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Guide to Submitting Reports and Notices in APHIS eFile

The information contained in this document is intended solely as guidance. 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.

Following the guidance contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations.

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Biotechnology Regulatory Services Animal and Plant Health Inspection Service United States Department of Agriculture

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GUIDE INFORMATION

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SUMMARY:	This guide assists stakeholders (responsible persons and the general public) with understanding the data requirements and due dates for compliance reports and/or notices submitted using APHIS eFile. APHIS protects and enhances U.S. agricultural and natural resources using a science-sound regulatory framework to ensure the safe introduction – including importation, interstate movement, and confined environmental release of certain organisms developed using genetic engineering. APHIS receives its regulatory authority from the Plant Protection Act of 2000, and implements regulations for certain organisms developed using genetic engineering (7 CFR part 340). For more information: https://www.aphis.usda.gov/biotechnology.	
DISCLAIMER:	The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Agency regulations.	





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INTRODUCTION TO REPORTS AND NOTICES

The Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) program safeguards agriculture and natural resources from risks that may be associated with the introduction (importation, interstate movement, and confined environmental release) of certain organisms developed using genetic engineering (regulated articles).

Any person or organization who intends to perform a confined field release of regulated articles that are subject to <u>7 CFR part 340</u> or wishes to move that those organisms between States or to import them into the United States requires an authorization from BRS as outlined in the regulations. When BRS issues an authorization, the applicant becomes responsible for submitting reports and/or notices about the status of the regulated articles.

Authorization holders use reports and notices to convey to BRS compliance-related information. Reports and notices have specific due dates and data requirements based on the regulated articles described in authorizations. BRS uses reports and notices for various purposes, such as initiating an inspection process or monitoring compliance.

BRS provides this *Guide to Required Reports and Notices* under <u>7 CFR part 340</u> to help stakeholders (responsible persons, agents, and the general public) understand the data requirements for reports and notices (<u>Appendix IV</u>) and the processes for completing them in APHIS eFile by their due dates. The appendices include additional resources to help you understand important regulatory definitions (<u>Appendix I</u>); view applicable regulations under <u>7 CFR part 340</u> related to reports and notices (<u>Appendix II</u>); and provides examples of templates for report attachments (<u>Appendix III</u>).

You are responsible for complying with the requirements in your authorization. BRS is updating supplemental permit condition (SPC) templates to address comments it received in response to the draft *Guide to Submitting Data for Reports and Notices in APHIS eFile* on a rolling basis, beginning with the most common permitting categories. BRS began using revised supplemental permit conditions for corn and soybean permits issued on or after October 1, 2024. This means supplemental permit conditions may vary among crop types. Please read your supplemental permit conditions to ensure you understand your required reports and notices and associated due dates.

If APHIS BRS acknowledges a notification, the following report is required: Field Test Report (FTR). A Planting/Environmental Release Report is also requested so that APHIS may verify releases occur only in approved locations and during valid date ranges. In order to submit a Field Test Report through eFile the system will prompt you to first submit a Planting/Environmental Release Report.



TIPS FOR NAVIGATING THIS DOCUMENT

USING HYPERLINKS

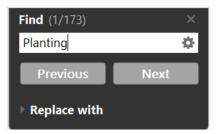
This document contains hyperlinks for items such as definitions throughout the document. A hyperlink will typically have a word in blue text with a line underneath it. To activate the hyperlink, click on the word/link. When you hover over the hyperlink, it will also provide you with the following directions.



Once you have completed looking at your hyperlink location, you can return to your original location by pressing and holding Alt and the left arrow on your keyboard.

SEARCHING THE DOCUMENT USING KEYWORDS

To search for keywords within the document, click on Ctrl and F on your keyboard. A "Find" pane will appear at the top of the screen. Enter a word in the box to find in the document. The example to the right searches for the word "Planting." The search function located 173 instances of the word in this document. To narrow down the search results, add additional words to your search, such as "Planting Reports."





GPS COORDINATE CONVERSION

GPS COORDINATE CONVERSION FROM DEGREES, MINUTES, SECONDS TO DECIMAL DEGREE FORMAT

BRS uses GPS coordinates to identify the authorized area and the area where you released regulated articles. If you are using technology that provides GPS coordinates in the Degrees, Minutes, Seconds format, you will have to convert these coordinates into decimal degrees for authorization applications, reports, and notices.

In this example below, the GPS provides the following GPS Coordinates in Degrees, Minutes, Second format:

Latitude: 38°58'08.65" N

Longitude: 76°55'31.60" W

To read this format, you would say 38 degrees 58 minutes 8.65 seconds North (for latitude) and 76 degrees 55 minutes 31.60 seconds West (for longitude).

To use the GPS coordinate conversion below, please add the appropriate information into each box and change the cardinal direction using the drop-down feature where appropriate. You may use the Tab key

Guide to Submitting Data for Reports and Notices

or click outside of the GPS Decimal Degree Format box to view your GPS coordinates.

Latitude Longitude

Cardinal
Degrees Minutes Seconds Direction

Cardinal
Degrees Minutes Seconds Direction

GPS Decimal Degree Format GPS Decimal Degree Format

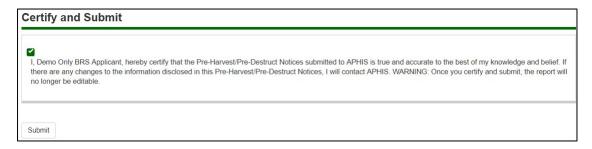
If you prefer not to use this document for converting your GPS coordinates, there are several websites that can make this conversion for you.



HOW TO SUBMIT REPORTS AND NOTICES

You must provide all required data for reports and notices as specified in your authorization, preferably as an electronic file in <u>APHIS eFile</u> (a web-based information management system), no later than the due date listed on your authorization. If you are unable to use APHIS eFile, you may instead submit your report/notice via email to <u>BRSCompliance@usda.gov</u> by providing the required data no later than the due date listed on your authorization.

- For step-by-step procedures and graphics specific to entering your data in APHIS eFile, please see our
 <u>Permit Application and Compliance Reporting Job Aid</u>.
- APHIS eFile uses information you provide in your environmental release report (previously called
 planting report) to populate subsequent reports. Based on the locations you submit as planted on
 your environmental release report, APHIS eFile will create corresponding release site and volunteer
 monitoring reports (if required) for you to complete. If you omit a planted location from your
 environmental release report, you will not be able to submit field test reports or volunteer
 monitoring reports for that location using APHIS eFile.
- APHIS eFile saves the information you enter for your reports and notices at each step. To submit the
 report or notice, you must certify the accuracy of the information by clicking a box and then click on
 the submit button to transmit the report.



