



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Chapter III

[Docket No. FSIS-2026-0001]

RIN 0583-AE09

Revising Establishment Size Definitions

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: FSIS is considering revising how it defines establishment sizes for purposes of its oversight of meat and poultry establishments and egg products plants. Since 1996, FSIS has used Hazard Analysis and Critical Control Point (HACCP) size categories, which are based on employee count and annual sales, to analyze the impact of regulations and tailor assistance to small entities. More recently, FSIS has also applied volume-based thresholds to categorize establishments to analyze the impact of regulations and for establishing Agency sampling frequencies or setting sampling requirements for the regulated industry. This advance notice of proposed rulemaking (ANPR) requests stakeholder input on whether FSIS should update its establishment size definitions and, if so, how.

DATES: Submit comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: FSIS invites interested persons to submit comments on this document.

Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website 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

<https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail*: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals*: Deliver to 1400 Independence Avenue SW, Jamie L Whitten Building, Room 350-E, Washington, DC 20250–3700. Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2026-0001.

Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 286-2255 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: April Regonlinski, Assistant Administrator for the Office of Policy and Program Development, at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

I. Background

FSIS is the public health agency within the USDA responsible for providing inspection of establishments producing meat, poultry, and egg products and verifying that these products are safe, wholesome, and properly labeled and packaged. FSIS carries out this mission under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*), which authorize the Secretary to make rules and regulations necessary for their efficient execution (21 U.S.C. 621, 463(b), and 1043).

FSIS is subject to the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601-612), which requires federal agencies to consider the economic impact of regulatory proposals on small businesses and consider less burdensome alternatives. FSIS must also comply with the

Small Business Regulatory Enforcement Fairness Act of 1996,¹ which requires agencies to publish Small Entity Compliance Guides for any final rule classified as “major” that is expected to significantly affect a substantial number of small businesses.

To meet the RFA requirements, FSIS has historically categorized establishments by HACCP size or production volume for regulatory analysis and to tailor assistance for small and very small establishments. Since 1996, FSIS has classified establishments as very small (fewer than 10 employees or annual sales under \$2.5 million), small (10–499 employees), or large (500 or more employees) under definitions established in the Pathogen Reduction/HACCP Systems final rule (61 FR 38806, July 25, 1996). These size definitions are applied to individual establishments and do not account for whether the establishment is part of a larger corporate structure. As of December 2025, there are 2,961 very small, 2,847 small, and 508 large FSIS regulated establishments.²

FSIS has used HACCP size categories to phase in requirements, such as notification and documentation for adulterated or misbranded product (77 FR 26929, May 8, 2012) and the regulations that prescribe procedures for controlling contamination throughout the slaughter and dressing process in 9 CFR 310.18(c) and recordkeeping requirements in 9 CFR 310.18(d) (84 FR52300, October 1, 2019). FSIS also used these categories to determine eligibility for reduced inspection fees (86 FR 37276, July 15, 2021). However, for reduced fees eligibility, FSIS applied the terms “small” and “very small” only to establishments unaffiliated with multiple or large businesses in a way that would effectively place them within the large establishment definition (86 FR 37276, 37277).

FSIS has also relied on various production volume thresholds. For example, the Nutrition Labeling of Meat and Poultry Products final rule included a phased implementation based on

¹ Pub. L. 104–121, title II, §§201–224, Mar. 29, 1996, 110 Stat. 857–862, as amended by Pub. L. 110–28, title VIII, §8302, May 25, 2007, 121 Stat. 204.

² USDA/FSIS, Meat, Poultry and Egg Product Inspection Directory, <https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory>.

annual production volume and the number of employees (58 FR 632, January 6, 1993). 9 CFR 317.400 and 381.500 also exempt small businesses from nutrition labeling of certain meat and poultry products based on annual production volume and the number of employees. In addition, FSIS exempts low-volume establishments, defined as producing an average of 1 to 1,000 pounds per day, from FSIS *Salmonella* sampling for certain raw pork products. FSIS also bases certain requirements on production volume. For example, FSIS requires different establishment sampling frequencies for very low-volume poultry establishments operating under Traditional Inspection (9 CFR 381.65(g)(2)) and very low-volume swine slaughter establishments (9 CFR 310.18(c)(2)).

FSIS has explored other ways to group establishments. In the Meat, Poultry, and Egg Product Inspection Directory Establishment Demographic Data supplemental dataset,³ which provides additional information about FSIS establishments, (e.g., establishment size, species slaughtered, and aggregate categorical production information), FSIS grouped establishments that produce processed products into five categories based on aggregated volume of all processed products estimated as total pounds per month. These categories are numbered 1-5 and are separated based on production volume. Category 1 is less than 10,000 lbs; Category 2 is greater than or equal to 10,000 lbs and less than 100,000 lbs; Category 3 is greater than or equal to 100,000 lbs and less than 1,000,000 lbs; Category 4 is greater than or equal to 1,000,000 lbs to 10,000,000 lbs; and Category 5 is greater than or equal to 10,000,000 lbs. Similarly, FSIS grouped slaughter establishments into five categories based on aggregated head slaughtered for the last 360 days using head counts. Category 1 is less than 1,000 head slaughtered; Category 2 is greater than or equal to 1,000 and less than 10,000; Category 3 is greater than or equal to 10,000 and less than 100,000; Category 4 is greater than or equal to 100,000 and less than 10,000,000; and Category 5 is greater than or equal to 10,000,000 head slaughtered. These

³ Dataset: Establishment Demographic Data, available at: <https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory>.

categorizations are publicly posted on the Meat, Poultry and Egg Product Inspection (MPI) Directory⁴.

II. National Advisory Committee on Meat and Poultry Inspection (NACMPI) Meeting and Recommendations

In September 2024, FSIS brought the issue of establishment size classification to NACMPI (89 FR 66669, August 16, 2024). The Agency asked the committee to review and advise FSIS on whether the Agency should change its definitions for establishment size categories (i.e., large, small, and very small)⁵ to better assess and describe current business operations as well as better determine the impact of FSIS policies on different size establishments.⁶

During the public meeting held on September 16–17, 2024, NACMPI members discussed how FSIS defines very small, small, and large establishments.⁷ They noted that the current definitions group together businesses that operate at very different scales. For example, an establishment with 11 employees and one with 499 employees are both considered “small,” even though their resources and production capacity may be vastly different. The committee also raised concerns about establishments that are classified as small but are owned by large firms, which may give them access to more support and funding than truly independent small businesses.

⁴ See FSIS Establishment Slaughter/Processing Data – MPI Supplement – Data Documentation, pg 3, available at https://www.fsis.usda.gov/sites/default/files/media_file/documents/Data-Documentation-MPI-Directory-Establishment-Demographic-Documentation.pdf.

⁵ Large establishments have 500 or more employees; small establishments have 10 or more employees, but fewer than 500; and very small establishments have fewer than 10 employees or annual sales of less than \$2.5 million.

⁶ Specifically, the Agency asked the committee to consider the following questions:

1) FSIS uses multiple size categories. Any concerns with continuing with that approach?; 2) What metric should FSIS use to define size categories for regulated establishments?; 3) How should FSIS account for establishment ownership when developing size categories?; 4) What size standards are commonly used within the industry for defining small and very small?; 5) Are there other applications for the current FSIS HACCP sizes outside of FSIS, such as within the industry? Are there repercussions outside of FSIS if establishment size classifications are changed?; 6) How should FSIS obtain data to determine if the establishment is a small entity under the Small Business Administration’s size definitions?; and 7) Are there sources of data, besides PHIS, that FSIS can use to better identify establishment size and ownership structures?

⁷ September 2024 NACMPI meeting transcript available at:

https://www.fsis.usda.gov/sites/default/files/media_file/documents/NACMPI_Plenary_Meeting_9-16-24_Transcript.pdf.

In its meeting report on the establishment size questions,⁸ NACMPI recommended that FSIS continue to use multiple establishment size classifications but also recommended that the Agency consider using two separate metrics to define establishment size. According to NACMPI, the primary metric should focus on production volume, which could help FSIS establish and implement regulatory requirements more effectively. The second metric should focus on business size (e.g., employee count, annual revenue, and corporate association), which could be used for purposes such as determining eligibility for grants and other support programs. The committee suggested that FSIS apply both metrics to every establishment, so that FSIS would categorize establishments based on product volume and based on business size. The committee also recommended that, when determining an establishment's eligibility for federal services and programs administered by other agencies (e.g., Agricultural Marketing Service (AMS) commodity contracts or other USDA assistance), FSIS or the applicable agency should consider whether a small or very small establishment receives significant support from a larger firm, such as an owner company. The committee further recommended that FSIS create a cross-disciplinary working group of legal and financial experts to advise on new establishment size categories, consider requiring the disclosure of corporate ownership structure information on all grant applications for federal services and programs, including grants of inspection, and conduct federal agency and stakeholder outreach to ensure any changes are clearly communicated and consistently applied.

