting the evolution of the food processing industry and consumer interest. Food manufacturers are responsible for compliance with the FSIS labeling rules and adherence to the process maintained by FSIS for the evaluation and approval of meat and poultry product labels.

This Guide provides the basic information necessary to devise a label for meat and poultry products and to understand the regulatory process administered by FSIS. Answers to the most commonly asked questions are incorporated. This Guide cannot possibly anticipate or address the large number of issues that may arise in developing product labeling. The FSIS

website ([www.fsis.usda.gov](http://www.fsis.usda.gov)) is a good source of information, providing the complete statutes, regulations, and policies. Included throughout the Guide are cross references to the relevant sources, found primarily in the End Notes. Some issues, particularly policy issues, will often require consultation with the Labeling and Consumer Protection Staff (LCPS), OPPEd, within FSIS.

Before delving into the details, the Guide begins with an overview of the principal jurisdiction over the label, labeling and advertising of foods at the federal level. The scope of USDA's jurisdiction and statutory reach with respect to covered and exempt meat and poultry products is detailed. The role of the states in regulating food labeling is also addressed, along with an explanation of the consistency required between state and federal law.

Section II provides an overview of the basic food labeling requirements, including the prior label approval process, establishment responsibilities, temporary label approvals, and other facets of the preapproval process. Sections III through XII address in detail each of the up to eight mandatory features that must be present on a meat or poultry label and other mandatory and optional information that may be on such a label. Appended to the Guide (Appendix A) is a discussion of the labeling requirements for egg products, which are also administered by FSIS. Other useful excerpts of labeling regulations and illustrations are included in various appendices as noted throughout the Guide.

This Guide cannot substitute for a careful review of the underlying statutes, regulations, policies, and guidance referenced throughout the Guide.

Consultation of the appropriate regulation, directive, and other guidance document, as well as the FSIS website, provides valuable information on devising an acceptable and compliant food label.

## **I. TIPS AND PITFALLS IN DESIGNING A FOOD LABEL**

- Begin label design with the mandatory labeling features required by FSIS regulations. Deviation from these requirements to accommodate marketing or other communication objectives does not ensure compliance.
- Ensure that placement and prominence requirements for each mandatory feature of the food label are met.
- Review brand names, marketing copy, and all other information presented on the label to determine if a regulated term is included.
- Make sure that foods subject to a standard of identity comply with the applicable FSIS requirement.
- Make sure that ingredients/components are properly declared in the ingredients statement.
- Novel or innovative products that trigger unique labeling issues should not be submitted to be evaluated by FSIS staff as part of the sketch-approval process. Instead, they should be addressed through direct contact with the staff. Firms should build into the product launch schedule the time necessary to allow for agency consideration of policy issues.
- Review ingredients statement for accuracy and completeness against formulation information. Fully consult ingredient suppliers to obtain all pertinent information as part of this review.
- Keep labeling files complete and current. Document generic approvals and permitted modifications along with final approvals that must be retained by the firm.
- Products that are not amenable and thus not subject to FSIS inspection must still comply with applicable labeling rules. Similarly, products not subject to prior approval (e.g., retail labeling) also must comply with applicable labeling requirements.
- Fully consult the resources available at the FSIS website and always consult the regulations, directives and other policies referenced in this Guide.

- If a label is not accurate, the label should not be used unless a temporary approval is obtained.

## **II. INTRODUCTION TO FOOD LABELING**

### **A. The Federal Agencies and Their Statutory Authority to Regulate Food Labeling**

The federal regulatory agencies that have jurisdiction over food products derive their authority to govern the labeling of these products from several principal statutes -- the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), the Agricultural Marketing Act (AMA), the Federal Food, Drug and Cosmetic Act (FFDCA), and the Fair Packaging and Labeling Act (FPLA). In addition, food advertising – which in certain instances serves as an extension of food labeling -- is subject to regulation by the Federal Trade Commission (FTC) under the Federal Trade Commission Act, which prohibits false and deceptive advertising.

#### **1. The United States Department of Agriculture’s Food Safety and Inspection Service (FSIS)**

FSIS has primary responsibility for the regulation of food labeling for meat and poultry products under the FMIA <sup>4</sup> and the PPIA <sup>5</sup> and is also authorized to regulate food labeling for exotic species of animals under the Agricultural Marketing Act of 1946. The FMIA and PPIA define the food “label,” in pertinent part, as “a display of written, printed, or graphic matter upon the immediate container of any article,” and define “labeling” as “all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” <sup>6</sup> USDA is authorized under the FMIA and the PPIA to regulate marking, labeling, or

packaging of meat, poultry, or processed parts to prevent the use of any false or misleading mark, label, or container. This broad definition makes FSIS regulations applicable to product labels and materials that accompany a product but are not attached to it, such as point-of purchase (POP) materials.<sup>7</sup> The scope of what constitutes a food label is discussed in further detail below.

The FMIA specifies the circumstances when products are misbranded. The FMIA provides, in part, that any carcass, meat or meat product is “misbranded” (1) if the product’s labeling is false or misleading in any particular way; (2) if it is offered for sale under the name of another food; (3) if it is an imitation of another food, unless it is labeled as such; (4) if its container is misleading; (5) unless it bears a label with the name of the manufacturer, distributor, and net quantity of contents; (6) if its labeling is not prominent and conspicuous; (7) if it purports to be a food with a standard of identity without conforming to the standard; (8) if it misrepresents itself as a food with a standard of fill; (9) if it does not bear a common or usual name (provided it is not covered by a standard of identity) and declare ingredients by common or usual name; (10) if it purports to be a food for special dietary use without conforming to FDA regulations on such products; (11) if it contains artificial flavoring, artificial coloring, or chemical preservatives that are not declared (with exceptions); and (12) if it fails to bear an inspection legend and establishment number.<sup>8</sup> It is intended that these provisions apply within the scope of the exceptions that may exist in the act. FSIS has similar authority under the PPIA with regard to poultry products.<sup>9</sup> False or misleading labeling

can trigger a charge of misbranding pursuant to the wide range of labeling requirements summarized in this Guide.

If a product is deemed misbranded, its manufacturer faces a wide range of penalties that can be imposed by FSIS.<sup>10</sup> These include withholding (rescinding) the use of labeling; product retention (prohibiting shipment); product detention (prohibiting sale from anywhere in the chain of commerce); request for product recall, press releases, and/or fines; and criminal prosecution. In addition, the facility producing misbranded product faces the possibility of inspection suspension or withdrawal.<sup>11</sup>

## **2. The U.S. Food and Drug Administration (FDA)**

FDA has primary statutory authority to establish labeling requirements for foods and food ingredients under its purview pursuant to the Federal Food, Drug and Cosmetic Act (“FFDCA”).<sup>12</sup> The FFDCA states, in a fashion similar to the statutes enforced by USDA, that a food product is misbranded, and is, therefore, in violation of the statute, if “its labeling is false or misleading in any particular ....”<sup>13</sup>

Similar to the FSIS-enforced statutes, the FFDCA defines a “label” as “a display of written, printed, or graphic matter upon the immediate container of any article.”<sup>14</sup> Further, the FFDCA defines “labeling” as: “labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”<sup>15</sup> This broad definition makes FDA regulations applicable to product labels and materials that accompany a product but are not attached to it. In addition, FDA has

regulatory authority under the Fair Packaging and Labeling Act (“FPLA”), a companion statute to the FFDCA. <sup>16</sup>

### **3. FSIS and FDA: Distinct Approaches to Labeling and Jurisdiction**

Prior approval by FSIS is required for all labels used for meat and poultry products before those products may be marketed in interstate commerce. There are distinct categories of prior approval, discussed below, that dictate the precise manner in which a label is “approved.” FSIS derives its authority for label approval from the provision in the Acts that states that no food article “shall be sold or offered for sale by any person in commerce under any name or other marking or labeling ...but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary.” <sup>17</sup> USDA interprets this statutory language as mandating the preapproval of all food labels before products that bear the mark of inspection may be offered for sale.

Responsibility for USDA’s pre-market label approval process rests with the FSIS Administrator. <sup>18</sup> Regulations and policies establish requirements for the content and design of labeling to ensure that labeling is truthful, accurate, and not misleading in order to prevent products from being misbranded. <sup>19</sup> Annually, FSIS evaluates approximately 60,000 labels that are sent to the Agency for evaluation and approval before they may be applied to product destined for commerce. Many more new and revised labels are subject to prior approval but are not submitted first for evaluation by the Agency, provided manufacturers ensure that such final labels fall within the conditions

specified in the generic labeling regulations (as elaborated upon below). In specified circumstances, labels that the Agency approved may be modified by manufacturers without resubmitting them to FSIS for evaluation. However, outside of these circumstances or instances where specific exceptions exist (e.g., for random weight packages), only labeling that has been approved by FSIS may be applied to meat and poultry products.

In contrast, FDA does not require prior label approval for food products under its jurisdiction.<sup>20</sup> FDA has promulgated regulations establishing requirements for all aspects of labeling and monitors labeling compliance primarily through random post-marketing surveillance. FDA reviews only a small portion of labels on food products falling under its jurisdiction. FDA's label review generally arises in connection with an informal request for review by a manufacturer, a trade complaint by a competitor, a consumer inquiry, or an FDA on-site inspection of a manufacturing facility.

Although FSIS has jurisdictional authority over food labeling for products containing meat and poultry, the FMIA and the PPIA explicitly authorize USDA (through FSIS) to exempt from its regulatory coverage food products which contain meat or poultry "only in relatively small portion or historically have not been considered by consumers as products of the meat food industry ...."<sup>21</sup> By statute, the Secretary *may* (not, *must*) exempt product applying either of the two stated criterion. Therefore, the statutes have long been applied by the Agency as including all products containing meat or poultry under FSIS jurisdiction (and, therefore, inspection). By default, all

other foods fall under the jurisdiction of FDA (and the statutes under which it operates), including the products of exotic species of livestock and kinds of poultry, (e.g., deer, elk, and pheasant.)<sup>22</sup>

The determination of whether a product falls under the jurisdiction of FSIS or FDA is referred to as “amenability.” Amenability decisions are based on how a product is formulated, not the composition of the finished product. USDA has set a rule that any food product containing the following is not subject to the FMIA or PPIA (i.e., to FSIS inspection): (1) 3 percent or less raw meat or less than 2 percent cooked meat, or (2) less than 2 percent cooked poultry meat, less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, giblets, fat, and meat in combination, (i.e., specific condition,) provided the poultry ingredients were prepared under domestic or foreign inspection and the product is not represented as a poultry product.<sup>23</sup> FSIS has formally adopted this rule with regard to poultry, but has not done so for meat products. Nonetheless, through decades-old policy, FSIS has applied a threshold level of meat that makes meat food products amenable consistent with the poultry regulations. Examples of meat products exempt from FSIS jurisdiction under one or the other criteria specified in the FMIA and implementing regulations include spaghetti sauces with less than 2 percent cooked meat, pork and beans, bagel dogs, and gravy mixes. Because the regulations state that the Secretary *may* exempt products, industry is strongly advised to seek clarification from FSIS in cases where the status of jurisdiction is in question.

As noted, by regulation, FSIS has further defined certain products as exempt from the definition of a “poultry product.”<sup>24</sup> These exemptions include product that contains less than 10 percent of cooked poultry skins, giblets, or fat separately and less than 10 percent of cooked poultry skins, giblets, fat, and meat or “mechanically separated skins of poultry,” as defined, and are not represented as a poultry product. Other exemptions include product in an institutional pack and used as soup bases or flavorings containing less than 15 percent cooked poultry meat and provided the specified conditions (as noted above) of the regulation are met.<sup>25</sup> Bouillon cubes, poultry broths, gravies, sauces, and flavorings also are exempt under the specified conditions (as noted above).<sup>26</sup>

These exemptions are null if the kind of poultry is listed in the product name without appropriate qualification. Appropriate qualification is using a term, such as “flavored,” that must be included as part of the product name (e.g., “Chicken Flavored Noodle Soup”) to distinguish the food product as different than a “poultry product” and, therefore, preserve the exemption. Products that meet the exemption factors and conditions, and that are labeled in this fashion, are subject to jurisdiction and regulation by FDA.<sup>27</sup>

FSIS has concurrent jurisdiction with FDA over the setting of standards of identity for food products.<sup>28</sup> The FMIA and PPIA state that USDA’s standards for any meat and poultry food products may not be inconsistent with standards established under the FFDCA.<sup>29</sup>

Finally, FDA has authority to approve the safety of food ingredients to be used in the production of food products, including meat or poultry products.<sup>30</sup> The meat and poultry inspection laws explicitly permit only FDA-sanctioned food ingredients (e.g., additives, GRAS substances, color additives) to be used in the production of meat and poultry products, which FSIS also must approve as suitable for use under prescribed conditions.<sup>31</sup>

FSIS requirements regarding legal status as safe for use in food differ somewhat from FDA. FSIS has developed policies and procedures to streamline its evaluation and approval of ingredients in meat and poultry products through close coordination with FDA.<sup>32</sup> FSIS has provided a great deal of useful guidance governing permitted use of safe and suitable ingredients. Beyond the scope of the Guide, there are several regulatory references that should be consulted.<sup>33</sup>

#### **4. The Federal Trade Commission (FTC)**

Section 12 of the Federal Trade Commission Act specifically states that the FTC shall prohibit the false advertisement of “foods, drugs, and cosmetics.”<sup>34</sup> Although the definition of “advertisement” excludes labeling, FTC has additional authority pursuant to section 5 of the FTC Act to prevent “unfair or deceptive acts or practices in or affecting commerce.”<sup>35</sup> This broad authority enables FTC to proceed against all unfair business practices, including false and misleading labeling of food products.<sup>36</sup> The FTC Act makes the dissemination of any false advertisement an unfair or deceptive

practice for the purpose of inducing, or that is likely to induce, the purchase of food or having an effect on interstate commerce. <sup>37</sup>

An advertising claim may be deemed false or misleading if it is not adequately substantiated pursuant to FTC guidelines. <sup>38</sup> FTC requires that companies that make claims about their products be able to substantiate these claims before they are made. FTC policy guidelines essentially provide that a representation of objective fact implies that the claimant has a reasonable basis for such fact. Different types of claims warrant different levels of substantiation. <sup>39</sup>

The courts have explicitly upheld FTC's authority to proceed against false labeling of food products. <sup>40</sup> FTC has statutory authority to obtain injunctive relief, and in some instances, damages. <sup>41</sup> FTC may also require "corrective" advertising if necessary to remedy the effects of past deception. <sup>42</sup> Thus, FTC is responsible for regulating claims about food that appear in advertising and certain other forms of labeling that may also constitute advertising.

FSIS and FTC, in practice, generally coordinate their activities to avoid duplication. FSIS takes the lead in addressing the labeling of meat and poultry products. Advertising of meat and poultry products is within the purview of the FTC. It is prudent to consult FSIS labeling regulations, rules and policies when developing advertising for meat and poultry products.

## **B. Role of the States -- Validity of State and Local Regulations that Affect the Food Label**

State requirements adopted under state law may not differ from, or conflict with, existing federal labeling laws and regulations. States are, therefore, prohibited from imposing requirements different from or in addition to federal labeling requirements. When state law directly conflicts with federal law, or attempts to regulate in an area Congress intended to be regulated solely by federal law, the state law is generally preempted, or superseded, by federal law. This is known as the “federal preemption” doctrine.<sup>43</sup>

The FMIA and the PPIA explicitly preempt state laws regulating labeling of meat and poultry products by providing that “marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act may not be imposed by any State.”<sup>44</sup>

The federal preemption established by the FMIA and PPIA was upheld by the United States Supreme Court in a case involving California net weight labeling requirements.<sup>45</sup> The Court held that the California law was different from the USDA net weight standard which permitted manufacturing deviations and allowances for variations caused by moisture loss. The California law was thus declared preempted by federal law, and therefore, unenforceable. Federal courts have repeatedly and consistently upheld federal preemption of FSIS labeling requirements in the face of differing state labeling rules or practices.<sup>46</sup>

A federal district court has ruled more recently that food packages that meet federal net weight labeling requirements may not be subjected to

sanction by state or local weights and measures officials based on the findings of limited retail inspections. In *Kraft Foods North America v. Rockland County Department of Weights and Measures*, the court held that reliance on limited retail inspection data gathered from small retail lot inspections to support a “short weight” violation conflicts with federal recognition of the “reasonable variation” that inevitably arises over the course of a production run. As previously stated, all labels on meat and poultry products destined for commerce must be in accordance with all applicable federal rules and approved by FSIS. Therefore, if a manufacturer’s product is accurately labeled under federal rules when packaged, product remains accurately labeled, regardless of where a portion of a given production lot is ultimately offered for sale. <sup>47</sup>

### **III. FSIS LABELING – SURVEY OF BASIC PRINCIPLES**

#### **A. When Packaging Must Bear Required Labeling**

FSIS labeling authority is very broad, extending from the labels appearing on the food package, before they are applied to the product, to point-of-purchase materials, including promotional brochures and shelf-talkers. <sup>48</sup> As mentioned previously, a “label” is a display of any printing, graphics stickers, seals or other written, printed or graphic matter upon the immediate container. <sup>49</sup> This regulatory authority over the food label can affect the processing and manufacturing operations of food companies. Meat and poultry products that do not bear the USDA-approved label, unless expressly exempt, may not be distributed in interstate commerce.

The manner in which a meat or poultry product is packaged when shipped from an inspected establishment determines what information should appear on the label of the packaged product. The rules vary depending upon whether the product is a processed or prepared meat or poultry product, or an unprocessed meat cut, or a poultry product, and upon the type of package or container in which the product is packed and shipped.

Immediate containers (e.g., bags, cardboard cartons, tray packs, and film bags enclosing processed or prepared meat products) can be considered “protective coverings” and exempt from marking and labeling requirements if placed within a shipping container that meets all mandatory labeling requirements (product name, handling statement, legend, establishment number, net weight, ingredients statement, signature line, nutrition facts, and safe handling instructions when required).<sup>50</sup> This exemption does not include the mandatory identification and marking required for the inner container of the meat food product. The shipping container that contains exempt immediate containers must be marked “Packed for Institutional Use Only” or with an equivalent statement of intended limited distribution from one federal establishment to another. The unlabeled product within the shipping container may not be removed for further distribution nor displayed or offered for sale at retail.

For unprocessed meat cuts, transparent film bags enclosing individual meat cuts in an unprocessed state can be considered “protective coverings” and exempt from the mandatory labeling requirements when

required information appears on the shipping container in which the immediate containers are placed. Unlike processed meats, unprocessed meats when shipped may be removed from the shipping container for resale and further distribution to retailers, hotels, restaurants, and similar institutions if the product itself or the film bag bears a legible official mark of inspection and the establishment number.

Poultry whole birds or individual cuts in protective coverings for export or sold to hotels, restaurants, or institutions only are exempt from the mandatory labeling of immediate containers, and no marking or labeling is permitted except in limited situations. The shipping container is considered the immediate container and should, therefore, include all mandatory features (product name, handling statement, legend, poultry plant number, net weight statement, ingredients statement, signature line, nutrition facts, and safe handling instructions when required.) A statement of limited use is not required to appear on the shipping container. Beyond these general requirements are specific provisions for certain types of products. <sup>51</sup>

### **B. The Prior Label Approval Process**

Prior approval of all food labels affixed to a meat or poultry product must be consistent with FSIS regulations. The evolution of the prior label approval process provides useful context for understanding the current requirements.

For many years, each label affixed to a meat or poultry product had to be submitted to FSIS for evaluation and approval. Any modifications to

the approved label required resubmission to FSIS for a new final approval. Only in certain instances could minor modifications be approved at the inspected establishment by the FSIS inspector. Over time, the number of label submissions for final approval grew substantially as the number of new and modified products increased. The current regulations reflect the Agency's decision to modify its prior label approval authority in a fashion that has dramatically reduced the number of labels that must actually be submitted for evaluation and approval by FSIS staff. The local inspector no longer plays a role in the preapproval process but has the authority to retain product that bears non-compliant labels.

Under the current regulations, final approval has been replaced with sketch approval based on submission of a label application to FSIS.<sup>52</sup> A sketch-approved label can be modified unilaterally by the company consistent with the flexibility specified by regulation, discussed below. In addition, specified types of product labels can be applied to meat and poultry products according to the generic labeling regulations without the need for submittal to FSIS, as long as the labels are in conformance with all applicable statutory, regulatory, and policy requirements. [To enhance the efficiency of its prior-approval process, FSIS encourages establishments to make use of the generically-approved labeling provisions. Establishments should consult with FSIS staff to resolve any uncertainty in this regard.]

