

DATE: **December 11, 2003**

TO: **AWT Membership**

FROM: **AWT Legislative/Regulatory Committee**

SUBJECT: **Clarification of alternatives to the discontinued USDA “White Book”**

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In an effort to keep you informed of regulatory changes which will or may affect a significant number of members, this overview is intended to clarify the discontinuance of the USDA FSIS program for listing of authorized products in the USDA “White Book”. An effort is also made to provide guidance regarding how this subject may best be handled for your company’s position in the affected marketplace.

Overview

Prior to 1999, any water treatment chemical used in a manufacturing plant *which was subject to inspection by the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS)* had to be authorized or “approved” for use by USDA and was included in a “List of Proprietary Substances and Non-Food Compounds” (the so-called “White Book”) sent out by the USDA to the FSIS local inspectors for their use.

In that year the USDA ceased publication of the “White Book” and mandated that in the future, regulated facilities (meat, poultry, pasteurized egg) under the inspection of USDA inspectors, would be responsible for insuring that the chemicals used in their facility are used and handled in a manner that does not cause the adulteration of food. For the facility, this meant that they were responsible for controlling access to chemicals to prevent accidental misuse, insure that the chemicals are used in a manner consistent with the manufacturer’s instructions, insure that empty containers are disposed of in a manner consistent with good manufacturing practices, and that the components of the chemical compounds used are not carcinogenic or poisonous under normal conditions of use and in the case where the chemicals can come in contact with food – such as steam that the products used meet the regulations spelled out in 21 CFR §173.310. The USDA FSIS did not mandate that a third party provide certification that the chemicals being used are in compliance.

In order to satisfy that the chemicals are not carcinogenic or poisonous in normal use and that they meet the regulations spelled out in 21 CFR §173.310, the food manufacturer will normally ask their supplier(s) for a letter of assurance. This documentation, substantiating compound safety and efficacy, is appropriate for all chemical compounds that are used in the areas of food processing, handling and storage and that do not otherwise require declaration on food labeling under Title 7 (part 59) and Title 9 (parts 317 and 381). This letter of assurance should contain the following:

1. Name and address of the supplier.
2. Brand name, code or other designation that uniquely identifies the compound. Identification should ensure that the specific chemical ingredients of the compound are traceable in the event of food contamination. This normally can be satisfied by providing a list of the chemical ingredients (not percentages) in the letter.
3. The letter should state that the material will be safe and effective under the intended conditions of use and will not adulterate the food product.
4. The letter should specify the applicable limits of the product to be used, feed rates of the product and how often it is to be used.

5. Signature of an official of the supplying firm.

A supplier's letter of assurance may be limited to a specific shipment, in which case it would be attached to the invoice, or it may be a continuing letter of assurance that need not accompany each shipment. New formulations, or changes in labeling involving product identification or usage should be accompanied by new letters of assurance.

As a water treatment professional you will probably be the person asked to supply a "letter of assurance". If your company does not blend or manufacture a product, the burden for this document would be placed on your blender or manufacturer. If you are a chemical blender or manufacturer, you have three options:

1. For compounds previously contained in the "White Book", a letter of assurance can be given if you have not changed the formulation or added different chemicals to the formulation and verified that none of your chemicals in the composition of the formulation have since been added to the FDA list of prohibited chemicals in 21 CFR §189. The letter of assurance can document that all of the above is true and it can reference that the product had previously been authorized by the USDA for use in the application.
2. For new chemicals, each component must be reviewed for FDA compliance using the guidelines specified in 21 CFR §170 - 189. If the formulation does meet the requirements, you may issue your own letter of assurance. This letter of assurance should document that the product has been reviewed by your technical staff for meeting the requirements put out in 21 CFR §170 – 189 and that you are providing this letter of assurance to document that the product is safe for use.
3. Lastly, you can have an independent or third party evaluation. This can be provided for a fee by NSF (National Sanitation Foundation), and possibly U/L (Underwriters Laboratories). The third party will provide you with a letter of assurance and in the case of NSF will publish a new "White Pages book", listing your product by name.

