nutrients found in a sampling of natural and process cheeses.

After the cheese alternate requirements were published in 1974, the Food and Drug Administration (FDA) added substitute and imitation products to its Food Labeling regulations (21 CFR 101.3(e)). In order for a product to be labeled a substitute, under current FDA regulations, a product must not be ''nutritionally inferior to the food for which it substitutes. * * *'' This FDA rule has many of the same requirements for cheese substitutes as the current NSLP cheese alternate requirements. As previously stated, the nutritional profile in the cheese alternate requirements was determined by averaging known nutrients found in natural and process cheeses.

Because cheese substitutes are not nutritionally inferior to the cheese for which they substitute, the Food and Consumer Service (FCS) would add cheese substitutes to the Food Buying Guide for Child Nutrition Programs (FBG), Program Aid number 1331, if this rulemaking is finalized as proposed. The FBG is the reference employed by schools and FCS to determine if meal components are reimbursable. CNP nutritional standards would not be affected as the FDA rule for substitutes is actually more specific than current FCS cheese alternate standards in that each cheese substitute must meet the specific nutritional profile of the cheese for which it is substituting. It is the intention of FCS to add cheese substitutes to the FBG with a 1:1 credit. Thus, a cheese substitute could contribute to the meal pattern in the same way as natural or process cheese currently does.

As part of the nutrition labeling regulations, FDA has updated 21 CFR 101.3(e)(4)(i), ''Identity labeling of foods in packaged form,'' to state that nutritional inferiority ''does not include a reduction in the caloric or fat content. * * *'' The FDA regulation, then, allows for a food product, even a reduced or lowfat version, to be considered a substitute for another if it is not nutritionally inferior. The cheese alternate requirements do not allow for these reductions and in fact require a cheese alternate to contain a minimum of 21% fat. This minimum fat requirement is inconsistent with FCS objectives to assist food service professionals to offer menus consistent with the ''Dietary Guidelines for Americans,'' jointly published by the Departments of Agriculture and Health and Human Services.

Two additional specifications for use of cheese alternate products as meat alternate products in NSLP would be removed by eliminating the existing FCS requirements in Appendix A to Part 210. The first is the requirement that cheese alternate products be combined with at least 50% natural or process cheese. This requirement was originally incorporated to keep the use of alternate foods limited to a maximum of 50% of the meat/meat alternate component. Under this proposed rule, cheese substitutes may be used instead of the blend of cheese and cheese alternates currently required to satisfy the meat/meat alternate component of a reimbursable meal. FCS does not believe that cheese substitutes need to be limited to 50% of the meat alternate portion of the meal, since the ''not nutritionally inferior'' requirement contained in FDA's food substitute regulation will assure that cheese substitutes are equivalent to cheese in all major nutrients found in cheese. Accordingly, in order to conform the regulations to the deletion of the cheese alternate section of Appendix A to 7 CFR Part 210, the words ''cheese alternate products'' are proposed to be deleted from 7 CFR 210.10(k)(3)(i) and 7 CFR 210.10a(d)(2)(i).

Another change that would result from the proposed deletion of the ''cheese alternate'' section is removal of the requirement that cheese alternates utilize an animal protein source. FDA's cheese substitute rule does not specify the need for a specific protein source as do the cheese alternate requirements. If the FDA rule for substitute foods is allowed to replace the cheese alternate requirements, the protein used in the production of the substitute cheese would not be limited to animal origin. There is no reason to exclude plant proteins since protein from plant sources can be as high quality as animal protein. Studies conducted subsequent to the inclusion of the animal protein requirement have shown that isolated soy protein can actually have a protein quality equal to casein, the animal protein in cheese. Allowing plant protein sources to be used will provide greater flexibility for manufacturers and will provide for a wider variety of cheese substitute products.

The proposed removal of the cheese alternate portion of Appendix A to Part 210 would eliminate FCS specifications for use of cheese alternates as meat alternates. This change would allow the use of cheese substitutes that are consistent with FDA regulations and allow for fat and calorie reductions. This change will add to the choices of products available to food service managers while reducing processors' regulatory burdens. In addition, the proposed removal of the cheese alternate requirements is consistent with the Department's ongoing efforts to promote school meals consistent with the ''Dietary Guidelines for Americans''.