• For specific information on what, when, and how to submit your reports and notices, refer to the following:

Guide to Submitting Data for Reports and Notices



- Permits: standard and supplemental permit conditions (SPCs) in your authorization.
- **Notifications:** performance standards and notification acknowledgement letter.
- If reports or notices contain data claimed as Confidential Business Information (CBI), you must submit both CBI and CBI-deleted versions When claiming CBI, use brackets [] to designate CBI information within the report. For more specific information please see <u>Guidance for Submitting</u> Confidential Business Information.

USING ATTACHMENTS FOR REPORTS AND NOTICES

If your SPCs require data elements or special reports/notices that are not identified in APHIS eFile, you can use the APHIS eFile comment section in the applicable report/notice to add a small amount of information (e.g., 100 characters or less). For a large amount of data or information, use an attachment to your applicable report/notice. This will commonly occur if you have an in-season volunteer monitoring and/or in-season flowering report requirement, which may be required in conjunction with the submission of an annual field test report. You can find step-by-step instructions on how to attach/add a supporting document to your report/notice in our <u>Permit Application and Compliance</u> <u>Reporting Job Aid</u>. When submitting report data as an attachment:

- You should copy and paste all data requirements from your supplemental permit conditions into a document and provide data to address each one. You may prefer to do this in Word or PowerPoint and then save it as a PDF. Doing so may help you when providing CBI and CBI-deleted information.
- For an example of a template, see <u>Appendix III Example Template for Report Attachment</u>.
- If you need assistance with this, please contact BRSCompliance@usda.gov.

SUBMITTING REPORTS VIA XML UPLOAD

If you are interested in uploading your reports via XML, please contact eFile.Communications@usda.gov and someone will assist you with the XML upload process.



QUICK GUIDE TO DUE DATES FOR REPORTS AND NOTICES

This quick guide provides examples of due dates for reports and notices identified in authorizations. You are responsible for complying with the requirements in your authorization. Please note that certain reports and notices or data fields apply to only certain types of authorizations (denoted with an *), such as Plant-Made Pharmaceutical or Industrial (PMPI) permits, multi-year permits, flowering reports, etc. Other data fields may be optional (denoted with 'optional'), unless such data is specifically required in your authorization. You must submit any required report or notice no later than the applicable due date listed in your authorization(s). Clicking on the title of a report will navigate you to Appendix IV, which provides detailed information about the data requirements for each report.

Report Type	Applicable Authorization Type (but not limited to)	Due Date	Example
Pre-Planting (Environmental Release) Notice* (APHIS eFile or other documents may call this Pre-Planting/Pre-Release Notice)	PMPI permits or other permits that include this requirement in SPCs	No later than 7 calendar days before the environmental release.	You plan to conduct your environmental release (planting) on May 10, 2022. You must submit your notice on or by May 3, 2022.
Planting (Environmental Release) Report	For all permits for environmental release for each applicable site/location.	Following an environmental release (e.g., planting or placement in an uncontained greenhouse or shade house), you must submit an environmental release report to APHIS within 30 days from the date of planting.	You conducted your environmental release (planting) on June 6, 2022. You submit your report on or before July 6, 2022. If you have released materials into the environment from multiple sites, and the
	For notifications for environmental release for each applicable site/location	Following an environmental release (planting) please submit a planting report to APHIS within 30 days from the date of planting.	releases occurred on June 6, 2022, at Site1, June 15, 2022, at Site2, and July 20, 2022, at Site3, please note the following reporting deadlines:
			You can combine Site1 and Site2 in one report and submit it by July 6, 2022, to ensure you report that June 6 release on time. You would have to submit Site3 in a separate report and submit it by August 19, 2022.
Report of No Planting/Release (Optional)	All permits for environmental release for each applicable site/location	If you do not make a release at the release site listed in your permit, you should submit a planting/release report of "no planting/release" no later than	You elected not to plant/release a regulated article at one or more locations authorized in your permit.

Report Type	Applicable Authorization Type (but not limited to)	Due Date	Example
		30 calendar days after the authorization expiration date.	Your permit expires on October 6, 2022. Your environmental release report that specifies "no planting/no environmental release" is due on or before November 5, 2022.
Pre-Flowering Notice*	PMPI Permits or other permits that include this requirement in your SPCs	For any plants allowed to flower during a field trial, you must submit a pre- flowering notice no later than 7 calendar days prior to the first anticipated flowering of the field trial.	You anticipate your trial will flower on or about July 8, 2022. You must submit your notice on or before July 1, 2022.
Flowering Report*	For permits that include this requirement in SPCs, see your SPCs	Due at the same time as your Annual Field Test Report and/or Final Field Test Report. See specific due dates below.	
Annual Field Test Report*	All multi-year permits	You must submit Annual Field Test Reports each year no later than 30 calendar days after the original effective date on your permit (i.e., on each year beginning 30 days after the original effective date of your permit; thus, if the effective date of the permit is April 1, the report is due no later than May 1 each consecutive year). This reporting frequency remains the same even if your permit is amended; your report remains due each year beginning 30 days after the original effective date of your permit. If you terminate the trial in year one, you must submit at least one Annual Field Test Report for	The effective date of your permit is April 1, 2022, your Annual Field Test Report is due no later than May 1, 2023. If your permit does not expire until April 1, 2025, you will be required to send in an additional report the following year on May 1, 2024. A Final Field Test Report will be due in 2025 even if you renew the permit. However, if you terminate during your first year, on March 15, 2023, you will be required to send us Annual Field Test Report no later than May 1, 2023,

