



United States Department of Agriculture

# Controls Over Meat, Poultry, and Egg Product Labels



Audit Report 24601-0002-23

June 2020

OFFICE OF INSPECTOR GENERAL

# Controls Over Meat, Poultry, and Egg Product Labels

## Audit Report 24601-0002-23

OIG evaluated FSIS' controls over meat, poultry, and egg product labels to ensure FSIS' approval of labels was accurate and supported.

### OBJECTIVE

Our objective was to evaluate FSIS' controls over meat, poultry, and egg product labels to ensure establishment claims that FSIS approves are accurate and supported.

### REVIEWED

We reviewed: (1) applicable laws, regulations, and agency policies, procedures, and guidance; (2) each label, application, and supporting documentation for 120 statistically selected labels; and (3) an additional 36 labels to ensure final label record compliance. We interviewed FSIS national officials, district officials, and IPP at select establishments.

### RECOMMENDS

LPDS should review the nine labels with insufficient supporting documentation and develop internal standard operating procedures to ensure compliance; review a sample of approved labels on a periodic basis; enhance its outreach efforts to establishments regarding applicable mandatory labeling features for generic labels; and update its directive to reflect regulatory requirements for sampling to generic labels to determine compliance with mandatory features.

### WHAT OIG FOUND

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) ensures that the Nation's commercial supply of meat, poultry, and egg products is correctly labeled and packaged, wholesome, and not adulterated. To ensure labels are truthful and not misleading, FSIS' Labeling and Program Delivery Staff (LPDS) review label applications and either approve product labels or request changes. FSIS also has inspection program personnel (IPP) at each establishment who are responsible for verifying that labels and related files (i.e., labeling records) meet requirements. We reviewed 120 label application packages for fiscal year (FY) 2018 to ensure that the labels FSIS approved were accurate and supported.

While we found that FSIS' controls over its approval of labels were generally effective, we determined that 9 of 60 required label application packages were either incomplete, inaccurate, or unsupported. We also found that 11 of 60 generic label application packages were either not supported or an applicable mandatory feature was missing or inaccurate. In addition, we determined that LPDS requested changes to 657 of 878 (74 percent) generic labels to ensure these labels met requirements. We also found that three establishments we visited did not make the required modifications in their final generic labeling records.

As a result, meat, poultry, and egg product labels may reflect inaccurate statements and claims made by establishments. Additionally, there is reduced assurance that establishments' generic labels meet requirements. Based on our sample results, we estimated that approximately 2,038 (15.00 percent) of the approved required labels and 161 (18.34 percent) of the approved generic labels may have one or more exceptions.

FSIS generally agreed with our recommendations and we accepted management decisions on all five recommendations.





United States Department of Agriculture  
Office of Inspector General  
Washington, D.C. 20250



DATE: June 15, 2020

AUDIT  
NUMBER: 24601-0002-23

TO: Paul Kiecker  
Administrator  
Food Safety and Inspection Service

ATTN: Cara LeConte, Chief Financial Officer  
Food Safety and Inspection Service  
Office of the Chief Financial Officer

FROM: Gil H. Harden  
Assistant Inspector General for Audit

SUBJECT: Controls Over Meat, Poultry, and Egg Product Labels

This report presents the results of the subject review. Your written response to the official draft is included in its entirety at the end of the report. We have incorporated excerpts from your response, and the Office of Inspector General's (OIG) position, into the relevant sections of the report. Based on your written response, we are accepting management decision for all five audit recommendations in the report, and no further response to this office is necessary. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer (OCFO).

In accordance with Departmental Regulation 1720-1, final action needs to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to OCFO.

Your written response to the official draft report expressed concerns with several aspects of our report. Your response stated that we evaluated the labels and related applications based on rigid standards, and we did not consider FSIS' history and expertise. In all of the exceptions noted, we presented your subject matter experts' explanations on why they agreed or disagreed with our conclusion. Your response also stated that Labeling and Program Delivery Staff (LPDS) incorrectly agreed with OIG that the processing procedures should include the condition that the product leaves the establishment (i.e., refrigerated or frozen). While FSIS officials then provided

a different verbal explanation and additional criteria for removing those exceptions from our report, the additional evidence did not change our conclusion or support FSIS' position.

Your agency's response also expressed concerns regarding our exceptions for required labels and what you term "speculative" conclusion regarding generic labels. We met with your agency's officials on numerous occasions to discuss these concerns and we made several edits to this report that we could support by evidence. In our last meeting, FSIS officials provided additional evidence and, based on that evidence, we reduced the number of exceptions we used in OIG's projections. However, agency officials have not provided sufficient documented evidence to support the other statements made in your response. Therefore, our report includes the facts and our conclusions supported with sufficient and appropriate evidence per Generally Accepted Government Auditing Standards.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (<http://www.usda.gov/oig>) in the near future.

# Table of Contents

---

<b>Background and Objectives.....</b>	<b>1</b>
<b>Section 1: FSIS Label Review and Approval Process.....</b>	<b>6</b>
<b>Finding 1: FSIS Needs to Document its Review and Approval Process for Required Labels.....</b>	<b>6</b>
<b>Recommendation 1.....</b>	<b>10</b>
<b>Recommendation 2.....</b>	<b>10</b>
<b>Recommendation 3.....</b>	<b>11</b>
<b>Finding 2: FSIS Needs to Improve Establishments’ Compliance with Generic Label Requirements .....</b>	<b>12</b>
<b>Recommendation 4.....</b>	<b>15</b>
<b>Recommendation 5.....</b>	<b>16</b>
<b>Scope and Methodology.....</b>	<b>18</b>
<b>Abbreviations .....</b>	<b>20</b>
<b>Exhibit A—FSIS District Offices, States, and Number of Establishments Visited.....</b>	<b>21</b>
<b>Exhibit B—Sampling Methodology for FSIS’ Controls Over Meat, Poultry, and Egg-Product Labels .....</b>	<b>22</b>
<b>Agency’s Response .....</b>	<b>27</b>



# Background and Objectives

---

## Background

The U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) enhances public health and well-being by protecting the public from foodborne illness and ensuring that the Nation’s meat, poultry, and egg products are safe and wholesome.<sup>1</sup> The Federal Meat Inspection Act,<sup>2</sup> the Poultry Products Inspection Act,<sup>3</sup> and the Egg Products Inspection Act<sup>4</sup> authorize FSIS to regulate over 6,000 Federally-inspected establishments nationwide. FSIS ensures that the Nation’s commercial supply of meat, poultry, and processed egg products—whether domestic or imported—is correctly labeled and packaged and not adulterated.<sup>5</sup> This includes FSIS’ approval of any establishment’s marking, labeling, or packaging of meat, poultry, or egg products to prevent the use of any false or misleading mark, label, or container. FSIS is responsible for administering and enforcing meat, poultry, and egg product labeling requirements, and establishments are responsible for ensuring that the labels used on their products are not false or misleading.

## Review Staff

FSIS’ Labeling and Program Delivery Staff (LPDS), located in Washington, D.C., review label applications and approve product labels to ensure they are truthful and not misleading. In fiscal year (FY) 2018, LPDS had 18 permanent staff who reviewed and approved approximately 14,000 meat, poultry, and egg product labels.<sup>6</sup> FSIS’ inspection program personnel (IPP) verify that the labels and related files (i.e., labeling records) located at establishments meet requirements.

## Requirements for Labels on Meat, Poultry, and Egg Products

FSIS requires certain meat and poultry labels to be submitted for review and approval (hereafter, referred to as “required” labels) while it considers other labels to be generically approved (hereafter, referred to as “generic” labels) and therefore not required to be submitted for approval. For egg products, there is no distinction between required and generic approval because all egg product labels must be submitted to FSIS for approval. FSIS approval for required labels remains in effect until an establishment makes changes that would cause the label to be false or misleading.

---

<sup>1</sup> 21 U.S.C. § 601 (meat); 21 U.S.C. § 451 (poultry); 21 U.S.C. § 1031 (egg products); 7 C.F.R. §§ 2.18 and 2.53 (delegations of authority).

<sup>2</sup> 21 U.S.C. § 601 *et seq.*

<sup>3</sup> 21 U.S.C. § 451 *et seq.*

<sup>4</sup> 21 U.S.C. § 1031 *et seq.*

<sup>5</sup> FSIS guidance states that “a product is adulterated if it bears or contains a substance that makes it injurious to health, or if it has been held, packed or produced under insanitary conditions.” FSIS, *Guidance for Determining Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of the Poultry Products Inspection Act*, page 4 (Apr. 2006).

