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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. **FSIS-2022-0015**]

Availability of Guideline for Label Approval

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

ACTION: Notice of availability and response to comments.

SUMMARY: On March 18, 2024, FSIS published a label approval guideline to help establishments meet new requirements for use of voluntary U.S.-origin label claims on FSIS-regulated products established by the final rule, *Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims* (89 FR 19470, March 18, 2024). FSIS is announcing updates to this guideline and responding to comments received on the guideline.

ADDRESS: A downloadable version of the guideline is available to view and print at: <https://www.fsis.usda.gov/policy/fsis-guidelines>.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled. The Agency administers a regulatory program for meat products under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), for poultry products under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and for egg products under the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). FSIS also provides voluntary reimbursable inspection services under the Agricultural Marketing Act (AMA) (7 U.S.C. 1622 and 1624) for eligible products not requiring mandatory inspection under the FMIA, PPIA, and EPIA.

Under the FMIA, PPIA, and EPIA, any meat, poultry, or egg product is misbranded if its labeling is false or misleading (21 U.S.C. 601(n)(1); 21 U.S.C. 453(h)(1); 21 U.S.C. 1036(b)). In particular, no product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling; and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling (9 CFR 317.8(a), 381.129(b), 590.411(f)(1)). FSIS has similar authority under the AMA concerning the false or misleading labeling of products receiving voluntary inspection services (7 U.S.C. 1622(h)(1)).

On March 18, 2024, FSIS published the final rule, *Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin*

Claims (89 FR 19470). The final rule amended FSIS labeling regulations to allow two specific voluntary U.S.-origin label claims, "Product of USA" and "Made in the USA," to be generically approved¹ for use on single ingredient FSIS-regulated products (i.e., products produced under FSIS mandatory or voluntary inspection services) derived from animals born, raised, slaughtered, and processed in the United States. Under the final rule, the two voluntary label claims "Product of USA" and "Made in the USA" are also generically approved for use on multi-ingredient FSIS-regulated products if: (1) All FSIS-regulated products in the multi-ingredient product are derived from animals born, raised, slaughtered, and processed in the United States; (2) all other ingredients, other than spices and flavorings, are of domestic origin; and (3) the preparation and processing steps for the multi-ingredient product have occurred in the United States. Also under the final rule, label claims other than "Product of USA" or "Made in the USA" that indicate that a preparation or processing step of an FSIS-regulated product is of U.S. origin are generically approved for use, but such claims will need to include the preparation and processing steps that occurred in the United States upon which the claim is made.²

¹ Labels that are generically approved under FSIS regulations may be used in commerce without prior submission to the Agency for approval. Products must bear all required labeling features and comply with the Agency's labeling regulations to be eligible for generic approval (9 CFR 412.2).

² The final rule applies to products sold in the domestic market. For products exported from the United States, FSIS will continue to verify that labeling requirements for the applicable country are met, as shown in the FSIS Export Library, available at: <https://www.fsis.usda.gov/inspection/import-export/import-export-library>.

On March 18, 2024, FSIS also announced the availability of the revised *FSIS Guideline on Label Approval* (89 FR 19470). FSIS published the revised guideline to help establishments meet the new requirements for use of voluntary U.S.-origin label claims on FSIS-regulated products and to provide examples of claims and the types of documentation that establishments may maintain to support use of the claims. FSIS requested comments on the guideline, and the Agency received three comments within the scope of the guideline updates during the 60-day comment period. On April 30 and May 15, 2024, FSIS hosted public webinars to provide an overview of the final rule and information about related labeling guidance.³ During the webinars, FSIS received several participant comments on the guideline. Since publication of the final rule, FSIS also has received several questions about the guideline through askFSIS, the Agency's Web-based and telephone-based application for addressing technical and policy-related questions.⁴

After review and consideration of all comments, FSIS has made changes to the guideline to clarify and update information on the use of voluntary U.S.-origin label claims. These changes to the guideline are summarized below and are discussed in more detail in FSIS' responses to comments. The revised guideline is available at the FSIS guideline webpage at:

<https://www.fsis.usda.gov/policy/fsis-guidelines>. Although

³ Webinar recordings and FSIS presentation materials are available at: <https://www.fsis.usda.gov/news-events/events-meetings/voluntary-labeling-fsis-regulated-products-u-s--origin-claims>.

