

**List of Subjects****29 CFR Part 4022**

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

**29 CFR Part 4044**

Employee benefit plans, Pension insurance, Pensions.

■ In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

**PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS**

■ 1. The authority citation for part 4022 continues to read as follows:

**Authority:** 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 128, as set forth below, is added to the table. (The introductory text of the table is omitted.)

**Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments**

\* \* \* \* \*

| Rate set | For plans with a valuation date |             | Immediate annuity rate (percent) | Deferred annuities (percent) |                |                |                |                |
|----------|---------------------------------|-------------|----------------------------------|------------------------------|----------------|----------------|----------------|----------------|
|          | On or after                     | Before      |                                  | i <sub>1</sub>               | i <sub>2</sub> | i <sub>3</sub> | n <sub>1</sub> | n <sub>2</sub> |
| *<br>128 | *<br>6-1-04                     | *<br>7-1-04 | *<br>3.50                        | *<br>4.00                    | *<br>4.00      | *<br>4.00      | *<br>7         | *<br>8         |

■ 3. In appendix C to part 4022, Rate Set 128, as set forth below, is added to the table. (The introductory text of the table is omitted.)

**Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments**

\* \* \* \* \*

| Rate set | For plans with a valuation date |             | Immediate annuity rate (percent) | Deferred annuities (percent) |                |                |                |                |
|----------|---------------------------------|-------------|----------------------------------|------------------------------|----------------|----------------|----------------|----------------|
|          | On or after                     | Before      |                                  | i <sub>1</sub>               | i <sub>2</sub> | i <sub>3</sub> | n <sub>1</sub> | n <sub>2</sub> |
| *<br>128 | *<br>6-1-04                     | *<br>7-1-04 | *<br>3.50                        | *<br>4.00                    | *<br>4.00      | *<br>4.00      | *<br>7         | *<br>8         |

**PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS**

■ 4. The authority citation for part 4044 continues to read as follows:

**Authority:** 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 5. In appendix B to part 4044, a new entry, as set forth below, is added to the

table. (The introductory text of the table is omitted.)

**Appendix B to Part 4044—Interest Rates Used to Value Benefits**

\* \* \* \* \*

| For valuation dates occurring in the month— |                |           | The values of i <sub>t</sub> are: |          |                |          |  |  |
|---------------------------------------------|----------------|-----------|-----------------------------------|----------|----------------|----------|--|--|
|                                             | i <sub>t</sub> | for t =   | i <sub>t</sub>                    | for t =  | i <sub>t</sub> | for t =  |  |  |
| *<br>June 2004                              | *<br>.0430     | *<br>1-20 | *<br>.0500                        | *<br>>20 | *<br>N/A       | *<br>N/A |  |  |

Issued in Washington, DC, on this 11th day of May 2004.

**Joseph H. Grant,**

*Deputy Executive Director and Chief Operating Officer, Pension Benefit Guaranty Corporation.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2004-0135; FRL-7358-9]

**Phosphomannose Isomerase and the Genetic Material Necessary for Its Production in All Plants; 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 in or on plant

commodities of phosphomannose isomerase and the genetic material necessary for its production in all plants when applied/used as plant-incorporated protectant inert ingredients. Syngenta Seeds, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues in or on all plant commodities of phosphomannose isomerase and the genetic material

necessary for its production in all plants.

**DATES:** This regulation is effective May 14, 2004. Objections and requests for hearings must be received on or before July 13, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP-2004-0135. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy 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.

**FOR FURTHER INFORMATION CONTACT:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8715; e-mail address: [mendelsohn.mike@epa.gov](mailto:mendelsohn.mike@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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

##### **II. Background and Statutory Findings**

In the **Federal Register** of October 22, 2003 (68 FR 60383) (FRL-7326-1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3E6748) by Syngenta Seeds, Inc., P.O. Box 12257, 3054 Cornwallis Road, Research Triangle Park, NC 27709-2257. This notice included a summary of the petition prepared by the petitioner Syngenta Seeds, Inc.. 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 in or on all plant commodities of phosphomannose isomerase and the genetic material necessary for its production in all plants.

