Proposed Rules

Federal Register
Vol. 63, No. 30
Friday, February 13, 1998

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 308, 318, and 381

[Docket No. 97–007N]

Notice of Policy Change; Elimination of Prior Approval for Proprietary Substances and Nonfood Compounds

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of policy change; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is revising its policy regarding Agency approval of nonfood compounds and proprietary substances prior to use in official meat and poultry establishments. The compounds and substances currently subject to prior approval include maintenance and operating chemicals (sanitizers, cleaning compounds, water treatments, lubricants, and pesticides) and proprietary food processing chemicals (branding inks, scalding agents, rendering agents, and denaturants). FSIS recently proposed to eliminate the sanitation regulations requiring prior approval of some of these compounds and substances (contained in 9 CFR Parts 308 and 381, Subpart H). FSIS now is announcing that it is eliminating the prior approval system for all-nonfood compounds and proprietary substances and specifically requests comment on alternatives to the current prior approval system.

DATES: Comments must be received on or before April 14, 1998.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket #97–007N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12 St., SW, Washington, DC 20250–3700. All comments submitted in response to this notice 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.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205–0699.

SUPPLEMENTARY INFORMATION:

Background

FSIS is planning to discontinue approving nonfood compounds and proprietary substances prior to use in official meat and poultry products establishments. Nonfood compounds are compounds used in official establishments, but which are not expected to become components of their products. Nonfood compounds subject to prior approval by FSIS include cleaning compounds, compounds for laundry use, paint removers, sanitizers, hand washing compounds, pesticides, boiler and water treatments, lubricants, solvents, and sewer and drain cleaners. Proprietary substances are used in the preparation of products. They are considered proprietary because all of their ingredients are not identified, either on the containers by common or chemical name or by some other means. Proprietary substances subject to prior approval by FSIS include: marking agents, such as branding and tattoo inks; food processing substances, such as poultry and hog scald agents and tripe denuding agents; denaturants; substances to control foaming in soups, stews, rendered fats, and curing pickle; and substances for cleaning or treating feet or other edible parts.

FSIS receives annually between 16,000 and 20,000 applications for approval of nonfood compounds and proprietary substances. It is important to note that many of these applications are requests for approval of formulation changes in or new use patterns for compounds and substances already approved for use in meat and poultry establishments. FSIS approves approximately 9,000 applications per year and rejects approximately 1,000. FSIS returns around 40 percent of the applications to applicants each year, for a variety of reasons: the application paperwork may not be complete; FSIS may request additional information, changes in chemical formulation, or revisions to the requested use patterns. FSIS annually publishes a list of the approved substances and compounds in FSIS Miscellaneous Publication No. 1419, ''*List of Proprietary Substances and Nonfood Compounds*'' (hereafter referred to as the *List*). This publication currently lists approximately 115,000 compound and substances produced by about 8,000 manufacturers.

FSIS does not test the products submitted for approval but evaluates them based on information submitted by manufacturers and other information in the Agency's files, including chemical formulations and information on proposed uses and labeling. FSIS also consults with the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Occupational Safety and Health Administration (OSHA) in regard to those Agencies' determinations concerning the safety and suitability of the compound for the requested use. Generally, FSIS consults with FDA regarding the status of the substance or compound as an FDA-approved direct or indirect food additive. Also, FSIS sometimes consults with FDA regarding nonfood compounds that have been reviewed as drugs, such as hand washing agents. FSIS generally consults with EPA concerning that Agency's review and registration of pesticides with labeling claims. FSIS may consult with OSHA if the intended use of the substance or compound raises worker health and safety concerns.

FSIS's prior approval program obviously is somewhat redundant with those of the aforementioned agencies. However, the approval of these compounds prior to their intended use provides some assurance to meat and poultry processors that use of the compounds and substances will not result in the adulteration or contamination of food products, providing they are used properly. Prior approval has also ensured that certain compounds, such as sanitizers, meet minimum standards of effectiveness when used as directed. Consequently, as an additional unintended benefit of the prior approval program, the FSIS *List* has served as a marketing tool for chemical manufacturers and distributors; inclusion in the *List* immediately renders a nonfood compound or proprietary substance more marketable to meat and poultry processors.

