

118TH CONGRESS
2D SESSION

H. R. 8538

To establish an interagency committee to coordinate activities of the Federal Government relating to biotechnology oversight, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2024

Mr. KHANNA (for himself and Mrs. BICE) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To establish an interagency committee to coordinate activities of the Federal Government relating to biotechnology oversight, 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 “Biotechnology Over-
5 sight Coordination Act of 2024”.

6 **SEC. 2. FINDINGS; PURPOSE.**

7 (a) FINDINGS.—Congress finds that—

8 (1) biotechnology harnesses the power of biol-
9 ogy to create new products and provides opportuni-
10 ties to grow the United States economy, provide jobs

1 for a skilled workforce, improve resilience of supply
2 chains, and improve the quality of human lives and
3 the environment; and

4 (2) a science-based, risk-proportionate, predict-
5 able, efficient, and transparent system to support
6 the safe use of products of biotechnology will enable
7 the United States to continue to be a world leader
8 in biotechnology research and development.

9 (b) PURPOSE.—The purpose of this Act is to coordi-
10 nate and enhance the efforts of the Federal Government
11 under the Coordinated Framework for the Regulation of
12 Biotechnology to protect health and the environment while
13 enabling the development, commercialization, and safe use
14 of products derived from plants, animals, and microorga-
15 nisms developed with biotechnology.

16 **SEC. 3. BIOTECHNOLOGY OVERSIGHT COORDINATION COM-**
17 **MITTEE.**

18 (a) ESTABLISHMENT OF COMMITTEE.—

19 (1) IN GENERAL.—The President, acting
20 through the Director of the Office of Science and
21 Technology Policy and the Director of the Office of
22 Management and Budget, shall establish an inter-
23 agency committee to coordinate activities of the Fed-
24 eral Government relating to biotechnology-specific

1 regulation and oversight (referred to in this section
2 as the “Committee”).

3 (2) CHARTER.—

4 (A) IN GENERAL.—Not later than 90 days
5 after the date of enactment of this Act, the
6 Committee shall—

7 (i) ratify a charter for the operation
8 of the Committee; and

9 (ii) make publicly available on the
10 Unified Website for Biotechnology Regula-
11 tion developed pursuant to Executive
12 Order 13874 (7 U.S.C. 3121 note; relating
13 to modernizing the regulatory framework
14 for agricultural biotechnology products)
15 (referred to in this section as the “Unified
16 Website”) that ratified charter.

17 (B) EXPANSION OR MODIFICATION.—The
18 Committee may expand upon or modify the ini-
19 tial ratified charter under subparagraph (A)(i)
20 as needed.

21 (b) MEMBERSHIP.—The Committee shall be com-
22 posed of the heads, or their designees, of agencies respon-
23 sible for biotechnology oversight, including—

24 (1) the Animal and Plant Health Inspection
25 Service, the Agricultural Marketing Service, and the

1 Food Safety and Inspection Service of the Depart-
2 ment of Agriculture;

3 (2) the Food and Drug Administration and the
4 National Institutes of Health of the Department of
5 Health and Human Services;

6 (3) the Environmental Protection Agency;

7 (4) the Office of Management and Budget;

8 (5) the Office of Science and Technology Policy;

9 and

10 (6) other Federal agencies or entities as deter-
11 mined appropriate by the Chair of the Committee.

12 (c) CHAIR.—The Director of the Office of Science
13 and Technology Policy shall serve as the Chair of the
14 Committee.

15 (d) REGULATORY STREAMLINING.—The Committee
16 shall expand or build upon efforts to coordinate bio-
17 technology oversight, including through measurable
18 steps—

19 (1) to align or clarify regulatory timelines, ap-
20 proaches, and data requirements;

21 (2) to facilitate information-sharing between
22 regulatory agencies, notwithstanding any other pro-
23 vision of law;

24 (3) to identify an initial point of contact for
25 each type of biotechnology product, including emerg-

1 ing products, and clear hand-offs from one process
2 or agency to another;

3 (4) to identify and minimize any areas of delay
4 relative to established timeframes, including by re-
5 ducing duplicative review and building upon prior re-
6 views to the maximum extent practicable; and

7 (5) to conduct periodic horizon-scanning for
8 emerging biotechnology processes and products to
9 ensure appropriate oversight.

10 (e) REPORT TO CONGRESS.—Not later than 1 year
11 after the date of enactment of this Act, and annually
12 thereafter, the Committee shall submit to Congress and
13 make publicly available on the Unified Website a descrip-
14 tion of the following:

15 (1) Actions taken and next steps under sub-
16 section (d), with a description of successes, specific
17 staffing and resource needs, and recommendations
18 for removing any identified barriers, including
19 changes to statutes, regulations, or guidance.