<sup>6</sup> In FY 2018, there were 13,588 required and 878 generic labels submitted to FSIS for approval.

An establishment must follow the required label process when it requests to use a label for a meat or poultry product<sup>7</sup> that is either: (1) under a temporary approval; (2) prepared under a religious exemption; (3) for export, if it deviates from FSIS labeling requirements; or (4) contains special statements and claims. LPDS may grant temporary approval for a previously approved final label that did not match the product in some way for reasons such as a slight change in an ingredient. LPDS grants temporary approval for such a label so the establishment can use its remaining pre-printed labels already in stock. LPDS may grant temporary approvals for a period not to exceed 180 calendar days, as long as the following four conditions are met:

- 1) The label would not misrepresent the product;
- 2) Use of the label would not present any potential health, safety, or dietary problems to the consumer;
- 3) Denial of the request would create undue economic hardship; and
- 4) An unfair competitive advantage would not result from the granting of the temporary approval.

“Special statements and claims” are claims, logos, trademarks, and other symbols on labels that are generally not defined in FSIS regulations<sup>8</sup> or the *Food Standards and Labeling Policy Book* (except for natural and negative claims).<sup>9</sup> Such special statements and claims include:

- “natural”;
- “gluten free”;
- “cage free”;
- “farm raised”; and
- “made with organic ingredients.”

Federal regulations deem generic labels to be generically approved by FSIS without submission to LPDS.<sup>10</sup> Generic labels are considered to be generically approved for meat and poultry products, providing that the label bears all applicable mandatory labeling features, in accordance with Federal regulations, and is not otherwise false or misleading in any particular.<sup>11</sup> Mandatory labeling features for both required and generic labels are:

- product name;
- safe handling statement (e.g., “keep frozen”);
- ingredients statement;
- address line (includes name and place of business of the manufacturer, packer, or distributor);
- net weight statement;
- inspection legend;<sup>12</sup>

---

<sup>7</sup> All regulated egg product establishments must submit formal applications, along with sketches of their egg product labels, to LPDS for review and approval.

<sup>8</sup> 9 C.F.R. §§ 412.1 and 412.2; 9 C.F.R. pt. 317; 9 C.F.R. pt. 381.

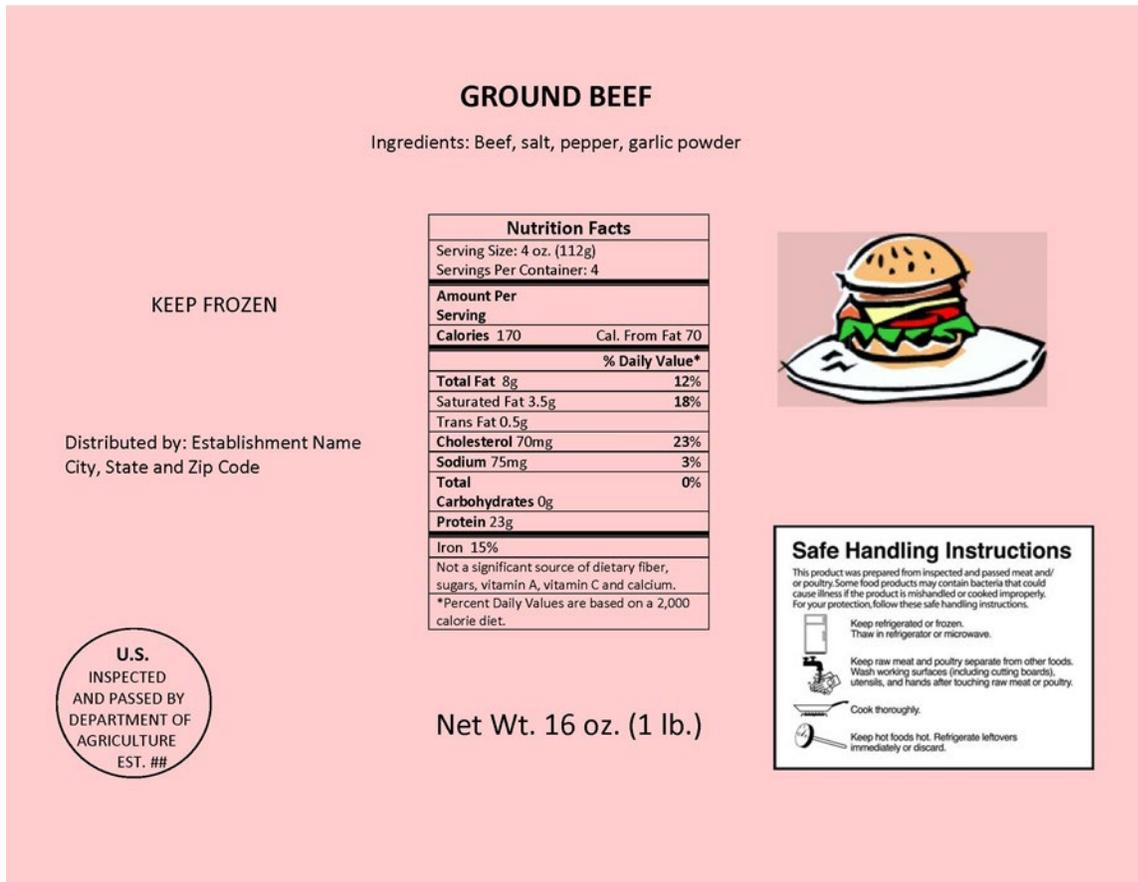
<sup>9</sup> FSIS, *Food Standards and Labeling Policy Book* (Aug. 2005).

<sup>10</sup> 9 C.F.R. § 412.2.

<sup>11</sup> 9 C.F.R. § 412.2; 9 C.F.R. pt. 317; 9 C.F.R. pt. 381.

<sup>12</sup> The “inspection legend” is a symbol identifying an establishment as federally inspected.

- safe handling instructions (for raw products); and
- nutrition facts panel (includes calories, serving size, etc.).



**Figure 1. Mandatory labeling features.**

Some generic labels may also contain certain special statements and claims that are defined in FSIS regulations<sup>13</sup> or the *Food Standards and Labeling Policy Book*.<sup>14</sup> Some of these statements and claims include:

- “Made in USA”;
- “Made with only white meat chicken”;
- “Made with 100% real cheese”;
- “BPA Free [packaging]”; and
- Kosher claims on products.

<sup>13</sup> 9 C.F.R. § 412.2; 9 C.F.R. pt. 317; 9 C.F.R. pt. 381.

<sup>14</sup> FSIS, *Food Standards and Labeling Policy Book* (Aug. 2005).

## Approval Process

Before an establishment can use a required label, it must submit the label to LPDS for review and approval. Establishments may use generic labels without prior review and approval by LPDS, but also have the option of voluntarily submitting them to LPDS for review and approval.<sup>15</sup>

The approval process begins with an establishment submitting a label application package, which includes a sketch of its label,<sup>16</sup> the label application, and documentation to support the statements and claims made.<sup>17</sup> While establishments may submit their applications through mail, LPDS recommends that establishments submit their label requests electronically through FSIS' Label Submission and Approval System (LSAS).<sup>18</sup> LSAS is a web-based label submission application that enables an establishment to upload supporting documentation required to demonstrate its compliance with applicable regulatory requirements for the label that the establishment plans to use.

Once received, LPDS performs a label review of the establishment's application and supporting documentation. LPDS' review and approval process for food product labels follows several criteria, such as Federal regulations,<sup>19</sup> agency guidance,<sup>20</sup> and policy handbooks.<sup>21</sup> Officials also conduct research and meet frequently as a group to ensure labels are truthful and not misleading. LPDS verifies that an establishment has displayed each applicable mandatory feature on the label and ensures compliance regarding any special statements or claims. LPDS will compare the statements and claims made on the label to the establishment's supporting documentation submitted with the application. LPDS may approve of using the label either as-is, with no changes needed to the label (i.e., "sketch approved"), or approved with modifications (i.e., "approved as modified").<sup>22</sup> LPDS may also return the label application to an establishment and request additional documentation or require an establishment to make appropriate changes.<sup>23</sup>

Once approved, LPDS returns the label application package to the establishment for it to make any modifications necessary in order to use the label on the associated food product. The establishments are required to make LPDS modifications before using the label. Ultimately, establishments are responsible for ensuring that their labels are not false or misleading and for also maintaining documentation in the form of a labeling record. According to an LPDS official,

---

<sup>15</sup> All regulated egg product establishments must submit formal applications, along with sketches of their egg product labels, to LPDS for review and approval.