Report Type	Applicable Authorization Type (but not limited to)	Due Date	Example
		the first year and a Final Field Test Report.	and a Final Field Test Report as required in your SPCs.
In-season Annual Volunteer Monitoring Report*	For permits that include this requirement in SPCs, see your SPCs	Due at the same time as your Annual Field Test Report.	
Pre-Harvest/ Termination Notice*	PMPI or other permits that include this requirement in SPCs	You must submit a pre- harvest/termination notice for a field trial no later than 21 calendar days prior to the initial anticipated harvest or termination date of the field trial.	You anticipate harvesting or terminating your field trial on October 8, 2022. You must submit your notice on or before September 17, 2022.
Final Field Test Report	All permits and notifications for environmental release	You must submit a Final Field Test Report no later than 180 calendar days after the authorization expiration date for each planted release site. You must submit this report even if you are authorized under a permit and APHIS issues a new permit for release at the release site.	The expiration date for your authorization is April 8, 2022. You must submit your report on or before October 5, 2022.
Interim Post- termination Volunteer Monitoring Report* (Previously called Annual Post- Termination Volunteer Monitoring Report)	For permits that include this requirement in SPCs, see your SPCs	Termination Volunteer Monitoring Report (VMR) are due annually as follows: The first Interim VMRs are due no later than 13 months after you terminated the environmental release. Subsequent Interim VMRs are due 1 year after the date you submitted the previous interim VMR; and The final year of volunteer monitoring is reported as a final	You terminate your field trial on April 3, 2021. Your first interim VMR is due no later than May 3, 2022. Your next interim VMR is due no later than May 3, 2023. For your final year of volunteer monitoring, you will submit a final volunteer monitoring report. Your last volunteer monitoring interval was on April 2, 2024, your final volunteer monitoring

Report Type	Applicable Authorization Type (but not limited to)	Due Date	Example
		VMR and is due 3 months following the end of the VMR period described in "Post-Termination Monitoring" for your permit.	report is due no later than July 2, 2024.
Post-termination Volunteer Monitoring Reports, Final	All permits for environmental release	A final VMR is due no later than 3 months following the end of the VMR period as described in "Post-Termination Volunteer Monitoring Requirements" for your permit.	Your last volunteer monitoring interval was March 15, 2022, your final report is due no later than June 16, 2022.
Volunteer Monitoring Report when Planting Back to Same Species, Regulated	For permits that include this requirement in SPCs, see your SPCs	If APHIS authorizes all or part of a release site to be planted to a regulated article of the same species for the next growing season: You must comply with the post-termination volunteer monitoring requirements of this permit until a new regulated planting occurs. Once the new planting occurs, you must follow the monitoring requirements for the planted area as described in the new permit. You must continue to monitor any unplanted areas according to the monitoring requirements of this permit.	Your 2022 permit authorized you to plant regulated corn at Site1. You decide to plant regulated corn again at Site1 authorized by your 2023 permit. You devitalized Site1 on September 5, 2022, and plan to plant back on May 1, 2023. You must volunteer monitor the entire Site1 until you plant back to regulated corn on May 1, 2023. On May 1, 2023, you can stop monitoring your plant back release site but must continue to volunteer monitor the area where the plant pack did not occur. You must continue to monitor this area for the remaining volunteer monitoring period noted in the original permit.
Return to General Use Notice – Cleaning*	PMPI Permits or other permits that include this	You must submit a notice for equipment or facilities you wish to return to general use no later	You wish to clean your combine so you can return it to general use by June

Report Type	Applicable Authorization Type (but not limited to)	Due Date	Example
	requirement in SPCs	than 14 calendar days prior to the anticipated cleaning.	16, 2022. You must submit your notice on or before June 2, 2022.
Reporting of Possible or Actual Unauthorized Release	All permits and notifications	In the event of a possible or actual Unauthorized Release, you must report the discovery to APHIS Compliance staff as follows: Contact APHIS Compliance staff within 24 hours of discovery: Phone: 301-851-3935 Email: BRSCompliance@usda.gov If your call advances to voicemail, you must leave a message describing the discovery. Subsequently, you must submit a written statement of facts describing the possible or actual Unauthorized Release within 5 days of discovery.	You discover regulated articles moved outside of your authorized trial location on June 6, 2022. You must contact BRS via phone at 301-851-3927 and/or via email at BRSCompliance@usda.gov within 24 hours. On or before June 11, 2022, you must submit a written description of the incident, including what occurred, how much material and where the material was moved, what was done with the material, and mitigation measures you have taken, and how you will prevent recurrence in the future.
Report of regulated article with characteristics substantially different or suffers any unusual occurrence	All permits and notifications	In the event of an unusual occurrence (excessive mortality or unanticipated effects on nontarget organisms) or substantially different characteristics of the regulated article from those listed in this authorization, you must report the discovery to APHIS Compliance staff via email (BRSCompliance@usda.gov) within 5 working days of discovery.	You discover a regulated article is not growing as expected on June 15, 2023. You must contact BRS via email at BRSCompliance@usda.gov no later than June 20, 2023.



VERSION HISTORY

March 21, 2025	Guide for Submitting Data for Reports and Notices in APHIS eFile updated to include reporting requirements for Notifications
October 22, 2024	Guide for Submitting Data for Reports and Notices in APHIS eFile addressing public comments; published with the Response to Comments
October 12, 2023	DRAFT Guide for Submitting Data for Reports and Notices in APHIS eFile published for public comment *replaces four previous guides: ePermits BRS Reports & Notices User Guide; Guidance for Submission of Planting/Environmental Release Reports and Reports of No Planting /Release Submitted Via Email or Mail; Guidance for Submission of Field Test Reports submitted via e-mail or
	mail; and Guidance for Submission of Volunteer Monitoring Reports submitted via e-mail or mail





APPENDIX I – DEFINITIONS

Below is a list of definitions that are important to understand the data requirements for the submission of reports and notices.

Authorization Number. APHIS eFile assigns an auto-generated number for your authorization (AUTH - 00000XXXX), which BRS uses as an identification number on correspondence, reports, etc.

Contact Information. Address, phone number (cell and office), and email address of the responsible person and agent (if any).

County. The county of the release site.

Deleterious Effects. Harmful or injurious effects on plants, non-target organisms, or the environment.

Destruction. The deliberate destruction of crops or agricultural products to render them useless for consumption or processing; may be accomplished by burning, grinding, mowing, or application of chemicals.

Devitalization. A procedure rendering plants or plant products or other organisms incapable of germination, growth, reproduction or persistence in the environment.

Effective Date. The first day an authorization is valid for authorized activities (i.e., the start date for an authorization).

APHIS eFile. A web-based system that allows users to apply for and receive import, interstate movement, transit, and release authorizations, apply for permit renewals and amendments, submit reports and notices, and receive regulatory guidance.

Environment. All the land, air, and water; and all living organisms in association with land, air, and water.

