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 August 23, 2021.

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 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 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.

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

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 askFSIS3 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.

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 $1.47.4 Using askFSIS and Public Health Information System (PHIS)5 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 2136 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 $6267 to $1,5668 if they no longer defibrinate blood.

Establishments that process edible blood will also benefit from labor cost savings. FSIS experts estimated 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 $28.469 per hour or approximately $0.5010 per minute based on 2019 estimates from the Bureau of Labor Statistics. Each establishment will save approximately $1,305 in labor costs per year,11 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.

### Table 1—Industry Annual Cost Savings Estimates

<table>
<thead>
<tr>
<th>Sodium Citrate Cost Savings/Year</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$9,390</td>
<td>$16,440</td>
<td>$23,490</td>
</tr>
</tbody>
</table>

3 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.

4 Sodium citrate prices were obtained from three laboratory websites, https://www.jarvet.com/, https://www.rpicorp.com/, https://www.tocris.com/. These websites were accessed on 11/30/2020.


7 $292.11 multiplied by .005 or $1.47.

8 1,065 gallons multiplied by $1.47 equals $1,566. Costs are rounded to the nearest dollar.


11 $28.46 divided by 60 minutes equals $0.4744 rounded to the nearest tenth of a cent to $0.47. 1.35 (2 + 5/2) minutes multiplied by the mid estimate of 3.5 ($28.46/60) 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.
TABLE 1—INDUSTRY ANNUAL COST SAVINGS ESTIMATES—Continued

<table>
<thead>
<tr>
<th>Low</th>
<th>Medium</th>
<th>High</th>
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<tbody>
<tr>
<td>Labor Cost Savings/Year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Cost Savings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Costs Savings annualized at a discount rate of 7% over 10 years</td>
<td>15,780</td>
<td>36,015</td>
</tr>
</tbody>
</table>

**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 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 determined that this final rule, which removes the defibrillation 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.

**USDA Non-Discrimination Statement**

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident. Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, and/or languages other than English) should contact the responsible Agency or USDA’s TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992.

Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: program.intake@usda.gov. USDA is an equal opportunity provider, employer, and lender.

**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 email 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 in 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:


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, DC.

Paul Kiecker
Administrator.

[FR Doc. 2021–13160 Filed 6–23–21; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Identification MCAL–2020–01213–T; Amendment 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This AD was prompted by reports indicating that the left- and right-hand elevator torque tube bearings were contaminated with sand and corrosion, restricting free rotation. This AD requires repetitive general visual inspections of the left- and right-hand elevator torque tube bearings for any sand, dust, or corrosion; repetitive functional tests of the elevator control system; and replacement of the elevator torque tube bearings if necessary. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 29, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of July 29, 2021.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H9S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email ac.yul@aero.bombardier.com; internet https://www.bombardier.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2021–0093.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2021–0093; or in person at Docket Operations between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email 9-avs-nyaco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2020–29, dated August 21, 2020 (referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. You may examine the MCAI in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2021–0093.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. The NPRM published in the Federal Register on February 24, 2021 (86 FR 11180). The NPRM was prompted by reports indicating that the left- and right-hand elevator torque tube bearings were contaminated with sand and corrosion, restricting free rotation. The NPRM proposed to require repetitive general visual inspections of the left- and right-hand elevator torque tube bearings for any sand, dust, or corrosion; repetitive functional tests of the elevator control system; and replacement of the elevator torque tube bearings if necessary. The FAA is issuing this AD to address sand contamination and corrosion of the elevator torque tube bearings, which could lead to binding or seizure of the bearings, and potentially lead to a reduction in or loss of airplane pitch control. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

• Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and

• Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information: