allergenic proteins, which typically are present at 1–80% of the total protein in an offending food, the average PMI concentration measured in raw grain derived from a line of transformed corn plants represents less than 0.00002% of the total protein. (This calculation is based on corn grain containing 10% total protein by weight, and assumes 2 ppm PMI in the grain.) Additionally, due to degradation *via* food processing methods, PMI will not likely be present in processed food products, or will be present in only trace quantities. PMI produced in transformed plants is not targeted to a cellular pathway for glycosylation. PMI activity, and therefore tertiary protein structure, is lost upon heating at 65 degrees C for 30 minutes. PMI rapidly degrades upon exposure to simulated mammalian gastric and intestinal fluids.

The genetic material occurring in the subject inert ingredient has been adequately characterized. This genetic material (*i.e.*, the nucleic acids deoxyribonucleic acid (DNA) and ribonucleic acid (RNA)), including regulatory regions, necessary for the production of PMI as an inert ingredient in all crops will not present a dietary safety concern. ''Regulatory regions'' are the DNA sequences such as promoters, terminators, and enhancers that control the expression of the genetic material encoding the protein. Based on the ubiquitous occurrence and established safety of nucleic acids in the food supply, a tolerance exemption under the FFDCA regulations has been established for residues of nucleic acids that are part of plant-incorporated protectants or associated inert ingredients 40 CFR 174.475 (66 FR 37817) (FRL–6057–5). Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of PMI protein in all crops.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Due to the ubiquitous occurrence of PMI in nature, it is conceivable that the human diet has always contained small amounts of PMI proteins that are similar to that produced in plants transformed with the *E. coli pmi* gene. The levels of PMI measured in raw grain from a line of transformed corn plants averaged *ca.* 1–2 ppm. Processed plant products or by-products used in food are unlikely to have measurable PMI protein, or will have only trace amounts. Oral exposure is not expected to result in adverse health effects, because of a demonstrated lack of toxicity to mammals and the rapid digestibility of the PMI protein. It is expected that any PMI protein consumed will be digested as conventional dietary protein.

ii. *Drinking water*. Little to no exposure *via* drinking water is anticipated. Due to the demonstrated mammalian safety profile of PMI, such exposure would not present a risk.

2. *Non-dietary exposure*. Non-dietary exposure is not anticipated, due to the proposed use pattern of the product. Exposure *via* dermal or inhalation routes is unlikely because the inert ingredient is contained within plant cells. However, if exposure were to occur by non-dietary routes, no risk would be expected because the PMI protein is not toxic to mammals.

E. Cumulative Exposure

Because there is no indication of mammalian toxicity of the PMI protein or the genetic material necessary for its production, it is reasonable to conclude that there will be no cumulative effects for this inert ingredient.

F. Safety Determination

1. *U.S. population*. The lack of mammalian toxicity at high levels of exposure to the PMI protein demonstrates the safety of the product at levels well above possible maximum exposure levels anticipated *via* consumption of food products produced from *pmi*-transformed plants. Moreover, little to no human dietary exposure to PMI protein is expected to occur *via pmi*-transformed food crops. Due to the digestibility and lack of toxicity of the PMI protein, and its very low potential to become an allergen in food, dietary exposure is not anticipated to pose any harm for the U.S. population. No special safety provisions are applicable for consumption patterns or for any population sub-groups.

2. *Infants and children*. Based on the mammalian safety profile of the inert ingredient and the proposed use pattern, there is ample evidence to conclude a reasonable certainty of no harm to infants and children.

G. Effects on the Immune and Endocrine Systems

The inert ingredient is derived from sources that are not known to exert an influence on the endocrine or immune systems.

H. Existing Tolerances

The registrant is not aware of any known existing tolerances or exemptions for PMI and the genetic material necessary for its production as an inert ingredient.

I. International Tolerances

The registrant is not aware that any Codex maximum residue levels exist for the PMI protein and the genetic material necessary for its production.

