Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

FSIS Expansion of Generic Labeling

Labeling and Program Delivery Staff
March 15, 2023

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Generic Approval Expansion Overview

Generic Approval Expansion Overview

- Effective on March 20, 2023, the final rule amends FSIS regulations to expand the categories of labels that may be approved generically

- These categories include labels for products that:

  - Bear negative claims (i.e., Gluten free, No MSG)
  - List organic ingredients in the ingredients statement (i.e., organic sugar, organic flour in the ingredients statements
  - Bear geographic logos, maps or flags (i.e., Italian flag, map of Texas)
  - Are for export and deviate from domestic requirements
  - Are produced under Voluntary inspection (e.g., rabbit, exotic species, closed faced sandwiches) - unless other conditions in 9 CFR 412.1 apply

- LPDS will no longer evaluate labels that are eligible for generic approval

Prior to 2023 Expansion

The following categories of labels require LPDS approval:

1. Labels for temporary approval (9 CFR 412.1(c)(4))
2. Labels for products produced under religious exemption (9 CFR 412.1(c)(1))
3. Labels with special statements and claims (9 CFR 412.1(c)(3))
4. Export labels bearing deviations from domestic requirements (9 CFR 412.1(c)(2))

All labels for product produced under Voluntary inspection must be submitted to LPDS for approval

LPDS evaluated labels that may be approved generically voluntarily submitted by establishments

After 2023 Expansion

Effective March 20, 2023, the following categories of labels require LPDS approval:

1. Labels for temporary approval (9 CFR 412.1(c)(4))
2. Labels for products produced under religious exemption (9 CFR 412.1(c)(1))
3. Labels with special statements and claims (9 CFR 412.1(c)(3))

Labels for product produced under Voluntary inspection do not require LPDS approval unless they fit in one of the categories listed above

LPDS will no longer evaluate labels that may be approved generically

Categories of Labels Requiring LPDS Approval

Temporary Label Approval

Temporary Label Approval – 9 CFR 412.1(c)(4)

- Temporary approvals are not affected by this generic expansion
- Granted on a case-by-case basis
- Are not to exceed 180 days, and may be granted up to 180-day extension
  - Plant transfers are granted for up to 60 days, and may be granted an additional 60-day extension

Temporary Label Approval – 9 CFR 412.1(c)(4)

- Address the conditions cited in 9 CFR 412.1(f)(1)
  - The proposed label would not misrepresent the product;
  - The use of the label would not present any potential health, safety, or dietary problems to the consumer;
  - The use of the label would not result in an unfair competitive advantage; and
  - Denial of the request would create undue economic hardship

- Clearly explain the specific labeling deficiencies that are present on the label
  - For example: Ingredients statement deficiencies must clearly list which ingredients are on the label but not in the product and which ingredients are in the product but not on the label.

- Complete previously approved label information in Box 6b of Form 7234-1 or in the “Approval Information” section of LSAS

- If requesting extension of a temporary approval, explain in detail why the extension is necessary

Examples of Common Reasons and Requests for Temporary Approval

- Incorrect legend on label (e.g., poultry legend on a meat label)
- Order of predominance of ingredients has changed
- Specific multi-ingredient item has changed resulting in incorrect sublisting of some ingredient (e.g., spice mix)
- New ingredient has been added to formulation but is not on the label
- Address of the establishment has changed
- Incomplete product name (e.g., “smoke flavor added” qualifier missing)

Religious Exempt

Religious Exemption – 9 CFR 412.1(c)(1)

- Religious-exempt products are not affected by this generic expansion
- Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products
- Poultry processed in accordance with:
    - Buddhist religious beliefs (head and feet remain on eviscerated poultry)
    - Confucian religious beliefs (poultry is not eviscerated, head and feet intact)
    - Islamic (or Halal) religious beliefs (poultry is eviscerated, head-on, with or without the feet intact, in ready-to-cook form)

Special Statements and Claims

Special Statements and Claims – 9 CFR 412.1(e)

- Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on the FSIS Guideline for Label Approval, last updated in January 2023

- List will be periodically updated to reflect commonly asked questions regarding special statements and claims

Special Statements and Claims – Examples

- Examples of special statements and claims that will continue to require LPDS approval:
  - Natural claims, e.g. “All Natural”, “100% Natural”
  - Claims of the use of non-genetically engineered ingredients
  - Claims regarding meat and poultry production practices (e.g., claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)

Special Statements and Claims: LPDS Approval Required

Example of a label bearing various special claims that require LPDS approval.

Expansion of Generic Labeling

Categories of Labels Affected by the Final Rule

- Effective on March 20, 2023, the final rule amends FSIS regulations to expand the categories of labels that may be approved generically

- These categories include labels for products that:

  - Bear negative claims (i.e., Gluten free, No MSG)
  - List organic ingredients in the ingredients statement (i.e., organic sugar, organic flour in the ingredients statements
  - Bear geographic logos, maps or flags (i.e., Italian flag, map of Texas)
  - Are for export and deviate from domestic requirements
  - Are produced under voluntary inspection (e.g., rabbit, exotic species, closed faced sandwiches) - unless other conditions in 9 CFR 412.1 apply