Whatever method you choose you will be in compliance with the FSIS guidelines. However, the responsibility for acceptance of your letter of assurance lies in the hands of your customer, because they are ultimately responsible for insuring the product meets the food safety guidelines.

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A more complete description of the relevant regulations is available on the AWT web site. It is likely that a variety of interpretations (particularly regarding the "letter of assurance") by local, state and federal inspectors, plant management, and other involved parties may mandate additional assurances. The recommendations here represent the best opinions of this committee but in no way should be construed as relieving each chemical manufacturer of their responsibility of familiarizing themselves with these regulations and insuring compliance with them.

We, as a committee, hope this overview aids in clarifying the changes in the USDA regulations and the alternatives for documenting to your client that your product meets the USDA FSIS guidelines. If you have any questions, we will be establishing a new

message board on the AWT “Members Only” web page – please list your questions and a member of the committee will respond. If at present you cannot logon to this section and you still have questions, call the AWT offices and talk to a member of the staff and they will pass your questions on to the committee.

Clarification of USDA White Book Discontinuance

The U.S. Department of Agriculture (USDA), Food Safety Inspection Service (FSIS), prior to October 20, 1999, issued letters of authorization for water treatment products, by specific product name, which could be used for specific purposes in facilities which were regulated by and/or inspected by the USDA FSIS. This list of authorized products was published in the USDA *List of Proprietary Substances and Nonfood Compounds*, also referred to as the USDA “White Book”. Many state inspectors also used this list of authorized products to verify that a particular product, by name, was “acceptable” for use for specific purposes.

The USDA FSIS product review and authorization program has been completely discontinued, and the food industry and federal inspectors no longer require USDA letters of authorization. The FSIS does **not** require that establishments (e.g., meat, poultry, pasteurized egg products) make available *any specific type of documentation*. FSIS will not sanction any particular organization’s certification as definitive evidence of compliance with FSIS requirements.

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*The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) inspects and regulates **meat and poultry products**. FSIS is responsible for ensuring that these products are safe, wholesome, and accurately labeled. FSIS also inspects **pasteurized egg products** (eggs that have been removed from their shells for further processing) produced in Federally inspected plants. **All other food products, other than those regulated by FSIS, fall under the regulatory authority of the Food and Drug Administration (FDA).***

[Source: Food Safety and Inspection Service; United States Department of Agriculture; Washington, D.C. 20250-3700; Frequently Asked Questions; Updated December 17, 2002... Frequently Asked Questions About Food Safety from the USDA Meat and Poultry Hotline <<http://www.fsis.usda.gov/OA/FAQ/hotlinefaq2.htm#p4>>

In theory, authorization and listing of products was only intended for and applied to federally inspected meat, poultry and pasteurized egg products facilities. In reality, this list of “authorized” products was sometimes applied, unnecessarily and sometimes incorrectly, to other food and food-related industries (i.e., milk and milk products).

Attachment 1 (Final Rule On Updated Sanitation Requirements For Meat And Poultry Establishments) provides an overview of the current USDA FSIS requirements for the meat and poultry (and pasteurized egg products) industry, as well as a summary of the reasons for the discontinuance of the USDA authorization White Book listings. It is important to understand their (USDA) *intent* in order to better understand what our possible options are, and how we, as an industry, can handle the apparent confusion and misinformation which seems to be occurring.

The USDA, to assist Federally inspected meat, poultry and pasteurized egg processors, has published a **guide** to assist in achieving the goal(s) of the USDA FSIS.

- a) Sanitation Performance Standards Compliance Guide. FSIS Web site: <<http://www.fsis.usda.gov/OPPDE/rdad/frpubs/SanitationGuide.htm>>
- b) Sanitation Performance Standards Compliance Guide; Appendix 1 (Past

Sanitation Regulations). FSIS Web site:

<http://www.fsis.usda.gov/OPPDE/rdad/frpubs/san_guide_app.htm#1>

- c) Sanitation Performance Standards Compliance Guide; Appendix 2 (Chemical Use). FSIS Web site:

<http://www.fsis.usda.gov/OPPDE/rdad/frpubs/san_guide_app.htm#2>

Appendix 2 of these performance standards is particularly relevant. The areas that apply to our business are included in *Attachment 2 (Appendix 2: Chemical Use)*. Water Treatment compounds are specifically addressed. Basically, these guidelines mirror previous rules from the now defunct USDA FSIS publication, "Guidelines for Obtaining Authorization of Compounds to Be Used in Meat and Poultry Plants".

