tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that 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 government.'' This final rule directly regulates growers, food processors, food handlers and foodretailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of theFFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policiesthat have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 18, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 is revised to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1246 is added to subpart D to read as follows:

§ 180.1246 Yeast Extract Hydrolysate from Saccharomyces cerevisiae: exemption from the requirement of a tolerance.

This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* on all food commodities when applied/used for the management of plant diseases.

[FR Doc. 04–4706 Filed 3–2–04; 8:45am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0003; FRL–7344–1]

Gellan Gum; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of gellan gum when used as an inert ingredient in a pesticide product. CP Kelco submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of gellan gum.

DATES: This regulation is effective March 3, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0003, must be received on or before May 3, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0371; e-mail address: *parker.james@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of

entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0003. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid =baa35b6058a65d5fafe66e7269d4d215&c=ecfr&tpl= =/ecfrbrowse/Title40/40cfrv21_02.tpl*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of July 16, 2003 (68 FR 42026) (FRL–7317–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 3E6567) by CP Kelco, 8355 Aero Dr., San Diego, CA 92123–1718. This notice included a summary of the petition prepared by CP Kelco. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of gellan gum (CAS No. 71010–52–1).

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Human Health Assessment

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by gellan gum are discussed in this unit. The information submitted in support of this petition included the review and evaluation of 14 toxicity studies performed using gellan gum by the Joint Expert Committee on Food Additives (JECFA) which is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). Gellan gum is also approved as a food additive in 21 CFR 172.665.

Gellan gum is produced through the fermentation of Pseudomonas elodea (a non-pathogenic bacteria). Gellan gum is a water-soluble polysaccharide that is composed of repeating units, which are called monosaccharides. These four units are one molecule of rhamnose (a sugar found in various plants), one molecule of glucuronic acid (an oxidized glucose molecule), and two molecules of glucose (a component of sucrose, which is common sugar). Gellan gum has a molecular weight greater than 70,000 with 95% above 500,000.

According to the CP Kelco website (*http://www.cpkelco.com*) gellan gum would typically be used in icings and frostings, jams and jellies, jellied candies such as gummy bears, and various fruit and bakery fillings. As the name indicates, when dissolved in water, gellan gum acts as a thickening or gelling agent, and can produce textures in the final product that vary from hard, non-elastic, brittle gels to fluid gels.

A. WHO/JECFA Evaluation

In 1990, gellan gum was evaluated by the JECFA. As part of their evaluation, they reviewed studies related to the absorption, distribution, and excretion of gellan gum (in rats). They also reviewed the following types of toxicological studies: Acute toxicity (in rats), short-term studies (in rats and monkeys), long-term/carcinogenicity (in mice, rats, and dogs), reproductive (in rats), and teratology (developmental) studies (in pregnant rats). The results of these reviews were discussed in the petitioner's July 16, 2003, Notice of Filing. The petitioner accurately and adequately stated the reviews performed by JECFA; therefore, the Agency has not reprinted them in their entirety in this final rule.

Selected summary information includes the following:

- Gellan gum was shown to be poorly absorbed and did not cause any deaths in rats which received a single large

dose (5 gram (g) per kilogram (kg) of body weight) in the diet or by gavage.

- Short-term (90-day) exposure of rats to gellan gum at levels up to 60 g/kg in the diet did not cause any adverse effects.
- In a 28-day study in prepubertal monkeys, no overt signs of toxicity were observed at the highest-dose level of 3 g/kg of body weight per day.
- In reproduction and teratogenicity studies in rats in which gellan gum was given at dose levels up to 50 g/kg in the diet, there was no evidence of interference with the reproductive process, and no embryotoxic or developmental effects were observed.
- Gellan gum was also shown to be non-genotoxic in a battery of standard short-term tests.
- In a study in dogs, which were treated for 1 year at dose levels up to 60 g/kg in the diet, there were no adverse effects that could be attributed to chronic exposure to gellan gum.
- In long-term carcinogenicity studies, gellan gum did not induce any adverse effects in mice or rats at the highest-dose levels of 30 g/kg and 50 g/kg in the diet, respectively.

The Agency notes that the dose levels used in these animal studies were in g/kg body weight not milligrams (mg)/kg as in most of the studies reviewed and evaluated by the Agency.

There was also a limited study on tolerance to gellan gum in humans. Results indicated that oral doses of up to 200 mg/kg of body weight administered over a 23-day period did not elicit any adverse reactions, although faecal bulking effects were observed in most humans.

