

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 314, 318, 320, 325, 327, 331, 381, 416, and 417

[Docket No. 00-043N]

#### Residue Control in a HACCP Environment

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Conceptual framework for program changes; notice of availability of documents and public meeting.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is publishing this document to advise the public of its intent to adapt its approach to the control of chemical residues in or on meat and poultry products in light of the implementation of the regulations in the Agency's Pathogen Reduction-Hazard Analysis and Critical Control Point Systems (PR/HACCP) final rule. The Agency is providing an opportunity for public participation in this effort. FSIS hopes that a wide variety of interested members of the public will consider how HACCP should affect the Agency's approach to preventing illegal chemical residues in or on FSIS-regulated products and will provide comments for improving consumer protection through a well-integrated, federal farm-to-table food safety strategy. Therefore, FSIS is providing a conceptual framework that sets out issues that the Agency wants to consider during its program review and in making decisions about how it should modify its approach to the control of chemical residues. FSIS is also making relevant materials available to the public. The Agency is soliciting written comments on the issues raised in this document, including those raised in the materials it references, and is seeking comments that contain additional information or raise additional issues. The Agency will hold a public meeting to discuss the issues presented in this

document and the issues raised by the comments submitted.

**DATES:** The public meeting will be held on December 11, 2000, from 9 a.m. to 5 p.m. Members of the public who wish to provide information or raise issues for discussion at the meeting should submit written comments before December 4, 2000.

**ADDRESSES:** Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00-43N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex Building, 300 12th Street, SW, Washington, DC 20250-3700. All comments submitted and documents referred to below will be available for public inspection in the Docket Clerk's office between 8:30 a.m. and 4:30 p.m., Monday through Friday. The public meeting will be held at the Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

**FOR FURTHER INFORMATION CONTACT:** Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health and welfare of consumers by, among other things, preventing the distribution of adulterated products of livestock and poultry. Under the FMIA and the PPIA, it is illegal to sell or transport, offer for sale or transportation, or receive for transportation, in commerce, products that are capable of use as human food that are adulterated (21 U.S.C. 458(a)(2)(A) and 610(c)(1)).

Both the FMIA and the PPIA include requirements for federal inspection, and they prohibit selling or transporting, offering for sale or transportation, or receiving for transportation, in commerce, products required to be inspected unless they have been inspected and passed (21 U.S.C. 458(a)(2)(B) and 610(c)(2)). Intrastate operations and transactions are effectively subject to the same requirements and prohibitions, pursuant

to a State inspection program or the designation of the State for federal inspection (21 U.S.C. 454(c)(1) and 661(c)(1)).

FSIS laid the foundation for modernizing its system of food safety regulation in July 1996, when it issued the PR/HACCP final rule (61 FR 38806). The Agency's regulations (9 CFR chapter III) now require federally inspected establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards can occur. The amended regulations also establish an approach to food safety regulation that relies less on after-the-fact detection of problems and more on verification of the effectiveness of an establishment's process controls that are designed to ensure food safety. In particular, the regulations on HACCP systems (part 417) require that an establishment-specific hazard analysis consider food safety hazards that can occur before, during, or after entry into the establishment, and they require the implementation of a HACCP plan that, for each production process, addresses the food safety hazard or hazards that are reasonably likely to occur (§ 417.2(a)(1), (b)(1), and (c)).

Under the HACCP system regulations, a food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption (§ 417.1). The possible sources from which food safety hazards might be expected to arise specifically include chemical contamination, pesticides, and drug residues (§ 417.2(a)(3)(iii), (a)(3)(iv), and (a)(3)(v)).

The standard for determining whether a food safety hazard is reasonably likely to occur in the production process is if *either* (1) the hazard historically has occurred, *or* (2) there is a reasonable possibility that the hazard will occur in the particular type of product being produced in the absence of preventive measures to control it (§ 417.2(a)(1)). For each hazard that is reasonably likely to occur, a HACCP plan must identify the preventive measures that the establishment will apply to control the hazard. These include critical control points (CCPs), the critical limits to be met at each CCP, procedures for (and documentation of) the monitoring of CCPs, corrective actions to be followed in response to any deviation from a

critical limit at a CCP, and verification procedures (§§ 417.2(c), 417.3(a), and 417.4(a)).