Section 408(c)(2)(A)(i) of the 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 exemption is “safe.” Section 408(c)(2)(A)(ii) of the 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. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require 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....” Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider “available information concerning the cumulative effects of a particular pesticide’s residues” and “other substances that have a common mechanism of toxicity.”

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. Toxicological Profile**

Consistent with section 408(b)(2)(D) of the 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.

EPA’s dietary and human health analysis of proteins expressed as PIPs and the inert ingredients associated with PIPs as marker proteins is based on the guidelines for microbial pesticides (See 40 CFR 158.740(b)(2)(i)). EPA recognizes that not all the guidance expressed in these test guidelines are necessarily appropriate for proteins. For instance, EPA does not expect a protein alone to exhibit infectivity or pathogenicity. Nonetheless, EPA believes that the approach used for the fermentation products of microbial agents applies equally well for proteins expressed in plants. Therefore, EPA expects acute oral toxicity with high doses of purified protein and specific criteria on protein degradation and similarity analyses to provide adequate information to reach a finding of a reasonable certainty of no harm in the aggregate for a PIP protein or an inert ingredient associated with a PIP. Such data have been submitted for pure phosphomannose isomerase (PMI) protein. These data demonstrate the safety of the products at levels well above maximum possible exposure levels that are reasonably anticipated in the crops.

The PMI protein is a new marker gene employing unusual carbohydrate metabolism to allow for selection of transformants in cell culture. Use of this

marker addresses some of the complaints received from the public about the possible adverse effects of using antibiotic resistance genes as selection markers. The PMI protein is a ubiquitous enzyme involved in carbohydrate metabolism and it, or a highly homologous enzymatic protein, is found expressed in many species including enteric bacteria, fungi, insects, some species of plants and nematodes, and even mammals including monkeys, mice and man. The PMI protein for which data was submitted in support of this tolerance determination was originally isolated from *Escherichia coli*, a common intestinal bacterium, which is considered a non-allergenic source of protein traits. Since the PMI protein is found in the human intestinal flora and a homologue is expressed by humans, it is logical to expect that there has always been a natural background exposure as well as a low quantity found in the human diet.

An acute oral study was submitted for the PMI protein. The acute oral toxicity data submitted support the prediction that the PMI protein would be non-toxic to humans. The mouse oral LD<sub>50</sub> for males, females, and combined was greater than 5,050 mg/kg of dosing solution or 3,080 mg/kg of PMI protein.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjogblad, Roy D., *et al.* "Toxicological Considerations for Protein Components of Biological Pesticide Products," Regulatory Toxicology and Pharmacology 15, 3-9 (1992)). Therefore, since no effects were shown to be caused by the PMI protein inert ingredient, even at relatively high dose levels, the PMI protein is not considered toxic. Further, amino acid sequence comparisons showed no similarity between the PMI protein to known toxic proteins available in public protein data bases.

Since PMI is a protein, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, and may be glycosylated and present at high concentrations in the food.

Data have been submitted that demonstrate that the PMI protein is rapidly degraded (2 minutes) by gastric fluid *in vitro*. Incubation at 65 and 95°C for 30 minutes inactivated PMI. The PMI protein showed no significant amino acid homology with known or putative allergenic proteins using either an 8 amino acid sequence stepwise comparison or an 80 amino acid fragment comparison. The proteins

identified as sharing significant amino acid similarity with the *E. coli* PMI are either proteins confirmed as having PMI activity in other organisms or proteins with inferred PMI enzymatic activity from the close amino acid sequence similarity with PMI and the organism's ability to mannose. The source organisms with significant similarity to PMI were identified as numerous bacteria, fungi, plants, insects, and mammals as well as a nematode and protist. This wide diversity of source organisms and the fact that PMI is involved in carbohydrate metabolism indicates that PMI is an essential enzyme involved with routine functions (i.e. housekeeping) and already has broad expression and exposure in humans and many food items.