## **1. Treatment of Retail Labels**

Generally, no claims may appear on retail labels unless prior approval is obtained. Although FSIS labeling policies apply at retail, FSIS does not require that point-of-purchase material receive prior approval unless it is shipped with the product (e.g., stickered-labels applied by the retailer placed in the shipping container at the establishment where product is packed.) FSIS will evaluate and seek necessary correction of such material brought to its attention or identified by routine marketplace surveillance.<sup>53</sup> Despite the absence of required preapproval, meat and poultry labels applied at retail must conform to all applicable FSIS labeling regulations.

A notable exception arises for so-called animal production claims (e.g., “raised without antibiotics”) whereby only claims that have been approved by FSIS through submission of a label application may appear on “retail labels.” The labels applied at retail are not required to have sketch approval, but the animal production claims must be preapproved by the Agency (i.e., via the label affixed to the shipping carton). A prerequisite for FSIS approval is an establishment’s written protocol that sets forth the parameters of the program to ensure the accuracy of the claim. Sometimes referred to as an “affidavit” or “testimonial” program, appropriate documentation validating adherence to the FSIS-accepted protocol must be submitted to the Agency.<sup>54</sup>

## **2. Establishment Responsibilities**

An establishment operates under a grant of inspection and bears certain responsibilities as a part of the label approval process. The processing

facility must create records of all final labeling, including sketch labels that have been approved. <sup>55</sup> Establishment records are to reflect modifications made to a sketch approval to the label prior to printing of the final labels. Records that must be maintained include all final labeling and “temporary” label approvals. The prior-approval process does not excuse an establishment from ensuring that its labeling fully complies with applicable FSIS labeling requirements. It is prudent for an establishment to contact FSIS staff directly when proposed product formulations or label claims raise policy issues or an establishment is unsure how to apply the labeling requirements.

Only labeling that is approved or expressly permitted may appear on product destined for interstate commerce. One cannot otherwise unilaterally modify labels unless a specific regulation allows for such change or addition (e.g., random weight packages.)

### **3. “Temporary” Label Approvals**

FSIS recognizes that in certain circumstances a manufacturer has labels that contain one or more minor errors. On a case-by-case basis, FSIS will allow for temporary use of a nonconforming label if the criteria set forth by regulation are met. Use of a label that is in error renders a product misbranded unless temporary approval is granted by FSIS for the particular label.

Temporary labels may be granted under the following conditions:

- (i) The proposed labeling would not misrepresent the product;

- (ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;
- (iii) Denial of the request would create undue economic hardship; and
- (iv) An unfair competitive advantage would not result from the granting of the temporary approval.

An application requesting temporary approval must address each of these considerations.<sup>56</sup>

Temporary approvals may be granted for a period not to exceed 180 calendar days. FSIS may also grant extensions of temporary approvals if the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.<sup>57</sup>

#### **4. Labels Approved Under the Generic Labeling Regulations**

FSIS allows generically approved labels to be applied to meat and poultry products in the exercise of its broad prior label approval authority. By regulation, FSIS specifies when generic approval can be undertaken by an establishment, foregoing the need to obtain a sketch approval requiring a submission of a label application directly to FSIS.<sup>58</sup> Products for which a standard of identity applies may be generically approved, provided that the labeling does not contain any special claims, including quality claims, nutrient content or health claims, negative claims, geographical origin claims, or guarantees. For labeling that is not for domestic product (i.e., marked “for export only”), the addition or deletion of the direct translation of a foreign language may be generically approved.

The final rule specifies numerous other types of labeling that are generically approved and, thus, need not be submitted to FSIS for sketch approval: single-ingredient products that bear no claims; products sold under contract specifications to the Federal government; labeling of shipping containers that contain fully- and properly-labeled immediate (inner) containers; food not intended for human consumption; meat inspection legends; inserts, tags, and other materials that bear no reference to the product and are not misleading; and the labeling for consumer test products not intended for sale.

#### **5. Modifications of Labels Made Under the Generic Labeling Regulations**

FSIS also specifies the changes that can be made to a sketch-approved label whereby the modified label is not resubmitted for a new “sketch” approval.<sup>59</sup> Any change not authorized by regulation triggers the need for submission of the revised label for sketch approval. Consultation with FSIS staff is prudent to ensure that, in a given circumstance, the flexibility afforded these requirements is fully realized. All such modifications should be documented by the establishment, similar to generic label-approval recordkeeping discussed above.

Permitted modifications or changes extend to the following features of a sketch-approved label: (1) proportionately enlarged or reduced labels; (2) substitution of any unit of measurement with its abbreviation, or vice versa; (3) a master or stock label from which the name and address of the distributor are omitted but to be applied before being used; (4) wrappers or other covers

bearing pictorial designs or illustrations; (5) change in the language or arrangement of opening or serving directions; (6) addition, deletion or amendment of on-pack coupons, cooking instructions, packer product code information or UPC information; (7) any change in the manufacturer's identification and address; (8) net weight statement; (9) recipe suggestions; (10) change in punctuation; (11) newly-assigned or revised establishment number; (12) open date information; (13) change in packing material; (14) brand name changes, provided there are no design changes and the name does not connote quality or other characteristics of the product; (15) deletion of the word "new"; (16) special handling statements; (17) safe handling instructions; (18) the amount of an ingredient that does not change the order in which the ingredients are declared; (19) color; (20) vignettes, provided they do not render the product labeling misleading; (21) company-initiated change in establishment number; (22) nutrition values, except that the serving size cannot be modified; (23) deletion of any claim or nonmandatory features of the label; and (24) addition or deletion of a direct translation of the English language into a foreign language for products marked "export only."

### **C. Regulatory References – Resource Tools**

FSIS labeling requirements and policies are found in the relevant statutes, implementing regulations, FSIS directives (including Policy Memoranda), FSIS notices, and the Food Standards and Labeling Policy Book. FSIS directives and FSIS notices are the two primary types of issuances that instruct FSIS inspection workforce and technical employees on how to carry

out their responsibilities. FSIS directives contain instructions of an indefinite duration, while notices are temporary instructions scheduled to expire no later than one year from the issuance date. The Food Standards and Labeling Policy Book is a compilation of policy and informal standards that have been established over years of labeling decisions assembled in a dictionary format. All of these useful references are found at the FSIS website ([www.fsis.usda.gov](http://www.fsis.usda.gov)). As part of its prior-approval process, FSIS routinely reviews policy issues on an ongoing basis. Therefore, it is important to consult these resources which are updated periodically. New policy questions should be directed to the appropriate FSIS staff.

#### **IV. MANDATORY REQUIREMENTS -- INTRODUCTION**

There are up to eight specific requirements for each product label: (1) product name, (2) inspection legend and establishment number, (3) handling statement, (4) net weight statement, (5) ingredients statement, (6) address line, (7) nutrition facts, and (8) safe handling instructions. Each of these requirements is discussed in detail below. The information must or may appear on specified areas of the label. In designing a label, it is important to understand what information must go where.

The placement and prominence of information of the mandatory requirements are specified by regulation. Generally, any required label information must be prominent, conspicuous (as compared to other words, statements, and designs on the label), and in such terms as “to render it likely to be read and understood by the ordinary individual under customary

conditions of purchase and use.”<sup>60</sup> To ensure that this threshold requirement is met, the regulations specify where and in what fashion certain required information must appear. These provisions vary depending on the particular required label statements, and are specified in the appropriate sections below.

#### **A. Principal Display Panel**

[9 C.F.R. § 317.2(d) (meat); 9 C.F.R. § 381.116(b) (poultry)]

The principal display panel, or “PDP,” is the part of the label most likely to be displayed, presented, shown, or examined under customary conditions to the consumer.<sup>61</sup> When a label bears alternate PDPs, information required to appear on the PDP shall be duplicated on each PDP. The PDP must include the name of the product, net quantity of contents, the official inspection legend, number of the official establishment, and, if necessary, a handling statement. The PDP must be large enough to accommodate mandatory labeling information required by statute or regulation.<sup>62</sup>

In determining the area of the PDP, the tops, bottoms, flanges at the top or bottoms of cans, and shoulders and necks of bottles and jars are excluded. The PDP is specifically defined as follows.

- For rectangular packages, one entire side, the area of which is at least the product of height times the width of that side.
- For a cylindrical or nearly cylindrical container, the area that is 40 percent of the product at the height of the container times the circumference of the container or a panel, the width of which is one-third of the circumference and the height of which is as high as the container.

- For a container with any other shape, 40 percent of the total surface area is considered the PDP.

Certain other special circumstances for placement of the PDP are specified as well.

### **B. Information Panel**

[9 C.F.R. § 317.2(m) (meat); 9 C.F.R. § 381.116(c) (poultry)]

The information panel typically is that part of the label immediately contiguous and to the right of the PDP. The information panel also can be the back panel or, for some boxes, any panel contiguous to the PDP. All information required to appear on the label of a package must appear either on the PDP or the information panel unless otherwise specified by regulation.<sup>63</sup> Certain other label information that may be placed on the information panel (unless on the PDP) includes: an ingredients statement, name and address of the manufacturer or distributor, and nutrition labeling, if required. The safe handling instructions may be placed anywhere on the label.

As with the PDP, information appearing on the information panel must be prominent and conspicuous.<sup>64</sup> Certain exemptions are permitted by regulation where the label is below a certain size due to the overall size of the food product's package.<sup>65</sup> An establishment may not deviate from regulatory requirements in an effort to accommodate optional information (e.g., product name not prominent to allow for large "new and improved" claim.)

## **V. PRODUCT NAME**

[9 C.F.R. § 317.2(c) (meat); 9 C.F.R. § 381.117 (poultry)]

### **A. Overview**

#### **1. Determining a Product's Name**

All meat and poultry products must be identified by a product name on the PDP. The regulations state that the product must be identified by the name specified by the standard, if there is one, or a common and usual name, or a truthful descriptive designation of the product. The regulations are intended to ensure that the product name accurately informs a consumer of a product's identity. In addition, there are detailed requirements in the regulations and labeling policies to ensure that the product identity is clear and prominent to the consumer.

In brief, if the product is represented as a product for which a standard of identity is established, the product must be identified by that name on the labeling, (e.g., "Chili con Carne" or "Chicken Soup".) If no standard of identity is established for a product, one must next consider if the product is identified by a common or usual name, if one exists (e.g., "Beef Shoulder Clod" or "Pork Loin".) Such a name may be established by regulation or common usage, and it must describe the basic nature of the product or its characterizing ingredients. In the absence of either a standard of identity or appropriate common or usual name, the identity statement must be a descriptive name. The descriptive name should accurately identify or describe

the basic nature of the food or its characterizing properties or ingredients (e.g., “Beef and Vegetables in Dough” or “Breaded Nugget-shaped Chicken Patty”.)

## **2. Placement and Prominence of Product Name**

The product name must appear prominently on the principal display panel. Certain regulations and Policy Memoranda specify the size (or relative size) of terms that appear as part of the product name. In general, words in product names or fanciful names may be of a different size, color, or type, but in all cases the words must be prominent, conspicuous, and legible. <sup>66</sup> No word in a product name (standardized name, a common or usual name, or descriptive name) should be printed in letters that are less than one-third the size of the largest letter used in any other word of the product name. This same requirement is applicable to fanciful names as well. For example, for a product labeled Chili Mac—Beans, Macaroni and Beef in Sauce, “Chili Mac” is the fanciful name, and “Beans, Macaroni, and Beef in Sauce” is the product name. No letter in “Chili Mac” may be smaller than one-third the size of the largest letter in “Chili Mac.” Furthermore, no letter in the true product name, (i.e., “Beans, Macaroni, and Beef Sauce,”) may be smaller than one-third of the largest letter in the true product name.

Product names in certain instances must be accompanied by a qualifying statement deemed necessary to ensure that the product name is not misleading. For example, for a turkey-ham product, “turkey” must appear in the same size, style, and color and on the same background as the word “ham.” The product name must be qualified with the statement “cured turkey thigh

meat.” The qualifying statement must be contiguous to the product name (when triggered), without intervening type or designs, not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and the same background as the product name and in the same size, style and color, and same background as the word “ham.”<sup>67</sup>

## **B. Standards of Identity**

[9 C.F.R. Part 319 (meat); 9 C.F.R. § 381 Subpart P (poultry)]

USDA has statutory authority to establish standards of identity for meat and poultry products. Under the FMIA and the PPIA, a product is “misbranded” if:

It purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations . . . unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard.<sup>68</sup>

A standard of identity prescribes a manner of preparation and the ingredients of a product that is to be labeled with a particular name. Numerous product standards have been established by regulation.<sup>69</sup> FSIS also has established informal policy standards by Policy Memoranda and through entries in its Food Standards and Labeling Policy Book. Foods subject to a standard of identity must be labeled with the name specified in the standard. A food that bears the name of a standardized food that does not satisfy the requirements of the applicable standard is misbranded. Examples of standardized products

include: “Ham,” “Ham Water Added,” “Hot Dogs,” “Chicken and Noodles,” and “Spaghetti Sauce with Meatballs.”

### **C. Common or Usual Name**

[9 C.F.R. § 319.1 (meat); 9 C.F.R. § 381.117 (poultry)]

The FMIA and PPIA authorize FSIS to promulgate common or usual names for meat and poultry food products. A product is misbranded unless it bears “the common or usual name of the food, if any there be.”<sup>70</sup> FSIS regulations state further that any product “for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products, insofar as specific ingredients or procedures are not (otherwise) prescribed or prohibited.” Examples of common or usual names include red meat primals, (e.g., beef round,) and subprimals, (e.g., beef sirloin steak.)

### **D. Descriptive Names**

[9 C.F.R. § 317.2(e) (meat); 9 C.F.R. § 381.117(a) (poultry)]

Descriptive terms may be used as a product’s statement of identity provided that no standard of identity or common or usual name exists. For meat products, “any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product.” For poultry products, FSIS requires “a truthful descriptive designation” absent a standard of identity or common or usual name. Product which has been prepared by a specific method, such as salting, smoking, drying, or chopping, must be so described unless the name implies,

or the manner of the packaging shows, that the product is subject to the particular form of processing. Examples of descriptive names include “Chicken and Vegetable in Dough” or “Breaded Nugget-shaped Chicken Patty.”

Unqualified meat terms common to the industry but uncommon to consumers, such as “picnic,” “butt,” and “loaf” must not be used as product names unless accompanied by terms descriptive of the product or with a list of ingredients, if the Agency determines that this is necessary to ensure that the label is not false or misleading. This labeling convention is only true for certain (non-specific) meat products. In contrast, the poultry regulations provide that “kind” (poultry species) be specified in the product name.

Manufacturers may also make use of a fanciful name accompanied by a descriptive term or name that is designed to ensure that consumers are not misled as to the identity, amount, or composition of a product. A product with the fanciful name “Fiesta Mexicana”, along with the descriptive term “Chicken Breasts with Salsa and Peppers”, is such an example. Use of fanciful names is especially common for a whole array of new or newly-formulated food products. A truly fanciful name will not convey a meaning that in any way relates to the nature of the product (e.g., Moon Pie.)

#### **E. Imitation Food Products**

[9 C.F.R. § 317.2(j)(1) (meat); 9 C.F.R. § 381.1(b) (poultry)]

A label for a product that is an imitation of another food shall bear the term “imitation” immediately preceding the name of the food imitated and in the same size and style of lettering as the product’s name. An ingredients

statement must follow the imitation product name. USDA has informally followed FDA's approach with regard to imitation labeling and products not being nutritionally inferior. Products that resemble but are not nutritionally inferior to standardized meat or poultry products need not bear the "imitation" designation, provided that the meat or poultry content is conspicuously disclosed.<sup>71</sup> If a product is nutritionally inferior to the standardized product, it must be labeled "imitation" as part of the product name.<sup>72</sup>

FSIS regulatory policy permits the marketing of products that are technically imitation solely because they do not adhere to the compositional requirements established for a standardized product or other traditional food with generally recognized, established contents (e.g., Ground Beef and Textured Vegetable Protein (TVP) Product.) This policy enables a food manufacturer to make a product that is nutritionally inferior and is designed to serve consumer preferences without the use of the stigmatizing term "imitation."

In response to consumer preference for lower fat alternatives to standardized foods, FSIS allows products to be nutritionally modified to reduce the fat, cholesterol, or sodium content through the addition of ingredients for fat or sodium replacement precluded or restricted by applicable standards.<sup>73</sup> Pursuant to this policy, qualifying products may bear the standardized name in conjunction with an appropriate nutrient content claim provided that consumers are informed of the actual components through labeling and certain other guidelines are followed. For example, meat products that combine fresh sausage, ground beef, or hamburger and other safe and suitable ingredients for

the principal purpose of replacing fat may be descriptively labeled. Such products are “Lean Ground Beef, Water, and Carrageenan Product,” “Low Fat Ground Beef With X% Solution of ...,” “Lean Beef Sausage, Water, and Carrageenan Product,” or “Reduced Fat Pork Sausage, Water, and Binders Product,” provided, in part, that the regulatory requirements for the nutrient content claims are satisfied.<sup>74</sup> Breakfast sausages, cooked sausages, and fermented sausages with modified fat content also may be identified by a nutrient content claim and a standardized or traditional name, such as “Low Fat Pepperoni” or “Reduced Fat Frankfurter.”<sup>75</sup>

#### **F. Geographic Origin**

[9 C.F.R. § 317.8(b)(1) (meat); 9 C.F.R. § 381.129(b)(2) (poultry)]

By regulation, terms having geographic significance generally may appear without qualification on the labeling of meat only when the product is made in the geographic area mentioned. Terms of geographic significance referring to a locality other than where the product was made may appear on the label of meat products only if qualified by the words “Style,” “Type,” or “Brand,” accompanied by a “Made In ...” phrase that properly identifies where the product is manufactured. The provisions governing poultry products are somewhat different and are separately described below.

Significant geographic areas that are qualified by the terms “style” and “type” may appear on the labels of meat products when there is a generally recognized style or type of product produced in that particular geographic area. FSIS permits use of geographic terms when accompanied by the qualifying

term if the manufacturer can demonstrate that there is a recognized “style” or “type.”<sup>76</sup> Therefore, a chili produced in California can be labeled “California Chili con Carne,” or since it is made in the southwestern United States, it could be labeled “Southwestern Chili con Carne.” On the other hand, a chili made in Nebraska could be labeled “Nebraska” or “Nebraska Style Chili con Carne,” or since there is a recognized southwestern style, it could be labeled “Southwestern Style Chili con Carne,” if it meets the style.

“Brand” is used as part of a product name or claim when a style or a type is not recognized or met. A qualifying statement identifying the place where the product is actually made must appear in proximity to “brand” when such qualifying term is required. Therefore, using the example of chili made in Nebraska above, if the products did not comply with the definition for “Southwestern Style,” the product must be labeled “Southwestern Brand Chili con Carne, Made in Nebraska.” The word “Brand” must be the same size and style of lettering as the geographic term, and it must be accompanied with a prominent qualifying statement identifying the particular locality in which the product is prepared.<sup>77</sup>

Where a geographic term has come into general usage as a trade name and has been approved by FSIS as not being geographically significant and, thus, generic, the term may be used without qualification, such as “Old El Paso.”<sup>78</sup> The regulation specifically states that the terms “Vienna,” “Genoa,” “Polish,” “Italian,” and other similar terms need not be accompanied with a qualifying descriptive term when used on the standardized product. In

addition, some trade names have been used so long and exclusively by a manufacturer so that it is generally understood by consumers to mean the product of a particular manufacturer, such as “Swiss Chalet.”<sup>79</sup>

In contrast to the meat regulations, FSIS poultry regulations specify that a geographic term only may be used to identify a poultry product if the product was actually produced in the locality stated on the label.<sup>80</sup>

However, as a matter of policy, FSIS has modified its treatment of geographic terms for poultry products to parallel the policy applied to meat products.

The underlying issue with respect to geographic origin is whether a product name truly connotes geographic significance to consumers or merely implies a product’s style and the importance this information is to consumers. A truthful representation of geographic origin is permitted, such as “Virginia Ham” that is produced in the Commonwealth of Virginia, or “Tennessee Peppersteak,” made in Tennessee.

