Proposed Rules

Federal Register
Vol. 77, No. 88
Monday, May 7, 2012

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 Part 424

[Docket No. FSIS–2011–0018]

RIN 0583–AD47

Food Ingredients and Sources of Radiation Listed and Approved for Use in the Production of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to remove sodium benzoate, sodium propionate, and benzoic acid from the list of substances that the regulations prohibit for use in meat or poultry products. Under this proposal, new uses of these substances in meat or poultry products would continue to be approved by the Food and Drug Administration (FDA) for safety and by FSIS for suitability. FSIS would add approved uses of these substances to the list of approved substances contained in the Agency's directive system.

DATES: Comments must be received by July 6, 2012.

ADDRESSES: FSIS invites interested persons to submit relevant comments on this proposed rule. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the online instructions at that site for submitting comments.
- *Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2011–0018. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Charles Williams, Acting Director, Policy Issuances Division, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–3700, (202) 690–2282.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Food Drug and Cosmetics Act (FFDCA), (21 U.S.C. 301 *et seq.*) FDA is responsible for determining the safety of ingredients and sources of irradiation used in the production of meat and poultry products, as well as prescribing safe conditions of use. 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.*), FSIS is responsible for determining the suitability of FDA-approved substances in meat and poultry products. Pursuant to a Memorandum of Understanding (MOU) that was implemented in January 2000, FDA and FSIS work together to evaluate petitions requesting the approval of new substances, or new uses of previously approved substances, for use in or on meat and poultry products. The MOU is available for viewing by the public in the FSIS docket room and on the FSIS Web site at: *http://www.fsis.usda.gov/Regulations_&_Policies/Labeling_FDA_MOU/index.asp.* If an ingredient is approved for use in meat or poultry products, FDA establishes the parameters of the approved use under its regulatory system. FSIS also lists the substance in FSIS Directive 7120.1, ''Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products,'' as part of a comprehensive listing of the substances that have been reviewed and that have been accepted as safe and suitable.

Prohibited Substances That May Conceal Damage or Inferiority—Regulatory Requirements

The regulations that prescribe requirements for the use of food ingredients and sources of radiation in meat and poultry products prohibit for use in such products substances that conceal damage or inferiority or that make the product appear better or of greater value (9 CFR 424.23(a)). Under the regulations, certain antimicrobial substances are prohibited for use in meat or poultry products because these substances have the potential to conceal damage or inferiority when used at certain levels (9 CFR 424.23(a)(3)). Among these substances are potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate. The regulations provide that these substances ''* * * may be used in or on any product, only as provided in 9 CFR Chapter III'' (9 CFR 424.23(a)(3)). Thus, while FSIS lists approved uses of other substances in its directive system, the Agency must codify any approved use of the substances listed in 9 CFR 424.23(a)(3) in the meat or poultry products inspection regulations.

Waivers of Regulatory Requirements

The meat and poultry products inspection regulations provide for the FSIS Administrator to ''* * * waive for limited periods any provisions of the regulations * * * to permit * * * experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements'' (9 CFR 303.1(h) and 381.3(b)). Under the regulations, FSIS may only grant waivers from the provisions in the regulations that are not in conflict with the purposes or provisions of the FMIA or PPIA (9 CFR 303.1(h) and 381.3(b)).

FSIS decides whether to grant requests for waivers after considering proposals and documentation submitted by establishments to demonstrate that the use of a new technology is scientifically sound; that it will facilitate definite improvements; and that issuing the waiver will not conflict with the provisions of the FMIA or PPIA, i.e., the conditions of use will not

result in an adulterated product or product labeling that misleads consumers.[1] If FSIS determines that the information submitted by an establishment supports the requested waiver, the Agency will waive the relevant provisions in the regulation for a limited period of time to allow the establishment to conduct an in-plant trial. The purpose of the in-plant trial is to gather data on the effects of the use of the new technology. FSIS reviews the data that are developed in the trial to determine whether they show that the purpose of the waiver is being met.

Petitions

On January 19, 2007, Kraft Foods Global, Inc. petitioned FSIS to amend the Federal meat and poultry products inspection regulations to permit the use of sodium benzoate and sodium propionate as acceptable antimicrobial agents that may be used in combination with other approved ingredients to inhibit the growth of *Listeria monocytogens* (*Lm*) in ready-to-eat (RTE) meat and poultry products. Kraft requested that FSIS permit the use of sodium benzoate in amounts of up to 0.1 percent (by weight of total product formulation) in combination with approved antimicrobial agents. Kraft requested that FSIS permit the use of sodium propionate in amounts up to 0.2 percent (by weight of total formulation) in combination with approved antimicrobial agents and adjuvants.

