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# 21 U.S. Code § 350a-1

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## Protecting infants and improving formula supply

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### **(a) Definitions**

#### **(1) In general**

In this section, the term “infant formula” has the meaning given such term in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)).

#### **(2) Omitted**

### **(b) Office of Critical Foods**

#### **(1) In general**

The Secretary shall establish within the Center for Food Safety and Applied Nutrition an office to be known as the Office of Critical Foods. The Secretary shall appoint a Director to lead such Office.

#### **(2) Duties**

The Office of Critical Foods shall be responsible for oversight, coordination, and facilitation of activities related to critical foods, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(ss)], as added by subsection (a)(2).

### **(c) Omitted**

### **(d) Report**

Not later than one year after December 29, 2022, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

- (1) the number of premarket submissions for new infant formula the Secretary has received under section 412(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(d)) each year since 2012;
- (2) how many of such submissions received requests from the Secretary for additional information;
- (3) how long after receiving such submissions the Secretary sent such requests for additional information;
- (4) what additional information the Secretary requested of the persons submitting such submissions; and
- (5) the date each new infant formula described in subparagraph (A) <sup>[1]</sup> was first marketed, if available.

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