<sup>16</sup> A "sketch" of a label is "a printer's proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location." 9 C.F.R. § 412.1(d).

<sup>17</sup> Supporting documentation includes, for example, a signed and dated document describing how the animals are raised and third-party verifications.

<sup>18</sup> Establishments that submit an application and supporting documentation through regular mail or fax will have their submissions uploaded by FSIS staff to LSAS and LPDS will use that system to review the submission for possible approval.

<sup>19</sup> 9 C.F.R. pt. 412; 9 C.F.R. pt. 317; 9 C.F.R. pt. 381; 9 C.F.R. pt. 590.

<sup>20</sup> FSIS, *Compliance Guideline for Label Approval* (Aug. 2017).

<sup>21</sup> FSIS, *Food Standards and Labeling Policy Book* (Aug. 2005).

<sup>22</sup> LPDS can approve label applications with modifications, such as requiring establishments to add a handling statement or address line.

<sup>23</sup> LPDS returns label applications, i.e., denies approval, when the establishment fails to follow the regulations.

each labeling record must include: a copy of the final label that is in use, the product formulation (i.e., ingredients), the processing procedure for the product, and any supporting documentation necessary to show that the label is consistent with the Federal meat and poultry regulations and policies regarding product labeling.<sup>24</sup>

## **FSIS Verification Activities at Establishments**

At each establishment, IPP verify regulatory compliance of final labels by reviewing labels for the presence of all applicable mandatory features and any other modifications requested by LPDS. IPP perform this verification activity—otherwise known as the general labeling task—by reviewing the establishment’s labeling records. The general labeling task is an internal control FSIS put in place to verify establishments’ compliance with FSIS’ final label requirements.<sup>25</sup>

IPP are located at regulated establishments and are responsible for performing the general labeling task when scheduled in the agency’s Public Health Information System (PHIS).<sup>26</sup> When a general labeling task is scheduled at an establishment, IPP will randomly select one or more labels—either required or generic—to verify compliance with applicable label requirements. In addition, IPP verify whether the establishment is maintaining an adequate labeling record for the selected meat or poultry products. If IPP find that an establishment’s label is not in compliance, they will document this noncompliance in PHIS via a noncompliance record. After FSIS prepares a noncompliance record, an establishment needs to bring the label into compliance. If the establishment wants to continue using the noncompliant label, it has the option to submit a new application to LPDS and request a temporary approval.

## **Objectives**

Our objective was to evaluate FSIS controls over meat, poultry, and egg product labels to ensure establishment claims that FSIS approves are accurate and supported.

---

<sup>24</sup> FSIS, *Compliance Guideline for Label Approval*, pp. 26-27 (Aug. 2017).

<sup>25</sup> GAO defines internal control as a process effected by an entity’s oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. In relation to this report, we define the general labeling task as one of those controls because FSIS verification activity is a process performed by the IPP to ensure that establishment/industry personnel follow labeling requirements.

<sup>26</sup> PHIS is a web-based application designed to automate paper-based business processes into one comprehensive, fully automated data-driven inspection system.

## Section 1: FSIS Label Review and Approval Process

---

### Finding 1: FSIS Needs to Document its Review and Approval Process for Required Labels

While FSIS' controls over its approval of meat, poultry, and egg product labels were generally effective, we determined that 9 (15.00 percent) of our statistical sample of 60 FSIS-approved, required label application packages were either incomplete or inaccurate. This occurred because FSIS relied on LPDS to review label application packages without having a documented review process or checklist to follow that ensured all criteria were verified. LPDS performed some quality control reviews for label approval determinations made by new employees, but it did not routinely review determinations made by experienced staff. As a result, required labels for meat, poultry, and egg product may reflect inaccurate statements and claims made by establishments. Based on our sample results, we estimate that approximately 2,038 (15.00 percent) of required labels approved by LPDS in FY 2018 may have one or more exceptions.<sup>27, 28</sup>

Required labels must be submitted by an establishment and approved by LPDS.<sup>29</sup> Establishments are required to submit a copy of the label, which can be a sketch of the label, along with an application with documentation to support any statements and claims made on the label.<sup>30</sup>

To conduct our audit work, we statistically selected 60 required labels that LPDS previously reviewed and approved for establishments to use in commerce. We reviewed each label, application, and other supporting documentation to confirm LPDS' decision to approve the label. We found that 9 of these 60 labels' applications or other supporting documents were either incomplete, inaccurate, or did not support the statements or claims made on the product label.

#### Incomplete or Inaccurate Label Application Packages

We identified a total of 9 of the 60 approved, required labels that had applications that were either incomplete or inaccurate. The following sections describe the types of incompleteness or inaccuracies that we noted in our review.

##### *Incomplete Processing Procedures*

We found that six labels' applications did not contain complete processing procedures, which are necessary for LPDS to determine whether an establishment used the correct handling statement. For example, if the processing procedures state that the product is frozen for shipping, then the product should be labeled, "keep frozen." Federal

---

<sup>27</sup> LPDS reviewed and approved 13,588 required labels in FY 2018. We are 95 percent confident that the true value of this estimate is between 967 and 3,607 required labels (7.12 percent and 26.55 percent, respectively).

<sup>28</sup> We defined exceptions as LPDS incorrect label approvals based on the establishments' documentation presented in a label application package.

<sup>29</sup> 9 C.F.R. § 412.1(a).

<sup>30</sup> Examples of supporting documentation include a signed and dated document describing how the animals are raised or third-party verifications.

regulations state that packaged food products requiring special handling to maintain their wholesome condition shall prominently display a statement on the product's principal display panel,<sup>31</sup> such as "keep refrigerated" or "keep frozen."<sup>32</sup> Our review of the establishments' label applications found that they did not submit complete processing procedures for these six labels. Since the establishment's label application did not contain a document or explanation on which processing procedures was used (refrigerated or frozen), we could not determine if the correct handling statement was displayed on the label or if the wholesome condition of the product could be affected.

LPDS officials initially agreed with these six exceptions and stated that the applications' "processing procedures should include the condition the product leaves the establishment to verify the handling statement is correct." During our review of the sample labels, we noted that 43 of the 60 required labels included complete processing procedures with the condition of the product leaving the establishment as required. However, subsequent to the issuance of the draft report, LPDS officials stated it does not matter which statement is used on the label as long as one of these statements is present. LPDS officials stated that it is the establishment's responsibility to determine which handling statement is correct. We disagree that either statement can be used since only one would be an accurate statement.

#### *Missing Product Formula*

We determined one label's application was incomplete because it did not contain the product formula, which describes the name and amount of ingredients used. The label was being used on a pork product that listed six ingredients, but we were unable to confirm that ingredient list because the product formula was missing. Without the product formula, LPDS cannot verify if any additional ingredients, including allergens, are in the product.

#### *Inaccurate Order of Ingredients*

We found one label's application that did not list the ingredients in the order of predominance. The label was for a chicken product which listed canola oil as the 16<sup>th</sup> ingredient on the label, but according to the product formula, it should have been listed as the 6<sup>th</sup> ingredient. Without a correct listing of ingredients, such labels could mislead consumers regarding the relative amounts of certain ingredients in food products.

---

<sup>31</sup> The principal display panel is the part of the label most likely to be displayed when offered for sale under customary conditions. FSIS, *A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products*, page 29 (Aug. 2007).

<sup>32</sup> 9 C.F.R. § 381.125(a); 9 C.F.R. § 317.2(k).

## *Ineligible Temporary Approval*

We found one label application package that received temporary approval from LPDS even though the establishment did not address all four of the required criteria for that type of approval.<sup>33</sup> Specifically, the establishment's label application package did not provide support to show that the denial of the request would create an undue economic hardship or an unfair competitive advantage by granting of the temporary approval.