⁴ <https://www.fsis.usda.gov/contact-us/askfsis>.

comments will no longer be accepted on this guideline through www.regulations.gov, FSIS will update the document as necessary if new information becomes available.

Summary of Changes to the Guideline

For purposes of voluntary U.S.-origin label claims under FSIS regulations,

- FSIS is clarifying that the meaning of "raised" is "from birth to slaughter."
- FSIS is clarifying that the term "harvested" may be used to mean "slaughtered."
- FSIS is clarifying that for purposes of meeting the requirements for use of the voluntary U.S.-origin label claims "Product of USA" or "Made in the USA" on multi-ingredient products, the requirement that "all other ingredients other than spices and flavorings" in the product must be of domestic origin does not include sub-ingredients of an ingredient (e.g., the soybean or wheat sub-ingredient in a soy sauce ingredient).
- FSIS is clarifying the definitions of "spices" and "flavorings."
- FSIS is clarifying that multi-ingredient products made with edible natural casings that are processed (e.g., cleaned) outside the United States are eligible for use of the voluntary U.S.-origin label claims "Product of USA" or "Made in the USA," provided that the product meets all other requirements under the rule.

- FSIS is clarifying that "Product of North America" is allowed as a voluntary label claim on products if the claim is truthful and not misleading and complies with the FSIS requirements in 9 CFR 317.8(b)(1) and 9 CFR 381.129(b)(2) for use of label terms having geographical significance (i.e., the animal from which the product was derived was born, raised, slaughtered, and processed in North America).
- FSIS is clarifying that a voluntary multi-country origin label claim that includes the United States and a foreign country (e.g., "Product of USA and Canada") is allowed on products, provided 1) the animal from which the product was derived was born, raised, slaughtered, and processed in either the United States or the listed foreign country; 2) in the case of a multi-ingredient product, all other ingredients (other than spices and flavorings) are of the origin of either the United States or the listed foreign country; and 3) the claim is accompanied by qualifying language describing the preparation and processing steps that occurred in the United States (e.g., "Product of USA and Canada, Packaged in the USA").
- FSIS is clarifying that, as with the claims "processed" and "manufactured," the term "produced" may not be used as a stand-alone label claim to describe the preparation and processing steps of a product that occurred in the

United States, as this term does not provide meaningful consumer information about the actual preparation and processing steps of the product that occurred in the United States.

- FSIS is providing additional examples of voluntary U.S.-origin label claims that may be used to describe the preparation and processing steps of a product that occurred in the United States (e.g., "Cooked in the U.S.A.").
- FSIS is clarifying the final rule's effect on the label display of certain U.S. State endorsement program logos.
- FSIS is clarifying that, under the final rule at the amended subsections 9 CFR 317.8(b)(1) and 9 CFR 381.129(b)(2), statements, words, pictures, designs, or devices depicting the United States, or a U.S. State or territory, may be used on the labels of products without a qualifying statement only if the animal from which the meat or poultry product was derived was born, raised, slaughtered, and processed in the United States, or U.S. State or territory. If the product does not meet these requirements, the depiction must be accompanied by a qualifying statement.
- FSIS is providing additional examples of the types of documentation that may be maintained to support a voluntary U.S.-origin label claim.

- FSIS is making a few editorial changes throughout the guideline for readability and clarity.

Summary of Comments and FSIS Responses

During the comment period for the guideline announced in the **Federal Register**, FSIS received three comments on the updated label approval guideline from one U.S. trade association representing the meat industry, one foreign trade association representing the meat industry, and one foreign country. Other comments were outside the scope of the updated guideline and discussed general opposition to the final rule by restating specific concerns included in the comments they submitted in response to the proposed rule. FSIS is not addressing those comments here. After the end of the comment period, FSIS also received from the public several askFSIS questions on the updated guideline. Finally, FSIS received several participant questions during the Agency's April and May 2024 public webinars on the final rule and updated label guideline.⁵ A summary of the relevant issues raised by these comments and questions and the Agency's responses follows.

