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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the implementation of reforms to enhance food safety and affordability, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. CAMMACK introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the implementation of reforms to enhance food safety and affordability, 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 “FDA Review and Eval-
5 uation for Safe, Healthy and Affordable Foods Act of
6 2026”.

1 **TITLE I—COMMON FOOD**
2 **INGREDIENTS**

3 **SEC. 101. EXCLUSION OF COMMON FOOD INGREDIENTS**
4 **FROM THE DEFINITION OF FOOD ADDITIVE.**

5 Section 201(s) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321(s)) is amended—

7 (1) in paragraph (5), by striking “or” at the
8 end;

9 (2) in paragraph (6), by striking the period at
10 the end and inserting “; or”; and

11 (3) by adding at the end the following:

12 “(7) a common food ingredient.”.

13 **SEC. 102. DEFINITION OF COMMON FOOD INGREDIENT.**

14 (a) **IN GENERAL.**—Section 201 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
16 adding at the end the following:

17 “(tt) The term ‘common food ingredient’ means a
18 food ingredient that was ordinarily consumed as a food,
19 or available for purchase as an independent article of food,
20 on or before January 1, 1958. Such term may include
21 fruits, vegetables, legumes, nuts, seeds, algae, meat, poul-
22 try, fish, grain ingredients, milk obtained from cows or
23 other lactating animals, honey, traditional bacterial cul-
24 tures, and any substance derived from such ingredients.”.

25 (b) **REGULATIONS.**—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services may, by regulation promulgated in
3 accordance with section 701 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 371), further
5 establish the list of common food ingredients in sec-
6 tion 201(tt) of such Act (as added by subsection (a)
7 of this section), consistent with such section 201(tt).

8 (2) PROCEDURES AND CONTENTS.—In promul-
9 gating regulations under paragraph (1), the Sec-
10 retary shall—

11 (A) rely on robust and reliable scientific
12 evidence, including publicly available data and
13 peer-reviewed research;

14 (B) consult, as appropriate, with qualified
15 third parties, including independent scientific
16 experts, academic institutions, and other rel-
17 evant stakeholders; and

18 (C) ensure that such regulations are con-
19 sistent with the protection of the public health
20 and the purposes of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 301 et seq.).

1 **TITLE II—GRAS NOTIFICATION**
2 **AND REGISTRY**

3 **SEC. 201. PROHIBITION ON INTRODUCTION OF FOODS**
4 **WITHOUT GRAS NOTIFICATION.**

5 Section 301 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 331) is amended by adding at the end the
7 following:

8 “(jjj) The introduction of a food into interstate com-
9 merce by an entity required to register under section 415
10 in violation of section 409(l) (relating to a mandatory
11 GRAS notification scheme).”.

12 **SEC. 202. ESTABLISHING MANDATORY GRAS NOTIFICA-**
13 **TION.**

14 Section 409 of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 348) is amended by adding at the end the
16 following:

17 “(l) MANDATORY NOTIFICATION RELATING TO A
18 SUBSTANCE THAT IS GENERALLY RECOGNIZED AS SAFE
19 FOR THE CONDITIONS OF ITS INTENDED USE.—

20 “(1) GRAS DETERMINATIONS REQUIRING NOTI-
21 FICATION.—

22 “(A) IN GENERAL.—A food containing a
23 substance described in section 201(s) shall not
24 be generally recognized as safe for the condi-
25 tions of its intended use under such section un-

1 less there is a notification in effect with respect
2 to such substance in compliance with this sub-
3 section.

4 “(B) GRAS BASED ON CONCLUSION AFTER
5 THE EFFECTIVE DATE.—An entity introducing
6 into interstate commerce a food containing a
7 substance for which the conclusion that such
8 substance is generally recognized as safe under
9 the conditions of its intended use is reached on
10 or after the effective date of this subsection
11 shall submit a notification in accordance with
12 paragraphs (2) through (4).

13 “(C) GRAS BASED ON CONCLUSION PRIOR
14 TO THE EFFECTIVE DATE.—With respect to an
15 entity introducing into interstate commerce a
16 food containing a substance for which the con-
17 clusion that such substance is generally recog-
18 nized as safe under the conditions of its in-
19 tended use was reached prior to the effective
20 date of this subsection, whether such conclusion
21 was made by the manufacturer or supplier, by
22 a third party scientific body, or by the Sec-
23 retary, paragraph (5) shall apply.

24 “(2) CONTENT OF NOTIFICATION SUBMITTED
25 AFTER THE EFFECTIVE DATE.—Subject to para-

1 graph (4), a notification submitted under paragraph
2 (1)(B)—

3 “(A) shall contain—

4 “(i) a signed statement and certifi-
5 cation that includes the name and intended
6 conditions of the substance;

7 “(ii) the identity, summary of the
8 method of manufacture, and specifications
9 of the substance; and

10 “(iii) a synopsis narrative that pro-
11 vides the basis for the conclusion that the
12 substance is generally recognized as safe
13 under the conditions of its use; and

14 “(B) may contain a narrative that provides
15 the basis for the conclusion that the substance
16 is generally recognized as safe under the condi-
17 tions of its use.

18 “(3) PROCEDURE.—

19 “(A) NOTIFICATION EFFECTIVE IN 90
20 DAYS.—Subject to subparagraphs (B) and (C),
21 a notification submitted under paragraph
22 (1)(B) shall become effective on the date that
23 is 90 days after the date on which such notifi-
24 cation is received.

1 “(B) SECRETARY DETERMINATION.—Dur-
2 ing the 90-day period under subparagraph (A),
3 the Secretary may review such information and
4 make a determination as to whether such infor-
5 mation is sufficient to establish that the sub-
6 stance is generally recognized as safe for the
7 conditions of its intended use.

8 “(C) REQUEST FOR ADDITIONAL INFORMA-
9 TION.—If the Secretary determines under sub-
10 paragraph (B) that the information provided
11 under subparagraph (A) is not sufficient to es-
12 tablish that a substance is generally recognized
13 as safe for the conditions of its intended use,
14 the notification shall not take effect at the expi-
15 ration of the 90-day period, and the Secretary
16 shall—

17 “(i) inform the entity that submitted
18 such notification;

19 “(ii) request from such entity a re-
20 vised notification, which shall contain, in
21 addition to the information already sub-
22 mitted under paragraph (2)—

23 “(I) information and data about
24 the dietary exposure of such sub-
25 stance;

1 “(II) the self-limiting levels of
2 use of such substance, in cir-
3 cumstances in which the amount of
4 the notified substance that can be
5 added to food is limited;

6 “(III) experience based on the
7 common use in food of such substance
8 before 1958, if the basis for the con-
9 clusion is through experience based on
10 common use in food;

11 “(IV) a narrative with respect to
12 the substance under paragraph
13 (2)(B); and

14 “(V) a list of supporting data
15 and information that form the basis of
16 the conclusion that the substance is
17 generally recognized as safe for the
18 conditions of its intended use.

19 “(D) REVISED NOTIFICATION.—

20 “(i) IN GENERAL.—If an entity sub-
21 mits a revised notification under subpara-
22 graph (C), the notification shall take effect
23 on the date that is 90 days after the date
24 on which the revised notification in sub-
25 paragraph (C) is received unless the Sec-

1 retary makes a negative determination
2 with respect to the substance.

3 “(ii) NEGATIVE DETERMINATION.—
4 The Secretary may make a negative deter-
5 mination under clause (i) if the Secretary
6 determines, based on the data and infor-
7 mation before the Secretary, that the con-
8 ditions of intended use of the substance
9 have not been shown to be generally recog-
10 nized as safe under paragraph (7) and in-
11 forms the notifier of such determination.

12 “(iii) TIMELINE.—The Secretary may
13 make a negative determination under this
14 subparagraph not later than 90 days after
15 the date the revised notification is received,
16 except that the Secretary may take two ex-
17 tensions, not to exceed 30 days each.

18 “(iv) NOTICE AND OPPORTUNITIES
19 FOR INPUT.—Prior to making a negative
20 determination under this subparagraph,
21 the Secretary shall take the following ac-
22 tions:

23 “(I) Provide the entity that sub-
24 mitted the notification notice of a ten-
25 tative negative notification and allow

1 the entity to address deficiencies in
2 the notification.

3 “(II) Provide the entity with an
4 opportunity for a public hearing con-
5 sistent with subsection (f) to address
6 objections to such determination. Not-
7 withstanding clause (iii), Secretary
8 may extend the period under such
9 clause to make a negative determina-
10 tion as necessary to provide an oppor-
11 tunity under this subclause.

12 “(4) ALTERNATIVE REQUIREMENTS FOR
13 THIRD-PARTY REVIEWED AND MODIFIED SUB-
14 STANCES AND USES.—

15 “(A) EVALUATION BY AN ESTABLISHED
16 SCIENTIFIC PANEL.—

17 “(i) IN GENERAL.—A substance that
18 has been reviewed by an established sci-
19 entific panel (including the Flavor Extract
20 Manufacturers Association Expert Panel or
21 a successor organization) and determined
22 by such panel to be generally recognized as
23 safe for the conditions of its intended use
24 shall be exempt from the notification re-

1 requirement under paragraph (2) if the es-
2 tablished scientific panel—

3 “**(I)** shares the conclusion of the
4 panel with the Secretary; and

5 “**(II)** submits a notification to
6 the Secretary containing the chemical
7 identity and conditions of intended
8 use of the relevant substance.