List of Subjects

7 CFR Part 210

Children, Commodity School Program, Food Assistance Programs, Grants programs—social programs, National School Lunch Program, Nutrition, Reporting and recordkeeping requirements, Surplus agricultural commodities.

7 CFR Part 225

Food Assistance Programs, Grant programs—Health, Infants and Children.

For the reasons set forth in the preamble, 7 CFR parts 210 and 225 are proposed to be amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

1. The authority citation for 7 CFR part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

§ 210.10 [Amended]

2. In 210.10, the first sentence of paragraph (k)(3)(i) is amended by removing the words '', cheese alternate products,''.

3. In 210.10a, the first sentence of paragraph (d)(2)(i) is amended by removing the words ''cheese alternate products,''.

4. In Appendix A, Alternate Foods for Meals, the section entitled ''Cheese Alternate Products'' is removed.

PART 225—SUMMER FOOD SERVICE PROGRAM

1. The authority citation for 7 CFR part 225 continues to read as follows:

Authority: Secs. 9, 13 and 14, National School Lunch Act, as amended (42 U.S.C. 1758, 1761 and 1762a).

§ 225.16 [Amended]

2. In 225.16, the first sentence of paragraph (f)(3) is amended by removing the words '', cheese alternate products,''.

Dated: September 15, 1995.

Ellen Haas,

Under Secretary for Food, Nutrition, and Consumer Services.

[FR Doc. 95–23910 Filed 9–26–95; 8:45 am]

BILLING CODE 3410–30–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–NM–108–AD]

Airworthiness Directives; McDonnell Douglas Model DC–10–10, –15, and –30 Series Airplanes and Model KC–10 (Military) Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas DC–10–10, –15, and –30 series airplanes and Model KC–10A (military) airplanes. This proposal would require inspections to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, and various follow-on actions. This proposal is prompted by reports of cracks found in the upper aft mating bolt hole of the wing pylon truss fitting located near the engine forward mount on Model DC–10–30 series airplanes, which were caused by fatigue-related stress. The actions specified by the proposed AD are intended to prevent fatigue-related cracking, which could lead to failure of the fitting, separation of a portion of the engine forward mount truss from the pylon, and consequent separation of the engine from the airplane.

DATES: Comments must be received by November 6, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–108–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 McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: Maureen Moreland, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5238; fax (310) 627–5210.

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 notice 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 proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 95–NM–108–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–108–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports of four cracks found in the upper aft mating bolt hole of the wing pylon truss fitting located near the engine forward mount on Model DC–10–30 series airplanes. Three of the four cracks were found on the No. 1 pylon truss fittings; the fourth crack was found on the No. 3 pylon truss fitting. Two of these cracks emanated toward the upper surface of the inboard fitting; the other two cracks emanated toward the upper surface of the outboard fitting. This cracking occurred on airplanes that had accumulated between 66,959 and 85,067 total flight hours and between 14,538 and 19,889 total landings. The cause of such cracking has been attributed to fatigue-related stress. The effects of such fatigue-related cracking could lead to failure of the fitting and separation of a portion of the engine forward mount truss from the pylon. This condition, if not corrected, could result in separation of the engine from the airplane.

The area where the cracking was found on the Model DC–10–30 series airplanes is identical to that of Model DC–10–10, –15, and KC–10A (military) series airplanes (regardless of the configuration of the truss fittings installed in the wing pylons). Therefore, Model DC–10–10, –15, and KC–10A (military) series airplanes may be subject to the same cracking problems.

The FAA has reviewed and approved McDonnell Douglas DC–10 Service Bulletin 54–108, dated February 9, 1995, which describes procedures for performing an ultrasonic or eddy current inspection to detect cracks of the upper aft mating bolt hole of the engine pylon truss fittings. It also describes various follow-on actions to perform (i.e., repair, various inspections, replacement, coldwork), depending on the results of the inspection. For cases where no cracks are detected during inspection, the service bulletin describes procedures for either conducting repetitive inspections, or installing a preventative modification and performing follow-on ultrasonic inspections. The preventative modification entails enlarging, cold working, and installing bushings in the upper aft and middle mating bolt holes. Repair or replacement of the affected truss fittings will ensure structural integrity of the forward mount assembly of the engine.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require repetitive ultrasonic or eddy current inspections to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, and various follow-on actions. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Operators should note that, although the service bulletin specifies that the operators should contact the manufacturer for disposition of certain conditions found, this proposal would require repair of those conditions to be accomplished in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Transport Airplane Directorate.

