

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—116th Cong., 2d Sess.

S. 3451

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.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. SCOTT of South Carolina (for himself and Mr. MURPHY)

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food Allergy Safety,
5 Treatment, Education, and Research Act of 2020” or the
6 “FASTER Act of 2020”.

7 **SEC. 2. FOOD ALLERGY SAFETY.**

8 (a) IN GENERAL.—Section 201(qq)(1) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(1)) is

1 amended by striking “and soybeans” and inserting “soy-
2 beans, and sesame”.

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

7 **SEC. 3. REPORT TO CONGRESS.**

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

15 (1) descriptions of ongoing Federal activities re-
16 lated to—

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

22 (B) the development of effective food al-
23 lergy diagnostics;

24 (C) the prevention of the onset of food al-
25 lergies;

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

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

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

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

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

20 (C) recommendations for the development
21 and implementation of a regulatory process and
22 framework that would allow for the timely,
23 transparent, and evidence-based modification of
24 the definition of “major food allergen” included
25 in section 201(qq) of the Federal Food, Drug

1 and Cosmetic Act (21 U.S.C. 321(qq)), includ-
2 ing with respect to—

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

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

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