When the term “Style” is used, there must be a method of preparation or other product attributes that distinguish or characterize the product in a manner similar to products peculiar to a geographic region. An establishment must demonstrate that such a style exists in order to use the geographic claim. By informal policy, FSIS has allowed establishments to rely upon an independent third-party authority (e.g., culinary institute) to establish that a particular “style” is associated with a specific geographic area and that the particular product(s) bearing the claim comport with this recognized style.

### **G. Country of Origin**

[9 C.F.R. § 327.14-.15]

FSIS requires imported meat and poultry products to bear the name of the country of origin, preceded by the words “Product of.”<sup>81</sup> On an immediate container, this country of origin statement must be immediately under the name of the product.<sup>82</sup> On an outside container, this statement accompanies the product name and establishment number in a prominent, legible manner.<sup>83</sup>

### **VI. USDA INSPECTION LEGEND**

[9 C.F.R. § 312 (meat); 9 C.F.R. § 381.96 (poultry)]

USDA regulations require a prominently displayed inspection legend and establishment or plant number on the principal display panel of all federally-inspected meat or poultry product containers unless there is a specific exception (e.g., on a metal clip.)<sup>84</sup> An official inspection legend is any symbol prescribed by regulations showing that a carcass or parts of carcasses were inspected and passed by FSIS in an official establishment in accordance with all federal regulations. An official establishment number is assigned to each establishment granted inspection service. The establishment number is used to identify all containers of inspected products prepared in the establishment. A product will be deemed “misbranded” if it fails to bear these features on its containers.<sup>85</sup>

The regulations prescribe requirements for the relative dimensions and placement of the inspection legend; and this inspection legend must be of

a sufficient size and of such color as to be conspicuously displayed and readily legible. <sup>86</sup> The use of a foreign language for all aspects of a label is acceptable provided the inspection legend and establishment or plant numbers also appear in English.<sup>87</sup> The products themselves are not required to be branded when shipped in properly-labeled containers or when shipped under an official government seal. There are regulations that specify in great detail the precise manner, method and location by which the legend must be placed on the label of an inspected product.

The required official inspection legend for inspected and passed poultry products should include the following wording, “Inspected for wholesomeness by U.S. Department of Agriculture.” <sup>88</sup> The establishment number is prefaced by a “P” designating that the product is a poultry product. This wording should be contained within a circle. The form and arrangement should be exactly as indicated in 9 C.F.R. 381.96. The appropriate official plant number (P-and the federal number) should be shown, but, if the number appears elsewhere on the labeling material, it may be omitted from the inspection mark.<sup>89</sup> If the number appears off the exterior of the container (e.g., on a metal clip,) a statement of its location must be printed contiguous to the legend (e.g., “Est. No. on metal clip”.)

Products consisting of mixed meat and poultry ingredients must contain either the official meat inspection legend or official poultry inspection legend, depending on which ingredients are present in greater amounts. If meat or poultry ingredients exist in equal proportions, either official legend

may be used. If meat and poultry ingredients exist in exact proportions and both appear in the product name, the official legend must reflect the ingredient appearing first in the product name.

## **VII. NET QUANTITY**

[9 C.F.R. § 317.2(h) (meat); 9 C.F.R. § 381.121 (poultry)]

USDA statutes and regulations establish specific labeling requirements governing statements of the net quantity of the food package offered for sale to the consumer in a retail setting. This information facilitates value comparisons among similar products by consumers. All labels on food sold at retail must bear an accurate statement of the quantity of the package content in terms of weight, measure, or numerical count.<sup>90</sup> Such a statement must appear on the principal display panel of all containers to be sold at retail intact.<sup>91</sup> The statement must be in terms of the package contents -- solid, liquid, semi-solid, or viscous.<sup>92</sup>

Reasonable quantity variations from the stated weight, caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviation in good manufacturing practices, are recognized and do not render a product to be misbranded.<sup>93</sup> Reasonable variations are permitted because of the nature of certain foods and the impossibility of developing completely accurate means of packaging.<sup>94</sup> Such variation may not be unreasonably large.<sup>95</sup> The Supreme Court held that the federal net weight requirements preempt state law requirements that do not permit reasonable variations, including unavoidable variations caused by moisture

loss during the course of good distribution practice.<sup>96</sup> Federal courts on several occasions have ruled that state or local enforcement practices in conflict with the FMIA or PPIA are preempted.<sup>97</sup>

#### **A. Expression of Net Quantity Statement**

The statement of quantity shall be expressed in terms of avoirdupois weight or liquid measure. The use of metric measurement as it relates to the net weight statement is voluntary because the FPLA exempts meat and poultry products from metric declaration. Where there is no general consumer usage to the contrary, the net quantity of contents statement for products sold in the U.S. should be expressed in terms of liquid measure if the product is liquid, or in terms of weight if the product is solid, semisolid, viscous, or a mixture of solid and liquid.<sup>98</sup> For example, a chili product would be measured in ounces and pounds, while a beef broth would be measured in fluid ounces. Thus, FSIS regulations require the terms “net weight” or “net wt.” to appear with the net quantity of contents when expressed in terms of weight and “net contents” or “content” when expressed in terms of fluid measure.<sup>99</sup> Packages containing at least one pound or pint, but not more than 4 pounds or 1 gallon, must be expressed as a “dual declaration.”<sup>100</sup> A dual declaration includes ounces or fluid ounces followed, in parenthesis, by the largest whole U.S. customary unit (e.g., pounds and pints or quarts and gallons.) Any remainder should be expressed in terms of ounces or common or decimal fractions of the pound for weight measure, and fluid ounces or common or decimal fractions of the pint or quart for fluid measure (e.g., “Net Wt. 24 oz. (1

lb. 8 oz.),” “Net Wt. 24 oz. (1.5 lbs.),” or “Net Wt. 24 oz. (1 ½ lb.).” <sup>101</sup>

Exceptions for random weight, small, and multi-unit packages, as well as certain packages containing margarine and bacon, are discussed below. <sup>102</sup>

### **B. Placement**

The net quantity of contents statement must appear in the lower 30 percent of the principal display panel of containers sold at retail intact in the following manner. <sup>103</sup>

- In lines generally parallel to the base of the containers. <sup>104</sup>
- In distinct contrast with other material on the package. <sup>105</sup>
- Separated from other printed label information appearing above and below it by a space at least equal to the height of the lettering used in the statement. <sup>106</sup>
- Separated from information appearing to its right and left by a space at least equal to twice the width of the letter “N” of the style or type of lettering used in the declaration. <sup>107</sup>

Packages that have a principal display panel of five square inches or less do not have to place the net quantity statement in the lower 30 percent of the principal display panel, provided that the declaration meets all other USDA requirements. <sup>108</sup>

### **C. Prominence**

Additionally, USDA prescribes specific type requirements for the net quantity statement.

- The declaration must be in “conspicuous and easily legible boldface print or type.” <sup>109</sup>
- The lettering may be no more than three times as high as it is wide. <sup>110</sup>

- The minimum type size for the statement is dependent on the area of the PDP, as described in the table below. <sup>111</sup>
- When both upper and lower case letters are used in the declaration, the height of the lower case “o” or its equivalent must meet the minimum type size requirements. <sup>112</sup>
- When only upper case letters are used, the height of the upper case letters must meet the minimum type size criteria. <sup>113</sup>
- When fractions are used, each numeral of the fraction must meet one-half the minimum height standards. <sup>114</sup>

<b>Area of the PDP In Square Inches</b>	<b>Minimum Type Size In Inches</b>
≤ 5	1/16
> 5-25	1/8
> 25-100	3/16
>100-400	1/4
> 400	1/2

#### **D. Exceptions and Other Special Requirements**

USDA permits the following exceptions from its requirements for the net quantity statement.

- **Individually–Wrapped, Random–Weight, Consumer–Size Packages Shipped in Bulk Containers; and**
- **Certain Meat and Poultry Products Subject to Shrinkage Through Moisture Loss**

The above-referenced products are not required to bear a net weight statement *when shipped from an official establishment*, provided that the shipping container bears a net weight shipping statement that expresses accurately the net quantity of contents in the container and is not

otherwise false or misleading. The individual, random-weight, consumer-size packages must bear a net weight statement prior to retail display and sale. The declarations on the shipping container and individual packages are exempt from the type size, dual declaration, and placement requirements described above, if an accurate net weight declaration is shown “conspicuously” on the principal display panel of the shipping container or package.<sup>115</sup>

- **Small Packages in Shipping Containers** -- Individually-wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages are exempt from USDA’s net quantity of contents labeling requirements, provided that the packages are in a shipping container that expresses accurately the net quantity of contents in the container and is not otherwise false or misleading.<sup>116</sup>
- **Small Packages in General** -- Individually-wrapped and labeled packages of less than ½ ounce net weight with labels declaring net weight, price per pound, and total price are exempt from the type size, dual declaration and placement requirements described above if an accurate statement of net weight is shown “conspicuously” on the principal display panel of the package.<sup>117</sup>
- **Sliced, Shingle-Packed Bacon in Rectangular Packages; and**
- **Margarine in One Pound Rectangular Packages (except packages containing whipped or soft margarine or packages containing more than four sticks)**

Provided that an appropriate net quantity statement appears on the principal display panel of the above-referenced products in a “conspicuous manner,” the statement is exempt from the dual declaration requirement and the requirement that the net quantity of contents declaration appear in the bottom 30 percent of the PDP.<sup>118</sup>

- **Certain Types of Consumer Packages of Poultry Products** – The Administrator may approve the use of labels that do not bear a net weight statement on the above-referenced packages, provided that: (1) the shipping container bears the statement, “Net weight to be marked on consumer packages prior to display and sale”; (2) the total net weight of the contents of the shipping container is marked on the container; (3) the shipping container also bears the statement: “Tare weight of consumer package” in “close proximity” to the tare weight of the consumer packaging, weighed to the nearest 1/8 ounce or less.<sup>119</sup>

Special net weight labeling rules are specified for multiunit retail packages (MRPs). An MRP is defined as a package containing two or more individually-packaged units that: (1) contain the identical commodity; (2) contain the same quantity of food; and (3) are intended to be sold as part of the MRP but are capable of being individually sold in full compliance with USDA regulations.<sup>120</sup> A net quantity statement is required on the outside label of the MRP. The statement must comply with the same requirements applicable to net quantity statements generally, as discussed above. In addition, net quantity statements for MRPs must also include the following:<sup>121</sup>

- The number of individual units;
- The quantity of each individual unit; and
- In parenthesis, the total quantity of contents of the multiunit package, except that the declaration of total quantity need not be expressed as a “dual declaration” (e.g., the declaration in ounces need not be followed by an additional parenthetical declaration in terms of the largest whole U.S. customary units.)

Examples of products that might bear this type of information could include pizza or soups.

## **VIII. INGREDIENTS LABELING**

[9 C.F.R. § 317.2 (meat); 9 C.F.R. § 381.118 (poultry)]

The ingredients statement provides the consumer with detailed information as to the constituents of a meat or poultry product. The number of ingredients, the multiple functions of ingredients, and the sophisticated methods for producing some ingredients create many challenges in applying the ingredient labeling requirements. Proper ingredients labeling requires

regulatory and technical expertise. An understanding as to the function an ingredient plays in the food is central to proper application of the ingredient labeling requirements.

#### **A. Overview: Basic Requirements**

An ingredients statement is required when a product is fabricated from two or more ingredients.<sup>122</sup> All ingredients must be declared by their common or usual names on the label in descending order of predominance by weight.<sup>123</sup> Order of predominance is determined based on the weight of ingredients as added to the formulation.<sup>124</sup> An ingredients statement is not required when the product name provides a complete identification of all ingredients in the food (e.g., “Chicken Breasts with Rosemary Extract”.) Ingredients present in individual amounts of two percent or less may be listed in other than descending order, provided that they are listed at the end of the ingredients statement preceded by a phrase such as “less than \_\_ percent of \_\_,” with the blank filled in with the “appropriate” threshold level of two percent, 1.5 percent, one percent, or 0.5 percent.<sup>125</sup> These quantifying statements should start with the threshold level of 2.0% and move down in 0.5% increments, (i.e., 1.5%, 1.0%, or 0.5%.) No ingredient in the quantifying statement may be greater than the stated threshold, and ingredients listed in the quantifying statement may be adjusted in the formulation without a change in the ingredients statement.

When two meat ingredients comprise at least 70% of the meat and meat by-product ingredients of a formula, and when neither ingredient is less

than 30% by weight of the total meat and meat by-products used, these meat ingredients may be interchanged in the formula without a change to the ingredients statement.<sup>126</sup> In such cases, the word “and” must be used in lieu of a comma between the two ingredients. This same rule applies to products containing poultry.<sup>127</sup> However, it does not apply to mixtures of meat and poultry.

An ingredient that conforms to a standard of identity (discussed above in connection with product names) is identified by the name specified by the applicable standard. When FDA standardized foods are used as ingredients in the preparation of meat or poultry products, the common or usual names of all ingredients in the standardized food must be listed, in parentheses, following the name of the standardized food (so-called “component listing”).<sup>128</sup> The Code of Federal Regulations and the Food Standards contain definitions for various food ingredients. Absent a specific FSIS requirement, the appropriate common or usual name as set forth by FDA is appropriate.<sup>129</sup> The Food Standards and Labeling Policy Book may also be consulted for recognized ingredient names.

There are two methods by which ingredients and sub-ingredients may be declared within the ingredients statement. The ingredients of a standardized food that is used as an ingredient in a food may either (1) be declared parenthetically following the name of the standardized ingredient (i.e., “component” labeling,) e.g., “cheddar cheese (milk, enzymes, salt)” or (2) declared by dispersing each ingredient in its order of predominance in the

ingredients statement of the product in which they are used without naming the standardized food specifically (i.e., “composite” labeling). Composite listing does not name the standardized food, (e.g., “meatballs” from various sources, each having similar but different formulations.) The affected ingredients in a composite declaration must be minor in nature and should be identified using one of the following acceptable formats:

- 1) Pepperoni (pork, beef, water, salt, spices, sodium nitrate (may also contain lactic acid starter culture, sugar, and sodium ascorbate));
- 2) Bacon bits (cured with water, salt, dextrose and/or sugar, and sodium nitrite); or
- 3) Pepperoni (pork, beef, water, sweeteners (contains one or more of the following: sugar, dextrose, fructose, corn syrup), salt, spices, sodium nitrate).<sup>130</sup>

FSIS allows the use of both component labeling and composite labeling within a singular ingredients statement.

Certain naming conventions, including the grouping of ingredients identified by a single term, are specified by FDA regulation and followed by FSIS.<sup>131</sup> The ingredient name usually must be specific as opposed to generic. Synonymous terms are interchangeable. Examples of interchangeable terms are frank, hot dog, and weiner, or corn syrup and corn syrup solids.

## **B. Artificial Flavorings, Colorings, and Chemical Preservatives**

### **1. Flavors – Specificity or Generic Identification**

Rules governing the labeling of artificial flavorings, colorings, and chemical preservatives are focused on ensuring that a product’s ingredients statement adequately informs a consumer of the product’s content.<sup>132</sup> A 1995 “Question and Answer” document issued by FSIS remains a valuable resource

to address these and other ingredient labeling issues.<sup>133</sup> FSIS permits the term “flavorings” to designate natural spices and natural spice extractives. “Spices” may be used to designate natural spices.<sup>134</sup>

The meat species and poultry “kind” must be identified as part of a flavor (e.g., “Dried (species or kind) stocks,” “Dried (species or kind) broth”.) Such ingredients may not be declared simply as “flavors” because dried stocks, dried broth and extracts, and blood fractions are of animal origin and must be so designated as “Dried (species) stock,” “Dried (species) broth,” “(species) extract,” or “Dried (species) plasma.”

Only ingredients that fall within the regulatory definition may be declared as “natural flavor,” “natural flavoring,” “flavor” or “flavoring.” These include essential oils, oleoresins, and spice extractives.<sup>135</sup> The term “spice” is used to refer to those spices listed in FDA regulations.<sup>136</sup>

Certain types of ingredients that are hydrolyzed must be identified by the source and cannot be identified generically as a “flavor.” Examples include: hydrolyzed (source) proteins, gelatin, hydrolyzed meat and meat by-products, autolyzed yeast, and autolyzed yeast extract.

The terms “artificial smoke flavoring added” or “smoke flavoring added” must be on the product label next to the product name and identified in the ingredients statement.<sup>137</sup> The same requirement applies with respect to meat products in several specific instances in which artificial colorings are added to the product.<sup>138</sup>

## **2. Color Additives**

FSIS requires color additives or the lake of a color additive subject to FDA certification to be identified by its common or usual name or the abbreviated names such as “FD&C Red No. 40,” “Red 40,” “FD&C Blue No. 1 Lake,” or “Blue 1 Lake.”<sup>139</sup> Color additives not subject to certification may be declared generically such as “Artificial Color” or “Color Added,” or they may be designated as “Colored with \_\_\_\_” or “\_\_\_\_ color,” with the blank filled with the name of the color additive.<sup>140</sup> Products containing any artificial coloring must note that fact on the immediate container of the product or, if there is none, the product itself.<sup>141</sup>

## **3. Chemical Preservatives**

Containers of products containing any chemical preservative must state that fact on the label.<sup>142</sup> Additional rules apply to antioxidants and other additives (e.g., possible product name qualifiers.) With respect to poultry products containing chemical preservatives, FSIS clarifies that the label statement must name the chemical preservative and the purpose of its use.<sup>143</sup>

## **C. Incidental Additives**

Federal regulations require that all ingredients used to formulate a meat or poultry product must be listed by their common or usual name on labeling. There are two exceptions to the rules. An ingredient that is classified by FDA as a secondary direct additive does not need to be labeled because it has only a momentary technical effect in food by definition. The other exception is for incidental additives according to FDA’s labeling regulations.<sup>144</sup>

FSIS exempts the mandatory declaration of “incidental additives” from an ingredients statement if they are present in insignificant amounts and serve no technical or functional effect in food, are used as a processing aid, or have migrated to food from equipment or packing materials.<sup>145</sup> Processing aids are a subcategory of incidental additives and are not considered ingredients since they are essentially substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any lasting technical effect in that food.

FSIS does not have a definition for incidental additives or processing aids. However, if a company believes that the use of a substance in the manufacture or formulation of a meat or poultry product is consistent with FDA’s labeling definition for an incidental additive processing aid, then data needs to be submitted to FSIS to substantiate conformance with the FDA regulation. FSIS will determine on a case-by-case basis whether a request for the specific use of an ingredient is consistent with FDA’s labeling definition of an incidental additive processing aid and thus, exempt from labeling.

These exceptions do not apply where FDA regulations require that use of a specific substance be disclosed for health or other reasons. For example, FDA requires that sulfiting agents that qualify as incidental additives must be labeled if present at levels exceeding an established level (10 ppm).<sup>146</sup>

#### **D. Labeling of Ingredients of Public Health Concern**

Because there are foods and food ingredients to which some individuals may have a sensitivity (i.e., an allergic reaction or intolerance), FSIS emphasizes the importance of accurate, informative product labeling. FSIS supports including voluntary statements on labels to alert people who have sensitivities or intolerances to the presence of specific ingredients, particularly the “big 8” allergens (wheat, crustaceans (e.g., shrimp , crab, lobster), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans) and other specific ingredients (monosodium glutamate (MSG), sulfites, lactose, and Yellow 5 (tartrazine). FSIS provides the following example: “Contains: milk, wheat gluten, soy.” FSIS further supports identifying the source of a specific ingredient in a parenthetical statement, (e.g., “whey (from milk)”.)

FSIS authorizes the use of factual labeling statements about a product’s manufacturing environment, (e.g., “Produced in a plant that uses peanuts,”) where good manufacturing practices and effective sanitation standard operating procedures (SSOPs) cannot reasonably eliminate the unintended presence of certain ingredients. In certain circumstances, the phrase “may contain (name of allergenic ingredient)” may be used on meat and poultry product labeling. However, the use of factual statements about a product’s manufacturing environment, (e.g., “Produced in a plant that uses peanuts,”) and the use of “may contain” statements, (e.g., “may contain peanuts”) may only be used in cases where establishments show that adequate SSOPs cannot effectively eliminate the cross-contact issue.

The Agency will consider any non-misleading symbols, statements, or logos to inform consumers of the presence of ingredients of public health concern in meat, poultry, or egg products. All requests must be submitted to the Agency as a policy inquiry and not as label-approval submissions.

