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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2026

A N A C T

RELATING TO STATE AFFAIRS AND GOVERNMENT -- RHODE ISLAND BIOTECHNOLOGY REGULATORY SANDBOX ACT

Introduced By: Representatives Place, Fascia, Hopkins, and Santucci

Date Introduced: January 28, 2026

Referred To: House Corporations

It is enacted by the General Assembly as follows:

SECTION 1. Title 42 of the General Laws entitled "STATE AFFAIRS AND GOVERNMENT" is hereby amended by adding thereto the following chapter:

CHAPTER 169

RHODE ISLAND BIOTECHNOLOGY REGULATORY SANDBOX ACT

42-169-1. Short title.

This chapter shall be known and may be cited as the "Rhode Island Biotechnology Regulatory Sandbox Act."

42-169-2. Definitions.

As used in this chapter:

(1) "Applicable agency" means a department or agency of the state that by law regulates biotechnology-related business activity, including licensing, compliance, and consumer protection requirements.

(2) "Applicant" means a biotechnology company, research institution, or entity applying for participation in the regulatory sandbox.

(3) "Consumer" means any person or entity that enters into a transaction to receive a biotechnology product or service tested within the regulatory sandbox.

(4) "Department" means the department of business regulation (DBR), responsible for overseeing the biotechnology regulatory sandbox program.

(5) “Innovation” means the use of emerging technology or novel applications of existing technology to solve industry challenges, improve efficiency, or enhance consumer access to biotechnology products or services.

(6) “Innovative biotechnology product or service” means any biotechnology-related product or service that incorporates an innovation and requires state licensure, authorization, or oversight under Rhode Island law.

(7) “Regulatory sandbox” means the biotechnology regulatory sandbox program, which allows approved participants to test biotechnology innovations under limited exemptions from certain state regulations.

(8) “Sandbox participant” means an entity whose application has been approved to test an innovative biotechnology product or service within the sandbox.

(9) “Test” means to provide an innovative biotechnology product or service under the conditions set forth in this chapter.

42-169-3. Establishment of the biotechnology regulatory sandbox.

(a) The biotechnology regulatory sandbox program is hereby established within the department.

(b) In administering the biotechnology regulatory sandbox, the department:

(1) Shall consult with each applicable agency;

(2) Establish a program to enable a person or entity to obtain limited access to the market in the state to test an innovative biotechnology product or service without obtaining a license or other state authorization that might otherwise be required;

(3) May enter into agreements with or follow the best practices of similar programs being administered in other states or federal agencies; and

(4) Shall not approve participation in the biotechnology regulatory sandbox by an applicant or any other participant who has been convicted, entered a plea of nolo contendere or entered a plea of guilty or nolo contendere held in abeyance, for a serious crime:

(i) Involving theft, fraud, or dishonesty; or

(ii) That bears a substantial relationship to the applicant’s or participant’s ability to safely or competently participate in the regulatory sandbox program.

(c) The department shall coordinate with federal and state agencies to ensure sandbox participation aligns with federal regulatory frameworks, including those of the FDA, USDA, and EPA.

42-169-4. Application process.

(a) An applicant shall submit to the department an application that:

(1) Includes a nonrefundable application fee sufficient to cover administration costs;

(2) Demonstrates the applicant is subject to the jurisdiction of the state;

(3) Demonstrates the applicant has established a physical or virtual location that is adequately accessible to the department, from which testing will be developed and performed and where all required records, documents, and data will be maintained;

(4) Contains relevant personal and contact information, including legal names, addresses, telephone numbers, email addresses, website addresses, and other information required by the department;

(5) Discloses criminal convictions of the applicant or other participating personnel, if any;

(6) Demonstrates that the applicant has the necessary personnel, financial and technical expertise, access to capital, and a developed plan to test, monitor, and assess the innovative biotechnology product or service; and

(7) Contains a description of the innovative biotechnology product or service to be tested, including statements regarding the following:

