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**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:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is removing from the Federal meat inspection regulations a requirement for the defibrination of livestock blood saved as an edible product. Defibrination is the process for removing the protein fibrin, which causes blood to clot. Removal of the defibrination requirement will not affect food safety, but it will allow the industry to meet a demand for non-defibrinated blood products.

**DATES:** This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS; Telephone: (202)-205-0495

**SUPPLEMENTARY INFORMATION:**

**Background**

On June 1, 2020, FSIS proposed to remove from the Federal meat inspection regulations a provision requiring the defibrination<sup>1</sup> of livestock blood saved as edible product (85 FR 33031). The Agency stated in the proposed rule that eliminating the requirement, along with its associated costs to industry, would not affect food safety, but would enable industry to meet a demand for non-defibrinated blood products.

FSIS noted in the proposal that, before 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.

Also, FSIS explained in the proposed rule that there had been no substantive changes governing the saving of livestock blood since 1974. Since that time, 9 CFR 310.20 has allowed 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 to prevent its becoming adulterated under the FMIA.

FSIS examined the peer-reviewed literature on coagulated, i.e., non-defibrinated, blood and did not identify any

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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.<sup>2</sup>

Furthermore, as is explained in the proposed rule, 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.

FSIS proposed to remove the defibrination requirement from the Federal meat inspection regulations for many of the same reasons it gave for eliminating the swine blood prohibition in 1974.

## **Final Rule**

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<sup>2</sup> 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.

This final rule is consistent with the proposed rule. FSIS is making no additional changes to the regulations in response to comments. FSIS is removing the defibrination requirement from 9 CFR 310.20.

Specifically, FSIS is revising the codified regulations to remove the word "defibrinated". Under this final rule, official establishments will still have the option to defibrinate blood, provided they meet all other requirements in 9 CFR 310.20. The regulations will continue to prohibit the defibrination of blood by hand. The regulations will also continue to require the use of anticoagulants that meet cited requirements in title 9 and title 21 of the Code of Federal Regulations.

#### **Comments and Response**

*Comments:* FSIS received two comments on the proposed rule. The first, from an industry association, was in agreement with the Agency's reasons for proposing to eliminate the blood defibrination requirement, including the lack of a food-safety benefit from the requirement and the fact that coagulated blood is a key ingredient in certain ethnic cuisines.

The second comment, from an individual, supported the practice of saving undefibrinated livestock blood as an edible product. The comment also underscored the benefits from eliminating the unnecessary costs associated with the defibrination requirement. The commenter stated that although these costs, as calculated in the Agency's economic analysis, may seem minimal when viewing a single employee performing a

single defibrination task, they add up in the course of a year and when considering the number of establishments affected.

*Response:* FSIS agrees with the commenters and appreciates their support for this deregulatory action.

**Executive Orders (E.O.s) 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 final 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.

FSIS has updated the estimated benefits for this final rule from those published in the proposed rule based on more recent data. The changes include: a slight increase in the number of askFSIS questions and establishments; updated wage rates for production employees; and updated anti-coagulant solution costs.

*Baseline*

From October 2015 to December 2, 2020, FSIS received 16 askFSIS<sup>3</sup> questions about defibrination from 15 slaughter establishments. Therefore, FSIS assumes that at least 15 establishments will be affected by this final rule.

#### *Expected Costs of the Final Rule*

There are no expected costs associated with this final rule. FSIS will allow coagulated blood to be saved for edible purposes.

#### *Expected Benefits of the Final Rule*

This final rule will 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 final rule will 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 will allow establishments additional flexibility to be innovative and to operate in the most efficient manner.

Removing the regulatory requirement for establishments to defibrinate livestock blood is expected to result in industry cost savings. Establishments will reduce anti-coagulant solution costs and labor costs associated with defibrination.

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<sup>3</sup> 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 2, 2020.

