§ 20.6 Submission of reports.

(a) * * * If the reporting exporter determines that the report forms cannot be received in the office specified in ''20.10 by the time specified in paragraph (k) of this section, the exporter shall transmit the information contained in the report forms by the use of FAX, telephone, or electronic submission. The required form must be subsequently submitted in accordance with § 20.6(k)(2). Exporters have the option to submit the weekly reports using an electronic reporting system (forms 97e, 98e, and 100e) which may be accessed via a secured Internet website. Reporting exporters should contact the Export Sales Reporting staff to obtain passwords and access to the Internet reporting site. Exporters also have the option of satisfying the requirements of Forms FAS–97, FAS–98, and FAS–100 by submitting ASCII comma delimited files via e-mail to the ESR mailbox at *esr@fas.usda.gov.*

* * * * *

(k) *Manner and time of reporting—(1) Manner.* An original of all report forms, other than electronic forms and ASCII comma delimited files, must be filed with the office specified in § 20.10. * * *

(2) *Time of filing reports.* Information required to be reported weekly (either via fax, telephone, or electronically) must be received in the office specified in § 20.10 no later than 11:59 p.m. eastern time, on each Monday or such other time as may be approved in advance by that office. * * *

■ 5. Section 20.7 is amended by revising the third sentence of the paragraph to read as follows:

§ 20.7 Confidentiality of reports.

* * * Information from daily reports filed by exporters will be made available to the public on the following business day at 9 a.m., eastern time. * * *

§ 20.10 [Amended]

■ 6. Section 20.10 is amended by adding the phrase ''FAX: (202) 690–3270 or (202) 690–3273'' after ''office''.

Signed at Washington, DC, on October 22, 2003.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 03–27590 Filed 10–31–03; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number TM–03–02]

RIN 0581–AC27

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect recommendations submitted to the Secretary by the National Organic Standards Board (NOSB). Consistent with recommendations from the NOSB, this final rule adds four substances, along with any restrictive annotations, to the National List, and revises the annotation of one substance.

EFFECTIVE DATE: This rule becomes effective November 4, 2003.

FOR FURTHER INFORMATION CONTACT: Richard H. Mathews, Program Manager, National Organic Program, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Standards (NOS) [7 CFR part 205], the National List (§§ 205.600 through 205.607). The National List is the Federal list that identifies synthetic substances and ingredients that are allowed and nonsynthetic (natural) substances and ingredients that are prohibited for use in organic production and handling. Since established, the National List has not been amended. However, under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB.

This final rule amends the National List to reflect recommendations submitted to the Secretary by the NOSB from November 15, 2000, through September 17, 2002. Between the specified time period, the NOSB has recommended that the Secretary add five substances to § 205.605 of the National List based on petitions received from industry participants. These substances were evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517 and 6518) and the NOS. The NOSB also recommended that the Secretary revise the annotation of one substance included within § 205.605.

The NOSB has recommended that the Secretary add additional substances to §§ 205.605 and 205.606 that have not been included in this final rule but are under review and, as appropriate, will be included in future rulemaking.

II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List:

§ 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)).''

This final rule amends paragraph (a) of § 205.605 by adding animal enzymes—without Lysosyme, calcium sulfate—mined, and glucono delta-lactone. This final rule also amends paragraph (b) of § 205.605 by adding cellulose.

This final rule revises current paragraph (b) of § 205.605 by amending an annotation to read 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.

III. Related Documents

Eight notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this final rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 65 FR 64657, October 30, 2000, (Animal enzymes); (2) 66 FR 10873, February 20, 2001, (Calcium sulfate); (3) 66 FR 48654, September 21, 2001, (Cellulose, and Potassium hydroxide); and (4) 67 FR 54784, August 26, 2002, (Glucono delta-lactone, and Tetrasodium pyrophosphate).

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary, at § 6517(d)(1), to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion onto or deletion from the

National List. The National List petition process is implemented under § 205.607 of the NOS. The current petition process (65 FR 43259) can be accessed through the NOP Web site at *http://www.ams.usda.gov/nop.*

A. Executive Order 12866

This action has been determined to be non-significant for purposes of Executive Order 12866, and therefore, does not have to be reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The final rule was reviewed under this Executive Order and no additional related information has been obtained since then. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under section 2115 of the OFPA (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 7 U.S.C. 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the Agricultural Marketing Service (AMS) performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000. AMS has also considered the economic impact of this action on small entities and has determined that this final rule will have an impact on a substantial number of small entities. However, AMS has determined that the impact on entities affected by this rule will not be significant. The effect of this rule will be to allow the use of additional substances in agricultural production and handling. This action relaxes the regulations published in the final rule and provides small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, will be minimal and entirely beneficial to small agricultural service firms. Accordingly, the Administrator of the AMS hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $750,000 and small agricultural producers are defined as those having annual receipts of less than $5,000,000.