One of the acceptable and recommended methods of meeting the new guidelines is issuance of letter of assurance to end users. There are guidelines for what this document should contain, but it is subject to interpretation... which may become our most difficult challenge. *Attachment 3 (Appendix 2: Chemical Use, Letters of Guaranty)* contains the specific text of the USDA FSIS guidelines.

An *alternative* method of documenting compound safety and efficacy (for its intended use) is to use a *third party authorization or certification program*. It should be noted that neither a letter of assurance or third party certification insures "acceptance" of a product, or its use.

As of this writing, we are aware of only two sources for third party review and authorization, NSF International and U/L (Underwriters Laboratories). Both companies are privately held, not-for-profit companies, and have essentially mirrored the discontinued USDA FSIS authorization program.

The following NSF memo can be found, in its entirety, on the NSF web site in pdf format: <http://www.nsf.org/usda/newsletter2.pdf>. **Note the March 31, 2004 date. If you intend to use NSF as a third party listing service, responding before this date could save you considerable money.** We have, as of this writing, been unable to find any specific information regarding the U/L listing program.

After December 2003, USDA-authorized products will not be included in the NSF White Book®. Starting January 1, 2004, only those formulations that have been independently reviewed and registered by NSF will be listed on the NSF website, updated daily (www.nsf.org/usda) and on the NSF White Book® CD-Rom, which is published annually. Historically, the NSF White Book® included these products to maintain continuity of the USDA list while adding new products via NSF Registration. However, due to various product changes that have occurred, USDA Food Safety Inspection Services (FSIS) is no longer accepting products solely based on their 1998 USDA approval. Manufacturers may now be asked to provide additional documentation confirming that the formulation has not changed since its approval in 1998. Alternatively, manufacturers can simply rely on NSF nonfood compound registration, which independently verifies that a formulation is appropriate for the intended end use based on the current regulations. NSF Registration is accepted and recognized worldwide.

The special discount review service for upgrading the previous USDA authorization to NSF registration will expire on March 31, 2004. This (Rollover) review service offering discounted fees is specifically designed for those products USDA listed in 1998 whose formulations have not been altered. Currently, this service involves the same complete review process for a new product (including a formulation and label check against the up-to-date NSF registration guidelines) and review feedback for re-submission. Starting April 1, 2004, all products will be reviewed under the fee schedule for a new product. Please call Kenji Yano, Program Manager, with any questions that you might have at 734.913.5738, or email at yano@nsf.org.

Summary

It is difficult to know how various inspectors and plant management will accept, in the long term, the two options available to us: Letter of Assurance, or third party evaluation and listing (NSF only, at this time). The lowest cost and most flexible method for most water treaters is to use a Letter of Assurance.

IF even one of our accounts, of any significant size or importance, decides at any time in the future that they “need” third party evaluation or listing, then it may be wise to consider using the NSF “rollover” option. There may be some savings in some cases, in using the rollover option. If a product has not changed in formulation since last published in the last USDA “White Book”, having that product listed with NSF *may* be somewhat less expensive than if you wait. After March 31, 2004, all products, whether previously listed or not, will be treated as new products. The NSF fee schedule can be found at <http://www.nsf.org/usda/nonfood_feeschedule.html>.

Additional background information, from the USDA FSIS website, is included in *Attachment 4 (Additional Background)*. This information may be valuable in helping explain this issue to your customers, prospects and employees.