Negative Claims

Negative Claims

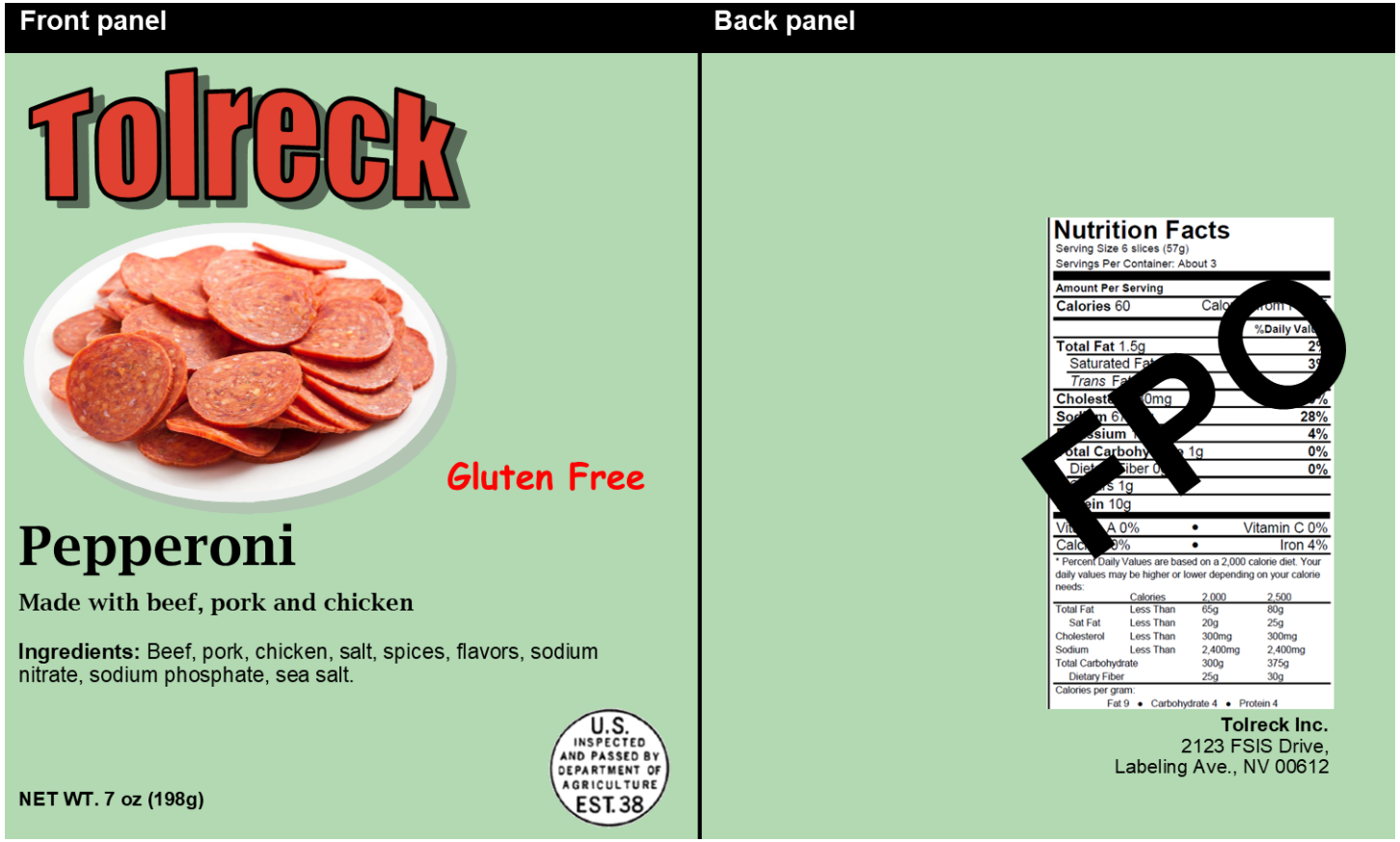
- “Negative” claims made on product labels that identify the absence of certain ingredients or types of ingredients will no longer be required to be approved by LPDS

- LPDS approval of labels that bear negative claims relating to the raising of the animal from which the product is derived (e.g., “no antibiotics administered”) or negative claims relating to the use of genetically modified ingredients will continue to be required

Gluten Free

- Claim requirements
  - The claims is allowed when the product does not contain any amount of gluten containing ingredients.
  - For example: wheat, barley, rye
- “Certified Gluten Free” is not generic and is required to be submitted to LPDS for approval

Gluten Free Label Example



Example of a label bearing a gluten free claim. This claim will be eligible for generic approval on March 20, 2023.