9 “**(ii)** **PROCEDURE.**—A notification
10 submitted under this subparagraph shall—

11 “**(I)** be automatically accepted by
12 the Secretary;

13 “**(II)** take effect on the date of
14 submission; and

15 “**(III)** be listed on the registry
16 under subsection (m) in accordance
17 with such subsection.

18 “**(iii)** **ESTABLISHED SCIENTIFIC**
19 **PANEL DEFINED.**—In this subsection, the
20 term ‘established scientific panel’ means a
21 scientific panel that—

22 “**(I)** is composed of individuals
23 who have the scientific training and
24 experience to evaluate the safety of
25 the relevant substances through sci-

1 entific procedures and who collectively
2 have expertise on the physical, chem-
3 ical, and biological properties of the
4 relevant substance and the scientific
5 questions reasonably expected to arise
6 with respect to the conditions of its
7 intended use; and

8 “(II) has established and main-
9 tains written policies and proce-
10 dures—

11 “(aa) to identify, disclose,
12 and address potential sources of
13 bias;

14 “(bb) to assess, manage,
15 and document conflicts of inter-
16 est and appearances of conflicts
17 of interest; and

18 “(cc) to document its delib-
19 erations, the scientific basis for
20 its conclusions, and the final de-
21 termination reached by the panel.

22 “(B) MODIFIED SUBSTANCE OR USE.—A
23 substance used in the food supply to a signifi-
24 cant degree prior to the date of enactment of
25 this subsection or that is the subject of a notifi-

1 cation under this subsection shall be exempt
2 from notification requirements under paragraph
3 (2) if the substance—

4 “(i) is intended for a new use that
5 does not substantially increase the antici-
6 pated dietary exposure to the substance;

7 “(ii) will not be produced with a sig-
8 nificant manufacturing change such that
9 the chemical identity or chemical charac-
10 terization is no longer substantially similar
11 to the substance in the registry or in use
12 in the food supply; and

13 “(iii) has not undergone any other
14 significant chemical change such that the
15 chemical identity or chemical characteriza-
16 tion of the substance is no longer substan-
17 tially similar to the substance that is used
18 in the food supply in the United States.

19 “(5) ALTERNATIVE REQUIREMENTS FOR SUB-
20 STANCES DETERMINED TO BE GRAS PRIOR TO THE
21 EFFECTIVE DATE AND COMMON FOOD INGREDI-
22 ENTS.—

23 “(A) IN GENERAL.—An entity under para-
24 graph (1)(C) may introduce a food containing a

1 substance described in such paragraph if one of
2 the following conditions are met:

3 “(i) The entity submits a notification
4 to the Secretary containing the chemical
5 identity and conditions of the intended use
6 of such substance.

7 “(ii) The substance, as of the day be-
8 fore the effective date of this subsection, is
9 listed on the Substances Added to Foods
10 database for the conditions of its intended
11 use.

12 “(B) VOLUNTARY SUBMISSIONS.—An enti-
13 ty under paragraph (1)(C) may voluntarily sub-
14 mit a notification of a common food ingredient
15 containing the common name of that ingredient
16 for inclusion in the registry.

17 “(C) PROCEDURE.—A notification sub-
18 mitted under subparagraph (A)(i) or (B)
19 shall—

20 “(i) be automatically accepted by the
21 Secretary after 30 days, unless the Sec-
22 retary has reviewed the substance subject
23 to the notification under subsection (o);

24 “(ii) take effect 30 days after the date
25 of receipt of the submission; and

1 “(iii) be listed on the registry under
2 subsection (m) in accordance with such
3 subsection.

4 “(D) TREATMENT OF SUBSTANCES ON
5 THE SUBSTANCES ADDED TO FOOD DATA-
6 BASE.—For the purposes of paragraph (1)(A),
7 a substance listed on the Substances Added to
8 Foods database on or before the effective date
9 of this subsection shall be treated as though a
10 notification was submitted under this subsection
11 with respect to such substance.

12 “(E) POST-MARKET REVIEW.—The Sec-
13 retary may review substances covered by this
14 paragraph under subsection (o)(6).

15 “(6) DETERMINATION THAT A SUBSTANCE IS
16 NO LONGER GRAS.—

17 “(A) IN GENERAL.—The Secretary may re-
18 view any substance listed on the registry under
19 subsection (m), including any substance for
20 which a notification has been submitted under
21 this subsection, to determine whether the sub-
22 stance is generally recognized as safe for the
23 conditions of its intended use.

24 “(B) TERMINATION OF GRAS STATUS.—
25 The Secretary may terminate the efficacy of a

1 notification under this subsection based on a
2 determination by the Secretary that the sub-
3 stance for which a notification has been sub-
4 mitted is no longer generally recognized as safe
5 for the conditions of its intended use following
6 the procedures in section 302 or 401, as appro-
7 priate.

8 “(C) EFFECT OF TERMINATION.—Subject
9 to this paragraph, an entity may continue use
10 of a substance for which a notification has been
11 terminated under subparagraph (B) for a pe-
12 riod of 2 years beginning on the date of such
13 termination.

14 “(D) IMMINENT AND SEVERE RISK.—

15 “(i) IN GENERAL.—Notwithstanding
16 subparagraph (C), the Secretary may re-
17 quire the immediate removal of a sub-
18 stance from use in interstate commerce if
19 the Secretary determines that there is a se-
20 vere and imminent risk that exposure to
21 the substance will cause severe illness or
22 death in people or animals under the con-
23 ditions of its intended use.

24 “(ii) OPPORTUNITY FOR HEARING.—

25 To make a determination under clause (i),

1 the Secretary shall provide an opportunity,
2 prior to the effective date of such deter-
3 mination, for the affected entity to request
4 an informal hearing to contest the deter-
5 mination consistent with section 423.

6 “(E) BASIS FOR DETERMINATIONS.—The
7 Secretary shall base any determination under
8 subparagraph (A) or (D) on the best available
9 scientific information available to the Secretary
10 by experts qualified in the relevant field and the
11 weight of scientific evidence based on well-es-
12 tablished scientific practices and principles, in-
13 cluding information not submitted by the noti-
14 fier.

15 “(F) ADULTERATION.—A food containing
16 a substance for which a notification has been
17 terminated under this paragraph shall not be
18 considered adulterated on the basis that it con-
19 tains such substance for the duration of the
20 shelf-life of such food if such food was intro-
21 duced on or before the date of termination or
22 during the 2-year period described in subpara-
23 graph (C).

24 “(7) TRANSITION PERIOD.—Any substance for
25 which the conditions of intended use are no longer

1 generally recognized as safe as the result of the en-
2 actment of this subsection shall be treated as though
3 the Secretary has terminated the efficacy of a notifi-
4 cation for such substance under paragraph (6).

5 “(8) REGULATIONS.—Not later than 2 years
6 after the date of enactment of this subsection, the
7 Secretary shall issue rules necessary to establish
8 procedures to carry out this subsection, including
9 procedures for—

10 “(A) submission, evaluation, response, and
11 inclusion of notifications under this subsection
12 on the registry under subsection (m); and

13 “(B) negative determinations under para-
14 graphs (3) and (6).

15 “(9) TRANSPARENCY AND CONFIDENTIALITY.—

16 “(A) CONFIDENTIALITY PERIOD.—

17 “(i) IN GENERAL.—Until the date
18 that is 120 days after the date on which
19 a notification under paragraph (1)(B) be-
20 comes effective, withdrawn, or rejected, the
21 Secretary shall keep all information sub-
22 mitted under such paragraph confidential.

23 “(ii) LIMITED DISCLOSURE.—In in-
24 stances where a notification for a sub-
25 stance has become effective and a duplica-

1 tive notification has been submitted or pro-
2 posed to the Secretary in the 120-day pe-
3 riod beginning on the effective date of the
4 notification, the Secretary—

5 “(I) may disclose in writing to
6 the notifier that a notification for the
7 substance is currently effective; and

8 “(II) at the Secretary’s discre-
9 tion, request that the duplicative noti-
10 fication be withdrawn or not sub-
11 mitted.

12 “(iii) LIMITED DISCLOSURE.—In in-
13 stances in which a notification for a sub-
14 stance has become effective, the Secretary
15 shall add the substance’s identity and uses
16 to the registry under subsection (m) con-
17 sistent with subsection (m)(2).

18 “(B) PUBLICATION.—On the date that is
19 120 days after the effective date of a notifica-
20 tion under paragraph (1)(B), the Secretary
21 shall make available on a public website the full
22 text of each effective notification submitted
23 under such paragraph, except that the Sec-
24 retary shall redact all information under sub-
25 paragraph (C).