A HACCP plan's CCPs are the points, steps, and procedures in a food process at which the establishment can apply control and, as a result, prevent, eliminate, or reduce to acceptable levels food safety hazards that could be introduced in the establishment and food safety hazards introduced outside the establishment (including hazards that occur before, during, and after entry into the establishment) (§§ 417.1 and 417.2(c)(2)). A plan's critical limits must be designed, at a minimum, to ensure that applicable targets or performance standards established by FSIS, and any other requirement in the Agency's regulations pertaining to the specific process or product, are met (§ 417.2(c)(3)).

FSIS phased in the applicability of part 417 requirements over a two year period, based on establishment size, beginning with large establishments (those with 500 or more employees) on January 26, 1998, and ending with very small establishments (those with fewer than 10 employees or annual sales of less than \$2.5 million) on January 25, 2000. The Agency is evaluating the results of HACCP implementation to date and is considering what further steps to take to increase the effectiveness of the HACCP approach to food safety—including steps that would better ensure the adequacy of industry members' HACCP plans and advance the ongoing transformation of the Agency's regulatory system (see "417.8). One focus of the Agency during this process will be its consideration of what approach should be taken to control chemical residues in light of the PR/HACCP final rule.

### Residue Control

FSIS-regulated products may be adulterated because they bear or contain residues of drugs, pesticides, and other chemicals used in animal production or present in the animals' environment (see 21 U.S.C. 453(g)(1), (g)(2), and (g)(3) and 601(m)(1), (m)(2), and (m)(3)). FSIS has not yet modified its regulatory requirements and program activities dealing with residues to reflect the implementation of HACCP plans at official establishments. Some companies have had difficulty understanding their responsibilities under the HACCP system regulations and integrating their residue control responsibilities with other regulatory requirements.

Since the 1960's, the public and private sectors have tried to meet the challenges presented by various types of adulteration that organoleptic

examination generally cannot detect. Residue control is a particularly appropriate candidate for an improved approach that involves a well-integrated and seamless, prevention-oriented farm-to-table strategy.

At the federal regulatory level, efforts to prevent residue-related food safety problems principally involve, in addition to FSIS, the Food and Drug Administration (FDA), acting under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 *et seq.*), and the Environmental Protection Agency (EPA), acting under the FFDCA, the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 *et seq.*), and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*). In their premarket approval programs, FDA and EPA consider what, if any, levels of drug and pesticide residues should be viewed as safe, and they evaluate potential exposure to toxic substances that may contaminate food. FDA also has federal regulatory responsibility for animal feeds and food producing animals.

At slaughter, FSIS looks for indications of illegal chemical use or exposure and collects carcass samples for residue analysis. The analytical components of the Agency's residue control activities are collectively known as the "National Residue Program" (NRP). The most recent NRP reports are the "1999 FSIS National Residue Program" and the "Domestic Residue Data Book National Residue Program 1998" (referred to informally as the "Blue Book" and the "Red Book", respectively.)

Initiated more than 30 years ago, the NRP has generally been a success. It has been instrumental in reducing the incidence of such residue violations as sulfamethazine in market hogs and in improving analytical capabilities for detecting chemical residues, including significantly increasing the number of compounds for which analyses can be performed. Additionally, FSIS has been instrumental in the development of screening tests that make more efficient use of resources and that facilitate residue detection. Other improvements include the development of sophisticated information exchange systems that aid communication both within the public sector and with interested private sector parties, and the development of collaborative educational efforts with producers that are supported by other USDA agencies. In recent years, FSIS' Animal Production Food Safety Staff has worked with States, producer groups, and others to develop and enhance producers' residue avoidance activities

and to help ensure that only nonviolative animals are presented for slaughter.

FSIS regulations directed at residue control and the Agency's implementing directives have grown more pointed during the past 30 years. In general, the regulations have become more detailed, have reflected a growing dependence on residue testing as the preferred means of control, and have increased FSIS' responsibility for this control function.<sup>1</sup> At the same time, communication and coordination among the agencies involved in residue control have improved, with multiple interagency committees and contacts.<sup>2</sup>

Despite these arrangements, more testing, and more government control, the outcome has not been optimal. Significant residue control issues have persisted. For example, certain market classes of domestic animals continue to have unacceptably high rates of residue violations.<sup>3</sup>

Discussed below is additional information about the basic design of the NRP, the relationship between residue control and HACCP, and practical considerations that need to be taken into account when reconsidering the approach to residue control. The document then discusses the resolution of a practical problem that arose during HACCP implementation that FSIS believes can serve as a first step in rethinking what ought to be the approach to residue control in a HACCP environment. Finally, other issues that FSIS believes need to be considered in order to determine what approach will best lead to optimal residue control in a HACCP environment are discussed.