NACMPI also addressed the potential alignment of FSIS size classifications with Small Business Administration (SBA) standards. SBA establishes size standards that are used by other agencies to determine which businesses qualify for federal assistance, including grants, loans, and contracts (see 13 CFR part 121). Currently, SBA uses the number of employees a firm has to

⁸ September 2024 NACMPI committee report available at: <https://www.fsis.usda.gov/news-events/publications/2024-nacmpi-reports>.

define small businesses in the North American Industry Classification System (NAICS) categories relevant to FSIS-regulated industries:⁹

- NAICS 311615 – Poultry Processing: 1,250 or fewer employees
- NAICS 311611 – Animal (except Poultry) Slaughtering: 1,150 or fewer employees
- NAICS 311612 – Meat Processed from Carcasses: 1,000 or fewer employees
- NAICS 311710 – Seafood Product Preparation and Packing: 750 or fewer employees
- NAICS 311999 – All Other Miscellaneous Food Manufacturing (includes egg processors): 700 or fewer employees.

The committee discouraged FSIS from adopting SBA standards, expressing concern that certain establishments might gain unfair advantages if FSIS were to apply SBA standards. Specifically, NACMPI was wary of exclusively using employee count or revenue to define establishment sizes, arguing that these metrics may not accurately reflect operational scale or ownership structures. Through this ANPR, FSIS is seeking broader stakeholder input to better understand the range of perspectives on how establishment sizes should be defined.

III. Requests for Comments and Data

FSIS is seeking public input to help inform potential changes to how the Agency defines establishment sizes to better reflect how establishments operate and are structured. FSIS invites comments on the following questions. Please explain your reasoning and include any supporting data, studies, or examples. To help FSIS review comments efficiently, please identify the question to which you are responding by its associated number and letter (e.g., “2”) or whether you are commenting on a topic not listed below.

1. How are establishments economically impacted by their current HACCP size determination?
2. How would a change in HACCP size classifications, or the implementation of a new classification system, impact an establishment?

⁹ [United States Small Business Administration \(SBA\), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective January 1, 2022. Available at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.](https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf)

3. What impact would there be on establishment if FSIS aligns its size classifications with the current SBA standards?
4. What factors should FSIS consider when determining whether size categories apply at the individual establishment level or the corporate ownership level?
5. Should FSIS create additional size categories? If so, how should additional size categories be defined and for what purposes?
 - a. What impact would it have on establishments if FSIS created additional size categories based on production and slaughter volume and product classification (e.g., HACCP category or slaughter class)? For example, FSIS currently categorizes establishments into five categories based on processing or slaughter volume in the MPI Directory (see above).
 - b. What impact would it have on establishments if FSIS established size categories for processing based on product characteristics other than HACCP category—for example, packaging type, intended use, target customer, or specific attributes such as Ready-to-Eat products that are post-lethality exposed?
 - c. What impact would it have on establishments if FSIS created additional size categories based on business size (e.g., employee count, annual revenue, or corporate association)? If company structure (e.g. corporate association, partnership, co-op, etc.) is taken into consideration, how should it be considered?
 - d. What single variable or combination of variables should FSIS consider in additional size categories (e.g., shift, operating days, type of products, slaughter class, building square footage)?
6. How do other organizations (e.g. Federal Agencies, state and local governments, businesses, or consumer groups) use FSIS HACCP size determinations?
7. What would be the least burdensome way for FSIS to collect and maintain records on establishment size?

- a. How often should FSIS verify updates (e.g., quarterly or annually)?
 - b. How should the information be collected (e.g., self-reported or collected by an inspector)?
 - c. How should FSIS verify accuracy of the information provided?
8. How do various size metrics and categories impact industry, consumers, and other government entities, particularly regarding: (a) Data sources that FSIS can use to better identify establishment size (b) Data on corporate ownership of FSIS inspected establishments and (c) Potential industry costs or benefits by aligning the HACCP size classifications with the SBA size classifications?

IV. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and 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, 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.

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To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at [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, Mail Stop 9410, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov.

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V. 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: <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.

Jeremy T. Reed,

Chief Operating Officer.

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