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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318 and 381

[Docket No. 95-001DF]

RIN 0583-AB97

Use of Sodium Citrate Buffered With Citric Acid in Certain Cured and Uncured Processed Meat and Poultry Products

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 permit the use of a solution of sodium citrate buffered with citric acid in cured and uncured processed whole-muscle meat and poultry products. This action is being taken in response to a petition requesting use of the solution to inhibit the growth of microorganisms, *Clostridium botulinum* in particular, and retain product flavor during storage.

DATES: This rule will be effective on June 24, 1996, unless adverse or critical comments are received on or before May 24, 1996. If adverse or critical comments are received, FSIS will publish a timely withdrawal of the final rule and a new proposed rule.

ADDRESSES: Send an original and two copies of written comments or notice of intent to submit adverse comments to: FSIS Docket Clerk, DOCKET #95-001DF, Room 4352, South Agriculture Building, 14th and Independence Avenue, SW., Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700. Make oral comments, as provided for under the Poultry Products Inspection Act (PPIA), to Mr. Charles R. Edwards, (202) 254-2565, after prior

arrangements have been made with his office. Data submitted by the petitioner and all comments received, including FSIS-prepared copies of oral comments, will be available for public inspection from 8:30 a.m. to 1:00 p.m., and from 2:00 p.m. to 4:30 p.m., Monday through Friday, Room 4352, in Room 4352, South Agriculture Building.

FOR FURTHER INFORMATION CONTACT:

Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700, (202) 254-2565.

SUPPLEMENTARY INFORMATION: The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the PPIA (21 U.S.C. 451 *et seq.*) prohibit addition of any substance to meat or poultry food products that may render the products adulterated. Federal meat and poultry inspection regulations prohibit the use of any substance in the preparation of any product unless it is approved in the tables of approved substances in 9 CFR 318.7(c)(4) and 381.147(f)(4).

FSIS was petitioned to approve the use of sodium citrate buffered with citric acid in cured and uncured whole-muscle processed meat and poultry products to inhibit the growth of microorganisms, *Clostridium botulinum* in particular, and to retain product flavor during storage. The petitioner requested that FSIS amend the regulations to permit sodium citrate buffered with citric acid to a pH of 5.6 and used at a level of 1.3 percent of the product formulation weight. Data submitted by the petitioner showed that after whole-muscle product is immersed in a marinade or injected with the solution, microbial growth is inhibited and the product's flavor is retained during storage.

The petitioner provided results of limited microbiological assays (total plate count, coliforms) and organoleptic (taste) tests conducted on products at least 6 weeks old. The results show that to effectively inhibit microbial growth, the sodium citrate must be buffered with citric acid to a pH of 5.6. The data, also, showed that proteins are destroyed and the product's appearance and texture becomes unacceptable to consumers when the buffered sodium citrate solution exceeds 1.3 percent of the product formulation weight.

After reviewing the petitioner's technical data, FSIS determined that the tables of approved substances in the meat and poultry regulations should be amended to allow the use of sodium citrate buffered with citric acid for the purposes and in the amounts requested by the petitioner. The technical data demonstrate the efficacy of buffered sodium citrate for these uses. Because sodium citrate and citric acid are generally recognized as safe (21 CFR 184.1033 and 21 CFR 184.1751) when used in accordance with good manufacturing practices, the wholesomeness of the product will not be affected. Therefore, FSIS is amending the tables of approved substances in 9 CFR 318.7(c)(4) and 381.147(f)(4) to allow the use of sodium citrate buffered with citric acid to a pH of 5.6 in cured and uncured processed whole-muscle meat and poultry products at a level not to exceed 1.3 percent of the formulation weight of the product.

FSIS expects no adverse public reaction resulting from this change in regulatory language. Therefore, unless the Agency receives adverse or critical comments, or a notice of intent to submit adverse comments within 30 days, the action will become final 60 days after publication in the Federal Register. If critical comments are received, the final rulemaking notice will be withdrawn and a proposed rulemaking notice will be published. The proposed rulemaking notice will establish a comment period.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant and, therefore, has not been reviewed by the Office of Management and Budget.

The Administrator has made an initial determination 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). The direct final rule will permit the use of an additional, alternative means of inhibiting the growth of microorganisms. Use of the buffered sodium citrate solution is voluntary. Small manufacturers opting to use the solution will be required to revise their product labels. Decisions by individual manufacturers on whether to use sodium citrate buffered with citric acid

in this manner would be based on their conclusions that the benefits outweigh the implementation costs.

Executive Order 12778

This direct final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted by the FMIA and PPIA from imposing any marking or packaging requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States.

This direct final rule is not intended to have retroactive effect.

There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this direct final rule. However, the administrative procedures specified in 9 CFR §§ 306.5 and 9 CFR 381.35, and 7 CFR § 59.310 must be exhausted prior to any judicial challenge of the application of the provisions of this direct final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA, or PPIA.

Paperwork Requirements

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this direct final rule. This rule requires manufacturers that opt to use sodium citrate buffered with citric acid to revise their product labels and submit such labeling to FSIS for approval.

Estimate of Burden: FSIS estimates that it takes 60 minutes to design and modify labels in accordance with these regulations. For label submissions, FSIS estimates a 15 minute response time to prepare the label application form, submit it, along with the label, to FSIS or to a label expeditor who will deliver the form and label to FSIS.

Respondents: Meat and poultry product establishments.

Estimated Number of Respondents: 200.

Estimated Number of Responses per Respondent: 25.

Estimated Total Annual Burden on Respondents: 6,250 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, South Agriculture Building, Room 3812, Washington, DC 20250-3700.

Comments regarding the need for and usefulness of the requirements, the accuracy of FSIS's burden hour estimate, ways to minimize the estimated burden, including through the use of automated collection techniques or other forms of information collection technology, or any other aspect of this collection of information discussion, to Lee Puricelli, Paperwork Specialist, see address above, and Desk Officer for Agriculture, Office of Information and

Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Comments are requested by June 24, 1996. To be most effective, comments should be sent to OMB within 30 days of the publication date of this direct final rule.

List of Subjects

9 CFR Part 318

Food additives, Meat inspection.

9 CFR Part 381

Food additives, Poultry inspection.

Final Rule

For the reasons discussed in the preamble, FSIS is amending 9 CFR parts 318 and 381 as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. In the chart in § 318.7(c)(4), under the Class of substance "Miscellaneous," a new entry for the substance "Sodium citrate buffered with citric acid to a pH of 5.6" is added at the end to read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

*	*	*	*	*	*
(c)	*	*	*		
(4)	*	*	*		

Class of substance	Substance	Purpose	Products	Amount
*	*	*	*	*
Miscellaneous				
*	*	*	*	*
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole-muscle meat food products, e.g., ham.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
*	*	*	*	*

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451-470, 7 CFR 2.18, 2.53.

4. In the table in § 381.147(f)(4), under the Class of substance "Miscellaneous," a new entry for the Substance "Sodium Citrate buffered with citric acid to a pH of 5.6" is added at the end to read as follows:

§ 381.147 Restrictions on the use of substances in poultry products.

*	*	*	*	*
(f)	*	*	*	
(4)	*	*	*	

Class of substance	Substance	Purpose	Products	Amount
*	*	*	*	*
Miscellaneous				
*	*	*	*	*
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole-muscle poultry food products, e.g., chicken breasts.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
*	*	*	*	*

Done at Washington, DC, on April 17, 1996.

Michael R. Taylor,
Acting Under Secretary for Food Safety.
[FR Doc. 96-9980 Filed 4-23-96; 8:45 am]
BILLING CODE 3410-DM-P

FEDERAL ELECTION COMMISSION

11 CFR Parts 100, 110 and 114

[Notice 1996-11]

Candidate Debates and News Stories

AGENCY: Federal Election Commission.

ACTION: Final rule and transmittal of regulations to Congress.