LPDS officials stated that it is not necessary for the establishment to clearly show that all four conditions are met. LPDS officials stated that its staff must make a judgment call to determine whether to grant temporary approval for a label that no longer exactly matches the product. However, the Federal regulation states, "Temporary approvals may be granted...under the following conditions: (i) ...label would not misrepresent the product; (ii) ...label 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."<sup>34</sup> In addition, FSIS' instructions on their website states, "*the four conditions...have to be met prior to receiving a temporary approval.*" Establishments are to "*provide details of all [four] conditions on the application.*"<sup>35</sup> Without receiving documentary support from the establishment or documenting LPDS' reasoning for granting the temporary approval, LPDS runs the risk of allowing this establishment to have an unfair competitive advantage over other establishments.

## **Unsupported Label Statements and Claims**

We identified a total of eight approved, required label application packages that did not include supporting documentation for the statements or claims made on the product label. Five of these eight labels included claims like "5g of protein per slice" or "0g total carbs and 0g trans fats"—nutrient content claims—and FSIS officials stated they used the nutrition facts panel of the label itself to support these claims. However, Federal regulations state that if information from the nutrition label [i.e., nutrition facts panel] is declared elsewhere on the label it is a nutrient content claim.<sup>36</sup> FSIS guidance states that nutrition factual statements, like "0 grams of carbohydrates," requires LPDS approval and support in the labeling record.<sup>37</sup> We found no information in the label application package to support LPDS' decision to approve these nutrition factual statements. For the three remaining labels with claims like "96 percent fat free" or "no synthetic colors," we found no support in the label application package and no explanation for why FSIS approved these labels. We concluded that these eight label applications needed either additional supporting documentation or an explanation on the reasons why LPDS approved these labels.

---

<sup>33</sup> Temporary approval for the use of a final label that may be deemed deficient in some particular [way] may be granted by the FSIS LPDS. Temporary approvals may be granted for a period not to exceed 180 calendar days.

<sup>34</sup> 9 C.F.R. § 412.1(f)(1).

<sup>35</sup> FSIS, Information Required for Requesting a Temporary Approval, <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/requesting-temporary-approval/requesting-temporary-approval> (last modified Mar. 11, 2019).

<sup>36</sup> 9 C.F.R. § 317.313(c); 9 C.F.R. § 381.413 (c).

<sup>37</sup> FSIS, *Compliance Guideline for Label Approval* (Aug. 2017).

We recognize that LPDS uses the nutrition facts panel to support nutrient content claims, i.e. on front of the package, for product labels. However, an LPDS staff stated that LPDS' review of the nutrition facts panel does not include verifying the accuracy of the data declared on the label with submitted supporting documentation from establishments. OIG maintains that without verifying the accuracy of the nutrition facts panel prior to label approval, nutrient content claims declared elsewhere on the product label may not be accurate. Subsequent to the issuance of the draft report, FSIS officials stated that, according to Federal regulations, the label of a product may contain a statement of the amount of a nutrient if the statement does not in any way implicitly characterize the level of the nutrient, and the statement is not false or misleading.<sup>38</sup> Therefore, we concluded that this issue should still be reported for full transparency but we are not including these eight exceptions in our projections.

In total, we concluded that nine labels needed additional establishment documentation or LPDS reviewer notes to document the reasons for approving a food label and related claims. To determine why these labels with incomplete supporting documentation were approved, we questioned the LPDS reviewers. Some of the LPDS reviewers stated it was an oversight on their part for some labels. According to LPDS officials, experienced staff conduct frequent meetings to discuss their review of label application packages. Any questions or comments that arise from the label reviews may be brought up at that time. However, we found that these meetings and related decisions on labels were not documented to establish a list of best practices or a standard.

In addition to our sample testing, we observed LPDS staff review and approve meat, poultry, and egg product labels and found that the staff used criteria from multiple websites, regulations, and policy books. When we requested a list of criteria for our sample testing, LPDS provided a list of website links that opened other multi-layered links to LPDS policies, Federal regulations, and directives. We found that LPDS did not have a centralized list or location for its staff to check to ensure they covered all label requirements before approval. We also found that LPDS did not have a written process for new or experienced staff to follow to help verify that information presented on a label met applicable criteria.

We discussed all of the issues we found with the required labels with LPDS. The officials stated that, in lieu of a documented process, LPDS relied upon their experienced staff to review and independently approve label application packages. An LPDS official explained that developing written procedures that would address every potential label approval situation would not be feasible. An FSIS official stated that the agency has been working to ensure that labels are being evaluated and approved consistently. In addition, while FSIS staff performed a second-level review of label application packages approved by newer staff, they did not routinely review experienced staff's label approval determinations.

FSIS' Management Control Program directive states that policies and procedures, such as instructions, ensure that program objectives are achieved.<sup>39</sup> Therefore, we recommend that LPDS document its review and approval process for all label application packages in order for LPDS to ensure that labels meet Federal regulations and agency requirements. In addition, LPDS should document its review and approval process to ensure that establishments provide

---

<sup>38</sup> 9 CFR § 317.313(i)(3) and 9 CFR § 381.413(i)(3).

<sup>39</sup> USDA FSIS Directive 1090.1, Rev. 3, *Management Control Program*, p. 16 (Jan. 6, 2011).

adequate support for special statements and claims. LPDS' reliance on establishments' generated nutrition panels for support for nutrient claims reduces the agency's assurance that statements and claims made on labels are not false and misleading. Finally, LPDS should develop and implement a process to review a sample of approved labels, on a periodic basis, to ensure its staff adhere to the label approval process. By implementing these corrective actions, LPDS could more effectively ensure compliance with its label approval process.

## **Recommendation 1**

For the nine labels with insufficient supporting documentation, LPDS should review these labels and update LSAS to annotate the agency's position for approving the label application.

### **Agency Response**

In its May 15, 2020, response, agency officials stated that:

FSIS has determined that 6 of the 9 labels that OIG cited as missing information on the application form are acceptable. The labels bear a handling statement as required by 9 CFR 317.2(k) and 9 CFR 381.125 for compliance with FSIS regulations, so the products are not misbranded. The one label approved as temporary is no longer in use, therefore, no notification or correction in LSAS is required. LPDS will make the necessary corrections for the remaining 2 labels and update the applications in LSAS.

The estimated completion date is September 30, 2020.

### **OIG Position**

We accept management decision on this recommendation.

## **Recommendation 2**

LPDS should develop internal standard operating procedures to ensure compliance with regulatory labeling requirements through the label approval process.

### **Agency Response**

In its May 15, 2020, response, agency officials stated that:

LPDS will develop internal standard operating procedures (SOPs) to ensure staff verify that labels comply with regulations throughout the label approval process.

The estimated completion date is January 31, 2021.

## **OIG Positon**

We accept management decision on this recommendation.

## **Recommendation 3**

LPDS should develop and implement a process or procedure to review a sample of approved labels on a periodic basis to ensure LPDS staff adhere to the label approval process.

## **Agency Response**

In its May 15, 2020, response, agency officials stated that:

LPDS will include all staff as part of the LSAS Quality Control (QC) procedures training currently used for new LPDS staff members. Labels will be randomly selected and routed to LPDS management for a second review for accuracy and compliance with FSIS regulations and policies.

The estimated completion date is January 31, 2021.

## **OIG Positon**

We accept management decision on this recommendation.

## **Finding 2: FSIS Needs to Improve Establishments' Compliance with Generic Label Requirements**

We reviewed a statistical sample of 60 FSIS-approved, generic label application packages and found that 11 labels were either not supported or an applicable mandatory feature was missing or inaccurate.<sup>40</sup> In FY 2018, LPDS reviewed and approved 878 generic labels but required modifications to 657 (74 percent) to ensure these labels met requirements. Further, we found that three establishments we visited did not make the required modifications in their final labeling records. This occurred because FSIS did not have an adequate process to determine establishments' compliance with generic labeling requirements. As a result, there is reduced assurance that establishments' generic labels used in commerce meet requirements. Based on our sample results for the 11 labels, we estimated that 161 of the 878 generic labels (18.34 percent) have one or more exceptions.<sup>41, 42</sup>

Federal regulations require generic labels to contain all applicable mandatory label features, such as an inspection legend (a symbol identifying an establishment as Federally-inspected), ingredients statement, safe handling statement, product name, address line, safe handling instructions, net weight, and nutrition facts.<sup>43</sup> FSIS allows establishments to use these labels without submission for approval, as long as the labels contain all applicable mandatory features and do not contain any special statements and claims.<sup>44</sup>

While Federal regulations do not require establishments to submit generic labels for review and approval, establishments have the option to voluntarily submit any generic label for LPDS review and approval.<sup>45</sup> In FY 2018, LPDS approved 878 generic labels submitted for review. We selected a statistical sample of 60 of those 878 approved generic labels and reviewed the establishments' label application packages. Of the 60 application packages we reviewed, we determined that LPDS approved 11 generic labels (18.34 percent) that were either not supported, missing a mandatory feature, or inaccurate.<sup>46</sup> Of these 11 generic labels:

- 9 label application packages had incomplete processing procedures, which are necessary for determining each label's "handling statement," a requirement that helps to maintain

---

<sup>40</sup> Of the 11 labels, 1 had both missing and inaccurate information.