As a result of recent communications with the Air Transport Association (ATA) of America, the FAA has learned that, in general, some operators may misunderstand the legal effect of AD's on airplanes that are identified in the applicability provision of the AD, but that have been altered or repaired in the area addressed by the AD. The FAA points out that all airplanes identified in the applicability provision of an AD are legally subject to the AD. If an airplane has been altered or repaired in the affected area in such a way as to affect compliance with the AD, the owner or operator is required to obtain FAA approval for an alternative method of compliance with the AD, in accordance with the paragraph of each AD that provides for such approvals. A note has been included in this notice to clarify this long-standing requirement.

There are approximately 376 Model DC–10–10, –15, and –30 series airplanes and Model KC–10 (military) airplanes of the affected design in the worldwide fleet. The FAA estimates that 228 airplanes of U.S. registry would be affected by this proposed AD. It would take approximately 5 work hours per airplane to accomplish the proposed inspections, at an average labor rate of $60 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $68,400, or $300 per airplane, per inspection.

The total cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

McDonnell Douglas: Docket 95–NM–108–AD.

Applicability: Model DC–10–10, –15, and –30 series airplanes and Model KC–10A (military) airplanes; as listed in McDonnell Douglas DC–10 Service Bulletin 54–108, dated February 9, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue-related cracking, which could lead to failure of the pylon truss fitting, separation of a portion of the engine forward mount truss from the pylon, and consequent separation of the engine from the airplane, accomplish the following:

(a) For Model DC–10–15, and –30 series airplanes and Model KC–10A (military) airplanes: Prior to the accumulation of 10,000 total landings on the pylon truss fitting or within 1,000 landings on the pylon truss fitting after the effective date of this AD, whichever occurs later, perform either an ultrasonic inspection or an eddy current inspection to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, in accordance with McDonnell Douglas DC–10 Service Bulletin 54–108, dated February 9, 1995.

(1) If no cracks are detected, repeat the inspections as follows:

(i) If the immediately preceding inspection was conducted using ultrasonic techniques, conduct the next inspection within 5,000 landings.

(ii) If the immediately preceding inspection was conducted using eddy current techniques, conduct the next inspection within 8,000 landings.

(2) Terminating action for the repetitive inspections required by paragraph (a)(1) of this AD is as follows:

(i) Accomplish the preventative modification in accordance with Condition 1 (bushing not installed), Option III, or Condition 2 (bushing installed), Option II, of the service bulletin, as applicable. And

(ii) Prior to the accumulation of 10,000 total landings on the pylon truss fitting following accomplishment of the modification, perform an ultrasonic inspection to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, in accordance with the service bulletin. And

(iii) Thereafter, repeat the ultrasonic inspection at intervals not to exceed 5,000 landings on the pylon truss fitting.

(3) If any crack is found in the pylon truss fitting during any inspection required by this paragraph, prior to further flight, repair it in accordance with the service bulletin. At the times specified in the service bulletin, perform follow-on actions in accordance with the service bulletin. In all cases, where the service bulletin indicates ''contact Douglas for disposition,'' the repair must be accomplished in accordance with a method approved by the Manager, Los Angeles ACO, FAA, Transport Airplane Directorate.

(b) For Model DC–10–10 series airplanes: Prior to the accumulation of 17,000 total landings on the pylon truss fitting or within 1,500 landings on the pylon truss fitting after the effective date of this AD, whichever occurs later, perform either an ultrasonic inspection or an eddy current inspection to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, in accordance with McDonnell Douglas DC–10 Service Bulletin 54–108, dated February 9, 1995.

(1) If no cracks are detected, repeat the inspections as follows:

(i) If the immediately preceding inspection was conducted using ultrasonic techniques, conduct the next inspection within 10,000 landings.

(ii) If the immediately preceding inspection was conducted using eddy current techniques, conduct the next inspection within 15,000 landings.