The U.S. organic industry at the end of 2001 included nearly 6,600 certified crop and livestock operations, including organic production and handling operations, producers, and handlers. These operations reported certified acreage totaling more than 2.34 million acres, 72,209 certified livestock, and 5.01 million certified poultry. Data on the numbers of certified handling operations are not yet available, but likely number in the thousands, as they would include any operation that transforms raw product into processed products using organic ingredients. Growth in the U.S. organic industry has been significant at all levels. From 1997 to 2001, the total organic acreage grew by 74 percent; livestock numbers certified organic grew by almost 300 percent over the same period, and poultry certified organic increased by 2,118 percent over this time. Sales growth of organic products has been equally significant, growing on average around 20 percent per year. Sales of organic products were approximately $1 billion in 1993, but are estimated to reach $13 billion this year, according to the Organic Trade Association (the association that represents the U.S. organic industry). In addition, USDA has accredited 85 certifying agents who have applied to USDA to be accredited in order to provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at *http://www.ams.usda.gov/nop.* AMS believe that most of these entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995, the existing information collection requirements for the NOP are approved under OMB number 0581–0181. No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by section 350(h) of the

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 ''Nonsysthetics 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 derivates 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.

Tertrasodium Pyrophospate 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)).''

* * * * *

(a) * * *

Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

* * * * *

Calcium sulfate—mined.

* * * * *

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

* * * * *

(b) * * *

* * * * *

Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

* * * * *

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.

* * * * *

Dated: October 27, 2003.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 03–27416 Filed 10–31–03; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. 02–088–3]

RIN 0579–AB47

Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations governing the possession, use, and transfer of listed biological agents and toxins in order to allow for the issuance of provisional registration certificates for individuals and entities and provisional grants of access to listed biological agents and toxins for individuals. These provisional measures are designed to provide additional time for the Attorney General to complete security risk assessments for those individuals and entities for which the Attorney General has received, by November 12, 2003, all of the information required to conduct a security risk assessment. This action is necessary to ensure that research and educational programs are not disrupted.

DATES: This interim rule is effective on November 3, 2003. We will consider all comments that we receive on or before January 2, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02–088–3, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–088–3. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 02–088–3'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information concerning the regulations in 7 CFR part 331, contact Dr. Robert Flanders, Chief, Pest Permit Evaluations Branch, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236, (301) 734–8758.

For information concerning the regulations in 9 CFR part 121, contact Dr. Denise Spencer, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231, (301) 734–3277.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). Title II of Pub. L. 107–188, ''Enhancing Controls on Dangerous Biological Agents and Toxins'' (sections 201 through 231), provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201–204) and the Department of Agriculture (subtitle B, sections 211–213, cited as the ''Agricultural Bioterrorism Protection Act of 2002''), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). For the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) has been designated as the agency with primary responsibility for implementing the provisions of the Act; the Animal and Plant Health Inspection Service (APHIS) is the agency fulfilling that role for the Department of Agriculture. The Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation has been designated as the agency with primary responsibility for implementing the Attorney General's responsibilities under the Act (*i.e.*, the security risk assessments).

In accordance with the requirements of the Act, on December 13, 2002, we published in the **Federal Register** (67 FR 76908–76938, Docket No. 02–088–1) an interim rule that established the standards and procedures governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health (referred to as overlap agents and toxins), to animal health, to plant health, or to animal and plant products (7 CFR part 331 for the plant-related provisions and 9 CFR part 121 for the overlap and animal-related provisions; referred to below collectively as the regulations). Also on December 13, 2002, the CDC published in the **Federal Register** (67 FR 76886–76905) an interim rule that established the standards and procedures governing the possession, use, and transfer of other select agents (42 CFR part 73).

The regulations require that individuals or entities possessing, using, or transferring biological agents or toxins listed in 7 CFR 331.3 or 9 CFR 121.3(d) must register with APHIS, while individuals or entities possessing, using, or transferring overlap agents or toxins must register with either APHIS or CDC. As part of the registration process, the responsible official(s), the alternate responsible official(s), the entity, and, where applicable, the individual(s) who owns or controls the entity must undergo a security risk assessment by the CJIS Division. Moreover, those individuals identified