<sup>41</sup> We are 95 percent confident that the true value of this estimate is between 85 and 264 generic labels (9.68 percent and 30.07 percent, respectively).

<sup>42</sup> We defined "exceptions" as LPDS incorrect label approvals based on the establishments' documentation presented in a label application package.

<sup>43</sup> 9 C.F.R. § 412.2.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> LPDS approved six generic labels "as is," without modifications, and five generic labels were "approved as modified."

the product's wholesome condition.<sup>47</sup> In addition, one of the nine labels did not list the zip code of the establishment, as required by regulations.<sup>48</sup>

- 1 label did not have the product ingredients in the correct order, as required by regulations;<sup>49</sup> and
- 1 label did not list the correct serving size, as required by regulations.<sup>50</sup>

LPDS officials agreed with our conclusions for these 11 label application packages. Some LPDS reviewers stated that it was a lack of oversight on their part and they missed verifying the support for those items during their review.

### **Establishments' Compliance Regarding Generic Labels**

While LPDS and IPP are responsible for administration and enforcement, such as verifying that labels are meeting applicable requirements, establishments are ultimately responsible for ensuring their labels are not false or misleading. However, our review found that establishments did not always ensure their generic labels contained the applicable mandatory features and IPP did not always enforce those requirements.

We analyzed data provided by LPDS from LSAS, which contained the total number of generic label applications that LPDS approved in FY 2018. In our review, LPDS required modifications to 657 of the 878 (74 percent) approved, generic label applications. As a result of LPDS modifications, establishments needed to make corrections to their labels in order for LPDS to consider the labels to be compliant with requirements. The LSAS data did not include reasons for these modifications; however, we were able to review the 60 label application packages in our sample and found that 43 labels (71.7 percent) required modifications to one or more of the eight applicable mandatory features (see Figure 2 for details).<sup>51</sup>

---

<sup>47</sup> Nine establishments did not completely list products' processing procedures in their label application packages, which state the condition in which the product must be kept, e.g., "keep refrigerated" or "keep frozen," once the product leaves the establishment. FSIS Form 7234-1, *Application for Approval of Labels, Marking or Device* (Nov. 16, 2011).

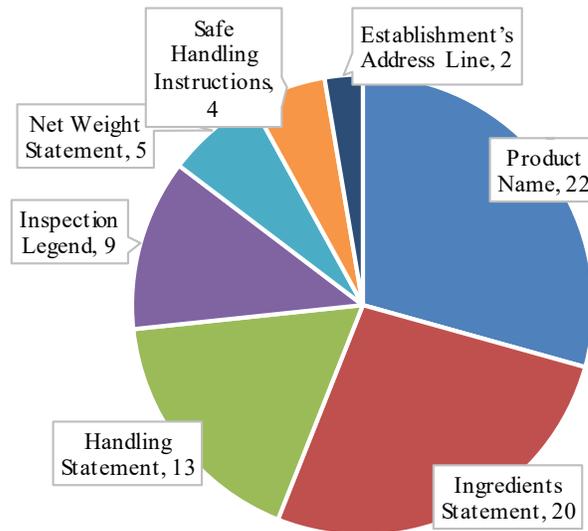
<sup>48</sup> 9 C.F.R. § 381.122.

<sup>49</sup> 9 C.F.R. § 317.2(f)(1).

<sup>50</sup> 9 C.F.R. § 317.309(b)(1).

<sup>51</sup> Our review determined that 25 of the 43 generic labels had multiple errors on the same label.

**Figure 2. Number of Modifications to Mandatory Features**



When we discussed the issue with LPDS officials, they acknowledged that 657 labels indeed required modifications but explained the large percentage of modifications could be due to minor changes rather than issues of noncompliance. However, our review determined that the requested modifications did cover noncompliance issues related to seven of the eight applicable mandatory features. We learned that LPDS does not track the number of generic labels used in commerce, so we were unable to determine the scale of the issue. However, based on the large number (657) of modifications in our sample,<sup>52</sup> we concluded that there could be generic labels in commerce that were not submitted for review that do not comply with FSIS requirements.

Out of the 10 establishments we visited during our audit, 3 establishments had a total of 4 generic labels to which LPDS required modifications. During our visits, we evaluated whether: (1) establishments made modifications to their generic labels, as required by LPDS; and (2) IPP verified and enforced compliance regarding generic labels at the establishments. Of the establishments we visited, we found that none made the LPDS-required modifications to the generic labels in its labeling records.

When we discussed this issue with the three establishments' personnel, they provided various reasons for why they did not make the label modifications required by LPDS. For example, we found that one establishment had submitted its label application twice for the same product. After receiving differing approval responses, it relied on the application that LPDS approved without modifications.<sup>53</sup> We reviewed both of these applications and confirmed that each application was approved by a different LPDS reviewer, who evaluated the identical label and

---

<sup>52</sup> The large number of exceptions in our sample refers to the number of labels that were approved with modifications by LPDS (required modifications).

<sup>53</sup> The establishment submitted its application a second time after not receiving what it perceived to be a timely response. The establishment received responses for both applications within 6 days of one another. Its first label application was approved as modified while the second label application was approved without modifications.

application but made different approval decisions. At the second establishment, we determined that the person responsible for labels was new to the position, had no knowledge of the labeling process, and was not aware of the modifications to either of the two labels due to being on the job for only 3 weeks. At the third establishment, personnel stated they did not understand why LPDS made certain modifications to the label and decided not to make the changes, as they did not agree. We also interviewed IPP at two establishments, and they stated they did not realize LPDS' requested modifications were not made because the products were not yet in production. Therefore, those labels were not yet subject to selection for a general labeling task review. After our visit to the second establishment, IPP issued a noncompliance record to the establishment as a result of it not making the requested label modifications. FSIS subsequently closed the noncompliance record.

Also during our establishment visits, we observed IPP's performance of a general labeling task. We determined that IPP did not specifically choose generic labels to review when performing a labeling task verification.<sup>54</sup> Federal regulations require IPP to select samples of generic labels from the labeling records to determine compliance with label requirements.<sup>55</sup> However, agency requirements do not incorporate these Federal regulations, which state that IPP are to randomly select one or more labels, required or generic, for verification from products in production.<sup>56</sup>

We discussed these issues with LPDS officials, who stated that LPDS needs to conduct more outreach to establishments to ensure they are aware of generic label requirements and added that LPDS has already started this process. Since establishments are not required to submit generic labels for approval, it is essential that establishments understand and comply with labeling requirements. In addition, when new regulations are approved,<sup>57</sup> LPDS officials stated that they will conduct more outreach to explain the updates and changes from the previous regulations to ensure establishments are knowledgeable of agency requirements. LPDS officials stated that they are committed to improving customer service and developing and delivering outreach focused on enhancing the communication of labeling information. LPDS is also committed to collaborating with FSIS' Office of Field Operations to ensure IPP have the tools they need to verify and enforce compliance with FSIS' labeling requirements.

Consumers expect product labels to be accurate when they choose products to purchase. If FSIS is not verifying a sample of generic labels, the agency runs the risk of inaccurate or unsupported product labels being in commerce. Therefore, we determined that LPDS needs to continue its efforts in performing outreach to establishments and to implement processes to verify generic labels are accurate and complete.

## **Recommendation 4**

LPDS should enhance its outreach efforts to establishments to ensure they are aware of all applicable mandatory labeling features for generic labels.

---

<sup>54</sup> Two establishments produced egg products and are required to submit all label applications to LPDS.

