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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 424

[Docket No. 99-028DF]

Food Additives for Use in Meat and Poultry Products: Sodium Diacetate, Sodium Acetate, Sodium Lactate and Potassium Lactate

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to increase permissible levels of sodium acetate as a flavor enhancer in meat and poultry products and of sodium diacetate as a flavor enhancer and as an inhibitor of the growth of certain pathogens. FSIS is also permitting the use of sodium lactate and potassium lactate in meat and poultry products, except for infant formulas and infant food, for purposes of inhibiting the growth of certain pathogens. FSIS is proceeding with this direct final rule in response to petitions submitted by Armour Swift-Ekrich and Purac America, Inc.

DATES: This rule will be effective March 20, 2000 unless FSIS receives written adverse comments within the scope of this rulemaking or written notice of intent to submit adverse comments within the scope of this rulemaking on or before February 22, 2000.

ADDRESSES: Submit adverse comments or notice of intent to submit adverse comments within the scope of this rulemaking to: FSIS Docket Clerk, Docket #99-028DF, Department of Agriculture, Food Safety and Inspection Service, Cotton Annex, Room 102, 300 12th Street, SW, Washington, DC 20250-3700. Any written comments submitted in response to this direct final

rule and reference materials will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert Post, Director, Labeling and Additives Policy Division, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0279.

SUPPLEMENTARY INFORMATION:

Background

FSIS was petitioned by Armour Swift-Ekrich to amend the Federal meat and poultry products inspection regulations to increase the amount of sodium diacetate and sodium acetate that may be added to meat and poultry products to levels up to 0.25 percent by weight of total formulation. The reason for the requested increase was for the purpose of inhibiting the growth of microorganisms, specifically *Lm*. The petitioner also requested that the Agency expand the approval to include potassium acetate and potassium diacetate.

The petitioner submitted data with the petition that it had gathered over ten years from experiments in its laboratories. FSIS determined that the data demonstrate that increasing the currently approved level of sodium diacetate to 0.25 percent effectively inhibits the growth of *Lm* in meat and poultry products. However, there was insufficient data submitted with the petition to allow an increase in the amount of sodium acetate to be used as an anti-microbial agent in meat and poultry products. Also, the Food and Drug Administration (FDA) has only approved sodium diacetate to be used as an anti-microbial in accordance with 21 CFR 184.1754. Therefore, FSIS is only approving sodium diacetate at a level up to .25 percent for anti-microbial use in meat and poultry products.

In a June 9, 1995, letter to the petitioner, FDA stated that it had no objection to sodium acetate and sodium diacetate to be used at levels up to .25 percent as flavoring agents. Therefore, to reflect FDA's action, FSIS will permit the use of sodium acetate and sodium diacetate to a level of up to .25 percent as flavoring agents in meat and poultry products.

FDA has not established a use level for potassium acetate or potassium diacetate as either flavoring agents or anti-microbials. Nor did the petitioner supply any data supporting the request for potassium acetate or potassium diacetate. Consequently, the Agency cannot permit the use of potassium acetate or potassium diacetate in meat and poultry products at this time.

FSIS also received a petition from Purac America, Inc. The petition requested that FSIS amend the Federal meat and poultry products inspection regulations to permit the use of sodium lactate and potassium lactate in fully cooked meat, meat food products, poultry, and poultry food products, except for infant foods and formulas, at levels up to 4.8 percent of total product formulation to inhibit the growth of certain pathogens such as *Lm* and *C. botulinum*.

FSIS found that adequate information exists to accept the use of sodium lactate and potassium lactate, singly or in combination, in all fully cooked meat and poultry food products at a level up to 4.8 percent by weight of total formulation for purposes of inhibiting the growth of certain pathogens. FDA has listed sodium lactate and potassium lactate for use with no limitations as long as they are used under good manufacturing practice as defined in 21 CFR 184.1(b). Both are currently approved by FSIS at levels up to 2 percent of total product formulation for use as flavors and flavor enhancers. FSIS will permit the use of sodium lactate and potassium lactate at a level of 4.8 percent in meat and poultry products to inhibit the growth of certain pathogens.

