

# Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

## DEPARTMENT OF AGRICULTURE

### Federal Crop Insurance Corporation

#### 7 CFR Part 457

[Docket ID FCIC–21–0004]

RIN 0563–AC72

### Common Crop Insurance Regulations; Dry Pea Crop Insurance Provisions and Dry Beans Crop Insurance Provisions

**AGENCY:** Federal Crop Insurance Corporation, U.S. Department of Agriculture (USDA).

**ACTION:** Final rule with request for comments.

**SUMMARY:** The Federal Crop Insurance Corporation (FCIC) amends the Common Crop Insurance Regulations, Dry Bean Crop Insurance Provisions and Dry Pea Crop Insurance Provisions. For the Dry Bean Crop Insurance Provisions and Dry Pea Crop Insurance Provisions, the intended effect of this action is to allow enterprise and optional units by type, to clarify policy provisions, and for consistency with other crop provisions that offer coverage on both winter and spring-planted acreage of the crop. The changes will be effective for the 2022 and succeeding crop years.

**DATES:** *Effective date:* June 24, 2021.

*Comment date:* We will consider comments that we receive by the close of business August 23, 2021. FCIC may consider the comments received and may conduct additional rulemaking based on the comments.

**ADDRESSES:** We invite you to submit comments on this rule. You may submit comments by either of the following methods, although FCIC prefers that you submit comments electronically through the Federal eRulemaking Portal:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and search for Docket ID FCIC–21–0004. Follow the instructions for submitting comments.

- *Mail:* Director, Product Administration and Standards Division, Risk Management Agency (RMA), U.S. Department of Agriculture, P.O. Box 419205, Kansas City, MO 64133–6205. In your comment, specify docket ID FCIC–21–0004.

Comments will be available for viewing online at [www.regulations.gov](http://www.regulations.gov).

**FOR FURTHER INFORMATION CONTACT:** Francie Tolle; telephone (816) 926–7829; or email [Francie.Tolle@usda.gov](mailto:Francie.Tolle@usda.gov). Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 or 844–433–2774 (toll-free nationwide).

#### SUPPLEMENTARY INFORMATION:

##### Background

The FCIC serves America's agricultural producers through effective, market-based risk management tools to strengthen the economic stability of agricultural producers and rural communities. FCIC is committed to increasing the availability and effectiveness of Federal crop insurance as a risk management tool. Approved Insurance Providers (AIP) sell and service Federal crop insurance policies in every state through a public-private partnership. FCIC reinsures the AIPs who share the risks associated with catastrophic losses due to major weather events. FCIC's vision is to secure the future of agriculture by providing world class risk management tools to rural America.

FCIC amends the Common Crop Insurance Regulations by revising 7 CFR 457.140, Dry Pea Crop Insurance Provisions, and by revising 7 CFR 457.150, Dry Bean Crop Insurance Provisions, to be effective for the 2022 and succeeding crop years.

For both 7 CFR 457.140, Dry Pea Crop Insurance Provisions, and 7 CFR 457.150, Dry Bean Crop Insurance Provisions, FCIC is allowing separate enterprise units by type.

Crop insurance units are an identifiable, insurable segment of land on which an insurable crop is grown, and separate production records have been kept. Enterprise units are all insurable acreage of an insured crop in the county in which the insured has a share on the date coverage begins for the crop year. Allowing separate enterprise units allows producers to be indemnified separately by type. The

benefit for producers is that a gain on one type will not be offset by the loss on another type. Currently, optional units by type are available for all types listed in the actuarial documents.

If an insured elects enterprise units for these types, further division of enterprise units is not allowed. The insured may elect one enterprise unit for all types, or a combination of types (for example, under the Dry Peas Crop Provisions, the insured may elect an enterprise unit for spring and smooth green types and a separate enterprise unit for the Austrian type, or separate enterprise units for each). Additionally, the acreage must each separately qualify for enterprise units and will be subject to the current requirements in the Basic Provisions.