1 “(C) CONFIDENTIAL INFORMATION AND
2 TRADE SECRETS.—Except as provided in sub-
3 paragraph (D), the Secretary may not disclose
4 any information that—

5 “(i) is exempt from disclosure under
6 section 552(b)(4) of title 5, United States
7 Code;

8 “(ii) is submitted or reported to, or
9 otherwise obtained by, the Secretary under
10 this subsection; and

11 “(iii) with respect to which a claim for
12 protection from disclosure is asserted
13 under subparagraph (E).

14 “(D) PIVOTAL SAFETY DATA.—Informa-
15 tion that is pivotal safety data submitted under
16 this subsection shall not be protected from dis-
17 closure under subparagraph (C).

18 “(E) PROTECTION FROM DISCLOSURE.—

19 “(i) ASSERTION OF CLAIM.—An entity
20 seeking to protect information from disclo-
21 sure under this subsection shall assert a
22 claim for protection from disclosure at the
23 time that such information is submitted, in
24 accordance with procedural rules issued by
25 the Secretary under this paragraph.

1 “(ii) REQUIRED CERTIFICATIONS.—A
2 claim asserted under clause (i) shall in-
3 clude a statement certifying that the enti-
4 ty—

5 “(I) has taken reasonable meas-
6 ures to protect the confidentiality of
7 the information;

8 “(II) has determined that the in-
9 formation is not required to be dis-
10 closed or otherwise made publicly
11 available under any other Federal law;
12 and

13 “(III) has a reasonable basis to
14 conclude that disclosure of the infor-
15 mation is likely to cause substantial
16 harm to the competitive person of the
17 entity.

18 “(F) REPORTS ON HANDLING OF INFOR-
19 MATION.—

20 “(i) INSPECTOR GENERAL REPORT.—
21 Not later than 1 year after the effective
22 date of this subsection, and annually there-
23 after, the Inspector General of the Depart-
24 ment shall submit to the Secretary, the
25 Committee on Health, Education, Labor,

1 and Pensions of the Senate, and the Com-
2 mittee on Energy and Commerce of the
3 House of Representatives, a report con-
4 taining—

5 “(I) an assessment of the prac-
6 tices and procedures of the Food and
7 Drug Administration for handling and
8 protecting confidential information
9 relative to best practices for the pre-
10 vention of economic espionage involv-
11 ing confidential information submitted
12 or reported to the Secretary under
13 this subsection; and

14 “(II) recommendations for im-
15 provements and corrective measures
16 to such practices and procedures.

17 “(ii) SECRETARY REPORT.—Not later
18 than 1 year after the date on which each
19 report is submitted under clause (i), the
20 Secretary shall submit to the Committee
21 on Health, Education, Labor, and Pen-
22 sions of the Senate and the Committee on
23 Energy and Commerce of the House of
24 Representatives, a report describing the
25 corrective actions, policies, and procedures

1 implemented by the Food and Drug Ad-
2 ministration to address issues identified by
3 each report under clause (i).

4 “(10) FINAL AGENCY ACTION.—A determina-
5 tion that a substance is not or no longer recognized
6 as safe under paragraph (3)(D)(ii) or paragraph (6),
7 respectively, shall constitute a final agency action
8 subject to judicial review.

9 “(11) EFFECTIVE DATE.—The effective date of
10 this subsection shall be the date that is 4 years after
11 the date of enactment of this subsection.”.

12 **SEC. 203. ESTABLISHMENT OF REGISTRY.**

13 Section 409 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 348), as amended by this Act, is further
15 amended by adding at the end the following:

16 “(m) REGISTRY OF CONCLUSIONS OF GRAS STA-
17 TUS.—

18 “(1) IN GENERAL.—Not later than 180 days
19 after the date of enactment of this subsection, the
20 Secretary shall make publicly available an inventory
21 of effective notifications under subsection (l), to be
22 known as the ‘Registry of Conclusions of GRAS Sta-
23 tus’ (referred to in this subsection as the ‘registry’).

24 “(2) UPDATE INTERVAL.—The Secretary shall
25 ensure that the registry reflects any effective notifi-

1 cation under subsection (l) not later than 30 days
2 after the date on which such notification becomes ef-
3 fective by adding the substance’s name and use to
4 the registry.

5 “(3) DATA.—Notwithstanding subsection (l)(9),
6 the Secretary shall include the chemical identity and
7 conditions of intended use of each substance for
8 which an effective notification has been submitted
9 under such subsection.”.

10 **SEC. 204. GENERALLY RECOGNIZED AS SAFE DEFINED.**

11 Section 201 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 321) is amended by adding at the end the
13 following:

14 “(uu)(1) In subsection (s), the term ‘generally recog-
15 nized as safe’, with respect to a substance, means that
16 such substance is generally recognized, among experts
17 qualified by the scientific training and experience to evalu-
18 ate the safety of the substance, as having been adequately
19 shown through scientific procedures to be safe for the con-
20 ditions of the intended use of the substance.

21 “(2) In this subsection, the term ‘safe’, with respect
22 to a substance, means that there is a reasonable certainty
23 in the minds of experts qualified by scientific training and
24 experience that no harm will result from the substance
25 under the conditions of its intended use.”.

1 **SEC. 205. ACCREDITATION OF ESTABLISHED SCIENTIFIC**
2 **PANELS.**

3 Section 409 of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 348), as amended by this Act, is further
5 amended by adding at the end the following:

6 “(n) ACCREDITED ESTABLISHED SCIENTIFIC PAN-
7 ELS FOR THIRD PARTY ASSESSMENTS OF GRAS SUB-
8 STANCES.—

9 “(1) ESTABLISHED SCIENTIFIC PANEL DE-
10 FINED.—In this subsection, the term ‘established
11 scientific panel’ means an entity accredited by the
12 Secretary to perform third-party reviews of sub-
13 stances to assess their status as generally recognized
14 as safe for the conditions of their intended use (re-
15 ferred to in this subsection as ‘GRAS status’) and
16 provide an alternative method for notification of
17 such status pursuant to subsection (l)(4).

18 “(2) ESTABLISHMENT OF PROGRAM; AUTHOR-
19 ITY TO ACCREDIT.—

20 “(A) IN GENERAL.—The Secretary may es-
21 tablish a program to accredit established sci-
22 entific panels to perform third-party reviews of
23 the GRAS status of eligible substances and to
24 submit determinations to the Secretary in ac-
25 cordance with subsection (l)(4).

1 “(B) FLAVOR EXTRACT MANUFACTURERS
2 ASSOCIATION EXPERT PANEL.—The Flavor Ex-
3 tract Manufacturers Association Expert Panel
4 shall be accredited as an established scientific
5 panel on the date of enactment of this sub-
6 section.

7 “(3) ACCREDITATION STANDARDS; APPLICA-
8 TION; TERM.—

9 “(A) APPLICATION.—A person seeking ac-
10 creditation for an established scientific panel
11 shall submit to the Secretary an application at
12 such time, in such manner, and containing such
13 information as the Secretary may require as es-
14 tablished in guidance to meet the criteria of
15 subsection (l)(4)(A)(iii).

16 “(B) STANDARDS.—The Secretary shall
17 accredit an applicant that demonstrates that
18 the applicant meets the criteria of subsection
19 (l)(4)(A)(iii).

20 “(C) TERM AND RENEWAL.—An accredita-
21 tion under this paragraph shall be for a term
22 established by the Secretary and shall be re-
23 newed upon a showing that the accredited per-
24 son continues to meet the standards under sub-
25 section (l)(4)(A)(iii).

1 “(D) WEBSITE LISTING ACCREDITED PAR-
2 TIES.—The Secretary shall establish a website
3 that lists accredited third-party certified estab-
4 lished scientific panels.

5 “(E) SUSPENSION AND WITHDRAWAL.—
6 The Secretary may suspend or withdraw ac-
7 creditation if the Secretary determines that the
8 accredited person no longer meets the stand-
9 ards of subsection (l)(4)(A)(iii) under this para-
10 graph or has failed to comply with requirements
11 of this paragraph, subject to such notice and
12 opportunity to respond as the Secretary may
13 provide.

14 “(4) AUDITS AND OVERSIGHT; RECORDS.—

15 “(A) ACCESS AND AUDITS.—The Secretary
16 may conduct audits and other oversight activi-
17 ties, including onsite assessments, to evaluate
18 the performance and compliance of established
19 scientific panels under this section.

20 “(B) RECORDS.—An established scientific
21 panel shall maintain such records as the Sec-
22 retary may require to support recommendations
23 and to permit oversight under paragraph (1).

24 “(C) CORRECTIVE ACTIONS.—If the Sec-
25 retary identifies deficiencies, the Secretary may

1 require corrective actions as a condition of con-
2 tinued accreditation.

3 “(5) GUIDANCE.—The Secretary may issue
4 such guidance as necessary to carry out this section.
5 Initial guidance shall be based on the document of
6 the Food and Drug Administration titled ‘Guidance
7 for Industry: Best Practices for Convening a GRAS
8 Panel’, dated December 2022, including any subse-
9 quent revisions to such document.”.