Definition of "Raised"

Comment: One foreign country and a few askFSIS submitters asked FSIS to clarify the definition of "raised" under the final rule for the purposes of determining whether an animal from

⁵ Webinar recordings and FSIS staff presentation materials are available at: <https://www.fsis.usda.gov/news-events/events-meetings/voluntary-labeling-fsis-regulated-products-u-s--origin-claims>.

which an FSIS-regulated product was derived was "raised" in the United States.

Response: FSIS has updated the guideline to clarify that "raised" means "raised from birth to slaughter" for the purposes of meeting the requirement for use of the voluntary U.S.-origin label claims "Product of USA" and "Made in the USA" under 9 CFR 412.3(a) and (b). Therefore, a claim of "raised" or "born and raised" is allowed under 9 CFR 412.3(c) as a voluntary U.S.-origin label claim other than "Product of USA" and "Made in the USA" when the animal from which the product was derived was raised in the United States for the entirety of its life (i.e., from birth to slaughter). When the animal was raised in the United States for a period less than from birth to slaughter, the claim must be accompanied by a truthful description of the length of time the animal was raised in the United States (e.g., the label claim "raised for at least 30 days in the USA" on a single ingredient beef chuck roast.)

Use of "Harvested" to Mean "Slaughtered"

Comment: A few askFSIS submitters asked whether FSIS will accept use of the term "harvested" to mean "slaughtered" to describe the preparation and processing steps of an FSIS-regulated product to accompany voluntary U.S.-origin label claims.

Response: FSIS has updated the guideline to clarify that the term "harvested" may be used to mean "slaughtered" for the

purposes of meeting the requirements for use of voluntary U.S.-origin label claims.

Domestic Sourcing of Sub-Ingredients

Comment: A few askFSIS submitters asked whether the sub-ingredients of ingredients in FSIS-regulated multi-ingredient products must be of domestic origin for such products to be eligible for the voluntary U.S.-origin label claims, "Product of USA" and "Made in the USA."

Response: FSIS has updated the guideline to clarify that for purposes of meeting the requirements under 9 CFR 412.3(b) for use of the voluntary label claims "Product of USA" and "Made in the USA" on multi-ingredient products, the requirement that "all other ingredients other than spices and flavorings" in the product must be of domestic origin does not include sub-ingredients of an ingredient. For example, if a pork sausage product labeled with the claim "Made in the USA" contains the ingredient soy sauce, the soy sauce needs to be of domestic origin, but the "sub-ingredients" of the soy sauce (e.g., soybeans or wheat), need not be of domestic origin. FSIS is making this change because the source of sub-ingredients may not be available to establishments using the U.S.-origin label claim or to FSIS inspectors verifying the claim meets labeling requirements.

Definition of "Spices" and "Flavorings"

Comment: One trade association, a few askFSIS submitters, and a few webinar participants asked FSIS to clarify the

definitions of "spices" and "flavorings" for the purpose of meeting the final rule requirements that all other ingredients (i.e., ingredients that are not FSIS-regulated products), other than spices and flavorings, must be of domestic origin for an FSIS-regulated multi-ingredient product label to bear the voluntary claims "Product of USA" or "Made in the USA".

Response: The terms "spices" and "flavorings" are defined in 9 CFR 317.2(f)(i)(A) and (B) and 381.118(c)(1) and (2). FSIS is using these definitions for the purposes of meeting the final rule requirements for the labeling of multi-ingredient FSIS-regulated products with the voluntary claims "Product of USA" or "Made in the USA", as well as compliance with other FSIS regulations that use these terms. FSIS has updated the guideline to clarify the definitions and provide citations to these regulations.

