October 22, 2024

Response to Comments
Guide to Submitting Data for Reports and Notices in APHIS eFile

On October 12, 2023, APHIS Biotechnology Regulatory Services (BRS) published a draft guide to assist developers with submitting data to meet permitting requirements for reports and notices on Regulations.gov (Docket APHIS-2023-0078). BRS invited the public to review and comment on the draft, resulting in feedback from one individual and one organization. This document summarizes and addresses the comments BRS received on the draft guide and clarifies whether any changes were made or will be made based on the feedback received.

We received comments on a range of different issues and grouped the comments into the following categories:

- Dates and data requirements for reports and notices
- Compliance requirements
- Technical challenges for APHIS eFile users
- Permits and alignment with data fields in APHIS eFile

Beyond these categories, we also received comments from an individual who did not address specific areas of concern or make any recommendations. BRS considers this comment out of scope for the guide and has not responded to it below.

Comments about Dates and Data Requirements for Reports and Notices

1. A commenter asked BRS about the due date for a final Volunteer Monitoring Report and asked BRS to revise the due date to allow submission of the report after fixed number of days following the permit's expiration date.

    Response
    Although we explored the possibility of adopting this suggestion, upon review, we do not believe the proposed change is possible for various reasons. The volunteer monitoring period is variable while the permit expiration date is set to one year after permit issuance for most annual crops. The length of the monitoring period depends on crop species, planting locations, and whether volunteers are found during the monitoring period. Additionally, volunteer monitoring must continue unless the last two volunteer monitoring dates identify no new volunteers. Because of these variables, BRS cannot adopt a standard due date for the final Volunteer Monitoring Report for all crops that coincides with the permit expiration date.

2. A commenter asked BRS to reconsider the due dates for Environmental Release Reports and, specifically, asked BRS to resume setting the due date as 30 days after planting rather than the 15th day of the month following the month of planting, which is the current practice.

    Response
    BRS will return to its prior practice of having Environmental Release Reports due 30 days after planting. Changing the due date for Environmental Release Reports will impact all permit

holders. BRS will ensure it proactively communicates this change to permit holders to ensure they have time to adjust their practices and systems to align with a change in due date. BRS anticipates implementing this change in permits issued on or after Oct. 1, 2024.

3. A commenter explained a practice of cultivating a field trial after the expiration date of a permit and asked whether permittees can use this cultivation date as the "termination" date in the Final Environmental Release Report (or a Post-Planting Report) that is entered in APHIS eFile.

   Response
   Most activities associated with a field trial must occur before a permit expires, including devitalizing actively growing plants through harvest (removal of shoots and seeds) or early destruction, such as mowing down a planting before it flowers. For purposes of the Final Environmental Release Report, the date plants are devitalized is the "termination date" that must be entered into APHIS eFile. Soil cultivation (i.e., turning soil to bury debris and/or weeds that may be present in soil) generally occurs after actively growing plants are devitalized and before the next planting occurs. Cultivating actively growing plants into the soil, in the absence of rendering them nonviable through another means (such as mowing or herbicide application), is not an adequate method to terminate a field trial, unless the plants were recently planted, failed to germinate, or damaged by severe weather.

4. Similarly, a commenter asked BRS to allow cultivation as a method to devitalize viable material at the conclusion of a field trial.

   Response
   As discussed above, in general, cultivation, alone, is not an adequate method to terminate a field trial. Devitalization generally occurs by mowing or cutting growing plants, which are typical practices that occur during harvest. BRS recognizes that some viable material (seed) could be left in a field after mowing or cutting (or a similar activity). Soil cultivation that incorporates debris and any remaining plant material into the soil to an adequate depth to promote decomposition ensures any remaining viable material does not move beyond the boundaries of the regulated area. Even with this step, some seed incorporated into the soil could remain viable and produce volunteer plants.

Comments about APHIS eFile Technical Challenges

1. A commenter asked BRS to reconsider requiring an affirmative report of "no environmental release" when a permittee elects not to plant in an authorized location. The commenter asked BRS to consider allowing APHIS eFile to automatically close an authorized location when the permittee does not submit an Environmental Release Report within 30 days of a permit's expiration date (i.e., BRS would assume no planting occurred at an authorized location unless it received an Environmental Release Report).

   Response
   The regulations require the submission of a report of no planting for all authorized locations where an environmental release did not occur (7 CFR § 340.5(i)(6)(i)). BRS continues to evaluate potential changes to APHIS eFile that may help permittees efficiently submit this information,

such as creating an action button that will allow permittees to affirm that no locations or no other locations were/will be planted.

Comments about Compliance Requirements

1. A commenter asked BRS to remove volunteer location and plant stage as data requirements for the Volunteer Monitoring Reports because they are required to report an unintentional release to USDA if flowering volunteers are detected and providing the information in the Volunteering Monitoring Reports as well creates duplicative reporting requirements.