**IX. ADDRESS (SIGNATURE) LINE**

[9 C.F.R. § 317.2(c)(3) & (g) (meat); 9 C.F.R. § 381.122 (poultry)]

FSIS requires the labels of meat and poultry products to include the name or trade name and place of business of the manufacturer, packer, or distributor for whom the product is prepared.<sup>147</sup> The manufacturer or packer name may appear on the label without qualification. The name of the distributor, however, must be preceded by a phrase such as “Prepared for \_\_\_” or “Distributed by \_\_\_.” If the business is listed in a telephone or city directory, the information listed for the place of business must include the city, state, and postal ZIP code. Otherwise, it must also include the street address.

**X. HANDLING STATEMENTS**

[9 C.F.R. § 317.2(k) (meat); 9 C.F.R. § 381.125(a) (poultry)]

Packaged products that require special handling to maintain their wholesome condition must have prominently displayed on the principal display panel the applicable handling statement “Keep Refrigerated,” “Keep Frozen,” or “Perishable—Keep Refrigerated or Frozen.”<sup>148</sup> The FSIS Administrator may also approve additional phrases of similar importance.

The statement “Keep Frozen” must appear on shipping containers for products that are distributed frozen and thawed prior to or during display for sale. Consumer-size containers holding such products must bear the statement “Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.” With respect to perishable canned products, this statement must appear in upper case letters, ¼ inch in height, for containers with a net weight of 3 pounds or less, or ½ inch in height for containers with a net weight over 3 pounds.

#### **XI. SAFE HANDLING INSTRUCTIONS**

[9 C.F.R. § 317.2(l) (meat); 9 C.F.R. § 381.125(b) (poultry)]

Safe handling instructions are required if the meat or poultry component of a product is raw or partially cooked (i.e., not considered ready-to-eat (RTE)), and if the product is destined for household consumers or institutional uses.<sup>149</sup> Safe handling instructions may appear on products that are not ready-to-eat (RTE) but include a fully cooked meat or poultry portion. Safe handling instructions should not be used on RTE products. Meat and poultry products intended for further processing at another official establishment also are exempt from this requirement. Under the heading “Safe Handling Instructions,” the safe handling information must appear on the label as follows.

This product was prepared from inspected and passed meat and or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

This statement is in turn accompanied by the following additional required statements.

- Keep refrigerated or frozen. Thaw in refrigerator or microwave. (This statement must appear next to a graphic illustration of a refrigerator.)<sup>150</sup>
- Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (This statement must appear next to a graphic illustration of soapy hands under a faucet.)
- Cook thoroughly. (This statement must appear next to a graphic illustration of a skillet.)
- Keep hot foods hot. Refrigerate leftovers immediately or discard. (This statement must appear next to a graphic illustration of a thermometer.)

These instructions must appear in lettering no less than 1/16 inch in height and be placed on the label “prominently with such conspicuousness as to render it likely to be read and understood under customary conditions of purchase and use.” The heading must be set in type size larger than the rationale statement and instructions. All safe handling information must be set off by a border and appear in one color printed on contrasting background of a single color.<sup>151</sup>

FSIS permits changes to the first statement and icon if specific handling information on the product conflicts with the safe handling instructions. For example, if the label of a frozen product states, “Do not thaw product, cook from frozen,” or “Do not thaw,” the first part of the safe handling statement may be changed to “Keep Frozen.” If a product is shelf stable and states, “No refrigeration necessary,” or “Refrigerate after opening,”

the icon of the refrigerator and the entire statement about refrigeration can be eliminated.

## **XII. NUTRITION LABELING**

### **A. Mandatory Nutrition Labeling - General Requirements**

In 1994, USDA adopted sweeping new regulations mandating that most foods bear nutrition labeling. Nutrition labeling now is required for all meat and poultry products intended for human consumption and offered for sale, except single-ingredient, raw products and other exempt products. Exempt products include products produced by small businesses, products intended for further processing, products not for sale to consumers, products prepared and sold at retail, and products in small packages (individually wrapped packages of less than ½ ounce net weight).<sup>152</sup> These exemptions are discussed more fully below, but it is important to note that with these exemptions, a nutrition claim, or any other nutrition information provided on the label or in labeling or advertising in any context and in any form, negates the exemptions and triggers the mandatory nutrition labeling requirements. The exemptions for certain other products, such as products intended for export and custom-slaughtered products, are not negated by nutrition claims.<sup>153</sup>

Generally, nutrition information must appear on the label of meat and poultry products. Gift packs may display nutrition information at a place other than on a product label, such as product label inserts, provided the label bears no nutrition claim.<sup>154</sup> Meat and poultry products in packages

having a total surface area greater than 40 square inches, but lacking sufficient space on the principal display panel and information panel for all required information, may use an alternate panel that customers could readily see. <sup>155</sup>

A product's nutrients are declared on its label. Certain nutrients must be declared, while others may be declared voluntarily. <sup>156</sup> The order in which certain nutrients must be declared, as well as certain definitions and requirements, are set forth below (the voluntary nutrients are identified as such). <sup>157</sup>

- Total Calories.
- Calories from Fat.
- Calories from Saturated Fat (voluntary).
- Total Fat. Total fat is defined as the total lipid fatty acids and is expressed as triglycerides.
- Saturated Fat. Saturated fat is defined as the sum of all fatty acids containing no double bonds.
- Trans Fat (voluntary).
- Stearic Acid (voluntary).
- Polyunsaturated Fat (voluntary). Polyunsaturated fat is defined as the *cis, cis*-methylene-interrupted polyunsaturated fatty acids.
- Monounsaturated Fat (voluntary). Monounsaturated fat is defined as the *cis*-monounsaturated fatty acids.
- Cholesterol.
- Sodium.
- Potassium (voluntary).

- Total Carbohydrate. Total carbohydrate is determined by subtracting the sum of the crude protein, total fat, moisture, and ash from the total weight of the product.
- Dietary Fiber.
- Soluble Fiber (voluntary).
- Insoluble Fiber (voluntary).
- Sugars. Sugars are defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose).
- Sugar Alcohol (voluntary). Sugar alcohol is defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA.
- Other Carbohydrate (voluntary). Other carbohydrate is defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present) other carbohydrates is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars.
- Protein. A statement of the number of grams of protein must be declared. Ordinarily it is not necessary to declare the percent of daily value of protein unless a protein claim is made for the product, or if the product is intended for children under 4 or infants. When the protein digestibility-corrected amino acid score (PDCAAS) of the food is less than 20 (for adults and children greater than 4,) or less than 40 (for children between 1 and 4,) either of the following shall be placed next to the protein content: (1) “not a significant source of protein,” or (2) a listing of the corrected amount of protein, expressed as percent of daily value.
- Vitamin A, Vitamin C, Calcium, and Iron. The percent of daily value must be declared for vitamin A, vitamin C, calcium, and iron, in that order, and any other vitamin or mineral for which a claim is made, provided FDA has established a recommended daily intake (RDI) for such vitamin and mineral.
- Vitamins and Minerals (voluntary). The declaration of the percent of daily value of other vitamins and minerals is voluntary if the vitamins and minerals are required for use in a standardized food that is used as an ingredient in another food or included solely for technological purposes. (The listing of other vitamins and minerals that may be

declared in the nutrition facts panel can be found in Section F of this part)

Generally, nutrient information must be presented using the nutrient names in the regulation, except “sugar alcohol” which may be declared by its specific name (e.g., xylitol) when there is only one sugar alcohol in the food. Detailed requirements are set forth specifying when each mandatory or voluntary nutrient must be declared. For example, nutrients whose declaration is usually voluntary must be declared when a claim is made about the nutrient. <sup>158</sup>

With the exception of the core nutrients (calories, total fat, sodium, total carbohydrate, and protein), nutrients that are present in insignificant amounts may be omitted from the list of nutrients and grouped in a summary statement (e.g., “Not a significant source of \_\_\_”.) The level of a nutrient that can be declared as (rounded to) zero is specified. The regulations also state the analytical methods for measurement of each nutrient. <sup>159</sup>

## **B. Full Format**

Nutrition information must be presented in a specified format and type size. <sup>160</sup> The order in which the nutrition information appears, and the headings that must be used, also are specified in regulations. <sup>161</sup> The quantitative amount of each nutrient must be declared, except for vitamins and minerals, which are expressed as a percent of daily value. <sup>162</sup> The percent of the Daily Reference Value (DRV), under the heading “% Daily

Value,” must be declared for total fat, saturated fat, cholesterol, sodium, potassium (if declared), total carbohydrate, and dietary fiber. The percent of daily value must be calculated and declared in the increments specified in the regulation. <sup>163</sup>

Typically, the nutrition panel also must contain a footnote, preceded by an asterisk that states: “Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.” <sup>164</sup> Additionally, the footnote must list the recommended daily values for the macronutrients on the basis of a 2,000 and 2,500 calorie diet. Calorie conversion information on a per gram basis may follow the footnote (e.g., “Calories per gram: fat 9, carbohydrate 4, protein 4”.) <sup>165</sup>

Variations in the presentation of nutrition information are permitted under certain circumstances. For example, nutrition information may be presented for two or more forms of the food (e.g., “as purchased” and “as prepared”) per ounce” and “per 100 grams;”) The regulatory requirements for dual declarations must be followed. The primary column is the food as packaged. <sup>166</sup>

Additionally, meat products that contain two or more products in the same package or packages that are used interchangeably for the same type of product may use an aggregate display, specifying the identity of each food next to the nutrition information. <sup>167</sup> This same format may be used to display information for two or more forms of the same product (e.g., raw and cooked.) <sup>168</sup>

### **C. Simplified Format**

A simplified format for nutrition information is permitted when a meat product contains “insignificant” amounts of any required nutrient other than core nutrients (calories, total fat, sodium, total carbohydrate, and protein.) <sup>169</sup>

An “insignificant amount” of a nutrient is defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars, and protein, it is an amount that can be declared as less than 1 gram. <sup>170</sup>

The simplified format must include:

- (1) Total calories, total fat, total carbohydrate, protein, and sodium; and
- (2) Calories from fat, as well as any of the mandatory nutrients that are present in the food in more than insignificant amounts.

If any required nutrient, other than a core nutrient, is present in an insignificant amount, it may be omitted from the tabular listing, provided the nutrition label includes the statement “Not a significant source of \_\_\_\_\_,” (with the blank filled in with the mandatory nutrients that are present in insignificant amounts). Otherwise, this statement is not necessary. <sup>171</sup>

The simplified nutrient information must be presented in essentially the same manner as required for the general format. The simplified format must also contain the statement, “Percent Daily Values are based on a 2,000 calorie diet,” and, if the term “Daily Value” is not spelled out, a statement that “DV” represents “Daily Value.”

#### **D. Tabular Format**

Packages with 40 square inches or less of available surface area may use a tabular label format. Extremely small labels that cannot accommodate the standard vertical column or tabular format may display the required nutrition information in a linear format specifically outlined by USDA. The use of this linear format is approved on a case-by-case basis. Because the linear format is very hard to read, companies must demonstrate that inability to fit the tabular format on the label.<sup>172</sup> Packages having 40 square inches or less of available labeling space may also use approved abbreviations as part of the nutrition facts panel. Below is a listing of the authorized abbreviations:

Serving size- Serv size

Servings per container- Servings

Calories from fat- Fat cal

Calories from saturated fat- Sat fat cal

Saturated fat- Sat fat

Monounsaturated fat- Monounsat fat

Polyunsaturated fat- Polyunsat fat

Cholesterol- Cholest

Total carbohydrate- Total carb

Dietary fiber- Fiber

Soluble fiber- Sol fiber

Insoluble fiber- Insol fiber

Sugar alcohol- Sugar alc

Other carbohydrate- Other carb <sup>173</sup>

#### **E. Compliance Requirements Governing Nutrition Labeling**

In calculating and presenting nutrition information, manufacturers must follow the compliance rules established by USDA. Methods for analyses are provided in the Agency's "Chemistry Laboratory Guidebook." If no USDA method is available or appropriate for a nutrient, the 1990 edition of the "Official Methods of Analysis," published by the AOAC International, should be followed. <sup>174</sup>

#### **F. Reference Daily Intakes and Daily Reference Values**

The label declaration of percent daily value of vitamins and minerals will be based on the following Recommended Daily Intake (RDI's): <sup>175</sup>

- Vitamin A, 5,000 international units
- Vitamin C, 60 milligrams
- Calcium, 1.0 grams
- Iron, 18 milligrams
- Vitamin D, 400 international units
- Vitamin E, 30 international units
- Vitamin K, 80 micrograms
- Thiamin, 1.5 milligrams
- Riboflavin, 1.7 milligrams
- Niacin, 20 milligrams
- Vitamin B6, 2.0 milligrams

- Folate acid, 0.4 milligrams
- Vitamin B12, 6 micrograms
- Biotin, 0.3 milligrams
- Pantothenic acid, 10 milligrams
- Phosphorus, 1.0 gram
- Iodine, 150 micrograms
- Magnesium, 400 milligrams
- Zinc, 15 milligrams
- Copper, 2 milligrams

The following Recommended Daily Intake (RDI) from the FDA regulations would also be permitted on a voluntary basis on USDA food products:

- Selenium, 70 micrograms
- Manganese, 2.0 milligrams
- Chromium, 120 micrograms
- Molybdenum, 75 micrograms
- Chloride, 3,400 milligrams

Immediately following the name of a nutrient or dietary component, the following synonyms may be used parenthetically:

- Calories—Energy
- Vitamin C—Ascorbic Acid
- Thiamin—Vitamin B1
- Riboflavin—Vitamin B2

- Folate—Folic acid or Folacin (Alternatively, folic acid or folacin may be listed without parentheses in place of folate.)

The label declaration of percent daily value of the following food components is based on the following Daily Recommended Value (DRV)'s:

- Fat, 65 grams
- Saturated fatty acids, 20 grams
- Cholesterol, 300 milligrams
- Total carbohydrate, 300 grams
- Fiber, 25 grams
- Sodium, 2,400 milligrams
- Potassium, 3,500 milligrams
- Protein, 50 grams

#### **G. Exemptions from Mandatory Nutrition Labeling**

As discussed above, the regulations either exempt certain foods from the mandatory nutrition labeling requirements or subject other foods to special labeling requirements. Generally, these exemptions only apply when a product's label and advertising make no nutrition claims and contain no nutrition information. The exemptions and the special labeling requirements, when applicable, are identified below.<sup>176</sup>

- Small Business. A company employing 500 or fewer people, specific products produced at 100,000 pounds of product per year or less qualifies for the exemption. All product based on the same formula is counted toward the 100,000-pound limit. For example, a business making pork sausage would aggregate the weight of its bulk, link, and patty products. Businesses may calculate the amount of pounds produced by averaging the most recent two years of production.
- Products Intended for Further Processing.
- Products Not for Sale to Consumers. For example, a free sauce packet included with egg rolls does not require nutrition labeling. This packet, however, may not be included in the product's net weight. If the sauce packet is either included in the net weight or not free, nutrition labeling is required.

- Individually-Wrapped Small Packages. Individually-wrapped packages of less than ½ ounce net weight are exempt.
- Products Custom Slaughtered or Prepared.
- Products Intended for Export Only.
- Certain Products Prepared and Sold or Served at Retail:
  - Ready-to-eat products packaged or portioned at retail
  - Multi-ingredient products (e.g., sausage) processed at retail
- Restaurant Menus.
- Foods for Infants and Children. Foods for children less than 2 years of age must bear nutrition labeling, except that the following nutrients may not be declared: calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol. Foods represented or purported to be for infants and children less than four years of age must bear nutrition labeling, except that such information shall not include the percent of Daily Value (DV) and the footnote information. Nutrient names and quantitative amounts by weight must be presented in separate columns.
- Small Packages. Foods in packages that have a total surface area available for labeling of less than 12 square inches are exempt, but the label must contain an address or telephone number that may be used to obtain the required nutrition information (e.g., “For nutrition information, call 1-800-123-4567”). When nutrition labeling is provided, either voluntarily or because of nutrition claims, all required information must meet certain size requirements.

#### **H. Voluntary Nutrition Labeling**

The nutrition labeling of single-ingredient, raw meat and poultry products is voluntary at this time. When voluntary nutrition labeling guidelines apply, a retailer or manufacturer must follow the mandatory nutrition labeling program with a few exceptions. Nutrition labeling may be declared “as consumed” or “as packaged,” and the number of servings per

container need not be included. The simplified labeling format also may be used.

When a retailer provides nutrition information at the point-of-purchase (e.g., signs or brochures), the listing of percent daily values of nutrients and required footnotes may be omitted, and formatting requirements do not apply. If a nutrition claim is made, however, all mandatory requirements apply.

“Significant participation” in the voluntary nutrition labeling program is required; otherwise, the products under the voluntary nutrition labeling guidelines will become mandatory. A retailer is considered to be participating at a “significant” level if it provides appropriate nutrition information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry it sells. “Significant participation” is evaluated every 2 years. Since participation in the voluntary nutrition labeling program was determined to be “not-significant” in 1996 and 1999, FSIS proposed mandatory nutrition labeling for products in the voluntary program.

### **I. Serving Sizes**

This section provides an overview of FSIS regulations concerning serving sizes, followed by a more detailed description of specific regulatory requirements such as how serving sizes are expressed on a product label. This section will also address reference amounts customarily consumed (RACC) per eating occasion and the conversion of RACC to labeled serving sizes (depending on the type and size of the product) and the exceptions to

these requirements. A summary of the procedures for determining the number of servings per container is also made available.

### **1. General Requirements**

For the purpose of nutrition labeling, nutrients and food components must be declared based on a serving of a food. “Serving size” is defined as the amount of food customarily consumed per eating occasion, expressed in an appropriate common household measure.<sup>177</sup> The serving size is based on the established RACC for the particular food.

Conversion from reference amount to serving size depends upon the nature of the product. For all meat and poultry products, the declaration of nutrient- and food-component content should be based on the product “as packaged,” except single-ingredient, raw product may be declared “as consumed.” There are two exceptions to raw, multi-ingredient products declaring nutrition information on the “as purchased” basis. FSIS has determined that for bacon products with a cook shrink of at least 60 percent and pork sausage type products with a cook shrink of at least 24 percent, the nutrition information may be declared on the “as cooked” basis only, since the nutrition information on the “as packaged” basis will not be useful to the consumer because the nutrient profile changes dramatically upon cooking. Cooking instructions must be included on the labeling of the bacon- and pork sausage-type products. All products may be declared in a second column “as consumed” if preparation and cooking instructions are clearly stated.

## **2. Common Household Measure**

The serving size must be expressed in a “common household measure” which is defined as a cup, tablespoon, teaspoon, piece, slice, fraction (e.g.,  $\frac{1}{4}$  pizza), ounce, or other common household equipment used to package food products (e.g., jar, tray.) The regulation lists in order of preference the measure that is suitable for the individual food: (1) cups, tablespoons, or teaspoons should be used whenever possible; (2) units such as piece, slice, tray, jar, and fractions of a whole (most appropriate for products such as pizza or quiche) are used when cup, tablespoon or teaspoon measurements are not applicable; and if neither of the prior two options are appropriate; (3) ounces, which must be expressed in 0.5-ounce increments. <sup>178</sup> Rounding should be indicated by the use of the term, “about.”<sup>179</sup> Permitted abbreviations are specified by regulation.<sup>180</sup>

The common household measure should be followed by the metric quantity in parenthesis (e.g., “2 slice [50 grams]”,) except for single-serving containers. If a manufacturer voluntarily provides the metric weight for a single-serving product in the net-weight declaration, the serving-size declaration need not include the metric conversion (e.g., “serving size 1 package.”) However, if the metric weight is included in both the net-weight and the serving-size declaration, they must be identical.

For single-serving products and meal-type products (e.g., can, box, package, meal, or dinner,) a description of the individual container or package should be used. For other products in discrete units (e.g., chop,

slice, link, patty,) a description of the individual unit should be used. For unprepared products used to prepare large discrete, units (e.g., pizza kit,) a fraction or a portion should be used.<sup>181</sup> When no other unit is applicable, the serving size is described in ounces. FSIS also permits ounce declarations for serving size for products in units like chicken breasts, pork chops, etc., if the individual units vary by more than 100% by weight. For example, when chicken breasts weigh between 3 ounces and 6 ounces, companies are permitted to label the product by ounces as opposed to the piece.