On July 26, 2010, Kemin Food Technologies petitioned FSIS to amend the regulations to permit the use of liquid sodium propionate and liquid sodium benzoate as acceptable antimicrobial agents in meat and poultry products. Kemin requested that FSIS approve the use of liquid sodium propionate to inhibit microbial growth in various meat and poultry products in amounts of up to 0.5 percent by weight of total product formulation. Kemin also requested that FSIS approve the use of liquid sodium propionate and sodium benzoate to prohibit microbial growth in various meat and poultry products in amounts of up to 0.4 percent by weight of total formulation, whereas liquid sodium benzoate will not exceed 0.1 percent of product formulation.

After receiving each petition, FSIS conducted an initial evaluation of the requested action to confirm that FDA had no objections to the safety of sodium benzoate, sodium propionate, or benzoic acid at the proposed levels of use. FSIS also considered each petition's supporting data on the suitability of these substances for use in meat and poultry products. From its initial evaluation of each petition, FSIS, in consultation with FDA, concluded that the petitioners had established the safety of sodium benzoate, sodium propionate, and benzoic acid at the proposed levels of use but that the Agency needed additional data to make a final suitability determination.

Therefore, in July 2007, FSIS issued a waiver to Kraft to conduct trials in 59 of its establishments on the use of sodium benzoate and sodium propionate, in combination with other ingredients, to control the growth of *Lm* in RTE meat and poultry products. Additionally, from September 2010 through March 2011, FSIS issued waivers to various meat and poultry products processing establishments to conduct trials on the use of antimicrobial agents containing liquid sodium propionate and propionic acid supplied by Kemin for *Lm* control in RTE meat and poultry products. FSIS granted the waivers to allow the companies to gather additional data on the suitability of these substances to support an amendment to the regulations.

As a condition of the waivers, both Kraft and Kemin were to track issues regarding consumer acceptance of products containing the substances at issue during the trial period and to identify any situations that resulted in consumer concerns about the products. The waivers also provided that both companies were to collect data to show that normal spoilage indicators are not masked in products treated with the substances, that nutrients are not adversely affected, and that product appearance (e.g., color) did not change when compared with untreated products. Another condition of the waivers was that the meat and poultry products formulated with the subject ingredients have an approved label that includes an accurate declaration of the ingredients in the appropriate order of predominance.

While operating under the waivers, both companies gathered sufficient data to support the use of sodium propionate, sodium benzoate, and benzoic acid as antimicrobial agents in RTE meat and poultry products. Accordingly, FSIS is initiating this rulemaking proposing to remove these substances from the list of substances prohibited for use in meat or poultry products. Should FSIS finalize this proposed rule, the Agency will list approved uses of these substances in FSIS Directive 7120.1. FSIS has extended the companies' regulatory waivers for the use of these substances pending the conclusion of this rulemaking.

Data on Suitability

To demonstrate that sodium benzoate, sodium propionate, and benzoic acid are suitable for their intended use as antimicrobial agents in meat and poultry products, Kraft submitted data collected from its in-plant-trials and from scientific studies that show that these substances do not conceal damage or inferiority or make products appear better or of greater value than they are under the proposed conditions of use.

Kraft submitted research findings to demonstrate that its proposed use of sodium benzoate and sodium propionate is effective in controlling the growth of *Lm* in RTE meat and poultry products. The research took into account the unique composition of diverse products, such as hot dogs, bologna, ham, and turkey breast. Kraft developed an approach to predicting the effect of antimicrobial ingredients on *Lm* growth and confirmed the findings with tests of different formulations. Kraft assessed treated products for quality, analyzed the nutritional composition of planned formulations, and considered the status of sodium benzoate and sodium propionate as generally recognized as safe (GRAS) substances under FDA requirements. Kraft's research demonstrated that differences in product composition, especially moisture, can influence antimicrobial activity and formulation needs. From its study, Kraft determined that the following formulations for the antimicrobial ingredients are effective in controlling the growth of *Lm:*

(1) A combination of 0.1 percent sodium benzoate and 0.1 percent sodium diacetate in some lower moisture products such as hot dogs;

(2) A combination of 0.1 percent sodium benzoate, 0.15 percent sodium diacetate, and 0.2 percent sodium propionate in high moisture products such as ham; and

(3) A combination of 0.1 percent sodium benzoate, 0.15 percent sodium diacetate, 0.2 percent sodium propionate, and 0.56 percent Lem-O-Fos® in turkey.

