Promotion Act, as amended by the Watermelon Research and Promotion Improvement of 1993 (7 U.S.C. 4901–4916), hereinafter referred to as the Act.

Background

On February 18, 1999, AMS published in the **Federal Register** (63 FR 8014) its plan to review certain regulations, including the Plan, under the criteria contained in sec. 610 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). Because many AMS regulations impact small entities, AMS decided, as a matter of policy, to review certain regulations which, although they may not meet the threshold requirement under sec. 610 of the RFA, merit review. The February 18 notice stated that AMS would list the regulations to be reviewed in AMS' regulatory agenda which is published in the **Federal Register** as part of the Unified Agenda. However, after further consideration, AMS has decided to announce the reviews in the **Federal Register** separate from the Unified Agenda. Accordingly, this notice and request for comments is made for the review of the Plan.

The purpose of the review will be to determine whether the Plan should be continued without change, amended, or rescinded (consistent with the objectives of the Act) to minimize the impacts on small entities. In conducting this review, AMS will consider the following factors: (1) The continued need for the Plan; (2) the nature of complaints or comments received from the public concerning the Plan; (3) the complexity of the Plan; (4) the extent to which the Plan overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the Plan has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the Plan.

Written comments, views, opinions, and other information regarding the Plan's impact on small businesses are invited.

Dated: March 10, 2000.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 00–6428 Filed 3–16–00; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318, 319, 381

[Docket No. 97–036A]

Other Consumer Protection (OCP) Activities

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this advance notice of proposed rulemaking to request comments on the need and desirability of revising its approach to verifying that meat and poultry products are not misbranded, economically adulterated, or otherwise unacceptable for reasons that do not necessarily raise food safety concerns. FSIS will refer to these program activities as ''other consumer protection'' (OCP) activities. This notice defines and describes FSIS' OCP activities and discusses the Agency's need for revised regulations and verification and enforcement procedures.

DATES: Comments must be received on or before June 15, 2000.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, DOCKET #97–036A, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250–3700. FSIS has made a technical paper available in the FSIS Docket Room and on the FSIS homepage (www.fsis.usda.gov).

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Director, Regulations Development and Analysis Division, Food Safety and Inspection Service, Washington, DC 20250–3700, at (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Definition of Other Consumer Protections (OCP)

As defined in the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), meat and poultry products are economically adulterated if any valuable constituent has been omitted or abstracted; any substance has been substituted; if damage or inferiority has been concealed in any manner; or if any substance has been added so as to increase its bulk or weight, or to reduce its quality or strength, or to make it appear better or of greater value than it is. Also, as defined in these Acts, meat and poultry products are misbranded if the labeling is false or misleading, or if the product purports to be a food for which there is a regulatory standard of identity, but the product fails to comply with that standard.

FSIS conducts a range of activities to ensure that meat and poultry products are not economically adulterated, misbranded, or otherwise unacceptable for reasons that do not necessarily raise food safety considerations. Some OCP activities are based on specific regulatory requirements. These are the food labeling requirements (Parts 317 and 381, Subpart N); definitions and standards of identify and composition (Parts 319 and 381, Subpart P); and the definitions of nonconformance and the finished product standards found in section 381.76. Other OCP activities are tied to specific regulations but are designed to verify that establishments are not producing economically adulterated or misbranded product as defined by the acts.

FSIS activities directed at preventing misbranded product from reaching the consumer include label review activities, formulation verification checks, net weight checks, and laboratory food chemistry analyses. (Note: The presence of illegal drug residues is considered a food safety issue.) FSIS activities that are designed to ensure that products have not been economically adulterated by the addition or undeclared substitution of lower valued ingredients include weighing poultry carcasses to verify that water retention limits are not exceeded during immersion chilling.

FSIS recognizes that its program activities do not fit cleanly into one of two well-defined categories, OCP and food safety. For example, while most consumers would view an unidentified ingredient as a misbranding issue, those with allergy concerns would view the same unidentified ingredient as a serious food safety concern. Similarly, many FSIS activities are related to enforcement of statutory provisions declaring that product is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. This provision speaks to both food safety and OCP concerns. FSIS conducts many activities to identify and prevent from entering commerce product that is unwholesome or unfit for human food but does not present a food safety concern. Examples of FSIS activities of this type include determining conformance with carcass Acceptable Quality Levels (AQL's)(e.g.,

checking the number of hairs remaining on the hide) and conducting boneless manufacturing meat reinspection tasks.