Because the use of these substances would change a product's formulation, FSIS expects that establishments choosing to use any of these substances will reassess their HACCP plans for the products in which the substances will be used. Such a reassessment is specified in 9 CFR 417.4(a)(3). Accordingly, FSIS expects that establishments using sodium diacetate, sodium lactate, or potassium lactate to inhibit the growth of pathogens will modify their HACCP plans to establish the use of the substance as a critical control point (CCP) or to incorporate the use into an existing CCP. Also, establishments that use sodium acetate, sodium diacetate, sodium lactate, or

potassium lactate in their products will need to revise the product's label as specified in part 317 or 318, subpart N.

The use of these substances at the levels that are being provided for by FSIS is not controversial, and FSIS expects no adverse comment to result from the changes that it is making. Therefore, unless the Agency receives written adverse comments within the scope of this rulemaking, or a written notice of intent to submit adverse comments within the scope of the rulemaking, within 30 days, the action will become final 60 days after publication in the **Federal Register**. If written adverse comments within the scope of the rulemaking are received, the final rulemaking notice will be withdrawn, and the Agency will publish a proposed rulemaking notice that includes a comment period.

Executive Order 12988

This direct final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This direct final rule: (1) Preempts all state and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 12866 and Regulatory Flexibility Act

This direct final rule has been determined to be not significant and, therefore, has not been reviewed by OMB.

Effect on Small Entities

This direct final rule will permit the use of sodium acetate as a flavor enhancer, sodium diacetate as a flavor enhancer and anti-microbial, and sodium lactate and potassium lactate as anti-microbials in meat and poultry products.

The use of these ingredients is voluntary. FSIS does not believe that any costs involved with HACCP plan reassessments or modifications, or changes to labels, will be significant. The decision by individual establishments to use any of these ingredients will be based on their conclusions that the benefits outweigh the implementation costs.

The Administrator, FSIS, has determined that this direct final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this direct final rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

Paperwork Requirements

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this direct final rule in accordance with the Paperwork Reduction Act and submitted an information collection request to the Office of Management and Budget for emergency clearance. Establishments that choose to use any of the substances approved by this direct final rule will have to make changes to their product labels. Also, because establishments using the substances will change their products' formulations, they will have to reassess their HACCP plans that cover production of the products, as specified in 417.4(a)(3). FSIS expects that most establishments using the substances approved for antimicrobials will most likely establish the use of the substance as a critical control point (CCP) or incorporate its use into an existing CCP.

Estimate of Burden: FSIS estimates that it will take 1 hour for establishments to develop any new product labels. Establishments will only need to make the label changes once. The Agency estimates that it will take 1 hour for establishments to reassess their HACCP plans. For purposes of this paperwork analysis, FSIS assumes that

all of the establishments it has estimated to use the substances will make changes to one HACCP plan one time. The Agency estimates that an establishment will spend about 5 minutes a day (250 days) completing 1 monitoring record and 2 minutes a day filing the record for one HACCP plan.

Respondents: Meat and Poultry product establishments.

Estimated Number of Respondents: 1,000.

Estimated Number of Responses per Respondent: 1 for label changes, 1 for HACCP reassessment; 250 for monitoring records, and 250 for filing the record.

Estimated Total Annual Burden on Respondents: 31,166.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, Room 109 Cotton Annex, Washington, DC 20250-3700.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the method and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond; including through use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lee Puricelli, see the address above, and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) Washington, DC 20253.

List of Subjects in 9 CFR Part 424

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

For the reasons discussed in the preamble, FSIS is amending 9 CFR part 424 of the Federal meat and poultry products inspection regulations 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. Section 424.21 is amended in the chart in paragraph (c) by adding in alphabetical order new entries for "potassium lactate," "sodium diacetate," and "sodium lactate" under

the class "Antimicrobial agents" and by revising the entries for "sodium acetate" and "sodium diacetate" under the class "Flavoring agents" to read as follows:

§ 424.21 Use of food ingredients and sources of radiation.