10 **TITLE III—ACTION ON FOOD**
11 **CHEMICAL SAFETY**

12 **SEC. 301. SYSTEMATIC PROGRAM FOR ASSESSMENT OF**
13 **CHEMICALS.**

14 Section 409 of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 348), as amended by this Act, is further
16 amended by adding at the end the following:

17 “(o) PROGRAM FOR FOOD CHEMICAL SAFETY.—

18 “(1) IN GENERAL.—Not later than September
19 30, 2026, the Secretary shall establish a systematic
20 program—

21 “(A) to conduct assessments of the safety
22 of chemicals in the food supply; and

23 “(B) to prioritize among such chemicals
24 for safety risk evaluation.

25 “(2) PRIORITY LIST.—

1 “(A) IN GENERAL.—Not later than Sep-
2 tember 30, 2027, and annually thereafter, the
3 Secretary shall publish a list of chemicals that
4 will be prioritized for risk assessment.

5 “(B) REQUEST FOR SUBMISSIONS.—In
6 carrying out subparagraph (A), the Secretary
7 shall publish—

8 “(i) a public notice requesting the
9 submission by interested persons of rec-
10 ommendations for which chemicals should
11 be considered for risk evaluation; and

12 “(ii) a public notice requesting the
13 submission by interested persons of sci-
14 entific and other information concerning
15 the safety of food additives, substances, or
16 other chemicals in food.

17 “(3) ASSESSMENT.—In conducting risk assess-
18 ments under paragraph (1)(A), the Secretary shall
19 evaluate whether a chemical is safe for the condi-
20 tions of its intended use under section 201(uu).

21 “(4) PUBLICATION.—The Secretary shall pub-
22 lish the results of an assessment conducted under
23 paragraph (1)(A) on the website of the Food and
24 Drug Administration.

1 “(5) USE.—The Secretary shall use assess-
2 ments conducted under paragraph (1)(A)—

3 “(A) to support determinations on the safe
4 conditions of the use of a food additive and
5 whether a substance is generally recognized as
6 safe for the conditions of its intended use; and

7 “(B) to identify the levels of chemicals that
8 shall be considered appropriate for the presence
9 of such chemical in food.

10 “(6) REGULATORY AUTHORITY.—

11 “(A) IN GENERAL.—If a safety issue is
12 identified with a food additive, a substance gen-
13 erally recognized as safe for the conditions of
14 its intended use, or another chemical, the Sec-
15 retary may, based on a risk evaluation con-
16 ducted under paragraph (1)(A), issue rules—

17 “(i) to specify conditions of use of
18 such food additive, substance, or chemical
19 to the safe conditions of use; or

20 “(ii) if the Secretary cannot prescribe
21 regulations adequate to ensure safe condi-
22 tions of use, to remove such food additive,
23 substance, or chemical from the food sup-
24 ply in accordance with this paragraph.

1 “(B) NOTICE AND PUBLIC COMMENT.—In
2 carrying out subparagraph (A), the Secretary
3 shall ensure adequate notice and public com-
4 ment in accordance with section 553 of title 5,
5 United States Code.

6 “(C) TRANSITION.—In carrying out sub-
7 subparagraph (A)(ii), the Secretary shall ensure
8 that an entity may continue use of a food addi-
9 tive, substance, or chemical described under
10 such subparagraph for a period of 2 years after
11 the date of such rulemaking.

12 “(D) IMMINENT AND SEVERE RISK.—

13 “(i) IN GENERAL.—Notwithstanding
14 subparagraph (C), in carrying out sub-
15 paragraph (A), the Secretary may require
16 the immediate removal of a food additive,
17 substance, or chemical from the food sup-
18 ply if the Secretary determines that there
19 is a severe and imminent risk that expo-
20 sure to the substance will cause severe ill-
21 ness or death in people or animals.

22 “(ii) OPPORTUNITY FOR HEARING.—
23 To make a determination under clause (i),
24 the Secretary must provide an opportunity,
25 prior to the effective date of such deter-

1 mination, for the affected entity to request
2 an informal hearing to contest the deter-
3 mination consistent with section 423.

4 “(E) BASIS FOR DETERMINATIONS.—The
5 Secretary shall base any determination under
6 this subsection on the best available scientific
7 information available to the Secretary by ex-
8 perts qualified in the relevant field and the
9 weight of scientific evidence based on well-es-
10 tablished scientific practices and principles, in-
11 cluding information not submitted by the noti-
12 fier.

13 “(F) ADULTERATION.—A food containing
14 a food additive, substance, or chemical that is
15 restricted or removed from the food supply
16 under subparagraph (A) shall not be considered
17 adulterated on the basis that it contains such
18 food additive, substance, or chemical for the du-
19 ration of the shelf-life of such food if such food
20 was introduced on or before the date on which
21 the regulation was issued.

22 “(G) FINAL AGENCY ACTION.—Any rule-
23 making under this paragraph shall constitute a
24 final agency action subject to judicial review.

1 “(7) REPORT.—Not later than 1 year after the
2 enactment of this subsection, and annually there-
3 after, the Secretary shall submit to Congress a re-
4 port on the activities of the program under this sub-
5 section, including agency actions taken in the prior
6 year or planned for the coming year consistent with
7 the assessment required by this subsection.”.

8 **TITLE IV—TECHNICAL**
9 **AMENDMENTS**

10 **SEC. 401. TECHNICAL AMENDMENTS.**

11 **[To Be Supplied]**

12 **TITLE V—FACILITY**
13 **REGISTRATION FEES**

14 **SEC. 501. FACILITY REGISTRATION FEES.**

15 (a) IN GENERAL.—Section 415(a) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 350d(a)) is
17 amended by adding at the end the following:

18 “(6) FACILITY REGISTRATION FEES.—

19 “(A) IN GENERAL.—Beginning 60 days
20 after the date of enactment of this paragraph,
21 each facility engaged in the manufacturing,
22 processing, packing, or holding of food intended
23 for human consumption in the United States
24 shall be subject to a fee described in subpara-
25 graph (B) for initial registration and for each

1 biennial registration renewal of the facility
2 under this subsection, except that facilities sole-
3 ly engaged in holding such food, farm mixed-
4 type facilities, and other facilities as designated
5 by the Secretary through rulemaking shall be
6 exempt from such fee. The total fees collected
7 under this paragraph may not exceed
8 \$50,000,000 in the aggregate for any fiscal
9 year.

10 “(B) FEE SCHEDULE.—

11 “(i) IN GENERAL.—For fiscal years
12 2027 through 2032, the following fee
13 schedule shall apply with respect to a fee
14 under subparagraph (A) for registration or
15 renewal:

16 “(I) Domestic facilities with rev-
17 enue equal to or greater than
18 \$1,000,000 per year shall be subject
19 to a maximum fee of \$1,000.

20 “(II) Domestic facilities with rev-
21 enue less than \$1,000,000 per year
22 shall be subject to a fee of \$250.

23 “(III) Foreign facilities shall be
24 subject to a maximum fee of \$1,000.

1 “(ii) REQUEST FOR RECORDS.—The
2 Secretary may request and review appro-
3 priate records for the current and pre-
4 ceding 2 fiscal years for facilities that
5 claim qualification for the reduced fee
6 under clause (i)(II).

7 “(C) FEE REQUIREMENTS.—

8 “(i) AVAILABILITY OF AMOUNTS.—
9 The fees collected under this paragraph—
10 “(I) are authorized to remain
11 available until expended;

12 “(II) shall be deposited in the
13 salaries and expenses account of the
14 Food and Drug Administration; and

15 “(III) shall be available only to
16 the extent provided in advance in ap-
17 propriations Acts.

18 “(ii) COVERED EXPENSES.—The
19 funds made available under this paragraph
20 shall be restricted solely to expenses for re-
21 views of notifications and postmarket re-
22 views of substances added to food intended
23 for human and animal consumption under
24 subsections (l) and (o) of section 409.

1 “(iii) COLLECTIONS AND APPROPRIA-
2 TIONS ACTS.—The fees collected under this
3 paragraph—

4 “(I) shall be retained in each fis-
5 cal year in an amount not to exceed
6 the amount specified in appropriation
7 Acts, or otherwise made available for
8 obligation, for such fiscal year; and

9 “(II) shall only be collected and
10 available to defray increases in the
11 costs of the resources allocated for the
12 process for reviews of notifications
13 and postmarket reviews of substances
14 added to food intended for human and
15 animal consumption under subsections
16 (l) and (o) of section 409 (including
17 increases in such costs for an addi-
18 tional number of full-time equivalent
19 positions in the Department to be en-
20 gaged in such process) over such
21 costs, excluding costs paid from fees
22 collected under this section, for fiscal
23 year 2026 multiplied by the adjust-
24 ment factor.

1 “(D) LIMITATION.—Fees may not be as-
2 sessed under this paragraph for a fiscal year
3 beginning after fiscal year 2026 unless appro-
4 priations for the salaries and expenses of the
5 Food and Drug Administration’s Human Foods
6 Program and related field activities for such fis-
7 cal year (excluding the amount of fees appro-
8 priated under this paragraph for such fiscal
9 year) are equal to or greater than—

10 “(i) the amount appropriated for the
11 salaries and expenses of the Human Foods
12 Program and related field activities for the
13 fiscal year 2026; multiplied by

14 “(ii) the adjustment factor applicable
15 to the fiscal year involved.