    Response
    BRS supports the commenter's suggestion. To implement this suggestion, BRS is updating supplemental permit conditions and data fields in APHIS eFile. BRS will change "volunteer location" and "plant stage" from mandatory fields to optional fields in APHIS eFile to avoid unintended impacts on developers with software systems designed to submit large numbers of reports. BRS anticipates releasing updated supplemental permit conditions for most crops and making the necessary changes in APHIS eFile by Oct. 1, 2024.

2. A commenter asked BRS to discontinue the practice of requiring Volunteer Monitoring Reports for sites that were planted but where no volunteer monitoring will occur because it is irrelevant for an activity that did not take place.

    Response
    The regulations require reports of volunteer monitoring activities and the submission of findings for all authorized release locations where an environmental release occurred. If no monitoring activities are conducted, a volunteer monitoring report of no monitoring is required to explain why no volunteer monitoring occurred (7 CFR § 340.5(i)(6)(ii)). Once BRS receives an Environmental Release Report there is a presumption that volunteer monitoring will occur unless BRS receives information describing why volunteer monitoring is not required (e.g., early termination), which occurs through this report.

3. A commenter asked BRS to remove the "expected completion date" data requirement from the Interim Volunteer Monitoring Report because it requires speculation and does not contribute meaningfully to determining compliance.

    Response
    BRS agrees with this suggestion. To implement this suggestion, BRS is updating supplemental permit conditions and data fields in APHIS eFile. BRS will change "expected completion date" from a mandatory field to an optional field to avoid unintended impacts on developers with software systems designed to submit large numbers of reports. BRS anticipates implementing updated supplemental permit conditions and making the necessary changes in APHIS eFile by Oct. 1, 2024.

4. A commenter asked BRS to reconsider its requirement for a separate Volunteer Monitoring Report for the perimeter zone that surrounds a release site because the distinction between field and fallow zone does not seem to add value to the data being collected.

Response
BRS agrees with this suggestion. To implement this suggestion, BRS is updating supplemental permit conditions. Volunteer monitoring reports apply to the entire authorized area and do not require a distinction between the planted area and the perimeter zone. However, if equipment is cleaned outside the authorized area and the location where equipment was cleaned requires volunteer monitoring, the data associated with volunteer monitoring outside the authorized area must be added in the comments field or as an attachment. BRS anticipates implementing updated supplemental permit conditions by Oct. 1, 2024.

5. A commenter indicated they often receive record and information requests from BRS inspectors that have already been made available to BRS inspectors through reports submitted in APHIS eFile. The commenter indicated that duplicative requests for the same information is time consuming and asked BRS to eliminate inspectors' redundant requests for information, such as a list of constructs, already submitted in the environmental release report.

   Response
   BRS appreciate this feedback. We are currently undertaking a review of our inspection and compliance processes as part of a business process improvement project. As part of this project, we are working to improve the consistency of our processes and reduce instances of duplicative requests for information during inspections. For example, we have updated our guidance for inspectors to clarify that they should not request lists of constructs if the data already appears in APHIS eFile. In addition, we have updated the email template used to request records prior to conducting a compliance inspection to avoid asking for records and information that is available to inspectors through APHIS eFile.

Comments about Technical challenges for APHIS eFile users

1. Commenters requested that BRS update APHIS eFile to improve formatting and speed of PDF file generation.

   Response
   Although BRS has taken steps to improve the APHIS eFile user experience over the past few years, we recognize there is continued interest in improved formatting and speed of generating PDF files. Permit applications can range in size from 11 to over 1200 pages of data and information that, at times, can impact processing times and formatting.

2. A commenter indicated there are inconsistencies between permits marked as Confidential Business Information (CBI) and permits marked as CBI deleted and asked BRS to resolve these inconsistencies.

   Response
   BRS appreciates this feedback. BRS identified the cause of extra pages being added between the Supplier/Developer and Construct sections of CBI/CBI-Deleted PDFs and addressed it. Because BRS is focusing its limited resources on other, high epriority APHIS eFile enhancements, it is not actively exploring solutions to improve the rate of PDF generation.

3. A commenter asked BRS to re-evaluate its requirement for full contact information, including address, for the responsible person (site agent) for each location because they have already provided address information for points of origins and destination.

    Response
    When completing an APHIS eFile permit application the site agent name and contact information (i.e., phone and email) are mandatory fields. Although APHIS eFile provides an address field for site agent, it is an optional field that applicants may elect to complete.

