

Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

#### E. Discussion of Comments

The proposed rule was published in the **Federal Register** on May 22, 2003, with a ten-day comment period ending on June 2, 2003. Eighteen comments were received on TM-03-02. All comments on the proposed rule were posted on the NOP website.

Commenters on proposed rule TM-03-02 were consumers, producers, processors, the NOSB, certifying agents, food industry organizations, and trade organizations. The comments received were for amending the National List of Allowed and Prohibited Substances by adding to: § 205.605(a): Calcium sulfate-mined, and glucono delta-lactone; and to § 205.605(b): animal enzymes-without Lysosyme, cellulose, and terasodium pyrophosphate. The commenters were also for amending the annotation for potassium hydroxide as follows: Potassium hydroxide-prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.

We received five comments on Calcium sulfate-mined, all of which were in support of adding it to the National List. Two of the commenters requested that the annotation be changed to the NOSB recommendation "allowed from non-synthetic sources only." They felt this annotation would cover the mined calcium sulfate as well as any other naturally derived forms, should they become commercially available. This substance will be added to the National List as published in the proposed rule because it would be redundant to state "from non-synthetic sources only" because the sub-section heading is "Nonsynthetics allowed."

Five comments were received in favor of adding Glucono delta-lactone to the National List. Four of the commenters requested it be added with the following annotation: "produced through microbial fermentation of carbohydrates only." This annotation would disallow the use of oxidation of D-glucose with enzymes, but enzymes are allowed in § 205.605(a). Accordingly, this annotation is not adopted. However, the listing is amended to add the annotation "production by the oxidation of D-glucose with bromine water is prohibited." This will allow only the microbial and enzymes oxidation production methods.

Six comments were received in favor of adding Animal enzymes-(Rennet-animal derived; Catalase-bovine liver; Animal lipase; Pancreatin; Pepsin; and

Trypsin) to the National List. All agreed, however, that it should be listed in § 205.605 (a) as an allowed nonsynthetic rather than § 205.605 (b) as an allowed synthetic. Because the NOSB recommended it as an allowed nonsynthetic, and it was inadvertently listed as an allowed synthetic, the substance will be moved to § 205.605 (a), allowed nonsynthetics.

Six comments were received in favor of adding Cellulose to the National List. One commenter was opposed to adding this substance to the National List because the substance is synthetic and the commenter believes that the substance is not essential to any product formulation. The commenter also stated that there are a number of analogous substances already on the National List as allowed substances that can fulfill the role. One commenter requested that the annotation be separated to avoid confusion with other cellulose derivatives that are used as food additives and have been rejected by the NOSB. The NOSB considered the issues raised by both commenters in formulating its recommendation and we believe that no further change is needed based on these comments. In light of this, this substance will be added to the National List as proposed.

Tetrasodium Pyrophosphate received six comments, three in favor of and three opposed to inclusion on the National List. Several commenters expressed concern over the recommended annotation. They indicated that the annotation is vague, confusing, undefined and needs clarification. They stated that the primary use of this substance appears to be to create a texture that is similar to a meat product, and that this directly conflicts with the criterion established in § 205.600(b)(4):

the substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law.

We believe these comments have merit, and accordingly, we have not added this substance to the National List. We will return the NOSB's recommendation on this substance to the NOSB for reconsideration.

Potassium hydroxide received six comments, five in favor of and one opposed to amending the annotation. The commenter opposed to the annotation amendment did not agree that the substance was essential to the peeling of peaches. The commenter stated that peach peeling production trials, without using the substance, were not exhaustive of the possibilities they

could have employed to gain a successful outcome and therefore the substance should not be allowed. The petitioner of this substance provided substantial supporting data that the NOSB considered in its review of the substance. The NOSB's recommended annotation change is based on all of the evidence provided. One commenter suggested this not be restricted to just peaches, but allowed for "peeling of Stone Fruit." However, the petitioner and the NOSB considered only peaches and not stone fruit generally. Accordingly, the annotation is amended as proposed.

Pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register**. This rule reflects recommendations submitted to the Secretary by the NOSB. The substances to be added to the National List were based on petitions from the industry and evaluated by the NOSB using criteria in the Act and regulations. Because these substances are critical to organic production and handling, the National List should be amended as soon as possible.

#### List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

■ For the reasons set forth in the preamble, 7 CFR part 205, subpart G is amended as follows:

#### PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

**Authority:** 7 U.S.C. 6501–6522.

■ 2. Section 205.605 is amended by:

■ a. Adding three substances to paragraph (a).

■ b. Adding one substance to paragraph (b).

■ c. Revising Potassium hydroxide in paragraph (b).

The additions and revisions read as follows:

**§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."**

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(a) \* \* \*