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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: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations 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. New uses of these substances in meat or poultry products will continue to be approved by the Food and Drug Administration (FDA) for safety and by FSIS for suitability. FSIS will add approved uses of these substances to the list of approved substances contained in the Agency's directive system.

DATES: Effective [INSERT DATE 60 DAYS AFTER PUBLICATION DATE].

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SUPPLEMENTARY INFORMATION:

Background

On May 7, 2012, FSIS issued a proposed rule entitled "Food Ingredients and Sources of Radiation Listed and Approved for Use in the Production of Meat and Poultry Products" and requested comments on the document (77 FR 26706). FSIS proposed 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.

As explained in the proposal, 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](http://www.fsis.usda.gov/Regulations%20&%20Policies/Labeling%20FDA%20MOU/index.asp). Under this MOU, if FDA and FSIS approve an

ingredient 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.

(The Directive is available at:

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf>)

The proposed rule also explained that, under FSIS's 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 hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate.

In 2006, 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 monocytogenes (Lm) in ready-to-eat (RTE) meat and poultry products. 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.

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 petitioner's supporting data on the suitability of these substances for use in meat and poultry products. FSIS 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 of provisions under 9 CFR 303.1(h) and 381.3(b) to enable Kraft to conduct various experimental trials involving 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 Kemin and to various meat and poultry product 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.

While operating under the waivers, the Kemin and Kraft 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. 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. Kemin also submitted findings supporting the use of its sodium propionate and propionic acid formulations.

The Kemin petition and supporting materials are available for viewing by the public on the FSIS Web site at [http://www.fsis.usda.gov/PDF/Petition Kemin.pdf](http://www.fsis.usda.gov/PDF/Petition%20Kemin.pdf). The Kraft petition is available at:

[http://www.fsis.usda.gov/PDF/Petition Kraft.pdf](http://www.fsis.usda.gov/PDF/Petition%20Kraft.pdf).

Final Rule

After considering the comments received and discussed below, FSIS 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 amending 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."

Under this final rule, 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. In that directive, FSIS will specify that sodium propionate (generally recognized as safe under 21 CFR 184.1784) can be used as an antimicrobial in various meat and poultry products in an amount not to exceed 0.5 percent (by weight of total formulation) when used alone. Sodium propionate is a direct food ingredient that must be labeled by its common or usual name in the ingredients statement of a product (21 CFR 101.4, 9 CFR 317.2(f), 381.118(a)).

The directive also will state that, when used as an antimicrobial, sodium benzoate can be used in various meat and poultry products at up to 0.1 percent when used alone (21 CFR 184.1733). Sodium benzoate is a direct food additive that must be labeled by its common or usual name in the ingredients statement of a product. Similarly, benzoic acid is a generally recognized as safe (GRAS) direct food ingredient that can be used in various meat and poultry products at up to 0.1 percent (21 CFR 184.1021 and similarly must be labeled (21 CFR 101.4, 9 CFR 317.2(f) and 381.118(a)).

The uses of these substances are consistent with FDA regulations and reflect the levels that the petitioners requested to use in meat and poultry products and that they provided supporting data. Also, the use of these substances enhances food safety by controlling Lm in RTE products.

The Kraft petition also addressed sodium diacetate (GRAS under 21 CFR 184.1754 when used as an antimicrobial agent under cGMP). The company intends to use this substance in combination with sodium benzoate and sodium propionate. Sodium diacetate is not one of the substances

considered in this rulemaking because is not prohibited by FSIS regulations. When sodium benzoate, sodium propionate, or sodium diacetate are used in combination with each other, the overall maximum level for the combination cannot exceed 0.1 percent (in accordance with 21 CFR 184.1(d)). FSIS will include this information in the directive.

As a result of amending 9 CFR 424.23(a)(3), the procedures for listing approved uses of sodium propionate, benzoic acid, and sodium benzoate in the FSIS directive will be consistent with the procedures for listing approved uses in meat and poultry products of other safe and suitable substances. Approved new uses of potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate will continue to be listed through rulemaking because the regulations (9 CFR 424.23(a)(3)) prohibit their use in meat and poultry products.

FSIS carefully considered all the comments received and developed the following responses.

Discussion of Comments

FSIS received 20 comments in response to the proposed rule. Members of the public submitted twelve, organizations related to the food industry five, and a food safety

consulting firm, a non-profit association, and a trade association each submitted one. Several commenters supported the proposal 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. They stated that the additives are effective as anti-Listerial agents and are suitable for specified uses in meat and poultry products.