4. Commenters asked BRS to review the current authorization numbering process and consider a permit numbering system like what existed in ePermits, the electronic permitting system predecessor of APHIS eFile. (P) Additionally, commenters asked BRS to change the format of permit amendment numbers back to a format where the amendment number relates back to the original permit number, for example by appending "a1" to the end of the permit number. (U)

    Response
    In 2019, BRS adopted the APHIS eFile system, which generates three unique numbers for each approved permit: an application number, an authorization number, and a permit number. When an applicant applies for a permit amendment, APHIS eFile generates a new application number and authorization number. Because the APHIS eFile system is built on a Salesforce platform, which uses an innate numbering system for each new iteration (e.g., application, authorization, and permit), we are unable to modify the numbering system to align with the number system used in the APHIS legacy ePermits system. With that said, the nomenclature suggested by the commenter exists with the permit number listed on issued BRS authorizations. When a BRS authorization is issued, a unique permit number is created and assigned to the issued authorization. This permit number remains consistent when an amendment authorization supersedes a previously issued authorization, with the only difference being the addition of the "a1" suffix.

5. A commenter asked BRS to develop a method for allowing applicants to submit permit amendments using Extensible Markup Language (XML), which is a feature that exists for initial permit applications. The commenter explained that XML submissions are more efficient than the web-based interface for applicants with large permit amendments.

    Response
    Following receipt of this comment, BRS evaluated the feasibility of developing an XML upload process for amended permit applications. We learned that although an XML process exists for initial applications, establishing a similar process for permit amendments would involve developing an entirely new module that would involve a significant level of effort and cost. As such, this type of enhancement is not feasible in the short-term given the high cost and other enhancements that are in the queue to complete.

6. A commenter asked BRS to address a technical issue during the amendment process that prevents an applicant from being able to access all existing documentation for a permit.

Response
BRS explored this concern and learned that Salesforce (the software used to build APHIS eFile) deployed a security update that impacts amended permit holders from viewing correspondence related to inspection outcomes that are associated with earlier versions of the permit. BRS identified this as high priority issue and worked to resolve the problem; it should work correctly moving forward.

7. A commenter asked BRS to allow applicants to submit more than 500 constructs (the current limit) on permit applications and explore how BRS can improve the efficiency of its permitting process by not undertaking a full review of constructs that were previously "approved" in a permit.

   Response
   BRS is presently undertaking a review of its permitting process. As part of this review, BRS evaluated whether it is possible to accept more than 500 constructs in a single application without detrimentally affecting review times. BRS is also evaluating how to consider "previously approved constructs" in a way that would decrease review times, while noting that some complexities exist, such as distinguishing between constructs that were included in interstate movement or importation permits from those included in environmental release permits. These improvements should streamline and promote consistency in our construct reviews.

Comments about Permits and alignment with data fields in APHIS eFile

1. A commenter asked BRS to make Supplemental Permit Conditions (SPCs) more uniform or crop specific. The commenter indicated this would make it easier for applicants to review during the permit process and implement across multiple, similar permits. The commenter also noted SPCs sometimes impose data reporting requirements that do not have corresponding fields in APHIS eFile, which requires permittees to provide this information using the "comments" field or by uploading attachments. The commenter asked BRS to develop corresponding entry fields for all data required in SPCs.

   Response
   BRS agrees that standardizing SPCs, to the extent that it is practical, would reduce permit application review times and provide greater consistency to stakeholders. To that end, BRS has been working to develop standard language for SPCs that can be used in most permits. BRS anticipates implementing these new, standardized SPCs by Oct. 1, 2024.

   As part of developing these standardized SPCs, BRS is working to ensure SPC requirements align with data fields in APHIS eFile. In instances where standard SPCs may not be appropriate, permit holders may still be required to provide unique information by typing in the comments section or by uploading supporting documents.

2. A commenter asked BRS to reconsider the need for street addresses for field release sites – a required field in the permit application using the XML process. The commenter explained that applicants already provide GPS coordinates to identify these locations.

Response
Applicants have previously flagged this concern for BRS and BRS indicated that, as an alternative to providing a street address, applicants may insert the GPS coordinate in the address field. BRS also shared this flexibility during its Stakeholder Meeting in November 2023 and will include it in a forthcoming update to its Permit User's Guide.

3. A commenter expressed interest in linked permits and asked BRS to explain the concept of linked permits and how linking permit applications may or may not be helpful for applicants.

Response
Linked permits are intended to speed up review times when applicants are submitting related material and data in more than one permit application. This could happen when there are more than 500 constructs, which need to be divided into more than one permit application because of the current size limit in APHIS eFile, but all the locations are the same among those applications. APHIS eFile does not provide a way for applicants to "link" permits at the time of application.

To link permits, applicants should contact BRS.eFile@usda.gov, list the AUTH numbers that are to be linked, and describe how they are linked. The benefit of linking permits include: the review of all permits is expedited since only one analysis of the locations needs to be done for all permits in the linked group. One set of reviewer reports are generated for all permits in the linked group, which expedites the manager review of the reports for all permits in the linked group. When all permits in the linked group are issued, they will have the same effective date. A potential drawback of linking permits could be, if there is a complex issue that needs to be resolved, then the processing of all permits in the linked group could be delayed while that issued is resolved.