118TH CONGRESS
2D SESSION

S. 4428

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

IN THE SENATE OF THE UNITED STATES

MAY 23, 2024

Mr. YOUNG (for himself and Mr. PADILLA) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Biotechnology Oversight Coordination Act of 2024''.

SEC. 2. FINDINGS; PURPOSE.

(a) FINDINGS.—Congress finds that—

(1) biotechnology harnesses the power of biology to create new products and provides opportuni-

ties to grow the United States economy, provide jobs for a skilled workforce, improve resilience of supply chains, and improve the quality of human lives and the environment; and

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

(b) PURPOSE.—The purpose of this Act is to coordinate and enhance the efforts of the Federal Government under the Coordinated Framework for the Regulation of Biotechnology to protect health and the environment while enabling the development, commercialization, and safe use of products derived from plants, animals, and microorganisms developed with biotechnology.

SEC. 3. BIOTECHNOLOGY OVERSIGHT COORDINATION COMMITTEE.

(a) ESTABLISHMENT OF COMMITTEE.—

(1) IN GENERAL.—The President, acting through the Director of the Office of Science and Technology Policy and the Director of the Office of Management and Budget, shall establish an interagency committee to coordinate activities of the Federal Government relating to biotechnology-specific

regulation and oversight (referred to in this section as the ''Committee'').

(2) CHARTER.—

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

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

(ii) make publicly available on the Unified Website for Biotechnology Regulation developed pursuant to Executive Order 13874 (7 U.S.C. 3121 note; relating to modernizing the regulatory framework for agricultural biotechnology products) (referred to in this section as the ''Unified Website'') that ratified charter.

(B) EXPANSION OR MODIFICATION.—The Committee may expand upon or modify the initial ratified charter under subparagraph (A)(i) as needed.

(b) MEMBERSHIP.—The Committee shall be composed of the heads, or their designees, of agencies responsible for biotechnology oversight, including—

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

Food Safety and Inspection Service of the Department of Agriculture;

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

(3) the Environmental Protection Agency;

(4) the Office of Management and Budget;

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

(6) other Federal agencies or entities as determined appropriate by the Chair of the Committee.

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

(d) REGULATORY STREAMLINING.—The Committee shall expand or build upon efforts to coordinate biotechnology oversight, including through measurable steps—

(1) to align or clarify regulatory timelines, approaches, and data requirements;

(2) to facilitate information-sharing between regulatory agencies, notwithstanding any other provision of law;

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

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

(4) to identify and minimize any areas of delay relative to established timeframes, including by reducing duplicative review and building upon prior reviews to the maximum extent practicable; and

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

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

(1) Actions taken and next steps under subsection (d), with a description of successes, specific staffing and resource needs, and recommendations for removing any identified barriers, including changes to statutes, regulations, or guidance.

(2) A summary of the duration of oversight with respect to biotechnology products, from the initial contact with a developer to a decision with respect to the biotechnology product, during a period of not less than 5 fiscal years preceding the date of the report, including—

(A) the type of product;

(B) the 1 or more types of review;

(C) the 1 or more agencies that reviewed that product; and

(D) an explanation of timelines where needed.

(f) UNIFIED PROCESS.—Not later than 180 days after the date of enactment of this Act, and annually thereafter, the Committee shall submit to Congress and make publicly available on the Unified Website the following:

(1) A singular, unified process to identify whether a plant, animal, or microorganism produced with biotechnology could reasonably have occurred naturally or been developed by conventional means (meaning the genetic sequences of the biotechnology product are present in the gene pool of the plant, animal, or microorganism or could have arisen through natural mutation mechanisms), taking into account existing agency assessments where appropriate.

(2) Measurable actions the Committee and any member of the Committee will take to implement or consider the unified process described in paragraph (1) in their oversight of biotechnology products, tak-

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

(3) Actions taken and progress made with respect to paragraph (2).

(g) MOLECULAR FARMING AND PRECISION FERMENTATION.—Not later than 180 days after the date of enactment of this Act, and annually thereafter, the Committee shall submit to Congress and make publicly available on the Unified Website a description of the following:

(1) Characteristics of organisms that may increase risk pathways or otherwise hinder the production of substances intended for extraction.

(2) Characteristics of organisms that may reduce risk pathways associated with the production of substances intended for extraction.

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

(4) Examples of organisms that—

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

(B) are amenable to some or all of the conditions described in paragraph (3).

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

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

(h) COORDINATION AND CONSULTATION.—

(1) COORDINATION.—The Committee shall coordinate, as appropriate, with—

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

(B) other relevant agencies.

(2) CONSULTATION.—The Committee shall regularly consult in a coordinated fashion regarding biotechnology oversight, including with respect to the reports under subsection (e), with States, Indian Tribes, territories, local governments, biotechnology developers and relevant industries, academic institutions, nongovernmental organizations, and other stakeholders.

(i) EXECUTIVE SECRETARIES.—

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

main a permanent employee of the Department of Agriculture.

(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES; ENVIRONMENTAL PROTECTION AGENCY.—The Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency may each appoint an Executive Secretary to serve the Committee, who shall be and remain a permanent employee of the Department of Health and Human Services and the Environmental Protection Agency, respectively.

(j) COMPTROLLER GENERAL REVIEW.—The Comptroller General of the United States shall—

(1) not later than 1 year after the date of enactment of this Act, begin a review to assess the efficacy of interagency coordination and other activities conducted by the Committee;

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

(3) not later than 2 years after the date of enactment of this Act, provide to Congress a report describing the current statutory authorities and oversight processes applicable to biotechnology-specific

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

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

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