No Artificial Colors and No Artificial Flavors

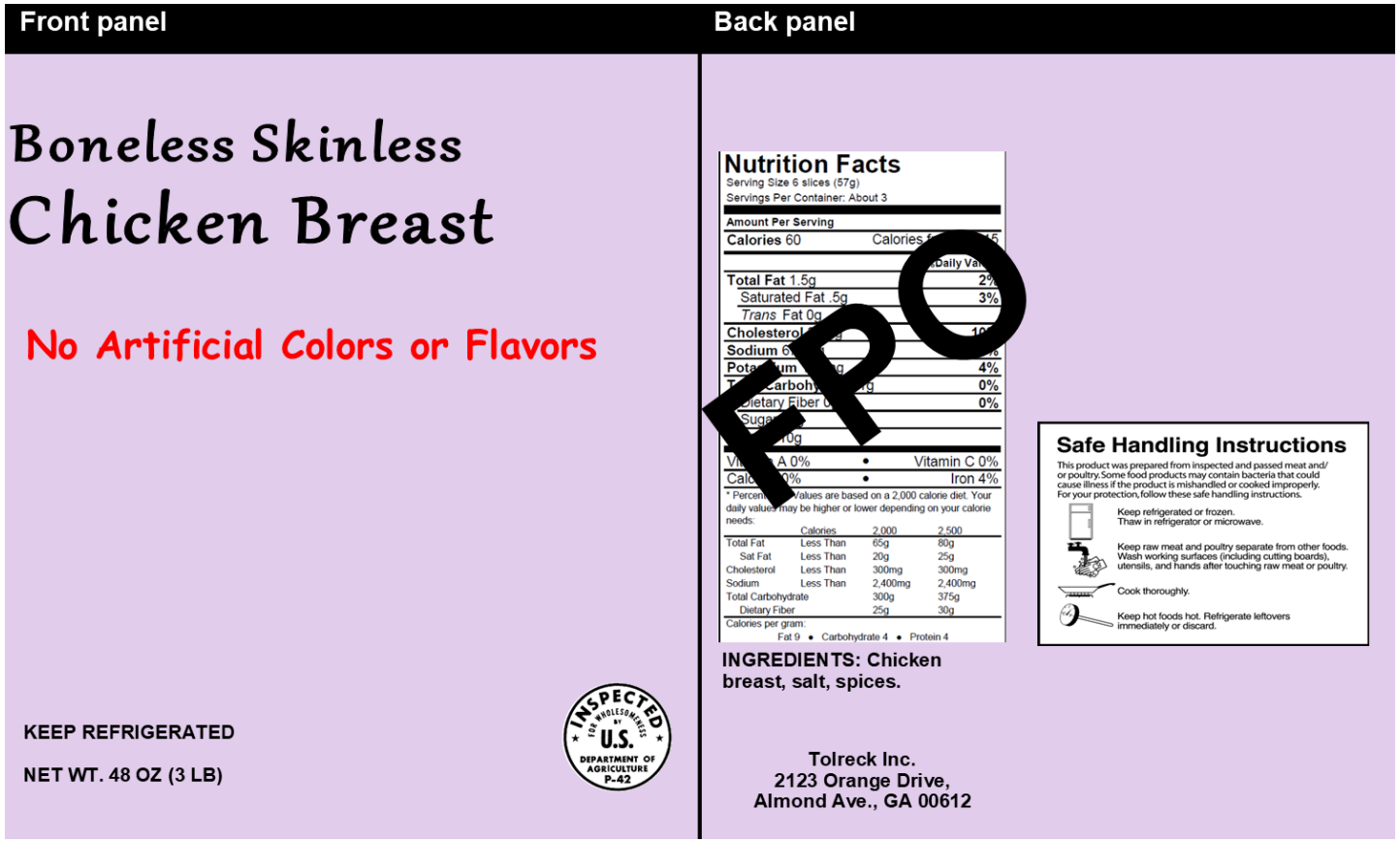
No Artificial Colors

- Claim Requirements - the label follows the entry in the Food Standards and Labeling Policy Book.
- The product should not contain any artificial colors described in the entry- “Artificially Colored Products.” e.g., FD&C Yellow No. 5

No Artificial Flavors

- Claim requirements - the product would not contain any artificial flavors.
- Not acceptable ingredients: Artificial Maple Flavor, Artificial Butter Flavor
- Acceptable ingredients: Monosodium Glutamate, Smoke flavor

No Artificial Colors and No Artificial Flavors Label Example

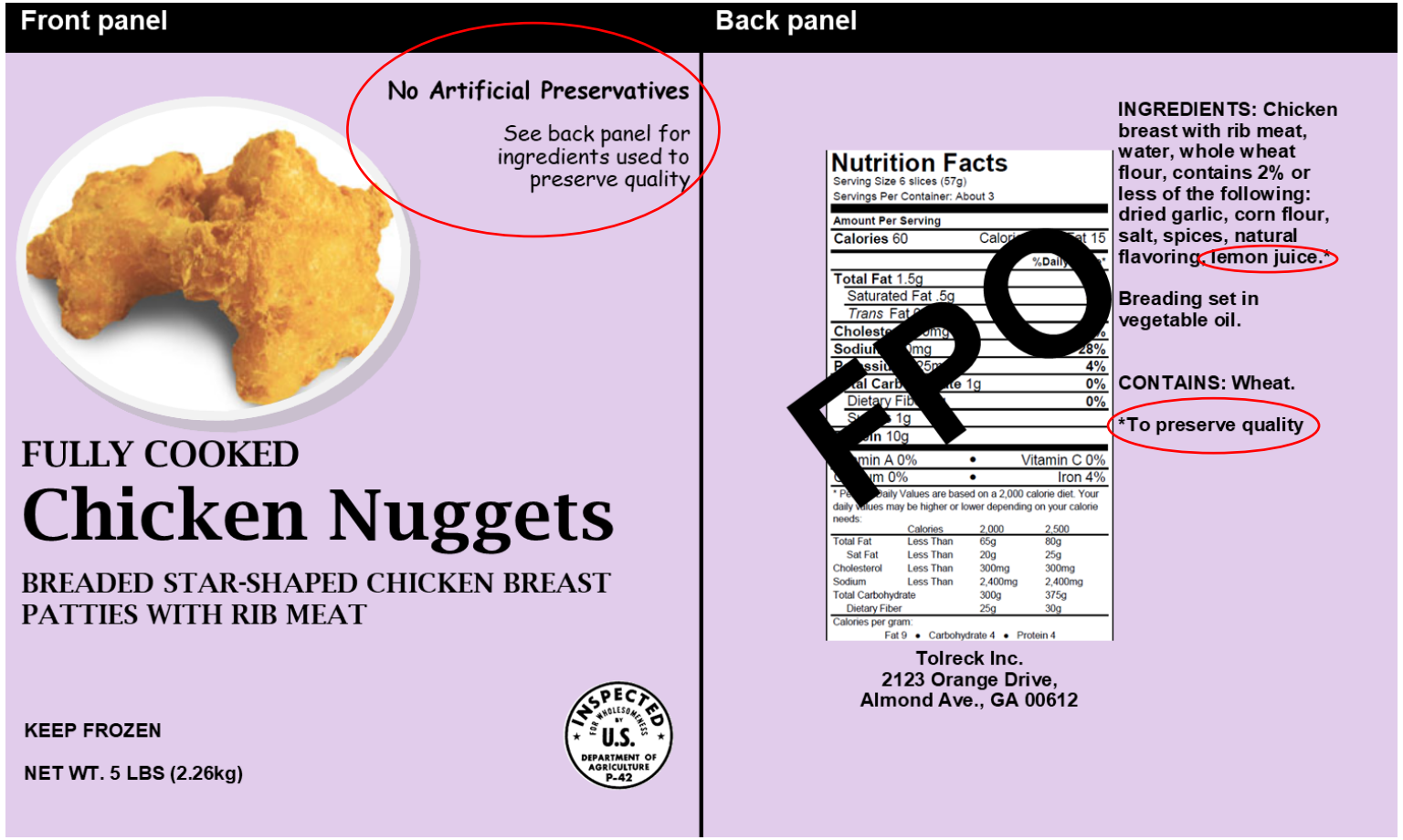


Example of a label bearing a no artificial colors or flavors claim. This claim will be eligible for generic approval on March 20, 2023.

