[____th] CONGRESS, [___] Session

[H.R. / S.] _____

To establish a permanent national program for the surveillance of pathogens in fresh produce, 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 "[Produce Pathogen Surveillance Act of 2027]" [alternative: "Make Produce Safe Again Act"].

SEC. 2. FINDINGS.

Congress finds the following:

(1) Fresh produce is a leading source of foodborne illness outbreaks in the United States, and fruits and vegetables have been estimated to account for about half of Salmonella illnesses.

(2) After a pilot in fiscal year 1999, the Agricultural Marketing Service launched the Microbiological Data Program in 2001 with appropriated funds of approximately $6,200,000, through cooperative agreements with 10 State departments of agriculture, using the statistical sampling design of the Pesticide Data Program.

(3) From 2001 through 2012, the Microbiological Data Program tested approximately 10,000 to 15,000 samples of fresh produce annually, more than 111,000 samples in all, and accounted for approximately 80 percent of Federal pathogen testing of fresh produce.

(4) The Microbiological Data Program isolated Salmonella, Shiga toxin-producing Escherichia coli, including E. coli O157:H7 and other strains carrying virulence genes associated with severe illness, enterotoxigenic E. coli and Listeria monocytogenes from fresh produce; many of those isolates matched strains from ill people, and its findings led to product recalls.

(5) During the 2008 Salmonella Saintpaul outbreak, the Microbiological Data Program tested more than 1,300 additional samples of implicated commodities, showing the value of standing surveillance capacity that can be redirected during an outbreak.

(6) The Microbiological Data Program had no program-specific authorizing statute. It operated under the general authority of the Agricultural Marketing Act of 1946 and annual appropriations, and report language accompanying the fiscal

year 2002 appropriation required that it be conducted as a "blind survey" that omitted the identity of growers, packers and distributors.

(7) The funding for the Microbiological Data Program was eliminated, and the program ceased operations on December 31, 2012. Since then, no Federal program has replaced its systematic, national surveillance of pathogens in fresh produce.

(8) By contrast, the Pesticide Data Program, on whose design the Microbiological Data Program was modeled, has continued without interruption under the direction of section 301 of the Food Quality Protection Act of 1996 (Public Law 104–170).

(9) [Recent outbreaks, including the 2026 Cyclospora outbreak, demonstrate the need for routine surveillance of fresh produce, including for parasites and viruses.]

SEC. 3. PURPOSE.

The purpose of this Act is to establish a permanent national program to collect statistically reliable data on the presence of pathogens in fresh produce, in order to—

(1) detect contaminated produce before or during distribution;

(2) support outbreak detection and investigation;

(3) measure the prevalence of pathogens in fresh produce over time;

(4) inform risk assessment and the evaluation of produce safety standards, including standards under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h);

(5) monitor antimicrobial resistance in pathogens found in fresh produce; and

(6) strengthen Federal-State cooperation in food safety.

SEC. 4. DEFINITIONS.

In this Act:

(1) COVERED COMMODITY.—The term "covered commodity" means a fresh fruit, vegetable, herb, sprout or nut selected by the Secretary under section 5(c), whether domestic or imported.

(2) PATHOGEN.—The term "pathogen" means a microorganism, virus or parasite capable of causing human illness, including Salmonella, Listeria monocytogenes, Shiga toxin-producing Escherichia coli, enterotoxigenic Escherichia coli, Shigella, [Cyclospora cayetanensis, hepatitis A virus, norovirus,] and any other organism designated by the Secretary in consultation with the Secretary of Health and Human Services.

(3) PROGRAM.—The term "Program" means the National Produce Pathogen Surveillance Program established under section 5.

(4) SECRETARY.—The term "Secretary" means the Secretary of Agriculture, acting through the Administrator of the Agricultural Marketing Service. [Alternative: the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.]

(5) STATE.—The term "State" means each of the several States, the District of Columbia, each territory of the United States, and each Indian Tribe.

SEC. 5. NATIONAL PRODUCE PATHOGEN SURVEILLANCE PROGRAM.

(a) ESTABLISHMENT.—Not later than [180 days] after the date of enactment of this Act, the Secretary shall establish a National Produce Pathogen Surveillance Program.

(b) SAMPLING.—Under the Program, the Secretary shall—

(1) collect and test not fewer than [15,000] samples of covered commodities each fiscal year;

(2) collect samples at distribution centers, terminal markets, ports of entry, retail and other points in the supply chain, [and at harvest or packing,] selected to represent not less than [50] percent of the population of the United States;

(3) sample imported covered commodities in at least the proportion in which they are present in the marketplace [, and not less than [25] percent of all samples]; and

(4) use statistically valid sampling plans developed with the National Agricultural Statistics Service and in consultation with the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs.