FSIS hopes that a wide variety of interested members of the public will consider how developments described in this document should affect the Agency's approach to preventing illegal chemical residues in or on FSIS-regulated products and the approach to providing improved consumer protection through a well-integrated, federal farm-to-table food safety strategy. The Agency is soliciting written comments, including the submission of additional information, and it will hold a public meeting to discuss broad policy and program

<sup>2</sup> Reference 1 is a list of FSIS regulations, directives, and notices.

<sup>1</sup> Reference 2 describes the interagency infrastructure.

<sup>3</sup> NRP results indicate that, over time, the majority of residue violations have involved illegal levels of animal drugs, particularly sulfonamides and antibiotics, apparently due to the failure of producers of a relatively small percentage of livestock and poultry to follow prescribed withdrawal times—that is, to use these drugs in accordance with the FDA regulations.

concerns, including the issues raised in this document and in the comments submitted.

FSIS intends to organize the public meeting so that a number of groups that include a variety of constituents consider one or more of the issues identified in this document. The materials referenced in this document (see footnotes) are available in the Docket Clerk's office, and they also will be available at the meeting. A variety of people with knowledge and experience about the particular topics to be considered will facilitate the groups. At the end of the day, the facilitator will report to the attendees at the general meeting on the comments of the participants in each group. This information will be considered in the development of policy and program activities for residue controls.

#### *Basic Program Design*

Although NRP testing is planned and conducted using several sampling schemes, there are essentially two broad purposes for all NRP residue sampling. They are:

- (1) *Prevalence sampling*: sampling to estimate the prevalence of residues of certain chemical compounds in the tissues of specific market classes of livestock and birds after they have been inspected and passed at slaughter; and
- (2) *Verification sampling*: sampling to determine whether one or more processes to control residues have been successful.

Prevalence sampling has encompassed national, annual testing of specific market class/compound pairs of livestock and birds (e.g., market hogs/sulfonamides) to determine whether a compound is a problem in that market class of animals; regional, seasonal, or market class specific testing, often in response to suspected problems of a more limited nature; and special testing programs initiated to meet the concerns of non-USDA entities, often international groups or countries that receive meat or poultry products. Prevalence sampling programs generally occur at one of four levels: 460 samples/year; 300 samples/year; 230 samples/year; or 90 samples/year. The 300 samples/year scheme provides a 95 percent confidence level that a problem occurring in 1 percent of the market class will be detected. The assumption that a greater than 1 percent violation rate will be discovered 95 percent of the time rests on the premise that normal-appearing inspected and passed carcasses constitute a sufficiently homogeneous population that this size sample can provide a national picture.

Currently, verification sampling of domestic products occurs after there has been a violation detected in carcasses from a particular producer. Typically, in such a case, subsequent livestock from the same producer are subjected to verification sampling until findings demonstrate that the production problem has been corrected. Verification sampling can also be generated by inspector observations, either ante-mortem or post-mortem, that suggest that a violative residue may be present. Verification sampling is also done on imports. FSIS samples products shipped to the United States from countries whose inspection systems, including their residue control programs, have been determined by FSIS to be equivalent.

#### *Relationship Between Residue Control and HACCP*

The PR/HACCP final rule established various requirements for inspected facilities producing meat and poultry products. These requirements include the following: (1) That establishments develop, implement, maintain, and keep records of their standard operating procedures for sanitation (Sanitation SOPs) (part 416), (2) that slaughter establishments implement generic *E. coli* testing and record and analyze results as a means of verifying the effectiveness of their slaughter and sanitary dressing process in preventing and removing fecal contamination from carcasses (§§ 310.25(a) and 381.94(a)), and (3) that establishments develop and implement HACCP plans to prevent, eliminate, or reduce to an acceptable level the food safety hazards reasonably likely to occur in their meat and poultry product production processes (part 417).