<sup>55</sup> 9 C.F.R. § 412.2(a).

<sup>56</sup> USDA FSIS Directive 7221.1, Rev. 1, *Prior Labeling Approval*, p. 3 (Jan. 6, 2014).

<sup>57</sup> In December 2019, FSIS published two new labeling guidelines that are out for public comment that ends February 25, 2020.

## Agency Response

In its May 15, 2020, response, agency officials stated that:

LPDS has already begun its outreach to establishments through developing and revising labeling guidance on the FSIS website. LPDS will also schedule generic labeling webinars for its stakeholders that will include training on the mandatory labeling features. Additionally, LPDS is planning to present webinars on recently published guidance to the FSIS Website. FSIS continues to send LPDS staff to meetings for various stakeholders (e.g., consulting firms and trade associations) presenting information on various labeling subject matter. These presentations include general labeling requirements including all mandatory features. LPDS will also continue to include entries in the Agency's *Constituent Update* (which provides weekly FSIS updates on the FSIS web page) on a biweekly basis to help industry understand and comply with FSIS labeling requirements. These entries provide information on various topics to help establishments comply with labeling requirements, such as information on completing the label application form, information on the label submission requirements for using special statements and claims, and information on label records that must be maintained by establishments.

The estimated completion date is May 31, 2021.

## OIG Positon

We accept management decision on this recommendation.

## Recommendation 5

Ensure that FSIS Directive 7221.1, Rev. 1 reflects the requirement in 9 C.F.R. § 412.2 (a)(2) that IPP verify that some generically approved labels in the establishment's labeling records contain the mandatory eight features. When IPP find noncompliance, they should document noncompliance and require establishments take appropriate corrective actions.

## Agency Response

In its May 15, 2020, response, agency officials stated that:

FSIS will revise FSIS Directive 7221.1 Rev. 1 to ensure IPP label verification activities include generically approved labels. IPP will document noncompliance and require establishments to change labels that are not in compliance with FSIS's labeling regulations and policies.

The estimated completion date is May 31, 2021.

## **OIG Positon**

We accept management decision on this recommendation.

## Scope and Methodology

---

To accomplish our objective, we evaluated FSIS’ controls over the review and approval of meat, poultry, and egg product labels for FY 2018. We performed our work at the FSIS national office and interviewed LPDS officials located in Washington, D.C. We also interviewed FSIS district officials from Des Moines, Iowa (District 25), and Philadelphia, Pennsylvania (District 60). We interviewed frontline supervisors at 10 non-statistically selected establishments in 4 States.<sup>58</sup> We performed audit fieldwork from June 2018 to October 2019.

In FY 2018, LPDS reviewed and approved 13,588 required and 878 generic label applications. We selected a statistical sample of 100 required and 87 generic label applications with a sequential, or stop-or-go, approach.<sup>59</sup> We elected to implement the stop-or-go approach and reviewed the first 60 labels in each sample. See Exhibit B for our sampling methodology.

We non-statistically selected 10 establishments within the Des Moines, Iowa, and Philadelphia, Pennsylvania, district offices. We selected these two districts because they contained: (1) various establishment sizes (large, small, and very small); (2) meat, poultry, and egg product establishments; and (3) labels that LPDS approved as required, generic, and “as-modified.” At the 10 establishments, we verified an additional 36 labels that were not in our statistical sample to assess establishments’ compliance with label requirements.

To accomplish our objectives, we:

- Reviewed applicable laws, regulations, and agency policies, procedures, and guidance related to the audit objective to gain an understanding of the written label requirements for FSIS and official establishments’ personnel;
- Interviewed FSIS national officials who review and approve label applications to gain an understanding of the general background, controls, and label review and approval process;
- Reviewed each label, application, and supporting documentation obtained from FSIS for the 120 labels—60 required and 60 generic—in our statistical sample;
- Evaluated the controls over the label processing procedures based on FSIS requirements and documented our results;
- Interviewed FSIS district officials to determine the controls over administration and enforcement of labeling activities at the establishments;

---

<sup>58</sup> See Exhibit A.

<sup>59</sup> After inspecting the first 60 samples for each of the 2 audit universes (required and generic), we observed that the sample objectives regarding precision could still be met while stopping the sampling early.

- Interviewed IPP at the 10 establishments to gain an understanding of their knowledge, roles, and responsibilities regarding FSIS label application submission requirements and label verification activities; and
- Reviewed and evaluated an additional 36 labels at the 10 establishments to ensure final label records complied with label requirements.

We used data from two FSIS information systems—LSAS and PHIS. FSIS supplied the universe data from LSAS, which contained both required and generic label applications and supporting documentation. We performed data validation procedures to verify the completeness of the universe data received before selecting our samples. We also used establishment profile data in PHIS to select the district offices and establishments. We compared the label application packages obtained from LSAS with the label records maintained at the establishments during our site visits. During the course of our audit, we did not solely rely on information in any agency information system, and we make no representation regarding the adequacy of any agency computer system, or the information generated from them because evaluating the effectiveness of information systems or information technology controls was not one of the engagement objectives.

We provided the universe data from LSAS to OIG’s Office of Data Sciences (ODS) to develop the sampling methodology and to calculate the projections based on our exceptions. Since we relied on the work by ODS specialists, we obtained documentation to ensure these specialists were qualified professionally, competent in the work we relied upon, and met independence standards.

We conducted this performance audit in accordance with Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Abbreviations

---

C.F.R.	Code of Federal Regulations
CI	confidence interval
FSIS	Food Safety and Inspection Service
FY	fiscal year
IPP	inspection program personnel
IT	information technology
LPDS	Labeling and Program Delivery Staff
LSAS	Label Submission and Approval System
ODS	Office of Data Sciences
OIG	Office of Inspector General
PHIS	Public Health Information System
U.S.C.	United States Code
USDA	U.S. Department of Agriculture

## Exhibit A—FSIS District Offices, States, and Number of Establishments Visited

---

The table below identifies the FSIS districts we visited and includes the district name and location, States covered by the district, and the number of States and establishments visited during the audit.

District Number and Location	States Covered	States Visited	Number of Establishments Visited
District 60 (Philadelphia, PA)	Connecticut, Massachusetts, Maine, New Hampshire, New York, Pennsylvania, Rhode Island, and Vermont	New York  Pennsylvania	3  2
District 25 (Des Moines, IA)	Iowa, Minnesota, North Dakota, South Dakota, and Wisconsin	Minnesota  Wisconsin	4  1
<b>Total</b>		<b>4</b>	<b>10</b>

## **Exhibit B—Sampling Methodology for FSIS’ Controls Over Meat, Poultry, and Egg-Product Labels**

---

### **Objective**

This statistical sample was designed by ODS to support OIG Audit 24601-0002-23. FSIS requires establishments to submit product label information for some product types. After an establishment submits product labeling information, FSIS reviews the information to ensure that label requirements are met. The objective of this audit was to evaluate FSIS’ controls over meat, poultry, and egg product labels to ensure establishments’ claims that FSIS approves are accurate and supported.

To help achieve this objective, we developed representative, random statistical samples of product labels for review.

### **Audit Universe**

The universe contains information related to product labels that were sent to FSIS as part of required or generic reviews. The audit team focused specifically on meat, poultry, and egg product labels. In order to ensure that FSIS was conducting complete and accurate reviews of product label information, we split the universe into two separate groups: required and generic product labels. These two groups are mutually exclusive and give the audit team the opportunity to observe whether or not required reviews are being performed and if generic reviews are being performed with the same degree of accuracy and completeness.

### **Sample Design**

We considered various sample designs and ultimately chose to audit 100 required labels and 87 generic labels, each randomly selected without replacement from those in the audit universes.<sup>60</sup>

### **Required Labels**

The sample size was determined based on the following factors:

- Audit universe: 13,588 required labels.
- Confidence level: We are reporting two-tailed, 95 percent confidence intervals (CI).
- Precision: We wanted to report CI no wider than 20 percent (i.e., average precision of 10 percent, and  $\pm 10$  percent if symmetrical around the point estimate) and consistent with sequential (or stop-or-go) sampling, per paragraph 3.64 and Appendix B of the American Institute of Certified Public Accountants’ *Audit Guide; Audit Sampling* (May 1, 2017).

---

<sup>60</sup> Microsoft Excel was used to select each simple random sample within the universe and report the selection order.

