



## Frito-Lay, Inc.

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Docket No. 2004D-0369  
Division of Dockets Management (HFA-305)  
FDA  
5360 Fishers Lane, rm. 1061  
Rockville, MD 20852

*Submitted electronically at <http://www.fda.gov/dockets/ecomments>*

**Subject: Comments to Docket No. 2004D-0369, "Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use"**

Dear Dr. Ditto,

Frito-Lay, Inc. welcomes the opportunity to comment on the draft recommendations for the safety review of new proteins in genetically altered plants. In our view maintaining the integrity of the food supply is of prime importance for both the FDA and the regulated community. In that light, we believe the safest alternative is to simply not permit the introduction of non-food proteins into food crops. However, we do have some recommendations as to how the guidance could be strengthened to better protect the American food supply.

### **General Comments**

Frito-Lay, Inc., based in Plano, TX is an operating division of PepsiCo, Inc., a Fortune 100 company. Frito-Lay is the world's largest manufacturer of savory snacks; annually in the U.S. we process more than one billion pounds of corn and 3.5 billion pounds of potatoes and potato flakes into favorite brands such as Lays<sup>®</sup>, Doritos<sup>®</sup>, Tostitos<sup>®</sup>, Chee.tos<sup>®</sup> and Fritos<sup>®</sup>. Protecting public health and the reputation of our brands are critical corporate product stewardship objectives. As such we are keenly interested in ensuring that the American food supply remains free from adulteration. Our primary focus is maintaining food safety, but we also recognize that even the perception of risk can create havoc in the marketplace. The Starlink<sup>®</sup> episode of 2000 was ample demonstration of this fact.

Frito-Lay is concerned that the use of food crops, such as corn, to produce non-food items will inevitably result in another incident such as occurred with StarLink<sup>®</sup>. A recent mishap involving ProdiGene was clear indication that our concerns are well-founded. Any adulteration of the food supply, whether by PMPs, PMIs, or any other substance not approved for food use has the potential to trigger a recall. Worse yet these episodes damage consumer confidence in the food supply. Frito-Lay devotes considerable resources towards making sure that incoming raw materials are free from

adulteration, and that our process controls and manufacturing environments reduce the risk of product adulteration to the lowest level practicable. The deliberate introduction of non-food substances into the food supply conflicts with our food safety programs and standards.

Our strong view is that food crops should not be used to produce non-food substances under any circumstance. We believe this practice will inevitably lead to adulteration of the food supply. If the FDA and USDA insist on allowing this practice, we offer the suggestions below as to how the draft guidance could be strengthened to better prevent the introduction of adulterants into the food supply.

### **Comments Concerning Items 1. and 3. of the Proposed Early Safety Evaluation**

With respect to the four topics on which FDA is requesting comment, Frito-Lay offers comments on numbers 1 and 3 only, as Frito-Lay does not develop transgenic plant varieties and will not be responsible for any data collection process of transgenic plant varieties or their allergenic potential of new, introduced proteins or toxins.

#### **Necessary for the Proper Performance of FDA; Utility of the Process and Resulting Information**

Frito-Lay believes the collection of data on new proteins produced in transgenic plant varieties and early safety evaluation of the collected data is necessary for FDA to properly fulfill its mandate to protect the American food supply. In addition, an early safety evaluation will provide useful information to the public and also reinforce consumer confidence in the safety and wholesomeness of the food they eat.

Safeguarding the US food and livestock feed supplies should be a critical priority for both the FDA and the US Department of Agriculture (USDA). Frito-Lay supports the safety evaluation of new proteins in transgenic plant varieties as an excellent new step towards accomplishing this mission and preventing another StarLink®-like incident. However, Frito-Lay is concerned that a program that is not mandatory and conducted in coordination with USDA's permitting process virtually guarantees the adventitious presence of unreviewed novel proteins in the food supply.

Frito-Lay believes strongly that no PMPs or PMIs should be introduced into food crops without an FDA safety evaluation. As part of this evaluation, FDA should make a prospective determination of the status of affected food products should this novel protein be inadvertently introduced into the food supply. Frito-Lay strongly urges FDA to work with USDA to prevent PMP and PMI products that have not undergone and successfully completed an early safety evaluation, or are not designated as GRAS, from being tested or grown in food crops.

We recommend that the threshold for FDA review be set at 10 acres cumulative total. Any trials or other activities which resulted in a cumulative total in excess of 10 acres would trigger a requirement for FDA safety review and determination of the status of food products should they become adulterated with this novel protein. This acreage limit is consistent with the US Environmental Protection Agency (EPA) requirement for an Experimental Use Permit (EUP) prior to field testing unregistered pesticides on more than 10 acres, including plant-incorporated-protectants, or PIPs. Frito-Lay notes that, in the case of PIPs, EPA requires a tolerance based on a safety evaluation for any field-

testing program for which an EUP is approved. Crop destruct EUPs are no longer allowed because of the potential for unintended contamination of food.

Limiting new transgenic plant varieties intended for food or livestock feed use to 10 acres or less until a satisfactory safety evaluation is completed is a minimum safeguard; a requirement for a safety evaluation before any field testing, no matter how small, makes even more public policy sense.

### **Ways to Enhance the Quality, Utility and Clarity of Information Collected for an Early Safety Evaluation**

Frito-Lay recommends that the data collected and analyzed by FDA, and the results of all safety evaluations (risk assessments), be made public on the CFSAN website. This information should be posted in a timely and transparent manner so that consumers, food companies and other stakeholders can be aware of the types of genes and/or gene products that are being introduced into the food supply.

To our knowledge no plant-made pharmaceutical product (PMP) has been granted GRAS status. We speculate that this is because these products do not belong in food, and generally do not meet the definition of GRAS. As such these materials cannot be allowed to adulterate the food supply. Even a trivial amount of an unapproved substance can have serious repercussions, as was demonstrated in 2002 when commercial soybeans were destroyed due to a tiny amount of volunteer corn from a ProdiGene PMP field trial in Nebraska. Apparently this genetically-modified “volunteer” corn (not approved for food use) was harvested with soybeans which were intended for food use. Fortunately, this contamination was discovered before the soybeans were transferred from the silos to food processors. Otherwise, a situation would have occurred that likely would have been a repeat of the StarLink® episode. Our point here is that this material should never have been allowed in corn, and a trial certainly should not have been conducted in the middle of the Corn Belt. At a minimum, a transparent review process would at least have alerted stakeholders to the risk of possible contamination and perhaps additional steps could have been taken by growers and grain facilities to further mitigate against risks.

### **Conclusions**

Frito-Lay once again states our opposition to the use of food crops to produce non-food substances. We believe this practice will inevitably lead to contamination of the food supply. With regard to the draft guidance, we offer the following suggestions as to how the proposal could be strengthened to better protect the food supply:

1. Make mandatory a requirement for safety evaluation by FDA of all non-food genes inserted into food crops. This safety evaluation should include a determination by FDA of the status of food products later found to contain these non-food genes or gene products.
2. This safety review should be required for any trial or trials with a cumulative total planting equal to or in excess of 10 acres.
3. All safety reviews and details about proposed trials should have adequate public notice to allow for response by interested stakeholders.

We urge FDA to institute a robust regulatory scheme to protect the food supply from contamination with PMPs or PMIs. Without such action we believe that contamination and adulteration of the food supply are inevitable.

Sincerely,

Rocco D. Papalia  
Sr. Vice-President,  
Frito-Lay Research & Development