

117TH CONGRESS
1ST SESSION

S. 578

AN ACT

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

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

5 **SEC. 2. FOOD ALLERGY SAFETY.**

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

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

14 **SEC. 3. REPORT TO CONGRESS.**

15 (a) **REPORT.**—Not later than 18 months after the
16 date of enactment of this Act, the Secretary of Health and
17 Human Services (referred to in this section as the “Sec-
18 retary”) shall submit to the Committee on Health, Edu-
19 cation, Labor, and Pensions of the Senate and the Com-
20 mittee on Energy and Commerce of the House of Rep-
21 resentatives a report that includes—

22 (1) descriptions of ongoing Federal activities re-
23 lated to—

24 (A) the surveillance and collection of data
25 on the prevalence of food allergies and severity
26 of allergic reactions for specific food or food in-

1 ingredients, including the identification of any
2 gaps in such activities;

3 (B) the development of effective food al-
4 lergy diagnostics;

5 (C) the prevention of the onset of food al-
6 lergies;

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

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

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

15 (A) strategies to improve the accuracy of
16 food allergy prevalence data by expanding and
17 intensifying current collection methods, includ-
18 ing support for research that includes the iden-
19 tification of biomarkers and tests to validate
20 survey data and the investigation of the use of
21 identified biomarkers and tests in national sur-
22 veys;

23 (B) strategies to overcome gaps in surveil-
24 lance and data collection activities related to
25 food allergies and specific food allergens; and

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

9 (i) the scientific criteria for defining a
10 food or food ingredient as a “major food
11 allergen” pursuant to such process, includ-
12 ing recommendations pertaining to evi-
13 dence of the prevalence and severity of al-
14 lergic reactions to a food or food ingredient
15 that would be required in order to establish
16 that such food or food ingredient is an al-
17 lergen of public health concern appropriate
18 for such process; and

19 (ii) opportunities for stakeholder en-
20 gagement and comment, as appropriate, in
21 considering any such modification to such
22 definition.

1 (b) PUBLICATION.—The Secretary shall make the re-
2 port under subsection (a) available on the internet website
3 of the Department of Health and Human Services.

Passed the Senate March 3, 2021.

Attest:

Secretary.

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