

## II. Conclusion

FDA concludes that the data establish the safety and utility of calcium formate as a feed acidifying agent, to lower the pH, in complete feeds for swine or poultry, and that the food additive regulations should be amended as set forth in this document.

## III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

## IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## V. Objections and Hearing Requests

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

### List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

## PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348.

■ 2. Add § 573.230 to subpart B to read as follows:

### § 573.230 Calcium formate.

The food additive calcium formate may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of butyraldehyde, formaldehyde, calcium hydroxide, and formic acid in water followed by purification and dried to produce a powder consisting of not less than 99.0 percent calcium formate (CAS 544-17-2). The additive meets the following specifications:

(1) The additive consists of minimum 30.5 percent calcium and minimum 68.5 percent formate.

(2) Trimethylolpropane (TMP) not to exceed 125 parts per million.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine or poultry feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(d) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that calcium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing calcium formate.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To ensure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning calcium formate.

(2) Statements identifying calcium formate as a possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows.

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act, and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

Dated: December 14, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF STATE

### 22 CFR Part 181

[Public Notice: 12266]

RIN 1400-AF63

### Publication, Coordination, and Reporting of International Agreements: Amendments; Correction

**AGENCY:** Department of State.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Department of State (“Department”) finalizes regulations regarding the publication, coordination, and reporting of international agreements, which were published for comment on October 2. No comments were received. In addition, the Department is amending one of the provisions to remove misleading text in the description of the criteria with respect to qualifying non-binding instruments in the amended rule.

**DATES:** This rule is effective on December 19, 2023.

**FOR FURTHER INFORMATION CONTACT:** Michael Mattler, Assistant Legal Adviser for Treaty Affairs, Office of the Legal Adviser, Department of State, Washington, DC 20520, (202) 647-1345, or at [treatyoffice@state.gov](mailto:treatyoffice@state.gov).

**SUPPLEMENTARY INFORMATION:** On October 2, 2023, the Department published a rulemaking (the “final rule”) that amended 22 CFR part 181 to implement section 5947 of the National Defense Authorization Act for Fiscal Year (FY) 2023 (Pub. L. 117-263) (“the NDAA”). Section 5947 amended 1 U.S.C. 112a and 1 U.S.C. 112b, known as the Case-Zablocki Act, regarding the publication, coordination, and reporting

to Congress of international agreements. For further background, see the final rule at 88 FR 67643.

The Department provided 30 days for public comment. No comments were received.

*Amendment to § 181.4*

The Department is removing the phrase “no single criterion or factor by itself is determinative” from § 181.4(b)(3)(i). The words were included in error, and this change is intended to avoid the regulation being interpreted to mean that a non-binding instrument could only constitute a qualifying non-binding instrument if multiple factors among those listed in (b)(3)(i)(A) through (G) weighed in favor of its significance.

**Regulatory Analysis**

*Administrative Procedures Act*

As with the original rulemaking, the Department is issuing this rule as a final rule, asserting the “good cause” exemption to the Administrative Procedure Act (5 U.S.C. 553(b)). We are past the deadline provided by Congress to implement this rule, also past the effective date of the statute itself. See the final rule for more information.

*Regulatory Flexibility Act/Executive Order 13272: Small Business*

This rulemaking is hereby certified as not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

*Congressional Review Act*

This rulemaking does not constitute a major rule, as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking.

*The Unfunded Mandates Reform Act of 1995*

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure nor would it significantly or uniquely affect small governments.

*Executive Orders 12372 and 13132: Federalism and Executive Order 13175, Impact on Tribes*

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of national government. Nor will the regulations have federalism implications warranting the application of Executive Orders 12372 and 13132. This rule will not have tribal implications, will not impose costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

*Executive Orders 12866 and 14094; 13563: Regulatory Review*

This rule has been drafted in accordance with the principles of Executive Order 12866, as amended by Executive Order 14094, and 13563. The rulemaking is mandated by a Congressional statute; therefore, Congress determined that the benefits of this rulemaking outweigh the costs. This rule has been determined to be a significant rulemaking under Executive Order 12866.

*Executive Order 12988: Civil Justice Reform*

This rule has been reviewed in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

*The Paperwork Reduction Act of 1995*

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulation. This rule contains no new collection of information requirements.

**List of Subjects in 22 CFR Part 181**

Treaties.

For the reasons set forth above, the State Department amends 22 CFR part 181 as follows:

**PART 181—COORDINATION, REPORTING AND PUBLICATION OF INTERNATIONAL AGREEMENTS**

■ 1. The authority section for part 181 continues to read as follows:

**Authority:** 1 U.S.C. 112a, 112b; and 22 U.S.C. 2651a.

■ 2. In § 181.43, revise paragraph (b)(3)(i) introductory text to read as follows:

**§ 181.4 Criteria with respect to qualifying non-binding instruments.**

\* \* \* \* \*

(b) \* \* \*

(3) \* \* \*

(i) Consistent with 1 U.S.C. 112b(k)(5)(A)(ii)(I), and except for a

non-binding instrument referred to in 1 U.S.C. 112b(k)(5)(B), a non-binding instrument that could reasonably be expected to have a significant impact on the foreign policy of the United States, and that meets the other elements set out in 1 U.S.C. 112b(k)(5), is a qualifying non-binding instrument within the meaning of the Act. The degree of significance of any particular instrument requires an objective wholistic assessment. In deciding whether a particular instrument meets the significance standard, the entire context of the transaction, including the factors set out below and the expectations and intent of the participants, must be taken into account. Factors that may be relevant in determining whether a non-binding instrument could reasonably be expected to have a significant impact on the foreign policy of the United States include whether, and to what extent, the instrument:

\* \* \* \* \*

**Joshua L. Dorosin,**

*Deputy Legal Adviser, Department of State.*

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**DEPARTMENT OF TRANSPORTATION**

**Federal Highway Administration**

**23 CFR Parts 470, 635 and 655**

[FHWA Docket No. FHWA-2020-0001]

**RIN 2125-AF85**

**National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Revision**

**AGENCY:** Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** The Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD) (also referred to as “the Manual”) is incorporated by reference within our regulations, approved by FHWA, and recognized as the national standard for traffic control devices used on all public roads, bikeways, or private roads open to public travel. The purpose of this final rule is to revise Standard, Guidance, Option provisions, and supporting information, relating to the traffic control devices in all parts of the MUTCD to improve safety for all road users by promoting uniformity, and to incorporate new provisions that reflect