However, this prior approval program is inconsistent with the new food safety strategy and approach set forth in FSIS Docket No. 93–016F, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' (61 FR 38806). Under these new regulations, every official meat and poultry establishment will be required to develop and implement HACCP, a science-based process control system designed to improve the safety of meat and poultry products. Establishments will be responsible for developing and implementing HACCP plans incorporating the controls necessary and appropriate to produce safe meat and poultry products. Consequently, establishments, not FSIS, will be responsible for determining whether the nonfood compounds and proprietary substances they use are safe and effective.

By terminating the prior approval program for nonfood compounds and proprietary substances and discontinuing publication of the *List*, FSIS will be able to redirect resources to better implement inspection under the HACCP regulations. FSIS will maintain, however, a small staff with expertise in nonfood compounds and proprietary substances. That staff will keep abreast of developments in this sector of chemical manufacturing, maintain liaison with outside organizations that have an interest in the area, and issue technical guidance, particularly to small meat and poultry plants, from time to time, as circumstances dictate.

FSIS will, of course, continue to require that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary additives and nonfood compounds. Enforcement activities in this regard will include, but are not limited to: organoleptic inspection of establishment premises and product; sampling for chemical residues as necessary; review of establishment records, including sanitation standard operating procedures, HACCP plans, and the use directions, pest control certifications, and other materials furnished to establishments by chemical manufacturers and suppliers; and requests for formulation information from chemical manufacturers themselves. In light of this, FSIS anticipates that establishments considering purchasing and using nonfood compounds and proprietary substances will demand formulation and other information from chemical manufacturers as part of their decision-making in the private marketplace. Manufacturers failing to provide such information could expect to lose their market share.

FSIS already has proposed to eliminate regulatory requirements for prior approval of certain nonfood compounds and proprietary substances in FSIS Docket No. 96–037P, ''Sanitation Requirements for Official Meat and Poultry Establishments'' (62 FR 45045; August 25, 1997). In that document, the Agency has proposed to clarify and consolidate the sanitation requirements for meat and poultry establishments, eliminate unnecessary differences between those regulations, make the existing sanitation regulations more compatible with the HACCP and sanitation Standard Operating Procedures (SOP) requirements, and convert command-and-control requirements to performance standards. As part of this comprehensive revision, FSIS proposed to eliminate the sanitation regulations that require certain equipment, processes, and nonfood compounds be approved by FSIS prior to use in meat or poultry establishments (contained in 9 CFR parts 308 and 381, subpart H). Compounds and substances currently requiring prior approval under the sanitation regulations include pesticides used in meat establishments (§ 308.3 (h)); disinfectants for implements used in dressing diseased meat carcasses (§ 308.8 (b)); and germicides, insecticides, rodenticides, detergents, and wetting agents used in poultry establishments (§ 381.60).

Compliance with Executive Order 12866

This action has been reviewed for compliance with Executive Order 12866. As this action is determined to be significant for purposes of Executive Order 12866, the Office of Management and Budget has reviewed it. FSIS has estimated that the adoption of this action is likely to generate net social benefits.

Executive Order 12866 requires identification and, if possible, quantification and monetization of incremental benefits and costs of this action. FSIS has identified two types of incremental benefits in the form of avoidance of costs that are currently being incurred by chemical manufacturers/distributors and by FSIS. These benefits are discussed below.

First, the action would eliminate the requirement that the chemical manufacturers file applications and obtain approval for nonfood compounds and proprietary substances prior to use. As stated above, FSIS receives between 16,000 and 20,000 applications per year. The economic burden of requesting FSIS approval of nonfood compounds and proprietary substances includes the administrative, mailing, and labor costs associated with preparing the required Agency forms. FSIS estimates that it takes about 25 minutes to prepare each submission. Assuming an hourly earnings rate of $20–$25 for each person preparing requests for prior approval, the annual economic burden is between $150,000 and $187,000. The elimination of this burden associated with the adoption of the proposed action would, therefore, translate into an incremental benefit of $150,000 and $187,000.