No Artificial Preservatives

- Claim requirements:
  - Required statement on the label
    - In immediate proximity to the claim, the label states “See back panel for ingredients used to preserve quality.”
  - Requirement in the ingredients statement
    - Each ingredient that is added to preserve the product would need to be declared and have an asterisk next to it
  - Statement on the back panel
    - Asterisk would link to the statement *ingredient to preserve quality or the shortened version of *to preserve quality

No Artificial Preservatives Label Example

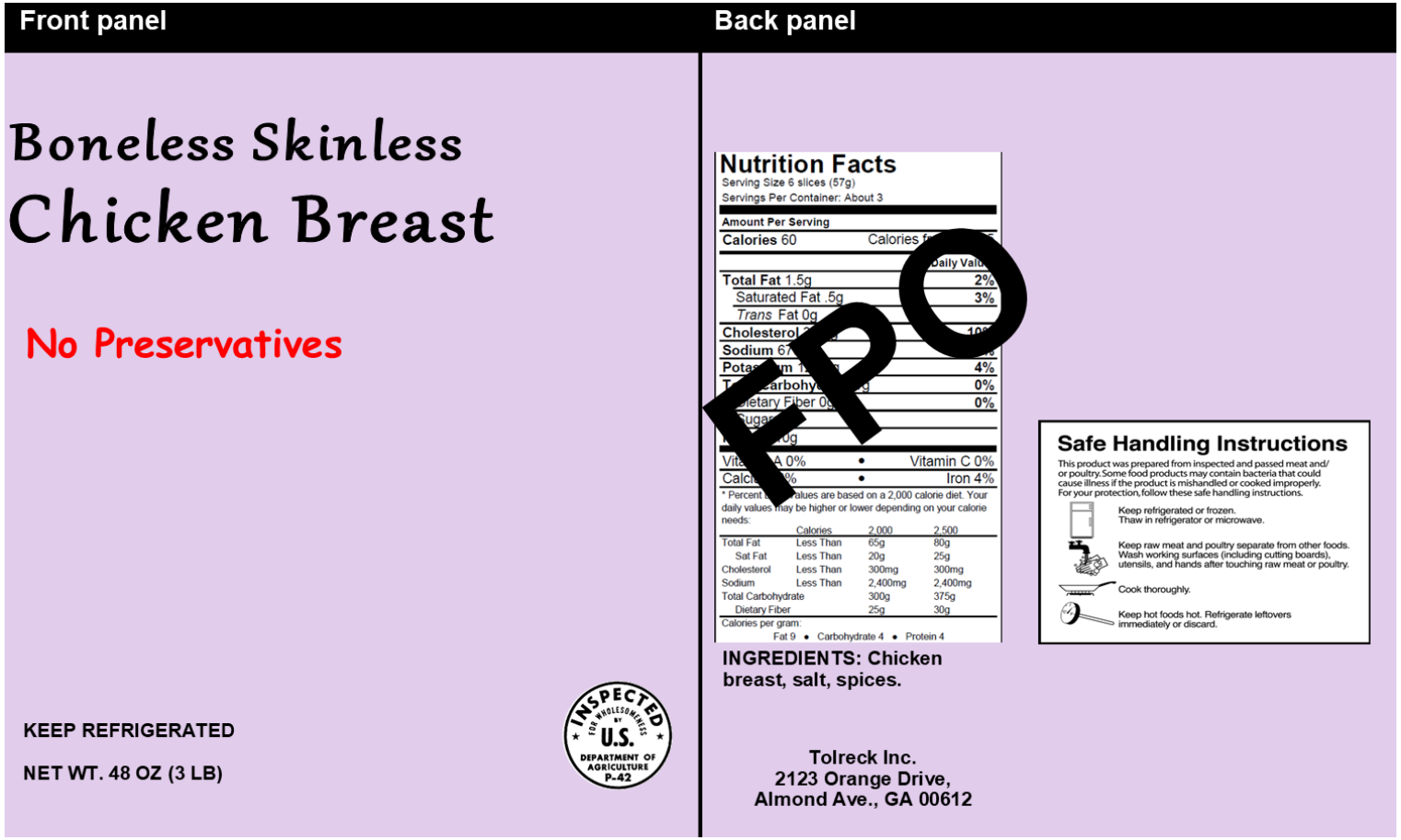


Example of a label bearing a no artificial preservatives claim. This claim will be eligible for generic approval on March 20, 2023.

No Preservatives

- Claim requirements
  - Ingredients statement and product formula cannot contain any sources of preservatives
- Common chemical preservatives (not acceptable)
  - Ascorbic Acid
  - Antioxidants (BHA, BHT, etc.)
  - Propionates (calcium propionate, sodium propionate)
  - Natamycin
  - Benzoates, etc.
- More information on chemical preservatives see 9 CFR 424.21 and FSIS Directive 7120.1
- Chemical Preservatives definition in 21 CFR 101.22 (a) (5).