In this ANPR, FSIS has defined OCP activities to include verification and enforcement activities that are directed to achieving objectives that do not necessarily, or primarily, involve food safety. Issues related to humane and religious exempt slaughter are not clearly OCP matters and, therefore are not addressed in this ANPR. Also, FSIS will address all issues related to egg products in future proposed rulemaking. In an effort to provide the public with more information about the Agency's current OCP activities and to illustrate the need for change, FSIS has made a technical paper available in the FSIS Docket Room (See ADDRESSES) and the FSIS homepage (www.fsis.usda.gov).

Need for Change

FSIS intends to propose change to its approach to OCP activities for three reasons. First, the Agency needs to clarify the respective roles and responsibilities of FSIS and industry. Second, the Agency needs to use the resources allocated to OCP activities more efficiently. Third, the Agency needs to be more accountable to the public on how it allocates its OCP resources and on the results that are being achieved.

The first reason for changing the Agency's approach to OCP activities is to clarify roles and responsibilities. As FSIS described in the preamble to its Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) final rule (61 FR 38806, 7/26/96), the responsibilities of FSIS and industry have become blurred. In part, this blurring has developed because some establishments rely on inspection program personnel to find deficiencies. It is more appropriate that inspected establishments take responsibility for meeting the regulatory requirements, and that FSIS personnel verify that establishments do so.

Responsibilities have also been blurred because of the excessive reliance of the FSIS inspection program on the detection and correction of problems after the fact, rather than on assurance that problems will be prevented systematically and by design in the first place.

The second reason for changing its approach to OCP activities is the need for FSIS to manage and allocate its resources more effectively and efficiently. In most cases, inspection program personnel routinely perform OCP verification activities at the same frequency in all plants. FSIS is considering that a more suitable use of inspection resources would be to base the rate of these verification checks on the compliance history of a particular establishment.

Finally, FSIS intends to change its approach to OCP activities to improve program accountability. By ''improving accountability,'' FSIS seeks to improve its measure of establishments'' compliance and its ability to inform the public about the industry's overall compliance with OCP requirements. Accountability also implies having more consistent and effective methods for making resource allocation decisions and explaining those decisions to all interested parties.

FSIS intends to develop an approach to OCP that measures compliance, targets the Agency's inspection resources, and provides program accountability.

Possible Approaches

FSIS is not contemplating a reduction in the level of attention that it pays to misbranding, economic adulteration, or wholesomeness issues. FSIS remains committed to protecting consumers from economic adulteration and improperly labeled products.

In preparing this ANPR, FSIS began with the premise that consumer protection concerns other than food safety are important to consumers, and that the public expects the Agency to provide a broad range of consumer protections that involve more than ensuring food safety.

This section outlines the changes that FSIS is evaluating and that will most likely be needed for FSIS to continue to protect consumers from economic adulteration, misbranding, and unwholesome products while enhancing food safety. These changes will likely occur in the four following areas:

1. Revision of FSIS regulations and guidance.
2. Inspected establishments taking more responsibility for producing products that comply with all OCP requirements.
3. Changes to FSIS verification activities.
4. Changes in approach to enforcement.

1. Revisions to FSIS Regulations

The change in approach to OCP activities will require that the Agency reform its regulations. Certain current regulations charge FSIS with responsibilities that more appropriately belong to the industry. For example, at the time when FSIS established the compliance monitoring system for cured pork products (9 CFR 381.19) the Agency's approach was to assume responsibility for ensuring establishments' compliance. Therefore, the system effectively became a government run quality control system. The regulations implementing the system go so far as to provide an exemption for establishments that take responsibility and institute their own quality control procedures. (Note: Published elsewhere in this issue of the **Federal Register**, FSIS is proposing to withdraw the regulations that prescribe the compliance monitoring system for cured pork products.)

FSIS will also carefully evaluate its prior label approval program and consider streamlining its label approval programs. The Agency also intends to consider what use, if any, it should continue to make of the Standards and Labeling Policy Book.

The Agency also intends to consider its role in ensuring the soundness and wholesomeness of raw products. As noted earlier, none of the product quality criteria for meat carcasses or raw meat products are published as regulations. The Agency requests comments on whether FSIS' regulations should contain quality criteria and if so, what the criteria should be.

The Agency has already initiated a review of the standards of identity and composition for meat products and poultry products. The Agency published an ANPR on September 9, 1996 (61 FR 47453). While that ANPR focused on the continuing need for the standards of identity and composition, it noted that, in light of budget constraints and the need to address higher priority food safety concerns, the Agency was examining whether any of its approaches to regulating meat products and poultry products for economic adulteration and mislabeling should be changed.

The Agency recognizes that some of its regulations are overly prescriptive in telling industry how it must comply with certain standards. For example, the Mechanically Separated (Species)(MS(S)) regulations (9 CFR 319.5) specify how many samples an establishment needs to analyze to ensure compliance. The Agency intends to institute rulemaking to revise these regulations. FSIS has tentatively concluded that the purposes for which it adopted these regulations can be achieved by the standards of composition that are already included in the regulations. The Agency also has proposed the removal of regulations that require Partial Quality Control (PQC) programs for specific production activities, such as the production of MS(s).