(i) How the innovative biotechnology product or service is subject to licensing or other authorization requirements outside of the biotechnology regulatory sandbox, including a specific list of all state laws, regulations, and licensing or other requirements that the applicant is seeking to have waived during the testing period;

(ii) How the innovative biotechnology product or service would benefit consumers;

(iii) How the innovative biotechnology product or service is different from other biotechnology products or services available in the state;

(iv) What risks may confront consumers who use or purchase the innovative biotechnology product or service;

(v) How participating in the regulatory sandbox would enable a successful test of the innovative biotechnology product or service;

(vi) A description of how the applicant will perform ongoing duties after the test;

(vii) How the applicant will end the test and protect consumers if the test fails, including providing evidence of sufficient liability coverage and financial reserves to protect consumers and to protect against insolvency by the applicant; and

(viii) Provides any other required information as determined by the department.

(b) An applicant shall file a separate application for each innovative biotechnology product or service the applicant wants to test.

(c) After the application is filed and before approving the application, the department may seek any additional information from the applicant that the department determines is necessary.

(d) Subject to subsection (e) of this section, and not later than ninety (90) days after the day on which a complete application is received by the department, it shall inform the applicant as to whether the application is approved for entry into the regulatory sandbox.

(e) The department and an applicant may mutually agree to extend the ninety (90) day timeline for the department to determine whether an application is approved for entry into the regulatory sandbox.

(f) The department shall consult with, and get approval from, each applicable agency before admitting an applicant into the regulatory sandbox. The consultation with an applicable agency may include seeking information about whether:

(1) The applicable agency has previously issued a license or other authorization to the applicant;

(2) The applicable agency has previously investigated, sanctioned, or pursued legal action against the applicant;

(3) Whether the applicant could obtain a license or other authorization from the applicable agency after exiting the regulatory sandbox; and

(4) Whether certain licensure or other regulations should not be waived even if the applicant is accepted into the regulatory sandbox.

(g) In reviewing an application under this section, the department shall consider whether a competitor to the applicant is or has been a biotechnology sandbox participant and weigh that as a factor in allowing the applicant to also become a biotechnology sandbox participant. If the department and each applicable agency approve admitting an applicant into the biotechnology regulatory sandbox, an applicant shall become a sandbox participant.

(h) The department may deny any application submitted under this section, for any reason, in the department's discretion.

(i) If the department denies an application submitted under this section, it shall provide to the applicant a written description of the reasons for the denial as a sandbox participant.

42-169-5. Regulatory relief and conditions.

(a) Approved participants may receive temporary exemptions from state laws or regulations that were identified by the participant's application and have been waived in writing by the department, except for:

(1) Human genetic modification prohibitions (e.g., germline editing).

(2) State or federal environmental protection laws deemed necessary.

(3) Ethical standards for human or animal research.

(b) The sandbox period shall not exceed twenty-four (24) months, with an option for

renewal based on further review.

(c) Participants shall submit quarterly progress reports detailing compliance, risks, and findings.

(d) By written notice, the department may terminate a participant's involvement in the regulatory sandbox for non-compliance, unethical conduct, or public safety concerns.

(e) A sandbox participant does not have immunity related to any criminal offense committed during the sandbox participant's time in the regulatory sandbox.

42-169-6. Consumer protections.

(a) Before providing an innovative biotechnology product or service to a consumer, a sandbox participant shall disclose the following to the consumer:

(1) The name and contact information of the sandbox participant;

(2) That the innovative biotechnology product or service is authorized pursuant to the regulatory sandbox and, if applicable, that the sandbox participant does not have a license or other authorization to provide a biotechnology product or service under state laws that regulate biotechnology products outside the regulatory sandbox;

(3) That the innovative biotechnology product or service is undergoing testing and may not function as intended and may expose the customer to financial risk;

(4) That the provider of the innovative biotechnology product is not immune from civil liability for any losses or damages caused by the innovative biotechnology product or service;

(5) That the state does not endorse or recommend the innovative biotechnology product or service;

(6) That the innovative biotechnology product or service is a temporary test that may be discontinued at the end of the testing period;

(7) The expected end date of the testing period; and

(8) That a consumer may contact the department to file a complaint regarding the innovative biotechnology product or service being tested and provide the department's telephone number and website address where a complaint may be filed.