No Preservatives Label Example

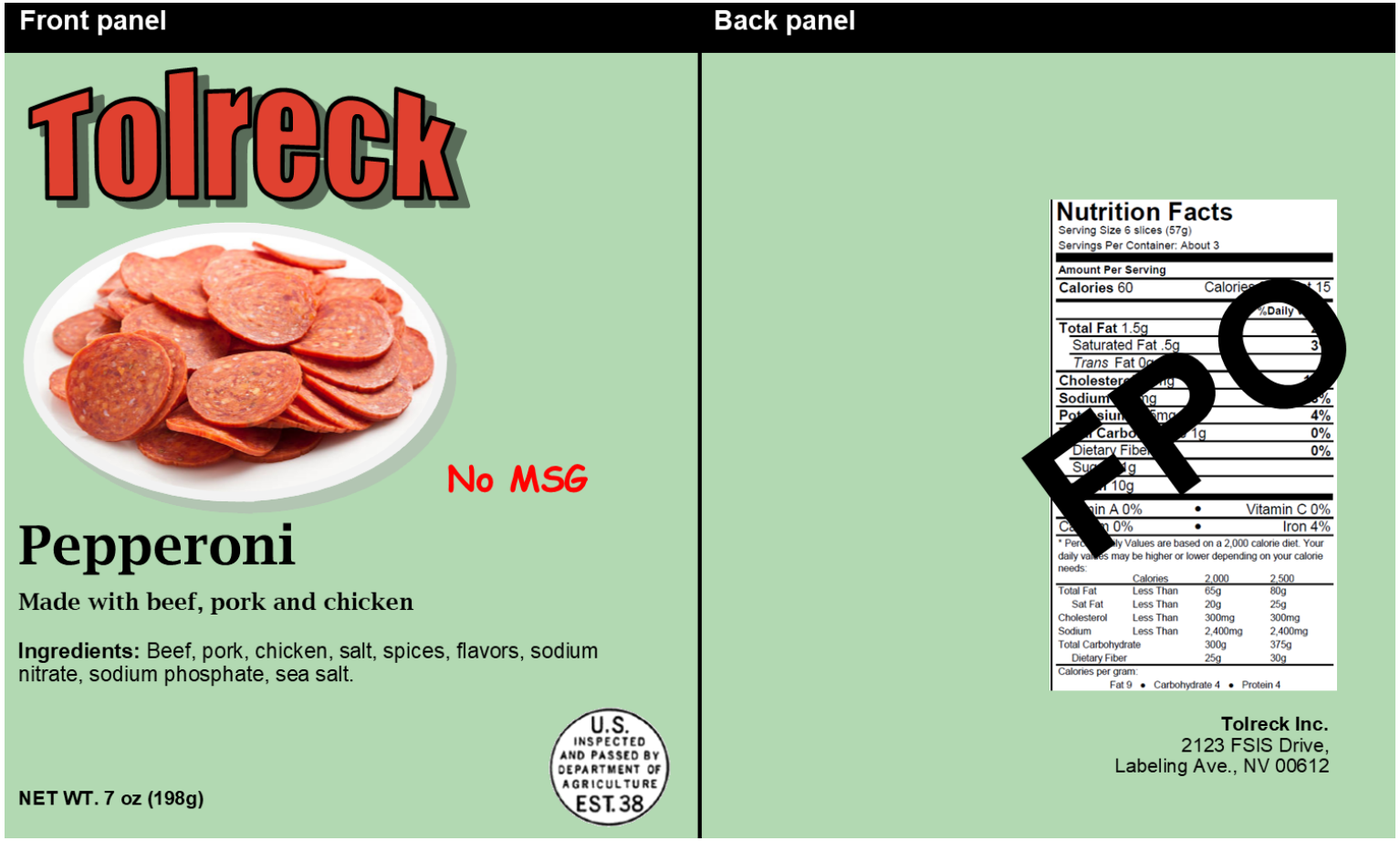


Example of a label bearing a no preservatives claim. This claim will be eligible for generic approval on March 20, 2023.

No MSG

- Claim requirements
  - The product does not contain monosodium glutamate or any sources of MSG
- Common Sources of MSG
  - Soy sauce and Worcestershire Sauce
  - Any ingredient that is hydrolyzed or autolyzed such as autolyzed yeast extract
  - Hydrolyzed proteins

No MSG Label Example



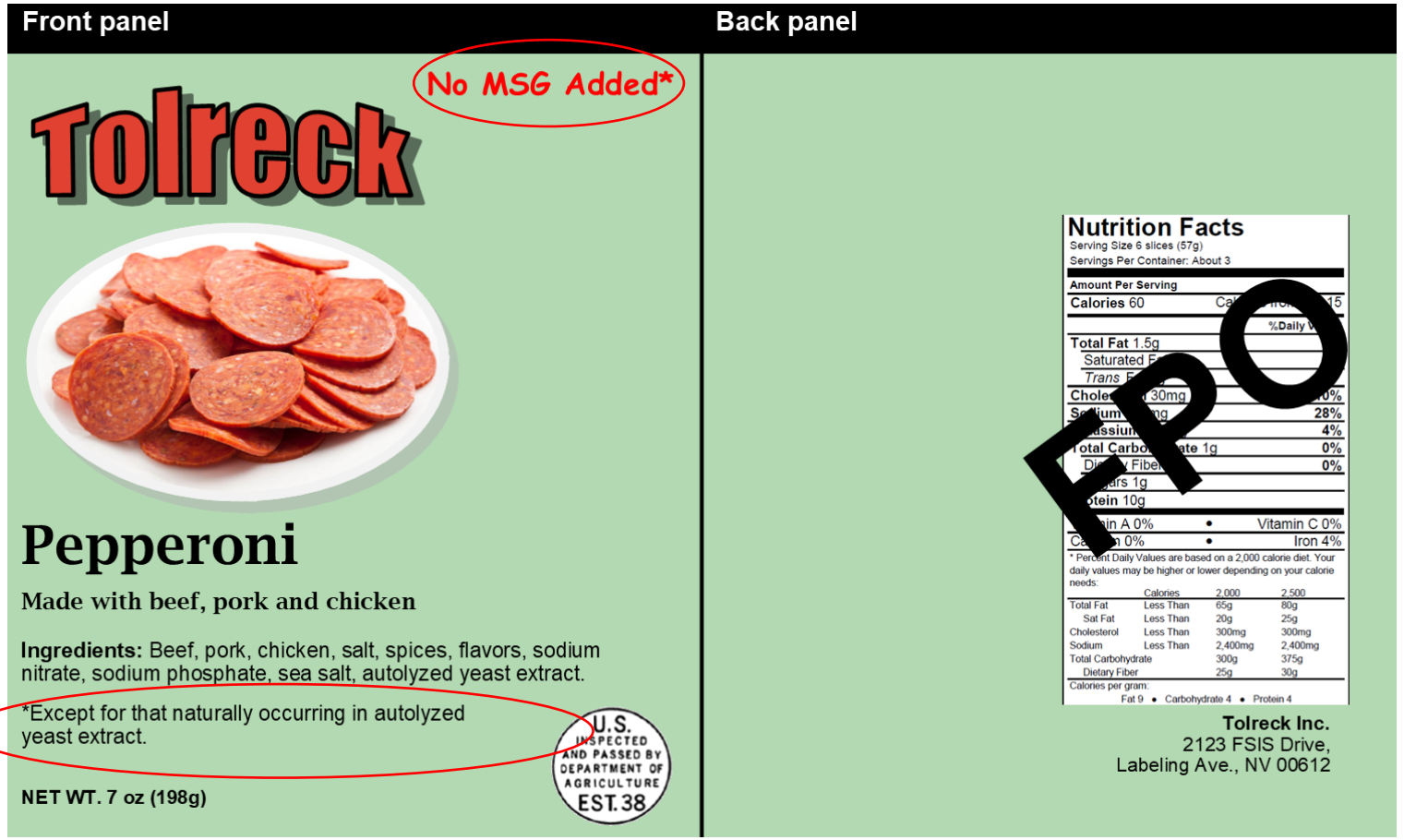
Example of a label bearing a no MSG claim. This claim will be eligible for generic approval on March 20, 2023.