Environmental Release ID (Planting ID in APHIS eFile). An identifier the responsible person provides and uses to designate different release sites planted/released at different times within temperate locations, or for different release times on the same release sites within tropical locations.

Instructions for using environmental release ID: If more than one release occurs at an authorized release site location during the authorization duration under your authorization (e.g., different times or different release sites within the same location) you must provide an Environmental Release ID for each release. A single release may span several days but cannot include a gap of more than 30 days in which release activities do not occur. An extended-release period—planned or unplanned (e.g., poor weather)—may be divided into two or more releases that each has a different Environmental Release ID. The Environmental Release ID may be meaningful words or a coded string of alphanumeric characters, such as "P1" or "planting_n" or "release_n".

Genetic engineering. The genetic modification of organisms by recombinant DNA techniques.

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GPS Coordinates. Unique identifier of a precise geographic location on the earth, usually expressed in alphanumeric characters as the combination of latitude and longitude.

Instructions for providing GPS coordinates to BRS: Please provide up to six sets of GPS coordinates to identify the release site corners. If only providing one set of GPS coordinates, make sure it represents the NW corner of the release site. GPS coordinates must be in decimal degree format (e.g., 38.969831, -76.926215), with accuracy to a minimum of five decimal places. Accurate GPS coordinates and maps ensure release sites can be identified throughout the lifecycle of the field trial even when evidence of the release is no longer visible, such as post-termination and after weather events that may destroy the trial. Identification of release site locations is essential for ensuring compliance with regulations, including in-season and volunteer monitoring activities.

Growing Season. The part of the year in which environmental conditions (i.e., rainfall, soil moisture, temperature, daylight) allow plants to grow.

Harvest. The activity of cutting and collecting crops, or the crops that are cut, collected, and removed from the fields.

In-Season. The period of the year when crops and other plants grow successfully. The length of a growing season varies from place to place.

Interstate. From any State into or through any other State. Trade, traffic, or other commerce (A) between a place in a State and a point in another State, or between points within the same State but through any place outside that State; or (B) within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States. From any State in to or through any other State.

Introduce or introduction. To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

Location Address. Street address or GPS coordinates of the authorized location (point or origin, destination, or release site).

Location Name (also called Release Site or Release Site Location in APHIS eFile). The release site's location name (farm level) is the same as it is listed in the issued authorization.

Location Unique ID. This is an alphanumeric code provided by the responsible person (during authorization application submission) to identify the specific release site of the environmental release, typically at the field level. It 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. You must use the same Unique ID in the *Environmental Release Report* provided in the issued authorization application submission.

Move (moving, movement). (A)To carry, enter, import, mail, ship, or transport; (B) to aid, abet, cause,

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¹ This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "from any State in to or through any other State."

or induce the carrying, entering, importing mailing shipping, or transporting; (C) to offer to carry, enter, import, mail, ship, or transport; (E) to release into carry, enter, import, mail, ship, or transport; (E) to release into the environment; or (F) to allow any of the activities described in a preceding subparagraph.²

Notice. Mechanisms by which a responsible person communicates compliance-related information about the introductions of regulated articles covered by permits. Each notice has specific requirements regarding due dates and required data. BRS uses notices for various purposes such as initiating an inspection process or monitoring compliance.

Notification. Notification is an administratively streamlined alternative to the permit process to obtain authorization to introduce certain regulated articles. To be qualify for notification, regulated articles must meet all six eligibility criteria outlined in <u>7 CFR § 340.3(b)</u> and the proposed introduction must adhere to all performance standards listed in <u>7 CFR § 340.3(c)</u>.

Organism. Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Permit. A written permit issued by the Administrator, for the introduction of a regulated article under conditions determined by the Administrator, not to present a risk of plant pest introduction.

Plant. Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a root, and a seed.

Plant pest. Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal.

Post-Termination. The time frame after you destroyed (terminated) the regulated articles that were released as authorized by your authorization.

Regulated article (regulated organism). Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Release into the environment (environmental release). The use of a regulated article outside the

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² This definition is from the Plant Protection Act; the definition 7 CFR part 340, which predates enactment of and is superseded by the PPA definition, is "to ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States."

constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

Report. Mechanisms by which a responsible person communicates compliance-related information about the introductions of regulated articles covered by authorizations. Each report has specific requirements regarding due dates required data. BRS uses reports for various purposes such as initiating an inspection process or monitoring compliance.

Responsible person (also called Permittee in some documents). The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the authorization and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possessions of the United States.

Termination. To destroy or devitalize (i.e., not able to develop, grow, or survive) the regulated material that were grown as authorized. Termination of the field trial must occur on or before the expiration date of the authorization, or as specified in the authorization, unless you are under permit, and it has been renewed.

Unusual Occurrence. Excessive mortality or morbidity of the regulated article, or unanticipated effect on a non-target organism.



APPENDIX II – APPLICABLE REGULATIONS FOR SUBMITTING REPORTS AND NOTICES UNDER 7 CFR PART 340

Regulations Under Permit

"Permit conditions. A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests." (7 CFR § 340.4(f))

"A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment." $(7 \text{ CFR } \S 340.4(f)(9))$

• BRS is deferring this requirement such that you must submit a final field test report no later 180 calendar days after the permit expiration date for each planted Release Site.

"APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences: Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article." (7 CFR \S 340.4(f)(10)(i))

"APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences: In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms)" (7 CFR § 340.4(f)(10)(ii))

Regulations Under Notification

"Field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment." (7 CFR § 340.3(d)(4))

• BRS is deferring this requirement such that you must submit a final field test report no later 180 calendar days after the expiration date of the authorization for each planted Release Site.

"The Administrator, shall be notified of any unusual occurrence within the time periods and in the manner specified in § 340.4(f)(10)." (7 CFR § 340.3(d)(5))

"APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences: Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article." (7 CFR § 340.4(f)(10)(i))

"APHIS shall be notified within the time periods and manner specified below, in the event of the following

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occurrences: In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms)." (7 CFR § 340.4(f)(10)(ii))





APPENDIX III – EXAMPLE TEMPLATE FOR REPORT ATTACHMENTS

APHIS eFile accepts different document formats for report attachments including PDFs, Word files, Excel files, and photos. Below is one simple way you can provide the data requirement for your reports.