Attachment 1

Final Rule On Updated Sanitation Requirements For Meat And Poultry Establishments

Source: USDA FSIS web site

<<http://www.fsis.usda.gov/OA/background/sanitation.htm>>

Published October, 1999

*Food Safety and Inspection Service
United States Department of Agriculture*

Washington, D.C. 20250-3700

Final Rule On Updated Sanitation Requirements For Meat And Poultry Establishments

SUMMARY

The U.S. Department of Agriculture's Food Safety and Inspection Service has published a final rule on updated sanitation requirements for official meat and poultry establishments. The rule converts many of the highly prescriptive sanitation requirements to performance standards and consolidates sanitary regulations applicable to both official meat and poultry establishments. The rule, published Oct. 20, 1999, in the Federal Register, takes effect on Jan. 25, 2000.

Establishments will be free to determine practices that meet sanitary requirements. FSIS will verify that the requirements are met.

Performance standards define the results to be achieved by sanitation, but not the specific means to achieve those results. Establishments have flexibility to determine what is appropriate and sufficient in maintaining sanitary conditions and preventing the adulteration of product; therefore, they can meet the sanitation performance standards in different ways. The performance standards are based on current science and are consistent with the Hazard Analysis and Critical Control Point philosophy of placing the responsibility for ensuring food safety on establishments.

If establishments are in compliance with the past sanitation requirements, they may continue their current sanitation practices and still be in compliance with the performance standards. Establishments that want to innovate may do so if they can maintain sanitary conditions and prevent the adulteration of product.

BACKGROUND

After a comprehensive review of the regulatory procedures and requirements, FSIS identified the need to revise the regulations governing official meat and poultry establishments. As a result, past regulations were redesigned to eliminate redundant, difficult to understand, outdated regulations; differences between the sanitation requirements for meat and poultry processes; and inconsistencies with HACCP systems and standard sanitation operating procedure regulations.

FSIS believes the past regulations impeded innovation and blurred the distinction between establishment and inspector responsibilities for maintaining sanitary conditions.

On Aug. 25, 1997, FSIS published in the Federal Register a proposal to revise its sanitation requirements for official meat and poultry establishments. FSIS initially solicited comments on the proposal for a 60-day period ending Oct. 24, 1997.

To clarify FSIS policy concerning nonfood compounds and proprietary substances, and to ensure that the public had many opportunities to submit comments on the sanitation proposal and its provisions concerning nonfood compounds and proprietary substances, FSIS reopened the comment period for 15 days, from Oct. 28, 1997, to Nov. 10, 1997.

REVISIONS TO THE REGULATION

FSIS revised the past regulations to remove obstacles to innovation previously caused by redundant, overly prescriptive, or obsolete sanitation regulations. Examples of revisions are described in the next few paragraphs.

Previously, implements such as knives or saws used in dressing diseased meat carcasses had to be cleansed either with 180° F water or a sanitizer approved by FSIS. This requirement limited the flexibility of establishments to use innovated means to sanitize such implements and to prevent the adulteration of product. The new performance standard requires that, "Equipment and utensils be maintained in sanitary conditions so as not to adulterate product." Establishments, therefore, have both the responsibility and the flexibility to determine the means that are most appropriate and effective within their processing environment to prevent product adulteration by dirty equipment and utensils.

The final rule also eliminates redundancy in the prior approval by FSIS of pesticides, cleaning compounds, and sanitizers, which have already been approved by federal agencies such as the Environmental Protection Agency or the Food and Drug Administration. **The new performance standard requires only that, "Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions."**

To eliminate overly prescriptive procedures and inconsistencies between the meat and poultry regulations regarding the lighting in establishments, FSIS revised the rule to make the lighting requirements the same for both meat and poultry establishments. The old regulation required poultry establishments to have 30-foot candles of light intensity on all working surfaces, while regulations for meat establishments only stated that establishments have abundant light, of good quality and well distributed. The new rule, applicable to both meat and poultry establishments, states there must be enough light of adequate quality to monitor sanitary conditions and processing operations to examine product for evidence of adulteration.

ENFORCEMENT

Through inspection, the agency will continue to ensure that companies follow safe practices and meet regulatory requirements. **Rather than telling processors how to do what they need to do, they are being told what they have to achieve—the 'how' is up to them.**

Under the new performance standards, FSIS inspection program employees continue to have the authority to take enforcement action to prevent adulterated product from entering commerce.

