

**Public Law 117–11
117th Congress
An Act**

Apr. 23, 2021
[S. 578]

Food Allergy
Safety,
Treatment,
Education, and
Research Act
of 2021.
21 USC 301 note.

21 USC 321 note.

Recommendations.
Strategies.

To improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Food Allergy Safety, Treatment, Education, and Research Act of 2021” or the “FASTER Act of 2021”.

SEC. 2. FOOD ALLERGY SAFETY.

(a) IN GENERAL.—Section 201(qq)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(1)) is amended by striking “and soybeans” and inserting “soybeans, and sesame”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023.

SEC. 3. REPORT TO CONGRESS.

(a) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

(1) descriptions of ongoing Federal activities related to—
 (A) the surveillance and collection of data on the prevalence of food allergies and severity of allergic reactions for specific food or food ingredients, including the identification of any gaps in such activities;

 (B) the development of effective food allergy diagnostics;

 (C) the prevention of the onset of food allergies;

 (D) the reduction of risks related to living with food allergies; and

 (E) the development of new therapeutics to prevent, treat, cure, and manage food allergies; and

(2) specific recommendations and strategies to expand, enhance, or improve activities described in paragraph (1), including—

 (A) strategies to improve the accuracy of food allergy prevalence data by expanding and intensifying current

collection methods, including support for research that includes the identification of biomarkers and tests to validate survey data and the investigation of the use of identified biomarkers and tests in national surveys;

(B) strategies to overcome gaps in surveillance and data collection activities related to food allergies and specific food allergens; and

(C) recommendations for the development and implementation of a regulatory process and framework that would allow for the timely, transparent, and evidence-based modification of the definition of “major food allergen” included in section 201(qq) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(qq)), including with respect to—

(i) the scientific criteria for defining a food or food ingredient as a “major food allergen” pursuant to such process, including recommendations pertaining to evidence of the prevalence and severity of allergic reactions to a food or food ingredient that would be required in order to establish that such food or food ingredient is an allergen of public health concern appropriate for such process; and

(ii) opportunities for stakeholder engagement and comment, as appropriate, in considering any such modification to such definition.

(b) PUBLICATION.—The Secretary shall make the report under subsection (a) available on the internet website of the Department of Health and Human Services.

Web posting.

Approved April 23, 2021.

LEGISLATIVE HISTORY—S. 578:

CONGRESSIONAL RECORD, Vol. 167 (2021):

Mar. 3, considered and passed Senate.

Apr. 14, considered and passed House.