Edible Natural Casings

Comment: A few webinar participants and askFSIS submitters asked whether the Agency will consider an edible natural casing to be an ingredient for the purposes of meeting the requirement under 9 CFR 412.3(b) that all other ingredients (i.e., ingredients that are not FSIS-regulated products) in a multi-ingredient product, other than spices and flavorings, must be of domestic origin for the product label to bear the voluntary U.S.-origin claims "Product of USA" or "Made in the USA."

Response: Under the final rule, edible natural casings from animals born, raised, slaughtered, and processed in the

United States are considered to be of domestic origin for purposes of meeting the final rule requirements for use of the voluntary U.S.-origin claims "Product of USA" and "Made in the USA" on FSIS-regulated multi-ingredient products. However, FSIS recognizes that most edible natural casings produced in the United States are exported to foreign countries to be processed (e.g., cleaned), then imported back to the United States for use as an ingredient in multi-ingredient meat products. Therefore, FSIS has updated the guideline to clarify that multi-ingredient FSIS-regulated products made with edible natural casings that are processed outside the United States are eligible for label use of the voluntary U.S.-origin claims "Product of USA" or "Made in the USA," provided that the product meets all other requirements under 9 CFR 412.3(b) for use of such claims. For example, a multi-ingredient pork sausage product may be labeled with the voluntary claim "Product of USA" if the product's edible natural casing was produced by an animal born, raised, processed, and slaughtered in the United States, but the casing was sent outside the U.S. to be processed (e.g., for further cleaning), provided that all other FSIS-regulated ingredients are derived from animals born, raised, slaughtered, and processed exclusively in the United States; all other ingredients, other than spices and flavorings, are of domestic origin; and the preparation and processing steps for the product occurred in the United States.

"Product of North America" and Multi-Country Origin Claims

Comment: A few askFSIS submitters asked whether under the final rule "Product of North America" is allowed as a voluntary label claim on an FSIS-regulated product when the animal from which the product was derived was born, raised, and slaughtered in North America, all product ingredients are of North America origin, and all processing steps occurred in North America. A few askFSIS submitters also asked whether multi-country claims that include the United States are allowed as voluntary label claims on FSIS-regulated products.

Response: FSIS has updated the guideline to clarify that, while it is not a U.S.-origin claim, "Product of North America" is allowed as a voluntary label claim on FSIS-regulated products if it is truthful and not misleading and complies with the FSIS labeling requirements in 9 CFR 317.8(b)(1) and 9 CFR 381.129(b)(2) (e.g., all animals from which the product was derived were born, raised, slaughtered, and processed in North America).

FSIS also has updated the guideline to clarify that voluntary multi-country label claims that include the United States are allowed for use on FSIS-regulated products, provided 1) the animal from which the product was derived was born, raised, slaughtered, and processed in the United States or the foreign country, and 2) the claim includes a qualifying statement describing all the preparation and processing steps that occurred in the United States. For example, a single ingredient pork product derived from an animal born, raised, and

slaughtered in the United States and Canada, and the meat then processed in the United States or Canada, may bear the label claim "Product of USA and Canada," provided the claim is accompanied by qualifying language describing the preparation and processing steps that occurred in the U.S (e.g., "Product of USA and Canada, packaged in the United States").

Voluntary U.S.-Origin Claims Other than "Product of USA" and "Made in the USA"

Comment: A few askFSIS submitters asked whether "Produced in the USA" is allowed under the final rule. One foreign country asked for confirmation whether "Processed in the United States" is allowed as a voluntary U.S.-origin claim.

Response: The final rule allows for the use of voluntary U.S.-origin label claims other than "Product of USA" or "Made in the USA," provided that the claim includes a description to indicate which preparation and processing steps occurred in the United States (9 CFR 412.3(c)). As stated in the final rule, this description needs to provide consumers meaningful information about the U.S.-origin components of the product's preparation and processing (89 FR 19470, 19475). Also as stated in both the final rule and draft guideline published in March 2024, the generalized claims "Processed in the United States" and "Manufactured in the United States" are so broad as to not provide consumers meaningful information about what preparation and processing steps occurred in the United States (89 FR 19470, 19475). FSIS has updated the guideline to add "Produced in the

United States" as a claim that is so broad as to not provide consumers meaningful information about which preparation and processing steps occurred in the United States. Therefore, "Produced in the United States" and "Processed in the United States" are not approved for use as standalone voluntary U.S.-origin label claims.