In this example, the developer found several data requirements listed in the supplemental permit conditions were not available to answer in APHIS eFile for the Flowering Report. For their permit, this report is required as part of their Annual Field Test Report. To ensure that APHIS receives a complete report, the developer copied the data requirements below and answered them for each date they monitored their trial (note this is a partial report). The developer started this process in Word so that it is easy for them to update or add to it as necessary. Once the report is completed they will save it as a PDF and upload it into their Annual Field Test Report using the <u>Permit Application and Compliance Reporting Job Aid</u> located on the <u>APHIS eFile Training</u> webpage under the Biotechnology Regulatory Services section.

Example Template for Flowering Report Attachment.

AUTH-00000XXXX

You must submit a Flowering Report as part of the Annual Field Test Report that provides a detailed report on flowering and includes:

- A. Indicate the dates you monitored the field trial and other monitored locations, as applicable.
- B. Indicate the location(s) you monitored, including the field trial (with any perimeter zone and border row areas), and any other areas where in-season volunteer monitoring is required.
- C. Indicate if flowering was observed. If yes, provide D to I:
- D. Indicate any dates upon which you identified flowers (if different than dates monitored)
- E. Number of flowers observed. If more than 100 flowers were identified, follow an estimation strategy and provide an estimate of the number.
- F. Whether any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occurred.
- G. The developmental stage of any flowers at the time of destruction (e.g., reproductive structures, visible flower buds, open flowers, pollen or seed)
- H. Any actions and dates of actions taken to remove or destroy flowers.
- I. Indicate if you have submitted a report indicating any unusual, early, out-of-season, or overabundance of flowering.

Does this application contain CBI? No

- A. Monitoring/Observation Date: 4/1/2022
- B. Location Monitored: Field Trial
- C. Were flowers observed: No
- D. Indicate any dates upon which flowers were identified if different from the monitoring date: N/A

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- E. Number of Flowers Observed: 0
- F. Did any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occur: No
- G. Development stage of Flowers: N/A
- H. Actions Taken: N/A1. Date of Action: N/A
- I. Have we ever submitted a report indicating any unusual, early, out-of-season, or overabundance of flowering occurred: No
- A. Monitoring/Observation Date: 4/2/2022
- B. Location Monitored: Field Trial
- C. Were flowers observed: Yes
- D. Indicate any dates upon which flowers were identified if different from the monitoring date: N/A
- E. Number of Flowers Observed: 2
- F. Did any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occur: No
- G. Development stage of Flowers: visible flower buds
- H. Actions Taken: N/A
 - 1. Date of Action: N/A
- I. Have we ever submitted a report indicating any unusual, early, out-of-season, or overabundance of flowering occurred: No
- A. Monitoring/Observation Date: 4/3/2022
- B. Location Monitored: Field Trial
- C. Were flowers observed: Yes
- D. Indicate any dates upon which flowers were identified if different from the monitoring date: N/A
- E. Number of Flowers Observed: 10
- F. Did any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occur: No
- G. Development stage of Flowers: visible flower
- H. Actions Taken: Flower removed
 - 1. Date of Action: 4/3/2022
- I. Have we ever submitted a report indicating any unusual, early, out-of-season, or overabundance of flowering occurred: No



APPENDIX IV – DATA REQUIREMENTS FOR REPORTS AND NOTICES

This section provides detailed data requirements for each report and notice required in your SPC.

PRE-PLANTING (PRE-ENVIRONMENTAL RELEASE) NOTICE

If you hold a BRS authorization for the environmental release of regulated articles, you may be required to submit a Pre-Planting (Pre-Environmental Release) Notice for all release site locations authorized in your permit.

Your permit's supplemental permit conditions will indicate whether a Pre-Planting (Pre-Environmental Release) Notices is required. Certain permits, like PMPI one-year and multi-year permits and crops with unique traits, may require this notice.

How to Submit Your Pre-Planting (Pre-Environmental Release) Notice (Pre-Planting/Pre-Release Notice in APHIS eFile)

See the How to Submit Your Reports and Notices in this document for more information.

If you need assistance with submitting your notice, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Pre-planting (Pre-Environmental Release) Notice

You must submit a Pre-Planting (Pre-Environmental Release) Notice, for each site listed on your permit, no later than seven calendar days before the environmental release (planting). The list below describes the data requirements for a Pre-Planting (Pre-Environmental Release) Notice, the information APHIS eFile will populate in the notice, and the information you should have on hand when submitting your notice.

Applicable Regulation: 7 CFR § 340.4(f)

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the permit:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Planned Planting/Release	You must provide the date on which the regulated article(s)
Start Date	release(s) is (are) expected to be released into the environment
	(planted) for each location.

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Comments	You may provide any additional information related to the release(s) that you want to share with BRS. Examples of such information include data elements that you provided in past
	reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

PLANTING (ENVIRONMENTAL RELEASE) REPORT AND REPORT OF NO PLANTING/ENVIRONMENTAL RELEASE

If you hold a BRS permit for the environmental release of regulated article, you must submit a Planting (Environmental Release) Report for all release sites/locations authorized in your permit.

BRS uses information from Planting (Environmental Release) Reports to track where and when regulated article has been released into the environment, to perform compliance inspections, and respond to regulatory incidents and emergency management situations, such as severe weather events.

For plants, there are three types of environmental releases under authorization: plantings of seed, transplanting of plants, and outdoor placement of plants grown in containers (including in structures that are not completely enclosed, such as shade houses, screen houses, or naturally ventilated greenhouse). You must submit a Planting (Environmental Release) Report that provides the location, shape, and size of these activities for each of your environmental releases.

For microbes or insects, an environmental release occurs each time you release your regulated article into the environment, and you must submit a Planting (Environmental Release) Report for this activity.

Submit only new (not previously reported) release information in each monthly report. Do not submit previously reported releases at the same location unless it is a new release at that location (e.g., a new plot, field or time with a new environmental release identifier, or if you are reporting an environmental release that replaces a regulated article that died).

BRS requests that notification holders submit planting (environmental release) reports in APHIS eFile. The information and manner of submission is the same for an environmental release regardless of the type of authorization (notification, release permit, interstate movement and release permit).

How to Submit Your Planting (Environmental Release) Report (Planting/Environmental Release Report in APHIS eFile): See the <u>How to Submit Your Reports and Notices</u> in this document for more information.

If you need assistance with submitting your Planting (Environmental Release) Report, please contact BRSCompliance@usda.gov.

For Multiple Plantings/Environmental Releases

When multiple releases occur under a single authorization, you must submit a Planting (Environmental Release) Report for each release. However, you (the responsible person or your acting agent) may define these as one or more releases, depending on factors that are meaningful, convenient, or important to your processes.