16 “(E) ANNUAL CERTIFICATIONS.—The Sec-
17 retary shall certify annually that—

18 “(i) the fees collected under this para-
19 graph have been utilized only for the pur-
20 poses identified in this paragraph; and

21 “(ii) sufficient funds for such pur-
22 poses are available through the collected
23 fees.

24 “(F) ANNUAL REPORT.—The Secretary
25 shall submit to Congress—

1 “(i) for each of fiscal years 2027
2 through 2030, an annual report assessing
3 the utilization of the fees collected under
4 this paragraph; and

5 “(ii) for fiscal year 2031, a summary
6 report assessing such utilization.

7 “(G) REAUTHORIZATION.—

8 “(i) CONSULTATION.—In developing
9 recommendations to present to the Con-
10 gress with respect to reauthorization of
11 this paragraph, the Secretary shall consult
12 with—

13 “(I) the Committee on Energy
14 and Commerce of the House of Rep-
15 resentatives;

16 “(II) the Committee on Health,
17 Education, Labor, and Pensions of
18 the Senate;

19 “(III) scientific and academic ex-
20 perts; and

21 “(IV) the regulated industry.

22 “(ii) PRIOR PUBLIC INPUT.—Prior to
23 beginning negotiations with the regulated
24 industry on the reauthorization of this
25 paragraph, the Secretary shall—

1 “(I) publish a notice in the Fed-
2 eral Register requesting public input
3 on the reauthorization;

4 “(II) hold a public meeting at
5 which the public may present its views
6 on the reauthorization;

7 “(III) provide a period of 30
8 days after the public meeting to ob-
9 tain written comments from the public
10 suggesting changes to this paragraph;
11 and

12 “(IV) publish the comments on
13 the public website of the Food and
14 Drug Administration.

15 “(iii) UPDATES TO CONGRESS.—The
16 Secretary, in consultation with regulated
17 industry, shall provide regular updates on
18 negotiations on the reauthorization of this
19 paragraph to the Committee on Health,
20 Education, Labor, and Pensions of the
21 Senate and the Committee on Energy and
22 Commerce of the House of Representa-
23 tives.

24 “(iv) PUBLIC REVIEW OF REC-
25 COMMENDATIONS.—After negotiations with

1 the regulated industry, the Secretary
2 shall—

3 “(I) present the recommenda-
4 tions developed under clause (i) to the
5 congressional committees specified in
6 clause (iii);

7 “(II) publish such recommenda-
8 tions in the Federal Register;

9 “(III) provide for a period of 30
10 days for the public to provide written
11 comments on such recommendations;

12 “(IV) hold a meeting at which
13 the public may present its views on
14 such recommendations; and

15 “(V) after consideration of such
16 public views and comments, revise
17 such recommendations as necessary.

18 “(v) TRANSMITTAL OF RECOMMENDA-
19 TIONS.—Not later than January 15, 2031,
20 the Secretary shall submit to Congress—

21 “(I) the revised recommendations
22 under clause (iv);

23 “(II) a summary of the views and
24 comments received under clause (iv);
25 and

1 “(III) any changes made to the
2 recommendations in response to such
3 views and comments.

4 “(vi) MINUTES OF NEGOTIATION
5 MEETINGS.—

6 “(I) PUBLIC AVAILABILITY.—The
7 Secretary shall make publicly avail-
8 able, on the public website of the
9 Food and Drug Administration, min-
10 utes of each negotiation meeting con-
11 ducted under this subparagraph be-
12 tween the Food and Drug Administra-
13 tion and the regulated industry, not
14 later than 30 days after the date of
15 the negotiation meeting.

16 “(II) CONTENT.—The minutes
17 described in subclause (I) shall sum-
18 marize, in sufficient detail, any sub-
19 stantive proposal made by any party
20 to the negotiations as well as signifi-
21 cant controversies or differences of
22 opinion during the negotiations and
23 their resolution.

1 “(H) SUNSET DATE.—This paragraph
2 shall cease to be effective September 30,
3 2032.”.

4 (b) CONFORMING AMENDMENTS.—Section 415(a) of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 350d(a)) is amended

7 (1) in the first sentence of paragraph (2), by
8 inserting “pay any required fee under paragraph (6)
9 and” after “shall”;

10 (2) in the first sentence of paragraph (3), by
11 inserting “any required fee under paragraph (6)
12 and” after “the Secretary”; and

13 (3) in paragraph (4), by inserting “and pay-
14 ment of any required registration fee under para-
15 graph (6)” after “paragraph (1)”.

16 **TITLE VI—MODERNIZING THE**
17 **REGULATION OF CRITICAL**
18 **FOODS AND OTHER FOODS**
19 **PACKAGED FOR CONSUMP-**
20 **TION BY INFANTS AND TOD-**
21 **DLERS**

22 **SEC. 601. REGULATION OF INFANT AND TODDLER FOOD.**

23 (a) DEFINITION OF INFANT OR TODDLER FOOD.—
24 Section 201 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 321), as amended by this Act, is further
2 amended by adding at the end the following:

3 “(vv) The term ‘infant or toddler food’ means food
4 packaged in a jar, pouch, tub, or box sold exclusively for
5 infants and toddlers up to the age of 24 months. The term
6 applies only to foods represented as intended to constitute
7 a sole or significant portion of the diet of such infants
8 and toddlers, and excludes foods that are merely suitable
9 for or capable of occasional consumption by such chil-
10 dren.”.

11 (b) CONTAMINANTS IN INFANT OR TODDLER
12 FOOD.—Chapter IV of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 341 et seq.) is amended by adding
14 at the end the following:

15 **“SEC. 425. ADMINISTRATIVE ORDERS FOR CONTAMINANTS**
16 **IN INFANT OR TODDLER FOOD.**

17 “(a) ADMINISTRATIVE ORDERS.—

18 “(1) IN GENERAL.—

19 “(A) ESTABLISHMENT OF LIMITS.—Within
20 the timeframe specified in paragraph (2), the
21 Secretary shall—

22 “(i) evaluate relevant health data,
23 available scientific evidence, achievability,
24 and other information that the Secretary
25 considers relevant; and

1 “(ii) based on such evaluation, estab-
2 lish limits for lead, cadmium, and arsenic
3 (or, as appropriate for the protection of
4 public health, species of these toxic ele-
5 ments) in infant or toddler food by admin-
6 istrative order published in the Federal
7 Register.

8 “(B) PUBLICATION OF PROPOSED OR-
9 DERS.—Prior to issuing an administrative order
10 under subparagraph (A), the Secretary shall
11 publish a proposed order in the Federal Reg-
12 ister and shall consider comments submitted to
13 a public docket for such proposed order, not-
14 withstanding the requirements of subchapter II
15 of chapter 5 of title 5, United States Code, and
16 chapter 6 of title 5, United States Code. Each
17 such proposed order shall set forth the proposed
18 limit and a substantive summary of the valid
19 scientific evidence supporting the proposed
20 limit.

21 “(2) TIMEFRAME.—

22 “(A) IN GENERAL.—The Secretary shall
23 issue proposed orders for limits on contami-
24 nants in infant or toddler food as follows:

1 “(i) For lead, not later than 1 year
2 after the date of enactment of this section.

3 “(ii) For arsenic and cadmium, not
4 later than 3 years after the date of enact-
5 ment of this section.

6 “(B) FINAL ORDERS.—The Secretary shall
7 issue each final administrative order under this
8 subsection not later than 18 months after the
9 date of issuance of the respective proposed
10 order as described in subparagraph (A).

11 “(b) ADDITIONAL CONTAMINANTS; CHANGES TO
12 LIMITS.—

13 “(1) ESTABLISHMENT; CHANGES.—If deter-
14 mined by the Secretary to be appropriate upon re-
15 view of relevant health data, available scientific data,
16 achievability based on readily available testing meth-
17 ods and recognizing the natural occurrence of con-
18 taminants in the environment, and other information
19 that the Secretary considers relevant, the Secretary
20 may, by administrative order published in the Fed-
21 eral Register—

22 “(A) establish limits for additional con-
23 taminants, including toxic elements and species
24 of those toxic elements, in infant or toddler
25 food; and

1 “(B) revise any limit established under
2 subsection (a) or this subsection.

3 “(2) PUBLICATION OF PROPOSED ORDERS.—

4 Prior to issuing an administrative order under para-
5 graph (1), the Secretary shall publish a proposed
6 order in the Federal Register and consideration of
7 comments to a public docket, notwithstanding the
8 requirements of subchapter II of chapter 5 of title
9 5, United States Code, and chapter 6 of title 5,
10 United States Code. Each proposed order published
11 in the Federal Register shall set forth the proposed
12 limit and a substantive summary of the relevant sci-
13 entific evidence concerning the proposed limit.

