§§ 3575.97—3575.99 [Reserved]

§ 3575.100 OMB control number.

The report and recordkeeping requirements contained in this regulation have been approved by the Office of Management and Budget and have been assigned OMB control number 0575–0137.

Subpart B—[Reserved]

Dated: May 17, 1999.

Jill Long Thompson,

Under Secretary, Rural Development.

[FR Doc. 99–13117 Filed 5–25–99; 8:45 am]

BILLING CODE 3410–XV–U

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 416 and 417

[Docket No. 99–025N]

Listeria Monocytogenes Contamination of Ready-to-Eat Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this document to inform manufacturers of ready-to-eat livestock and poultry products of the Agency's views about the application of the hazard analysis and critical control point (HACCP) system regulations to contamination with *Listeria monocytogenes.*

FSIS believes that the findings from testing a range of ready-to-eat products and information from investigations of outbreaks of listeriosis constitute changes that could affect an establishment's hazard analysis or alter the HACCP plan for affected products. Therefore, establishments must reassess their HACCP plans for ready-to-eat livestock and poultry products. If reassessment results in a determination that *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur in the establishment's production process, then it is a type of microbiological contamination that must be addressed in a HACCP plan.

In this document, FSIS is setting out several factors that it believes an establishment should consider when performing its reassessment. Also, FSIS is making guidance material available that establishments may find helpful. (See **ADDRESSES**). FSIS invites comments on the factors addressed in this document and on its guidance material.

DATES: Comments may be submitted by July 26, 1999.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 99–025N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250–3700. All comments submitted in response to this document 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.

Guidance material is available from the Inspection Systems Development Division, FSIS, USDA, Room 202, Cotton Annex Building, 300 12th Street SW, Washington, DC 20250–3700, phone (202) 720–3219, Fax (202) 690–0824. The material is also available on the FSIS Homepage: *http://www.fsis.usda.gov/index.htm*

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

SUPPLEMENTARY INFORMATION:

Regulatory Context

The Food Safety and Inspection Service (FSIS) administers the 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 preventing the distribution of livestock and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne illness from livestock and poultry products to the maximum extent possible, FSIS issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule on July 25, 1996 (61 FR 38806). These regulations require federally inspected establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

Part 416, the regulations on Sanitation Standard Operating Procedures (SOP's), requires establishments to develop, implement, and maintain written SOP's for sanitation that describe daily procedures that are sufficient to prevent direct contamination or adulteration of products (§ 416.11 and 416.12(a)). Part 417, the regulations on HACCP systems, requires a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures an establishment can apply to control those hazards in the production of particular products (§ 417.2(a)). Whenever a hazard analysis reveals one or more such hazards, the regulations require the establishment to develop and implement a written HACCP plan, for each product, that includes specified controls for each hazard so identified (§ 417.2(b)(1) and (c)).

When FSIS issued the Pathogen Reduction-HACCP Systems final rule, it responded to questions about the link between Sanitation SOP's and HACCP plans by noting the importance of Sanitation SOP's as tools for meeting existing sanitation responsibilities and preventing direct product contamination and adulteration and their appropriateness as near-term procedures—that is, for implementation prior to HACCP implementation and, in a sense, as a prerequisite to HACCP. In response to concerns about redundancy, the Agency noted that a sanitation procedure incorporated into a validated HACCP plan need not be duplicated in the establishment's Sanitation SOP's. FSIS also anticipated that some Sanitation SOP procedures, such as those addressing pre-operational cleaning of facilities, equipment, and utensils were likely to remain in an establishment's Sanitation SOP's. (61 FR 38834.)

The HACCP system regulations require an official establishment to develop and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur in the production process ((§ 417.2(a), (b)(1), and (c)). Paragraph (a)(1) of § 417.2 specifies the purpose of a hazard analysis: ''to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards.'' Ten potential hazard areas, including microbiological contamination, are listed to guide establishments in this analysis (§ 417.2(a)(3)).

Section 417.2(a)(1) also provides that a food safety hazard is reasonably likely to occur if a prudent establishment would establish controls because the hazard historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

The likelihood that a potential food safety hazard will occur in the production process for a particular

product at a given location, and the identification and adequacy of preventive measures to control a likely hazard, must be determined by each establishment. Obviously, conditions may well change over time. For this reason, the HACCP system regulations require every establishment to reassess HACCP plan adequacy at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (§ 417.4(a)(3)). When reassessment reveals that a plan no longer meets the requirements for the contents of a HACCP plan, the establishment must modify the plan immediately (§ 417.4(a)(3)).

Listeria Monocytogenes

Listeria monocytogenes is a type of pathogenic bacteria often found in the intestines of healthy animals (including humans) and in the environments in which food producing animals are raised and processed (*e.g.*, in soil, water, and vegetation and on the surfaces of equipment, floors, and walls). Therefore, food may be contaminated with this microorganism and, after cooking or other treatment to destroy the pathogen, may be recontaminated.

