Guidance for Submission of Field Test Reports (Annual Field Test Reports and Final Field Test Reports) Submitted Via Email or Mail

Process

Annual field test reports (also referred to as annual reports) and final field test reports submitted via email or mail are entered into ePermits by Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (APHIS BRS) staff on behalf of the regulated entity. This process ensures field test information in reports submitted via mail or email is readily available and identified by APHIS, enhances BRS' oversight of regulated field trials, and also supports recommendations in USDA Office of Inspector General Controls Over APHIS' Introduction of Genetically Engineered Organisms Audit Report 50601-0001-32.

Submission of Field Test Report Information

APHIS strongly encourages the electronic submission of all reports and notices via ePermits using the link under "My Reports and Notices."

Instructions are submitting reports via ePermits are located here: BRS Reports and Notices User Guide.pdf

Other options are email or mail. If submitting using these methods, both Confidential Business Information (CBI) and CBI-deleted or non-CBI copies should be sent to:

BRS E-mail: BRSCompliance@aphis.usda.gov

OR

BRS Mail: Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) Regulatory Operations Program 4700 River Rd. Unit 91 Riverdale, MD 20737

Note: This is general guidance, and required information that must be reported may vary based on the specific field trial or associated Supplemental Permit Conditions. Please contact BRS via email (<u>BRSCompliance@aphis.usda.gov</u>) or phone (BRS Compliance: 301-851-3879) for assistance and guidance.

Due Date of Report

All environmental releases of regulated articles under notification or permit require the submission of a final field test report, preferably as an electronic file, within six months of the

The information contained in this document is intended as guidance, and reflects APHIS' current interpretation of applicable statutes and regulations Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations Language implying that guidance is mandatory (e g , "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement

Conversely, following the guidelines contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations This guidance is to be used in conjunction with the USDA-APHIS BRS User's Guide for Notification and Permits User's Guide

termination of the field test. Termination is typically defined by harvesting or destroying the regulated article(s). Because APHIS does not always know the actual termination date in advance, APHIS defers this requirement so the final field test report is due no later than six months after the expiration of the authorization. The final field test report is required, even if BRS authorizes all or part of any field test sites to be planted back to a regulated article of the same species (e.g., a new authorization).

Annual reports must be submitted to APHIS no later than 30 calendar days after the anniversary date (one-year increments from the effective date listed on the permit). If the permit has been amended, the annual report is due 30 days from the anniversary date (one year increments from the effective date) of the ORIGINAL permit. For a three-year permit (multiyear) an annual report is required at the end of the first and second year (two annual reports). If the trial is terminated in year one, you must submit at least one annual report for the first year and a "final" field test report. On the last year of a three-year permit no annual report is required; however a "final" field test report is required, even if the permit is renewed, and the renewal number must be indicated in the final field test report.

Information to be Provided

In general, the information needed to satisfy the requirements in a field test report (annual or final) should be arranged in a tabular, spreadsheet format. The information described below is consistent with the ePermits module that allows the web form entry or XML uploading of field test report information into the system. For field test reports, APHIS is requesting that the same information be provided.

Final Field Test Reports

An example of a final field test report follows:



- 1. Authorization Number. Report the notification or permit number.
- 2. Institution. Report the institution name.
- **3.** Article. Report the regulated article.
- 4. State. Report the name of the State in which the planting/release occurs.
- **5.** County. Depending on the State or territory, report the name of the County, parish, borough or municipality in which the planting/release occurs.
- 6. Location Name. Report the release site's Location name (farm level) the same as it is listed in the authorization. *Location Name is used to designate the location, such as "Green's Farm."

- 7. Location Unique ID. This is an alphanumeric code that more specifically identifies the release site of the planting/release, typically at the field level and is used, among other reasons, to link all reports for the same field location. It can be any combination of letters or numbers that you choose, but it must be unique for each release site within each authorization. If a Unique ID was provided for this release site in the authorization, the applicant must use the same Unique ID in the field test report.
- 8. Report Date. Date of report submission.
- **9. Planting/Release occurred.** Indicate whether or not a planting/release has occurred at each authorized release site. There are two possible entries: Use a "Y" if a planting/release occurred or an "N" if the release site was not planted/released under this authorization. If a location was not planted, provide explanation.

NOTE: Final field test reports require that each release site be accounted for. Thus, each site must have either a no-planting record or one or more planting records, each complete with phenotypic designations and all constructs that were released.