14 “(c) CRITERIA.—Each limit established under this
15 section shall represent the level at which the applicable
16 contaminant may render the food injurious to health, tak-
17 ing into account—

18 “(1) achievability based on readily available
19 testing methods;

20 “(2) the natural occurrence of contaminants in
21 the environment;

22 “(3) the protection of the public health; and

23 “(4) the extent to which the presence of the
24 contaminant in the food cannot be avoided.

1 “(d) ADULTERATED FOOD.—Infant or toddler food
2 shall be deemed adulterated under section 402(j) if it
3 bears or contains any contaminant in excess of the limits
4 established under this section.

5 “(e) PERIODIC REVIEW.—The Secretary shall peri-
6 odically review the limits established under this section to
7 consider whether such levels should be revised, following
8 the process described in subsection (c).”.

9 (c) ADULTERATION.—Section 402 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amend-
11 ed by adding at the end the following:

12 “(j) If it is an article of infant or toddler food that
13 bears or contains any contaminant in excess of the limits
14 established under section 425.”.

15 **TITLE VII—CONTAMINANTS IN**
16 **INFANT AND TODDLER FOOD**

17 **SEC. 701. SAMPLING AND TESTING FOR CONTAMINANTS IN**
18 **INFANT AND TODDLER FOOD.**

19 (a) IN GENERAL.—Chapter IV of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as
21 amended by this Act, is further amended by adding at the
22 end the following:

23 **“SEC. 426. SAMPLING AND TESTING FOR CONTAMINANTS IN**
24 **INFANT AND TODDLER FOOD.**

25 “(a) SAMPLING AND TESTING.—

1 “(1) IN GENERAL.—The owner, operator, or
2 agent in charge of a food facility that manufactures
3 or processes infant or toddler food, in final product
4 form, shall collect representative samples of such
5 food in accordance with the sampling plan required
6 by paragraph (2) and conduct testing of the samples
7 for contaminants, including toxic elements for which
8 a limit is established.

9 “(2) REQUIREMENT FOR SAMPLING PLAN.—

10 “(A) IN GENERAL.—The owner, operator,
11 or agent in charge of a facility required to con-
12 duct testing under paragraph (1) shall—

13 “(i) prepare a written sampling plan
14 for all sampling and testing required under
15 this section; and

16 “(ii) ensure that all sampling and
17 testing conducted under this section is con-
18 ducted in accordance with the sampling
19 plan.

20 “(B) REQUIREMENTS.—The sampling plan
21 shall identify—

22 “(i) the number of sampling units and
23 sample unit size based upon appropriate
24 criteria for identifying, in a representative

1 fashion, the levels of contaminants in each
2 food; and

3 “(ii) one or more scientifically valid
4 test methods and procedures to be used to
5 analyze the samples.

6 “(C) GUIDANCE.—Not later than 24
7 months after the date of enactment of this sec-
8 tion, the Secretary shall issue guidance to assist
9 food facilities in developing sampling plans.
10 Such guidance may, as determined appropriate
11 by the Secretary, address when samples should
12 be tested for specific species of contaminants,
13 including toxic elements and their species.

14 “(3) CONTAMINANTS TO BE TESTED.—Each
15 sample shall be tested for levels of lead, cadmium,
16 arsenic, and any other contaminant, including other
17 toxic elements, that the Secretary may specify, and
18 in accordance with the sampling plan required under
19 paragraph (2).

20 “(4) FREQUENCY OF TESTING.—The sampling
21 and testing conducted under this section shall be
22 conducted at least once per quarter of each calendar
23 year.

24 “(b) RECORDKEEPING.—

1 “(1) IN GENERAL.—The owner, operator, or
2 agent in charge of a facility required to conduct test-
3 ing under subsection (a)(1) shall maintain, for not
4 less than 2 years or the shelf-life of the food prod-
5 uct, whichever is longer, records documenting the
6 sampling and testing conducted under this section.

7 “(2) REQUIREMENTS.—Records required to be
8 maintained under this subsection shall include the
9 records that demonstrate that the sampling and ana-
10 lytical testing is conducted in accordance with the
11 sampling plan required by subsection (a), includ-
12 ing—

13 “(A) a copy of the sampling plan;

14 “(B) a detailed description of the foods
15 sampled and tested (including for each food the
16 lot number (or lot numbers), product label, and
17 list of ingredients, as appropriate);

18 “(C) the number of samples and tests per-
19 formed;

20 “(D) the size and number of items in each
21 sample unit, identification of the entity con-
22 ducting the sampling;

23 “(E) identification of the entity conducting
24 the testing;

25 “(F) analytical methods used;

1 “(G) the date of the testing;

2 “(H) the date of the analytical testing re-
3 port; and

4 “(I) the results of the analytical testing.

5 “(3) APPLICABILITY.—This subsection applies
6 to all records of sampling and testing conducted
7 under this section, regardless of the findings.

8 “(c) LABORATORY ACCREDITATION.—The owner, op-
9 erator, or agent in charge of a food facility required to
10 conduct testing under subsection (a)(1) shall ensure that
11 testing conducted pursuant to this section is performed
12 in accordance with international standards by a laboratory
13 that is accredited for the tests being performed by an ac-
14 creditation body that conforms to international accredita-
15 tion standards. Testing conducted for the purposes of
16 compliance with this section is not subject to the require-
17 ments regarding laboratory accreditation described in sec-
18 tion 422.

19 “(d) ADULTERATED FOOD.—A food shall be deemed
20 adulterated under section 402(k) if the owner, operator,
21 or agent in charge of a food facility that manufactures
22 or processes such food is subject to the requirements of
23 this section and fails to comply with the requirements of
24 this section with regard to that food, and the food exceeds
25 the limits for the specified contaminant.

1 “(e) RECORDS AVAILABILITY.—

2 “(1) IN GENERAL.—The owner, operator, or
3 agent in charge of a food facility required to conduct
4 testing under subsection (a)(1) shall make all
5 records required under this section available prompt-
6 ly to the Secretary, upon request, for inspection and
7 copying. Upon request of the Secretary, the owner,
8 operator, or agent in charge shall provide within a
9 reasonable time an English translation of records
10 maintained in a language other than English.

11 “(2) RECORDS AVAILABILITY IN LIEU OF AN IN-
12 SPECTION.—Any records that the Secretary may in-
13 spect under this section shall, upon the request of
14 the Secretary, be provided to the Secretary, in ad-
15 vance of or in lieu of an inspection, within a reason-
16 able timeframe, within reasonable limits, and in a
17 reasonable manner, and in either electronic or phys-
18 ical form, at the expense of the owner, operator, or
19 agent in charge of a food facility required to conduct
20 testing under subsection (a)(1). The Secretary’s re-
21 quest shall include a sufficient description of the
22 records requested.

23 “(3) CONFIRMATION.—Upon receipt of the
24 records requested under paragraph (2), the Sec-
25 retary shall provide to the owner, operator, or agent

1 in charge of a food facility required to conduct test-
2 ing under subsection (a)(1) confirmation of receipt.

3 “(4) AUTHORITY OF THE SECRETARY.—Noth-
4 ing in this subsection supplants the authority of the
5 Secretary to conduct inspections otherwise permitted
6 under this Act or under the Public Health Service
7 Act.

8 “(f) EFFECTIVE DATE.—The requirements for sam-
9 pling and testing under this section shall be effective 180
10 days after the date on which the Secretary publishes the
11 final guidance document described in subsection
12 (a)(2)(C).”.

13 (b) ADULTERATION.—Section 402 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 342), as
15 amended by this Act, is further amended by adding at the
16 end the following:

17 “(k) If it is an article of infant or toddler food and
18 the owner, operator, or agent in charge of a food facility
19 that manufactures or processes such food is subject to the
20 requirements of section 426 and fails to comply with the
21 requirements of section 426 with regard to that article,
22 and the food exceeds the limit for the specified contami-
23 nant.”.

1 **TITLE VIII—REPORT FINAL**
2 **PRODUCT POSITIVE TEST RE-**
3 **SULTS FOR RELEVANT**
4 **PATHOGENS**

5 **SEC. 801. REQUIREMENTS FOR INFANT FORMULAS.**

6 Section 412 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 350a) is amended—

8 (1) in subsection (e)—

9 (A) in paragraph (1)—

10 (i) in the first sentence, by striking
11 “promptly” and inserting “, within 24
12 hours of acquiring such knowledge,”; and

13 (ii) in the second sentence, by striking
14 “the infant formula” and inserting “an in-
15 fant formula”;

16 (B) by redesignating paragraph (2) as
17 paragraph (4);

18 (C) in paragraph (4), as so redesignated,
19 by striking “paragraph (1)” and inserting
20 “paragraphs (1) and (2)”; and

21 (D) by inserting after paragraph (1) the
22 following:

23 “(2) If the result of any finished product testing of
24 an infant formula that has been processed by the manu-
25 facturer is confirmed as a positive analytical result for a

1 microorganism (as described in section 106.55 of title 21,
2 Code of Federal Regulations (or any successor regula-
3 tion)), the manufacturer shall—

4 “(A) within 24 hours of acquiring such con-
5 firmation, notify the Secretary of such confirmation
6 unless the finished product has not left an establish-
7 ment subject to the control of the manufacturer, in
8 which case the manufacturer shall notify the Food
9 and Drug Administration of the positive analytical
10 result for a microorganism with respect to the fin-
11 ished product within 24 hours of completing the
12 manufacturer’s root cause investigation;

13 “(B) consult with the Secretary for proper dis-
14 posal and properly dispose of the affected product;
15 and

16 “(C) provide to the Secretary results and iso-
17 lates from a positive sample of such infant formula
18 finished product if after submitting mitigation meas-
19 ures to the Secretary, there are two repeat positives
20 within 6 months that have the same root cause as
21 the source of the contamination. The isolates shall
22 be de-identified from the manufacturer and shall be
23 aggregated in a data trust established by a memo-
24 randum of understanding with industry. The data

1 shall not be posted in a publicly available database
2 that tracks whole genome sequencing.

