

117TH CONGRESS
1ST SESSION

S. 578

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.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2021

Mr. SCOTT of South Carolina (for himself, Mr. MURPHY, Ms. COLLINS, Mrs. GILLIBRAND, Mr. TILLIS, Mr. BLUMENTHAL, Ms. BALDWIN, Mr. MARSHALL, and Mr. WARNOCK) introduced the following bill; which was read twice, considered, read the third time, and passed

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

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

1 **SEC. 2. FOOD ALLERGY SAFETY.**

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

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

10 **SEC. 3. REPORT TO CONGRESS.**

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

18 (1) descriptions of ongoing Federal activities re-
19 lated to—

20 (A) the surveillance and collection of data
21 on the prevalence of food allergies and severity
22 of allergic reactions for specific food or food in-
23 gredients, including the identification of any
24 gaps in such activities;

25 (B) the development of effective food al-
26 lergy diagnostics;

1 (C) the prevention of the onset of food al-
2 lergies;

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

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

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

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

19 (B) strategies to overcome gaps in surveil-
20 lance and data collection activities related to
21 food allergies and specific food allergens; and

22 (C) recommendations for the development
23 and implementation of a regulatory process and
24 framework that would allow for the timely,
25 transparent, and evidence-based modification of

1 the definition of “major food allergen” included
2 in section 201(qq) of the Federal Food, Drug
3 and Cosmetic Act (21 U.S.C. 321(qq)), includ-
4 ing with respect to—

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

15 (ii) opportunities for stakeholder en-
16 gagement and comment, as appropriate, in
17 considering any such modification to such
18 definition.

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

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