Questions and Answers: Biotechnology Regulatory Services

Last Modified:

Below is a comprehensive list of questions and answers on a variety of Biotechnology Regulatory Services (BRS) topics.

If you are unable to find the answer to your question, contact us.

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Notifications

For applications involving the import or interstate movement of a modified plant

You may upload a blank document or a document that indicates additional information is not required.

For applications involving the introduction (release) of a modified plant

Absent certain information, BRS may not be able to conclude that the release would meet the performance standards, and thus we may not be able to acknowledge the notification. For this reason, we encourage (but do not require) you to attach a document that describes how you will meet the performance standards related to release found at 7 CFR 340.3(c)(2), (3), (5), and (6):

- When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with nonregulated plant materials of any species which are not part of the environmental release.
- The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.
- The field trial must be conducted such that:
    - The regulated article will not persist in the environment, and
    - No offspring can be produced that could persist in the environment.
- Upon termination of the field test:
    - No viable material shall remain which is likely to volunteer in subsequent seasons, or
    - Volunteers shall be managed to prevent persistence in the environment.

Permits

For applications involving the import or interstate movement of a modified organism

You must attach a document that describes all intermediate destinations and the uses at such locations (for example, greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).

For applications involving the introduction into the environment (release) of a modified organism

The eFile permit application covers the information requirements detailed in 7 CFR 340.4(b), except those listed below 7 CFR 340.4(b)(11), (12), and (14). Thus, applicants must attach a document that includes a detailed description of:

- All intermediate destinations, uses, and/or distribution of the regulated article (for example, greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).
- The proposed procedures, processes, and safeguards that will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.
- The proposed method of final disposition of the regulated article.

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