The potential for the PMI protein to be food allergens is minimal. Regarding toxicity to the immune system, the acute oral toxicity data submitted support the prediction that the PMI protein would be non-toxic to humans. As noted above, toxic proteins typically act as acute toxins with low dose levels. Therefore, since no effects were shown to be caused by the PMI protein inert ingredient plant-incorporated protectants, even at relatively high dose levels, the PMI protein is not considered toxic.

#### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the 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).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers, such as infants and children) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the PMI inert ingredient plant-incorporated protectants chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the PMI protein inert ingredient plant-incorporated protectants are contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. Oral exposure, at very low levels, may occur from ingestion of food

products and, potentially, drinking water. However, a lack of mammalian toxicity and the digestibility of the PMI protein inert ingredient plant-incorporated protectants have been demonstrated. The use sites for the PMI protein inert ingredient plant-incorporated protectants are all agricultural associated with the control of plant pests. Therefore, exposure via residential or lawn use to infants and children is not expected. Even if negligible exposure should occur, the Agency concludes that such exposure would present no risk due to the lack of toxicity demonstrated for the PMI protein.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Because of the lack of toxicity demonstrated for the PMI protein and because there is no indication of mammalian toxicity to these plant-incorporated protectant inert ingredients, we conclude that there are no cumulative effects for the PMI protein.

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

##### A. Toxicity and Allergenicity Conclusions

The data submitted and cited regarding potential health effects for the PMI protein include the characterization of the expressed PMI protein in corn, as well as the acute oral toxicity, and *in vitro* digestibility of the protein. The results of these studies were determined applicable to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered.

Data was submitted that adequately shows that the PMI test material derived from microbial cultures, which was the material used for testing purposes, is biochemically and functionally similar to the PMI protein produced in the plant. Production of microbially produced protein was chosen in order to obtain sufficient material for testing. Proteins have a certain predictable metabolic fate: Once ingested, proteins are broken down by the combination of secreted acid and digestive enzymes into peptides that are absorbed and

turned into new molecules by the body's protein synthetic processes.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., *et al.* "Toxicological Considerations for Protein Components of Biological Pesticide Products," Regulatory Toxicology and Pharmacology 15, 3-9 (1992)). The acute oral toxicity data submitted supports the prediction that the PMI protein would be non-toxic to humans. Since no effects were shown to be caused by PMI, even at relatively high dose levels (greater than 5,050 mg/kg body wt. of dosing solution or 3,080 mg/kg body wt. of PMI protein), the PMI protein are not considered toxic. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial pesticide products like *Bacillus thuringiensis* (Bt). See 40 CFR 158.740(b)(2)(i). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study to verify the observed effects and clarify the source of these effects (Tiers II and III). Since no adverse reactions occurred at near limit dose testing with PMI protein, no further testing of PMI protein is indicated. Thus, residue chemistry data were not required for a human health effects assessment of the subject PMI plant-incorporated protectant inert ingredients because of the lack of mammalian toxicity.

Available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children), and safety factors, which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data, were not considered. See section 408(b)(D) of the FFDCA. Since PMI was tested in an acute oral toxicity test and found to have no adverse effects, showed no unusual stability to digestive enzymes or heat, and had no amino acid similarity to known toxic or allergenic proteins, no mammalian toxicity was identified. The lack of mammalian toxicity at high levels of exposure to the PMI protein demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated in crops. Given the lack of toxicity at high dose levels, several orders of magnitude above the expected dietary exposure from submitted expression data, no additional safety factors to account for the use of animal data were deemed necessary to provide a

reasonable certainty of no harm to the aggregate exposure to PMI.

The genetic material necessary for the production of the plant-incorporated protectant inert ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. The genetic material (DNA, RNA) necessary for the production of PMI protein in plant crops have been exempted under the blanket exemption for all nucleic acids (40 CFR 174.475).

