

# MARKETING CLEANERS AND SANITIZERS TO FOOD ESTABLISHMENTS

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## I. INTRODUCTION

- A. **Purpose:** The discontinuation of the USDA prior authorization program for non-food compounds and proprietary substances has raised significant marketing concerns for suppliers of cleaners and sanitizers used on food contact surfaces. This session will focus on how to market cleaners and sanitizers to meat and poultry facilities and other food establishments in the absence of the USDA prior authorization program.
- B. **Overview:** In addressing this topic, we will first review the history and background of the USDA authorization program. We will discuss how the system worked and the discontinuation of the program and its implications. Further, we will talk about how products can be marketed in the wake of the program and offer suggestions for marketing cleaners and sanitizers to food establishments.

## II. HISTORY OF THE USDA PRIOR AUTHORIZATION PROGRAM

Until HACCP regulations were implemented, the Food Safety Inspection Service (FSIS) enforced sanitation requirements in meat and poultry facilities through hands-on involvement by inspectors in day-to-day operational sanitation procedures, in addition to issuing prescriptive sanitation requirements and other detailed guidance materials.

As part of this regulatory oversight of sanitation, FSIS required meat and poultry facilities to only use cleaners and sanitizers that had been approved under the USDA authorization program. The purpose of this program was to ensure that the use of these products would not result in the contamination or adulteration of meat and poultry.

Under the authorization program, USDA created "guidelines for the authorization of non-food compounds and proprietary substances" which set forth criteria that products had to meet in order to be approved for use in meat and poultry facilities. In fact, USDA established guidelines for general cleaning compounds, sanitizers, disinfectants, compounds for laundry use, hand soaps, pesticides, and other similar products.

Manufacturers would submit products to USDA for approval. The agency would not test the products but would evaluate them based on the information submitted

by the manufacturer in addition to consulting with other appropriate federal agencies such as FDA and EPA. If the products met the USDA guidelines, the agency would issue a letter of authorization and include the products in its List of Non-Food Compounds and Proprietary Substances, effectively declaring these products lawful. Companies could then feel comfortable selling these products to meat and poultry facilities. The listing and the letter of authorization, therefore, were the keys to marketing cleaners, sanitizers and other non-food compounds.

Further, other food related establishments that were not subject to the jurisdiction of USDA and FSIS (i.e.: restaurants, grocery stores, cafeterias, retail food outlets) and some non-food institutions began to rely on USDA listing. Many made it a condition of purchase that cleaners and sanitizers be authorized under the USDA program. In this regard, the USDA authorization and listing became a crucial marketing tool and the authorization program went far beyond the purpose for which it was intended by USDA and FSIS.

### III. DISCONTINUATION OF THE USDA AUTHORIZATION PROGRAM

- A. **Notice of Discontinuation:** USDA and FSIS provided notice of the intent to discontinue the USDA prior authorization program in two *Federal Register* notices. These notices were published on August 25, 1997 and February 13, 1998. The program was officially dismantled in July 1998.
- B. **Products Affected:** Products affected by the discontinuation of the USDA prior authorization program include cleaning compounds, compounds for laundry use, sanitizers, disinfectants, hand washing compounds, pesticides, boiler and water treatments, solvents, lubricants, and sewer and drain cleaners.
- C. **Rationale for Discontinuation:** The command and control style regulations which gave rise to the USDA prior authorization program were replaced by the new Hazard Analysis and Critical Control Points (HACCP) system. The HACCP system is a performance oriented standard and the old regulations were viewed as inconsistent with the spirit and intent of the new program. HACCP intends to define the results to be achieved by sanitation, but not the specific means to achieve those results.

Under HACCP, all meat and poultry establishments must (1) identify critical control points during their processes where hazards, such as microbial contamination, can occur; (2) establish controls to prevent or reduce those hazards; and (3) maintain records documenting that the controls are working as intended. In addition, facilities are required to implement standard operating procedures for sanitation.