FSIS agrees that adding sodium propionate to the list of approved ingredients also provides meat and poultry processors greater flexibility in formulating new products while protecting the food supply against Listeria. Moreover, sodium propionate and propionic acid, which are GRAS (21 CFR 170.30, 21 CFR 184.1784) for use as antimicrobials under current good manufacturing practices, have been confirmed as safe and effective at inhibiting Lm. Sodium propionate does not mask spoilage or negatively affect sensory attributes. This ingredient provides the benefit of lowering sodium contribution in meat and poultry products, while extending shelf-life.

The following is a discussion of the relevant issues raised in the comments.

Comment: A commenter asked why there were no tests involving the human body after eating the substances. Another commenter expressed concern about the cumulative effects of combined dosages of sodium benzoate, sodium propionate, and benzoic acid on children.

Response: FSIS and FDA do not conduct tests of the effects of food ingredients directly on humans. For a GRAS substance, such as the substances discussed in this rule, generally available data and information about the use of the substance are known and widely accepted and FDA has a basis for concluding that there is consensus among qualified experts that the data and information establish that the substance is safe under the conditions of its intended use (21 CFR 170.36(c)(4)(i)(C)). For a food additive, privately held data and information about the use of the substance are sent by the sponsor to FDA. FDA then evaluates the data and information to determine whether they establish that the substance is safe under the conditions of its intended use (21 CFR 171.1).

FSIS and FDA have evaluated all the data and determined that the uses of these substances considered in

this rule are safe for individual consumers, including children.

Comment: A few commenters disapproved removing sodium benzoate, sodium propionate, and benzoic acid from the list of substances prohibited from use in meat and poultry products because they stated that these ingredients would have harmful effects on human health. One commenter explained that, as a potential consumer of harmful additives, she found the evidence submitted by Kraft Foods and Kemin Food Technologies insufficient to prove that all three agents are safe for use in meat and poultry products. Specifically, the commenter stated that Kemin had relied on old research (a 1973 study conducted by the Select Committee on Generally Recognized as Safe Substances) to prove the safe use of sodium benzoate and benzoic acid and that new research must be performed to ensure the safety of benzoic acid for public use.

Another commenter expressed concern because Kraft stated that it used Lem-O-Fos in its meat and poultry products to "enhance antimicrobial activity." The commenter stated that studies have shown that when benzoic acid is mixed with citric acid it forms benzene, which is a

carcinogen. In the commenter's opinion, the substances should be kept separate from one another or concrete evidence must prove that the mixture does not constitute a hazard to consumers.

Another commenter stated that, in the early 1990s, the FDA urged companies not to use benzoate in products that also contain ascorbic acid. The commenter noted that a lawsuit filed in 2006 by private attorneys ultimately forced Coca-Cola, PepsiCo, and other soft-drink makers in the United States to reformulate affected beverages -- typically fruit-flavored products. According to this commenter, soft-drink makers are now eliminating the use of benzoate in combination with vitamin C worldwide. This commenter stated that these developments should cause FDA and FSIS to reconsider whether benzoate should continue to be classified as GRAS. Another stated that the GRAS status of the sodium benzoate should be reviewed to take into account changes in consumer diets and advances in science and technology. The commenter also stated that FSIS should not expand its use until a safety assessment is done and noted that the European Union is in the process of reviewing its safety now.

Response: FDA and FSIS have considered the points made by the commenters and have determined that there are no human health hazards arising from the approved uses that will be listed in FSIS Directive 7120.1.

The conditions under which benzene is produced in soft drinks are different from the conditions under which benzene could be produced in ready-to-eat (RTE) meats. RTE meats have a pH close to neutral, are continuously refrigerated or stored at room temperature (canned RTE meats), and are protected from excessive exposure to light. Therefore, the use of sodium benzoate in RTE meats does not present a safety concern even if combined with Vitamin C or similar compounds.

Regarding the concern that the GRAS status of sodium benzoate should be reviewed, FDA has confirmed that the petitioner's intended use of sodium benzoate is covered under the GRAS regulations (at 21 CFR 184.1733) and that there are no safety issues with the intended use. FSIS accepts the conclusion of FDA. Further, FSIS is aware that the Codex Committee on Food Additives (1995)¹ has also

1 Codex Alimentarius Committee on Food Additives. 1995. Codex General Standard for Food Additive, Codex Stan 192, pg 80. Available at: <http://www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=9>. Accessed November 9, 2012.

approved the use of benzoates in cured (including salted) and dried non-heat treated processed (including comminuted) meat and poultry products, at a maximum level of 0.1 percent.