In addition, Kraft submitted three studies to address concerns about the potential use of the substances to conceal damage or mask inferiority. First, Kraft assessed whether the proposed uses of sodium benzoate and sodium propionate would affect normal indicators of spoilage. The results of two shelf life studies on the spoilage issue showed that there was very little

[1] For Agency New Technology waiver procedures, see *http://www.fsis.usda.gov/Regulations_&_Policies/New_Technologies/index.asp.*

difference in spoilage characteristics among products formulated with the antimicrobial treatments being evaluated and products formulated without antimicrobials. Second, Kraft conducted a nutritional composition test for moisture, protein, fat, ash, and sodium content. Other than a reduction in ash and an increase in moisture as lactate solids are replaced by water, the study found no differences in nutritional composition between products treated with the substances and untreated products. Finally, Kraft evaluated the efficacy and spoilage characteristics of sodium benzoate and sodium propionate in vacuum packaging or modified atmosphere packaging with nitrogen and carbon dioxide and found that the type of packaging did not have a technical effect on the efficacy and spoilage characteristics of sodium benzoate and sodium propionate. Furthermore, Kraft conducted consumer research to demonstrate that there is consumer acceptance, that normal spoilage indicators were not masked, that nutrients were not adversely affected, and that product appearance was not changed as compared to untreated product. The Kraft petition and supporting material are available for viewing by the public on the FSIS Web site at: *http://www.fsis.usda.gov/PDF/Petition_Kraft.pdf.*

In its petition, Kemin submitted data collected from in-house trials and university research that demonstrate that its proposed applications of ≤ 0.5 percent liquid sodium propionate alone or ≤ 0.4 percent for the liquid blend of sodium propionate with benzoate are effective in controlling the growth of *Lm* in cured turkey and cooked chicken breast. Kemin noted that a comparison of test results with previous studies and predictive models suggests that moisture, pH, NaCl, added nitrite, storage temperature, and perhaps meat type, are significant factors in determining the efficacy of various antimicrobials. The petition explained that validation of the most effective use rates of any antimicrobial treatments will need to be performed on a case-by-case basis to account for many variables that can affect microbial growth and efficacy in specific RTE meat and poultry products.

To show that its proposed uses of liquid sodium propionate alone or in a blend with sodium benzoate do not conceal damage or inferiority when used in meat or poultry products, Kemin conducted studies to demonstrate that the use of these substances does not affect normal spoilage indicators in RTE poultry products. The studies compared products containing Kemin's antimicrobial treatments at use rates of 0.3, 0.4, and 0.5 percent sodium propionate alone, or 0.4 percent when combined with sodium benzoate, with an untreated control or a product containing the current industry standard lactate. The studies showed that, although growth of spoilage microorganisms was significantly different in products from replicate trials, the competitive microflora did not appear to have been affected by Kemin's antimicrobial substances, and normal spoilage indicators were not disguised. In addition, Kemin submitted data to demonstrate that proposed uses of liquid sodium propionate alone or in a blend with sodium benzoate do not negatively affect color, texture and other sensory attributes, nutritional profile, or consumer acceptance when used at rates of up to 0.5 percent alone or 0.4 percent with sodium benzoate.

The Kemin petition and supporting material are available for viewing by the public on the FSIS Web site at *http://www.fsis.usda.gov/PDF/Petition_Kemin.pdf.*

Proposed Rule

FSIS has reviewed the data that Kraft and Kemin have submitted in support of their petitions and has determined that sodium benzoate, sodium propionate, and benzoic acid, under the conditions proposed in the petitions, are both safe and suitable for use as antimicrobial agents in certain RTE meat and poultry products. Therefore, FSIS is proposing to amend 9 CFR 424.23(a)(3) to remove these substances from the list of prohibited substances that may be used ''* * * in or on any product, only as provided in 9 CFR Chapter III.''

If this proposed rule is finalized, use of these substances in or on meat or poultry products will continue to be approved by FDA for safety and by FSIS for suitability. FDA will continue to establish the parameters of the approved use under its regulatory system, and FSIS will list approved uses of these substances in the table of approved substances in Directive 7120.1. The proposed amendment will make the procedures for listing approved uses of sodium propionate, benzoic acid, and sodium benzoate consistent with the procedures for listing other safe and suitable substances. This proposed rule will also expedite the listing of substances, such as sodium benzoate and sodium propionate, which enhance food safety by controlling *Lm* in RTE products.

