

Marketing Cleaners & Sanitizers to Food Establishments

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History of USDA Authorization

- Hands on involvement by inspectors
- Authorization of cleaners and sanitizers for meat and poultry plants
- Creation of guidelines for authorization
- List of Non-Food Compounds and Proprietary Substances
- Reliance on USDA authorization as condition of purchase

Discontinuation of the USDA Program

- Notices published on August 25, 1997 and February 13, 1998
- Officially dismantled in July 1998
- Affects all products, including: cleaning and hand washing compounds, sanitizers and disinfectants

Discontinuation of the USDA Program

- Rationale: HACCP, a performance oriented standard
- Old command and control style regulations are viewed as inconsistent
- Responsibility for selecting appropriate cleaners and sanitizers falls on the meat & poultry establishments

Discontinuation of the USDA Program

- No more prior authorization of products
- No more evaluation of cleaners and sanitizers for any reason
- No List of Non-Food Compounds and Proprietary Substances

What USDA/FSIS Will Continue to Do

- Provide advice where requested
- Require that cleaners/sanitizers are safe
- Assure that cleaners/sanitizers do not adulterate food or create insanitary conditions
- Require that all food-contact surfaces are cleaned “as frequently as necessary.”
- Provide assistance to other federal agencies

Marketing Cleaners and Sanitizers

To lawfully enter meat and poultry plants, all products must either:

1. Have been previously authorized by USDA; or
2. Be accompanied by documentation that certifies that the product is safe when used as intended

Letter of Guaranty

- Attests to the product's safety and effectiveness
- No required format or language
- Format and language will vary depending on the nature and use of the product

Letter of Guaranty

Contents

1. Name and address of supplier
2. Designation identifying the product
3. Statement of safety and efficacy
4. Statement of compliance
5. Any limits of use or special directions
6. Signature

Letter of Guaranty

Statement of Safety and Efficacy

- “Product will neither adulterate food or create insanitary conditions if used in accordance with directions for use.”
- “Product is safe for use in federally inspected meat and poultry plants if used in accordance with directions for use.”

Letter of Guaranty

Statement of Compliance

- “Product complies with FDA requirements for sanitizers used on food contact surfaces set forth at 21 CFR 178.1010.”
- “Product is registered with EPA pursuant to FIFRA as a sanitizer for food contact surfaces.”

Letter of Guaranty

Statement of Compliance: Relevant Regulations

- Food contact surface sanitizers: 21 CFR 178.1010
- Fruit & vegetable washes: 21 CFR 173.315
- Boiler water treatments: 21 CFR 173.310
- Lubricants: 21 CFR 178.3570
- FDA Tentative Monograph

Letter of Guaranty

Previously Approved Products

- Proof of prior authorization is sufficient documentation
- May also be accompanied by a letter of guaranty noting that the formulation has not been altered or changed

Letter of Guaranty

- May be attached to each individual shipment; or
- May be issued one time as a “continuing letter of assurance.”
- Statements on the letter may subject a company to potential civil liability

Allowable Marketing Claims

Previously Authorized Products

- May still note that they have been authorized by USDA

Unauthorized Products

- “Product is formulated in accordance with criteria set forth in the USDA guidelines”

Allowable Marketing Claims

New Private Labels and New Brand Names

- May refer to underlying authorized formulation but may not claim that the specific private label product is authorized

Other Acceptable Claims

- “Product meets USDA performance standard for *insert type of product*”
- “Product complies with CFR ??????”

Enforcement

- USDA does *not* oversee the marketing of products
- The Federal Trade Commission (FTC) has jurisdiction over marketing activities, including all label and literature claims.

Guidance Documents

- Guidelines for Obtaining Authorization of Compounds to Be Used in Meat & Poultry Plants
- Sanitation Performance Standards Compliance Guide
- FSIS Directive on the Sanitation Standard for Meat & Poultry Establishments

Third Party Certification

- Required documentation can come from a third party certifier
- FSIS has encouraged the development of third party certification programs