These requirements were designed to improve the safety of meat and poultry products, thereby reducing the incidence of foodborne illness attributable to these products. These requirements also assist the Agency in meeting one of its other regulatory objectives: to separate and clarify the roles of the government inspection force and the regulated industry.

Sanitation SOP implementation was a vitally important first step in getting the inspection force out of the role of functioning as the quality control department for plants. Key features of part 417 requirements reinforced this objective: the requirement that establishments, not FSIS, conduct (or have conducted for them) a hazard analysis (§ 417.2(a)(1)), the absence of HACCP plan approval by FSIS, the lack of FSIS-specified CCPs, the requirement that establishments validate the adequacy of their HACCP plans

(§§ 417.4(a)), and the specification of consequences for incomplete corrective actions (§§ 417.2(e) and 417.6). All of these emphasize the distinctly different roles of FSIS and the establishment. These regulations underscore the companies' responsibility for producing meat and poultry products that are safe, and make clear that the Agency will hold them accountable for failing to do so.

The preamble to the PR/HACCP final rule discussed other important features of the Agency's overall food safety strategy, including regulatory reform, that provide flexibility and encourage company innovation and a farm-to-table approach that extends beyond the slaughter and processing establishments where most FSIS activities have occurred (61 FR 38810-11). FSIS is aware that the command-and-control nature of many of its regulations may discourage or impede establishments from taking full responsibility for the production of safe, complying products. In some cases, these regulations dictate to establishments exactly how something must be done; in other cases, FSIS carries out the activity itself and does not accept results from other sources. To address this problem, FSIS is converting many of its regulatory requirements into performance standards that allow an establishment to determine how it will meet a requirement, while still ensuring that appropriate requirements are in place.

FSIS is also aware that food safety problems may arise at many points along the farm-to-table continuum, not just in inspected establishments. Invisible hazards may be introduced at the production, distribution, or consumption levels. Therefore, FSIS has committed itself to working cooperatively with others concerned with food safety to encourage hazard prevention and control at every step in the process where a problem could arise.

As explained above, part 417 makes clear that violative residues present food safety hazards that may be reasonably likely to occur, and, therefore, slaughter establishments must consider the likelihood of their occurrence in developing HACCP plans. Nevertheless, some companies have found it difficult to integrate part 417 requirements with other FSIS regulations, including those that address residue control, even though § 417.2(c)(3) directly addresses the need to design critical limits to ensure that regulatory requirements are met. Part 417 also addresses FSIS activities with respect to establishments' HACCP systems and makes clear that FSIS will conduct activities to verify the

adequacy of HACCP plans, including records review, direct observation or measurement at a CCP, and sample collection and analysis (§ 417.8).

FSIS believes that it is appropriate now to rethink the current approach to residue control. On the one hand, industry must develop more effective systems of residue control. On the other, FSIS will need to shift its focus to verification testing to ensure residue requirements are met, so that only safe meat and poultry products reach the public. The Agency believes that this will result in a more effective residue control program and a more efficient use of its resources.

Full HACCP implementation gives FSIS and its constituents the opportunity to consider what approach is best to resolve problems of residue control by plants and what approach is best to accomplish effective integration of HACCP and residue control requirements.

#### *Practical Considerations*

(1) Historically, residue control programs have engendered controversies. There may be several underlying reasons, including persistent consumer concerns about the hazards they cannot see and cannot readily manage themselves. Obviously, chemical hazards in meat and poultry products cannot be managed by the individual consumer through usual techniques such as cooking or careful handling. The Food Marketing Institute (FMI) has conducted surveys of consumer attitudes and actions with regard to food safety. Even after many years of documented improvement of residue control in domestic meat and poultry products, and even with the increasing availability of data about the success of residue control, annual FMI surveys reveal that consumers continue to be concerned about residues.<sup>4</sup>

(2) Management of the hazards presented by chemical residues depends on persons with several different, but highly technical, scientific qualifications: toxicologists, chemists, epidemiologists, veterinarians, microbiologists, statisticians, and others who sometimes have not regarded open communication with the less expert public as a critical task. Additionally, in the United States and most countries, the scientists who are involved in the management of the hazards presented by chemical residues are not all employed by the same government agency and naturally develop different

perspectives and concerns. Thus, a program that encompasses the kind of coordination and communication that is included in the United States' system is necessary. Communication about that system, and public involvement in shaping it, however, can be improved.