FSIS also notes that if a label claim is so broad as to not provide meaningful information about what preparation and processing steps of a product occurred in the United States (e.g., "Processed in the United States," "Manufactured in the United States," or "Produced in the United States"), the claim is not approved, even if the claim is combined with a claim that does provide meaningful preparation and processing information. For example, "Processed and Packaged in the USA" would not be approved for use as a voluntary label claim on an FSIS-regulated product; however, "Sliced and Packaged in the USA" would be approved as a voluntary U.S.-origin label claim.

Comment: One trade association asked FSIS to provide in the guideline additional examples of voluntary U.S.-origin label claims other than "Product of USA" and "Made in the USA" that may be used to indicate the preparation and processing steps of an FSIS-regulated product that occurred in the United States. Specifically, the commenter asked FSIS to clarify whether the voluntary label claim "Cooked (in the United States)" is allowed under the final rule.

Response: As discussed in the final rule, voluntary U.S.-origin label claims other than "Product of USA" or "Made in the USA" may be used on FSIS-regulated products, provided they include descriptions that provide meaningful consumer information about which preparation and processing steps occurred in the United States (89 FR 19470, 19475; see 9 CFR 412.3(c)). FSIS has updated the guideline to include additional examples of descriptions that provide consumers meaningful information about the U.S. preparation and processing steps of FSIS-regulated products, including "cooked."

U.S. State Endorsement Programs

Comment: One trade association and several askFSIS submitters requested clarification on the final rule's effect on U.S. State agriculture endorsement program ("State endorsement program") logos. The trade association specifically stated that FSIS should exempt such program logos (e.g., "Go Texan") from the new requirements for use of voluntary U.S.-origin label claims. The commenter argued that the State endorsement program logo labeling option is essential to address the burden of the final rule's requirements for voluntary "Product of USA" and "Made in the USA" label claims.

Response: Under the requirements at 9 CFR 412.3(a), (b), and (d) for the use of the voluntary claims "Product of (U.S. State)" or "Made in (U.S. State)," if a State endorsement program logo includes the statement "Product of (U.S. State)" or "Made in (U.S. State)," the product must meet the final rule

requirements for the label use of the voluntary claims "Product of (U.S. State)" or "Made in (U.S. State)." For example, a single ingredient poultry product labeled with a State endorsement program logo that includes the statement "Product of (U.S. State)" must be derived from an animal born, raised, slaughtered, and processed in that State.

Further, if a State endorsement program logo includes the image of the State's flag, the logo may be used on the label of an FSIS-regulated product without a qualifying statement only if the product meets the final rule requirements for label display of the U.S. flag, or a U.S. State or territory flag.

Specifically, under 9 CFR 412.3(e), the standalone label use of a State endorsement program logo that includes the image of the State's flag will need to meet the requirements for use of voluntary "Product of (U.S. State)" and "Made in (U.S. State)" label claims. However, if the product does not meet all requirements under 9 CFR 412.3(e), a State endorsement program logo that includes the State's flag image may be used to designate the State origin of components of an FSIS-regulated product's preparation and processing as long as the logo is accompanied by a description of the preparation and processing steps that occurred in the State upon which the claim is being made. For example, a beef product that does not meet all requirements for a voluntary "Product of (U.S. State)" claim may be labeled with a State endorsement program logo that includes the image of the State's flag, but the logo must be accompanied

by a description of the preparation and processing steps that occurred in the state (e.g., "beef harvested and packaged in (U.S. State)."

Finally, if a State endorsement program logo does not include the statement "Product of (U.S. State)" or "Made in (U.S. State)," and does not include an image of the State flag or other geographic emblematic design, the logo may be used on the label of an FSIS-regulated product if the establishment maintains supporting documentation for use of the logo. The guideline provides information about what kinds of documentation are sufficient to support the logo use. The final rule concerns voluntary U.S.-origin label claims. Establishments can choose to use a voluntary U.S.-origin label claim for which a particular product is eligible or not make any type of U.S.-origin label claim (see 89 FR 19470, 19478).

