GLUTEN FREE WATCHDOG

Comments submitted by Tricia Thompson, MS, RD
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In response to Docket Number FDA-2021-N-0553-0005
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Dear FDA,

This comment concerns FDA Docket Number FDA-2021-N-0553-0005, FDA draft guidance: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders.

This draft guidance is taking the preemptive position that FDA will NOT consider a petition asking FDA to establish regulatory requirements for gluten-containing grains under FALCPA standards because FDA will only consider regulating allergens that cause acute and sometimes life-threatening immune responses, and because FDA implies in Footnote No. 42 that consumers with celiac disease are already protected under FDA's gluten-free labeling rule (20 CFR. § 101.91).

Therefore, the guidance essentially cuts off the petition rights of millions of consumers with celiac disease merely because they do not suffer acute and life-threatening reactions to gluten. As FDA is well-aware, gluten is dangerous to consumers with celiac disease and the only treatment is total avoidance of any foods containing gluten-containing grains.

For FDA to decide **now** not to even consider a **later** petition from the celiac disease community for additional regulation of gluten-containing grains under FALCPA standards is arbitrary and tremendously unfair to vulnerable consumers who have a right to petition their government for appropriate regulations.

Key failures in the draft guidance related to celiac disease:

- **Why is FDA narrowing petition rights to only those foods that cause IgE-mediated reactions?**
    - FDA intends to consider whether a food allergen is of public health importance **only when** "there is robust evidence that an adverse reaction to the food or component of food is IgE-mediated."

- This creates an extremely narrow and unacceptable window for petitioning for additional regulations.

- **Why is FDA ignoring the May 10, 2021 allergen recommendations from the FAO/WHO Expert Committee regarding Risk assessment of Food Allergens for Codex (cited in the FDA draft guidance at Ref.45)?**

  - The Expert Committee, comprised of "scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry," reviewed a list of allergens in existence since 1999 and "determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies **and coeliac disease** should be included on the list of foods and ingredients . . . ." The Expert Committee then retained "cereals containing gluten" on the 1999 list of allergens whose presence should always be declared in the list of ingredients on a food label.

  - If the FAO/WHO Committee Expert Committee thinks gluten-containing grains are harmful enough to the population (based on prevalence, severity and potency) to require mandatory disclosure, **how can FDA credibly decide now that it will not later consider a citizen petition on this very same topic?**

  - FDA's Footnote No. 42 in the draft guidance references the gluten-free labeling rule (20 CFR. § 101.91) when discussing the FAO/WHO Committee recommendations, suggesting that FDA thinks that rule adequately addresses the concerns of consumers regarding gluten in the United States. It does not. See below.

  - The United States is fairly unique in the world for NOT including gluten-containing grains within allergen legislation. See https://farrp.unl.edu/IRChart

- **Why has FDA already made up its mind that it will not impose additional regulations on gluten-containing grains beyond the gluten-free labeling rule?**

  - In its draft guidance, FDA explains that it denied a 2008 citizen petition asking them to "[amend] … FALCPA to include barley and rye in the list of common allergens requiring disclosure on packaging" because it "did not include adequate information to show that rye and barley are common causes of severe IgE mediated food allergies."

  - FDA knows that gluten-containing grains do not cause these types of reactions in people with celiac disease and so therefore will not meet the guidance's narrow criteria.

- The draft guidance makes clear that a similar petition will also fail FDA's limiting standards of consideration under the draft guidance.

- **Why does FDA rely on the Gluten Free Labeling Rule (20 CFR. § 101.91) in Footnote 42 to suggest existing regulations are protective enough of consumers who must avoid gluten-containing grains?**

    - The Rule is limited to regulating only those products that carry a voluntary "gluten-free" claim.

    - For products not labeled "gluten-free," consumers with celiac disease have no way of knowing if the food they are consuming contains gluten-containing grains other than wheat (already covered under FALCPA).
        - Ingredients that do or may contain barley protein include malt, malt extract, malt syrup, malt vinegar, natural smoke flavor, yeast extract, and natural flavors.

    - Therefore, citizens must be able to petition FDA for additional regulations for required disclosure of gluten-containing grains under FALCPA standards.

In sum, this draft guidance unfairly and arbitrarily closes the door on consumers with celiac disease (a well-documented condition affecting millions of people) who wish to petition their government for more protective regulations.

- FDA should be willing to receive citizen petitions regarding foods that cause **<u>any</u>** immune-mediated adverse reaction.
- FDA should not limit its review of citizen petitions to only foods causing IgE-mediated reactions and acute and life-threatening responses.

Thank you for your consideration.

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