FSIS does not contemplate changes to residue control that would significantly alter the involvement in it of different types of highly skilled professionals or the close coordination that exists among food safety agencies in regard to it. FSIS does, however, contemplate changes that would make it even clearer that inspected establishments are responsible for analyzing the hazards from chemical residues and for taking measures to control those hazards that are reasonably likely to occur.

(3) The public health hazards presented by violative residues may be underestimated by the public whose attention is currently drawn to health hazards associated with pathogens in meat and poultry products. Two possible reasons for this may be a sense of security about the effectiveness of the current residue program and the usually longer-term consequences of residue control failures when compared to the immediate consequences of failures to control pathogenic organisms.

Although there is competition for finite resources, FSIS does not contemplate changes to its residue control program that would reduce its effectiveness or its importance. In fact, FSIS expects that the environment established by full HACCP implementation should lead to more efficient and effective residue control.

(4) Residue control activities have been the subject of well-publicized international controversies. The United States is a major exporter and importer of meat and poultry products. In addition, its agricultural production systems for meat and poultry products are substantially different from those of the many countries with which it trades. Determining whether such different systems impose equivalent requirements has not been an easy task.

FSIS does not contemplate changes that would undermine the exportation of meat and poultry products, but it is likely to ask that producers and processors take more responsibility for ensuring that residue violations are prevented. If producers and processors do so, FSIS will be able to assume a true verification role, as contemplated by HACCP.

#### **Rethinking the Approach to Residue Control—Best Available Practices**

FSIS believes that efforts to solve a practical problem that arose during

HACCP implementation provide the initial steps for rethinking the approach to residue control in a HACCP environment. An establishment that slaughters principally cull dairy cows, a market class of livestock with an historically high incidence of drug residue violations, had not included any residue controls in its HACCP plan because it assumed that FSIS would continue to take the lead responsibility in this area. Findings of violative levels of drug residues in carcasses of animals slaughtered at the establishment resulted in the issuance of FSIS Noncompliance Records (NRs). (The NR, FSIS Form 5400.5-4, is the Agency's official record of noncompliance and serves as notification to an establishment of its failure to comply with one or more regulatory requirements. See FSIS Directive 5400.5.)

In response to this situation, a coalition of industry members and trade associations and other interested parties met with the Agency. They expressed a number of concerns. They were concerned about the high number of NRs issued at some establishments because of repeated violations in cull dairy cows. They also were concerned about the lack of consistency regarding the taking of screening samples for residues of certain antibiotics in similar types of establishments. They requested that the Agency clarify its instructions to its supervisory veterinary medical officers (SVMOs) regarding the taking of screening samples for residues of certain antibiotics. They also requested assistance in obtaining rapid laboratory results so that the appropriate disposition of carcasses could be determined quickly.

The coalition offered to share information that the large majority of establishments had that slaughter cull dairy cows, including the identification of suppliers of residue-violative animals, and notifications issued by a slaughtering establishment to such suppliers of a violative residue finding that might indicate that future purchases would be restricted. Coalition members suggested that, over time, such an approach might result in an actual decrease in violative residue findings in cull dairy cows.

Since the initial discussions, there have been several important developments:

—FSIS reviewed its instructions to SVMOs about the post-mortem observations that should trigger performance of a screening test for residues of certain antibiotics, and it found that there was a discrepancy between the Agency's training of

<sup>4</sup>Reference 3 is "Trends in the United States: Consumer Attitudes and the Supermarket," 2000, Food Marketing Institute.

SVMOs and the instructions they received on the job for this matter. FSIS remedied this situation by issuing a new notice that is consistent with the training given to SVMOs.<sup>5</sup> The notice is expected to result in more screening tests being performed. —FSIS determined that it could accomplish its laboratory confirmation analyses of screening positive results within a short timeframe. —FSIS has told establishments that if their HACCP plans include residue controls that constitute the best available preventive practices for slaughter establishments, if they implement those controls effectively, and if they supply FSIS with information about violators, then the Agency will not treat violative residue findings by the establishment that are followed by appropriate corrective actions as noncompliance (see § 417.3(a)).