When a serving size, determined by the reference amount, falls exactly halfway between two servings sizes (e.g., 2.5 tbsp), the size should be rounded up to the next incremental size.<sup>182</sup> All gram and milliliter quantities equivalent to the household measure should be rounded to the nearest whole number, except quantities less than 5 g (mL). Quantities between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL), and quantities less than 2 g (mL) should be expressed in 0.1 g (mL) increments.<sup>183</sup>

### **3. Reference Amounts Customarily Consumed (RACC) Per Eating Occasion**

The reference amounts reflect the amount of food customarily consumed per eating occasion and are based on the edible portion of food and on the major intended use of the food. There are alternate reference amounts for food intended for infants or children under 4 years old.<sup>184</sup> FSIS has approved the use of the following ready-to-serve RACCs listed below that are not codified in the regulation:

- Appetizers (e.g., Meat (or poultry) hors d'oeuvres, mini eggrolls, mini pizza rolls, bagel pizza) - 85 grams RACC
- Beans with meat (or poultry), plain or in sauce - 130 grams for beans in sauce or canned in liquid and refried beans prepared; 90 grams for others prepared; 35 grams dry RACC
- Meat hot dog (or poultry hot dog) chili sauce – 2 tbsp RACC
- Paste for garnishing - 15 grams RACC
- Stuffed cherry peppers - 30 grams RACC
- Vegetables, sauce, and bacon bits (or poultry bacon bits) - 110 grams RACC
- Rendered poultry fat – 1 tbsp RACC

The reference amount of a product that requires cooking or the addition of water or other ingredients is the amount required to prepare one reference amount of the final product. The reference amount for products that represent two or more foods packaged and presented to be consumed together (e.g., lunch meat with cheese and crackers) is typically the sum of the proportional reference amounts for each individual food in the package, provided the reference amount for the combination product is not specifically listed.

Reference amounts must be used to determine whether a product meets the criteria for nutrient content claims and health claims. Reference amounts may be established or amended by submitting a petition to FSIS. The petition requirements are specified by regulation. <sup>185</sup>

#### **4. Converting Reference Amounts Customarily Consumed (RACCs) to Labeled Serving Sizes**

##### **a. Products in discrete units**

The serving size for products in discrete units (e.g., hot dogs, sliced luncheon meats) and products consisting of two or more foods packaged to be consumed together (e.g., beef fritters and barbeque sauce) generally is the number of whole units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent, of the reference amount, the serving size shall be one unit. If a unit weighs more than 50 percent, but less than 67 percent, of the reference amount, the manufacturer may declare one or two units as the serving size. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving only if it can reasonably be consumed at a single eating occasion.<sup>186</sup>

The serving size for products in large, discrete units that are usually divided for consumption (e.g., pizza, quiche) is the fractional slice of the food that most closely approximates the reference amount for the product category. The fractions are 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be divisible by 2 or 3. For packages used to prepare the large, discrete unit (e.g., pizza kits), the serving size may be the fraction of the package used to make the reference amount of the large, discrete unit.<sup>187</sup>

For assortments of meat or meat food products (e.g., variety packs), nutrient content may be expressed for the entire package or individual products.

### **b. Bulk products**

The serving size for bulk products (e.g., whole roast beef, whole chicken, large cans of chili, Individually Quick Frozen (IQF) chicken, vegetable pasta, and sauce products) and products consisting of two or more foods packaged to be consumed together (e.g., roast beef and potatoes) is the amount in household measure that most closely approximates the reference amount for the product category. For “mixed dishes measurable by the cup” sold as IQF products, the serving size is the amount of frozen product it takes to make 1 cup of the ready-to-serve product. This amount of frozen product is usually slightly larger than the 1 cup, ready-to-serve serving size since the product compacts when cooked.

### **c. Meal-type products**

The serving size for meal products that come in single-serving containers is the entire content (“edible portion only”) of the package. The serving sizes for meal products that do not have RACCs are based on the RACC of the main ingredients and a portion of the other ingredients. For example if a meal consisted of a beef roast, gravy, and a separate package of potatoes, the company would base the serving size on 3 ounces of beef with the gravy and potato component proportioned evenly among the number of servings of the beef. Meal products do not base serving size on the sum of reference amounts. Additionally, FSIS has permitted companies to label multiple-serve meal products as a “meal for X” and a serving size of “1/x of package.”

For a package containing two or more foods packaged and presented to be consumed together where the main ingredient is presented in discrete units (e.g., chicken fritters and corn), the serving size is the number of discrete units of the main ingredient, plus proportioned minor ingredients used to make the reference amount.

A package containing several varieties of single-serving units, or a product having two or more compartments containing different foods, must provide nutrition information for each variety of food per serving size that is based on the reference amount for each food category. For single-serving containers, the serving size must be one unit.

A product that is packaged and sold individually (i.e., single-serving containers) and that contains less than 200 percent of the reference amount, must be labeled as one serving. Products that have reference amounts of 100 grams (or 100 milliliters) or larger may declare the number of servings as either one or two when the package contains more than 150 percent but less than 200 percent of the reference amount. Packages sold individually that contain 200 percent or more of the reference amount may be declared as one serving if the entire package reasonably can be consumed in one eating occasion <sup>188</sup>.

#### **d. Exceptions**

There are four specified exceptions to the rules for converting reference amount to serving size: weight control products, meal products, variety packages, and single-serving containers. For products intended for

weight control and available only through a weight control program, a serving size may be selected by the manufacturer that is consistent with the meal plan of the program. Such products must bear a statement, “for sale only through the underlying \_\_\_\_\_ program (fill in the blank with the name of the appropriate weight control program,) (e.g., “Smith’s Weight Control”).)

### **5. Servings Per Container**

Detailed procedures are established for determining the number of servings per container, including the increments in which the serving should be declared and procedures for rounding. The number of servings should be rounded to the nearest whole number, except the number of servings between 2 and 5 servings should be rounded to the nearest 0.5 serving. Rounding should always be indicated by “about.”<sup>189</sup>

Random weight products may be declared as “varied” provided the nutrition information is based on the reference amount expressed in ounces. When the serving size is required to be expressed on a drained solids basis and the number of servings vary because of natural variations in unit size (e.g., pickled pigs feet,) the manufacturer may state the typical number of servings per container as “usually 5 servings.”

The number of servings in packages containing single-serving containers should be the number of individual containers. For packages containing several multi-serving units, the number of servings is determined by multiplying the number of individual multi-serving units by the number of servings in each individual unit.

The nutrient- and food-component content should always be based on the product as packaged or purchased. Products packed in water, brine, or oil not customarily consumed, however, shall declare the content of the drained solids.<sup>190</sup> If oil or broth is included in the net weight, nutrition information must be declared for both the oil and broth. Product that is sold “bone-in” must determine the average percentage of bone and deduct that amount when calculating the number of servings per container.

Those products commonly combined with other ingredients or otherwise prepared before consumption may declare nutrient contents on the basis of the product alone or “as-consumed,” provided that the type and quantity of the ingredients to be added and the specific method of preparation is specified. For example, a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving) and another set for the soup when prepared.<sup>191</sup>

### **XIII. NUTRIENT CONTENT CLAIMS GENERALLY**

#### **A. General Requirements**

##### **1. Basic Principles Claims**

A food label may not bear an express or implied claim that characterizes the level of a nutrient in a food (nutrient content claim) unless the term has been defined by regulations.<sup>192</sup> An express nutrient content claim is considered to be “any direct statement about the level (or range) of a nutrient in the food” (e.g., “low sodium”.) An implied nutrient content claim includes any claim that describes the food or an ingredient therein in a

manner that suggests that a nutrient is absent or present in a certain amount (e.g., “high in oat bran” or “only 6 grams of fat”), or suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”). A manufacturer must comply with the nutrient content claim regulations if a label claim statement constitutes an express or implied claim. If a product label bears a nutrient content claim, nutrition labeling is required even if the product would otherwise be exempt.

The RACCs are the basis for determining the serving size of foods and are used in determining whether a product meets the criteria for a nutrient content claim, unless otherwise specified. Claims may not be based on the level of a nutrient present in the declared serving size. If the declared serving size differs from the applicable reference amount and the product does not qualify for the claim based on the stated serving size, the claim must be followed by the criteria for the claim. In addition, the panel must include a statement referring the consumer to the nutrition label for information about the nutrient that is the subject of the claim (e.g., “very low sodium, 35 mg or less per 55 grams”). The criteria for the claim must be immediately adjacent to the most prominent claim in legible print and in a size no less than that required for net weight. <sup>193</sup>

## **2. Various General Requirements**

The regulations for the nutrition labeling of meat and poultry products describe several general labeling requirements pertaining to nutrient content claims. For example, information provided as part of the nutrition panel is not considered a nutrient content claim. However, if this information is stated elsewhere on the label (e.g., on the principal display panel,) it could be considered an implied claim and regulated as such.<sup>194</sup>

FSIS regulations also define what constitutes a “substitute” food.<sup>195</sup> A “substitute” food is one that may be used interchangeably with another food that it resembles (i.e., to which it is organoleptically, physically, and functionally similar,) and to which it is not nutritionally inferior. Products that are intended to be “substitute foods,” but are nutritionally inferior, must be labeled as an imitation food. The regulations provide further guidance concerning this definition. What constitutes a “substitute food” is relevant to many of the defined claims.

Foods that qualify for a “low” claim, or labels that represent that a nutrient is absent, without the benefit of special processing, alteration, formulation, or reformulation, must bear a qualifying statement immediately accompanying the claim (e.g., “lard, a sodium-free food”.) In addition, FSIS takes the position that “free” or “low” before the name of a food implies that a food is lower in the particular nutrient than other foods of the same type. Therefore, only if a food has been specially processed, altered, formulated, or reformulated to produce a lower amount of the particular nutrient may it bear

a “free” or “low” claim preceding the product name (e.g., “low sodium beef noodle soup”.)<sup>196</sup>

Placement and prominence requirements are specified for nutrient content claims. The type size and style of a nutrient content claim may be no larger than two times that of the statement of identity of the food for which the claim is made. The regulations setting forth the specific definitions for each of the claims explained below include detailed placement and prominence requirements. Labeling information required to accompany certain nutrient content claim, whose type size is not specified by regulation, is required to be no less than 1/16 in height.<sup>197</sup>

### **3. Numeric and Percent Declarations**

A statement about the amount or percentage of a nutrient that implicitly characterizes the level of a nutrient is permitted if the food qualifies for a defined claim (e.g., “less than 10 grams of fat per serving”.)<sup>198</sup> If the food bearing the factual claim does not qualify for an applicable claim for the nutrient that is the subject of the factual statement, it must be accompanied by a disclaimer adjacent to the statement that the food is not low in, or a good source of, the nutrient for which the claim is made (e.g., only contains 200 milligrams of sodium per serving, not a low sodium food.) This requirement is intended to avoid a misleading impression that, for example, a food that contains “less than 300 calories” is a low calorie food. The regulations specify prominence and placement requirements for the disclaimer statement. Finally, a factual statement that does not implicitly characterize the level of a

nutrient and is not false or misleading is permitted and no disclaimer is required (e.g., “100 calories” or “5 grams of fat”.) Percent fat free claims are addressed separately and are explained below. <sup>199</sup>

#### **4. Relative Claims -- General Requirements**

Relative claims are those statements that compare the level of a nutrient in a food to the level of a nutrient in an appropriate reference food. Relative claims include: “light,” “reduced,” “less” (or “fewer”,) and “more.” This section of the Guide discusses the basic requirements applicable to all relative claims. Later sections of the Guide that address each of the specific claim’s definitions do not repeat these general requirements. <sup>200</sup>

##### **a. Appropriate Reference Food**

FSIS regulations governing the use of reference foods must be followed. <sup>201</sup> Generally, for relative claims “less,” “fewer,” and “more,” the reference food may be a similar product or a dissimilar product. For “light,” “reduced,” and “added” claims, the reference product should be a similar product. <sup>202</sup>

##### **b. Information that Must Accompany a Relative Claim**

The following explanatory information must accompany a relative claim:

- identity of the reference food and the percentage (or a fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified (e.g., 50 percent less fat than (reference food) or 1/3 fewer calories than (reference food)); and

- a clear and concise quantitative information statement comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food must appear adjacent to the most prominent claim or on the information panel contiguous to the nutrition panel (e.g., fat reduced from 10 g to 5 g or calories reduced from 200 to 120.)

A relative claim describing a reduction in the level of a nutrient (e.g., “light,” “less”) is not permitted if the nutrient content of the reference food qualifies as “low” for that nutrient. This restriction is intended to avoid use of the claim to highlight trivial reductions in the level of a nutrient.

Use of the term “modified” is separately defined.<sup>203</sup> A “modified” claim may be used in the statement of identity (i.e., the product name) of a food that bears a relative claim (e.g., “reduced”), if followed immediately by the name of the nutrient whose content has been altered (e.g., “modified fat product”.) The statement of identity must be accompanied by a comparative statement such as “contains 35% less than \_\_\_\_\_,” and provide the explanatory information required for relative claims, as explained above.<sup>204</sup>

### **5. Claims for Main Dish and Meal-Type Products are Defined Separately**

[9 C.F.R. § 317.313(l)&(m) (meat); 9 C.F.R. § 381.413(l) &(m) (poultry)]

For the purpose of making a nutrient content claim, a “main dish product” must do the following:<sup>205</sup>

- make a significant contribution to the diet by weighing at least 6 ounces per labeled serving;
- contain at least two 40-gram portions of food, or combinations of foods, from two or more of the following four food groups: (1) bread, cereal, rice and pasta; (2) fruits and vegetables; (3) milk, yogurt and cheese;

and (4) meat, poultry, fish, dry beans, eggs and nuts; excluding most sauces, as well as gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

- be represented as, or is in a form of a “main dish” (e.g., not a beverage or dessert.)

For the purpose of making a nutrient content claim, a “meal-type product” must do the following: <sup>206</sup>

- make a significant contribution to the diet by weighing at least 10 ounces per labeled serving;
- contain at least three 40-gram portions of food, or combinations of foods, from two or more of the following four food groups: (1) bread, cereal, rice and pasta; (2) fruits and vegetables; (3) milk, yogurt and cheese; and (4) meat, poultry, fish, dry beans, eggs and nuts; excluding most sauces, as well as gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and
- be represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, or entrée.

## **6. Exemptions**

Claims contained in the brand name of a product in use before November 27, 1991, that have not been defined are exempt from these specific regulatory restrictions, provided the brand name is not otherwise deemed false or misleading. <sup>207</sup> An exempt brand name must still comply with the requirements pertaining to the prominence of a claim, the referral statement, and disclosure of nutrients in the referral statement. An implied nutrient content claim may otherwise be part of a brand name if the claim has been authorized by FSIS. Claims that are part of a product name by virtue of a standard of identity, as of November 27, 1991, are not subject to

the nutrient content regulations, nor would the name be deemed an implied claim or subject to the referral statement or disclosure requirements.

Apart from brand names, a statement that describes the percentage of a vitamin or mineral in the food in relation to a Recommended Daily Intake (RDI) level, unless the claim is specifically prohibited, is exempt from the nutrient content claims regulations. <sup>208</sup>

## **B. Specific Nutrient Content Claims**

### **1. “High,” “Good Source” and “More” Claims**

[9 C.F.R. 317.354 (meat) and 9 C.F.R. 381.454 (poultry)]

A claim made about the level of a nutrient in a food in relation to the Recommended Daily Intake (RDI) or Daily Recommended Value (DRV) (excluding total carbohydrate) may only be made if the claim is defined within this section of the Guide. Therefore, claims may only be stated using the terms specified by the regulation. <sup>209</sup>

#### **a. “High” Claims**

The terms “high,” “rich in,” or “excellent source of” may be used if the claimed nutrient is present in the individual food at 20 percent or more of the RDI or the DRV per reference amount customarily consumed (RACC). Main dish and meal products would qualify for this claim if the 20 percent level is reached and the label identifies the food component that is the subject of the claim (e.g., “the serving of broccoli in this product is high in vitamin C”.) <sup>210</sup>

### **b. “Good Source” Claims**

The terms “good source,” “contains,” or “provides” may be used if the claimed nutrient is present in the individual food between 10 to 19 percent of the RDI or DRV per RACC. Main dish and meal products would qualify for this claim if the 10 to 19 percent level is reached and the label identifies the food component that is the subject of the claim. <sup>211</sup>

### **c. “More” Claims**

The comparative claim “more” may be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium present in an individual food if the claimed nutrient is present in the food at 10 percent more of the applicable RDI or DRV per RACC as compared to an appropriate reference food. The explanatory information required for relative claims (explained above) must accompany the claim. <sup>212</sup>

A “more” or similar claim may describe a main dish or meal product if the food contains at least 10 percent more of the applicable RDI or DRV than an appropriate reference food, per 100 grams. The other requirements stated with respect to an individual food similarly apply to the claim when made for a main dish or meal product. <sup>213</sup>

## **2. “Light” and “Lite” Claims**

[9 C.F.R. 317.356 (meat) and 9 C.F.R. 381.456 (poultry)]

The terms “light” and “lite” may be used without further qualification. If a product derives 50 percent or more of its calories from fat, its fat content must be reduced by 50 percent or more per RACC as compared

to an appropriate reference food. If a product derives less than 50 percent of its calories from fat, the number of calories must be reduced by at least one-third per RACC or its fat content must be reduced by 50 percent or more compared to an appropriate reference product.

As required with other relative claims, the identity of the reference product must be clearly declared, and quantitative information comparing the fat and calorie content of the product must be prominent. A “light” or “lite” claim may not be made on a product that meets the definition of “low fat” or “low calorie.”

The terms “light” and “lite” may be used on a main dish or meal-type product if the product qualifies for the “low calorie” or “low fat” claims and if a statement on the product’s PDP explains the meaning of the claim.<sup>214</sup>

### **3. “Sodium” and “Salt” Claims**

#### **a. “Sodium Free” Claims**

The terms “sodium free,” “free of sodium,” “no sodium,” “zero sodium,” “without sodium,” “trivial source of sodium,” “negligible source of sodium,” or “dietary insignificant source of sodium” may be used if the individual food contains less than 5 milligrams of sodium per reference amount (or in the case of a main dish or meal product less than 5 milligrams of sodium per labeled serving size). In addition, the food may not contain any ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the

statement, “adds a trivial amount of sodium,” or a similar specified statement. If the food meets these conditions without the benefit of special processing, it must include an appropriate qualifying statement (e.g., “leaf lettuce, a sodium free food”.) <sup>215</sup>

### **b. “Very Low Sodium” Claims**

The terms “very low sodium” or “very low in sodium” may be used if the individual food has an RACC that contains 35 milligrams or less per RACC (and per 50 grams if it is a small-serving size food). If the food qualifies for this claim without the benefit of special processing, an appropriate qualifying statement must accompany the claim (e.g., “potatoes, a very low sodium food”.) <sup>216</sup>

For a main dish or meal product, the sodium content is measured per 100 grams. The requirements for an individual food are otherwise applicable. <sup>217</sup>

### **c. “Low Sodium” Claims**

The terms “low sodium,” “low in sodium,” “little sodium,” “contains a small amount of sodium,” or “low source of sodium” may be used if the individual food contains 140 milligrams or less sodium per RACC (and per 50 grams if it is a small-serving size food). Individual products with an RACC greater than 30 grams, or 2 tablespoons, and containing 140 mg or less sodium per RACC also qualify. <sup>218</sup> If the food qualifies for the claim without

the benefit of special processing, an appropriate qualifying statement must accompany the claim (e.g., “spinach, a low sodium food”.)<sup>219</sup>

For main dish and meal products, the food would qualify for this sodium claim if it contained 140 milligrams or less sodium per 100 grams.

#### **d. “Reduced Sodium” Claims**

The terms “reduced sodium,” “reduced in sodium,” “sodium reduced,” “less sodium,” “lower sodium,” or “lower in sodium” may be used if the individual food contains at least a 25 percent reduction in sodium as compared to an appropriate reference food. The claim must be accompanied by explanatory information required for relative claims.<sup>220</sup>

For main dish and meal products, the 25 percent reduction in sodium is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. No food may bear a “reduced sodium” claim if the reference food qualifies for a “low sodium” claim.

