

Peer Review Plan

Title of the Review: Safety Assessment of Gluten Exposure Peer Review

Tentative Assessment:

- Influential Scientific Information
 Highly Influential Scientific Assessment

Agency Contact: P Michael Bolger

Officer or Center: Center for Food Safety and Applied Nutrition

Subject of the Review: Safety assessment of gluten exposure in a sensitive subpopulation group, specifically individuals with celiac disease.

Purpose of the Review: Evaluate risk assessment per questions in peer review charge.

Type of Review

- Individual Reviews (Letter Review)
 Panel Review
 Alternative Process (Briefly Explain): _____

Timing of Review: Approximately 30 days beginning about September 26, 2008.

Number of Reviewers:

- 3 or less
 4 to 10
 More than 10

Primary Disciplines/Types of Expertise of Reviewers: At Minimum: Toxicology, Exposure Analysis, Epidemiology

Reviewers Selected by:

- Agency
 Designated Outside Organization

Public Nominations Requested for Review Panel:

- Yes
 No

Opportunities for the Public to Comment:

- Yes
 No

If Yes, briefly state how and when will these opportunities be provided: FDA will publish a notice of availability of the safety assessment in the Federal Register and open a public docket prior to or about the time the document is sent to the peer reviewers.

Peer Reviewers Provided with Public Comments:

- Yes
- No

