HOUSE BILL 97

J1 (4lr1369)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by Delegates Taveras and Pasteur, Pasteur, Pena-Melnyk, Cullison, Alston, Bagnall, Bhandari, Chisholm, Guzzone, Hill, Hutchinson, S. Johnson, Kaiser, Kerr, Kipke, R. Lewis, Lopez, Martinez, M. Morgan, Reilly, Rosenberg, Szeliga, White Holland, and Woods

Read and Examined by Proofreaders: Proofreader. Proofreader. Sealed with the Great Seal and presented to the Governor, for his approval this day of at o'clock, M. Speaker. CHAPTER AN ACT concerning Baby Food - Toxic Heavy Metals - Testing and Labeling (Rudy's Law) FOR the purpose of requiring, beginning on a certain date, manufacturers of baby food to conduct certain testing on baby food for toxic heavy metals before packaging individual units of baby food for sale or distribution in the State; requiring, beginning on a certain date, manufacturers of baby food to include certain information related to toxic heavy metals on the manufacturer's website and on the baby food product label; requiring a consumer to report baby food to the Maryland Department of Health if the consumer believes, based on certain information, that the baby food is being sold in the State with toxic heavy metals that exceed limits established by the

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

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Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Italics indicate opposite chamber/conference committee amendments.



1 2	<u>U.S. Food and Drug Administration;</u> and generally relating to baby food and toxic heavy metals.												
3 4 5 6 7	Article – Health – General Section 21–330.4 Annotated Code of Maryland												
8 9	•												
10	Article – Health – General												
11	21-330.4.												
12 13	(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.												
14 15 16	(2) (1) "BABY FOOD" MEANS FOOD PACKAGED IN A JAR, POUCH, TUB, OR BOX SOLD SPECIFICALLY FOR BABIES AND CHILDREN UNDER THE AGE OF 2 YEARS.												
17 18	(II) "BABY FOOD" DOES NOT INCLUDE INFANT FORMULA, AS DEFINED IN 21 U.S.C. § 321(Z).												
19 20	(3) "MANUFACTURER" INCLUDES A FOOD MANUFACTURER, FOOD PROCESSOR, AND FOOD PACKER.												
21	(4) "PRODUCTION AGGREGATE" MEANS A QUANTITY OF PRODUCT												
22	THAT IS INTENDED TO HAVE UNIFORM COMPOSITION, CHARACTER, AND QUALITY												
23	AND IS PRODUCED ACCORDING TO A MASTER MANUFACTURING ORDER.												
24	(4) (5) "PROFICIENT LABORATORY" MEANS A LABORATORY <u>THAT:</u>												
25	(I) IS ACCREDITED UNDER THE STANDARDS OF THE												
26	INTERNATIONAL ORGANIZATION FOR STANDARDIZATION												
27	STANDARDIZATION/INTERNATIONAL ELECTROTECHNICAL COMMISSION												
28	<u>17025:2017;</u>												
20													
29	(II) USES AN ANALYTICAL METHOD AT LEAST AS SENSITIVE AS												
30 31	THE ANALYTICAL METHOD DESCRIBED IN SECTION 4.7 OF THE U.S. FOOD AND DRUG ADMINISTRATION ELEMENTAL ANALYSIS MANUAL FOR FOOD AND RELATED												
32	PRODUCTS; AND												