#### **e. “Salt” Claims**

“Salt” is not considered synonymous with “sodium.” References to salt content, such as “unsalted,” “no salt,” or “no salt added,” are deemed potentially misleading and subject to regulation. The term “salt free” may only be used if the food is “sodium free”. In addition, the terms “unsalted,” “without added salt,” and “no salt added” may be used for a food only if:

- (1) no salt is added during processing;
- (2) the food that it resembles and for

which it substitutes is normally processed with salt; and, (3) if it is not “sodium free,” the statement “not a sodium free food” is declared contiguous to the nutrition information on the information panel. <sup>221</sup>

#### **4. “Nutrient Content” Claims for Fat, Fatty Acids and Cholesterol Content**

[9 C.F.R. 317.362 (meat) and 9 C.F.R. 381.462 (poultry)]

##### **a. “Fat Content” Claims**

###### **(1) “Fat Free” Claims**

The terms “fat free,” “free of fat,” “no fat,” “zero fat,” “without fat,” “nonfat,” “trivial source of fat,” “negligible source of fat,” or “dietarily insignificant source of fat” may be used if the food contains less than 0.5 grams of fat per RACC or in the case of a main dish or meal product less than 0.5 grams of fat per labeled serving. In addition, the food may not contain any added ingredient that is a fat or is generally understood by consumers to contain fat unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the statement, “adds a trivial amount of fat,” or similar specified statement. If the food meets these conditions without the benefit of special processing, it must include an appropriate qualifying statement (e.g. “broccoli, a fat free food”). <sup>222</sup>

###### **(2) “Low Fat” Claims**

The terms “low fat,” “low in fat,” “contains a small amount of fat,” “low source of fat,” or “little fat” may be used if the individual food contains 3 grams or less of fat per RACC, and per 50 grams if it is a small serving size

food. If the food qualifies for the claim without the benefit of special processing, it must be accompanied by an appropriate qualifying statement.

A main dish or meal must meet the 3 grams or fewer criterion per 100 grams and not derive more than 30 percent of calories from fat. The requirements for an individual food are otherwise applicable.<sup>223</sup>

### **(3) “Reduced Fat” Claims**

The terms “reduced fat,” “reduced in fat,” “fat reduced,” “less fat,” “lower fat,” or “lower in fat” may be used if the individual food contains 25 percent less fat than the appropriate reference food. The claim must be accompanied by the explanatory information required for relative claims.

For main dish and meal products, the 25 percent reduction in the fat is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. No food may bear a “reduced fat” claim if the reference food qualifies for a “low fat” claim.<sup>224</sup>

### **(4) “Percent Fat-Free” Claims**

A “percent fat-free” or “percent lean” claim is restricted to products that qualify as “low fat.” The percent reduction and the words “fat free” must be in uniform type size. Separately, a “100 percent fat-free” claim may only be made on foods that meet the criteria for “fat-free,” contain less than 0.5 grams of fat per 100 grams, and contain no added fat. A synonym for “percent fat free” is “percent lean.”<sup>225</sup>

## **b. “Fatty Acid Content” Claims**

Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Placement and prominence requirements are specified. Declaration of cholesterol content may be omitted if the food contains less than two milligrams of cholesterol per RACC (or per labeled serving for main dish and meal products), and fat content may be omitted if fat is present at 0.5 grams or less per reference amount (or per labeled serving for main dish and meal products). The declaration of total fat may also be omitted if the food qualifies for a “low fat” claim. In addition to these general requirements, the regulation sets forth detailed requirements for specific claims that are permitted.<sup>226</sup>

### **(1) “Saturated Fat-Free” Claims**

The terms “saturated fat-free,” “free of saturated fat,” “no saturated fat,” “zero saturated fat,” “without saturated fat,” “trivial source of saturated fat,” “negligible source of saturated fat,” or “dietary insignificant source of saturated fat” may be used if the food contains less than 0.5 grams of saturated fat and less than 0.5 grams trans fatty acid per RACC (or in the case of a main dish or meal product less than 0.5 grams of saturated fat and less than 0.5 grams trans fatty acid per labeled serving size).<sup>227</sup>

In addition, the food may not contain any ingredient that is a saturated fat or is generally understood by consumers to contain saturated fat unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the statement, “adds a

trivial amount of saturated fat,” or similar specified statement. If the food meets these conditions without the benefit of special processing, it must include an appropriate qualifying statement.

### **(2) “Low In Saturated Fat” Claims**

The terms “low in saturated fat,” “low saturated fat,” “contains a small amount of saturated fat,” “low source of saturated fat,” or “a little saturated fat” may be used if the individual food contains 1 gram or less of saturated fatty acids per RACC and not more than 15 percent of calories from saturated fatty acids. If the food qualifies for the claim without the benefit of special processing, it must be accompanied by an appropriate qualifying statement, which clearly refers to all food of its type and not merely to the particular food to which the label is attached.<sup>228</sup>

For a main dish or meal product, the food must contain 1 gram or less of saturated fat and fewer than 10 percent calories from saturated fat, measured per 100 grams. The requirements for an individual food are otherwise applicable.<sup>229</sup>

### **(3) “Reduced Saturated Fat” Claims**

The terms “reduced saturated fat,” “reduced in saturated fat,” “saturated fat reduced,” “less saturated fat,” “lower saturated fat,” or “lower in saturated fat” may be used if the individual food contains 25 percent less saturated fat per RACC than an appropriate reference food. The explanatory information required for relative claims must accompany the claim.<sup>230</sup>

For a main dish or meal product, the food must contain 25 percent less saturated fat per 100 grams than an appropriate reference food. The requirements for an individual food are otherwise applicable. A food cannot be labeled with a “reduced saturated fat” claim if the reference food qualifies for a “low saturated fat” claim.

**c. “Cholesterol Content” Claims**

**(1) “Cholesterol Free” Claims**

The terms “cholesterol free,” “free of cholesterol,” “zero cholesterol,” “without cholesterol,” “no cholesterol,” “trivial source of cholesterol,” “negligible source of cholesterol,” or “dietary insignificant source of cholesterol” may be used if:

- the individual food contains 2 milligrams or less of cholesterol per reference amount (or in the case of a main dish or meal product per labeled serving size);
- the food contains no ingredient generally understood by consumers to contain cholesterol, unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk which refers consumers to the statement, “adds a trivial amount of cholesterol,” or similar specified statement;
- the food contains 2 grams or less of saturated fat per reference amount (or for a main dish or meal product per labeled serving); and
- the food qualifies for the claim without the benefit of special processing, it must include an appropriate qualifying statement.

A main dish or meal product may generally bear a “cholesterol free” claim if it meets the requirements set forth above for individual foods,

but the 2 milligrams cholesterol and 2 grams saturated fat criteria are measured per 100 grams, rather than per reference amount. <sup>231</sup>

### **(2) “Low in Cholesterol” Claims**

The terms “low in cholesterol,” “low cholesterol,” “contains a small amount of cholesterol,” “low source of cholesterol,” or “little cholesterol,” may be used to describe food that does not exceed the applicable disclosure level for total fat if the food:

- has a RACC greater than 30 g or greater than 2 tbsp;
- contains 20 milligrams or less of cholesterol per reference amount and per 50 grams if it is a small-serving size food;
- contains 2 grams or less of saturated fat per reference amount; and
- qualifies for the claim without the benefit of special processing, it must include an appropriate qualifying statement.

A main dish or meal product may generally bear a “low cholesterol” claim if it meets the requirements set forth above for individual foods, but the 20 milligrams cholesterol and 2 grams saturated fat criteria are measured per 100 grams, rather than per reference amount. <sup>232</sup>

### **(3) “Reduced Cholesterol” Claims**

The terms “reduced cholesterol,” “reduced in cholesterol,” “cholesterol reduced,” “less cholesterol,” “lower cholesterol,” or “lower in cholesterol” may be used if the food:

- has been specially formulated, altered or processed to reduce its cholesterol content by at least 25 percent from the reference food it replaces and for which it substitutes if the reference food has a

significant market share (i.e., 5 percent or more of a national or regional market);

- contains 2 grams or less of saturated fat per reference amount; and
- is accompanied by information required for relative claims.

The placement and prominence requirements for the fat content statement are specified. A “reduced cholesterol” claim is not permitted for any food if the reference food qualifies for a “low cholesterol” claim.

The “reduced cholesterol” claim also may be used on main dish or meal products if the product has been specifically formulated to reduce cholesterol by 25 percent, or if the main dish or meal contains 2 grams or less of saturated fat per 100 grams of product.<sup>233</sup> The identity of the reference product and the percent that the cholesterol has been reduced must be declared in immediate proximity to the “reduced cholesterol” claim.<sup>234</sup>

#### **d. “Lean” and “Extra Lean” Claims**

The term “lean” may be used to describe an individual food as packaged when it contains less than 10 grams of fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol per reference amount and per 100 grams. For a main dish or meal to qualify as “lean,” it must meet these specified levels for fat, saturated fat, and cholesterol per 100 grams and per labeled serving.

The term “extra lean” may be used to describe products that contain less than 5 grams of total fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol per reference amount and per 100

grams. For main dish or meal products, these levels apply per 100 grams and per labeled serving size. <sup>235</sup>

## **5. “Fiber” Claims**

A claim that represents the level of dietary fiber in a food is permitted if the level of the nutrient would qualify for a claim (i.e., “high,” “more,” or “good source”.) If the food is not low in total fat, the label must disclose the level of total fat per labeled serving (e.g., “contains 12 grams (g) of total fat per serving”.) This statement must appear in immediate proximity to the claim. <sup>236</sup>

## **6. “Healthy” Claims**

The term “healthy” or any other derivative of the term “health” may be used to describe an individual food provided the food (1) meets the requirements for “low fat” and “low saturated fat;” (2) does not contain more than 60 milligrams of cholesterol per RACC and labeled serving size (per 50 grams if the RACC is less than 30 grams); (3) does not contain more than 480 milligrams of sodium per RACC and labeled serving size (per 50 grams if the RACC is less than 50 grams); and (4) contains 10 percent or more of RDI or DRV per reference for one of the following: vitamin A, vitamin C, iron, calcium, protein, or fiber. Single-ingredient, raw foods need not meet the sodium requirement, and instead of meeting the fat and cholesterol requirements, single-ingredient, raw foods may meet the total fat, saturated fat, and cholesterol criteria for “extra lean.” <sup>237</sup>

A “healthy” main dish or meal must meet the requirements for low

fat and low saturated fat requirements for main dish and meal-type products (i.e., 3 grams or less of total fat per 100 grams of product and not more than 30 percent of the calories from fat, and 1 gram or less of saturated fat per 100 grams of product and less than 10 percent of the calories from saturated fat.) Main dish and meal-type products that weigh less than 12 ounces per serving (container) cannot contain more than 60 milligrams of cholesterol per labeled serving while main dish and meal-type products weighing more than 12 ounces per serving (container) may contain no more than 90 milligrams of cholesterol per labeled serving. Additionally, main dish and meal-type products may contain up to 600 milligrams of sodium. Main dish products weighing 6 to 10 ounces per serving need only meet the RDI or DRV level for two of the listed nutrients, and meal-type products weighing 10 or more ounces need only meet the level for three of the nutrients. <sup>238</sup>

#### **7. Claims Related to Usefulness in Reducing or Maintaining Body Weight**

Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear (1) nutrition labeling, unless exempt, and (2) a conspicuous statement of the basis upon which the food claims to be of special dietary usefulness. If the food achieves its special dietary usefulness by use of a non-nutritive ingredient (i.e., one not utilized in normal metabolism), the label must contain a statement that discloses the non-nutritive ingredient and its percentage by weight, except if such ingredient is a non-nutritive sweetener, in which case the percentage by weight does not have to be declared. <sup>239</sup> If a nutritive

sweetener, as well as a nonnutritive sweetener is added, the presence of both must be declared.

Foods purporting to be “low calorie,” “reduced calorie,” or otherwise containing fewer calories than a reference food must comply with the nutrient content claim regulations. Except as provided below, a food may be labeled with terms such as “diet,” “dietetic,” “artificially sweetened,” or “sweetened with non-nutritive sweetener” only if the claim is not false and misleading and the food is labeled “low calorie” or “reduced calorie” or bears another comparative claim according to the nutrient content claim regulations. The exemptions to the previous requirement include (1) the use of a term that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term “diet” that clearly shows that the food is offered solely for dietary use other than regulating body weight (e.g., for low sodium diets); and (2) the use of a term on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal.<sup>240</sup>

## **8. “Health” Claims**

A “health” claim describes a relationship between a food and a disease or health-related condition. FSIS has not issued regulations providing for the use of a “health” claim. Many such claims have been authorized for use by FDA on labeling of food products subject to its jurisdiction. FSIS will consider on a case-by-case basis the use of an FDA-regulated “health” claim or such a “health” claim in conjunction with a

third-party certification program. An example is the American Heart Association’s heart-check mark, which maintains its own criteria for eligibility and includes a “health” claim in conjunction with its certifying mark (e.g., “Meets American Heart Association food criteria for saturated fat and cholesterol for healthy people over age 2. While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.”)

## **9. “Calorie Content” Claims**

### **a. “Calorie Content” Claims**

#### **(1) “Calorie Free” Claims**

The terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietary insignificant source of calories” may be used if the individual food contains less than 5 calories per reference amount. If the food meets the requirements without the benefit of special processing, the claim may be accompanied by a statement such as, “a low calorie food” (e.g., cider vinegar, a calorie free food.) <sup>241</sup>

#### **(2) “Low Calorie” Claims**

The terms “low calorie,” “few calories,” “contains a small amount of calories,” “low source of calories,” or “low in calories” may be used if the individual food contains no more than 40 calories per reference amount (except for sugar substitutes) and per 50 grams for dehydrated products, etc., if it is a small-serving-size food. A small-serving-size food is a food with a

reference amount of 30 grams or less or 2 tablespoons or less (“small serving size food”). If the food qualifies for the claim without the benefit of special processing, it must be labeled to clearly refer to all products of its type and not merely the particular brand to which the label attaches (e.g., “celery, a low calorie food”.)

The requirements for a “low calorie” main dish or meal product are similar. That is, these products must contain 120 calories or less per 100 grams and meet the other requirements specified above for individual foods. <sup>242</sup>

### **(3) “Reduced Calorie” Claims**

The terms “reduced calorie,” “reduced in calories,” “calories reduced,” “fewer calories,” “lower calorie,” or “lower in calories” may be used if an individual food contains at least 25 percent fewer calories per RACC as compared to an appropriate reference food. The claim must be accompanied by explanatory information required for relative claims. For a main dish or meal product, the 25 percent reduction in calories is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. The claim is not permitted for any food if the reference food meets the definition of “low calorie.” <sup>243</sup>

#### **b. “Sugar Content” Claims**

##### **(1) “Sugar Free” Claims**

The terms “sugar free,” “free of sugar,” “no sugar,” “zero sugar,” “without sugar,” “sugarless,” “trivial source of sugar,” “negligible source of

sugar,” or “dietary insignificant source of sugar” may be used if the food contains less than 0.5 grams of sugar per RACC (or in the case of a main dish or meal product per labeled serving.) In addition, the food may not contain any ingredient that is a sugar or is generally understood by consumers to contain sugars or sweeteners unless the ingredient, as declared in the ingredients statement, is accompanied by an asterisk that refers consumers to the statement, “Adds a trivial amount of sugar,” or a similar specified statement. The food must be labeled “low calorie” or “reduced calorie” or bear a relative claim of special dietary usefulness, or the “sugar free” claim must be accompanied by the statement, “not a low calorie food,” or a similar specified statement. <sup>244</sup>

## **(2) “No Added Sugar” Claims**

The terms “no added sugar,” “without added sugar,” and “no sugar added” may be used only if:

- no amount of sugars, or any other ingredient that contains sugar that functionally substitutes for added sugars, is added during processing or packaging;
- the product does not contain an ingredient containing added sugars, such as jam, jelly, or concentrated fruit juices;
- the sugar content has not been increased by the amount present in the ingredients by the use of enzymes or similar means, except where the intended functional effect of the process is not to increase the sugar content of a food, and a functionally-insignificant increase in sugars results; and
- the food that it resembles and for which it substitutes normally contains added sugars.

- In addition, if the food does not qualify as “low calorie,” a statement must direct the consumers’ attention to the nutrition panel for further information on sugar and calorie content.

The requirements governing “sugar free” claims are not applicable to a factual statement that a food is unsweetened, or contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content (e.g., juices). <sup>245</sup>

### **(3) “Reduced Sugar” Claims**

The terms “reduced sugar,” “reduced in sugar,” “sugar reduced,” “less sugar,” “lower sugar,” or “lower in sugar” may be used if the sugar content in the individual food is reduced by 25 percent per RACC as compared to an appropriate reference food. The claim must be accompanied by the explanatory information required for relative claims. For main dish and meal products, the 25 percent reduction in sugars is measured per 100 grams as compared to an appropriate reference food. The requirements for an individual food are otherwise applicable. <sup>246</sup>

## Appendix A

### Egg Products Labeling

#### I. Egg Products Labeling

Egg product labels bearing official USDA identification markers must be approved and comply with all applicable regulations. There are seven requirements for egg products labeling: product name; manufacturer's name; official identification; USDA approval number; ingredients statement; net weight statement; and nutrition information.

##### a. Product Name

Eggs are defined as the "shell egg" of the domesticated chicken, turkey, duck, goose, or guinea. Egg products are any dried, frozen, or liquid eggs, with or without added ingredients.<sup>247</sup> All egg product labels must include the name and state of the product, (e.g., dried, frozen, liquid, or whole egg, egg yolks, egg whites,) and must appear in print size similar to the most prominent printing on the label. In addition, a trade name may be used in conjunction with the product identity.

Products formulated from eggs that do not meet the applicable definitions must be identified by an appropriately descriptive name that is not false or misleading. Food products containing eggs in relatively small proportions or which historically have not been considered to be egg products may not be labeled as an egg product (e.g., omelet mix, egg nog mix, noodles, cake mixes).<sup>248</sup> These products, along with "imitation" egg products are eligible for identification with the USDA inspection legend only under the voluntary egg products inspection program.<sup>249</sup>

##### *Whole Eggs*

Liquid or frozen whole eggs are eggs of domestic hens broken from the shells with the yolks and whites in their natural proportion.<sup>250</sup> A combination of whites and yolks in other than natural proportions, such as "accidentally broken" whole eggs, may be identified as whole eggs provided the egg solids content is standardized to 24.2% or greater.<sup>251</sup> Whole eggs may be mixed, or mixed and strained, and must be pasteurized or otherwise treated to destroy all viable *Salmonella* micro-organisms.

Dried eggs (or dried whole eggs) or frozen eggs are prepared by drying or freezing liquid eggs with such precautions that the finished food is free of viable *Salmonella* micro-organisms. If the glucose content of the eggs was reduced during the drying process, the statements "Glucose removed for stability" or "Stabilized, glucose removed" must immediately follow the product name.<sup>252</sup>

## *Egg Yolks*

Egg yolks, liquid egg yolks, yolks, and liquid yolks are yolks of eggs of the domestic hen so separated from the whites thereof as to contain not less than 43 percent total egg solids. <sup>253</sup> Egg yolks may be mixed, or mixed and strained, and must be pasteurized or otherwise treated to destroy all viable *Salmonella* micro-organisms. Egg yolks may be dried or frozen according to applicable regulations.

Dried egg yolks (or dried yolks) or frozen egg yolks are prepared by either drying or freezing egg yolks with such precautions so that the finished food is free of viable *Salmonella* micro-organisms. Similar label statements for glucose removal must be included if necessary.

## *Egg Whites*

Egg whites, liquid egg whites, or liquid egg albumen is the food obtained from eggs of domestic hens, broken from the shells and separated from the yolks. <sup>254</sup> Egg whites may be mixed, or mixed and strained, and must be pasteurized or otherwise treated to destroy all viable *Salmonella* micro-organisms. Any optional use of ingredients such as whipping aids must be named on the PDP or panels of labels prominently and conspicuously so ordinary individuals under customary conditions of purchase are likely to understand them. <sup>255</sup> Egg whites may be dried or frozen according to applicable regulations.

If egg whites are dried, the product name may be “dried egg whites,” “egg white solids,” “dried egg albumen,” or “egg albumen solids.” If the lysozyme and avidin content of the product is reduced during the drying process, the product name must be immediately preceded or followed by the statement “lysozyme and avidin reduced.” <sup>256</sup> When dried eggs are used in another fabricated food product, these statements do not need to follow the product name.