- Expected exception rate: We did not have reliable historical information to help estimate this rate, so we used an exception rate of 50 percent since this rate provided the most conservative sample size.

## Generic Labels

The sample size was determined based on the following factors:

- Audit universe: 878 generic labels.
- Confidence level: We are reporting two-tailed, 95 percent confidence intervals (CI).
- Precision: We wanted to report CI no wider than 20 percent (i.e., average precision of 10 percent, and  $\pm 10$  percent if symmetrical around the point estimate) and consistent with sequential (or stop-or-go) sampling, per paragraph 3.64 and Appendix B of American Institute of Certified Public Accountants' *Audit Guide; Audit Sampling* (May 1, 2017).
- Expected exception rate: We did not have reliable historical information to help estimate this rate, so we used an exception rate of 50 percent since this rate provided the most conservative sample size.

## Results

After inspecting the first 60 samples for each of the two audit universes—required and generic—auditors observed that the sample objectives regarding precision could still be met while stopping the sampling early. The results in the tables provided are projected to the required and generic audit universes of 13,588 and 878 labels, respectively. We used the Clopper-Pearson<sup>61</sup> approach to compute the exact CI for the hypergeometric distribution (sampling without replacement). In the case where only one finding was identified in the sample of 60, this CI approach yielded a negative lower bound, so we replaced these lower bounds with the actual number of findings from the sample, which was one.

---

<sup>61</sup> Clopper, C.J. & Pearson, E.S., *The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomial*, *Biometrika*, Vol. 26, No. 4, pp. 404-413, (Dec. 1934).

## Statistical Estimates

<b>Required Labels</b>					
N = 13588		number of required labels in our universe			
n = 60		number of required labels in our sample			
Criteria	Number of Exceptions	95% Lower Bound	Estimate	95% Upper Bound	Precision
Handling Statement	6	512	1,359	2,784	8.36%
as a %		3.77%	10.00%	20.49%	
Interpretation: Based on our sample results, we estimate that 1,359 labels (10.00 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 512 (3.77 percent) and 2,784 labels (20.49 percent).					
Ingredients Statement	2	55	453	1,565	5.56%
as a %		0.40%	3.33%	11.52%	
Interpretation: Based on our sample results, we estimate that 453 labels (3.33 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 55 (0.40 percent) and 1,565 labels (11.52 percent).					
Temporary Approval	1	5	227	1,213	4.45%
as a %		0.04%	1.67%	8.93%	
Interpretation: Based on our sample results, we estimate that 227 labels (1.67 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 5 (0.04 percent) and 1,213 labels (8.93 percent).					
Overall projection	9	967	2,038	3,607	9.71%
as a %		7.12%	15.00%	26.55%	
Interpretation: Based on our sample results, we estimate that 2,038 labels (15.00 percent) in our audit universe have one or more exceptions. We are 95 percent confident that the true value of this estimate is between 967 (7.12 percent) and 3,607 labels (26.55 percent).					

<b>Generic Labels</b> <sup>62</sup>					
N = 878		number of generic labels in our universe			
n = 60		number of generic labels in our sample			
<b>Criteria</b>	<b>Number of Exceptions</b>	<b>95% Lower Bound</b>	<b>Estimate</b>	<b>95% Upper Bound</b>	<b>Precision</b>
Handling Statement	9	64	132	230	9.45%
as a %		7.29%	15.03%	26.20%	
Interpretation: Based on our sample results, we estimate that 132 labels (15.03 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 64 (7.29 percent) and 230 labels (26.20 percent).					
Address Line	1	1	15	77	4.33%
as a %		0.11%	1.71%	8.77%	
Interpretation: Based on our sample results, we estimate that 15 labels (1.71 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 1 (0.11 percent) and 77 labels (8.77 percent).					
Nutrition Facts Panel	1	1	15	77	4.33%
as a %		0.11%	1.71%	8.77%	
Interpretation: Based on our sample results, we estimate that 15 labels (1.71 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 1 (0.11 percent) and 77 labels (8.77 percent).					
Ingredients Statement	1	1	15	77	4.33%
as a %		0.11%	1.71%	8.77%	
Interpretation: Based on our sample results, we estimate that 15 labels (1.71 percent) in our audit universe have an exception in this criteria tested. We are 95 percent confident that the true value of this estimate is between 1 (0.11 percent) and 77 labels (8.77 percent).					
Overall projection	11	85	161	264	10.19%
as a %		9.68%	18.34%	30.07%	
Interpretation: Based on our sample results, we estimate that 161 labels (18.34 percent) in our audit universe have one or more exceptions. We are 95 percent confident that the true value of this estimate is between 85 (9.68 percent) and 264 labels (30.07 percent).					

<sup>62</sup> With respect to our overall projection regarding generic labels, one label had two exceptions identified. Thus, there are a total of 11 labels with exceptions that were identified.



**FOOD SAFETY AND INSPECTION SERVICE  
RESPONSE TO AUDIT REPORT**





United States Department of Agriculture

---

Food Safety and  
Inspection Service

1400 Independence  
Avenue, SW,  
Washington, D.C.  
20250

TO: Gil H. Harden  
Assistant Inspector General  
Office of Inspector General

FROM: Paul Kiecker / s / May 15, 2020  
Administrator  
Food Safety and Inspection Service

SUBJECT: OIG Official Draft Report, Controls Over Meat, Poultry,  
and Egg Product Labels, Audit Number 24601-0002-23

FSIS appreciates the opportunity to review and comment on this Official Draft report. The Food Safety and Inspection Service (FSIS) reviewed the Official Draft report and has general and technical comments followed by a response to each recommendation.

**FSIS General and Technical Comments**

OIG's audit of FSIS' Controls Over Meat, Poultry, and Egg product Labels report is flawed in several areas. OIG has misinterpreted specific labeling regulations and how they are applied to the labeling review process. OIG has not acknowledged FSIS repeated corrections or comments to the report.

FSIS believes for this audit to achieve its intended purpose of evaluating the Agency's label review and approval program to determine whether there are ways that the program can be improved, OIG needs to understand FSIS' labeling regulations. OIG acquiring an understanding of FSIS's labeling regulations would help OIG understand the context in which the label review and approval program functions.

OIG evaluated the program based on a rigid set of standards that do not accurately reflect FSIS's regulations or do not consider FSIS's history and expertise in implementing the regulations and reviewing labels.

**Finding 1: FSIS Needs to Document its Review and Approval Process for Required Labels**

On pages 8-9 in Finding 1 under "Incomplete or Inaccurate Label Application Packages" section, OIG states that "since the establishment's label application did not contain a document or explanation on which processing procedure was used (refrigerated or frozen), we could not determine if the correct handling statement was displayed on the label or if the wholesomeness of the product could be affected."

This statement is problematic for several reasons. Generally, whether a product is refrigerated, or frozen, may affect the shelf life but not the overall wholesome condition of the product. The regulations do not require that establishments submit information concerning whether a product will be kept refrigerated or frozen to support the label (9 CFR 317.2(k)).

As FSIS mentioned in discussions with OIG, under the label application and FSIS regulations, refrigeration and freezing are not ordinarily considered “processing” or “preparing.” The label application instructions for block #16 state that “Poultry Products provide complete processing procedures as required in 9 CFR 381.134.” The poultry regulations cited in block #16 of the application include information concerning ingredients and methods of preparation. In addition, the term “process” is defined in the poultry products inspection regulations to mean “to conduct any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up or manufactured or processed.” (9 CFR 381.1(b)). These regulations further specify that “the term ‘process’ does not refer to freezing of poultry products, except when freezing is incidental to operations otherwise classed as ‘processing’ under this paragraph.”

Block #16 of the label application requests for meat products that applicants complete processing procedures as required. In the meat regulations (9 CFR 301.2), the term “prepared” means: “slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.” The meat regulations define the term “prepared” rather than “processed,” but the meaning is consistent with the definition of the term “process” in the poultry regulations.

Lastly, it is not up to FSIS to determine whether a product should be refrigerated or frozen. That is a determination made by the producer of the product based on marketing considerations. FSIS’s responsibility is to ensure that if the product is not shelf stable, it bears one of those statements, or that if the product is being held under conditions that do not comply with the label statement, it acts to remove the product from commerce or rescind FSIS label approval and require that the establishment correct the label. Thus, OIG is faulting FSIS for not enforcing a records submission requirement that does not exist, and OIG’s statement that 15 of the label applications (both required and generic labels) it reviewed were incomplete is simply wrong. FSIS’s responsibility in this area is to verify that the products have a handling statement consistent with the nature of the product, which the Agency performs daily during the labeling review process.