(2) Terminating action for the repetitive inspections required by paragraph (b)(1) of this AD is as follows:

(i) Accomplish the preventative modification in accordance with Condition 1

(bushing not installed), Option III, or Condition 2 (bushing installed), Option II, of the service bulletin, as applicable. And

(ii) Prior to the accumulation of 18,000 total landings on the pylon truss fitting following accomplishment of the modification, perform an ultrasonic inspection to detect cracks of the upper aft mating bolt hole of the wing pylon truss fittings, in accordance with the service bulletin. And

(iii) Thereafter, repeat the ultrasonic inspection at intervals not to exceed 10,000 landings on the pylon truss fitting.

(3) If any crack is found in the pylon truss fitting during any inspection required by this paragraph, prior to further flight, repair it in accordance with the service bulletin. At the times specified in the service bulletin, perform follow-on actions in accordance with the service bulletin. In all cases, where the service bulletin indicates ''contact Douglas for disposition,'' the repair must be accomplished in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles ACO, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on September 21, 1995.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–23913 Filed 9–26–95; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 95N–0295]

Prominence of Name of Distributor of Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the labeling regulations to remove the requirement that the manufacturer's name be more prominent than the distributor and to permit the names of distributors to be prominently displayed on biological product container labels, package labels, and labeling. This proposed change in the labeling requirements is intended to facilitate flexible manufacturing, packaging, distribution, and labeling arrangements, and to harmonize labeling regulations applicable to biologic products licensed under the Public Health Service Act with the corresponding labeling regulations applicable to drugs approved under the Federal Food Drug and Cosmetic Act (the act). FDA is considering further revisions to the labeling requirements.

DATES: Comments by December 26, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson or Tracey Forfa, Center for Biologics Evaluation and Research (HFM–630), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is being issued in accordance with the principles set forth in Executive Order 12866 and the steps described in President Clinton's memorandum of March 4, 1995, announcing his ''Regulatory Reinvention Initiative.'' Executive Order 12866 directs Federal agencies and the Office of Information and Regulatory Affairs to implement measures that will reform and streamline the regulatory process. President Clinton's memorandum of March 4, 1995, sets forth four steps toward regulatory reform, one of which instructs agencies to revise those regulations that are in need of reform. FDA believes that this regulation is in keeping with these principles without compromising the agency's commitment to protect the public health.

Under Executive Order 12866, FDA published a notice in the Federal Register of January 20, 1994 (59 FR 3043), announcing FDA's plan to review and evaluate all significant regulations for their effectiveness in protecting the public health, while avoiding an unnecessary regulatory burden. In the Federal Register of June 3, 1994 (59 FR 28821 and 28822), FDA published two notices announcing the review and evaluation of certain biologic and blood and blood product regulations by the Center for Biologics Evaluation and Research (CBER). The intent of the review and evaluation was to identify those regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary.

FDA held a public meeting on January 26, 1995, that was announced in the Federal Register on January 9, 1995 (60 FR 2351). The public meeting was a forum for the public to voice comments regarding the review and evaluation of regulations being undertaken by CBER.

Some of the comments from the public meeting held to discuss the CBER regulations review questioned the need for the manufacturer's name to be the most prominent name on the label. Requests were made asking that CBER consider revising the labeling regulations so that developers of innovative new products would be able to have their names on the label, even if they contract out the manufacturing of the product. The labeling regulation addressing the name of the selling agent or distributor (§ 610.64 (21 CFR 610.64)), currently requires that the name of the manufacturer of the biological product be more prominently displayed on the label than the name of the selling agent or distributor. FDA announced its intention to issue a proposed rule to revise § 610.64 in the April 1995 National Performance Review Report, ''Reinventing Regulation of Drugs and Medical Devices.'' FDA made a commitment to issue the proposed rule within 6 months of the report.

II. The Proposed Rule

The proposed rule is intended to facilitate flexible manufacturing, packaging, distribution, and labeling arrangements. FDA recognizes that small innovator firms may not have the facilities to manufacture commercial quantities of the product. Such innovator firms want the flexibility to contract out part or all of the manufacturing steps without being required to feature the product manufacturer's name more prominently on the label. In some cases manufacturers and distributors would prefer to have the option and the freedom to negotiate with each other for the prominence of the various firm names on the label.

The proposed rule is also intended to reduce the regulatory burden on manufacturers who produce both biologics and other drugs by harmonizing this labeling requirement with the labeling provisions approved