[FR Doc. 03–26412 Filed 10–21–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2003–0034; FRL–7331–2]

Draft Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database; Request for Comment; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is convening a 1–day public meeting to receive comments from persons reporting data required by the Inventory Update Rule (IUR) on the draft instructions for reporting in 2006. The instructions have been revised in response to amendments to 40 CFR part 710 promulgated on January 7, 2003, which substantially modify the information which must be reported for the partial updating of the Toxic Substances Control Act (TSCA) Chemical Inventory Database beginning in 2006.

DATES: The public meeting will commence at 9:30 a.m. on Wednesday, October 22, 2003, and end at approximately 2 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Suites Houston, 2400 West Loop South, Houston, TX 77027.

Persons planning to attend the public meeting are encouraged to register with the technical contact person identified below. Persons registering for the meeting will receive by e-mail a copy of the draft instructions prior to the meeting. Prior registration is not required to attend the public meeting.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Fredric C. Arnold, Economics, Exposure, and Technology Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460–0001; telephone number: (202) 564–8521; e-mail address: *arnold.fred@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture chemical substances currently subject to reporting under the IUR as amended on January 7, 2003, and codified as 40 CFR part 710. Persons who process chemical substances but who do not manufacture or import chemical substances are not required to comply with the requirements of 40 CFR part 710. Potentially affected entities may include, but are not limited to:

Chemical manufacturers and importers currently subject to IUR reporting, including manufacturers and importers of inorganic chemical substances (NAICS codes 325 and 32411).

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions at 40 CFR 710.48. If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact 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 OPPT–2003–0034. 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 EPA's Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. EPA's Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. EPA's Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

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/*.

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

EPA is convening a public meeting to receive comments on the instructions for reporting to the 2006 partial updating of TSCA Chemical Substance Inventory Database. EPA is required by section 8(b) of TSCA to compile and update an inventory of chemical substances manufactured or imported in the United States. Every 4 years, manufacturers (including importers) of certain chemical substances on the Chemical Substance Inventory have been required to report data specified in the TSCA section 8(a) IUR, 40 CFR part 710. Past updates included information on the chemical's production volume, site-limited status, and plant site information. Amendments to the IUR promulgated on January 7, 2003 (68 FR 848) (FRL–6767–4) expanded the data reported on certain chemicals to assist EPA and others in screening potential exposures and risks resulting from manufacturing, processing, and use of TSCA chemical substances. At the same time, EPA amended the IUR regulations to increase the production volume threshold, which triggers reporting requirements from 10,000 lbs per year to 25,000 lbs per year and established a new higher threshold of 300,000 lbs per year above which manufacturers must report additional information on down-stream processing and use of their chemical substances. The 2003 amendments to the IUR also revoked the exemption from reporting for inorganic chemical substances, provided a partial exemption from reporting of processing and use information for chemical substances of low current interest, and continued the current exemption from reporting for polymers, microorganisms, and naturally occurring chemical substances. These changes modify requirements for information collected in calendar year 2005 and submitted in 2006 and thereafter. The public meeting may be of interest to persons currently reporting under the IUR and to manufacturers of inorganic chemical substances.

The public meeting will include a series of presentations by representatives of EPA on the instructions for reporting for the 2006 partial updating of the TSCA Chemical Inventory Database. Presentation topics will include reporting requirements, instructions for completing the reporting form, how to assert confidentiality claims, and how to submit completed reports to EPA. After each presentation, persons attending the public meeting will be invited to comment on the clarity, completeness, and usefulness of the instructions. Comments may also be submitted in writing following the public meeting. Comments should be submitted within 30 days after the meeting to receive timely attention. The purpose of the public meeting is to receive input for improving the instructions; subsequent meetings are planned for 2004, to provide training to persons who must report in 2006, under the IUR.

There is no charge for attending this public meeting.

List of Subjects

Environmental protection, Chemicals, Reporting and recordkeeping requirements.

Dated: October 17,2003.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 03–26737 Filed 10–20–03; 2:26 pm]

BILLING CODE 6560–50–S