Moreover, HACCP regulations transfer total responsibility for the safety of meat and poultry products to the processing establishment. Consistent with this

philosophy, USDA also transferred total responsibility of selecting and using appropriate cleaners and sanitizers to the regulated meat and poultry establishments. These facilities must ensure that the meat and poultry products they process will not be contaminated or adulterated by the cleaners and sanitizers that they use.

This transfer of responsibility from FSIS inspectors to the meat and poultry facilities also allowed USDA and FSIS to redirect valuable resources that could be better applied to ensuring the implementation of HACCP regulations.

D. **What the USDA and FSIS have Discontinued:** The discontinuation of the prior authorization program means that:

1. Prior authorization for cleaners and sanitizers is no longer necessary to market products to meat and poultry establishments.
2. USDA will no longer evaluate cleaners and sanitizers.
3. USDA and FSIS will no longer publish the List of Proprietary Substances and Non-Food Compounds.

E. **What USDA and FSIS Will Continue To Do:** In the absence of the USDA prior authorization program, USDA and FSIS will continue to:

1. Provide advice concerning cleaners and sanitizers and whether they are appropriate. (FSIS, Labeling and Additives Policy Division: 202-205-0279).
2. Require that the cleaners and sanitizers used by meat and poultry facilities are safe and effective under conditions of use (bottom-line HACCP requirement). Further, cleaning compounds, sanitizing agents and other chemicals used in the operation of the establishment must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. (This aspect will be enforced by organoleptic testing, sampling for chemical residues, review of records such as SOPs for sanitation, and request for information from manufacturers.)
3. Require that all food-contact surfaces (including food-contact surfaces of equipment and utensils) be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
4. Require that non-food contact surfaces of facilities, equipment, and utensils used in food establishments be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

5. Provide assistance to federal agencies in the evaluation of new direct/indirect food additives (this may include cleaners and sanitizers.)

*\*\*Note:* The language in the USDA final rule regarding the types of cleaners that should be used is very vague. USDA provides guidelines, but the guidelines are based on previously existing (non-performance oriented) USDA requirements.

#### IV. HOW TO MARKET CLEANERS AND SANITIZERS IN THE ABSENCE OF THE USDA PRIOR AUTHORIZATION PROGRAM

As noted, meat and poultry facilities and other food related establishments have often conditioned their purchase of cleaners and sanitizers on USDA authorization and listing. Now that it is no longer available, a critical marketing tool has been taken away. What does this mean?

A. **Lawful Use of Cleaners and Sanitizers in a Meat and Poultry Facility:** In the absence of the USDA prior authorization program, there are only two ways in which cleaners and sanitizers can lawfully enter a meat and poultry facility:

1. If the product was *previously authorized* by USDA and/or included in the List of Proprietary Substances and Non-Food Compounds; or
2. The meat and poultry facility has *documentation* on hand to certify that the cleaning compound is safe and effective when used as instructed. This documentation can be in the form of a manufacturer's or supplier's letter of guaranty stating that the compound is safe when used as intended and will not have any deleterious effects on meat or poultry. Certification by a third party would also be acceptable.

*\*\*\*Note:* Although the requirements outlined in detail below apply specifically to USDA regulated meat and poultry facilities, companies are urged to adopt the same general approach when selling cleaners to all food establishments, including restaurants, grocery stores, cafeterias, and retail food outlets. As mentioned, the now-defunct USDA prior authorization program was relied upon by food related establishments that were not subject to the jurisdiction of USDA. Companies may wish to consider adopting a general marketing and sales program to be used when selling cleaners to *all* food-related facilities.

B. **Letter of Guaranty:** USDA and FSIS have recommended that manufacturers and suppliers of cleaners and sanitizers provide food establishments with a letter of guaranty attesting to the product's safety and effectiveness if the product was not previously included on the agency list of approved products (i.e.: all products introduced after the discontinuation of the prior authorization program).

1. **Format:** Please note that FSIS does not require that the letter of guaranty or other documentation adhere to any specified format or contain specific language. The Agency realizes that documentation substantiating the safety of a chemical cleaner and/or sanitizer varies with the nature and intended use of the particular chemical product.