Second, FSIS incurs considerable costs in processing and approval or disapproval of the products. FSIS could re-allocate these resources to better implement the new HACCP requirements. One measure of this allocative efficiency is the amount of savings in administrative costs if FSIS were to eliminate the approval/disapproval program without redirecting resources to administration of the performance-based standards. The value of this allocative efficiency could not, however, be quantified because of uncertainty and unavailability of the required data. The required budgetary data overlap with the data for other regulatory functions of FSIS.

To sum up, the value of incremental benefits of the proposed action could be monetized only partially and amounts to $150,000 to $187,000 per year.

Social Costs

The incremental benefits of the proposed action need be compared with the incremental social costs to obtain the net social benefit (if the benefits exceed the costs) or the net social cost (if the costs exceed the benefits). FSIS has identified two types of social costs. The first type of social cost is the additional marketing expense that would be incurred by the industry. Currently, the industry is not required to incur much of this expense, because, as noted earlier, inclusion of the industry's products in FSIS's *List* serves as a marketing tool. After FSIS discontinues publication of the *List*, the chemical industry might have to develop additional methods to advertise and publicize its products for marketing. These marketing expenditures would represent incremental costs to society. Ideally, these costs should be quantified and juxtaposed against the value of incremental benefits referred to above. Unfortunately, FSIS could not quantify these costs because currently the industry does not incur these costs so that the required data are not available.

The second type of cost item is the expenditure on research required to develop and test nonfood compounds and proprietary substances that are demonstrably safe and effective. FSIS anticipates, however, that the elimination of the FSIS prior approval would not significantly change these costs. Chemical manufacturers will continue to be required to demonstrate the safety and efficacy of their products to FDA, EPA, and/or OSHA, as required. Because FDA, EPA, and OSHA will review the safety and efficacy of these compounds and substances in food processing environments, FSIS assumes that chemical manufacturers will continue to conduct the same sort of research to determine whether or not their products are safe and effective.

Furthermore, FSIS expects that meat and poultry establishments will request, as a condition of purchase, that chemical manufacturers somehow certify the safety and efficacy of their products. Establishments will keep on file any information provided by chemical manufacturers (written approvals from other agencies, letters of guaranty, etc.) as part of sanitation SOP, HACCP, or other records. FSIS inspectors may ask to review such information if they have questions about the composition or use of nonfood compounds and proprietary substances. FSIS anticipates, therefore, that manufacturers will continue to conduct research on nonfood compounds and proprietary substances in order to demonstrate their safety and efficacy to meat and poultry establishments, as well as to Federal Agencies.

It is acknowledged that the chemical manufacturing and distributing industry's costs of marketing would increase, but such an increase would bring about greater economic efficiency as it would internalize their costs by elimination of the external subsidy that was provided by FSIS. The industry's cost of research and development to demonstrate safety and efficacy of nonfood compounds and proprietary substances would not decrease because the industry would be required to continue this practice to comply with similar requirements by EPA, FDA or OSHA. Therefore, the only increase in the cost would be the additional expenditures on marketing the products. Moreover, this cost increase would be voluntary on the chemical manufacturers and distributors and would not be required by the proposed action.

Conceptually, it is possible that the value of subsidy provided by FSIS by publishing the *List* is greater than the marketing cost to be incurred by the chemical manufacturers and distributors. This is because publication of the *List* increases the value of information provided to the public at large. Such a provision tends to encourage entry of newer firms into the meat and poultry industries to compete with the existing firms. The non-publication of the *List* would, therefore, reduce the value of this information and hence reduce the social benefit. In practice, we could not quantify or monetize the value of this information to the society at large because of non-availability of data.

