

117TH CONGRESS
2D SESSION

H. R. 7358

To amend the Federal Food, Drug, and Cosmetic Act to apply the exempt infant formula requirements to certain human donor milk, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 2022

Ms. DELAURO (for herself and Ms. SCHRIER) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to apply the exempt infant formula requirements to certain human donor milk, 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 “Donor Milk Safety
5 Act”.

1 **SEC. 2. APPLICATION OF EXEMPT INFANT FORMULA RE-**
2 **QUIREMENTS TO CERTAIN HUMAN DONOR**
3 **MILK.**

4 Section 412(h) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 350a(h)) is amended by adding at
6 the end the following:

7 “(3) Effective beginning one year after the date of
8 the enactment of this paragraph, the exemption under
9 paragraph (1) shall apply with respect to human milk
10 which has undergone any bioburden reduction process in
11 the same manner as such exemption applies with respect
12 to infant formula described in such paragraph. Not later
13 than one year after such date of enactment, the Secretary
14 shall make such revisions as may be necessary to the regu-
15 lations prescribed by the Secretary under paragraph (2)
16 to carry out the preceding sentence.”.

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