For example, for chemical sanitizer used on food contact surfaces, the documentation should show that the product complies with the FDA regulations for sanitizing solutions set forth at 21 CFR 178.1010 and is registered with EPA, if required. For an antislip agent, the documentation requirements may be satisfied with a letter of guaranty and use instructions from the manufacturer certifying that the product will neither adulterate food nor create insanitary conditions if used in accordance with the directions.

2. **Contents:** USDA and FSIS recommend that a letter of guaranty contain the following elements:
  - a. Name and address of the product's supplier.
  - b. Brand name, code or other designation identifying the product.
  - c. Statement of safety and efficacy. Example statements include:
    - \* "Product will neither adulterate food product nor 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 the directions for use."
    - \* "Product is effective against salmonella."
  - d. Statement of compliance: This element has the most relevance for those products that must meet the requirements of other regulatory agencies such as those established by the EPA and FDA. For example, sanitizers intended for use on food contact surfaces must meet the FDA regulations set forth in 21 CFR 178.1010 as well as be registered with EPA as a pesticide, if required.
    - 1) Examples of statements of compliance for chemical sanitizers to be used on food contact surfaces include:

- \* "Product complies with the FDA requirements for sanitizers used on food contact surfaces set forth in 21 CFR 178.1010."
- \* "Product is registered with EPA pursuant to the Federal Insecticide, Fungicide and Rodenticide Act as a sanitizer for use of food-contact surfaces."

2) Relevant regulations that may be cited include:

- \* Food contact surface sanitizers: 21 CFR 178.1010
- \* Fruit and vegetable washes: 21 CFR 173.315
- \* Boiler water treatments: 21 CFR 173.310
- \* Lubricants: 21 CFR 178.3570
- \* Egg shell cleaning products: FDA Egg List
- \* Antibacterial hand soaps: FDA Tentative Monograph (1994)

e. Any or limits of use special directions relevant to meat and poultry facilities.

Example: "Before using this cleaning compound in food processing areas, food products and packaging materials must be removed from the room or carefully protected. After using such cleaning compound, all surfaces must be thoroughly rinsed with potable water."

f. Signature

3. ***Previously authorized products:*** If the product previously was included in the List of Proprietary Substances and Nonfood Compounds or if a letter of authorization was issued for the product, proof of such authorization is sufficient documentation (i.e., a copy of the authorization letter or a copy of the List will suffice).

However, products that were previously authorized may also be accompanied by a letter of guaranty that notes that the product was previously authorized and that the formula has not been altered or changed in any way. An example of an appropriate statement is:

\* "Product was authorized by USDA under the prior authorization program and its formula has not been changed

4. The letter may be attached to a specific shipment (i.e., such as when it is attached to the invoice); or it may be in the form of a continuing letter of assurance that need not accompany each shipment. New formulations and changes in labeling involving product identification or usage should be accompanied by new letters of assurance.
5. **Liability:** It is important to understand that the statements made on a letter of guaranty may potentially subject your company to substantial civil liability. If your letter of guaranty contains false or misleading statements, you can be held responsible for adverse consequences associated with the use of your product. For example, if your letter of guaranty notes that the product will not adulterate food and food *is* adulterated as a result of using your product, your company can be held liable.

C. **Allowable Marketing Claims:** In the absence of the USDA prior authorization program, many companies are concerned about what type of marketing claims they can make when selling their food establishment cleaners and sanitizers. The following lists some acceptable marketing claims and when they can be used.

1. ***Previously Authorized Products:*** Products that were previously authorized under the USDA prior authorization program are still considered "authorized" products. Therefore, it is allowable to continue to make statements such as "Authorized by USDA for use in federally inspected meat and poultry plants."
2. ***Unauthorized Products:*** An example of an allowable claim for a product that has never been authorized by USDA but which meets the guidelines previously used by USDA in conjunction with the prior authorization program is:

\* "Product was formulated in accordance with the criteria established in the *Guidelines for Obtaining Authorization of Compounds to Be Used in Meat and Poultry Plants*, Agriculture Handbook No.562."

3. ***New Private Label:*** A previously authorized formulation will now be sold by a new distributor, under a new private label for which authorization has not been specifically granted. What type of claim can be made?