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For example, if two releases occur within a 30-day period, you may submit the release information in either one or two reports. If the releases occur more than 30 days apart, you must submit separate Planting (Environmental Release) Reports. All Planting (Environmental Release) Reports, including multiple releases, must be submitted no later than 30 days from the date of planting/environmental release for all permits.

Typical Data for Requirements for Planting (Environmental Release) Report:

Following an environmental release (e.g., planting or placement in an uncontained greenhouse or shade house), you must submit a Planting (Environmental Release) Report to APHIS within 30 days of the date of planting/environmental release for all permits. Your report will include the Environmental Release Unique ID (this differs from Location Unique ID) and, if you replanted a Release Site, you must provide an Environmental Release Unique ID for the subsequent release.

Submission of planting/environmental release report data is a precursor to submission of other reports or data for an authorized release site in APHIS eFile. If you don't submit planting report data you will not be able to enter any other data within APHIS eFile for that site, which could cause you to have a compliance issue due to late reporting or failure to report some required information related to your environmental release.

Applicable Regulations 7 CFR § 340.4(f).

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the authorization:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)

Data Requirements to Include for Each Authorized Release Site:

Data Requirements	Description
Environmental Release (Unique) ID	This is your release identifier. If you replant a release site, you must provide a unique ID for each release.
In APHIS eFile this is called "Planting ID"	
Release Start Date	Provide the date each planting/environmental release occurred in the relevant release site(s) location.
In APHIS eFile this is called "Start Date"	

Data Requirements	Description
Anticipated Termination Date	Provide the date on which the regulated article(s) release(s) is (are) expected to be harvested or terminated prior to harvest.
In APHIS eFile this is called "Anticipated Harvest/Destruction Date"	
Total Acreage of Released Organism(s) Under Authorization In APHIS eFile this is called "Quantity" (Acres)	Report the total acreage of the release regulated article under authorization. • Do not include border rows or perimeter zones when calculating the size, even though they are considered part of the trial and treated as regulated during the release. - If, for some reason, your reported size includes border rows and perimeter zones, please use the comment section to indicate these locations are part of your total area. • For complex field designs that involve releases under multiple authorizations at one field location, report the release size separately for each authorization, excluding border rows and perimeter zones.
Constructs Released	After entering the above information, click on Save. Prompts for Constructs will appear:
Click on Save, after entering the information above to enter construct and GPS coordinate information	 Under "Constructs" click on "+ Add" List all constructs approved on the authorization that you released for each location Unique ID by doing the following: Click inside of the "Search Construct" box, start typing your construct, and select it from the provided list. Or click on the hyperlink "See List of Constructs" and select the appropriate construct from the list. You may add Lines/Events, but this is optional. Click on "Save" and repeat the process to add any additional constructs released.
GPS Coordinates (in Decimal Degrees)	After entering the above information, click on Save and prompts for Constructs and GPS coordinates will appear:
Click on Save, after entering the information above to enter construct	 Under GPS coordinates click on "Add GPS Coordinates": Enter the Latitude and Longitude of your released regulated article.
and GPS coordinate information	Please provide up to six sets of GPS coordinates to identify the release site corners. If only providing one set of GPS coordinates, make sure it represents the NW corner of the release site. GPS coordinates must be in decimal degree format (e.g., 38.969831, -76.926215), with accuracy to a minimum of five decimal places.



Data Requirements	Description
Comments	You may provide any additional information related to the release(s) that you want to share with BRS. Examples of such information include data elements that you provided in past reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

Typical Data Requirements for No Planting/Environmental Release Report

If you do not make a release at release site(s) listed in your authorization, *you may submit a planting/release report of "no planting/release"* to indicate that you do not intend to plant a regulated trial at that authorized location.

Do not identify sites as "no planting/no environmental release" in your environmental release reports in APHIS eFile if you will, or will likely, plant/release at these locations prior to the expiration date of your authorization. Only note a site as "no planting/no environmental release" in a *Planting (Environmental Release) Report* if you are certain no releases will occur at a given site before the authorization expires. If you have inadvertently reported a "no planting/no environmental release" for a site you intend to plant, contact BRSCompliance@usda.gov so we can correct your report in APHIS eFile. If you do not contact us, you will not be able to enter a planting for that site and you will not be able to enter any other data within in APHIS eFile for that site, which could cause you to have a compliance issue due to late reporting or not reporting an environmental release.

PRE-FLOWERING NOTICE

If you have been approved and issued a BRS permit for the environmental release of regulated articles, you may be required to submit a Pre-Flowering Notice for all release site locations authorized in your permit. Pre-Flowering Notice is required typically if your regulated article is authorized to flower.

How to Submit Your Pre-Flowering Notice

See the How to Submit Your Reports and Notices in this document for more information.

If you need assistance with submitting your Pre-Flowering Notice, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Pre-Flowering Notice

If you are required to submit a Pre-Flowering Notice for any plants allowed to flower, you must submit the Notice no later than seven calendar days prior to the first anticipated flowering of the field trial.

Applicable Regulations: 7 CFR § 340.4(f).

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the permit:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State

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- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)
- Environmental Release ID (Unique ID) (in APHIS eFile this is called "Planting ID")

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
The earliest anticipated flowering start date	Based on observations, the date you believe flowering will start for each field trial.
Comments	Provide as text any comments or miscellaneous information relating to the release. Examples of such information include data elements that you provided in past reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

ANNUAL FIELD TEST REPORT

For multi-year permits, you are typically required to submit an Annual Field Test Report for each year the permit is authorized, except for the last year when you are required to submit a Final Field Test Report (see <u>Final Field Test Report</u> in this document for more information).

You must submit Annual Field Test Reports to APHIS no later than 30 calendar days after the anniversary date of the original permit (one-year increments from the effective date listed on the permit, e.g., if the effective date of the permit is April 1, the report is due no later than May 1 each consecutive year). If the permit has been amended, you must submit the Annual Field Test Report no later than 30 days after the anniversary date (one-year increments from the effective date) of the ORIGINAL permit.

If you terminate the trial in year one, you must submit at least one Annual Field Test Report for the first year and a Final Field Test Report.