In response to these modest shifts in the Agency's approach, several establishments are exploring what might be considered to be the best preventive practices available to slaughterers. These include:

- ensuring that all animals brought into an establishment for slaughter are identified, so that they can be traced back to the producers of them, with receiving as a CCP;
- Notifying animal producers in writing of both violative and high, but not violative, residue findings, with such notification including a discussion of the issues involved, the company's future expectations, and an indication that repeat violators will not be future suppliers;
- Exploring the possibilities for the establishment of state-certified, and possibly USDA Cooperative State Research, Education, and Extension Service-verified, voluntary residue avoidance programs comparable to those developed by major producer trade organizations, so that slaughter establishments could add to their purchase specifications a requirement that suppliers participate in such programs and supply certifications to that effect; and
- Exploring the possibilities for live animal testing, so that slaughter establishments could have a rapid, convenient verification tool.

FSIS notes that there is a considerable methods development agenda that must be accomplished before the potential for live animal testing can be fully realized, but some existing efforts may aid this process. For example, the European

Union (EU) expects testing at the producer level,<sup>6</sup> and thereby has created a demand for such methods.<sup>7</sup> In addition, there are efforts underway to facilitate the timely recognition and acceptance of test kit methods by providing independent, third-party scientific validation and accreditation of test kit performance claims.<sup>8</sup>

There may be models in Europe for other forms of public-private cooperation in residue control. In the Netherlands, there is a National Plan for Residues implemented by two ministries. Analyses for drug and pesticide residues in meat, poultry, and eggs are performed on a variety of sample types (muscle, fat, liver, kidney, and urine) taken from animals at slaughterhouses and on farms. There is also a private sector quality assurance group that provides support to producer groups that use its seal in marketing. The laboratory for the quality assurance group uses the same analytical methods as the government laboratories, and its results are considered to be equivalent to those of the government laboratories, including as a basis for action against producers of violative animals.

It is likely that additional models in use in other countries could provide concepts for the United States to consider as it reviews residue control in a HACCP environment.

#### **Residue Control in a HACCP Environment—Issues To Be Considered**

Almost fifteen years ago, the National Academy of Sciences (NAS) issued the first of several reports commissioned by FSIS that analyzed and commented upon the status and future of the nation's meat and poultry inspection system. The July 1985 report, titled "Meat and Poultry Inspection System, The Scientific Basis of the Nation's Program," paid particular attention to the NRP because it was a principal means through which chemical hazards were addressed.<sup>9</sup> The report provides a useful framework for reconsidering the management of chemical hazards because it is HACCP oriented, and because most of the elements on which it focused still appear relevant today.

The areas addressed by NAS include the 10 discussed below. They are addressed here in order to raise issues that need consideration in the course of reconsidering the Agency's approach to residue control.

#### *(1) Public Protection as the Primary Objective*

The 1985 report determined that public protection was the primary objective of the NRP, and it remains the primary objective today. One issue that needs to be considered now is what full HACCP implementation adds to the potential for public health protection against chemical hazards. The Agency believes that it explicitly adds responsibility for establishments, through the hazard analysis, to determine whether chemical contamination, pesticides, or drug residues are food safety hazards reasonably likely to occur, and if so, it adds the responsibility for the establishment to control them through the HACCP system. Industry's enhanced role in this area will enable FSIS to optimize its effectiveness by allowing it to focus upon verifying that safe and wholesome product enters commerce.

If public protection is to be the primary focus of the Agency's residue control program, a question remains as to how the Agency should respond to requests by receiving countries to test for compounds that this country's risk analysis has not determined to be of public health significance. Where additional testing is requested, current FSIS policy is to not use federal funds for it; rather, the expense is borne by the exporter. For example, meat and poultry products exported from the United States to the EU are subjected to additional residue testing for some compounds that are banned in the EU but that may be used, in accordance with FDA regulations, in the United States. They also are tested for compounds that are approved for use in both the EU and the United States, but for which the EU mandates testing and for which the current U.S. program does not conduct tests. Only product eligible for export to the EU is being sampled for these compounds, and the analyses are performed in independent laboratories at industry expense.<sup>10</sup> In light of HACCP, an issue that needs to be considered is what other possible approaches might be developed for this matter.

#### *(2) Focus on Prevention*

The July 1985 NAS report indicated that the NRP was improved, but that it was nevertheless still deficient in its focus on prevention. An issue that needs to be examined in this area is what full implementation of HACCP has added to the capacity of the government

<sup>6</sup> Reference 5 is Council Directive 96/23/EC.