Regarding the European Union's evaluation, the European Food Safety Authority (EFSA) issued a data call June 1, 2012, on the occurrence in foods and beverages of certain food additives (sorbates, benzoates, and gallates) that were already permitted in the EU before January 20, 2009. Benzoic acid and sodium benzoate are among the ingredients on the list. The data are to be used to re-evaluate the ingredients. We understand from EFSA that the report on this re-evaluation will be available in late Spring 2013. When the re-evaluation is completed, experts in this Agency, and particularly in FDA, will consider the results and their possible implications. At this time, however, the available evidence supports the safety of the use of these ingredients.

Comment: One commenter supported the proposed rule but suggested that more studies be conducted on the effects of these three preservatives in higher dosages (higher than the use levels currently permitted under the FDA GRAS

regulations), possible allergic reactions through contact or ingestion and the extent of those reactions, and potential alternatives to these preservatives that produce the same outcome without the use of preservatives.

Response: The levels that FSIS would allow to be used under this rule have not been shown to cause allergic reactions. Data on uses at higher levels would be evaluated under the joint FDA and FSIS ingredient approval system.

Data in the scientific literature on the amounts of these substances that are necessary to trigger or give rise to allergic reactions are not available. Food additives, such as benzoic acid and benzoates, have been known to cause hypersensitivity reactions. Such reactions are known to be very unusual in healthy individuals. However, in some cases, doses as low as 50 mg of benzoates have been shown to cause allergic reactions in individuals already suffering from allergic reactions. Information on the effects of these doses on healthy individuals is not currently available. Therefore, it is important that food additives or ingredients that may cause severe allergic or hypersensitivity reactions be appropriately declared in the ingredient statement on the product label.

Industry is likely to pursue research on the preservatives that are the subject of this rulemaking and on others. FSIS and FDA will continue to review new substances for safety and suitability under the MOU.

Comment: A commenter recommended not specifying a pH range of 4.8 to 5.2 percent for the use of sodium propionate as indicated in the Kemin petition, increasing the permissible use level of propionate when used in combination with other antimicrobial ingredients, and specifying that the substances are to be used in meat and poultry, including RTE products. The commenter explained that a higher pH provides several benefits including greater stability of the antimicrobial solution, better handling and shipping classifications, and improved sensory characteristics in finished meat products.

The commenter further stated that not including a pH specification in the approved ingredient listing in the FSIS Directive will provide room for innovation and fair competition in the market. Moreover, a permitted use level of sodium propionate in RTE meat and poultry products is necessary because the firm's testing results indicate that propionate, when combined with commonly used existing

antimicrobials for meat and poultry (e.g., lactate, acetate, and diacetate), is required at higher levels to ensure safety of uncured high-moisture items.

Response: As noted above, sodium propionate that meets food grade standards as outlined in the Food Chemicals Codex, when used in accordance with 21 CFR 184.1784, is GRAS for use as an antimicrobial agent in meat products with no other limitations than cGMP. Therefore, FSIS will not specify a pH level in its Directive 7120.1. Also, since 21 CFR 184.1784 does not prescribe a maximum use level for sodium propionate, when the substance is used in combination with another antimicrobial agent, the maximum level for the combination is governed by the maximum use level of the other antimicrobial. For example, when sodium propionate is used in combination with sodium benzoate, the maximum level for the mixture is not to exceed 0.1 percent. When sodium propionate is used in combination with sodium diacetate, the maximum use level for the mixture is not to exceed 0.25 percent.

The directive will specify the uses of benzoic acid, sodium benzoate, and sodium propionate in meat and poultry products, including RTE meat and poultry products.

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 final rule has been determined not to be significant and therefore has not been reviewed by the Office of Management and Budget (OMB) under EO 12866.

The rule will benefit companies that want to use these substances in the production of meat and poultry products by expediting the approval process. It will 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. The rule also will 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 final 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 final rule.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the FSIS Administrator has determined that this final rule will not have a significant impact on a substantial number of small entities. This determination is based primarily on the fact that the final rule will not affect the process for approving new uses of sodium benzoate, sodium propionate, and benzoic acid in meat or poultry products. This final rule will 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.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This 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 final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA, PPIA, or EPIA.

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.

Additional Public Notification

FSIS will announce the availability of this final rule on-line through the FSIS Web page located at

[http://www.fsis.usda.gov/regulations & policies/Interim & Final Rules/index.asp](http://www.fsis.usda.gov/regulations%20&%20policies/Interim%20&%20Final_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 e-mail 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 e-mail 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](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 is amending 9 CFR Part 424 as follows:

PART 424-- PREPARATION AND PROCESSING OPERATIONS

1. The authority citation for part 424 continues 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. In § 424.23, revise paragraph (a)(3) to read 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: February 28, 2013

Alfred V. Almanza,

Administrator.

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