Other Reports Embedded in the Annual Field Test Report in APHIS eFile
For multi-year permits, you may be required to submit a Flowering Report and/or an In-Season
Volunteer Monitoring Report. Please check your supplemental permit conditions to see if these

Volunteer Monitoring Report. Please check your supplemental permit conditions to see if these reports are required for your specific permit. In addition, these reports may have data requirements that do not appear in APHIS eFile, if this is the case, this information should be included as an attachment to your report.

How to Submit Your Annual Field Test Report [Field Test Report (Annual or Final) in APHIS eFile] See the How to Submit Your Reports and Notices in this document for more information.

If you need assistance with submitting your Environmental Release Report, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Annual Field Test Report

The Annual Report must reflect the current status and observations to date and the following

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information for each authorized trial site:

Applicable Regulations: 7 CFR § 340.4(f).

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the permit:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
Indicate if you rendered the regulated article nonviable (i.e., not able to develop, grow, or survive) prior to harvest APHIS eFile Question: Was any planted material destroyed before harvest?	If yes, answer the following in APHIS eFile: When you answer "Yes", the following appears: • Pre-harvest destruction date - Enter the date you rendered the regulated article nonviable • Pre-harvest destruction description, add the following: - Actual stage of plant development when rendered nonviable (e.g., vegetative or reproductive) - Destruction method (e.g., mowing, burning, soil cultivation, herbicide application, disposal at authorized landfill) and - Destruction location
Indicate if you harvested the regulated article and any viable material APHIS eFile Question: Was any planted material harvested?	 If yes, answer the following: Provide the harvest completion date For the following requirements you must choose "All terminated offfield" or "Both" for the APHIS eFile question "How was it terminated?" See section below for more details.
Indicate if you retained or destroyed the harvested regulated article APHIS eFile Questions: How was it terminated? • All terminated in-field • All terminated off-field • Both	 If you retained the regulated article, choose "All terminated off-field" for, "How was it terminated?", and choose "All stored or contained" or "Both (some of each)" for, "How was off-field terminated material disposed?" and provide the following information: Under Description of storage location and material placed in storage The location (including address and description) of contained facility where you stored the viable regulated article Under Stored Material Type A description of what you stored at that location, and

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Data Requirements	Description
	Under Stored or contained quantity Quantity of stored regulated article
How was off field terminated material disposed? • All stored or contained • All destroyed • Both (some of each)	If destroyed material, choose "All destroyed" or "Both (some of each)" for, "How was off-field terminated material disposed?" and provide the following information: • Under Off-field Destruction Description - Describe the method of destruction or disposal (e.g., burned,
Choose the appropriate response for your trial	ground, authorized landfill) and Under Off-field Destruction DateDate of destruction
If you rendered the regulated article or associated viable material nonviable at the release site	If you rendered your regulated article or associated viable material nonviable at the release site (choose "All terminated in-field" for, "How was it terminated?"), provide the following information: • Under the In-field termination completion date:
	 Provide the date you rendered the regulated article and associated material nonviable in the field. In the In-field termination description box add the following: Describe how you rendered the regulated article nonviable in the field to include the method of destruction (e.g., burned, hammer-milled) and/or disposition method(s) (e.g., tilled, remained untilled).
APHIS eFile Questions: How was it terminated? • All terminated in-field • All terminated off-field • Both	If your regulated article was removed from the field and destroyed/devitalized or disposed of off-site (choose "All terminated off-field" or "Both" for "How was it terminated?" and "All destroyed" for "How was off field terminated material disposed?"), provide the following information under the question:
Choose the appropriate response for your trial	 Under Off-field destruction date: Provide the date Under Off-field destruction description: Methods taken to destroy/devitalize regulated article under permit (e.g., burned, ground up, etc.)
How was off field terminated material disposed? • All stored or contained • All destroyed	If the regulated article under permit was removed from the field (harvested) and placed in storage (choose "All terminated off-field" or "Both" for "How was it terminated?", and "All stored or contained" or "Both (some of each)" for "How was off-field terminated material disposed?")
Both (some of each)	Regulated material may be removed from the field and stored. You must store viable regulated material so that it is securely

Data Requirements	Description
Choose the appropriate response for your trial	 contained, and its identity maintained. Provide the following information: Under Stored or contained quantity and Stored Units: The approximate amount of viable regulated article under permit that was stored and Under Stored Material Type: Enter what type of regulated article under permit is being stored (e.g., seed, ears) Under Description of storage location and material placed in storage: Enter the location (including address and description) of the contained facility where the material is stored. Provide the location the material is stored including any available
Indicate if any regulated article under permit remains growing at the release site Question in APHIS eFile: Is any planting material still growing in the field?	 address, and a description of the storage location. If yes, answer the following: How much planted material is still growing in the field, in acres: Report the total size of the remaining release, including only the area occupied by the regulated article. If nothing has been devitalized, this will be the same as the "Total Acreage of Modified Plant(s) (Quantity (Acres)" in APHIS eFile) you recorded for your <i>Environmental Release Report</i>. You must submit the size in acres; use no more than five decimal places. APHIS prefers that border rows not be included in this figure, even though they usually are treated as regulated during the release. For complex field designs that involve releases under multiple permits at one field location, report the release size separately for each permit, excluding border rows. Border rows may optionally be included in the reported area but are not required to be reported; however, the acres released overall release occurrences (including border rows) must sum to be equal to or less than the authorized area provided in the issued permit. If your reported area includes border rows in the total acres reported, please add this information to the comments section of the report. Description of material still growing in the field: Provide a description of the material Provide the APHIS BRS authorization number authorizing you to continue the release
Indicate if annual inseason monitoring for volunteers is required	If yes, answer the following: Under Monitoring Start Date:



Data Requirements	Description
Question in APHIS eFile: Is monitoring for volunteers during the field test required?	 Indicate start date(s) of in-season volunteer monitoring for each field trial (environmental release (planting) date of field trial) Under Monitoring End Date: Indicate estimated end date(s) of in-season volunteer monitoring interval for each field trial (optional).
	If you are required to do annual in-season volunteer monitoring and are required to submit a report for annual in-season volunteer monitoring with your Annual Field Test Report, after you save the Annual Field Test Report, an "Observations" prompt will appear. To enter annual in-season volunteer monitoring information click on "Add Observations". See the section Annual Field Test Report Inseason Volunteer Monitoring Report, Annual section below for requirements.
Indicate if annual inseason monitoring for any flowering/anthesis is required Question in APHIS eFile: Is monitoring for flowering during the field test required?	 If yes, answer the following: Did Flowering Occur? Indicate if flowering occurred. If Yes, Is flowering authorized under your authorization? Indicate if flowering is authorized under this permit. If Yes, Are you required to submit a flowering report? Indicate if you are required to submit a flowering report If flowering occurred and you are required to submit a flowering report with your Annual Field Test Report after you save the document, an "Observations" prompt will appear. To enter Flowering Report information, click on "Add Observations". See the Flowering section below for requirements.
Comments	Provide as text any comments or miscellaneous information relating to the release. Examples of such information include data elements that you provided in past reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

IN-SEASON VOLUNTEER MONITORING REPORT, ANNUAL

As part of the Environmental Release Report, Annual, you may be required to provide a detailed report of in-season monitoring for volunteers and/or sexually compatible species. Please confirm this is a required report by looking at the supplemental permit conditions for your specific permit.

