Rules and Regulations

Federal Register
Vol. 90, No. 121
Thursday, June 26, 2025

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318, 325, 331, 351, 381, 560

[Docket No. FSIS–2025–0014]

RIN 0583–AE03

Publication Method of Lists of States With and Without State Meat or Poultry Inspection Programs

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

ACTION: Final rule.

SUMMARY: FSIS is amending the Federal meat and poultry products inspection regulations to remove its lists of states that do not operate their own meat or poultry inspection (MPI) programs that are ''at least equal to'' FSIS' Federal inspection programs and have therefore been designated for FSIS' Federal inspection. FSIS is also amending the regulations to remove or revise related cross references to the lists. Going forward, FSIS will maintain lists of states with and without MPI programs on its website to ensure that the public has accurate and timely access to information about State and Federal inspection programs.

DATES: The final rule is effective on June 26, 2025.

FOR FURTHER INFORMATION CONTACT: Denise Eblen, Acting Deputy Under Secretary for the Office of Food Safety, at (202) 205–0495 or *docketclerk@usda.gov* with a subject line of ''Docket No. FSIS 2025–0014.'' Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS has the authority to designate states that do not maintain MPI programs ''at least equal to'' FSIS' Federal inspection programs (21 U.S.C. 645, 661(c), 454(c), 460(e)) and to recognize those that do (21 U.S.C. 661(a), 454(a)). FSIS has historically codified its list of states without MPI programs in 9 CFR 331.2, 331.6, 381.221, and 381.224.

FSIS is removing these lists from its regulations and will instead maintain up-to-date lists on the FSIS website at *www.fsis.usda.gov.* FSIS is also removing or revising related cross references to the lists of designated states without MPI programs. These changes will improve transparency, accuracy, and ease of access for stakeholders.

This rule is solely an administrative change to the format and location of the lists of designated states without MPI programs. This action will not change FSIS' criteria for approving state MPI programs. FSIS will continue to review state MPI programs to verify that they are ''at least equal to'' FSIS' Federal inspection. Because FSIS is not required to do so, it will not publish a notice in the **Federal Register** if it terminates a designation and approves a new state MPI program. Additionally, this action will not change FSIS' process for terminating state MPI programs. FSIS will publish a notice in the **Federal Register** if it designates or redesignates a state under 21 U.S.C. 661(c) or 454(c).

This rule is not subject to the Administrative Procedure Act (APA) requirement to publish a notice of proposed rulemaking and provide the public with the opportunity to comment before issuing a final rule because this action falls under the exceptions outlined in 5 U.S.C. 553 (A) and (B). Specifically, the APA exempts rules related to agency procedure or practice, or when the agency for good cause finds that notice and comment is impracticable, unnecessary, or contrary to the public interest. Since the removal of FSIS' lists of States without MPI programs and the decision to maintain them on the FSIS website is an administrative update that does not alter the substantive rights or duties of stakeholders, it qualifies for these exemptions. This rule will streamline information dissemination and improve accessibility without impacting FSIS' regulatory framework or regulated entities' responsibilities.

Executive Orders (E.O.s) 12866, 13563, 14215, and 14192

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will determine whether a regulatory action is significant as defined by E.O. 12866 and will review significant regulatory actions. OIRA has determined that this final rule is not significant as defined by E.O. 12866. E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 14215 amends E.O. 12866 to ensure Presidential supervision and control of the entire executive branch and to require that all executive departments and agencies submit for review all proposed and final significant regulatory actions to OIRA before publication in the **Federal Register**. The Department has developed the final rule consistent with E.O. 13563 and E.O. 14215.

This final rule is considered an E.O. 14192 deregulatory action.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), OIRA has designated this final rule as not a major rule as defined by 5 U.S.C. 804(2).

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required, however, if the head of an

agency or an appropriate designee certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because this rule is an administrative change, FSIS has concluded and hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included.

Executive Order 13175

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. FSIS has assessed the impact of this rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under Executive Order 13175.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), FSIS has reviewed the final rule. The Administrator has determined that this rulemaking would not impact information collection, paperwork, or recordkeeping activities.

E-Government Act Compliance

The Department is committed to complying with the E-Government Act, 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

E.O. 13132; Federalism Summary Impact Statement

The final rule is an administrative change that will have no effect on States and local governments, so FSIS anticipates that this rule will not have implications for federalism. FSIS will maintain lists of states with and without MPI programs on its website to ensure accurate and timely access to information about State and Federal inspection programs. Therefore, under Section 6(b) of the E.O., a federalism summary is not required.