(b) The disclosures required in this section shall be provided to a consumer in a clear and conspicuous form and, for an Internet or application-based innovative biotechnology product or service, a consumer shall acknowledge receipt of the disclosure before a transaction shall be completed.

(c) The department may require that a sandbox participant make additional disclosures to a consumer.

42-169-7. Data reporting.

(a) A sandbox participant shall retain records, documents, and data produced in the ordinary course of business regarding an innovative biotechnology product or service tested in the regulatory sandbox.

(b) If an innovative biotechnology product or service fails before the end of a testing period, the sandbox participant shall notify the department and report on actions taken by the sandbox participant to ensure consumers have not been harmed as a result of the failure.

(c) The department shall establish quarterly reporting requirements for a sandbox participant, including information about any customer complaints.

(d) The department may request records, documents, and data from a sandbox participant and, upon the department's request, a sandbox participant shall make such records, documents, and data available for inspection by the department.

(e) If the department determines that a sandbox participant has engaged in, is engaging in, or is about to engage in any practice or transaction that is in violation of this chapter or that constitutes a violation of state or federal criminal law, the department may remove a sandbox participant from the biotechnology regulatory sandbox.

(f) By January 1, 2028, the department shall provide an annual written report to the general assembly that provides:

(1) Information regarding each biotechnology sandbox participant.

(2) Recommendations regarding the effectiveness of the biotechnology regulatory sandbox program.

(3) Potential regulatory reforms.

42-169-8. Exit strategy and post-sandbox regulatory pathways.

(a) At least thirty (30) days before the twenty-four (24) month sandbox period ends, a participant shall:

(1) Notify the department that the sandbox participant will exit the biotechnology regulatory sandbox, discontinue the sandbox participant's test, and will stop offering any innovative biotechnology product or service in the regulatory sandbox within sixty (60) days after the day on which the trial period ends; or

(2) Seek an extension in accordance with § 42-169-9.

(b) Subject to subsection (c) of this section, if the department does not receive notification as required by subsection (a) of this section, the regulatory sandbox testing period ends at the end of the twenty-four (24) month testing period and the sandbox participant shall immediately stop offering each innovative biotechnology product or service being tested.

(c) If a test includes offering an innovative biotechnology product or service that requires

ongoing duties, the sandbox participant shall continue to fulfill those duties or arrange for another person to fulfill those duties after the date on which the sandbox participant exits the regulatory sandbox.

42-169-9. Extensions.

(a) Not later than thirty (30) days before the end of the regulatory sandbox testing period, a sandbox participant may request from the department an extension of the regulatory sandbox testing period for the purpose of obtaining a license or other authorization.

(b) The department shall make a decision as to whether it will grant or deny the request for an extension by the end of the regulatory sandbox testing period.

(c) The department may grant an extension in accordance with this section for not more than twelve (12) months after the end of the regulatory sandbox testing period.

(d) A sandbox participant that obtains an extension in accordance with this section shall provide the department with a written report every three (3) months that provides an update on efforts to obtain a license or other authorization required by law, including any submissions for licensure or other authorization, rejected applications, or issued licenses or other authorizations.

42-169-10. Rules and regulations.

The department shall promulgate rules and regulations necessary for the administration and implementation of the biotechnology regulatory sandbox program.

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO STATE AFFAIRS AND GOVERNMENT -- RHODE ISLAND BIOTECHNOLOGY REGULATORY SANDBOX ACT

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This act would establish the biotechnology regulatory sandbox program within the department of business regulation (DBR) to enable a person or entity to obtain limited access to the market in the state to test an innovative biotechnology product or service without obtaining a license or other state authorization that might otherwise be required.

This act would take effect upon passage.

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