FSIS will acknowledge that in its discussion with OIG, the Labeling and Program Delivery Staff (LPDS) officials incorrectly agreed with OIG that the processing procedures should include the condition that the product leaves the establishment (i.e., refrigerated or frozen). However, at the initial meeting and on at least two other occasions, FSIS has explained the correct policy yet OIG has not acknowledged these

verbal and written corrections. For FSIS to require submission of additional information for label approvals, we would need to conduct rulemaking or other public notice with no public health benefit. Additionally, FSIS would need to assess costs and benefits; at this time, FSIS anticipates no benefits because there are currently no problems to address. Therefore, FSIS still maintains that the six labels should be removed from OIG's count of labels that had applications that were incomplete or inaccurate and as a result, OIG only found three such labels in error.

On page 10 of its draft report, OIG states they found one label application package that received temporary approval even though the establishment did not address all four of the required criteria for temporary approval. This statement suggests that the application for temporary approval that FSIS approved, and OIG reviewed, is incomplete or inaccurate. FSIS disagrees with this statement. FSIS needs to find that the four conditions set out in the regulation for granting temporary approval are met. OIG is correct that, if FSIS grants an application without documentary support in the application with respect to one of the conditions, it is vulnerable to having its judgment reversed by a reviewing court should the Agency be sued. It is likely that the establishment met all four conditions of the label application; however, FSIS does not have adequate records concerning that label approval. At this time, the approved temporary label is now expired, per the date on the label application since temporary approvals expire after six months. Thus, this label should not be included as incomplete or inaccurate and should not be included with the 9 labels referenced in Recommendation 1 of the report.

On pages 10 - 11, under the section "Unsupported Label Statements and Claims," OIG states that 8 approved and required label application packages did not include supporting documentation for the statement and claims made on the product label because they relied on nutrition fact information. As stated in the report, FSIS officials use the nutrition facts panel of the label itself to verify that claims are truthful and not misleading. OIG maintains that without FSIS verifying the accuracy of the nutrition facts panel prior to label approval, statements of the amount of a nutrient declared elsewhere on the product label may be inaccurate. Nutrition labeling has appeared on food labels for more than 25 years, and there has been no evidence of any significant misstatements of amounts declared on nutrition labels. In 9 CFR 317.309 (h), FSIS set out, after full notice and comment rulemaking, how it would monitor compliance with respect to nutrition labels. In the preamble to the final rule, FSIS stated that it would not require that establishments submit analytical data to support nutrient values and content claims on food labels (58 FR 656). Thus, as FSIS made clear in the regulations, FSIS does not require nutrition data to be submitted with label applications submitted for approval. To require additional information from establishments would be an added cost and burden on industry. Given this regulatory history, the issue OIG raises on page 11 is without merit, and this entire section of the report should be stricken. OIG is suggesting that

establishments need to submit additional documentation to FSIS without considering the regulatory history or costs and benefits of new requirements.

### **Finding 2: FSIS Needs to Improve Establishments' Compliance with Generic Label Requirements**

Under this finding, FSIS disagrees with the conclusion on page 13 that there is a reduced assurance that establishments' generic labels used in commerce meet requirements because FSIS does not have an adequate process to determine whether establishments generic labels meet requirements.

On page 13, for the reasons stated above, FSIS maintains the 9 label applications cited for incomplete processing procedures to determine the handling statement should be removed from the report.

Under the section "Establishment's Compliance Regarding Generic Labels," specifically on page 15, OIG states that, based on the large number of modifications that FSIS made in the generic labels that had been submitted to it for approval, there could be generic labels in commerce that were not submitted to FSIS for review and that do not comply with FSIS requirements. FSIS believes that this statement is completely speculative.

Although labels were voluntarily submitted to the Agency that were approved with modifications, that does not mean that labels that are not submitted will require modifications. Therefore, OIG should remove the last sentence in the first paragraph on page 15 from its report.

### **FSIS' Response to OIG's Recommendations**

#### **Finding 1: FSIS Needs to Document its Review and Approval Process for Required Labels**

##### **Recommendation 1**

For the 9 labels with insufficient supporting documentation, LPDS should review these labels and update LSAS to annotate the agency's position for approving the label application.

##### **FSIS Response**

FSIS has determined that 6 of the 9 labels that OIG cited as missing information on the application form are acceptable. The labels bear a handling statement as required by 9 CFR 317.2(k) and 9 CFR 381.125 for compliance with FSIS regulations, so the products are not misbranded. The one label approved as temporary is no longer in use, therefore, no notification or correction in LSAS is required. LPDS will make the necessary corrections for the remaining 2 labels and update the applications in LSAS.

**Estimated Completion Date:** September 30, 2020.

**Recommendation 2**

LPDS should develop internal standard operating procedures to ensure compliance with regulatory labeling requirements through the label approval process.

**FSIS Response**

LPDS will develop internal standard operating procedures (SOPs) to ensure staff verify that labels comply with regulations throughout the label approval process.

**Estimated Completion Date:** January 31, 2021

**Recommendation 3**

LPDS should develop and implement a process or procedure to review a sample of approved labels on a periodic basis to ensure LPDS staff adhere to the label approval process.

**FSIS Response**

LPDS will include all staff as part of the LSAS Quality Control (QC) procedures training currently used for new LPDS staff members. Labels will be randomly selected and routed to LPDS management for a second review for accuracy and compliance with FSIS regulations and policies.

**Estimated Completion Date:** January 31, 2021

**Finding 2: FSIS Needs to Improve Establishments' Compliance with Generic Label Requirements**

**Recommendation 4**

LPDS should enhance its outreach efforts to establishments to ensure they are aware of all applicable mandatory labeling features for generic labels.

**FSIS Response**

LPDS has already begun its outreach to establishments through developing and revising labeling guidance on the FSIS website. LPDS will also schedule generic labeling webinars for its stakeholders that will include training on the mandatory labeling features. Additionally, LPDS is planning to present webinars on recently published guidance to the FSIS Website. FSIS continues to send LPDS staff to meetings for various stakeholders (e.g., consulting firms and trade associations) presenting information on various labeling subject matter. These presentations include general labeling requirements including all mandatory features. LPDS will also continue to include entries in the Agency's *Constituent Update* (which provides weekly FSIS updates on the FSIS web page) on a biweekly basis to help industry understand and comply with FSIS labeling requirements.

These entries provide information on various topics to help establishments comply with labeling requirements, such as information on completing the label application form, information on the label submission requirements for using special statements and claims, and information on label records that must be maintained by establishments.

**Estimated Completion Date:** May 31, 2021 (although outreach activities will be ongoing)

**Recommendation 5**

Ensure that FSIS Directive 7221.1, Rev. 1 reflects the direction in 9 CFR § 412.2 (a)(2) that IPP verify that some generically approved labels in the establishment's labeling records contain the mandatory eight features. When IPP find noncompliance, they should document noncompliance and require establishments change their labels to meet requirements.

**FSIS Response**

FSIS will revise FSIS Directive 7221.1 Rev. 1 to ensure IPP label verification activities include generically approved labels. IPP will document noncompliance and require establishments to change labels that are not in compliance with FSIS's labeling regulations and policies.

**Estimated Completion Date:** May 31, 2021

Learn more about USDA OIG  
Visit our website: [www.usda.gov/oig](http://www.usda.gov/oig)  
Follow us on Twitter: @OIGUSDA

Report Suspected Wrongdoing in USDA Programs

OIG Hotline: [www.usda.gov/oig/hotline.htm](http://www.usda.gov/oig/hotline.htm)

Local / Washington, D.C. (202) 690-1622  
Outside D.C. (800) 424-9121  
TTY (Call Collect) (202) 690-1202

Bribery / Assault  
(202) 720-7257 (24 hours)



In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Agencies, offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal

Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at How to File a Program Discrimination Complaint and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: [program.intake@usda.gov](mailto:program.intake@usda.gov).

USDA is an equal opportunity provider, employer, and lender.

All photographs on the front and back covers are from USDA's Flickr site and are in the public domain. They do not depict any particular audit or investigation.