According to 9 CFR 424.21, sodium citrate is a FSIS-approved anti-coagulant that can be used to defibrinate blood. FSIS estimates that the 2020 sodium citrate solution cost per gallon of blood is \$1.47<sup>4</sup>. Using askFSIS and Public Health Information System (PHIS)<sup>5</sup> data, FSIS determined that all 15 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 213<sup>6</sup> 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 establishments will save approximately \$1,096 per year, with a range of \$626<sup>7</sup> to \$1,566<sup>8</sup> if they no longer defibrinate blood.

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<sup>4</sup> 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 11/30/2020.

The average sodium citrate price per milliliter was \$0.08. This price was multiplied by the conversion rate of 3,785.412 ml per gallon to get the average sodium citrate price per gallon of \$292.11. 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 \$292.11 multiplied by .005 or \$1.47.

<sup>5</sup> 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 accessed on December 2, 2020.

<sup>6</sup> 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>.

<sup>7</sup> 426 gallons multiplied by \$1.47, the sodium citrate cost per gallon of blood, equals \$626. Costs are rounded to the nearest dollar.

<sup>8</sup> 1,065 gallons multiplied by \$1.47 equals \$1,566. Costs are rounded to the nearest dollar.

Establishments that process edible blood will also benefit from labor cost savings. FSIS experts estimate that it 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 is \$28.46<sup>9</sup> per hour or approximately \$0.50<sup>10</sup> per minute based on 2019 estimates from the Bureau of Labor Statistics. Each establishment will save approximately \$1,305 in labor costs per year<sup>11</sup>, with a range of \$426 to \$2,663 if they no longer defibrinate blood.

FSIS estimated that at least the 15 establishments that submitted askFSIS questions about defibrination from October 2015 to December 2, 2020 will benefit from the cost savings associated with this final rule. The total estimated annual industry cost savings are detailed in Table 1.

<b>Table 1. Industry Annual Cost Savings Estimates</b>			
	<b>Low</b>	<b>Medium</b>	<b>High</b>
Sodium Citrate Cost Savings/Year	\$9,390	\$16,440	\$23,490
Labor Cost Savings/Year	\$6,390	\$19,575	\$39,945
Total Cost Savings	\$15,780	\$36,015	\$63,435
Total Costs Savings annualized at a discount rate of 7% over 10 years.	\$15,780	\$36,015	\$63,435

<sup>9</sup> Wage estimate of \$14.23 obtained from the Bureau of Labor Statistics, May 2019 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 \$28.46 per hour.

<sup>10</sup> \$28.46 divided by 60 minutes equals \$0.4743 rounded to the nearest tenth of a cent to \$0.50.

<sup>11</sup> 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.



## **Regulatory Flexibility Act Assessment**

The FSIS Administrator has made a determination that this final rule will 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 will benefit from the cost savings associated with this final rule. However, the benefits to small and very small establishments, as indicated by the total savings estimates in Table 1 (\$15,780 to \$63,435 over 10 years), will not be significant. Of the 15 establishments that submitted askFSIS questions about defibrination from October 2015 to December 2, 2020, about 67 percent were classified as small, by Hazard Analysis and Critical Control Point (HACCP) size, and 33 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.

## **Paperwork Reduction Act**

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

## **Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs

designated this rule as not a "major rule," as defined by 5 U.S.C. 804(2).

### **Environmental Impacts**

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 final rule, which removes the defibrination requirement from 9 CFR 310.20, will not create any extraordinary circumstances that would result in this normally excluded action's 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(6) 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.

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#### **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: <https://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: <https://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**

### **9 CFR Part 310**

Meat and meat products, Blood.

For the reasons set forth in the preamble, FSIS amends 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

2. Revise § 310.20 to read as follows:

#### **§ 310.20 Saving of blood from livestock as an edible product**

Blood may be saved for edible purposes at official establishments provided it is derived from livestock, the carcasses of which are inspected and passed, and the blood is collected and handled in a manner so as not to render it adulterated under the Federal Meat Inspection Act and regulations issued pursuant thereto. The defibrination of blood intended for human food purposes shall not be done with the

hands. Anticoagulants may be used in accordance with 21 CFR chapter I, subchapter A and subchapter B, or by regulation in 9 CFR chapter III, subchapter A or subchapter E.

Done, at Washington, D.C.

**Paul Kiecker**  
*Administrator.*

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