No MSG Added*

- Claim requirements – No monosodium glutamate, does have natural sources of MSG
  - Disclaimer statement connecting to the No MSG added *claim
    - *except for that naturally occurring in (identify the natural sources of MSG)
    - Must be adjacent to the claim, or on the same panel and connected by a symbol

- Natural sources of MSG
  - Soy sauce
  - Worcestershire sauce
  - Autolyzed yeast extract
  - Hydrolyzed protein

No MSG Added* Label Example

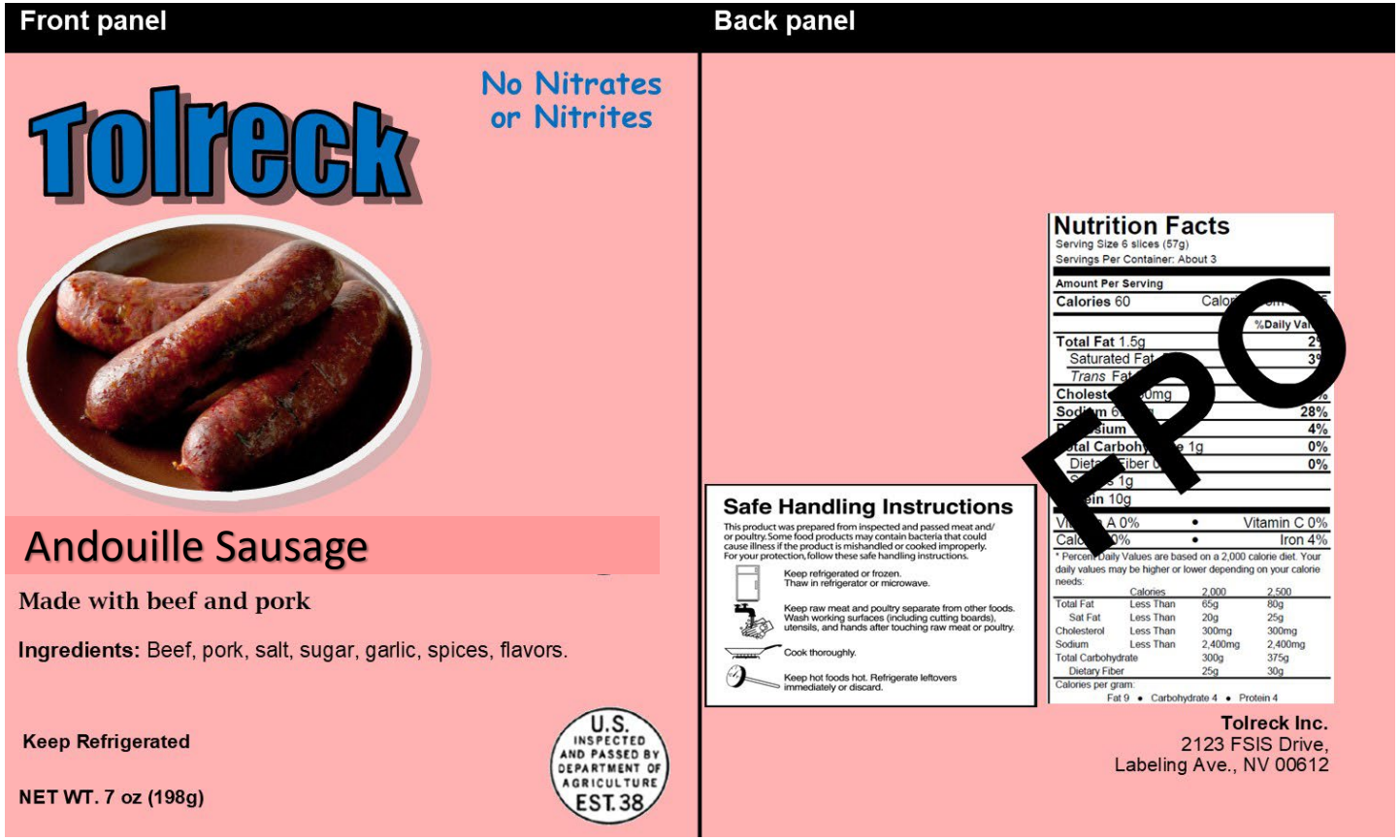


Example of a label bearing a no MGS added claim. This claim will be eligible for generic approval on March 20, 2023.

No Nitrites and Nitrates

- Claim requirements
  - Ingredients statement and product formula cannot contain any sources of nitrites and nitrates (sodium nitrite/nitrate, potassium nitrite/nitrate)
- Natural sources of nitrites and nitrates (not acceptable)
  - Sea salt
  - Cultured celery powder
  - Celery powder
  - Cultured celery juice
  - Celery juice
- Includes labels identified as “uncured” following 9CFR 317.17.