Because authorization was never granted directly to the distributor, the distributor cannot claim that USDA authorizes the new private label product. However, the distributor may refer to the underlying authorized formulation if the distributor does not mind revealing the identity of the

supplier. Otherwise, the distributor is free to make other truthful marketing claims such as that contained in No. 2 above.

4. ***New Brand Name***: A previously authorized formulation will now be sold by the same supplier under a new brand name. What type of claim can be made?

The supplier cannot make a claim that USDA has authorized the new brand name product because authorization was not granted for that specific brand name product, despite the fact that the formulation is unchanged. The supplier can refer to the original, authorized product as long as the claim is worded carefully and does not suggest that the new brand name has been specifically authorized.

5. ***Miscellaneous***: Other marketing claims are permissible provided they convey truthful information about the product and they are not misleading. Examples include:

- \* "Product meets USDA performance standards for *insert type of product*."
- \* "Product complies with CFR ???"
- \* "Product is safe for use in federally inspected meat and poultry plants if used in accordance with directions."

6. ***Enforcement***: It is important to note that USDA does not oversee the marketing of products and does not have any enforcement authority. Rather, the Federal Trade Commission (FTC) has jurisdiction over marketing activities, including general label and literature claims. USDA does, however, have jurisdiction over the existence and availability of documentation, including the letter of guaranty.

The FTC will analyze all marketing claims and label statements in accordance with the agency's general principles. Basically, the FTC will be on the lookout for any statements that are false and/or misleading.

D. **Other Documents That May Be Helpful in the Marketing of Cleaners and Sanitizers to Various Food Establishments**

1. ***Guidelines for Obtaining Authorization of Compounds to Be Used in Meat and Poultry Plants***: Companies may wish to obtain a copy of this FSIS publication. These guidelines were used by USDA in conducting the prior authorization program. They provide criteria for various types of cleaning products and are of great value in developing and marketing cleaners and sanitizers for use in food related facilities.

2. ***Sanitation Performance Standards Compliance Guide:*** This publication was issued October 13, 1999 and is intended to provide guidance to meat and poultry establishments on how to comply with the FSIS final rule on Sanitation Requirements for Official Meat and Poultry Establishments (issued October 20, 1999). Among other things, this publication explicitly addresses the appropriate formulation for cleaners, sanitizers and other non-food compounds and explains how they may be used safely in food establishments. These guidelines are based on FSIS's regulatory experience, the requirements of other Federal agencies, and the criteria used by USDA in conjunction with the prior authorization program.

Although the guidelines are directed primarily to regulated meat and poultry plants, manufacturers of cleaners and sanitizers should find them useful in developing and marketing their products.

3. ***FSIS Directive on the Sanitation Standards for Meat and Poultry Establishments:*** This document is intended to provide FSIS inspectors with instruction as to how to conduct their inspections and enforce the new sanitation performance standards for meat and poultry establishments. It also provides information of value to suppliers of cleaning products who sell to such establishments. Of particular interest is Attachment IV, which specifically addressed the use of cleaning compounds in meat and poultry establishments.

**\*\*Note:** Almost all of the above referenced documents are available electronically at [www.issa.com](http://www.issa.com). Go to the Legislative & Regulatory Section and enter the "Reference Library." You will find most of the documents under the heading "Food Safety." If you do not have Internet access, please contact ISSA and we will be happy to forward the documents to you.

## V. **THIRD PARTY CERTIFICATION**

As mentioned, the required documentation can be provided by a third-party provider. Further, FSIS has encouraged third-party standards organizations and laboratories to develop systems for testing and certifying nonfood compounds and proprietary substances such as cleaners and sanitizers. According to FSIS, such certification would encourage the development and marketing of effective, safe and innovative products. Formulators of cleaners and sanitizers may find value in using the services of a credible third-party certifying organization.

The National Sanitation Foundation (NSF) has established a third-party certifying service. NSF is an independent, non-profit organization widely recognized for its scientific and technical expertise in the health and environmental services. For

over 50 years, NSF has provided third-party conformity assessment services, in addition to establishing standards and providing specialized education.

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