### **b. Manufacturer’s Name**

Under the Fair Packaging and Labeling Act, the name and place of business of the manufacturer, packer, or distributor must be included on the PDP. <sup>257</sup> / The statement of the place of business must include the street address, city, state and zip code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. <sup>258</sup> /

### **c. Official Identification**

The U.S. Department of Agriculture maintains inspections of all official plants and the processing of egg products under the authority of the Egg Products Inspection Act. <sup>259</sup> / Each official egg processing plant granted

inspection services is assigned an official plant number. <sup>260</sup>/ A shield containing the letters “USDA” is the official identification symbol, and when it is used in connection with an egg product, it constitutes a representation that the product has been officially inspected. Egg products that bear the inspection mark must be processed in an official plant from edible shell eggs or other edible egg products. <sup>261</sup>/ Plants may not have more than one plant number.

The official shield must be printed on the PDP of the label using the design and wording shown below.



The plant number may be printed within the shield or elsewhere on the container. <sup>262</sup>/ When the plant number is not printed within the shield, the letter “P” or the word “Plant” must precede it. When the official shield is used on more than one label panel, it must be identically printed for each use. If a label does not bear all mandatory labeling information, it may not bear the official shield.

In addition, all shell eggs packaged for consumers must be labeled to indicate that refrigeration is required, (e.g., “Keep Refrigerated”,) or words of similar meaning. <sup>263</sup>

#### **d. USDA Approval Number**

Labels for use on egg products must be preapproved. A separate label approval number containing one letter and a three-digit number (e.g., M001) is assigned to each label that has been approved. The assigned USDA approval number must be printed within a rectangular box and needs to be no larger than the smallest printing on the label. Labels identifying imported egg products will contain a two-letter prefix, (e.g., CN001) and labels approved for identification of products for export only will have a one-letter code.

Self-adhesive strip labels may be used without approval; in conjunction with previously-approved printed labels provided the strip label does not cover any required labeling information showing the packer or

distributor's name and address; the product identity for whole eggs, egg yolks, or egg whites; or the state of the product.

#### **e. Ingredients Statement**

Only food-grade ingredients may be used in the production of egg products. Each of the ingredients used in egg products must be declared on the label as required by 21 C.F.R. Parts 101 and 130. Ingredients must be listed in order of descending proportion by weight on the PDP.

When approved, potable water may be added as a carrier for certain ingredients and additives used in the formulation of liquid or frozen egg products. The percentage of water added must be declared on the label in the ingredients statement in descending order of proportion by weight and shown as either “\_\_\_% water” or “with \_\_\_% water as a carrier.” <sup>264</sup>

When optional ingredients, such as monosodium phosphate, are used as preservatives, the label must bear the statement “Monosodium phosphate (or monopotassium phosphate), with \_\_ percent water as a carrier, added to preserve color.” <sup>265</sup> The blank must be filled in with the percent by weight of water used in proportion to the weight of the finished food. This optional ingredients statement must appear on the PDP or panels prominently and conspicuously. If an optional anticaking ingredient is used, the label must bear the statement, “Not more than 1 percent silicon dioxide added as an anticaking agent,” or “Less than 2 percent sodium silicoaluminate added as an anticaking agent,” whichever is applicable. <sup>266</sup>

Color may not be added to whole eggs, egg yolks, egg whites, salted or sugared whole eggs, and salted or sugared egg yolks. Any egg product that contains an additive which imparts color, including color additives certified as being natural, are considered to be artificially colored, and the product label must state that color has been added. If the color additive is derived from a natural source and a letter of certification is provided to the national office, the label must state that the additive has been added to color the product. This declaration may be made in the ingredients statement, (e.g., “annatto extract (artificial color)” or “colored with annatto extract.”) <sup>267</sup>

#### **f. Net Weight Statement**

Each egg product label must contain a net weight statement. The net weight statement must appear in the lower 30 percent of the label in lines generally parallel to the base on which the package rests and must appear as a distinct item on the label. The statement must be separated from any other printing above, below, or to either side of it by a space at least equal to the height of the letters in the net weight statement. A dual declaration net weight statement is only required on retail packages containing less than 4 pounds.

Regulations for the declaration of net quantity of contents can be found at 21 C.F.R. § 101.105.

**g. Nutrition Information**

Egg or egg product labels which may be distributed for retail sale must comply with FDA regulations governing nutrition labeling.<sup>268</sup> Egg products packaged for institutional use are not required to bear nutrition information, however, if a nutrient content or health claim is made, product labeling must comply with all nutrient content claim regulations.

Nutrition labeling is required when nutrients, such as proteins, vitamins, and minerals are added to the product, or when a nutritional claim or information is presented on the labeling, except if a nutrient is included in the product solely for technological purposes. If a nutrient is included solely for technological purposes it may be declared solely in the ingredients statement.<sup>269</sup>

## End Notes

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- <sup>1</sup> 21 U.S.C. §§ 601 *et seq.* (meat); 21 U.S.C. §§ 451 *et seq.* (poultry).
- <sup>2</sup> FSIS also regulates the labeling of egg products. These separate requirements are summarized at Appendix A of this Summary.
- <sup>3</sup> A misbranded food bears false or misleading labeling, while an adulterated food contains a poisonous or deleterious substance or otherwise poses a risk to consumer health. *See*, 21 U.S.C. §§ 453 and 601.
- <sup>4</sup> 21 U.S.C. § 601 *et seq.*
- <sup>5</sup> 21 U.S.C. § 451 *et seq.*
- <sup>6</sup> 21 U.S.C. § 601(o) and (p) (meat); 21 U.S.C. § 453(s) (poultry).
- <sup>7</sup> 21 U.S.C. § 607 (meat); 21 U.S.C. § 457 (poultry).
- <sup>8</sup> 21 U.S.C. § 601(n).
- <sup>9</sup> 21 U.S.C. § 453(h).
- <sup>10</sup> *See, e.g.*, 21 U.S.C. § 672-673 (meat); 21 U.S.C. § 467(a) – 467(b) (poultry).
- <sup>11</sup> 21 U.S.C. § 671 (meat); 21 U.S.C. § 467 (poultry).
- <sup>12</sup> 21 U.S.C. § 301 *et seq.*
- <sup>13</sup> *Id.* § 343(a).
- <sup>14</sup> 21 U.S.C. § 321(k).
- <sup>15</sup> *Id.* § 321(m). Under the FFDCA a manufacturer can be sanctioned in several ways if it violates a labeling requirement. FDA may seek a court order preventing the production and sale of misbranded foods. *Id.* § 332. Misbranded foods may also be confiscated by the government. *Id.* § 334. Moreover persons violating the FFDCA can be imprisoned for selling or offering for sale misbranded foods. *Id.* § 333.
- <sup>16</sup> 15 U.S.C. § 1451 *et seq.* The FPLA establishes requirements for package labels of all consumer commodities, including most foods. It defines the package as “any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers.” *Id.* § 1459(b).
- <sup>17</sup> 21 U.S.C. § 607(d) (meat); 21 U.S.C. § 457(c) (poultry). USDA has similar authority over egg products under the EPIA, 21 U.S.C. §1036(b).
- <sup>18</sup> *Id.*
- <sup>19</sup> 9 C.F.R. Part 317 *et seq.* (meat); 9 C.F.R. § 381.115 *et seq.* (poultry).
- <sup>20</sup> FDA has not taken the position adopted by USDA nor is it clear that the FFDCA or FPLA permit implementation of a preapproval system.
- <sup>21</sup> 21 U.S.C. § 601(j) (meat).
- <sup>22</sup> “Meat,” “meat food product,” livestock,” “poultry,” and “poultry product” are defined by the FMIA and the PPIA (21 U.S.C. §§ 601 and 453), respectively, and the Federal meat and poultry inspection regulations (9 C.F.R. §§ 301.2 and 381.1, respectively) and do not include species of livestock or kinds of birds other than those specifically listed.
- <sup>23</sup> Standards and Labeling Policy Book at “Amenability,” p.6 (meat); 9 C.F.R. § 381.15(a)(1) (poultry).
- <sup>24</sup> 9 C.F.R. 381.15(a)(1)-(5). See regulation for complete listing of exempt poultry products.
- <sup>25</sup> 9 C.F.R. § 381.15(b).
- <sup>26</sup> 9 C.F.R. § 381.15(c). *See also* 9 C.F.R. § 381.15(d) (exception for fat capsules and sandwiches containing poultry products and/or specified conditions).
- <sup>27</sup> *See* 9 C.F.R. § 381.15(e).
- <sup>28</sup> 21 U.S.C. § 607(c) (meat); 21 U.S.C. § 457(b) (poultry).
- <sup>29</sup> *Id.*
- <sup>30</sup> 21 U.S.C. §§ 348.
- <sup>31</sup> 21 U.S.C. § 601(m)(2); 21 U.S.C. § 453(g)(2). FSIS and FDA have established procedures for the joint review of ingredients that are not addressed in this Guide. See the FSIS website.
- <sup>32</sup> *See* 9 C.F.R. Parts 310, 318, 319, and 381. FSIS regulations establish a general prohibition on the use in a meat or poultry product of any food ingredient that would render it adulterated

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or misbranded, or which is not approved in Parts 424, 318, and 319 of the regulations, or "by the Administrator [of FSIS] in specific cases." The Section further provides that ingredients and sources of radiation listed or approved for use in meat and poultry products in 21 C.F.R. (i.e., FDA's regulations) will be listed for such use in FSIS's regulations "unless precluded from such use or further restricted in Parts 318 or 319 (pertaining to meat products), or Subparts O and P, of Part 381 (pertaining to poultry products). For example, a product standard might not permit the use in a particular product of an ingredient otherwise approved for use in meat or poultry. The Administrator may also list or approve for use in the new combined table of approved substances any such food ingredients or sources or radiation.

<sup>33</sup> [ADD ingredient references]

<sup>34</sup> 15 U.S.C. § 52.

<sup>35</sup> 15 U.S.C. § 45(a)(l).

<sup>36</sup> *Fresh Grown Preserve Corp. v FTC*, 125 F.2d 917 (2d Cir. 1942) (FTC has jurisdiction to prevent unfair competition by means of false labeling and misbranding, regardless of the kind of product).

<sup>37</sup> 15 U.S.C. § 45.

<sup>38</sup> FTC's deception and advertising substantiation policy statements have been adopted in Commission decisions, and are intended to guide manufacturers as to what level of substantiation is necessary to support a claim. See Deception Policy Statement, appended to *Cliffdale Associates, Inc.*, 103 F.T.C 110, 174-184 (1983); Ad Substantiation Policy Statement, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839-42 (1984), *aff'd*, 1986-1 Trade Cas. (CCH) ¶ 67,103 (D.C. Cir. 1986). **[SBS Update cites]**

<sup>39</sup> For example, claims relating to health and safety concerns, such as claims about the healthfulness of a particular product, require a relatively high level of substantiation. See *National Commission on Egg Nutrition*, 89 FTC 89, 192 (1976), *aff'd* 570 F.2d 157 (7th Cir.), *cert. denied*, 439 U.S. 821 (1978); *Thompson Medical Co.*, 104 FTC at 821.

<sup>40</sup> See *Houbigant v. Federal Trade Commission*, 139 F.2d 1019 (2d Cir. 1944), *cert. denied*, 323 U.S. 763 (1944) (FDA does not have exclusive jurisdiction over false and misleading labeling); *Fresh Grown Preserve Corp.*, 125 F.2d 917. **[SBS Update cites]**

<sup>41</sup> 15 U.S.C. §§ 52, 53(a). Upon violation of final cease and desist orders, FTC can seek: (1) consumer redress in the form of recession or reformation of contracts, refunds, or damages, 15 U.S.C. § 57b(b); (2) civil penalties, 15 U.S.C. § 45(m); or (3) criminal penalties if a violation of section 12 was committed with intent to defraud or expose consumers to health and safety risks. 15 U.S.C. § 54(a).

<sup>42</sup> See *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

<sup>43</sup> Under the Supremacy Clause of the U.S. Constitution, U.S. Const., Act VI cl. 2., federal laws and regulations are held to preempt state legislation in two circumstances. First, federal law is intended to preempt when a state legislates in a field that Congress intended to occupy. Second, when state and federal laws are in direct conflict, and compliance with both is impossible, federal law takes precedence.

<sup>44</sup> 21 U.S.C. § 678 (meat); 21 U.S.C. § 467(e) (poultry).

<sup>45</sup> *Rath Packaging Co.*, 430 U.S. 519 (1977).

<sup>46</sup> *Id.* See also *American Meat Institute v. Pridgeon*, 724 F.2d 45 (6th Cir. 1984) (state statute requiring posting of placards indicating product's nonconformance with state ingredient standards held unconstitutional); *Armour v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973) (marking, labeling, packaging, and ingredient requirements of FMIA preempt any state-imposed labeling requirements).

<sup>47</sup> *Kraft Foods North America, Inc. v. Rockland County*, (S.D.N.Y. Feb. 26, 2003) (Memorandum Order granting motion for summary judgment). An appeal of this decision was dismissed.

<sup>48</sup> As noted previously, labeling includes all labels or other written, printed, or graphic matter on or accompanying the article. 21 U.S.C. §§ 321(m), 601(o)(p), 453(s). See *U.S. v. Jorgensen*, 144 F.3d 550, 558 (S.D. Cal. 1998)(brochures accompanying meat product are considered

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labeling); *see also* *Kordell v. United States*, 335 U.S. 343 (1948); *United States v. Sene X Eleemosynary Corporation*, 479 F. Supp. 970, 979 (S.D. Fla. 1979) (neither physical attachment nor concurrent shipment of labeling is required to give FDA jurisdiction).

<sup>49</sup> *See* 9 C.F.R. § 317.2(a); 9 C.F.R. § 381.1(b).

<sup>50</sup> *See* 9 C.F.R. §§ 301.2 and 381.1(b) (definition of “immediate container”); 9 C.F.R. § 317.2 (definition of “protective covering”); *See also* Policy Memo 090B (Directive 7220.1) and the Food Standards and Labeling Policy Book at 137 (“Protective Coverings, Poultry” entry).

<sup>51</sup> *See, e.g.*, 9 C.F.R. § 316.10(b) (markings for smaller varieties of sausage); and 9 C.F.R. § 327.14 (foreign meat cuts must bear “Product of (country of origin)”).

<sup>52</sup> “Sketch” labeling is a printer’s proof or equivalent, which clearly shows all labeling features, size, location and indication of final color. Sketch labels can be hand-drawn, computer generated or by other reasonable facsimile.

<sup>53</sup> FSIS Directive 7220.1 (including Policy Memorandum 114A (August 18, 1994)).

<sup>54</sup> At one time, raising claims relating to the absence of antibiotic drug residues were allowed by FSIS. Now, FSIS is requiring that the few remaining programs be phased out. *See* FSIS website for further information on regulation of animal production and related claims.

<sup>55</sup> 9 C.F.R. § 317.4(a) (meat); 9 C.F.R. § 381.132(a), 9 C.F.R. § 320.14(b) (11)(meat); 9 C.F.R. § 381.175(b)(6)

<sup>56</sup> 9 C.F.R. § 317.4(f) (meat); 9 C.F.R. § 381.132(f) (poultry).

<sup>57</sup> 9 C.F.R. § 317.4(f)(2).

<sup>58</sup> Under the rule, FSIS will select samples of generically-approved labeling from the records maintained by companies and institute appropriate action if false or misleading labeling is identified.

<sup>59</sup> 9 C.F.R. § 317.5 (meat); 9 C.F.R. § 381.133 (poultry).

<sup>60</sup> 9 C.F.R. § 317.2(b); 9 C.F.R. 381.115(b).

<sup>61</sup> 9 C.F.R. § 317.2(d) (meat); 9 C.F.R. § 381.116 (poultry). Various labeling rules specify particular prominence and placement requirements beyond this general requirement.

<sup>62</sup> Such information may not be obscured by packaging or labeling design, vignettes, crowding, or lack of contrasting colors, which could be confusing and thus deemed misbranded under the labeling statutes. 9 C.F.R. 317.2 (meat); 9 C.F.R. § 381.116 (poultry).

<sup>63</sup> 9 C.F.R. § 317.2 (meat); 9 C.F.R. § 381.116 (poultry).

<sup>64</sup> *Id.*

<sup>65</sup> 9 C.F.R. § 317.2 (meat); 9 C.F.R. §381.121 (poultry).

<sup>66</sup> *See* FSIS Directive 7220.1 (Policy Memorandum 87A) (September 16, 1985)).

<sup>67</sup> 9 C.F.R. § 381.171.

<sup>68</sup> 21 U.S.C. § 601(n)(7) (meat); 21 U.S.C. § 453(h)(7) (poultry).

<sup>69</sup> 9 C.F.R. § 319 *et seq.* (meat); 9 C.F.R. § 381.155 *et seq.* (poultry). FSIS follows notice and comment rulemaking procedures prescribed by the Administrative Procedure Act in promulgating these standards.

<sup>70</sup> 21 U.S.C. § 601(n)(9) (meat); 21 U.S.C. § 453(h)(9) (poultry).

<sup>71</sup> Policy Memorandum 69 (March 23, 1984). Nutritional inferiority is defined consistent with the requirement of 21 C.F.R. § 101.3(e)(4) as any reduction in the content of an essential nutrient that is present at 2% or more of the U.S. RDI per serving of protein or any of the vitamins or minerals for which U.S. RDIs are established.

<sup>72</sup> 9 C.F.R. § 317.2(j) (meat); 9 C.F.R. § 381.1(b) (misbranded) (iii). Note, meat pizza containing (misbranding) (iii) cheese substitutes must have a ratio of at least 1 part cheese, 9 parts cheese substitutes. Products not meeting this cheese ratio standard require additional qualification about the characterizing ingredients to be stated in the food label. *See* Policy Memorandum 1 (May 6, 1980); *Anthony J. Pizza v. Wisconsin Dept. of Agriculture*, 676 F.2d 701 (1982) (unreported; Circuit Court upheld USDA cheese policy preempting inconsistent Wisconsin regulation).

<sup>73</sup> 9 C.F.R. § 319.10(meat); 9 C.F.R. § 381.172(poultry).

<sup>74</sup> 9 C.F.R. § 319.10(meat); 9 C.F.R. § 381.172(poultry).

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<sup>75</sup> 9 C.F.R. § 319.10(meat); 9 C.F.R. § 381.172(poultry).

<sup>76</sup> 9 C.F.R. § 317.8(b)(1). *See also* USDA Policy Memorandum 68 (February 9, 1984).

<sup>77</sup> 9 C.F.R. § 317.8(b)(1).

<sup>78</sup> *Id.* There is a city named “El Paso,” but there is no city named “Old El Paso.” Accordingly, FSIS does not consider “Old El Paso” a geographically significant location.

<sup>79</sup> Policy Memorandum 68 (February 9, 1984).

<sup>80</sup> 9 C.F.R. § 381.129(b)(2).

<sup>81</sup> 9 C.F.R. § 327.14.

<sup>82</sup> *Id.* The immediate container must also bear the establishment number assigned by the foreign meat inspection agency.

<sup>83</sup> 9 C.F.R. § 327.15.

<sup>84</sup> The official establishment or plant number may appear in one of the following locations: (1) inside or outside of the legend; (2) anywhere on the exterior of the container; or (3) off of the exterior when a statement identifies the location of the number. When the official inspection legend is off the exterior of the container, it may be properly located on the back of a paper label of a canned product, on a metal clip used to close casings or bags, or on other packaging or labeling material in the container when a statement of its location is printed contiguous to the official legend, such as, “EST no. on metal clip.” *See* 9 C.F.R. §317.2(1) (meat); 9 C.F.R. § 381.123 (poultry).

<sup>85</sup> 9 C.F.R. § 301.2 (12) (misbranded) (meat); 9 C.F.R. § 381.1(b)(misbranded)(xii) (poultry).

<sup>86</sup> 9 C.F.R. § 312.2(b)(1) (meat); 9 C.F.R. § 381.123(b)(2) (poultry).

<sup>87</sup> 9 C.F.R. § 317.2(b) (meat); 9 C.F.R. § 381.128 (poultry).

<sup>88</sup> 9 C.F.R. § 381.96 (poultry). This requirement is unique to poultry.

<sup>89</sup> *Id.* 9 C.F.R. § 381.96 (poultry).

<sup>90</sup> 9 C.F.R. § 317.2(h) (meat); 9 C.F.R. § 381.121(a) (poultry).