No Nitrites and Nitrates Label Example

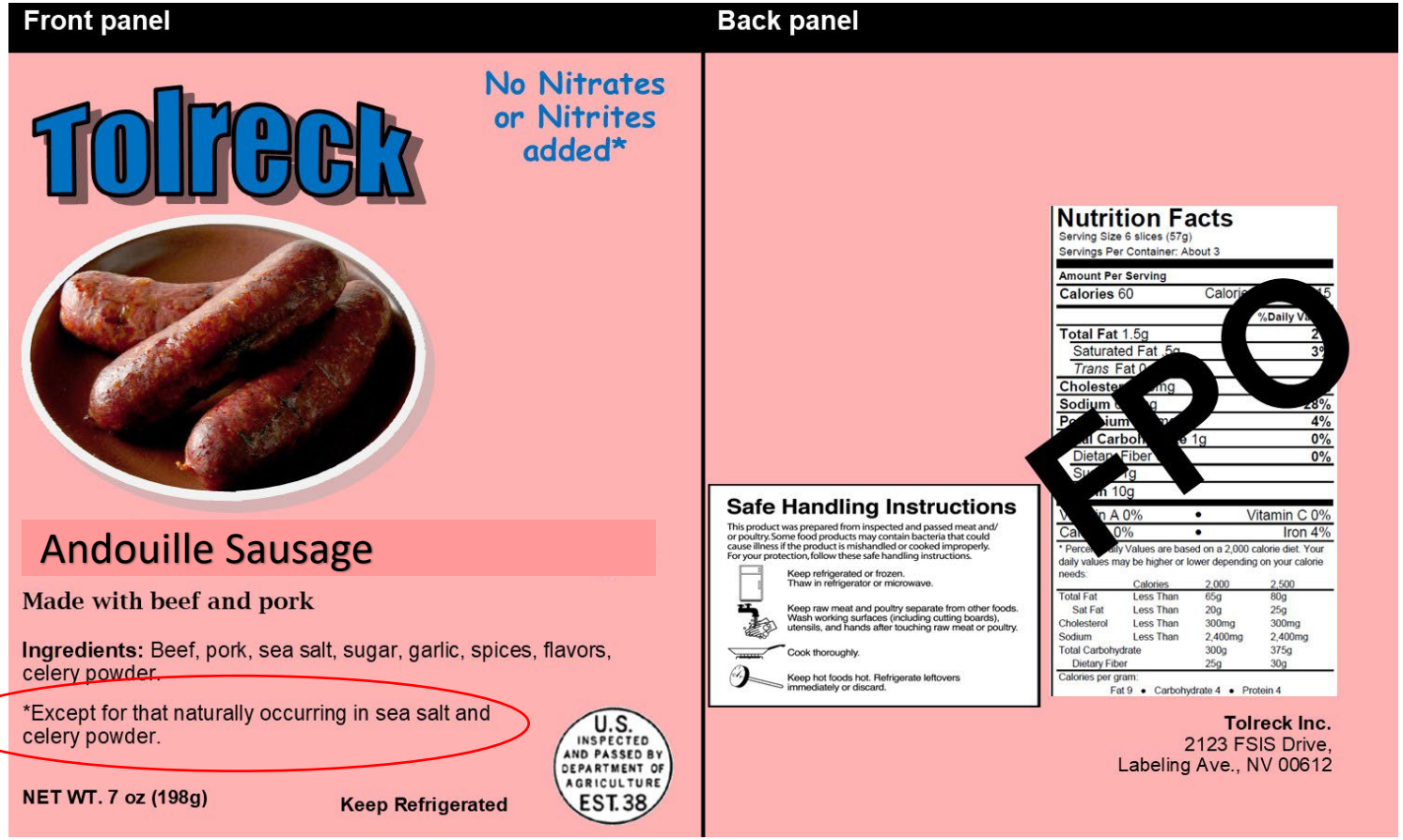


Example of a label bearing a no nitrates or nitrites claim. This claim will be eligible for generic approval on March 20, 2023.

No Nitrites and Nitrates Added*

- Claim requirements – No nitrite/nitrate, does have natural source of nitrate/nitrite
  - Disclaimer statement *except for that naturally occurring in (identify the natural sources of nitrites and nitrates)
  - Must be adjacent to the claim, or on the same panel and connected by a symbol
- Natural sources of nitrites and nitrates (acceptable)
  - Sea salt
  - Cultured celery powder
  - Celery powder
  - Cultured celery juice
  - Celery juice
- Includes labels identified as “uncured” following 9CFR 317.17.

No Nitrites and Nitrates Added* Label Example



Example of a label bearing a no nitrates or nitrites added claim. This claim will be eligible for generic approval on March 20, 2023.

Geographic claims

Flag or Map from another Geographical Location or Region

- “Geographic landmarks” displayed on a product label, such as a foreign country's flag, monument, or map will no longer require FSIS review prior to entering commerce
    - For example:
        - a Polish flag depicted on a Polish sausage product label, or
        - an outline of the State of Nevada depicted on a product label for beef produced in Nevada
- Labels with flags or maps that represent a location or region other than the one the product was made must:
    - Include a “Made in (location)” statement adjacent to the map, flag or monument, or
    - Include a “style,” “type,” or “brand” statement, plus a statement identifying the country, State, Territory, or locality in which the product is prepared following 9 CFR 317.8 (b) (1) or 9 CFR 381.129(b) (2)
    - Defined Styles – see the FSIS Policy Book.
    - Undefined styles – third party documentation in the labeling record to address the geographical claims only (cannot be contrary to products standards/regulations)

State Endorsement Programs with an Emblematic Design or Geographic Term

- State endorsement programs that have a geographic emblematic design (e.g., Nevada Made with the map or flag of Nevada)
- State Endorsement Programs that have a geographic term, but do not have a geographic emblematic design (e.g., Pride of New York or Kentucky Proud)
- The product is required to meet the following criteria:
    - Include a certification or letter from State Program in the labeling records
- Generally, these products are expected to be made in that region or locality, and meet the program requirements

Organic Ingredients in the Ingredient Statement

Organic Ingredients in the Ingredient Statement

- Ingredients listed as certified “organic” under the Agricultural Marketing Service’s (AMS’s) National Organic Program in a product label’s ingredients statement will no longer require FSIS review prior to entering commerce
  - Example: “Ingredients: Beef, Organic Salt, Natural Flavors and Organic Spices”

- Support for the organic ingredients must be included in the labeling records

- Organic claims outside of the ingredient statement will continue to require LPDS approval
  - Example: “Made with organic ingredients,” organic claims displaying a percentage of organic ingredients, and certifying a total product as organic

Export Labels with Deviations

Export Labels with Deviations

- Export labels with deviations from domestic requirements will no longer require LPDS approval
- Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments
- Includes ensuring that any labeling deviations on meat and poultry products are allowed per the importing country's laws (9 CFR 317.7 and 381.128)
- The establishment is responsible for ensuring that labels comply with labeling requirements of the country to which the product is exported
- Supporting documentation (e.g., a letter from the importer) may be included in the labeling record.
- FSIS Export Library

Voluntary Inspection

Voluntary Inspection

- Before this final rule, labels for products produced under these voluntary inspection programs were not able to be generically approved

- This final rule will permit generic approval for these products unless the label meets the conditions in 9 CFR 412.1 (i.e., temporary approval, special statements or claims)

- Types of products for which FSIS provides voluntary inspection services under the authority of the Agricultural Marketing Act include:

    - Rabbits
    - Certain non-amenable species of livestock and poultry, such as elk, bison, and migratory waterfowl
    - Products that contain meat or poultry but are not under FSIS jurisdiction, e.g., closed-faced sandwiches

Additional information on Label Approval

Points of Clarification on Generic Approval

- Labels will be generically approved if they meet the criteria listed in 9 CFR 412.2(b)
- Establishments do not generically approve labels.
- FSIS Inspectors do not generically approve labels.
- FSIS in-plant inspection personnel will continue to conduct in-plant label verification activities for all labels including labels that are generically approved.

- Establishments Do create and maintain the generic labeling record.