3 “(3) Not later than 90 days after the date of receipt
4 of a notification under paragraph (1) or (2), the Secretary
5 shall confirm through the collection of documentation that
6 the manufacturer submitting the notification performed,
7 or is performing, appropriate corrective action. The manu-
8 facturer shall make such documentation available to the
9 Secretary during an inspection and, upon request of the
10 Secretary, electronically or by other means.”.

11 **TITLE IX—ENVIRONMENTAL** 12 **MONITORING**

13 **SEC. 901. REQUIREMENTS FOR ENVIRONMENTAL MONI-** 14 **TORING FOR CRONOBACTER SPP. AND SAL-** 15 **MONELLA SPP.**

16 Section 412 of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 350a) is amended by adding the following:

18 “(n) REQUIREMENTS FOR ENVIRONMENTAL MONI-
19 TORING FOR CRONOBACTER SPP. AND SALMONELLA
20 SPP.—

21 “(1) IN GENERAL.—A manufacturer of pow-
22 dered infant formula shall establish and implement
23 an environmental monitoring program to verify the
24 effectiveness of sanitation and hygiene controls
25 where the food has the potential to be exposed to

1 Cronobacter spp. or Salmonella spp. The environ-
2 mental monitoring program shall be written and in-
3 clude procedures for determining the sampling loca-
4 tion, number of samples to be taken, and timing and
5 frequency of sample collection and testing.

6 “(2) SAMPLING LOCATION AND NUMBER OF
7 SAMPLES.—The sampling locations from which sam-
8 ples will be collected and the number of sites to be
9 tested during routine environmental monitoring shall
10 be adequate to determine whether sanitation and hy-
11 giene controls are effective.

12 “(3) TIMING AND FREQUENCY.—The timing
13 and frequency for collecting and testing samples
14 shall be adequate to determine whether sanitation
15 and hygiene controls are effective.

16 “(4) RECORDS.—

17 “(A) AVAILABILITY TO THE SECRETARY.—
18 A manufacturer of powdered infant formula
19 shall make all records required under this sub-
20 section available promptly to the Secretary,
21 upon request, for inspection and copying.

22 “(B) PERIOD OF MAINTENANCE.—Records
23 of environmental monitoring shall be estab-
24 lished and maintained for not less than 2 years

1 or the shelf-life of the infant formula, whichever
2 is longer.

3 “(C) RECORDS IN ADVANCE OF OR IN LIEU
4 OF AN INSPECTION.—Any records that the Sec-
5 retary may inspect under this subsection shall,
6 upon the request of the Secretary, be provided
7 to the Secretary by the manufacturer, in ad-
8 vance of or in lieu of an inspection, within a
9 reasonable timeframe, within reasonable limits,
10 and in a reasonable manner, and in either elec-
11 tronic or physical form, at the expense of the
12 manufacturer. The Secretary’s request shall in-
13 clude a sufficient description of the records re-
14 quested.

15 “(D) CONFIRMATION OF RECEIPT.—Upon
16 receipt of the records requested under para-
17 graph (C), the Secretary shall provide to the
18 manufacturer confirmation of receipt.

19 “(5) AUTHORITY OF THE SECRETARY.—Noth-
20 ing in this subsection supplants the authority of the
21 Secretary to conduct inspections otherwise permitted
22 under this Act.

23 “(6) EFFECTIVE DATE.—The requirements for
24 environmental monitoring for *Cronobacter* spp. and
25 *Salmonella* spp. under this subsection shall be effec-

1 tive 180 days after the date of enactment of this
2 subsection.

3 “(7) RULE OF CONSTRUCTION.—Nothing in
4 this subsection shall be construed to exempt an in-
5 fant formula manufacturer from the requirements of
6 this Act, including the requirements in this section
7 and section 418.”.

8 **TITLE X—MANDATORY RECALL**

9 **SEC. 1001. MANDATORY RECALL.**

10 Section 423(a) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 350l(a)) is amended by inserting
12 after “animals,” the following: “or if the Secretary deter-
13 mines through any means that an article of infant or tod-
14 dler food (other than infant formula) bears or contains
15 a contaminant that renders the product adulterated under
16 section 402(a)(1),”.

1 **TITLE XI—SHARING FOOD SAFE-**
2 **TY INFORMATION WITH**
3 **STATE, LOCAL, TRIBAL, AND**
4 **TERRITORIAL AUTHORITIES;**
5 **INFORMATION DISCLOSURE**
6 **DURING FOOD SAFETY INCI-**
7 **DENTS**

8 **SEC. 1101. CONFIDENTIAL INFORMATION.**

9 (a) INFORMATION SHARING AND DISCLOSURE DUR-
10 ING FOOD SAFETY INCIDENTS.—Section 708 of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379) is
12 amended by adding at the end the following:

13 “(d) SHARING FOOD SAFETY INFORMATION WITH
14 STATE, LOCAL, TRIBAL, AND TERRITORIAL AUTHORI-
15 TIES.—

16 “(1) IN GENERAL.—In carrying out this Act,
17 the Secretary may provide shipping and distribution
18 information relating to an article of food subject to
19 recall that is protected under section 1905 of title
20 18, United States Code, or that is otherwise exempt
21 from disclosure pursuant to section 552(b) of title 5,
22 United States Code, to a State, local, Tribal, or ter-
23 ritorial government agency with counterpart func-
24 tions related to food safety. The owner of any infor-
25 mation provided by the Secretary under this para-

1 graph may object to the disclosure under the appli-
2 cable provisions of 552(b) of title 5, United States
3 Code and part 20 of title 21, Code of Federal Regu-
4 lations (or any successor regulations).

5 “(2) CONFIDENTIALITY.—A State, local, Tribal,
6 or territorial government agency in receipt of infor-
7 mation provided by the Secretary under paragraph
8 (1) shall not disclose such information without the
9 permission of the Secretary or the owner of the in-
10 formation. Any State, local, Tribal, or territorial law
11 that may require disclosure of documents or infor-
12 mation in the possession of a State, local, Tribal, or
13 territorial government agency is preempted as ap-
14 plied to a request for information provided by the
15 Secretary under paragraph (1). The Secretary may
16 grant an agency’s request to disclose such informa-
17 tion when necessary to effectuate a recall of a food.

18 “(e) INFORMATION DISCLOSURE DURING FOOD
19 SAFETY INCIDENTS.—The Secretary may disclose to
20 State, local, Tribal, and territorial authorities information
21 that identifies a person that has received an article of food
22 in interstate commerce subject to recall obtained from a
23 person that is confidential and protected under section
24 1905 of title 18, United States Code, when the disclosure
25 advances public health protection during a food safety in-

1 cident. For purposes of the preceding sentence, a food
2 safety incident includes a foodborne illness outbreak. The
3 Secretary may enter into memoranda of understanding
4 with nonprofit stakeholder organizations representing in-
5 dustry that would allow the disclosure of commodity-spe-
6 cific, non-confidential information regarding foodborne ill-
7 ness outbreaks when such information sharing would expe-
8 dite an investigation into a food safety incident.”.

9 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
10 tion alters the authority of the Secretary of Health and
11 Human Services to provide nonpublic information to
12 State, local, Tribal, or territorial authorities, or to disclose
13 confidential commercial information.

14 (c) CONFORMING AMENDMENT.—Section 301(j) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 331(j)) is amended, in the first sentence, by inserting “to
17 a State, local, Tribal, or territorial authority as specified
18 in section 708(d),” after “of the Department,”.

