# Survey on Biotechnology Product Regulation (Pharmaceutical products)

The National Security Commission on Emerging Biotechnology (NSCEB) is gathering input to modernize the U.S. biotechnology product regulation and create simpler, faster, science-based pathways to market. This input will guide follow-on work to the Commission's April 2025 report, which called for streamlining regulation of biotechnology products. Read the report at: biotech.senate.gov.

NSCEB staff are seeking concrete, actionable ideas across sectors, including defense, industrial products, food, agriculture, and healthcare. We ask interested parties to share their ideas for statutory reform via the survey links below by July 16, 2025.

- The survey for pharmaceutical products is at https://forms.office.com/g/UzuXTfRcEq, with the full list of questions detailed below.
- The survey for industrial, food, agricultural, and other products is at https://forms.office.com/g/xCvb9Sjv3v.

## Important Information on Participation and Privacy

This survey has 29 questions and cannot be saved part-way. You may wish to draft responses offline.

- We encourage you to provide your name, organization, location, and email address, but you are not required to do so to complete the survey.
- We will not quote or individually attribute responses to this survey in NSCEB products written for public dissemination without first contacting you.
- Your participation in this survey is completely voluntary. You may choose not to participate, and you are free to withdraw from the survey at any time.
- By participating in this survey, you are consenting for your responses to be part of a de-identified summary that could be included in NSCEB products written for public dissemination. Summarized responses may be used to inform policy development supporting the recommendations in the NSCEB's April 2025 final report.
- We may contact you to follow up on your survey response, but you will have the opportunity to opt out of being contacted at the end of the survey.
- Your responses will only be accessed by authorized personnel, and we will not share your data with any third parties without your consent.
- The information provided is not subject to the Privacy Act of 1974, as amended, or to the Paperwork Reduction Act of 1995, as amended.

If you have any questions about this survey or the use of your data, please contact Anastasia Bodnar at Anastasia_Bodnar@biotech.senate.gov.

## About You and Your Organization

Please provide the following information about you and your organization.

1. First name
2. Last name
3. Job title
4. Location *(U.S. state or country)*
5. Organization *(If any)*
6. Are you responding on behalf of your organization?
    a. Yes
    b. No
7. Organization type *(Select one)*
    a. Early-stage company (< 50 employees or pre-revenue)
    b. Small/medium company (50-499 employees or revenue < $100 M)
    c. Large company (≥ 500 employees or revenue ≥ $100 M)
    d. Trade association
    e. Professional society
    f. Academic (college, university, research institute)
    g. Non-governmental or philanthropic organization
    h. Government entity (federal, state, local, tribal)
    i. Legal, consulting, or advisory services
    j. Other (please describe)
8. What sectors are your products most closely aligned with? *(Select all that apply)*
    a. Pharmaceuticals and healthcare (e.g., therapeutics, vaccines, gene therapies)
    b. Wellness (e.g., cosmetics, supplements)
    c. Consumer goods (e.g., clothing, pet health)
    d. Defense and industrial (e.g., fuel, chemicals, materials, enzymes, packaging)
    e. Food and agriculture (e.g., foods, ingredients, fertilizers, pesticides)
    f. Environment (e.g., bioremediation, carbon capture)
    g. Other (please describe)
9. What organisms do you most commonly work with? *(Select all that apply)*
    a. Cell-free systems
    b. Microorganisms for use in closed systems
    c. Microorganisms for environmental release
    d. Plants and plant cells (including multicellular fungi)
    e. Animals and animal cells
    f. Other (please describe)

## Your Experience with U.S. Biotechnology Regulation

Please describe your experience with U.S. regulation of pharmaceuticals and related products that are produced with biotechnology. When responding, please:

- Specify the agency and/or type of product, when appropriate.
- Be brief, but specific, and share examples, if possible.
- Feel free to skip any questions that are not applicable.

10. Which federal agencies or offices have you interacted with regarding the regulation or oversight of pharmaceuticals and related products produced with biotechnology? *(Select all that apply)*
    a. Department of Health and Human Services (HHS) Centers for Disease Control (CDC)
    b. HHS Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER)
    c. HHS FDA Center for Drug Evaluation and Research (CDER)
    d. HHS FDA Center for Devices and Radiological Health (CDRH)
    e. Department of Commerce (DOC) Bureau of Industry and Security (BIS)
    f. Other (please describe)

11. Have you encountered any of the following regulatory challenges? *(Select all that apply)*
    a. Lengthy review timelines
    b. High cost of user fees
    c. High cost of required studies
    d. Facility registration
    e. Post-market compliance burden
    f. Lack of clear guidance
    g. Unclear agency jurisdiction
    h. Duplicative data requirements
    i. Unpredictable regulatory process
    j. Other (please describe)

12. Describe a concrete example of one or more regulatory challenges that you selected above. *(~500 words or less)*

13. Based on your experience, what single aspect of the current U.S. regulatory system most impedes innovation or commercialization of biotechnology products? *(~500 words or less)*

## Your Experience with International Biotechnology Regulation

Please describe your experience with international regulation of pharmaceuticals and related products that are produced with biotechnology. When responding, please:

- Be brief, but specific, and share examples, if possible.
- Feel free to skip any questions that are not applicable.