If an insured elects enterprise units for multiple types and does not qualify for separate enterprise units, there are options based on the timing of the discovery:

- If the insured elects separate enterprise units for multiple types and the AIP discovers the enterprise unit qualifications are not separately met for all types:

(1) On or before the acreage reporting date, the insured may elect:

(a) All types in which the insured elected an enterprise unit for meeting the requirements in section 34(a)(4) as separate enterprise units, and basic or optional units for any acreage that is not reported and insured as an enterprise unit, whichever the insured reports on the acreage report and for which the insured qualifies;

(b) One enterprise unit for all acreage of the crop in the county provided the insured meets the requirements in section 34(a)(4); or

(c) Basic or optional units for all acreage of the crop in the county, whichever the insured reports on the acreage report and for which the insured qualifies.

(2) After acreage reporting date, the insured may have one enterprise unit comprised of all acreage in the county of the crop provided the insured meets requirements in section 34(a)(4), or the AIP will assign a basic unit structure for all acreage of the crop in the county.

- If an insured elects an enterprise unit for only one type and the AIP discovers the enterprise unit qualifications are not met for that type:

(1) On or before the acreage reporting date, the insured's unit division for all

acreage of the crop in the county will be based on basic or optional units, whichever the insured reports on the acreage report and for which the insured qualifies; or

(2) After the acreage reporting date, the AIP will assign the basic unit structure for all acreage of the crop in the county.

FCIC is also revising the first sentence in redesignated paragraph (b) to eliminate the need to list all optional unit choices from the Basic Provisions. This allows the Dry Pea Crop Provisions and Dry Bean Crop Provisions to follow, without a new regulation, the Basic Provisions optional unit division language when and if those provisions in the Basic Provisions are updated.

FCIC is adding a new paragraph (c) to state that if types are only available by written agreement, separate enterprise units or optional units for those types are not available. This is consistent with enterprise unit and optional unit provisions in other Crop Provisions, such as Coarse Grains Crop Provisions.

Other changes specific to 7 CFR 457.140, Dry Pea Crop Insurance Provisions, are as follows:

1. Throughout the Crop Provisions, FCIC is removing the reference to United States Standards for Split Peas. The standards for Split Peas are used by processors but are not applicable to producers.

2. Section 1—FCIC is revising the definition of Local Market Price by removing the reference to United States Standards for Split Peas. Producers, grower groups, buyers, and GIPSA graders have stated that the Split Pea Standards only apply to processors and not to growers. Therefore, FCIC is removing the Split Pea references to reduce any potential confusion for growers.

3. Section 2—FCIC is designating the undesignated paragraph in section 2 as paragraph (b) and adding a new paragraph (a) to allow enterprise and optional units by type, regardless of whether the type is listed in the actuarial documents or the type is insured by written agreement.

4. Section 3—FCIC is revising paragraphs (c)(1) and (2) to replace the phrase “insured fall-planted dry pea acreage” with the phrase “insurable fall-planted dry pea acreage.” Paragraph (c) provides guidance regarding the date by which producers can make changes to their insurance coverage depending on the status of their fall-planted acreage. The provisions previously stated that if producers have “insured” fall-planted acreage, no changes can be made after the fall sales closing date. FCIC received input from insurance companies that

the phrase “insured fall planted acreage” implied that if producers planted fall-planted acreage but chose not insure it, then they would have until the spring sales closing date to make changes to the insurance coverage on the spring-planted acreage. That was not the intent of the provisions. All acreage of the crop in the county must be insured. If the producer plants fall-planted acreage and it meets the insurability requirements in section 6, then it must be insured. Therefore, FCIC is revising the language to indicate if producers planted “insurable” fall-planted acreage, then no changes may be made after the fall sales closing date.

Other changes to 7 CFR 457.150, Dry Bean Crop Insurance Provisions, are as follows:

1. Throughout the Crop Provisions, FCIC is removing the Basic Provisions section titles when the section number is a sufficient reference. This is consistent with changes being made in other Crop Provisions.

2. Section 1—FCIC is revising the definition of Type to allow enterprise and optional units for types insured by written agreement. Written agreements in this instance would allow producers to insure dry beans that would otherwise not be insurable based on an insurance offer unique to that producer. This change would address optional units (as well as enterprise units by type) when the producer has a written agreement providing coverage for a type not shown in the actuarial documents of the county in question. It also would give producers the same coverage available in the Dry Pea Crop Provisions and provide equitable treatment.

