



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 310

[Docket No. FSIS-2020-0005]

RIN 0583-AD81

**Elimination of the Requirement to Defibrinate Livestock Blood
Saved as an Edible Product**

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service is proposing to remove a provision from the Federal meat inspection regulations that requires the defibrination of livestock blood saved as an edible product. This proposed action would eliminate a regulatory requirement and its associated costs to industry without affecting food safety. Moreover, it would allow industry to fulfill a demand for non-defibrinated blood products.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: FSIS invites interested persons to submit comments on the proposed rule. Comments may be submitted by one 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 on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2020-0005. 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, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development, FSIS; Telephone: (202)-720-0399.

SUPPLEMENTARY INFORMATION:

Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) to protect the health and welfare of consumers. FSIS is responsible for ensuring that the nation's commercial supply of meat and meat food products is safe, wholesome, not adulterated, and correctly labeled and packaged. Under the FMIA, FSIS has broad authority to promulgate rules and regulations necessary to carry out this mission (21 U.S.C. 621). However, like all executive branch agencies, FSIS must also prudently manage the costs associated with governmental imposition of private expenditures required to comply with its regulations (Executive Order (E.O.) 13771). FSIS, therefore, has a responsibility to identify and eliminate burdensome regulations that are not necessary to ensure the safety of meat and meat food products.

The Federal meat inspection regulations govern the saving of livestock blood for edible purposes (9 CFR 310.20). Prior to 1974, the regulations allowed establishments to collect edible blood from all livestock, except swine. However, in 1974, the Agency promulgated 9 CFR 310.20, which removed the swine blood prohibition, finding that it was not necessary for food safety (39 FR 1973, January 16, 1974). In the 1974 rule, the Agency also reasoned that the prohibition was burdensome, in that it denied specialty food producers a source of swine blood for their products.

There have been no substantive changes governing the saving of livestock blood since 1974. Since that time, 9 CFR 310.20 allows establishments to save edible blood from all livestock, including swine, provided the animals' carcasses are inspected and passed and the blood is collected, *defibrinated*, and handled in a manner so as not to render it adulterated under the FMIA. Defibrination is the process of preventing fibrin from forming in blood -- fibrin being an insoluble protein that causes blood to coagulate. Defibrination, therefore, results in blood that does not clot and remains in a liquid state. As explained below, FSIS is proposing to remove the defibrination requirement from the Federal meat inspection regulations for many of the same reasons it eliminated the swine blood prohibition in 1974.

Proposed Rule

FSIS is proposing to remove the defibrination requirement from 9 CFR 310.20. Blood collected from inspected and passed livestock carcasses and handled in a manner so as not to render it adulterated under the FMIA is safe for human consumption. FSIS conducted a review of the peer-reviewed literature regarding coagulated, i.e. non-defibrinated, blood and did not identify any scientifically supportable food safety concerns. Thus, FSIS believes coagulated blood, like fluid blood, is safe for human consumption, provided the blood is saved from

inspected and passed animals, and the blood is otherwise produced and prepared in compliance with all other FSIS regulations.

Therefore, FSIS believes the defibrination requirement is not necessary to ensure food safety in accordance with the FMIA.¹

Furthermore, FSIS has become aware that some establishments are interested in collecting coagulated blood for use in human food products, including specialty and ethnic food products that require coagulated blood as an ingredient. Such foods include variations of blood sausage, blood pudding, and blood tofu. The current defibrination requirement denies specialty and ethnic food producers a source of coagulated blood, thereby placing an unnecessary economic burden on them and on the livestock slaughter establishments that could provide coagulated blood. This proposed rule would rectify that situation.