* * * * *

(c) * * *

Class of substance	Substance	Purpose	Products	Amount
* Antimicrobial Agents	* Potassium lactate	* To inhibit microbial growth	* Various meat and poultry products, except infant formulas and infant food.	* 4.8% by weight of total formulation.
	Sodium diacetate	do	do	0.25% by weight of total formulation.
	Sodium lactate	do	do	4.8% by weight of total formulation.
* Flavoring agents; Protectors and Developers.	* Sodium acetate	* To flavor products	* Various meat and poultry products.	* Not to exceed 0.25% of formulate in accordance with 21 CFR 184.1721.
	Sodium diacetate	do	do	Not to exceed 0.25% of formulate in accordance with 21 CFR 184.1754.

Done at Washington, DC, on: December 23, 1999.

Thomas J. Billy,
Administrator.

[FR Doc. 00-1220 Filed 1-19-00; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33-7789; 34-42327; 35-27123; 39-2380; IC-24235]

RIN 3235-AG96

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Commission is adopting an updated edition of the EDGAR Filer Manual and is providing for its incorporation by reference into the Code of Federal Regulations.

EFFECTIVE DATE: January 24, 2000. The new edition of the EDGAR Filer Manual (Release 6.75) will be effective on January 24, 2000. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of January 24, 2000.

FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, Michael E. Bartell at (202) 942-8800; for questions concerning investment company filings, Ruth Armfield

Sanders, Senior Special Counsel, or Shaswat K. Das, Attorney, Division of Investment Management, at (202) 942-0978; and for questions concerning Corporation Finance company filings, Herbert Scholl, Office Chief, EDGAR and Information Analysis, Division of Corporation Finance, at (202) 942-2930.

SUPPLEMENTARY INFORMATION: Today we are adopting an updated EDGAR Filer Manual ("Filer Manual"), which describes the technical formatting requirements for the preparation and submission of electronic filings through the Electronic Data Gathering, Analysis, and Retrieval (EDGAR) system.¹ Filers must comply with the provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.² Filers should consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.³

¹ We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33-6986 (Apr. 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on October 18, 1999. See Release No. 33-7752 (October 20, 1999) [64 FR 56430].

² See Rule 301 of Regulation S-T (17 CFR 232.301).

³ See Release Nos. 33-6977 (Feb. 23, 1993) [58 FR 14628], IC-19284 (Feb. 23, 1993) [58 FR 14848], 35-25746 (Feb. 23, 1993) [58 FR 14999], and 33-6980 (Feb. 23, 1993) [58 FR 15009] in which we comprehensively discuss the rules we adopted to govern mandated electronic filing. See also Release No. 33-7122 (Dec. 19, 1994) [59 FR 67752], in which we made the EDGAR rules final and applicable to all domestic registrants; Release No. 33-7427 (July 1, 1997) [62 FR 36450], in which we adopted minor amendments to the EDGAR rules;

The purpose of this new version of EDGAR and the Filer Manual (Release 6.75) is to add new form types and delete several old ones.⁴

We have added the following submission types to EDGAR:

- *SC TO-C*—Written communication relating to an issuer or third party tender offer not by the subject company.

- *SC 14D9-C*—Written communication by the subject company relating to a tender offer by a third party.

- *SC TO-I and SC TO-I/A*—Tender offer schedule and amendment filed by the issuer.

- *SC TO-T and SC TO-T/A*—Tender offer schedule and amendment filed by a third party.

- *425-A* prospectus or other communication in connection with business combination transactions.

- *N-6 and N-6/A*—Submission types for registration statements and pre-effective amendments for separate accounts (unit investment trusts) if we adopt our proposed Form N-6.⁵

Release No. 33-7472 (Oct. 24, 1997) [62 FR 58647], in which we announced that, as of January 1, 1998, we would not accept in paper filings that we require filers to submit electronically; Release No. 34-40935 (Jan. 12, 1999) [64 FR 2843], in which we made mandatory the electronic filing of Form 13F; and Release No. 33-7684 (May 17, 1999) [64 FR 27888], in which we adopted amendments to implement the first stage of EDGAR modernization.

⁴ We have added the new Williams Act submission types to accommodate the new rules that will become effective January 24, 2000. See Release No. 33-7760 (Oct. 22, 1999) [64 FR 61408].

⁵ See Release Nos. 33-7514; IC-23066 (Mar. 2, 1998) [63 FR 13988], in which we proposed new