Labeling Records

- Establishments are required to keep records of all labels, which must include:
  - Final label applied to product
  - Product formulation
  - Processing procedures
  - Supporting documentation, including prior sketch approval from LPDS (if applicable)

- Required records prescribed by 9 CFR 320.1(b)(10), 381.175(b)(6), and 412.1

- Supporting documentation needed to show that the label is consistent with the Federal meat and poultry regulations and policies on labeling as described in 9 CFR 412.1

- Labeling record for any label generically approved must include a complete copy of the original LPDS approval (if the original required LPDS approval)

- ASKFSIS public Q/A responses provide clarification on labeling records

“Blanket” Approval

- Allows certain information to be added to multiple labels without having to submit each individual label bearing the same type of information for approval

- Covers multiple labels or product lines
  - e.g., Front of Pack nutrition statements

- Application for a blanket approval must include:
  - completed application form 7234-1
  - copy of at least one of the product labels
  - attachment that indicates a list of prior approved products or line of products to which the same information will be applied, e.g., FOP nutrition

Modifications to Sketch Approved Labels with Special Claims

- Once a label is approved with a special statement or claim, changes can be made generically that are unrelated to the special claim, e.g., brand name, net weight, updating nutrition facts values, serving sizes (must be based on RACCs or longstanding appetizer RACC) and in some cases formulation changes

- FSIS Guideline to Label Approval

Regulatory Considerations for New Claims

- Claims must be truthful and not misleading (9 CFR 317.8 and 381.129)
- Establishments should:
  - Reach out to LPDS through askFSIS to confirm the acceptability of proposed language for a new claim before submission.
  - Explain the meaning and intent of the new claim.
  - If applicable, provide documentation to support that the new claim is truthful and not misleading.
- LPDS will determine if the new claim is acceptable, and if so, if it requires LPDS approval or is eligible for generic approval

Label Submission and Approval System

Label Submission and Approval System (LSAS)

- LSAS is the electronic submission system for label applications
- Integrates and implements a secure electronic label application process for establishments to submit label applications and appeals
- All labels requiring LPDS approval must be reviewed in LSAS.
- Most labels are now submitted via LSAS; faster than paper.
- To get an LSAS account, you must first get an e-Authentication account
- Enrollment instructions at: https://www.fsis.usda.gov/guidelines/2005-0002

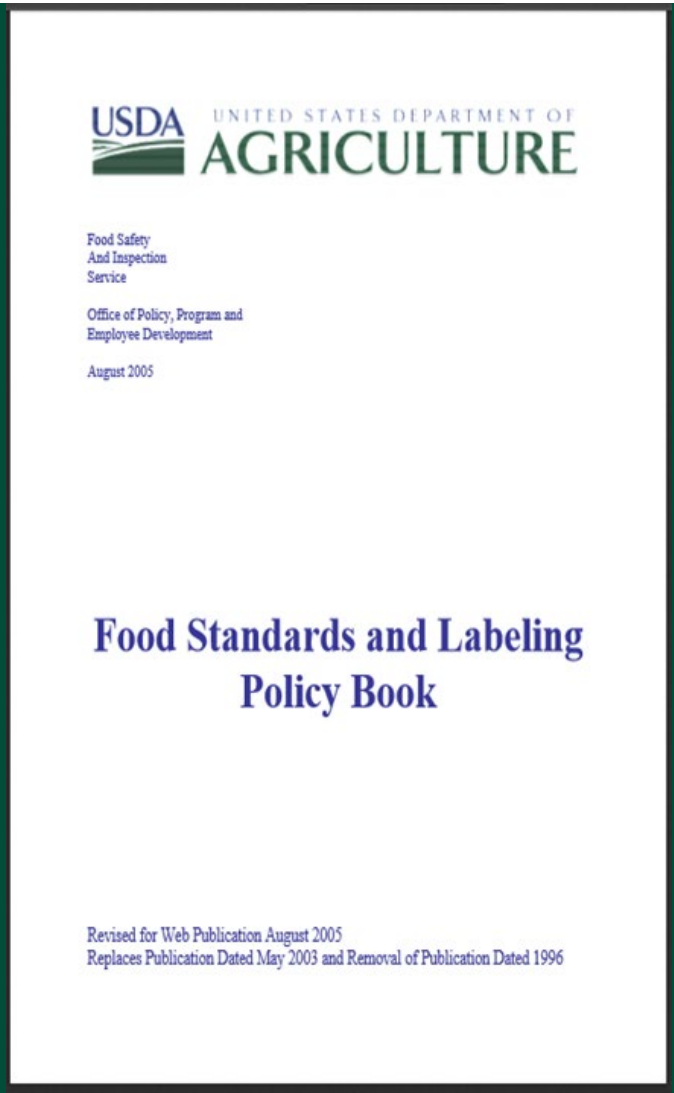
Generic Label Advisor (GLA)

- The GLA is a tool that guides applicants through a series of questions to determine if a label application requires submission.
- Will be updated to reflect the new generic labeling regulations
- GLA is not required for generic approval or for submission of a label application through LSAS.
- A GLA certificate is not a generic approval.
- ASKFSIS public Q/A responses provide clarification on the GLA

Resources

Food Standards and Labeling Policy Book

- FSIS has decided to stop adding policy guidance to the Food Standards and Labeling Policy Book
- FSIS will continue to amend or remove existing items in the book, as necessary, but it will no longer add new material to it
- The Agency will convey new labeling policy by other means, such as compliance guidelines



FSIS Guideline for Label Approval

- FSIS Guideline for Label Approval available on FSIS website
- Updated January 2023 to reflect the changes in the final rule
- Will be periodically updated to reflect commonly asked questions regarding special statements and claims
    - 60-day comment period
- Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval
    - Including negative and geographic claims

Other Guidelines

- FSIS updated both the Animal Raising Claims Guideline and the Non-GMO Guideline in December 2019.
  - FSIS Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions
  - "Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products."
- Other guidelines relating to ingredients, nutrition, claims, and other labeling policies and procedures is available on the FSIS labeling homepage: https://www.fsis.usda.gov/inspection/compliance-guidance/labeling

FSIS Constituent Update

- FSIS frequently publishes “Tips for Faster Label Approval Process” in the online FSIS Constituent Update
- Since 2019, sample topics include:
  - Supporting documentation guidance
  - Temporary label application suggestions
  - Clarifications on editing vs. appealing applications
- To sign up for FSIS email subscription service: https://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service
- Archived listing of past Constituent Updates: https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/constituent-updates

USDA Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Submit Questions to askFSIS

- AskFSIS

Call:

- Main: 301.504.0878

Labeling Procedures

- Labeling and Label Approval

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