<sup>91</sup> 9 C.F.R. § 317.2(h)(1) (meat); 9 C.F.R. § 381.121(c) (poultry).

<sup>92</sup> *See* 9 C.F.R. § 317.2(h)(4) (meat); 9 C.F.R. § 381.121(c)(5) (poultry).

<sup>93</sup> 9 C.F.R. § 317.2(h)(2) (meat); 9 C.F.R. § 381.121(c)(6) (poultry).

<sup>94</sup> *Rath Packing*, 430 U.S. at 536. *See also Kraft Foods, supra.*

<sup>95</sup> 9 C.F.R. § 317.2(h)(2) (meat); 9 C.F.R. § 381.121(b)(6) (poultry).

<sup>96</sup> *Rath Packing*, 430 U.S. at 524. *See also Kraft Foods, supra.*

<sup>97</sup> *See e.g., Rath Packing*, 430 U.S. at 526; *Kraft Foods, supra*; *Cook Family Foods v. Voss*, 781 F. Supp. 1458, 1466 (C.D. Cal. 1991)(finding express preemption under the FMIA).

<sup>98</sup> 9 C.F.R. § 317.2(h)(4) (meat); 9 C.F.R. § 381.121(c)(5) (poultry).

<sup>99</sup> 9 C.F.R. § 317.2(h)(3) (meat); 9 C.F.R. § 381.121(c)(5) (poultry).

<sup>100</sup> 9 C.F.R. § 317.2(h)(5) (meat); 9 C.F.R. § 381.121(c)(5) (poultry).

<sup>101</sup> *Id.*

<sup>102</sup> *See* 9 C.F.R. § 317.2(h)(9), (12) (meat); 9 C.F.R. § 381.121(c)(8), (9) (poultry).

<sup>103</sup> 9 C.F.R. § 317.2(h)(3) (meat); 9 C.F.R. § 381.121(c)(2) (poultry).

<sup>104</sup> *Id.* Broth is an example of when this type of net weight declaration would be employed.

<sup>105</sup> *Id.*

<sup>106</sup> 9 C.F.R. § 317.2(h)(8) (meat); 9 C.F.R. § 381.121(c)(4) (poultry).

<sup>107</sup> *Id.*

<sup>108</sup> 9 C.F.R. § 317.2(h)(3) (meat); 9 C.F.R. § 381.121(c)(2) (poultry).

<sup>109</sup> 9 C.F.R. § 317.2(h)(1) (meat); 9 C.F.R. § 381.121(c)(2) (poultry).

<sup>110</sup> 9 C.F.R. § 317.2(h)(7) (meat); 9 C.F.R. § 381.121(c)(3)(vi) (poultry).

<sup>111</sup> 9 C.F.R. § 317.2(h)(6) (meat); 9 C.F.R. § 381.121(c)(3)(i)-(v) (poultry).

<sup>112</sup> 9 C.F.R. § 317.2(h)(7) (meat); 9 C.F.R. § 381.121(c)(3)(vi) (poultry).

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> 9 C.F.R. § 317.2(h)(9)(i) (meat); 9 C.F.R. § 381.121(c)(9)(i) (poultry).

<sup>116</sup> 9 C.F.R. § 317.2(h)(9)(ii) (meat); 9 C.F.R. § 381.121(c)(9)(ii) (poultry).

<sup>117</sup> 9 C.F.R. § 317.2(h)(9)(iii) (meat); 9 C.F.R. § 381.121(c)(9)(iii) (poultry).

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118 9 C.F.R. § 317.2(h)(9) (iv) and (v).  
119 9 C.F.R. § 381.121(a).  
120 9 C.F.R. § 317.2(h)(12) (meat); 9 C.F.R. § 381.121(c)(8)(ii) (poultry).  
121 *Id.*  
122 See 9 C.F.R. § 317.2(c)(2) (meat); 9 C.F.R. § 381.118 (poultry).  
123 9 C.F.R. § 317.2(f) (meat); 9 C.F.R. § 381.118(a)(1) (poultry).  
124 See Standards and Labeling Policy Book.  
125 9 C.F.R. § 317.2(f)(1)(vi)(A) (meat); 9 C.F.R. § 381.118(a)(2)(i) (poultry).  
126 9 C.F.R. § 317.2(f)(1)(v).  
127 9 C.F.R. § 381.118(f).  
128 FSIS Directive 7237.1.  
129 FSIS has adopted a range of standards for certain product categories but otherwise has few defined ingredient names. FDA’s regulations provide detailed criteria from which a common or usual name designation may be used. See 21 C.F.R. § 102.5.  
130 Policy Memorandum 72 (May 18, 1984).  
131 See 21 C.F.R. § 101.4. For example, dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as “eggs.” See also 9 C.F.R. § 317.2(f)(1)(ii) (corn syrup and corn starch solids deemed synonymous).  
132 21 U.S.C. § 343(k) (FDA); 21 U.S.C. § 601(n)(11) (meat); 21 U.S.C. § 453(h)(11) (poultry).  
133 FSIS, Consumer Labeling and Protection, “Proprietary Mixture Suppliers and Manufacturers Questions and Answers,” March 17, 1995 available on FSIS website.  
134 9 C.F.R. § 317.2(f)(1)(i) (meat); 9 C.F.R. § 381.118(c) (poultry).  
135 9 C.F.R. § 317.2(f) (1)(i)(B) (meat); 9 C.F.R. § 381.118(c)(2) (poultry).  
136 21 C.F.R. §§ 182.10, 184.  
137 9 C.F.R. § 317.2(j)(3) (meat); 9 C.F.R. § 381.119 (poultry). Any other permitted artificial flavoring must be identified as “artificial flavoring” in the ingredients statement. 9 C.F.R. § 317.2(j)(4).  
138 9 C.F.R. § 317.2(j)(5)-(7).  
139 FSIS Directive 7237.1.  
140 *Id.*  
141 9 C.F.R. § 317.2(j)(9) (meat); 9 C.F.R. § 381.119(b) (poultry). See also Policy Memorandum 113 (June 24, 1988).  
142 9 C.F.R. § 317.2(j)(12) (meat); 9 C.F.R. § 381.120 (poultry).  
143 9 C.F.R. § 381.120.  
144 21 C.F.R. 101.100(a)(3).  
145 21 C.F.R. § 101.100(a)(3). USDA follows the FDA regulation as a matter of policy. USDA’s treatment of incidental additives differs from that of FDA in one respect. In declaring sulfites that are sometimes considered incidental additives, when the total product contains less than 10 ppm sulfites but a separable component contains more than 10 ppm, USDA requires that the sulfiting agent be declared in the ingredients statement. Policy Memorandum 094B (December 17, 1986). FDA provides that a sulfite is exempt from labeling as an incidental additive if it is less than 10 ppm only for the product as a whole. 21 C.F.R. § 101.100(a)(4).  
146 21 C.F.R. § 101.100(a)(4).  
147 9 C.F.R. § 317.2(c)(3) and (g) (meat); 9 C.F.R. § 381.122 (poultry).  
148 9 C.F.R. § 317.2(k) (meat); 9 C.F.R. § 381.125(a) (poultry).  
149 9 C.F.R. § 317.2(l) (meat); 9 C.F.R. § 381.125(b) (poultry).  
150 Any portion of this statement in conflict with the product’s specific handling instructions may be omitted.  
151 9 C.F.R. §§ 317.2(l) (meat); 9 C.F.R. § 381.125(b) (poultry).  
152 9 C.F.R. § 317.400 (meat); 9 C.F.R. § 381.500 (poultry).  
153 9 C.F.R. § 317.400 (meat); 9 C.F.R. § 381.500 (poultry).  
154 9 C.F.R. § 317.302(b) (meat); 9 C.F.R. § 381.402(b) (poultry).  
155 9 C.F.R. § 317.302(c) (meat); 9 C.F.R. § 381.402(c) (poultry).

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- 156 9 C.F.R. § 317.309(c) (meat); 9 C.F.R. § 381.409(c) (poultry).  
157 9 C.F.R. § 317.309(c) (meat); 9 C.F.R. § 381.409(c) (poultry).  
158 9 C.F.R. § 317.309(c) (meat); 9 C.F.R. § 381.409(c) (poultry).  
159 9 C.F.R. § 317.309(c) (meat); 9 C.F.R. § 381.409(c) (poultry).  
160 9 C.F.R. § 317.309(d) (meat); 9 C.F.R. § 381.409(d) (poultry).  
161 9 C.F.R. § 317.309(d) (meat); 9 C.F.R. § 381.409(d) (poultry).  
162 9 C.F.R. § 317.309(d)(7) (meat); 9 C.F.R. § 381.409(d)(7) (poultry).  
163 9 C.F.R. § 317.309(c) (meat); 9 C.F.R. § 381.409(c) (poultry).  
164 9 C.F.R. § 317.309(d)(9) (meat); 9 C.F.R. § 381.409(d)(9) (poultry).  
165 9 C.F.R. § 317.309(d)(10) (meat); 9 C.F.R. § 381.409(d)(10) (poultry).  
166 9 C.F.R. § 317.309(e) (meat); 9 C.F.R. § 381.409(e) (poultry).  
167 9 C.F.R. § 317.309(d)(13) (meat); 9 C.F.R. § 381.409(d)(13) (poultry).  
168 9 C.F.R. § 317.309(e) (meat); 9 C.F.R. § 381.409(e) (poultry).  
169 9 C.F.R. § 317.309(f) (meat); 9 C.F.R. § 381.409(f) (poultry).  
170 9 C.F.R. § 317.309(f) (meat); 9 C.F.R. § 381.409(f) (poultry).  
171 9 C.F.R. § 317.309(f) (meat); 9 C.F.R. § 381.409(f) (poultry).  
172 9 C.F.R. § 317.309(g) (meat); 9 C.F.R. § 381.409(g) (poultry).  
173 9 C.F.R. § 317.309(g)(2) (meat); 9 C.F.R. § 381.409 (g)(2) (poultry).  
174 9 C.F.R. § 317.309(h) (meat); 9 C.F.R. § 381.409(h) (poultry).  
175 9 C.F.R. § 317.309(c) (meat); 9 C.F.R. § 381.409(c) (poultry).  
176 9 C.F.R. § 317.400 (meat); 9 C.F.R. § 381.500 (poultry).  
177 9 C.F.R. § 317.312 (meat); 9 C.F.R. § 381.412 (poultry).  
178 9 C.F.R. § 317.309(b)(7) (meat); 9 C.F.R. § 381.409(b)(7) (poultry).  
179 9 C.F.R. § 317.309(b)(7) (meat); 9 C.F.R. § 381.409(b)(7) (poultry).  
180 The following abbreviations for units may be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce. For the purposes of nutrition labeling, a teaspoon means 5 mL, a tablespoon means 15 mL, a cup means 240 mL, and 1 oz means 28 g.  
181 9 C.F.R. § 317.309(b)(7) (meat); 9 C.F.R. § 381.409(b)(7) (poultry).  
182 9 C.F.R. § 317.309(b)(7) (meat); 9 C.F.R. § 381.409(b)(7) (poultry).  
183 9 C.F.R. § 317.309(b)(9) (meat); 9 C.F.R. § 381.409(b)(9) (poultry).  
184 9 C.F.R. § 317.312 (meat); 9 C.F.R. § 381.412 (poultry).  
185 9 C.F.R. § 317.312(g) (meat); 9 C.F.R. § 381.412(g) (poultry).  
186 9 C.F.R. § 317.309(b) (meat); 9 C.F.R. § 381.409(b) (poultry).  
187 9 C.F.R. § 317.309(b) (meat); 9 C.F.R. § 381.409(b) (poultry).  
188 9 C.F.R. § 317.312 (meat); 9 C.F.R. § 381.412 (poultry).  
189 9 C.F.R. § 317.309(b)(10) (meat); 9 C.F.R. § 381.409(b)(10) (poultry).  
190 9 C.F.R. § 317.309(b)(11) (meat); 9 C.F.R. § 381.409(b)(11) (poultry).  
191 9 C.F.R. § 317.309 (b)(15) (meat); 9 C.F.R. § 381.409 (b)(15) (poultry).  
192 9 C.F.R. § 317.313(b) (meat); 9 C.F.R. § 381.413(b) (poultry).  
193 9 C.F.R. § 317.313(p) (meat); 9 C.F.R. § 381.413(p) (poultry).  
194 9 C.F.R. § 317.313(c) (meat); 9 C.F.R. § 381.413(c) (poultry).  
195 9 C.F.R. § 317.313(d) (meat); 9 C.F.R. § 381.413(d) (poultry).  
196 9 C.F.R. § 317.313(e) (meat); 9 C.F.R. § 381.413(e) (poultry).  
197 9 C.F.R. § 317.313(f)(g) (meat); 9 C.F.R. § 381.413(f)(g) (poultry).  
198 9 C.F.R. § 317.313(i)(1) (meat); 9 C.F.R. § 381.413(i)(1) (poultry).  
199 9 C.F.R. § 317.313(i) (meat); 9 C.F.R. § 381.413(i) (poultry).  
200 9 C.F.R. § 317.313(j) (meat); 9 C.F.R. § 381.413(j) (poultry).  
201 9 C.F.R. § 317.313(j) (meat); 9 C.F.R. § 381.413(j) (poultry).  
202 9 C.F.R. § 317.313(j) (meat); 9 C.F.R. § 381.413(j) (poultry).  
203 9 C.F.R. § 317.313(k) (meat); 9 C.F.R. § 381.413(k) (poultry).  
204 9 C.F.R. § 317.313(j) (meat); 9 C.F.R. § 381.413(j) (poultry).  
205 9 C.F.R. § 317.313(l),(m) (meat); 9 C.F.R. § 381.413(l),(m) (poultry).  
206 9 C.F.R. § 317.313(l) (meat); 9 C.F.R. § 381.413(l) (poultry).

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- 207 9 C.F.R. § 317.313(q) (meat); 9 C.F.R. § 381.413(q) (poultry).
- 208 9 C.F.R. § 317.313(q) (meat); 9 C.F.R. § 381.413(q) (poultry).
- 209 9 C.F.R. § 317.354 (meat); 9 C.F.R. § 381.454 (poultry).
- 210 9 C.F.R. § 317.354(b) (meat); 9 C.F.R. § 381.454(b) (poultry).
- 211 9 C.F.R. § 317.354(c) (meat); 9 C.F.R. § 381.454(c) (poultry).
- 212 9 C.F.R. § 317.354(e) (meat); 9 C.F.R. § 381.454(e) (poultry).
- 213 9 C.F.R. § 317.354(e) (meat); 9 C.F.R. § 381.454(e) (poultry).
- 214 9 C.F.R. § 317.356 (meat); 9 C.F.R. § 381.456 (poultry).
- 215 9 C.F.R. § 317.361 (meat); 9 C.F.R. § 381.461 (poultry).
- 216 9 C.F.R. § 317.361 (meat); 9 C.F.R. § 381.461 (poultry).
- 217 9 C.F.R. § 317.361 (meat); 9 C.F.R. § 381.461 (poultry).
- 218 9 C.F.R. § 317.361(b)(4) (meat); 9 C.F.R. § 381.461(b)(4) (poultry).
- 219 9 C.F.R. § 317.361 (meat); 9 C.F.R. § 381.461 (poultry).
- 220 9 C.F.R. § 317.361(b)(6) (meat); 9 C.F.R. § 381.461(b)(6) (poultry).
- 221 9 C.F.R. § 317.361(c) (meat); 9 C.F.R. § 381.461(c) (poultry).
- 222 9 C.F.R. § 317.362(b)(1) (meat); 9 C.F.R. § 381.462(b)(1) (poultry).
- 223 9 C.F.R. § 317.362(b)(2),(3) (meat); 9 C.F.R. § 381.462(b)(2),(3) (poultry).
- 224 9 C.F.R. § 317.362(b)(5) (meat); 9 C.F.R. § 381.462(b)(5) (poultry).
- 225 9 C.F.R. § 317.362(b)(6) (meat); 9 C.F.R. § 381.462(b)(6) (poultry).
- 226 9 C.F.R. § 317.362(c) (meat); 9 C.F.R. § 381.462(c) (poultry).
- 227 9 C.F.R. § 317.362(c) (meat); 9 C.F.R. § 381.462(c) (poultry).
- 228 9 C.F.R. § 317.362(c)(2) (meat); 9 C.F.R. § 381.462(c)(2) (poultry).
- 229 9 C.F.R. § 317.362(c)(3) (meat); 9 C.F.R. § 381.462(c)(3) (poultry).
- 230 9 C.F.R. § 317.362 (c)(4) (meat); 9 C.F.R. § 381.462(c)(4) (poultry).
- 231 9 C.F.R. § 317.362(d)(1) (meat); 9 C.F.R. § 381.462(d)(1) (poultry).
- 232 9 C.F.R. § 317.362(d)(2),(3) (meat); 9 C.F.R. § 381.462(d)(2),(3) (poultry).
- 233 9 C.F.R. § 317.362(d)(5) (meat); 9 C.F.R. § 381.462(d)(5) (poultry).
- 234 9 C.F.R. § 317.362(d)(5) (meat); 9 C.F.R. § 381.462(d)(5) (poultry).
- 235 9 C.F.R. § 317.362(e) (meat); 9 C.F.R. § 381.462(e) (poultry).
- 236 9 C.F.R. § 317.354(d) (meat); 9 C.F.R. § 381.454(d) (poultry).
- 237 9 C.F.R. § 317.363 (meat); 9 C.F.R. § 381.463 (poultry).
- 238 9 C.F.R. § 317.363 (meat); 9 C.F.R. § 381.463 (poultry).
- 239 9 C.F.R. § 317.380 (meat); 9 C.F.R. § 381.480 (poultry).
- 240 9 C.F.R. § 317.380(e) (meat); 9 C.F.R. § 381.480 (e) (poultry).
- 241 9 C.F.R. § 317.360(b)(1) (meat); 9 C.F.R. § 381.460(b)(1) (poultry).
- 242 9 C.F.R. § 317.360(b)(2),(3) (meat); 9 C.F.R. § 381.460(b)(2),(3) (poultry).
- 243 9 C.F.R. § 317.360(b)(4) (meat); 9 C.F.R. § 381.460(b)(4) (poultry).
- 244 9 C.F.R. § 317.360(c)(1) (meat); 9 C.F.R. § 381.460(c)(1) (poultry).
- 245 9 C.F.R. § 317.360(c)(2)(3) (meat); 9 C.F.R. § 381.460(c)(2)(3) (poultry).
- 246 9 C.F.R. § 317.360(c)(4) (meat); 9 C.F.R. § 381.460(c)(4) (poultry).
- 247 7 C.F.R. § 94.2 (2004).
- 248 7 C.F.R. § 57.5 (2004).
- 249 21 C.F.R. § 101.3 (2004). “Imitation” is defined as a food product formulated to resemble another food covered by a standard of identity, when the formulated product is nutritionally inferior.
- 250 21 C.F.R. § 160.115 (2004).
- 251 *Id.*
- 252 21 C.F.R. § 160.105 (2004).
- 253 21 C.F.R. § 160.180 (2004). This percentage is determined by the method prescribed in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13<sup>th</sup> Ed. (1980), sections 17.006 and 17.007 under “Total Solids, Vacuum Method (3) - Official Final Action,” which is incorporated by reference.
- 254 21 C.F.R. § 160.140 (2004).
- 255 21 C.F.R. § 160.145(d) (2004).

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<sup>256</sup> *Id.* Requirements for lysozyme and avidin content reduction are found in section 160.140(a).  
<sup>257</sup> 21 C.F.R. § 101.5 (2004).  
<sup>258</sup> *Id.*  
<sup>259</sup> 7 C.F.R. § 94.2 (2004).  
<sup>260</sup> 9 C.F.R. § 590.150 (2004).  
<sup>261</sup> 9 C.F.R. § 590.413 (2004).  
<sup>262</sup> 9 C.F.R. § 590.412 (2004).  
<sup>263</sup> 9 C.F.R. § 590.410 (2004).  
<sup>264</sup> 21 C.F.R. § 160.110 (2004).  
<sup>265</sup> 21 C.F.R. § 160.115 (2004).  
<sup>266</sup> 21 C.F.R. § 160.105 (2004). The use of anticaking agents is specified in paragraph (a).  
<sup>267</sup> 21 C.F.R. § 101.22(k)(2) (2004).  
<sup>268</sup> 21 C.F.R. Part 101 (2004).  
<sup>269</sup> 9 C.F.R. § 590.411 (2004).