<sup>7</sup> Reference 6 is a list of live animal test methods.

<sup>8</sup> Reference 7 is general information describing the AOAC Institute and its activities.

<sup>9</sup> Reference 8 is the chapter of the 1985 NAS report (Chapter 4) that addressed control of chemical hazards.

<sup>10</sup> Reference 9 is extra residue requirements for the EU.

<sup>5</sup> Reference 4 is FSIS Notice 24-00.

to enhance residue control programs' focus on prevention.

As articulated in the preamble to the PR/HACCP final rule (61 FR 38807-08), HACCP is a science-based system of process control, designed to prevent food safety problems during the processing of food rather than to detect them after they have occurred. This raises the question of what producers and processors should be doing to identify and promote the acceptance of validated preventive measures.

In 1985, NAS suggested that the NRP was handicapped by the lack of traceback capabilities as well as by the low numbers of samples for residue testing. NAS also suggested that analysis of test results needed to produce a better characterization of the hazards, rather than just an enumeration of them across market class/compound dimensions. This raises the issue of how full HACCP implementation contributes to addressing these deficiencies.

### *(3) Clear Tolerance Levels Available on All Important Substances*

In 1985, NAS identified this feature as improved, but still needing more progress. The process of setting tolerances has changed significantly since 1985. Tolerance setting is a function performed by FDA and EPA and, thus, minimally affected by FSIS program changes. Therefore, FSIS considers this issue to be minimally affected by full HACCP implementation.

### *(4) Sampling Scheme Adequate for Prevention*

In 1985, NAS was critical of the NRP's monolithic sampling strategy. NAS suggested that the strategy ought to be revised to provide for more sampling, true probability sampling, and sampling designed to adequately characterize the nature and distribution of contaminants. NAS also suggested that random sampling schemes other than simple random sampling should be considered and that substantial technical advice from experts on sample surveys should be obtained.

There are certainly alternative sampling strategies that could be used in the residue control effort. FSIS might choose to sample certain historically problematic market classes intensively to define baseline conditions; from those baseline conditions, the Agency could consider promulgating performance standards for some market class/compound combinations that have been historically troublesome. Alternatively, FSIS could propose performance standards based on historical results from its own

program.<sup>11</sup> In either case, establishments would be responsible for achieving these standards. FSIS would verify whether they were meeting the standards, and failure to meet the standards would have HACCP system consequences.

The Agency could also consider an approach that takes into account the amount of establishment sampling being done in determining the amount of FSIS testing that is appropriate. In fact, if FSIS verifies that an establishment has included residue control in its HACCP plan and is following corrective action procedures after any violative finding, with records available for Agency personnel to review, it would logically be expected that FSIS would consider limiting its residue testing.

Another alternative sampling strategy could involve adding marketbasket testing to FSIS activities and combining all FSIS results with any available test results from industry—animal producers as well as processors. Analysis of such a body of data might be possible and might provide a more comprehensive picture of residue control. Other countries may have experience with approaches that combine public and private testing.

Other issues that need to be considered here are what new approaches that combine producer, processor, and government activities into a multifaceted and more comprehensive residue control approach can and should be implemented now that HACCP has been fully implemented, and what needs to be done to accomplish this.

### *(5) Risk Assessment*

NAS recommended that risk assessment play a prominent role in each of the first four areas discussed above. FSIS experience with risk assessment in the realm of microbial hazards is somewhat limited, although growing. FSIS has completed a risk assessment for *Salmonella enteritidis* in shell eggs and egg products, and it soon will complete a risk assessment for *E. coli* O157:H7 in ground beef and a *Listeria monocytogenes* risk ranking with FDA. Some people believe that risk assessment is less difficult in the realm of chemical hazards. The interagency Surveillance Advisory Team recently completed a significant change in the way compounds are selected for analysis any given year.<sup>12</sup>

FSIS believes the following issues need to be considered in this area: How

should the Agency establish an agenda for risk assessment in the realm of controlling chemical hazards; how should the Agency allocate resources for its growing risk assessment needs; is the Animal and Plant Health Inspection Service's approach—which involves setting standards for risk assessments, and then permitting outside parties who meet those standards to perform risk assessments—useful; and what does full HACCP implementation bring in terms of these risk assessments?