In its conclusions, the JECFA Committee indicated that the potential laxative effect (at high intakes of gellan gum) should be taken into account when used as a food additive. The JECFA Committee also allocated an ADI (average daily intake) of ''not specified'' to gellan gum, which means that a specific limit on the average daily intake of gellan gum was not needed.

B. FDA Evaluation

Gellan gum is approved by the Food and Drug Administration (FDA) as a direct food additive when added to foods as a stabilizer or thickener according to good manufacturing practices when used according to the following conditions (21 CFR 172.665):

- The additive is a high molecular weight polysaccharide gum produced from Pseudomonas elodea by a pure culture fermentation process and purified by recovery with isopropyl alcohol.
- The strain of Pseudomonas elodea is non-pathogenic and non-toxic in man and animals.
- The additive is produced by a process that renders it free of viable cells of Pseudomonas elodea.

C. Conclusions

The evaluations performed by WHO and FDA indicate a substance of lower toxicity. The only concern that has been indicated for gellan gum as indicated by the JECFA Committee was a possible laxative effect which occurs only at high intakes of gellan gum. This laxative effect likely occurs as a result the body's limited ability to absorb gellan gum.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

A. Dietary Exposure

1. *Food.* Gellan gum has been safely used as a food additive for over 10 years in various food formulations. Foods which can commonly contain gellan gum include frostings, gelatins, puddings, fillings, jams, milk products, fruit juices, and soft candy. CP Kelco supplied to the Agency, the direct use levels (expressed as percent) of gellan gum in a variety of food formulations. The typical amount of gellan gum used as a food additive does not exceed 0.5% of the processed food.

Given the use of gellan gum as a thickening or jelling agent, there is a ''built in'' limitation as to the amount needed. Too much gellan gum would over-thicken, making the pudding or jam too stiff for the intended use. According to information provided by CP Kelco, the maximum percent of gellan gum in a food formulation to achieve the desired thickening or jelling effect would be less than 2%.

Gellan gum has a molecular weight which is greater than 70,000 with 95% above 500,000. Such large substances are not easily absorbed, as demonstrated by the rat metabolism study which indicated poor absorption. The constituents of gellan gum are naturally occurring materials (sugar monosaccharides) that, in fact, are found in living organisms.

Gellan gum is approved for use as a direct food additive by FDA. To the best of the Agency's knowledge gellan gum has been used for over 10 years as a stabilizer and thickener—as a gelling agent in foods without any reported incidence. The Agency estimated an annual U.S. population exposure for gellan gum using the annual production information provided by CP Kelco (100,000 kg) and a U.S. population estimate of approximately 290,809,777 as of July 1, 2003, from the U.S. census website (*http://eire.census.gov/popest/data/national/popbriefing.php*). The Agency estimated annual exposure of gellan gum to the U.S. population is approximately 0.94 mg/person/day.

Equation used to calculate exposure provided below:

100,000 (kg/year) / (290,809,777 (people) x 365 (days/year)) = 0.94

100,000,000,000 (mg/year) / 106,145,568,605 (people/day/year) = 0.94 mg/person/day

The amount of gellan gum that could occur in food as a result of its use as an inert ingredient in a pesticide product should not significantly increase the amount of gellan gum in the food supply above those amounts currently permitted by FDA. Furthermore, it is unlikely that the manner which gellan gum is used in pesticide formulations will differ significantly from it's use as a direct food additive due to ''built in'' limitations based on the desired thickening or gelling effect.

2. *Drinking water exposure.* Gellan gum is composed of repeating monosaccharides. When mixed with water, gellan gum acts as a thickener, thus producing a viscous solution. Eventually, the material will degrade to the constituent monosaccharides: Two glucose molecules, one glucuronic molecule, and one rhamnose molecule. The rate at which this occurs will

depend on the size of the ''bead'' that forms when dissolved in water. While physical/chemical degradation processes (such as hydrolysis) would occur, it is more likely that gellan gum would be degraded via microbial degradation. Due to the lower toxicity of the degradates, the naturally occurring sugars, there are no concerns for exposure to gellan gum in drinking water.

B. Other Non-occupational Exposure

The Agency believes that the potential for the use of gellan gum in and around the home exists.

1. *Dermal exposure*. Based on the high molecular weight of gellan gum, it is not likely to be absorbed through the skin.

2. *Inhalation exposure*. Based on the fact that gellan gum is a polysaccharide which would degrade into naturally occurring sugars, it is not likely to cause any adverse effects when inhaled. The resulting molecules are normally found in living organisms (including humans) and would be metabolized normally.

V. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to gellan gum and any other substances, and gellan gum does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that gellan gum has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. The JEFCA committee has evaluated reproductive and teratogenicity (developmental) toxicity studies in rats in which gellan gum was given at dose levels up to 50 g/kg in the diet and found no indication of increased susceptibility. Based on the WHO/JECFA evaluation of gellan gum, EPA has not used a safety factor analysis to assess the risk of gellan gum. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety for U.S. Population, Infants and Children

The JECFA Committee reviewed and evaluated 14 toxicity studies and as a result of their review and evaluation, JECFA determined an ADI (Acceptable Daily Intake) of ''not specified.'' The only concern was for the potential laxative effect at high intakes. FDA has also approved the use of gellan gum as a direct food additive when used as a stabilizer and thickening agent (21 CFR 172.665).

Based on the available information which includes an Agency estimated-daily exposure of 0.94 mg/kg/day, toxicity studies conducted in g/kg body weight rather than mg/kg body weight (with few to no effects), evaluations by both FDA and WHO/JEFCA, and the high molecular weight of gellan gum, the EPA finds that exempting gellan gum (CAS No. 71010–52–1) from the requirement of a tolerance will be safe.

VIII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . .'' EPA has been working with interested stakeholders to develop a screening and testing program, as well as a priority-setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing gellan gum for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for gellan gum.

D. International Tolerances

Gellan gum is used as a food additive in many countries. The Agency is not aware of any country requiring a tolerance for gellan gum nor have any CODEX Maximum Residue Levels (MRL's) been established for any food crops at this time.

E. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL–6807–8)) to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification. The results of the review and evaluation performed by WHO/JECFA as well as FDA's approval of gellan gum as a direct food additive, indicate a substance of lower toxicity. Therefore, gellan gum (CAS No. 71010–52–1) is to be classified as a List 4A inert ingredient.

IX. Conclusion

Based on the information in the official public docket, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of gellan gum (CAS No. 71010–52–1). Accordingly, EPA finds that exempting gellan gum from the requirement of a tolerance will be safe.

X. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was

provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0003 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 4, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–-5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit X.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0003, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the

development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications '' is defined in the Executive order to include regulations that 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 government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.''''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. In § 180.950, the table in paragraph (e) is amended by adding alphabetically the following entry to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical	CAS No.
* * * * *	
Gellan gum	71010–52–1
* * * * *	

[FR Doc. 04–4707 Filed 3–2–04; 8:45 am]

BILLING CODE 6560–50–S

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 1817

RIN 2700–AC94

Performance Period Limitations

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This final rule amends the NASA FAR Supplement (NFS) by clarifying that the five-year limitation on contracts applies to all procurement award instruments including agreements, orders under a Federal Supply Schedule, or other indefinite delivery/indefinite quantity contracts awarded by other agencies. The current NFS language has been interpreted to exclude certain types of award instruments, such as basic ordering agreements or blanket purchase agreements, from the five-year limitation. This change will ensure consistent application of the five-year performance period limitation and the waiver process for all award instruments.

EFFECTIVE DATE: March 3, 2004.

FOR FURTHER INFORMATION CONTACT: Eugene Johnson, NASA, Office of Procurement, Program Operations Division (Code HS), Washington, DC 20546; (202) 358–4703; e-mail: *eugene.johnson-1@nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The NFS at 1817.204(e)(i) currently states that the five-year limitation (basic plus option periods) applies to all NASA contracts regardless of type. This has been interpreted to mean that the limitation does not apply to agreements such as basic ordering agreements and blanket purchase agreements. This interpretation is not consistent with the intent of the limitation and does not support NASA's efforts to maximize opportunities for competition. This final rule clarifies that the limitation is applicable to all award instruments. This change to the NFS is being issued as a final rule since it does not have a significant effect beyond the internal operating procedures of NASA. Comments may be submitted to the above address.

B. Regulatory Flexibility Act

This final rule does not constitute a significant revision within the meaning of FAR 1.501 and Public Law 98–577, and publication for public comment is not required. However, NASA will consider comments from small entities concerning the affected NFS Part 1817 in accordance with 5 U.S.C. 610.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes do not impose recordkeeping or information collection requirements which require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Part 1817

Government procurement.

Tom Luedtke,

Assistant Administrator for Procurement.

■ Accordingly, 48 CFR Part 1817 is amended as follows:

■ 1. The authority citation for 48 CFR Part 1817 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).