- **10.** Acres Planted. Report the total acreage of the regulated article(s) planted, including only the area planted/released with the regulated article(s). This quantity must be submitted in acres; use no more than three decimal places. APHIS prefers border rows not be included in this figure, even though they are treated as regulated during the release. For complex field designs that involve planting/releases under multiple authorizations at one field location, report the planting/release size separately for each authorization, excluding border rows. For microbes and insects report the largest area of release. Provide the planting/release size only if you entered "Y" for "planting/release occurred" (**#9** above).
- **11. CBI information**. Use a "Y" if any fields within the field test report are CBI. If information within the report is CBI, use brackets [] to designate CBI information within the report. If CBI is involved, please submit both a CBI and CBI-deleted version.
- **12. Constructs**. The applicant must provide the constructs involved with each planting/release.
- **13. Lines/Events**. The applicant must provide the lines/events involved with each planting/release.
- 14. Pre-harvest destruction. Indicate if any of the material was terminated early and if any planted material was destroyed before harvest. If the field trial was terminated early for any reason and no material was removed from the field test site, answer "Y." Possible descriptions of early termination include: "test was terminated early and plowed under before flowering," and "poor weather conditions resulted in the loss of the crop."

If yes, provide the pre-harvest destruction completion date. Describe the reason and method of termination, as well as the plant stage at the time of termination (e.g.,

flowering, seed set). Do not answer "Y" if you harvested material early and removed it from the field. This material should be accounted for under harvest.

Provide this information only if you entered "Y" for "planting/release occurred" (**#9** above).

Note: The pre-harvest destruction completion date should precede the harvest completion date.

- **15. Harvest completion.** Indicate if any of the planted material was harvested. If so, provide the harvest completion date and area in acres that was harvested.
- **16. Termination of field test and final disposition of harvested material**. Describe how the viable harvested material was devitalized/disposed of. Indicate whether the harvested material was devitalized/disposed of in-field, was devitalized/disposed of off-field, or if the material was devitalized/disposed of both in-field and off-field (both).

Termination of field test in-field means that all of the viable harvested material was devitalized/disposed of in the field, including being incorporated into the soil by plowing under, being burned in the field, etc., and none of the material was physically removed from the field. If the material was devitalized/disposed of in the field and not removed from the field, provide the date the field test was completely terminated and describe the method of termination, including whether material was devitalized prior to disposition.

Termination of field test off-field means that all of the viable harvested material was physically removed from the field by hand carrying, trucks, etc. If material was removed from the field and stored, see **#17** below. If material was removed from the field and devitalized/disposed of off-site, such as in a municipal landfill, describe how it was disposed of and provide the date of off-site disposal, location (including address if applicable, amount of material, type of material (seed, other plant parts) and whether material was devitalized prior to disposition).

Both means some material was devitalized/disposed of in the field and some was removed. Both methods must be described.

If any viable material was devitalized, indicate type of material devitalized, method of devitalization (e.g. burning, autoclaving, etc.), devitalization completion date, acreage devitalized and location where material was devitalized.

- **17. Storage of harvested material.** If viable material was removed from the field and placed in **storage**, describe the type of viable material stored (e.g., seed, stem cuttings, etc.) and provide the amount of viable material that was stored, and a description (e.g., barn, building, bin) of the storage location including address where applicable.
- **18. Regulated material still growing at the field test site.** Any regulated material still growing in the field test must be accounted for. For example, if perennial plant material

was rolled into a permit, or if the material is covered under an existing permit that is going to or has been renewed, then account for this material and identify the permit or notification number under which it is authorized. If viable material is still growing in the field, provide the quantity of material in acres and provide a description of the material.

- **19. Deleterious effects and methods of observation and data.** Report any deleterious effects observed on plants, non-target organisms, or the environment. Include any relevant methods of observations, observations on other crops, and resulting data and analysis.
- **20. Report of accidental or unauthorized release, substantially different characteristics, or unusual occurrence.** Indicate if you have submitted any of the following:
 - A report on the accidental or unauthorized release of the regulated article
 - A report that characteristics of the permitted species are substantially different from those listed in the application, or
 - A report of any unusual occurrence.

Unusual occurrences during an introduction may require immediate notification to APHIS, particularly if plant characteristics are found to be different from those described in the original notification/permit.

21. Additional Comments. Provide any comments or additional information relating to the field trial. Such information may include information the applicant has provided in the past or desires to add to the ePermits record, and additional information that is required by APHIS BRS to be submitted in your report. Examples include other crop observations, whether all or part of the field test site planted under a previous authorization was planted back under this authorization, permit renewal information, plant stage at time of termination, and type of viable material stored. Note that multiple comments and information may be provided for each location.

Annual Reports

Annual reports must reflect the current status and observations to date and must include the required information listed in #1-21 above.