

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.

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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.,