- 1 (III) DEMONSTRATES PROFICIENCY IN QUANTIFYING EACH
- 2 TOXIC ELEMENT TO AT LEAST 6 MICROGRAMS OF THE TOXIC ELEMENT TO KILOGRAM
- 3 OF FOOD THROUGH AN INDEPENDENT PROFICIENCY TEST BY ACHIEVING A Z-SCORE
- 4 THAT IS LESS THAN OR EQUAL TO PLUS OR MINUS TWO.
- 5 (5) (6) "QR CODE" MEANS A MACHINE-READABLE CODE.
- 6 CONSISTING OF AN ARRAY OF SQUARES, USED FOR STORING AN INTERNET WEBSITE
- 7 IN ORDER TO ACCESS A WEBPAGE.
- 8 (7) "REPRESENTATIVE SAMPLE" MEANS A SAMPLE THAT CONSISTS
- 9 OF A NUMBER OF UNITS THAT ARE DRAWN BASED ON RATIONAL CRITERIA, SUCH AS
- 10 RANDOM SAMPLING, AND INTENDED TO ENSURE THAT THE SAMPLE ACCURATELY
- 11 PORTRAYS THE MATERIAL BEING SAMPLED.
- 12 (6) (8) "TOXIC HEAVY METAL" MEANS ARSENIC, CADMIUM, LEAD,
- 13 OR MERCURY.
- 14 (B) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION,
- 15 ON OR AFTER JANUARY 1, 2025, A PERSON MAY NOT SELL, DISTRIBUTE, OR OFFER
- 16 FOR SALE BABY FOOD IN THE STATE THAT CONTAINS TOXIC HEAVY METALS THAT
- 17 EXCEED THE LIMITS ESTABLISHED BY THE U.S. FOOD AND DRUG ADMINISTRATION.
- 18 (2) A PERSON MAY SELL, DISTRIBUTE, OR OFFER FOR SALE BABY
- 19 FOOD MANUFACTURED BEFORE JANUARY 1, 2026.
- 20 (1) BEGINNING JANUARY 1, 2025, EACH MANUFACTURER OF
- 21 BABY FOOD SHALL TEST A REPRESENTATIVE SAMPLE OF EACH PRODUCTION
- 22 AGGREGATE OF THE MANUFACTURER'S FINAL BABY FOOD PRODUCT FOR EACH
- 23 TOXIC HEAVY METAL BEFORE PACKAGING INDIVIDUAL UNITS OF BABY-FOOD FOR
- 24 SALE OR DISTRIBUTION IN THE STATE.
- 25 (2) THE TESTING REQUIRED UNDER PARAGRAPH (1) OF THIS
- 26 SUBSECTION SHALL BE CONDUCTED BY A PROFICIENT LABORATORY AT LEAST ONCE
- 27 PER MONTH.
- 28 (3) A MANUFACTURER MAY TEST THE FINAL BABY FOOD PRODUCT IN
- 29 ACCORDANCE WITH PARAGRAPH (1) OF THIS SUBSECTION BEFORE PACKAGING
- 30 INDIVIDUAL UNITS OF BABY FOOD FOR SALE OR DISTRIBUTION.
- 31 (c) (d) On the request of the Department, a manufacturer of
- 32 BABY FOOD SHALL PROVIDE THE RESULTS OF THE TESTING CONDUCTED UNDER
- 33 SUBSECTION (B) (C) OF THIS SECTION TO AN AUTHORIZED AGENT OF THE
- 34 **DEPARTMENT.**

- 1 (D) (E) BEGINNING JANUARY 1, 2026, EACH MANUFACTURER OF BABY 2 FOOD SHALL:
- 3 (1) MAKE PUBLICLY AVAILABLE ON THE MANUFACTURER'S WEBSITE 4 FOR EACH BABY FOOD PRODUCT SOLD, MANUFACTURED, DELIVERED, HELD, OR
- 5 OFFERED FOR SALE IN THE STATE:
- 6 (I) THE NAME AND LEVEL OF EACH TOXIC HEAVY METAL 7 PRESENT IN THE FINAL BABY FOOD PRODUCT AS DETERMINED BY THE TESTING 8 CONDUCTED UNDER SUBSECTION (B) (C) OF THIS SECTION; AND
- 9 (II) SUFFICIENT INFORMATION, SUCH AS THE PRODUCT NAME, 10 UNIVERSAL PRODUCT CODE, OR LOT OR BATCH NUMBER, TO ENABLE CONSUMERS 11 TO IDENTIFY THE FINAL BABY FOOD PRODUCT; AND
- 12 (III) A LINK TO THE U.S. FOOD AND DRUG
 13 ADMINISTRATION'S WEBSITE THAT INCLUDES THE MOST RECENT U.S. FOOD AND
 14 DRUG ADMINISTRATION GUIDANCE AND INFORMATION ABOUT THE HEALTH
 15 EFFECTS OF THE TOXIC HEAVY METALS ON CHILDREN; AND
- 16 (2) INCLUDE IF THE BABY FOOD IS TESTED FOR A TOXIC HEAVY
 17 METAL SUBJECT TO AN ACTION LEVEL, REGULATORY LIMIT, OR TOLERANCE
 18 ESTABLISHED BY THE U.S. FOOD AND DRUG ADMINISTRATION UNDER 21 C.F.R. §
 19 109, INCLUDE ON THE BABY FOOD PRODUCT LABEL:
- 20 <u>(I) THE FOLLOWING STATEMENT: "FOR INFORMATION ABOUT</u>
 21 <u>TOXIC HEAVY METAL TESTING ON THIS PRODUCT, SCAN THE QUICK RESPONSE (QR)</u>
 22 CODE."; AND
- 23 (II) A QR CODE OR OTHER MACHINE-READABLE CODE THAT
 24 ALLOWS CONSUMERS TO ACCESS ON THE MANUFACTURER'S WEBSITE OR THE BABY
 25 FOOD PRODUCT INFORMATION PAGE:
- 26 (I) 1. THE TEST RESULTS FOR THE TOXIC HEAVY METALS; 27 OR AND
- 28 (H) 2. A QR CODE OR OTHER MACHINE-READABLE CODE
 29 THAT-LINKS TO A PAGE ON THE MANUFACTURER'S WEBSITE CONTAINING THE TEST
 30 RESULTS FOR THE TOXIC HEAVY METALS LINK TO THE WEBPAGE ON THE U.S. FOOD
 31 AND DRUG ADMINISTRATION WEBSITE THAT INCLUDES THE MOST RECENT
 32 GUIDANCE AND INFORMATION ABOUT THE HEALTH EFFECTS OF THE TOXIC HEAVY
 33 METAL ON CHILDREN.

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		Speaker of the House of Delegates.										

President of the Senate.