20 (2) A summary of the duration of oversight
21 with respect to biotechnology products, from the ini-
22 tial contact with a developer to a decision with re-
23 spect to the biotechnology product, during a period
24 of not less than 5 fiscal years preceding the date of
25 the report, including—

- 1 (A) the type of product;
- 2 (B) the 1 or more types of review;
- 3 (C) the 1 or more agencies that reviewed
- 4 that product; and
- 5 (D) an explanation of timelines where
- 6 needed.

7 (f) UNIFIED PROCESS.—Not later than 180 days

8 after the date of enactment of this Act, and annually

9 thereafter, the Committee shall submit to Congress and

10 make publicly available on the Unified Website the fol-

11 lowing:

12 (1) A singular, unified process to identify

13 whether a plant, animal, or microorganism produced

14 with biotechnology could reasonably have occurred

15 naturally or been developed by conventional means

16 (meaning the genetic sequences of the biotechnology

17 product are present in the gene pool of the plant,

18 animal, or microorganism or could have arisen

19 through natural mutation mechanisms), taking into

20 account existing agency assessments where appro-

21 priate.

22 (2) Measurable actions the Committee and any

23 member of the Committee will take to implement or

24 consider the unified process described in paragraph

25 (1) in their oversight of biotechnology products, tak-

1 ing into account that organisms identified via the
2 process described in paragraph (1) would continue to
3 be regulated with product-specific oversight.

4 (3) Actions taken and progress made with re-
5 spect to paragraph (2).

6 (g) MOLECULAR FARMING AND PRECISION FER-
7 MENTATION.—Not later than 180 days after the date of
8 enactment of this Act, and annually thereafter, the Com-
9 mittee shall submit to Congress and make publicly avail-
10 able on the Unified Website a description of the following:

11 (1) Characteristics of organisms that may in-
12 crease risk pathways or otherwise hinder the produc-
13 tion of substances intended for extraction.

14 (2) Characteristics of organisms that may re-
15 duce risk pathways associated with the production of
16 substances intended for extraction.

17 (3) Conditions that are useful for containing or
18 segregating organisms produced with biotechnology
19 that may reduce risk pathways associated with the
20 production of substances intended for extraction.

21 (4) Examples of organisms that—

22 (A) fit some or all of the characteristics
23 described in paragraph (2); and

24 (B) are amenable to some or all of the con-
25 ditions described in paragraph (3).

1 (5) Measurable actions the Committee and any
2 member of the Committee will take to implement or
3 consider the characteristics described in paragraph
4 (2) and the conditions described in paragraph (3)
5 into their oversight of biotechnology products.

6 (6) Actions taken under paragraph (5) and
7 progress made with respect to those actions.

8 (h) COORDINATION AND CONSULTATION.—

9 (1) COORDINATION.—The Committee shall co-
10 ordinate, as appropriate, with—

11 (A) other working groups and committees
12 of the Federal Government; and

13 (B) other relevant agencies.

14 (2) CONSULTATION.—The Committee shall reg-
15 ularly consult in a coordinated fashion regarding
16 biotechnology oversight, including with respect to the
17 reports under subsection (e), with States, Indian
18 Tribes, territories, local governments, biotechnology
19 developers and relevant industries, academic institu-
20 tions, nongovernmental organizations, and other
21 stakeholders.

22 (i) EXECUTIVE SECRETARIES.—

23 (1) DEPARTMENT OF AGRICULTURE.—The Sec-
24 retary of Agriculture shall appoint an Executive Sec-
25 retary to serve the Committee, who shall be and re-

1 main a permanent employee of the Department of
2 Agriculture.

3 (2) DEPARTMENT OF HEALTH AND HUMAN
4 SERVICES; ENVIRONMENTAL PROTECTION AGEN-
5 CY.—The Secretary of Health and Human Services
6 and the Administrator of the Environmental Protec-
7 tion Agency may each appoint an Executive Sec-
8 retary to serve the Committee, who shall be and re-
9 main a permanent employee of the Department of
10 Health and Human Services and the Environmental
11 Protection Agency, respectively.

12 (j) COMPTROLLER GENERAL REVIEW.—The Comp-
13 troller General of the United States shall—

14 (1) not later than 1 year after the date of en-
15 actment of this Act, begin a review to assess the ef-
16 ficacy of interagency coordination and other activi-
17 ties conducted by the Committee;

18 (2) not later than 18 months after the date of
19 enactment of this Act, provide to Congress a briefing
20 of the initial findings of the Comptroller General
21 with respect to the activities of the Committee; and

22 (3) not later than 2 years after the date of en-
23 actment of this Act, provide to Congress a report de-
24 scribing the current statutory authorities and over-
25 sight processes applicable to biotechnology-specific

1 regulation of products derived from plants, animals,
2 and microorganisms developed with biotechnology,
3 including a description of opportunities to reduce
4 gaps, duplication, overlap, and fragmentation.

5 (k) EXCLUSIONS.—This Act shall not apply to human
6 medical research and products that are regulated solely
7 by the Food and Drug Administration.

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