FSIS is not proposing to remove potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate from the list of prohibited substances in 9 CFR 424.23(a)(3) because the petitions did not include data on the use of these substances in meat or poultry products. Therefore, if this proposed rule is finalized, approved new uses of potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate would continue to be listed through rulemaking. FSIS requests comments and supporting data on whether the Agency should remove any of these substances from 9 CFR 424.23(a)(3) and list their approved new uses in FSIS Directive 7120.1.

Executive Order 12866, Executive Order 13563, and Regulatory Flexibility Act

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been determined to be not significant and therefore has not been reviewed by the Office of Management and Budget (OMB) under EO 12866.

This proposed rule would eliminate the need for FSIS to conduct rulemakings each time that the use of certain substances identified in § 424.23(a)(3), i.e., sodium propionate, sodium benzoate, and benzoic acid, is found to be safe by FDA and suitable by FSIS for use in the production of meat and poultry products at specified levels. This proposed rule would benefit companies that want to use these substances in the production of meat and poultry products by expediting the approval process. It would also benefit consumers by expediting the approved use of substances that enhance food safety by controlling the growth of *Lm* in RTE meat and poultry products. This proposed rule would make the approval process for new uses of sodium propionate, sodium benzoate, and benzoic acid in meat and poultry products consistent with the process for obtaining approval for other safe and suitable substances.

There are no expected costs associated with this proposed rule. All substances intended for use in the production of meat and poultry

products will continue to be subject to FDA evaluation for safety and FSIS evaluation for suitability. Company costs and the agencies' costs associated with these evaluations will not be affected by this proposed rule should it become final. The only change would be the process for listing the substances specified in this proposal after they have been approved.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the FSIS Administrator has made a preliminary determination that this proposed rule will not have a significant impact on a substantial number of small entities. This determination is based primarily on the fact that the proposed rule would not affect the process for approving new uses of sodium benzoate, sodium propionate, and benzoic acid in meat or poultry products. This proposed rule would make the process of listing approved uses of these substances more efficient by eliminating the need for FSIS to conduct rulemaking each time a new use is approved.

Paperwork Reduction Act

This rule does not contain any new information collection or record keeping requirements that are subject to the Office of Management and Budget (OMB) approval under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule: (1) Has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.300 through 590.370, respectively, must be exhausted before any judicial challenge may be made of the application of the provisions of the proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA, PPIA, or EPIA.

Additional Public Notification

FSIS will announce the availability of this proposed rule on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Proposed_Rules/index.asp.*

FSIS also will make copies of this **Federal Register** publication available through the *FSIS Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Update* is communicated via Listserv, a free email subscription service for industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The *Update* also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/.* Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password-protect their accounts.

List of Subjects in 9 CFR Part 424

Food additives, Food packaging, Meat inspection, Poultry and poultry products.

For the reasons set forth in the preamble, FSIS proposes to amend 9 CFR part 424 as follows:

PART 424—PREPARATION AND PROCESSING OPERATIONS

1. The authority citation for part 424 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

2. Revise § 424.23(a)(3) as follows:

§ 424.23 Prohibited uses.

* * * * *

(a) * * *

(3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate, may be used in or on any product, only as provided in 9 CFR chapter III.

* * * * *

Done at Washington, DC, on May 1, 2012.

Alfred V. Almanza,

Administrator.

[FR Doc. 2012–10871 Filed 5–4–12; 8:45 am]

BILLING CODE 3410–DM–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 49

RIN 3038–AD83

Swap Data Repositories: Interpretative Statement Regarding the Confidentiality and Indemnification Provisions of Section 21(d) of the Commodity Exchange Act

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed interpretative statement.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is proposing this interpretative statement to provide guidance regarding the applicability of the confidentiality and indemnification provisions set forth in new section 21(d) of the Commodity Exchange Act (''CEA'') added by section 728 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The Commission requests comment on all aspects of the proposed interpretative statement. The proposed interpretative statement clarifies that the provisions of section 21(d) should not operate to inhibit or prevent foreign regulatory authorities from accessing data in which they have an independent and sufficient regulatory interest, even if that data also has been reported pursuant to the CEA and Commission regulations.

DATES: Comments must be received on or before June 6, 2012.

ADDRESSES: Comments, identified by RIN number 3038–AD83, may be sent by any of the following methods:

- *Agency Web site, via its Comments Online process: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.
- *Mail:* David A. Stawick, Secretary of the Commission, Commodity Futures