Environmental Impact

This final rule will not have a reasonably foreseeable significant effect on the quality of the human environment. The rule is an administrative change that merely updates how FSIS communicates information about state and Federal inspection programs to the public. Accordingly, this action is appropriately subject to the categorical exclusion from the preparation of an Environmental Assessment or an Environmental Impact Statement as authorized under 7 CFR 1b.3(a)(1) of the USDA regulations.

Lists of Subjects

9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 325

Meat inspection, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 331

Intergovernmental relations, Meat inspection.

9 CFR Part 351

Administrative practice and procedure, Exports, Meat inspection, Oils and fats, Reporting and recordkeeping requirements.

9 CFR Part 381

Meat inspection, Poultry and poultry products.

9 CFR Part 560

Fish, Food grades and standards, Intergovernmental relations, Seafood.

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 318.1 [Amended]

■ 2. In § 318.1, paragraph (h)(2) is amended by removing the phrase ''in § 331.2 of this subchapter'' and adding in its place ''under section 301(c) of the Act.''

PART 325—TRANSPORTATION

■ 3. The authority citation for part 325 continues to read as follows:

Authority: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 325.1 [Amended]

■ 4. In § 325.1, paragraph (c) is amended by removing the phrase ''under § 331.2 of this subchapter'' and adding in its place ''under section 301(c) of the Act.''

§ 325.11 [Amended]

■ 5. In § 325.11, paragraph (e) is amended by removing the phrase ''listed in § 331.2 of this subchapter'' and adding in its place ''designated under section 301(c) of the Act.''

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

■ 6. The authority citation for part 331 continues to read as follows:

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

§ 331.2 [Removed and reserved]

■ 7. Section 331.2 is removed and reserved.

§ 331.3 [Amended]

■ 8. Amend § 331.3 by:
■ a. In the introductory text removing the phrase ''in § 331.2.''
■ b. In paragraph (f) removing the phrase ''as shown in § 331.6.''

§ 331.6 [Removed and reserved]

■ 9. Section 331.6 is removed and reserved.

PART 351—CERTIFICATION OF TECHNICAL ANIMAL FATS FOR EXPORT

■ 10. The authority citation for part 351 continues to read as follows:

Authority: 7 U.S.C. 1622, 1624; 7 CFR 2.17(g) and (i), 2.55.

§ 351.2 [Amended]

■ 11. In § 351.2, paragraph (g) is amended by removing the phrase ''in § 331.2 of this chapter'' and adding in its place ''under section 301(c) of the Act.''

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 12. The authority for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 1633; 21 U.S.C. 451–472; 7 CFR 2.7, 2.18, 2.53.

§ 381.6 [Amended]

■ 13. In § 381.6, paragraph (b) is amended by removing the phrase ''in § 381.221.''

§ 381.10 [Amended]

■ 14. In § 381.10, paragraph (d)(3) is amended by removing the phrase ''designated State or organized territory listed in § 381.221 that is also identified in § 381.224'' and adding in its place ''State or organized territory designated under both sections 5(c) and 11 of the Act.''

§ 381.145 [Amended]

■ 15. In § 381.145, paragraph (a) is amended by removing the phrase ''in § 331.2 of this chapter'' and adding in its place ''under section 301(c) of the Act.''

§ 381.221 [Removed and reserved]

■ 16. Section 381.221 is removed and reserved.

§ 381.222 [Amended]

■ 17. Amend § 381.222 by:

■ a. In the introductory text removing the phrase ''in § 381.221.''

■ b. In paragraph (e) removing the phrase ''as shown in § 381.224.''

§ 381.224 [Removed and reserved]

■ 18. Section 381.224 is removed and reserved.

§ 381.225 [Amended]

■ 19. In § 381.225, paragraph (a) introductory text is amended by removing the phrase ''listed in § 381.221'' and adding in its place ''designated under section 5(c) of the Act.''

PART 560—STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS

■ 20. The authority for part 560 continues to read as follows:

Authority: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 560.4 [Amended]

■ 21. Amend § 560.4 by:

■ a. In the introductory text

■ i. Removing the phrase ''requirements in part 331 of this chapter'' and adding in its place ''following requirements.''

■ ii. Removing '', including.''

■ b. In paragraph (c) removing the phrase ''in 9 CFR 331.6.''

Done at Washington, DC.

Denise Eblen,

Acting Deputy Under Secretary for the Office of Food Safety.

[FR Doc. 2025–11816 Filed 6–25–25; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2025–N–1245]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Muscular Dystrophy Newborn Screening Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the muscular dystrophy newborn screening test into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the muscular dystrophy newborn screening test's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 26, 2025. The classification was applicable on December 12, 2019.

FOR FURTHER INFORMATION CONTACT: Irene Tebbs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3526, Silver Spring, MD 20993–0002, 240–402–0283, *Irene.Tebbs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the muscular dystrophy newborn screening test as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to