#### *B. Infants and Children Risk Conclusions*

Section 408(b)(2)(C) of the FFDCA provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety), which often are referred to as uncertainty factors, are incorporated into EPA risk assessment either directly or through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

In this instance, based on all the available information, the Agency concludes that the PMI protein and the genetic material necessary for its production in all plants are not toxic and, therefore, that there are no threshold effects of concern. As a result, the Agency has determined that the additional margin of safety is not necessary to protect infants and children and that not adding any additional margin of safety will be safe for infants and children.

#### *C. Overall Safety Conclusion*

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of the PMI protein and the genetic material necessary for its production in all plants. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for the PMI plant-incorporated protectant inert ingredients.

### **VII. Other Considerations**

#### *A. Endocrine Disruptors*

FQPA requires EPA to develop a screening program to determine whether

certain substances, including all pesticide chemical (both inert and active ingredients), may have an effect in humans that is similar to an effect produced by 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, it is not anticipated that testing of PMI protein for endocrine effects will be required. The PMI inert ingredients are proteins, derived from sources that are not known to exert an influence on the endocrine system. Therefore, the Agency is not requiring information on the endocrine effects of PMI proteins at this time.

#### *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. Further, there was a finding of no toxicity or allergenicity for the PMI plant-incorporated protectant inert ingredients and they act simply as marker proteins.

#### *C. Codex Maximum Residue Level*

No Codex maximum residue levels exists for the plant-incorporated protectant inert ingredient marker protein phosphomannose isomerase (PMI) protein and the genetic material necessary for its production in all plants.

### **VIII. Objections and Hearing Requests**

Under section 408(g) of the 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the FFDCA, as was provided in the old sections 408 and 409 of the 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-2004-0135 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 July 13, 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 (1900L), 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 Suite 350, 1099 14<sup>th</sup> St. NW, Washington, DC 20005. 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 (202) 564-6255.

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](mailto: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 VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0135, 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 **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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).

### **IX. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the tolerance

requirement under section 408(d) of the 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 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 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 the 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.

#### X. 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: May 6, 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 continues to read as follows:

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

■ 2. Section 180.1252 is added to subpart D to read as follows:

**§ 180.1252 Phosphomannose isomerase and the genetic material necessary for its production in all plants; exemption from the requirement of a tolerance.**

Phosphomannose isomerase (PMI) protein and the genetic material necessary for its production in plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in plant commodities. Genetic material necessary for its production means the genetic material which comprise genetic material encoding the PMI protein and its regulatory regions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the PMI protein.

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#### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

##### 48 CFR Part 1812

**RIN 2700–AD00**

#### Clauses Authorized for Use in Commercial Acquisitions

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the NASA FAR Supplement (NFS) by removing the NASA specific clause regarding Central Contractor Registration (CCR) from the list of clauses authorized for use in acquisitions of commercial items. The NASA CCR clause was removed from the NFS in a final rule published in the

**Federal Register** on February 3, 2004, however the rule failed to remove the clause from part 1812. This change corrects this omission.

**DATES:** *Effective Date:* May 14, 2004.

#### FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

##### A. Background

Item I of FAC 2001–16 revised the FAR to require registration of contractors in the Central Contractor Registration (CCR) database prior to award of any contract, basic agreement, basic ordering agreement, or blanket purchase agreement. As a result, NASA’s specific coverage of CCR was no longer required and Subpart 1804.74—Central Contractor Registration and its associated clause at 1852.204–74 were deleted from the NFS under a final rule published in the **Federal Register** on February 3, 2004. Due to an oversight, the rule failed to remove 1852.204–74 from the list of clauses authorized for use in acquisitions of commercial items contained in the 1812.301, “Solicitation provisions and contract clauses for the acquisition of commercial items.” This final rule corrects this omission by removing the reference to 1852.204–74.

This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

##### B. Regulatory Flexibility Act

This final rule does not constitute a significant revision within the meaning of FAR 1.501 and Pub. L. 98–577, and publication for public comment is not required. However, NASA will consider comments from small entities concerning the affected NFS part 1812 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.*