1 **TITLE XII—EXPANSION OF THE**
2 **ACCREDITED THIRD- PARTY**
3 **CERTIFICATION PROGRAM**

4 **SEC. 1201. EXPANSION OF THE ACCREDITED THIRD-PARTY**
5 **CERTIFICATION PROGRAM.**

6 (a) REVISED DEFINITIONS.—Section 808 of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 384d) is
8 amended—

9 (1) by amending subsection (a)(6) to read as
10 follows:

11 “(6) ELIGIBLE ENTITY.—The term ‘eligible en-
12 tity’ means a foreign or domestic entity, including a
13 foreign or domestic facility subject to registration
14 under section 415, in the food supply chain that
15 chooses to be audited by an accredited third-party
16 auditor or the audit agent of such accredited third-
17 party auditor.”; and

18 (2) by amending subsection (a)(7) to read as
19 follows:

20 “(7) REGULATORY AUDIT.—The term ‘regu-
21 latory audit’ means an audit of an eligible entity—

22 “(A) to determine whether such entity is in
23 compliance with the provisions of this Act; and

24 “(B) the results of which determine—

1 “(i) whether an article of food manu-
2 factured, processed, packed, or held by
3 such entity is eligible to receive a food cer-
4 tification under section 801(q);

5 “(ii) whether a facility is eligible to
6 receive a facility certification under section
7 806 for purposes of participating in the
8 program under section 806; or

9 “(iii) whether a facility is eligible to
10 receive a food or facility certification for
11 other purposes described in subsection
12 (c)(2)(B)(iii).”.

13 (b) REMOVING LIMITATIONS ON THE USE OF CER-
14 TIFICATIONS.—Section 808(c)(2) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 384d(c)(2)) is amend-
16 ed—

17 (1) in subparagraph (A), by striking “food cer-
18 tification, described in section 801(q), or facility cer-
19 tification under section 806(a), as appropriate, to
20 accompany each food shipment for import into the
21 United States from an eligible entity,” and inserting
22 “food certification or facility certification for pur-
23 poses described in subparagraph (B), as appro-
24 priate,”; and

1 (2) by amending subparagraph (B) to read as
2 follows:

3 “(B) PURPOSE OF CERTIFICATION.—

4 “(i) CERTIFICATIONS CONCERNING
5 IMPORTED FOODS.—The Secretary shall
6 use certification provided by accredited
7 third-party auditors to determine, in con-
8 junction with any other assurances the
9 Secretary may require under section
10 801(q), whether a food satisfies the re-
11 quirements of such section.

12 “(ii) VOLUNTARY QUALIFIED IM-
13 PORTER PROGRAM.—The Secretary shall
14 use certification provided by accredited
15 third-party auditors to determine whether
16 a facility is eligible to be a facility from
17 which food may be offered for import
18 under the voluntary qualified importer pro-
19 gram under section 806.

20 “(iii) ANALYZING RISKS AND
21 PRIORITIZING INSPECTIONS AND OTHER
22 REGULATORY ACTIVITIES.—The Secretary
23 may consider the results of regulatory au-
24 dits and food or facility certifications pro-
25 vided by accredited third-party auditors

1 under this section in analyzing risks and
2 prioritizing inspections and other regu-
3 latory activities as appropriate for the pro-
4 tection of public health.”.

5 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

6 (1) Section 808(b)(1)(A) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 384d(b)(1)(A))
8 is amended to read as follows

9 “(A) RECOGNITION OF ACCREDITATION
10 BODIES.—Not later than 2 years after the date
11 of enactment of the FDA Review and Evalua-
12 tion for Safe, Healthy and Affordable Foods
13 Act of 2026, the Secretary shall establish a sys-
14 tem for the recognition of accreditation bodies
15 that accredit third-party auditors to certify that
16 eligible entities meet the applicable require-
17 ments of this section.”.

18 (2) Section 808(c) of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 384d(c)) is amended—

20 (A) in paragraphs (1)(B) and (2)(A), by
21 striking “(or, in the case of direct accreditation
22 under subsection (b)(1)(A)(ii), the Secretary)”;

23 (B) in paragraph (2)(C)(i), by striking
24 “food certification under section 801(q) or a fa-
25 cility certification described under subpara-

1 graph (B)” and inserting “food certification or
2 a facility certification described under this sec-
3 tion”; and

4 (C) in paragraph (6)—

5 (i) in subparagraph(A)(i), by striking
6 “food certified under section 801(q) or
7 from a facility certified under paragraph
8 (2)(B)” and inserting “food or facility cer-
9 tified under this section”;

10 (ii) in subparagraph (C)(ii), by strik-
11 ing “requirements under section 801(q) of
12 certifying the food, or the requirements
13 under paragraph (2)(B) of certifying the
14 entity” and inserting “requirements for
15 certifying the food or facility under this
16 section”; and

17 (D) in paragraph (7)(B)(i), by striking
18 “through direct accreditation under subsection
19 (b)(1)(A)(ii) or”.

20 (3) Section 808(d) of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 384d(d)) is amend-
22 ed—

23 (A) in paragraph (1), by striking “or” at
24 the end;

1 (B) in paragraph (2), by striking the pe-
2 riod at the end and inserting “; or”; and

3 (C) by adding the following: ; and

4 “(3) otherwise seeks certification for purposes
5 of subsection (c)(2)(B)(iii).”.

6 (d) IDENTIFICATION AND INSPECTION OF FACILI-
7 TIES.—Section 421(a)(1) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 350j(a)(1)) is amended—

9 (1) by redesignating subparagraph (F) as sub-
10 paragraph (G); and

11 (2) by inserting after subparagraph (E) the fol-
12 lowing:

13 “(F) Whether the facility that manufac-
14 tured, processed, packed, or held such food
15 holds a certification demonstrating compliance
16 with a third-party food safety standard that has
17 been determined by the Secretary to be aligned
18 with regulations issued by the Food and Drug
19 Administration relating to preventive controls to
20 ensure the safety of human food.”.

1 **TITLE XIII—NATIONAL**
2 **UNIFORMITY AND PREEMPTION**
3 **SEC. 1301. NATIONAL UNIFORMITY AND PREEMPTION**
4 **STANDARD.**

5 Chapter IV of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 341 et seq.) is amended by inserting after
7 section 402 (21 U.S.C. 342) the following:

8 **“SEC. 402A. NATIONAL UNIFORMITY AND PREEMPTION FOR**
9 **USE, LABELING, SALE, AND MARKETING.**

10 “(a) IN GENERAL.—The provisions of sections 409,
11 412, 425, 426, and 721 shall supersede any and all State
12 requirements or prohibitions relating to the use, labeling,
13 sale, or marketing, in interstate commerce, of—

14 “(1) a food, food additive, color additive, die-
15 tary ingredient or supplement, food ingredient (in-
16 cluding a common food ingredient), substance gen-
17 erally recognized as safe for the conditions of its in-
18 tended use under section 409(m), or food contact
19 substance;

20 “(2) any substance that may be expected, di-
21 rectly or indirectly, to become a component or other-
22 wise affect the characteristics of any food; or

23 “(3) any added or naturally occurring sub-
24 stance in food (referred to in this section referred to
25 as a ‘food substance’);

1 that is not identical to the requirements established in sec-
2 tions 409, 412, 425, 426, or 721.

3 “(b) PROHIBITION ON LABELING STATEMENT RE-
4 QUIREMENTS.—The prohibition on labeling requirements
5 under subsection (a), includes any statement, vignette, or
6 other representation on a label or in labeling as defined
7 in section 201(k) or in labeling as defined in section
8 201(m) that indicates, directly or by implication, that such
9 food—

10 “(1) presents or may present a risk or hazard
11 to health or safety;

12 “(2) presents or may present consequences as a
13 result of consumption; or

14 “(3) shall be identified for any reason other
15 than declaration in a list of ingredients as required
16 under subsections (g) or (i) of section 403, or other
17 disclosure required by sections 201 or 403.

18 “(c) ENFORCEMENT.—Nothing in this section shall
19 be construed to prohibit a State from taking any regu-
20 latory or enforcement action, such as an inspection, man-
21 datory recall, civil administrative order, embargo, deten-
22 tion order, or court proceeding involving food adulteration
23 under a State statutory requirement identical to a food
24 adulteration requirement under section 402.

25 “(d) RULE OF CONSTRUCTION.—

1 “(1) IN GENERAL.—Nothing in this Act shall
2 be construed to alter, limit, or otherwise affect the
3 authority of the Federal Trade Commission under
4 section 5 or section 12 of the Federal Trade Com-
5 mission Act (15 U.S.C. 45, 52). This Act shall be
6 interpreted in a manner consistent with such author-
7 ity, and shall not be construed to preclude, displace,
8 or duplicate any enforcement, rulemaking, or guid-
9 ance issued by the Federal Trade Commission. Fur-
10 ther, nothing in this Act may be construed to limit,
11 alter, or affect the authority of the Secretary of Ag-
12 riculture with respect to the labeling, marketing, in-
13 spection, or certification of food products under the
14 Federal Meat Inspection Act (21 U.S.C. 601 et
15 seq.), the Poultry Products Inspection Act (21
16 U.S.C. 451 et seq.), the Egg Products Inspection
17 Act (21 U.S.C. 1031 et seq.), the Agricultural Mar-
18 keting Act of 1946 (7 U.S.C. 1621 et seq.), or the
19 Organic Foods Production Act of 1990 (7 U.S.C.
20 6501 et seq.), or to preempt or otherwise conflict
21 with any requirement or standard established or ap-
22 proved by the Secretary under such Acts.

23 “(2) EXCLUSION.—This section shall not apply
24 to a State requirement adopted by a State public

- 1 initiative or referendum enacted prior to September
- 2 1, 1997.”.