Depictions of Geographical Significance

Comment: A few askFSIS submitters commented generally about the effect of the final rule on various types of geographic depictions of the United States, or a U.S. State or territory, on the labels of FSIS-regulated products (e.g., the display of the map of the Commonwealth of Virginia on a label of a poultry product).

Response: FSIS has updated the guideline to clarify that, under the final rule at the amended subsections 9 CFR 317.8(b)(1) and 9 CFR 381.129(b)(2), statements, words, pictures, designs, or devices depicting the United States, or a

U.S. State or territory, may be used on the labels of FSIS-regulated products only if the animal from which the meat or poultry product was derived was born, raised, slaughtered, and processed in the depicted geographical location. For the purposes of using statements, words, pictures, designs, or devices depicting the United States, or a U.S. State or territory, on a multi-ingredient FSIS-regulated product, under 9 CFR 317.8(b)(1) and 381.129(b)(2), other ingredients in the product need not be of domestic origin. If the product does not meet these requirements, the depiction must be accompanied by a qualifying statement describing the preparation and processing steps of the animal from which the product was derived that occurred in the United States, or U.S. State or territory. For example, a label for a multi-ingredient poultry patty product derived from an animal that was born, raised, slaughtered, and partially processed in North Carolina, then packaged in Arizona, that includes the outline of the State of Arizona must be accompanied by a qualifying statement describing the preparation and processing steps that occurred in Arizona (e.g., "Packaged in Arizona").

Exported Products

Comment: One trade association asked about the use of the voluntary "Product of USA" label claim to meet requirements for products exported from the United States. Specifically, the commenter asked the Agency to clarify whether pressure-sensitive labels or stamps are acceptable under the final rule for the

purpose of meeting export requirements. The commenter further stated that it is unclear whether the "Product of USA" statement may be used on labels intended for use on both products for the U.S. market and exported products.

Response: As explained in the final rule, the regulatory requirements for voluntary U.S.-origin label claims do not apply to products intended for export from the United States (89 FR 19470, 19478). Additional export requirements maintained by foreign countries that have been officially communicated to FSIS by the importing country can be accessed in the FSIS Export Library.⁶ All products intended for the domestic market must meet the requirements under the final rule for use of voluntary U.S.-origin label claims, including "Product of USA." As with all FSIS-regulated products labeled either for the domestic market or export from the United States, manufacturers may use pressure sensitive stickers on existing labeling material to cover inaccurate and/or misleading labeling information with corrected text.⁷

Recordkeeping Requirements

Comment: One trade association argued that the guideline describes recordkeeping and traceability requirements that are nearly unattainable for establishments that choose to use a voluntary U.S.-origin label claim. Specifically, the commenter

⁶ FSIS Export Library, available at: <https://www.fsis.usda.gov/inspection/import-export/import-export-library>.

⁷ See *FSIS Guideline on Pressure Sensitive Stickers*, May 2020, available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/FSIS-GD-2020-0004_0.pdf.

stated that maintaining documented traceability of products from derived animals' U.S. birth, raising, slaughter, and processing are unreasonable in the absence of a mandatory animal identification system and an effective traceability program.

Response: The final rule established general recordkeeping requirements that provide flexibility for establishments that choose to use a voluntary U.S.-origin label claim on FSIS-regulated products. The final rule includes examples of the types of documentation that may be maintained to support a voluntary U.S.-origin label claim (9 CFR 412.3(f)).

Establishments may choose which types of documentation to maintain, based on the particular U.S.-origin claim they seek to use and other considerations relevant to the product (89 FR 19470, 19483). As published with the final rule, the label guideline also provided examples of the types of documentation that may be maintained to support a voluntary U.S.-origin label claim. In response to the comment, FSIS has updated the guideline to provide an additional example of supporting documentation.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://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

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Denise Eblen,

Deputy Administrator.

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