

LC002741

## IN GENERAL ASSEMBLY

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

Referred To: House Corporations

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

## RHODE ISLAND BIOTECHNOLOGY REGULATORY SANDBOX ACT

6       This chapter shall be known and may be cited as the “Rhode Island Biotechnology  
7       Regulatory Sandbox Act.”

9 As used in this chapter:

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

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

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

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

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

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

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

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

14           **42-167-3. Establishment of the biotechnology regulatory sandbox.**

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

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

18           (1) Shall consult with each applicable agency;

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

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

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

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

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

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

33           **42-167-4. Application process.**

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

- 1           (1) Includes a nonrefundable application fee sufficient to cover administration costs;
- 2           (2) Demonstrates the applicant is subject to the jurisdiction of the state;
- 3           (3) Demonstrates the applicant has established a physical or virtual location that is  
4 adequately accessible to the department, from which testing will be developed and performed and  
5 where all required records, documents, and data will be maintained;
- 6           (4) Contains relevant personal and contact information, including legal names, addresses,  
7 telephone numbers, email addresses, website addresses, and other information required by the  
8 department;
- 9           (5) Discloses criminal convictions of the applicant or other participating personnel, if any;
- 10          (6) Demonstrates that the applicant has the necessary personnel, financial and technical  
11 expertise, access to capital, and a developed plan to test, monitor, and assess the innovative  
12 biotechnology product or service;
- 13          (7) Contains a description of the innovative biotechnology product or service to be tested,  
14 including statements regarding the following:
- 15           (i) How the innovative biotechnology product or service is subject to licensing or other  
16 authorization requirements outside of the biotechnology regulatory sandbox, including a specific  
17 list of all state laws, regulations, and licensing or other requirements that the applicant is seeking  
18 to have waived during the testing period;
- 19           (ii) How the innovative biotechnology product or service would benefit consumers;
- 20           (iii) How the innovative biotechnology product or service is different from other  
21 biotechnology products or services available in the state;
- 22           (iv) What risks may confront consumers who use or purchase the innovative biotechnology  
23 product or service;
- 24           (v) How participating in the regulatory sandbox would enable a successful test of the  
25 innovative biotechnology product or service;
- 26           (vi) A description of how the applicant will perform ongoing duties after the test;
- 27           (vii) How the applicant will end the test and protect consumers if the test fails, including  
28 providing evidence of sufficient liability coverage and financial reserves to protect consumers and  
29 to protect against insolvency by the applicant; and
- 30           (viii) Provides any other required information as determined by the department.
- 31          (b) An applicant shall file a separate application for each innovative biotechnology product  
32 or service the applicant wants to test.
- 33          (c) After the application is filed and before approving the application, the department may  
34 seek any additional information from the applicant that the department determines is necessary.

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

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

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

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

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

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

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

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

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

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

27           **42-167-5. Regulatory relief and conditions.**

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

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

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

33           (3) Ethical standards for human or animal research.

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

1 renewal based on further review.

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

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

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

8 **42-167-6. Consumer protections.**

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

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

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

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

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

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

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

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

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

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

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

34 **42-167-7. Data reporting.**

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

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

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

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

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

16           (f) By January 1, 2027, the department shall provide an annual written report to the general  
17 assembly that provides:

18           (1) Information regarding each biotechnology sandbox participant.

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

21           (3) Potential regulatory reforms.

22           **42-167-8. Exit strategy and post-sandbox regulatory pathways.**

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

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

29           (2) Seek an extension in accordance with § 42-167-9.

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

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

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

4 **42-167-9. Extensions.**

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

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

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

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

16 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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- 1
- This act would establish the biotechnology regulatory sandbox program within the
- 2
- department of business regulation to enable a person or entity to obtain limited access to the market
- 3
- in the state to test an innovative biotechnology product or service without obtaining a license or
- 4
- other state authorization that might otherwise be required.
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