S. 3451

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,*

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food Allergy Safety, Treatment, Education, and Research Act of 2020" or the "FASTER Act of 2020".

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 in-

1 gredients, 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

4

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 December 9, 2020.

Attest:

Secretary.

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