2. Changes to FSIS Verification Activities

FSIS is responsible for verifying that industry is complying with regulatory requirements. A verification activity can have a narrow establishment-by-establishment focus or an industry-wide scope. FSIS believes that it can operate more efficiently and effectively by making greater use of surveys.

A verification survey can involve either collecting product samples that are sent to laboratories for analysis or conducting in-plant activities such as formulation checks. Collecting product labels that are sent to a central location for review is another type of verification survey. The survey approach to verification allows the Agency to: (1) draw conclusions about overall industry compliance, (2) inform the public, i.e., improve ''accountability,'' and (3) use such industry-wide findings as inputs to subsequent resource allocation decisions.

Surveys are not, however, sufficient to verify compliance at individual establishments. The Agency intends to use surveys and other information resources to target establishments where overall compliance with OCP requirements is not satisfactory. In these establishments, FSIS could focus verification activities on specific products and specific requirements.

FSIS' approach to OCP verification has historically been to select a task or sampling frequency for a specific regulatory requirement, e.g., once per week or once per shift, and then apply that fixed frequency to all establishments where the requirement applies. To improve the effectiveness of verifying establishments' compliance with OCP requirements, FSIS needs to conduct inspection procedures and collect samples at the point in the production and distribution process where doing so is most efficient, and where taking these actions makes the most sense.

The concepts of measuring the level of compliance, or evaluating whether a particular level of compliance is acceptable or unacceptable, have not been adequately incorporated into FSIS regulatory design initiatives. FSIS must devise a more comprehensive and methodical approach to verification that would involve the sequential steps of: (1) Measuring compliance; (2) evaluating the level of compliance to determine causes of noncompliance, and whether there are feasible interventions that might be effective in improving compliance; (3) implementing interventions; and, (4) reassessing the overall level of compliance.

For example, FSIS has considered using a ''building-block'' approach to net weight compliance that has been advanced by the Codex Alimentarius Commission. This approach is modeled on a statistical limits of variance technique developed by Switzerland for application to imported, prepackaged foods. Inspection program personnel would make limited inspections for net weight compliance at retail. If the sampling technique indicates a compliance problem, additional inspection of the same product would be made at retail and, if necessary earlier in the marketing chain, such as the processing plant. If the problem continues following notification of the producers, a more precise enforcement test would be applied. This approach should lead to a more efficient and effective verification system.

Another potential innovation for verification would involve the development of an annual OCP verification plan. Annual plans would describe and assess findings from the previous year, consider the applicability of findings from ongoing research projects, and define areas of emphasis for the current year. FSIS is developing a list of factors to be considered in setting OCP priorities. These factors would include findings from consumer research and findings from analysis of consumer and industry complaints.

FSIS also believes it is practical to solicit and use input from its inspection program personnel in setting its OCP priorities.

Additionally, FSIS could use consumer research to help set its priorities for verifying the industry's OCP compliance. FSIS could use existing consumer research such as surveys compiled by trade organizations or develop its own consumer surveys to determine whether consumers are concerned about any particular OCP issues. Based on the findings, FSIS could use this information to focus its OCP verification activities. This approach would be responsive to consumer concerns.

The above examples are intended to illustrate the kinds of approaches that the Agency is considering for OCP verification. Whatever final decisions it makes, the Agency's verification activities must:

- Yield data that will allow the Agency to draw accurate conclusions about establishments' compliance.
- Permit the Agency to allocate inspection and laboratory resources to product categories that have been shown to present compliance problems, while requiring inspected establishments to maintain satisfactory control of their production processes and products.
- Provide appropriate bases for enforcement actions against establishments or companies producing and shipping economically adulterated or misbranded products.
- Accommodate any changes to the system of product standards of identity that the Agency may adopt.

3. Changes in Enforcement Approach

FSIS also needs to change its enforcement approach to repeated noncompliance with OCP requirements. FSIS will evaluate each OCP noncompliance in terms of an establishment's overall compliance record to determine whether the establishment has an effective system in place to ensure compliance with all OCP requirements and standards. For example, the Agency will not view added water noncompliance as independent from species substitution noncompliance or independent from noncompliance with fat and protein requirements.

FSIS is examining how best to communicate to establishments its findings of noncompliance and FSIS' conclusions regarding the adequacy of the establishment's control system. The role of FSIS is to verify compliance and take enforcement actions when the overall level of OCP noncompliance reaches a level that indicates that an establishment is not controlling its OCP processes effectively.