Listeria monocytogenes can cause listeriosis, a serious and sometimes fatal illness, for which pregnant women, newborns, the elderly, and people with weakened immune systems are at risk. The most common manifestation of listeriosis is meningitis. It also can cause miscarriages and stillbirths. Advances in molecular subtyping methods have improved scientists' ability to associate Listeria monocytogenes with particular products and to detect outbreaks of listeriosis.

Since the late 1980's, FSIS and the Food and Drug Administration (FDA) have worked with food manufacturers to improve procedures for ensuring that ready-to-eat foods (*i.e.*, products that may be consumed without any further cooking or other preparation) are free of *Listeria monocytogenes*. In addition, for the past decade, FSIS has conducted a microbiological testing program in which the Agency samples ready-to-eat livestock and poultry products, including cooked and fermented sausages, cooked corned beef, sliced ham and luncheon meats, beef jerky, cooked uncured poultry, and salads and spreads, in federally inspected establishments. (For the Agency's current testing program instructions, see FSIS Directive 10,240.2, Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System.) FSIS treats ready-to-eat products in which *Listeria monocytogenes* is found as adulterated under the FMIA or the PPIA (21 U.S.C. 453(g) or 601(m)).

Between 1989 and 1993, the rate of illness from *Listeria monocytogenes* declined. Over the next several years, there did not appear to be any further decline, however, and since last fall, there has been an increase in the number of cases caused by a specific subtype—a previously rare ''E'' pattern—of *Listeria monocytogenes*. The Centers for Disease Control, U.S. Public Health Service, Department of Health and Human Services (DHHS), have reported 101 illnesses, 15 adult deaths and 6 stillbirths or miscarriages associated with this ''E'' pattern. Using methodological advances that provide more specific information about pathogens isolated from foods and humans, public health agencies have obtained information associating the ''E'' pattern subtype of *Listeria monocytogenes* with livestock and poultry products.

FSIS currently is evaluating a range of measures, both short- and long-term, to improve public health protection against this pathogen. In aid of this evaluation, FSIS held a public meeting on February 10, 1999, at which research, regulation, and education activities along with industry and government procedures, were discussed.

Controlling Listeria Monocytogenes Contamination

FSIS is publishing this document to advise federally inspected establishments of the Agency's current position on one aspect of the public health strategy to deal with *Listeria monocytogenes* contamination and to provide an opportunity to comment on that position as FSIS continues to develop a comprehensive strategy. FSIS is concerned because some establishments have not reassessed their HACCP plans after recent outbreaks of listeriosis caused by contaminated ready-to-eat livestock and poultry products, and after some establishments have produced ready-to-eat products adulterated with *Listeria monocytogenes*. If *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur in an establishment's production process, then it must be addressed in a HACCP plan. It would not be sufficient to claim that the hazard is adequately dealt with in the establishment's Sanitation SOP. HACCP plan reassessment is necessary to determine whether the plan appropriately addresses this hazard.

FSIS views investigations of recent outbreaks of listeriosis and findings of *Listeria monocytogenes* contamination, along with other information now available on the prevalence and persistence of this foodborne pathogen, as sufficient evidence that some establishments' present approach to the food safety hazard presented by ready-to-eat livestock food and poultry products adulterated with *Listeria monocytogenes* does not comply with part 417 requirements. Therefore, FSIS believes that § 417.4(a)(3) requires that establishments reassess the HACCP plans that cover ready-to-eat livestock and poultry products.

Put another way, the Agency does not see how—given the current record of contamination incidents and information now available on the prevalence and persistence of the microorganism, its ability to survive under adverse conditions, and the apparent susceptibility of some products to contamination—an establishment that produces a ready-to-eat product (other than one that is thermally processed-commercially sterile, in accordance with part 318, subpart G, or part 381, subpart X, of the regulations) could have confidence that, in operation, the HACCP plan for the product meets part 417 requirements.

FSIS' conclusion addresses only the need for HACCP plan reassessment. FSIS cannot predict the likelihood that an establishment producing ready-to-eat products would be required under the regulations to incorporate, or alter, controls to prevent *Listeria monocytogenes* contamination in one or more HACCP plans as a result of plan reassessment. FSIS does believe, however, that given current knowledge, *Listeria monocytogenes* contamination should be considered to be reasonably likely to occur in the production of ready-to-eat livestock and poultry products, especially if an establishment has produced products adulterated with *Listeria monocytogenes*, or if the establishment is producing one or more ready-to-eat products that are susceptible to *Listeria monocytogenes* contamination in an environment that is not known to be free of this pathogen.

FSIS urges establishments that produce ready-to-eat livestock and poultry products to perform the reassessment of their HACCP plans within 30 days of the publication of this document. FSIS will instruct its inspection personnel to verify that reassessments were conducted. If an establishment does not reassess its HACCP plan in accord with this document, FSIS will evaluate the establishment's compliance with Part 417.