3. Section 2—FCIC is designating the undesignated paragraph in section 2 as paragraph (b) and adding a new paragraph (a) to allow enterprise and optional units by type, as described above.

#### **Effective Date, Notice and Comment, and Exemptions**

The Administrative Procedure Act (APA, 5 U.S.C. 553) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves specified actions, including matters relating to contracts. This rule governs contracts for crop insurance policies and therefore falls within that exemption.

This rule is exempt from the regulatory analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996.

For major rules, the Congressional Review Act requires a delay the

effective date of 60 days after publication to allow for Congressional review. This rule is not a major rule under the Congressional Review Act, as defined by 5 U.S.C. 804(2). Therefore, this final rule is effective on the date of publication in the **Federal Register**. Although not required by APA or any other law, FCIC has chosen to request comments on this rule.

#### **Executive Orders 12866 and 13563**

Executive Order 12866, “Regulatory Planning and Review,” and Executive Order 13563, “Improving Regulation and Regulatory Review,” 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). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The requirements in Executive Orders 12866 and 13563 for the analysis of costs and benefits apply to rules that are determined to be significant.

The Office of Management and Budget (OMB) designated this rule as not significant under Executive Order 12866, “Regulatory Planning and Review,” and therefore, OMB has not reviewed this rule and analysis of the costs and benefits is not required under either Executive Order 12866 or 13563.

#### **Clarity of the Regulation**

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on this rule, we invite your comments on how to make the rule easier to understand. For example:

- Are the requirements in the rule clearly stated? Are the scope and intent of the rule clear?
- Does the rule contain technical language or jargon that is not clear?
- Is the material logically organized?
- Would changing the grouping or order of sections or adding headings make the rule easier to understand?
- Could we improve clarity by adding tables, lists, or diagrams?
- Would more, but shorter, sections be better? Are there specific sections that are too long or confusing?
- What else could we do to make the rule easier to understand?

## Environmental Review

In general, the environmental impacts of rules are to be considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347) and the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508). FCIC conducts programs and activities that have been determined to have no individual or cumulative effect on the human environment. As specified in 7 CFR 1b.4, FCIC is categorically excluded from the preparation of an Environmental Analysis or Environmental Impact Statement unless the FCIC Manager (agency head) determines that an action may have a significant environmental effect. The FCIC Manager has determined this rule will not have a significant environmental effect. Therefore, FCIC will not prepare an environmental assessment or environmental impact statement for this action and this rule serves as documentation of the programmatic environmental compliance decision.

## Executive Order 12988

This rule has been reviewed under Executive Order 12988, “Civil Justice Reform.” This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. Before any judicial actions may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR part 11 are to be exhausted.

## Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

RMA has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that require Tribal consultation under E.O. 13175. The regulation changes do not have Tribal implications that

preempt Tribal law and are not expected have a substantial direct effect on one or more Indian Tribes. If a Tribe requests consultation, RMA will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified in this rule are not expressly mandated by Congress.

## The Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions of State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including cost benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of \$100 million or more in any 1 year for State, local or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined in Title II of UMRA, for State, local, and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

## Federal Assistance Program

The title and number of the Federal Domestic Assistance Program listed in the Catalog of Federal Domestic Assistance to which this rule applies is No. 10.450—Crop Insurance.

## Paperwork Reduction Act of 1995

In accordance with the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, subchapter I), the rule does not change the information collection approved by OMB under control numbers 0563–0053.

## USDA Non-Discrimination Policy

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(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 (for example, Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 or 844–433–2774 (toll-free nationwide). 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 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 mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: [OAC@usda.gov](mailto:OAC@usda.gov).

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## List of Subjects in 7 CFR Part 457

Acreage allotments, Crop insurance, Reporting and recordkeeping requirements.