Net Social Benefits

FSIS believes that the incremental costs of marketing would be less than the incremental benefits identified and monetized above. These benefits include the benefits to the industry in the form of savings from the expenses of avoiding the economic burden of mailing and filing the Agency forms. Furthermore, the internalization of marketing costs by the firms in the industry would bring about a more competitive industry where product prices would more accurately reflect the marginal costs of production. The current system of publishing the *List* is tantamount to subsidization of the industry by FSIS. This subsidy brings about inefficiencies in the industry. Adoption of the proposed action would remove this subsidy and bring about a more competitive and efficient industry. A competitive industry is more likely to bring about greater product innovations in the chemical industry to ensure safer meat and poultry products. Also, the transparency in the chemical industry where prices reflect marginal costs would enable the chemical industry to make more informed choices.

To sum up, FSIS believes the incremental benefits are likely to exceed the incremental costs so that there are net social benefits associated with the proposed action. Also, the distribution burden of the incremental costs and benefits is not likely to be inequitable because, while the marketing costs for chemical manufacturers and distributors would increase, these businesses would also realize the benefits of reduced costs of filing forms required for approval of their products by FSIS.

Compliance with Regulatory Flexibility Act

FSIS certifies that the proposed action will not bring about a significant economic impact on a substantial number of small entities in the chemical manufacturing and distribution industry. The costs of developing and testing their products would not increase because, as noted earlier, these firms already incur similar development and testing costs to comply with health and safety requirements of FDA, EPA, and OSHA. Furthermore, production and distribution of proprietary substances and nonfood compounds is such a small segment of total production of these firms that it is not listed separately as a 4-digit industry in the Standard Industrial Classification (SIC) Manual published by the Office of Management and Budget (1987). For example, some of the proprietary substances and nonfood compounds are grouped in SIC 2842 with over a dozen other products.

FSIS also assures that there will not be any adverse economic impact on small meat and poultry plants as a result of discontinuation of publication of the *List.* This assurance is based on two reasons. As noted earlier, the manufacturers and distributors of proprietary substances and nonfood compounds will be required to continue their research and testing of their products to comply with FDA, EPA, and OSHA requirements. Small meat and poultry plants would also rely on documentation submitted by the chemical manufacturers and distributors to these agencies for meeting of their products. Also, in the long run, competition should ensure that chemical manufacturers and distributors maintain or improve the safety and efficacy features of their products so as to preserve or increase their market shares.

There will be no adverse economic impact on small communities, cities, and municipalities because these entities are not engaged either in production or distribution of proprietary substances and nonfood compounds, or in the meat and poultry products.

Alternatives to the Proposed Action

No Action

FSIS considered continuing the current prior approval program requirements, *i.e.*, taking no action, but has decided against it because the prior approval requirements are inconsistent with HACCP, economically inefficient, and somewhat inequitable. The HACCP requirements clearly define industry's responsibility for the safety of meat and poultry products, but provide the industry with greater flexibility to innovate and to customize their processes to the nature and volume of their production. The current prior approval requirements are inconsistent with HACCP and economically inefficient because they are based on a ''command and control'' regulatory

system that often fails to provide incentives to entrepreneurs to innovate new products, processes, and technologies which can result in safer meat and poultry products. Also, as noted earlier, the incremental costs of continuing the current system are likely to exceed the incremental benefits. The existing program is inequitable because it imposes the same amount of administrative burden on small and large chemical manufacturers and distributors; the relative burden is greater on small plants because, unlike large size plants, they cannot spread the costs over a larger quantity of output.

User Fees

FSIS considered the alternative of setting up a system of user fees charged to chemical manufacturers and distributors to cover the costs of approval or disapproval of the products. FSIS did not propose this alternative for several reasons. One is that the incremental costs of setting up such a system would probably exceed the incremental benefits. The incremental costs of this alternative would include the costs of setting up an administrative system of user charges for over 100,000 proprietary substances and nonfood compounds. The user fees should recover the total costs of administration of the program. These costs cannot be identified, let alone quantified, making it virtually impossible to set up a structure of user fees.

Alternatively, the user fees could be based on the value of benefits to the firms in the industry or to society at large. This approach would require quantification of the benefits. As noted above, only a small part of the benefits to chemical manufacturers and distributors could be quantified, so that this amount would fail to cover comprehensive costs of the program.

Finally, FSIS did not propose this alternative because the Agency does not have legislative authority to levy user charges to recover the costs of such a program. Although the Agricultural Marketing Service (AMS) has authority to levy user fees, it is not responsible for ensuring the safety of meat, poultry, and egg products. The Agricultural Reorganization Act of 1994 (Public Law 103–354) consolidated food safety responsibility with respect to these products under FSIS. Therefore, AMS is unlikely to be suitable to administer a user fee-funded program with a food safety objective.

Prior Approval by Third Parties

FSIS considered the feasibility of allowing industry recognized, non-government organizations or laboratories to test and certify nonfood compounds and proprietary substances for safety and efficacy. Chemical manufacturers could voluntarily submit samples of their products to third-party organizations, or qualified independent laboratories (e.g., Underwriters Laboratories) for testing and consequent approval or disapproval. The theoretical rationale for this option is that competing firms in compliance with the standards or exceeding them would have ample incentive to publicize the fact that their product(s) are approved by third party organizations and/or independent laboratories.

However, FSIS sees several disadvantages to this alternative. First, there is the potential for conflict of interest. For example, a laboratory testing and approving nonfood compounds and proprietary substances for a particular chemical manufacturer could be testing other products for that same manufacturer; hence there could be a perception that, to maintain its business, it would readily approve the proprietary substances and nonfood compounds.

Second, the complexity of the task of approving 16,000 to 20,000 products per year would probably require numerous laboratories specializing in different substances; the economies of scale associated with a standardized testing and rating system would not be realized.

Finally, the incremental costs of the approval/disapproval process to the laboratory or organization would likely exceed the incremental benefits of revenues from the fees earned by the laboratory organization, unless the fees were set so high that they covered the total costs plus a reasonable profit. If the fees were set too high, they could drive many small and marginal manufacturers and distributors of proprietary substances and nonfood compounds out of the market. Such an outcome would render this industry less competitive.

Nevertheless, FSIS specifically requests comments on whether an industry-recognized, non-government organization or laboratory could provide prior approval or a similar service to chemical manufacturers and distributors of nonfood compounds and proprietary substances. It is possible that a centralized, technically expert, third party could play an effective role in facilitating the marketing and appropriate use of nonfood compounds and proprietary substances. Economic theory suggests that, where the primary users and beneficiaries of a Federal service are a relatively circumscribed group, that group should bear the cost of the service. Therefore, FSIS requests comments on whether prior approval should be provided by a non-government agency, what type of prior approval system that would be appropriate and feasible within a user fee system, and whether interest in obtaining such a service is sufficient to support its costs.

Conclusion

In conclusion, FSIS is eliminating its prior approval program for nonfood compounds and proprietary substances. This prior approval program is somewhat redundant with the reviews performed by other Federal agencies and inconsistent with FSIS's HACCP regulations. FSIS is requesting comment on possible alternatives to its prior approval program for nonfood compounds and proprietary substances, including the feasibility of industry-recognized, non-government organizations or laboratories providing prior approval or similar services to chemical manufacturers .

Done in Washington, DC, February 4, 1998.

Thomas J. Billy,

Administrator, Food Safety Inspection Service.

[FR Doc. 98–3725 Filed 2–12–98; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–96–AD]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company Model 172R Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Cessna Aircraft Company Model 172R airplanes. The proposed action would require modifying lower forward doorpost bulkhead by installing rivets. The proposed AD is the result of a report from the manufacturer that these rivets were erroneously omitted during manufacture of some of the new production airplanes. The actions specified by the proposed AD are intended to prevent reduced structural rigidity at the forward doorpost bulkhead, which, if not corrected, could result in structural cracking and possible loss of control of the airplane.