### *(6) Adequate Analytical Tools and Testing Capacity*

The Agency and its partners, such as FDA, have made great strides in the development of methods for residue testing and in the capability of laboratories to conduct analyses for residues (which even in 1985 were recognized as greatly improved). However, full implementation of HACCP may bring opportunities for greater progress, because it could create new markets for high quality laboratory work or new analytical methods.

Issues that need to be considered include the following: What are the needs for laboratory capacity, and what new analytical methods are needed; should the Agency consider recognizing test results for residues from State and private laboratories that have appropriate accreditation; and how can the Agency facilitate the development of new testing methods, particularly for live animals?

### *(7) A Trained Inspection Force*

Issues that need to be considered in this area include the following: What training does the FSIS inspection force need regarding residue control in a full HACCP implementation situation; and what training do those in the regulated industries and others need regarding residue control in a full HACCP implementation situation?

### *(8) Close Links to Regulatory Enforcement*

Much has changed since 1985, including a major FSIS reorganization and implementation of the PR/HACCP final rule. An issue that needs to be considered is what opportunities do the Agency's realignment and other activities in support of full HACCP implementation create for linkage between residue control and enforcement.

FSIS intends to proceed with its regulatory reform agenda and to apply the principles that guide it to complete its agenda, which includes residue control reform. (See the Agency's advance notice of proposed rulemaking,

<sup>11</sup> Reference 10 summarizes recent FSIS data that could serve as the basis for performance standards.

<sup>12</sup> Reference 11, sections 5 and 6 of the current Blue Book, describes the new approach.

“FSIS Agenda for Change: Regulatory Review” (60 FR 67469, December 29, 1995), and Reference 1.) In this regard, issues that need to be considered include the following: What amendments to the regulations and other materials that cover residue control are needed; are additional efforts at interagency coordination regarding residue control necessary, and if so, what should they be?

FSIS has adopted the practice of supplementing its regulations with guidance material for industry. Issues that need to be considered include the following: What new or improved guidance materials are needed regarding residue control; what improvements in these materials can be made to ensure that industry members obtain the greatest benefit possible from them?

#### (9) Useful Information Systems

Implementation of HACCP has significantly modified most of the Agency's information system needs. Considering residue control alone, what are the critical information system needs in this area?

FSIS knows that EPA and FDA both need information regarding residues. The following issues need to be considered here: Who else needs information regarding residues, and who has the needed information; what are the constraints on sharing information regarding residues; how can obstacles to the sharing of information be overcome; and what resources are available for obtaining and sharing information?

#### (10) Priorities Are Set Through an Open Process

The NAS strongly suggested that an open process, readily available to a wide spectrum of constituents, be used to establish priorities for the control of chemical hazards in the meat and poultry supply. The upcoming public meeting is a first step in an effort to meet that goal. FSIS would like to know what other efforts might be useful in opening up the process.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this rule, FSIS will announce the publication of this document 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 will 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 to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

Done at Washington, DC, on November 22, 2000.

**Thomas J. Billy,**

*Administrator.*

[FR Doc. 00-30309 Filed 11-27-00; 8:45 am]

**BILLING CODE 3410-DM-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 98-NM-139-AD]

RIN 2120-AA64

#### Airworthiness Directives; Aerospatiale Model ATR42-200, -300, and -320 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the superseding of an existing airworthiness directive (AD), applicable to all Aerospatiale Model ATR42-300 and -320 series airplanes. The existing AD requires repetitive ultrasonic inspections to detect cracking of certain lugs on the main landing gear (MLG), replacement of cracked lugs with new or serviceable parts, and a follow-on inspection; and provides for an optional terminating action for the repetitive inspections. This action would remove that terminating action and require new repetitive inspections of the rubber sealant to detect shearing, and corrective action, if necessary. This action also would require new one-time visual and fluorescent penetrant inspections to detect discrepancies of certain lugs and refurbishment of the MLG barrel and swing lever assemblies, which would terminate the

requirements of this proposed AD. This action would also revise the applicability of the existing AD. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to detect and correct discrepancies of the MLG barrel lower lugs, which could result in reduced structural integrity and possible collapse of the MLG.

**DATES:** Comments must be received by December 28, 2000.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 98-NM-139-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

#### FOR FURTHER INFORMATION CONTACT:

Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; fax (425) 227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this