(c) SELECTION OF COMMODITIES AND PATHOGENS.—

(1) IN GENERAL.—The Secretary shall, not less than once every [2] years, select covered commodities and pathogens for testing, based on outbreak data, consumption patterns, risk assessments and recommendations from the agencies listed in subsection (b)(4) and the advisory committee established under section 10.

(2) MINIMUM PATHOGENS.—Each covered commodity shall be tested for, at a minimum, Salmonella, Listeria monocytogenes and Shiga toxin-producing Escherichia coli (including E. coli O157:H7), unless the Secretary publishes a written finding, with supporting data, that testing a commodity for a pathogen is not scientifically warranted.

(d) TESTING METHODS.—The Secretary shall—

(1) use validated analytical methods, which may include culture-independent screening methods, provided that a result is reported as confirmed only after isolation of the pathogen or another confirmation method validated by the Commissioner of Food and Drugs;

(2) retain enrichment broths or other sample material from each sample that screens positive but is not confirmed, for not less than [90 days], to allow additional testing;

(3) perform whole-genome sequencing on each pathogen isolate obtained; and

(4) submit sequence data to [the National Center for Biotechnology Information and the PulseNet system] not later than [7] days after the isolate is obtained.

(e) ANTIMICROBIAL RESISTANCE.—The Secretary shall test bacterial isolates obtained under the Program for antimicrobial resistance and report the results to the National Antimicrobial Resistance Monitoring System.

(f) ISOLATE COLLECTION.—The Secretary shall maintain a collection of isolates obtained under the Program, with associated sample data, and make isolates available to Federal, State and academic researchers under procedures established by the Secretary.

(g) OUTBREAK SURGE TESTING.—At the request of the Director of the Centers for Disease Control and Prevention or the Commissioner of Food and Drugs, the Secretary may redirect or add sampling and testing under the Program to support the investigation of an outbreak of foodborne illness. Samples collected under this subsection shall not count against the minimum in subsection (b)(1).

SEC. 6. COOPERATIVE AGREEMENTS WITH STATES.

(a) IN GENERAL.—The Secretary shall carry out sampling and testing under the Program through cooperative agreements with State departments of agriculture, State public health laboratories, or both.

(b) USE OF FUNDS.—A State may use funds received under a cooperative agreement for personnel, equipment, laboratory accreditation, sample collection, testing, sequencing and data reporting.

(c) LABORATORY STANDARDS.—Each participating laboratory shall be accredited [to ISO/IEC 17025] and shall participate in proficiency testing specified by the Secretary.

(d) NON-SUPPLANTATION.—Funds provided under this section shall supplement, and not supplant, State funds for food safety testing.

SEC. 7. SAMPLE RECORDS, NOTIFICATION, CONFIRMATION AND RESPONSE.

(a) SAMPLE RECORDS.—For each sample, the Secretary shall record the commodity, brand, lot or other identifying codes, country of origin and, where available from the shipping container, invoice or other records at the point of collection, the names of the grower, packer and distributor.

(b) NO BLIND SAMPLING.—Notwithstanding any other provision of law, the Secretary shall not carry out the Program as a blind survey or remove information described in subsection (a) from sample records, unless a provision of law enacted after the date of enactment of this Act expressly refers to this subsection.

(c) NOTIFICATION OF PUBLIC HEALTH AGENCIES.—Not later than [24 hours] after a laboratory obtains a presumptive or confirmed positive result, the Secretary shall notify the Commissioner of Food and Drugs, the Director of the Centers for Disease Control and Prevention, and the public health and agriculture agencies of each affected State, including the State in which the product was grown or packed, if known.

(d) NOTIFICATION OF FIRMS.—The Secretary shall promptly notify the firm from which a sample was collected, and, where known, the grower, packer and distributor, of a presumptive or confirmed positive result.

(e) CONFIRMATION.—The Secretary shall perform confirmatory testing on each presumptive positive result as rapidly as practicable, and shall retain sample material where feasible to allow additional testing.

(f) RESPONSE.—Nothing in this Act limits the authority of the Commissioner of Food and Drugs or a State to take action, including a recall, based on results under the Program.

SEC. 8. DATA AND PUBLIC REPORTING.

(a) DATABASE.—The Secretary shall maintain a database of all sampling and testing results under the Program, which shall be available to Federal, State, local and Tribal public health agencies.

(b) PUBLIC DATA.—Not less than [quarterly], the Secretary shall publish on a public website aggregate results by commodity, pathogen, region, country of origin and time period.