Issues for Public Comment

FSIS is soliciting comments on all aspects of its OCP activities. FSIS requests comments from all interested parties, including individuals, consumer groups, inspected establishments and industry groups, academia, importers and exporters, State and local governments, and the international community. The following questions are provided to facilitate public comment on this ANPR.

1. What level of resources should FSIS allocate to OCP program activities? What criteria should FSIS consider in allocating its resources between food safety and OCP issues?

2. What role, if any, should the Agency have in examining raw product for quality defects?

3. What priorities should FSIS give to misbranding concerns? For example, should the presence of excess sodium take priority over a misleading picture on a label?

4. Should FSIS continue testing products to determine compliance with

requirements related to fat content or water retention, or whether the product is fresh or frozen? If so, how should FSIS prioritize the sampling of products?

5. Should FSIS consider which OCP issues concern consumers? If so, how could FSIS determine this? For example, are there existing data FSIS can use or should FSIS conduct its own consumer surveys? To what extent should FSIS use information about consumers' concerns to prioritize the verification of the industry compliance with the OCP requirements?

6. How should FSIS weigh the severity of noncompliance that leads to public health concerns versus noncompliances related to OCP concerns? What sanctions or penalties are appropriate for economic adulteration? How should FSIS deal with establishments that demonstrate no deliberate intent to cheat the public but experience intermittent problems of noncompliance that result in misbranding or economic adulteration?

7. What enforcement strategy is appropriate for addressing noncompliance with OCP requirements? What portion of the Agency's enforcement resources should be allocated to OCP concerns? What levels of noncompliance with OCP requirements warrant the use of severe sanctions, such as withholding the marks of inspection?

8. The Agency believes that inspected establishments need to have systems, i.e., quality control systems, managerial systems, or administrative systems, that ensure compliance with OCP requirements. Should FSIS consider promulgating a general process control regulation, or are there alternatives to such a regulation that would still enable the Agency to effectively and efficiently verify that an establishment's control systems for OCP requirements are satisfactory?

Executive Order 12866 and Regulatory Flexibility Act

This advance notice of proposed rulemaking has been reviewed under Executive Order 12866. This rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

FSIS is seeking the data necessary to assess how the regulatory changes discussed in this document might affect various sectors of the meat and poultry industries. Therefore, the Agency invites comment on potential effects, including economic costs or benefits.

Departmental Regulation 4300–4, ''Civil Rights Impact Analysis''

Pursuant to Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' dated September 22, 1993, FSIS will conduct a civil rights impact analysis on any proposed rule that results from this ANPR. To improve the Agency's analysis, FSIS is seeking the data necessary to assess how the resulting regulatory changes discussed in this document might affect minorities, women, and persons with disabilities.

ANPR's generally are designed to provide information and receive public comments on substantive issues that may lead to new or revised agency regulations or instructions. Public involvement in all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are made aware of this ANPR and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update.

FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at *http://www.fsis.usda.gov*. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** Notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information with a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Office of Congressional and Public Affairs, at (202) 720–5704.

FSIS will use a variety of methods to reach consumers and those individuals who work directly with consumers—information multipliers—to publicize the issues identified in this OCP ANPR. FSIS will send electronic messages to electronic discussion lists that reach thousands of educators, health professionals, media, industry representatives, and consumers. FSIS will use Department mailing lists for minority media and constituent groups to send information releases that can be published in local newspapers. In addition, FSIS intends to translate briefing materials and consumer information into Spanish in order to encourage publication in non-English media that directly reach consumers.

FSIS expects to arrange for one or more public meetings to be held in large urban areas with diverse populations in order to encourage public participation by individuals not typically represented by consumer-organizations or who do not have access to electronic communication, including fax machines, internet-accessible equipment, televisions, radios, or non-English printed materials.

FSIS does not expect that this ANPR or resulting rulemaking will have an adverse effect on its own employees since the ratio of tasks performed on OCP activities will be shifted more in favor of tasks performed on food safety activities.

Done at Washington, D.C., March 13, 2000.

Thomas J. Billy,

Administrator.

[FR Doc. 00–6642 Filed 3–16–00; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318, 319, and 327

[Docket No. 97–012P]

Elimination of Requirements for the Compliance Monitoring System for Cured Pork Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the meat inspection regulations by removing the regulations that prescribe the Agency's compliance monitoring system for cured pork products. Removing these regulations will not affect the regulatory requirements that industry is responsible for meeting. The proposal will remove requirements that specify the frequency with which FSIS samples these products and the enforcement actions that the Agency will take in response to specific laboratory findings from analysis of product samples. FSIS is proposing to remove these prescriptive controls on itself because the Agency intends to institute a new approach to sampling and testing meat and poultry products to verify that the products meet regulatory requirements