Set out below are factors that FSIS believes are relevant in determining whether *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur in the production process and in identifying preventive measures that establishments can apply to control the hazard. Reassessments of HACCP plans should take these factors into account. FSIS is providing technical information and other Agency guidance material. (See ADDRESSES to obtain copies.) The Agency invites comments on this guidance material and the factors set out below.

(1) *Pathogen Levels in Starting Materials* FSIS believes that it is crucial that each establishment know the characteristics of its starting materials and, in particular, keep itself informed about evidence of *Listeria monocytogenes* contamination of the raw materials or source of raw materials that the establishments use.

(2) *Validation of Lethality Treatment* FSIS believes industry members must comply rigorously with the HACCP plan validation requirements of § 417.4(a)(1), especially in ensuring that the establishment can successfully apply a scientifically appropriate lethality treatment under its commercial operating conditions (see 61 FR 38826–38827). Until the establishment demonstrates that it achieves the anticipated lethality effect under actual in-plant conditions, effectiveness is theoretical, and the plan is not validated.

(3) *Exposure to Contamination After Lethality Treatment* The available evidence on the presence of *Listeria monocytogenes* in food processing environments appears to indicate an increased potential for the contamination of product after a food is processed to destroy pathogenic microorganisms. Therefore, an establishment's reassessment of its HACCP plans needs to address such potential contamination. Establishments should account for finished product characteristics such as water activity, pH, and the presence or absence of one or more barriers that inhibit pathogen growth. The HACCP plan must incorporate any hazards identified by the reassessment.

(4) *Evidence of Product Contamination* FSIS believes that any finding of *Listeria monocytogenes* in an establishment's ready-to-eat product, whether in government or industry test results, is substantial, and perhaps conclusive, evidence that *Listeria monocytogenes* contamination is a food safety hazard that is reasonably likely to occur in its production process for that product. Therefore, in the event of such a finding, FSIS' position is as follows. If the establishment's HACCP plan does not already provide for the control of *Listeria monocytogenes*, and absent substantial, scientifically supportable reasons, that HACCP plan must be modified to address the *Listeria monocytogenes* hazard and incorporate appropriate controls. If the establishment's HACCP plan does address and control for *Listeria monocytogenes*, the establishment must take the appropriate corrective actions in accord with the requirements of 9 CFR 417.3. FSIS inspection personnel will verify that the establishment has taken the necessary corrective actions.

Done at Washington, DC, on May 19, 1999.

Thomas J. Billy,

Administrator.

[FR Doc. 99–13223 Filed 5–25–99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–SW–47–AD; Amendment 39–11182; AD 99–11–11]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model SA–365N, N1, N2, N3, and SA–366G1 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to Eurocopter France Model SA–365N, N1 and SA–366G1 helicopters, that currently requires repetitive inspections of the main gearbox (MGB) magnetic chip plug and oil filter if certain part number/modification level MGB's are installed. This new action expands the helicopter model and MGB applicability to include the SA–365N2 and N3 helicopters and all variants of the MGB. It also requires installing a MGB planetary gear shaft (gear shaft) vibration level monitoring unit (VLMU); inserting procedures into the Rotorcraft Flight Manual (RFM) for a preflight vibration check using the VLMU and inserting a related emergency procedure and limitation for an inoperative VLMU into the RFM. This action is prompted by two occurrences of gear shaft cracks. The actions specified by this AD are intended to detect cracks in the MGB planetary gear shaft, which could lead to failure of the MGB and subsequent loss of control of the helicopter.

DATES: Effective June 10, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 10, 1999.

Comments for inclusion in the Rules Docket must be received on or before July 26, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 98–SW–47–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Shep Blackman, Aerospace Engineer, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5296, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: The FAA issued Priority Letter AD 97–15–15 on July 18, 1997, prompted by two occurrences of MGB planetary gear shaft cracks, AD 97–15–15 was published in the **Federal Register** on February 6, 1998 (63 FR 6069). It requires that the magnetic chip plug on any MGB that was not modified in accordance with MOD 077244 be inspected after every flight and the MGB oil filter be inspected after the last flight of each day or at intervals not to exceed 12 hours time-in-service (TIS). The presence of any ferrous chips or any reports of abnormal vibrations by the flight crew requires a MGB ground vibration evaluation before further flight. Eurocopter France has recently advised the FAA that the potential for planetary gear shaft cracks exists for all MGB variants, regardless of modification level, currently authorized for installation on FAA-certified Model SA–365/366 helicopters. The temporary installation of the VLMU enables the flight crew to more easily and accurately assess the vibration level of the MGB prior to each flight. The manufacturer is pursuing a redesign of the affected MGB that will probably result in a mandatory