14. Are you testing or commercializing a product outside of the United States because another jurisdiction offered a faster, cheaper, or clearer regulatory pathway? Describe the country, the specific advantages, and the outcome for your product. *(~500 words or less)*

15. Have you have sought approval for or launched a biotechnology product in China? Describe the end-to-end experience (e.g., timelines, data requirements, post-market obligations), and highlight any elements that differed markedly from U.S. expectations. *(~500 words or less)*

16. In what ways, positive or negative, have regulatory practices in China affected your business or product? *(~500 words or less)*

17. Are you facing competition from companies whose products appear to have gained an asymmetric advantage from China's regulatory environment (e.g., accelerated human trials, reduced pre-clinical packages, local-partner mandates)? Provide examples and describe the impact on your U.S. or allied market plans. *(~500 words or less)*

## Improving U.S. Biotechnology Regulation

Please share concrete ideas for improving U.S. regulation of pharmaceuticals and related products that are produced with biotechnology. We are particularly seeking ideas for statutory amendments. When responding, please:

- Cite the relevant title and section of the U.S. Code or the relevant regulation, when appropriate.
- Specify the agency and/or type of product, when appropriate.
- Be brief, but specific, and share examples, if possible.
- Feel free to skip any questions that are not applicable.

18. Overall, do current statutes provide the needed clarity and flexibility needed to develop and commercialize pharmaceuticals and related products that are produced with biotechnology?
    a. Yes
    b. No

19. What specific statutes would you like to see amended to improve U.S. regulation of pharmaceuticals and related products that are produced with biotechnology? *(Select all that apply)*
    a. Not sure
    b. Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. §§ 301-399i
    c. Public Health Service Act (PHSA) 42 U.S.C. § 201 et seq.
    d. Toxic Substances Control Act (TSCA) 15 U.S.C. §§ 2601-2697
    e. Virus-Serum-Toxin Act (VSTA) 21 U.S.C. §§ 151-159
    f. Animal Health Protection Act (AHPA) 7 U.S.C. §§ 8301-8322
    g. Plant Protection Act (PPA) 7 U.S.C. § 7701 et seq.
    h. Other (please describe)

20. What specific statutory, regulatory, or other changes would enable FDA to expand its use of technology (e.g., NAMs, newly qualified biomarkers, in-silico modeling, AI-assisted triage and risk assessments) to reduce review timelines? *(~500 words or less)*

21. What specific statutory, regulatory, or other changes would empower FDA to waive, modify, or replace traditional clinical trial elements (e.g., fixed-dosing studies, long-term animal studies, rigid enrollment targets) when scientific justification exists? *(~500 words or less)*

22. Which specific statutory, regulatory, or other changes would reward first innovators (e.g., extended data-package exclusivity, secure-data audit requirements, stronger trade-secret safeguards) and deter AI-enabled "fast followers," especially from adversary nations, from capturing U.S. or allied market share? *(~500 words or less)*

23. What specific statutory, regulatory, or other changes would enable federal agencies to better prepare for novel or emerging pharmaceuticals and related products produced with biotechnology (e.g., living microbial therapeutics, platform technologies such as modular mRNA systems) before such products reach clinical review? *(~500 words or less)*

24. What specific statutory, regulatory, or other changes would enable increased interagency coordination (e.g., a unified submission portal, shared data standards, joint interagency review committees)? *(~500 words or less)*

*25.* Which specific statutory, regulatory, or other changes would enable increased alignment of U.S. and other countries' oversight (e.g., mutual recognition of review elements, trusted foreign-reviewer programs, secure data-sharing agreements)? *(~500 words or less)*

## Additional Information

26. You may use this space to provide any additional comments. *(~500 words or less)*

27. Are there other subject matter experts whom NSCEB should contact as part of this survey? If yes, please share their name, title, organization, and email address.

28. May we email you with additional questions? If yes, please enter your email address below.
    a. Yes, NSCEB can contact me.
    b. No, I do not want to be contacted.

29. Your email address