SUMMARY: The Federal Election Commission is issuing revised regulations governing candidate debates and new stories produced by cable television organizations. These regulations implement the provisions of the Federal Election Campaign Act (FECA) which exempt news stories from the definition of expenditure under certain conditions. The revisions indicate that cable television programmers, producers and operators may cover or stage candidate debates in the same manner as broadcast and print news media. The rules also restate Commission policy that news organizations may not stage candidate debates if they are owned or controlled by any political party, political committee or candidate.

DATES: Further action, including the publication of a document in the Federal Register announcing an effective date, will be taken after these regulations have been before Congress for 30 legislative days pursuant to 2 U.S.C. 438(d).

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, or Ms. Rosemary C. Smith, Senior Attorney, 999 E Street NW., Washington, DC 20463, (202) 219-3690 or (800) 424-9530.

SUPPLEMENTARY INFORMATION: The Commission is publishing today the final text of revisions to its regulations at 11 CFR 100.7(b)(2), 100.8(b)(2), 110.13 and 114.4(f) regarding news stories and candidate debates produced by cable television operators, programmers and producers. The revised rules also address candidate debates sponsored by news organizations owned or controlled by candidates, political parties and political committees. These provisions implement 2 U.S.C. 431(9) and 441b, provisions of the Federal Election Campaign Act of 1971, as amended (the Act or FECA), 2 U.S.C. 431 *et seq.*

On February 1, 1996, the Commission issued a Notice of Proposed Rulemaking (NPRM) in which it sought comments on proposed revisions to these regulations. 61 FR 3621 (Feb. 1, 1996). Four written comments were received from the Internal Revenue Service (IRS), the Federal Communications Commission (FCC), Turner Broadcasting System, Inc. (Turner), and the National Cable Television Association, Inc. (NCTA). A public hearing on these changes was scheduled for March 20, 1996. The hearing was subsequently canceled when the Commission received no requests to testify.

Section 438(d) of Title 2, United States Code, requires that any rules or regulations prescribed by the Commission to carry out the provisions of Title 2 of the United States Code be transmitted to the Speaker of the House of Representatives and the President of the Senate 30 legislative days before they are finally promulgated. These regulations were transmitted to Congress on April 18, 1996.

Explanation and Justification for 11 CFR 100.7(b)(2), § 100.8(b)(2), § 110.13, and § 114.4(f)

The FECA generally prohibits corporations from making contributions or expenditures in connection with any election. 2 U.S.C. 441b. However, the definition of "expenditure" in section 431(9) indicates that news stories,

commentaries, and editorials distributed through the facilities of any broadcast station, newspaper, magazine, or other periodical publication are not considered to be expenditures unless the facilities are owned or controlled by a political party, political committee, or candidate. 2 U.S.C. 431(9)(B)(i). This statutory exemption forms the basis for the Commission's long-standing regulations at 11 CFR 100.7(b)(2) and 100.8(b)(2) exempting such communications from the definitions of contribution and expenditure. Section 431(9) is also the basis underlying sections 110.13 and 114.4(f), which permit broadcasters and *bona fide* print media to stage candidate debates under certain conditions.

The Commission has decided to expand the types of media entities that may stage candidate debates under sections 110.13 and 114.4 to include cable television operators, programmers and producers. Hence, revised sections 110.13(a)(2) and 114.4(f) allows these types of cable organizations to stage debates under the same terms and conditions as other media organizations such as broadcasters, and *bona fide* print media organizations. New language in sections 110.13, 100.7(b)(2) and 100.8(b)(2) also permits cable organizations, acting in their capacity as news media, to cover or carry candidate debates staged by other groups. Examples of the types of programming that the Federal Communications Commission considers to be *bona fide* newscasts and news interview programs are provided in The Law of Political Broadcasting and Cablecasting: A Political Primer, 1984 ed., Federal Communications Commission, at p. 1994-99.

The revised rules are consistent with the intent of Congress not "to limit or burden in any way the first amendment freedoms of the press * * *." H.R. Rep. No. 93-1239, 93d Cong., 2d Sess. at 4 (1974). In *Turner Broadcasting System, Inc. v. Federal Communications Commission*, _____ U.S. _____, 114 S.