## Final Rule

For the reasons discussed above, FCIC amends 7 CFR part 457 as follows:

## PART 457—COMMON CROP INSURANCE REGULATIONS

■ 1. The authority citation for 7 CFR part 457 continues to read as follows:

**Authority:** 7 U.S.C. 1506(l), 1506(o).

■ 2. Amend § 457.140 as follows:

■ a. In the introductory text, remove “2021” and add in its place “2022”;

■ b. In section 1, in the definition of “Local Market Price”, remove the term “Split Peas,”;

■ c. Revise section 2;

■ d. In section 3, in paragraphs (c)(1) and (2), remove the word “insured” and add in its place “insurable”; and

■ e. In section 13, in paragraph (e)(2)(i), remove the phrase “Split Peas,”.

The revision reads as follows:

### § 457.140 Dry pea crop insurance provisions.

\* \* \* \* \*

2. Unit Division.

(a) In addition to enterprise units provided in section 34(a) of the Basic

Provisions, you may elect separate enterprise units by type, as provided in this section, if allowed by the actuarial documents. If you elect enterprise units by type, you may not elect enterprise or optional units by irrigation practices.

(1) You may elect separate enterprise units by type unless otherwise specified in the Special Provisions. For example, if you have Spring Austrian Peas and Spring Desi Chickpea types, you may elect one enterprise unit for the Spring Austrian Peas type or one enterprise unit for the Spring Desi Chickpeas type, or separate enterprise units for both types. Any acreage which is not reported and insured as an enterprise unit will be insured as a basic unit or optional unit if requirements are met. For example, if you only have Spring Austrian Peas and Spring Desi Chickpea types, you may have an enterprise unit for the Spring Austrian Peas type acreage and basic or optional units for the Spring Desi Chickpeas type acreage.

(2) You must separately meet the requirements in section 34(a)(4) of the Basic Provisions for each enterprise unit.

(3) If you elected separate enterprise units for multiple types and we discover enterprise unit qualifications are not separately met for all types in which you elected enterprise unit and such discovery is made:

(i) On or before the acreage reporting date, you may elect to insure:

(A) All types in which you elected an enterprise unit for meeting the requirements in section 34(a)(4) as separate enterprise units, and basic or optional units for any acreage that is not reported and insured as enterprise unit, whichever you report on your acreage report and for which you qualify;

(B) One enterprise unit for all acreage of the crop in the county provided you meet the requirements in section 34(a)(4); or

(C) Basic or optional units for all acreage of the crop in the county, whichever you report on your acreage report and for which you qualify; or

(ii) At any time after the acreage reporting date, your unit structure will be one enterprise unit for all acreage of crop in the county provided you meet the requirements in section 34(a)(4). Otherwise, we will assign the basic unit structure for all acreage of crop in the county.

(4) If you elected an enterprise unit for only one type and we discover you do not qualify for an enterprise unit for that type and such discovery is made:

(i) On or before the acreage reporting date, your unit division for all acreage of the crop in the county will be based on basic or optional units, whichever

you report on your acreage report and for which you qualify; or

(ii) At any time after the acreage reporting date, we will assign the basic unit structure for all acreage of the crop in the county.

(b) In addition to, or instead of, establishing optional units as provided in section 34(c) in the Basic Provisions, separate optional units may be established for each dry pea type (designated in actuarial documents and including any type insured by written agreement).

(c) Enterprise and optional units by type may be further divided by acreage of contract seed types and dry pea types not grown under a processor/seed company contract even if they share a common variety provided each dry pea type is grown on separate acreage and the production is kept separate.

\* \* \* \* \*

■ 3. Amend § 457.150 as follows:

■ a. In the introductory text, remove “2017” and add “2022” in its place;

■ b. In section 1, in the definition of “Type”, add the phrase “or insured by written agreement” at the end of the definition;

■ c. Revise section 2;

■ d. In section 3, in paragraph (a), remove the phrase “(Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities)”;

■ e. In section 4, remove the phrase “(Contract Changes)”;

■ f. In section 5, remove the phrase “(Life of Policy, Cancellation, and Termination)”;

■ g. In section 6, remove the phrase “(Report of Acreage)”;

■ h. In section 7, in paragraph (a) introductory text:

■ i. Remove the phrase “(Insured Crop)”;

■ ii. Add a space between “Basic Provisions” and “(§ 457.8)”;

■ i. In section 8, introductory text, remove the phrase “(Insurable Acreage)”;

■ j. In section 9, introductory text, remove the phrase “(Insurance Period)”;

■ k. In section 10, introductory text, remove the phrase “(Causes of Loss)”;

■ l. In section 11:

■ i. In paragraph (a), remove the phrase “(Replanting Payment)”;

■ ii. In paragraph (d), remove the phrases “(Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities)” and “(Annual Premium)”;

■ m. In section 12, remove the phrase “(Duties in the Event of Damage or Loss)”.

The revision reads as follows:

**§ 457.150 Dry bean crop insurance provisions.**

\* \* \* \* \*

2. Unit Division.

(a) In addition to the definition of basic unit in section 1 of the Basic Provisions, all acreage of contract seed beans qualifies as a separate basic unit. For production based seed bean processor contracts, the basic unit will consist of all the acreage needed to produce the amount of production under contract, based on the actual production history of the acreage. For acreage based seed bean processor contracts, the basic unit will consist of all acreage specified in the contract.

(b) In addition to enterprise units provided in section 34(a) of the Basic Provisions, you may elect separate enterprise units by type, as provided in this section, if allowed by the actuarial documents. If you elect enterprise units by type, you may not elect enterprise or optional units by irrigation practices.

(1) You may elect separate enterprise units by type unless otherwise specified in the Special Provisions. For example, if you have Great Northern and Pinto types, you may elect one enterprise unit for the Great Northern type or one enterprise unit for the Pinto type, or separate enterprise units for both types. Any acreage which is not reported and insured as an enterprise unit will be insured as a basic unit or optional unit if requirements are met. For example, if you only have Great Northern and Pinto types, you may have an enterprise unit for the Great Northern type acreage and basic or optional units for the Pinto type acreage.

(2) You must separately meet the requirements in section 34(a)(4) of the Basic Provisions for each enterprise unit by type.

(3) If you elected separate enterprise units for multiple types and we discover enterprise unit qualifications are not separately met for all types in which you elected enterprise units and such discovery is made:

(i) On or before the acreage reporting date, you may elect to insure:

(A) All types in which elected an enterprise unit for meeting the requirements in section 34(a)(4) as separate enterprise units, and basic or optional units for any acreage that is not reported and insured as an enterprise unit, whichever you report on your acreage report and for which you qualify;

(B) One enterprise unit for all acreage of the crop in the county provided you meet the requirements in section 34(a)(4); or

(C) Basic or optional units for all acreage of the crop in the county,

whichever you report on your acreage report and for which you qualify; or

(ii) At any time after the acreage reporting date, your unit structure will be one enterprise unit for all acreage of the crop in the county provided you meet the requirements in section 34(a)(4). Otherwise, we will assign the basic unit structure for all acreage of the crop in the county.

(4) If you elected an enterprise unit for only one type and we discover you do not qualify for an enterprise unit for that type and such discovery is made:

(i) On or before the acreage reporting date, your unit division for all acreage of the crop in the county will be based on basic or optional units, whichever you report on your acreage report and for which you qualify; or

(ii) At any time after the acreage reporting date, we will assign the basic unit structure for all acreage of the crop in the county.

(c) In addition to, or instead of, establishing optional units as provided in section 34(c) in the Basic Provisions, a separate optional unit may be established for each bean type (designated in actuarial documents and including any type insured by written agreement).

(d) Enterprise and optional units by type may be further divided by acreage of contract seed beans if the seed bean processor contract specifies the number of acres under contract. Contract seed beans produced under a seed bean processor contract that specifies only an amount of production or a combination of acreage and production, are not eligible for separate enterprise or optional units.

\* \* \* \* \*

**Richard Flournoy,**

*Acting Manager, Federal Crop Insurance Corporation.*

[FR Doc. 2021-13115 Filed 6-23-21; 8:45 am]

**BILLING CODE 3410-08-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:** 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 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.<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**

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

<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.