FSIS is proposing to remove the word "defibrinated" from the codified regulations. Under the proposed rule, official establishments would still have the option to defibrinate blood, provided they meet all other requirements in 9 CFR 310.20. The regulations would continue to prohibit the defibrination of blood by hand. The regulations would also continue to require

¹ FSIS Notice 22-19 instructs inspection program personnel on how to verify that edible blood, including coagulated blood, is collected and handled in a manner to be fit for use in human food. FSIS will periodically review data generated by such verification activities to ensure that establishments are following proper food safety practices pertaining to the collection of edible blood.

the use of anticoagulants that meet cited requirements in title 9 and title 21 of the Code of Federal Regulations.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

E.O.s 12866 and 13563 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). E.O. 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 designated as a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Baseline

From October 2015 to December 3, 2019, FSIS received 15 askFSIS² questions about defibrination from 14 slaughter establishments. Therefore, FSIS assumes that at least 14 establishments would be affected by this proposed rule.

² askFSIS is a web-based computer application designed to help answer technical and policy-related questions from inspection program personnel, industry, consumer groups, other stakeholders, and the public. This data was received on December 4, 2019.

Expected Costs of the Proposed Rule

There are no expected costs associated with this proposed rule. If this proposed rule is finalized, FSIS would allow coagulated blood to be saved for edible purposes.

Expected Benefits of the Proposed Rule

The proposed rule would benefit slaughter establishments that manufacture livestock blood and processing establishments that use the blood in their products, such as blood sausage, blood tofu, and blood pudding. This proposed rule would allow slaughter establishments manufacturing livestock blood for edible purposes to package and sell the item in its customary coagulated form, enhancing the marketability for these niche products. In addition, removing the unnecessary, prescriptive requirements would allow establishments additional flexibility to be innovative and to operate in the most efficient manner.

Removing the regulation that requires establishments to defibrinate livestock blood is expected to result in industry cost savings. Establishments would reduce anti-coagulant solution costs and labor costs associated with defibrination.

According to 9 CFR 424.21, sodium citrate is a FSIS approved anti-coagulant that can be used to defibrinate blood. FSIS estimated that the 2019 sodium citrate solution cost per

gallon of blood was \$1.39³. Based on askFSIS and Public Health Information System (PHIS)⁴ data, all 14 establishments that process edible blood are small or very small establishments. FSIS experts estimated that small establishments that process edible blood products process two to five gallons of edible blood per production day. These establishments operate about 213⁵ production days per year, which means that they each process an estimated 426 to 1,065 gallons of edible blood per year. Each of these establishment would save approximately \$592⁶ to \$1,480⁷ in anti-coagulate solution cost per year if they no longer defibrinate blood.

Establishments that process edible blood would also benefit from labor cost savings. FSIS experts estimate that it

³ Sodium citrate prices were obtained from three laboratory websites, <https://www.jorvet.com/>, <https://www.rpicorp.com/>, <https://www.tocris.com/>. These websites were accessed on 11/27/2019.

The average sodium citrate price per milliliter was \$0.07. This price was multiplied by the conversion rate of 3,785.412ml per gallon to get the average sodium citrate price per gallon of \$277.09. According to 9 CFR 424.21, the sodium citrate solution cannot exceed 0.5 percent based on the ingoing weight of the product. Therefore, the price of sodium citrate per gallon of blood would be \$277.09 multiplied by .005 or \$1.39.

⁴ PHIS is FSIS's electronic data analytic system, used to collect, consolidate, and analyze data in order to improve public health. FSIS used data from (PHIS) to identify these establishments by Hazard Analysis and Critical Control Point (HACCP) category. This data was received on December 10, 2019.

⁵ Viator. C. Et. al. 2015. RTI International "Costs of Food Safety Investments" prepared by Catherine L. Viator, Mary K. Muth, and Jenna E. Brophy. The contract number is No. AG-3A94-B-13-0003. The order number is AG-3A94-K-14-0056. Table 2-5. Available at <http://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES>.

⁶ 426 gallons multiplied by \$1.39 sodium citrate cost per gallon of blood equals \$592. Costs are rounded to the nearest dollar.

⁷ 1,065 gallons multiplied by \$1.39 equals \$1,480. Costs are rounded to the nearest dollar.

takes one production worker two to five minutes to defibrinate one gallon of livestock blood. FSIS estimated the total compensation rate of a production employee was \$27.36⁸ per hour or approximately \$0.50⁹ per minute based on 2018 estimates from the Bureau of Labor Statistics. Each establishment would save approximately \$1,305 in labor costs per year¹⁰, with a range of \$426 to \$2,663 if they no longer defibrinate blood.

FSIS estimated that at least the 14 establishments that submitted askFSIS questions about defibrination from October 2015 to December 3, 2019 would benefit from the cost savings associated with this proposed rule. The total estimated annual industry cost savings are detailed in Table 1. FSIS requests comments and data on the total number of establishments that save livestock blood for edible purposes.

Table 1. Industry Annual Cost Savings			
	Low Estimate	Medium Estimate	High Estimate
Sodium Citrate Cost	\$8,288	\$14,504	\$20,720

⁸ Wage estimate of \$13.68 obtained from the Bureau of Labor Statistics, May 2018 National Industry-Specific Occupational Employment and Wage Estimates for the Processing Workers (Occupational Code 51-3023) in the Animal Slaughtering and Process Industry (NAICS code 311600). <https://www.bls.gov/oes/current/oes513023.htm> . FSIS multiplied the mean hourly wage rate by a benefits factor of 2, to obtain a total compensation rate of \$27.36 per hour.

⁹ \$27.36 divided by 60 minutes equals \$0.456 rounded to the nearest tenth of a cent to \$0.50.

¹⁰ 3.5 (2+5/2) minutes multiplied by the mid estimate of 3.5 (2+5/2) gallons of blood per production day multiplied by 213 production days, multiplied by the labor cost per minute (\$0.50). The costs are rounded to the nearest dollar.

Savings/Year			
Labor Cost Savings/Year	\$5,964	\$18,270	\$37,282
Total Cost Savings	\$14,252	\$32,774	\$58,002
Total Costs Savings annualized at a discount rate of 7% over 10 years.	\$14,252	\$32,774	\$58,002

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Small and very small establishments would benefit from the cost savings associated with this proposed rule. However, the benefits to small and very small establishments would not be significant based on the total savings estimates in Table 1 (\$14,252 to \$58,002 over 10 years). Of the 14 establishments that submitted askFSIS questions about defibrination from October 2015 to December 3, 2019, about 64 percent were classified as Hazard Analysis and Critical Control Point (HACCP) size small and 36 percent were HACCP size very small. Under the HACCP size definitions, large establishments have 500 or more employees and small establishments have fewer than 500 but more

than 10 employees. Very small establishments have fewer than 10 employees or annual sales of less than \$2.5 million.

Executive Order 13771

Consistent with E.O. 13771 (82 *FR* 9339, February 3, 2017), FSIS has estimated that this proposed rule would yield cost savings. Assuming a 7 percent discount rate, a perpetual time horizon, and a starting year of 2020, the proposed rule, if finalized, is estimated to yield approximately \$25,003 (2016\$) in annual cost savings. Therefore, if finalized as proposed, this rule would be an E.O. 13771 deregulatory action.

Paperwork Reduction Act

There are no new paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Expected Environmental Effects

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies

categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)).

FSIS has determined that this proposed rule, which would remove the defibrination requirement from 9 CFR 310.20, would not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4 of the U.S. Department of Agriculture regulations.

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.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in,

deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at:

http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative. Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this

Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this 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 *Constituent Update* is available on the FSIS Web page. Through 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/subscribe>. Options range from recalls to export information, 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 310

Blood, Meat and meat products.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

PART 310—POST-MORTEM INSPECTION

1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53

§ 310.20 [Amended]

2. In § 310.20, remove “, defibrinated,” from the first sentence in the paragraph.

Done, at Washington, D.C.

Paul Kiecker

Administrator.

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