For More Information

- * *Technical questions: Dr. Daniel Engeljohn, Director, Regulations Development and Analysis Division, Office of Policy, Program Development, and Evaluation, (202) 720-5627*
- * *Media inquiries: (202) 720-9113*
- * *Congressional inquiries: (202) 720-3897*
- * *Constituent inquiries: (202) 720-8594*
- * *Consumer inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.*

For Further Information Contact:

FSIS Congressional and Public Affairs Staff

Phone: (202) 720-3897

Fax: (202) 720-5704

Attachment 2

Appendix 2: Chemical Use

Appendix 2: Chemical Use

General Standards

1. *Establishments are responsible for ensuring the safety and efficacy of nonfood compounds and proprietary substances.*
2. *Nonfood compounds and proprietary substances should not adulterate meat or poultry;*
 - a. *Should not create or lead to inspection interference;*
 - b. *Should not create or lead to conditions of insanitation;*
 - c. *Should be safe and effective under the conditions of use;*
 - d. *Should be identified, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.*
3. *Product labeling from suppliers should clearly provide identity of product, the address of manufacturer or supplier, and intended use.*
4. *All working and storage containers of nonfood compounds and proprietary substances should be clearly and individually identified with the product name or common name of the material.*
5. *Materials that are: known human carcinogens; mutagens or teratogens classified as hazardous substances; heavy metals; or hazardous compounds classified as extremely or super toxic, should not be allowed in the plants unless it is established that the substance will not become a component of edible product according to the levels exempted under the threshold of regulation process indicated in Title 21 CFR Section 170.39.*

Water Treatments:

Examples

- * *Formerly "G1" General potable water treatment compounds.*
- * *Formerly "G2" Phosphate potable water treatment compounds.*
- * *Formerly "G3" Silicate potable water treatment compounds.*
- * *Formerly "G4" Chlorine potable water treatment compounds.*
- * *Formerly "G5" Cooling and retort water treatment compounds.*
- * *Formerly "G6" Compounds for treating boilers, steam lines, where the steam produced may contact edible products and/ or cooling systems where the treated water may not contact edible products.*
- * *Formerly "G7" Compounds for treating boilers, steam lines, and/or cooling systems where neither the treated water nor the steam produced may contact edible products. This does not include compounds added to water used to cook and cool containers of meat and poultry products.*

Standards

1. *Boiler water treatments where the steam may contact food must be formulated in compliance with 21 CFR, Section 173.310.*
2. *Ion-exchange resins used for water purification must be formulated in compliance with 21 CFR, Section 173.25.*
3. *Additives used in water in which fruits and vegetables are washed must be formulated in compliance with CFR 21, Section 173.315 and defoamers found in 21 CFR, Section 173.340(a)(2).*
4. *Additives used in water for preflushing of animal casings must be GRAS.*
5. *Processing additives are appropriate for use provided that the quantities of these compounds are controlled, monitored and limited to the amount sufficient for the purpose of such use.*
6. *Processing additives for potable water treatments should be composed of appropriate substances which are prior sanctioned by FDA or GRAS and limited to the following:*
 - a. *In potable water, phosphate should not exceed 10 ppm, silicate should not exceed 10 ppm, and chlorine should not exceed 5 ppm.*
 - b. *In other processing applications, chlorine should not exceed 50 ppm in carcass wash and 20 ppm on trimmed or reprocessed poultry carcasses.*
7. *Compounds containing the sodium or potassium salts of nitrate, sulfite, bisulfite or metabisulfite should be decharacterized so their effect on the heme pigments in meat products is prevented. Decharacterization may be achieved by the addition of colorant to prevent mishandling or by other means such as creation of a basic environment to prevent the formation of acid species of these additives.*
8. *Additives containing nitrite, borate, and nitrate containing treatments for nonprocessing water should be colored distinctly (traditionally, blue or green) to avoid accidental misuse.*

Attachment 3

Appendix 3: Chemical Use (Letters of Guaranty)

Letters of Guaranty

Documentation substantiating compound safety and efficacy, such as letters of assurance, are appropriate for all chemical compounds that are used in the areas of food processing, handling, and storage, and that do not otherwise require declaration on food labeling under Title 7 (part 59) and title 9 (parts 317 and 381). A letter of assurance should contain the following:

- 1. Name and address of supplier.*
- 2. Brand name, code or other designation which uniquely identifies the compound. Identification should ensure that the specific chemical ingredients of the compound are traceable in the event of food contamination.*
- 3. The letter shall state that the material will be safe and effective under the intended conditions of use and will not adulterate food product.*
- 4. The letter should specify the applicable limits, if appropriate, under intended conditions of use.*
- 5. Signature of an official of the supplying firm.*

A supplier's letter of assurance may be limited to a specific shipment, in which case it would be attached to the invoice, or it may be a continuing letter of assurance that need not accompany each shipment. New formulations, or changes in labeling involving product identification or usage, should be accompanied by new letters of assurance.

For Further Information Contact:

*Food Safety and Inspection Service
Regulations and Directives Development Staff
Telephone: 202-720-5627
Fax: 202-690-0486
E-mail: FSIS.Regulations@fsis.usda.gov*

Attachment 4

Additional Background

Meat and Poultry Establishments

Excerpt from Page 56408...

On February 13, 1998, FSIS announced in a notice (FSIS Docket No. 97-007N; 63 FR 7319) that it did, in fact, intend to discontinue approving all nonfood compounds and proprietary substances prior to their use in official meat and poultry products establishments. FSIS emphasized that it would continue to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary additives and nonfood compounds. Further, FSIS also explained its plan to maintain a small staff with expertise in nonfood compounds and proprietary substances.

Excerpt from Page 56408...

The FMIA [Federal Meat Inspection Act] and PPIA [Poultry Products Inspection Act] require that meat and poultry products be neither adulterated nor misbranded through the use of proprietary substances and nonfood compounds. Meat and poultry establishments are responsible for ensuring that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately. In light of these requirements, FSIS anticipates that establishments considering purchasing and using nonfood compounds or proprietary substances will demand formulation or other information from chemical manufacturers before making purchase decisions. Manufacturers who fail to provide such information could lose their market share.

FSIS inspection program employees will continue to verify that proprietary substances and nonfood compounds do not adulterate meat and poultry products. Enforcement activities in this regard will include, but will not be limited to, direct observation of establishment operations and inspection of an establishment's premises and product, as well as sampling of product for chemical residues, as necessary, and review of establishment records. Establishments will document the use of proprietary substances and nonfood compounds in a variety of records, depending on the nature of the compound and its use. FSIS inspection program employees will review Sanitation SOP's, HACCP plans, use directions, pest control certifications, letters of guarantee, and other materials furnished to establishments by chemical manufacturers and suppliers.

In response to comments, FSIS is finalizing an additional regulatory requirement in regard to the use of nonfood compounds and proprietary substances in Sec. 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since, as stated above, documentation substantiating the safety of a chemical varies with the nature and intended uses of that chemical.

Excerpt from Page 56409...

Comment: Some commenters maintained that small establishments lack the resources

and technical expertise to determine whether chemical compounds are safe and effective and, therefore, would be adversely affected by the elimination of FSIS review and approval. Several of these commenters urged FSIS to provide guidance material to industry concerning the appropriate formulation and use of nonfood compounds and proprietary substances.

Response: FSIS does not anticipate that the elimination of its prior approval program will substantially affect small meat and poultry establishments. These establishments are or should be already aware of which chemicals have been approved by FSIS. Moreover, competition will compel chemical manufacturers to provide meat and poultry establishments of all sizes with data that establish that their compounds are safe and effective. Likewise, FSIS is making available guidelines for compliance with the sanitation performance standards that explicitly address the appropriate formulation and safe use of nonfood compounds and proprietary substances. The guidelines are based upon the FSIS's regulatory experience, the requirements of other Federal agencies, and the criteria previously used by FSIS for reviewing and approving nonfood compounds and proprietary substances. Establishments should refer to those guidelines. Furthermore, although the guidelines are directed primarily to regulated meat and poultry establishments, chemical manufacturers may find them useful in developing and marketing their products.