(c) ANNUAL REPORT.—Not later than [March 1] of each year, the Secretary shall publish and submit to the appropriate committees of Congress a report on the Program for the previous fiscal year, including the number of samples tested, positive results, sequencing findings, antimicrobial resistance findings, matches to clinical isolates, resulting recalls and public health actions, and trends over time.

(d) DISCLOSURE OF CONFIRMED POSITIVES.—Notwithstanding section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, the identity of a product, brand, lot, grower, packer, distributor and firm from which a sample yielding a confirmed positive result was collected shall not be considered confidential commercial information or a trade secret. Not later than [48 hours] after a result is confirmed, the Secretary shall publish on the public website described in subsection (b) the commodity, pathogen, product and brand name, lot or other identifying codes, the names of the grower, packer and distributor where known, the date and location of collection, and any recall or public health action taken. The Secretary shall otherwise protect confidential commercial information in accordance with section 552(b)(4) of title 5, United States Code.

SEC. 9. RELATIONSHIP TO OTHER LAW.

(a) SURVEILLANCE PURPOSE.—The Program is a surveillance program. A result under the Program shall not by itself be the basis for a civil penalty under this Act.

(b) NO PREEMPTION.—Nothing in this Act preempts any State or local law or limits any authority under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the FDA Food Safety Modernization Act (Public Law 111–353).

(c) COORDINATION.—The Secretary shall coordinate the Program with produce safety activities under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h) and with the sampling programs of the Food and Drug Administration to avoid duplication.

(d) PESTICIDE DATA PROGRAM.—The Secretary may use the sampling sites, State cooperative agreements and sample-collection personnel of the Pesticide Data Program to carry out the Program, provided that funds for the Pesticide Data Program are not reduced as a result.

SEC. 10. ADVISORY COMMITTEE.

The Secretary shall establish a Produce Surveillance Advisory Committee, composed of representatives of State agriculture and public health laboratories, academic scientists, consumer organizations, and growers and the produce industry, with consumer and public health members making up not less than one-half of the membership, to advise on sampling plans, commodity and pathogen selection, and use of the data.

SEC. 11. GAO EVALUATION.

Not later than [4] years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress an evaluation of the effectiveness of the Program in detecting contaminated produce and supporting outbreak investigations.

SEC. 12. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this Act [$25,000,000] for each of fiscal years [2028 through 2032], to remain available until expended, of which not less than [60] percent shall be provided to States under section 6.

Open Policy Choices

- **Agency home.** USDA AMS matches the MDP, the PDP and the state lab network. FDA has the regulatory authority under FSMA.
- **Funding level.** The MDP's roughly $5 million a year, about $11 million for FY2001 parity, or a larger figure for sequencing, parasites, viruses and imports.
- **Disclosure.** Sec. 8(d) requires naming firms and brands with confirmed positives, consistent with Bill's FDA petitions on naming consignees and outbreak-linked firms. Decide the publication window (48 hours is a placeholder). Sec. 7(b) protects disclosure against a return to blind sampling.
- **Sampling point.** Distribution only, as under the MDP, or also at harvest and packing. AMS argued in 2002 that sampling near the consumer best estimates exposure.
- **Imports.** Marketplace share only, or a fixed minimum such as 25%.
- **Pathogen floor.** Whether Cyclospora, hepatitis A and norovirus belong in the mandatory list in Sec. 5(c)(2) or stay discretionary.
- **Short title.** Neutral, or the "Make Produce Safe Again" framing for bipartisan appeal. The MDP was a Bush-era program.

Key Sources for This Revision

- USDA AMS, "Microbiological Data Program" (program objectives, legislative authority, funding and workload), January 2001.
- USDA AMS, "Microbiological Data Program (MDP): An Overview of MDP Principles and Objectives," June 20, 2001.
- USDA AMS Science and Technology Programs, "Responses to Public Meeting Questions Regarding the Microbiological Data Program," March 28, 2002.
- USDA AMS, "MDP Progress Update and 2008 Data."
- Reddy, Wang, Adams & Feng, *J. Food Prot.* 79:6–16 (2016) (Salmonella, 2002–2012).
- Feng & Reddy, *Appl. Environ. Microbiol.* 79:6917–6923 (2013) (STEC virulence).
- Feng & Reddy, *J. Food Prot.* 77:820–823 (2014) (ETEC).
- Feng, Councell, Keys & Monday, *Appl. Environ. Microbiol.* 77:343–345 (2011) (STEC in spinach and lettuce).
- Monday et al., *Appl. Environ. Microbiol.* 72:3062–3065 (2006) (Ont:H52 produce and clinical isolates).

- Food Quality Protection Act of 1996, Pub. L. 104–170, § 301.