Comment: A few commenters, including several non-government standard-setting organizations, strongly supported third-party review and certification of nonfood compounds and proprietary substances.

Response: FSIS encourages third-party standards organizations and independent laboratories to develop systems for testing and certifying nonfood compounds and proprietary substances. Such certification would encourage the development and marketing of effective, safe, and innovative products. Chemical manufacturers whose products meet FSIS performance standards and other agency requirements will have ample incentive to publicize the fact that their products are approved by third party organizations or independent laboratories. It is not likely that FSIS will officially sanction any particular organization's certification as definitive evidence of compliance with FSIS requirements. However, FSIS would obviously give careful consideration to valid third-party certifications when questions arise regarding the safety of a nonfood compound or proprietary substance.

Excerpt from Page 56409 and 56410...

Comment: One trade association cited concerns regarding labeling and marketing claims for nonfood compounds and proprietary substances previously approved and listed by FSIS. This commenter requested that FSIS explicitly allow manufacturers of previously approved chemicals to market them as such.

Response: FSIS will neither approve nor disapprove marketing claims or labeling for the nonfood compounds and proprietary substances used in establishments. Chemical manufacturers may market or label their products as being previously approved by FSIS, as long as their claims are truthful and not misleading, as is required by applicable law. Meat and poultry establishments should keep in mind that since FSIS is discontinuing its prior approval program for these products, previous approval of a

product by FSIS does not necessarily mean that it is safer or more effective than a new product that has not been reviewed and approved.

Documentation required to be available under the regulation may cite that products were previously approved by FSIS for a particular use and that the formulation of that product has not changed. This information may facilitate decisions by FSIS program employees when reviewing documentation that substantiates the safety of a nonfood compound or proprietary substance.

Excerpt from Page 56413...

In response to comments, FSIS is finalizing a new requirement in regard to the use of nonfood compounds and proprietary substances in Sec. 416.4(c): ``Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since the specific documentation substantiating the safety of a chemical will almost certainly vary as to the nature and use of that chemical. Most, if not all, of the nonfood compounds and proprietary substances used by meat and poultry establishments already are sold with documentation substantiating their safety and efficacy. Pesticides, for example, have labels and documentation demonstrating registration with EPA; chemical sanitizers used on food contact surfaces often are accompanied by documentation, such as letters of guarantee, stating that the compound complies with the relevant FDA regulations in 21 CFR 178.1010. Therefore, FSIS has concluded that the finalized documentation requirement will place no new economic burden on the manufacturers or consumers of most of these compounds.

Excerpt from Page 56414...

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA and the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are within their jurisdiction and outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA and PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States.

This rule is not intended to have retroactive effect.

Excerpt from Page 56414 and 56415...

Finally, the Agency is adding a new information collection requirement in Sec. 416.4(c): "Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review." FSIS is not requiring that establishments make available any specific type of documentation since documentation substantiating the safety of a chemical varies as to the nature and use of that chemical. Further, most, if not all, of the nonfood compounds and proprietary

substances used by meat and poultry establishments already are sold with documentation substantiating their safety and efficacy. Nevertheless, manufacturers will be compelled to make such documentation available to their customers, if they are not doing so already. FSIS estimates that the impact of this requirement on these manufacturers will be quite minimal, since until the recent discontinuation of the FSIS prior approval program, these manufacturers had been required to supply FSIS with documentation attesting to the safety of their products.

FSIS estimates that there are approximately 8,000 chemical manufacturers selling about 115,000 compound and substances to official meat and poultry establishments. There are approximately 6,186 official meat and poultry establishments. The following calculations were based upon the assumption that each chemical manufacturer sells, and each official establishment uses, an average of 14 compounds and substances.

Estimate of Burden: The public reporting burden for this collection of

[Page 56415]

information is estimated to average 30 minutes for chemical manufacturers to provide documentation and 10 minutes for establishments to file the information.

Respondents: Meat and poultry establishments and chemical manufacturers.

Estimated Number of Respondents: 14,186.

Estimated Number of Responses per Respondent: 14.

Estimated Total Annual Burden on Respondents: 132,403 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, Cotton Annex Building, Room 109, Washington, DC 20250.