How to Submit Your In-season Volunteer Monitoring Report, Annual: This report is embedded in your Environmental Release Report, Annual in APHIS eFile

Once you have completed entering your data for the Annual Field Test Report and click on save an observation prompt will appear for you to enter your data requirements. See the <u>How to Submit Your</u>

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Reports and Notices in this document for more information.

If you need assistance with submitting your In-season Volunteer Monitoring Report, Annual, please contact BRSCompliance@usda.gov.

Typical Data Requirements for In-season Volunteer Monitoring Report, Annual

An In-season Volunteer Monitoring Report that you must submit as part of the Environmental Release Report, Annual provides a detailed report on in-season monitoring for volunteers and/or sexually compatible species.

Applicable Regulations: 7 CFR § 340.4(f).

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description		
Indicate start date(s) of in-season monitoring for each field trial	Provide the date(s) you started your in-season monitoring for each field trial (this information is entered into the Annual Field Test Report, before adding the observation information).		
Indicate estimated end date(s) of in-season monitoring for each field trial	Provide the estimated end date(s) of in-season monitoring for each field trial (this information is entered into the Annual Field Test Report, before adding the observation information) (optional).		
To start adding volunteer	To start adding volunteer monitoring observation information click on "Add Observation"		
Indicate the dates you monitored the field trial	 Under Observation Date: Enter a single observation date. For each new observation date, you must add a new observation. 		
In APHIS eFile this is called "Observation Date"	Please reference your specific supplemental permit conditions to determine your duration (period) and frequency (intervals) for volunteer monitoring. You should have a date for each time you monitored your trial. For example, if you are to monitor every 30 days and you started monitoring on April 1, 2022, your next volunteer monitoring should be around May 1, 2022. If weather or field conditions are not conducive for monitoring (e.g., rain, flood), you may undertake this monitoring up to 2 days earlier or 2 days later.		



Data Requirements	Description
Provide the number of in-season volunteers or sexually compatible relatives observed In APHIS eFile this is called "Number of Volunteers"	 Provide the number of volunteers observed (number only). If you observed more than 100 in-season volunteers or sexually compatible relatives, follow an estimation strategy, and provide an estimate of the number. If you observed no volunteers, specify "no volunteers observed". If you have a lot of information to add to the report, BRS suggests you upload the information into the report as a Word, PDF, Excel, or PowerPoint document. Unfortunately, APHIS eFile will not allow more than one observation at a release site location for a particular day; if you have observations for different locations at the same site (e.g. fallow zone and equipment cleaning area) on the same date you may need to attach a file to provide this information. For more information about uploading documents into your report, see Appendix III.
Provide the developmental stage of the in-season volunteers found *If this information is required by your SPC, please include it in your report. Check your SPC for confirmation.	 Add the development stage of volunteer observed (optional unless required by your SPC). Some examples of developmental stages include but are not limited to seedling, vegetative, or flowering.
Any actions, including dates, taken to remove or destroy in-season volunteers	 Under Action Taken or In an Attached Document: Add actions taken. Please review your permit conditions, there may be specific or approved methods listed for your specific permit.

FLOWERING REPORT

As part of the Annual Field Test Report, you may be required to submit a Flowering Report for all release site locations authorized in your permit. Flowering reports are required typically if your regulated article under permit is authorized to flower. However, please confirm this is a required report by looking at the supplemental permit conditions for your specific permit.

How to Submit Your Flowering Report (this report is embedded in your Annual Field Test Report in APHIS eFile):

Once you have completed entering your data for the Annual Field Test Report and click on save an observation prompt will appear for you to enter your data requirements. See the How to Submit Your Reports and Notices in this document for more information.



If you need assistance with submitting your Flowering Report, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Flowering Report

A Flowering Report that you must submit as part of the Annual Field Test Report provides a detailed report on flowering.

Applicable Regulations: 7 CFR § 340.4(f).

Important Note: Currently the Add Observation section for adding your flowering report says volunteers in APHIS eFile. If you need to add both a volunteer monitoring report and a flowering report, please ensure that you add a comment to indicate which type of report you are entering.

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
Indicate start date(s) of flower monitoring for each field trial	Under "Comments" or in an attached documentIndicate the start date(s) for each field trial.
	Reference your supplemental permit conditions to determine your start date for your flowering report.
	If you have a lot of information to add to the report, BRS suggests you upload the information into the report as a Word, PDF, Excel, or PowerPoint document. For more information about uploading documents into your report, see <a blue;"="" color:="" href="#expecialstyle=">Appendix III .
Indicate end date(s) of flower monitoring for each field trial	Under Comments or In an Attached DocumentIndicate the end date(s) for each field trial.
	Reference your SPCs to determine your end date for your flowering report.
	If you have a lot of information to add to the report, BRS suggests you upload the information into the report as a Word, PDF, Excel, or PowerPoint document. For more information about uploading documents into your report, see Appendix III .

Indicate the dates you	Under Observation Date:
monitored the field trial	
	To start adding flower monitoring observation information click on
In APHIS eFile this is called	Add Observation. Enter a single observation date. For each new
"Observation Date"	observation date, you must add a new observation.
	Reference your specific supplemental permit conditions to determine
	your duration (period) and frequency (intervals) for flower monitoring.
	You should have a date for each time you monitored your trial. For
	example, if you are to monitor every 30 days and you started
	monitoring on April 1, 2022, your next volunteer monitoring should be
	around May 1, 2022.
The number of flowers	Under Number of Volunteers:
observed	
	• Enter the number of flowers observed. If more than 100 flowers
	were identified, follow an estimation strategy and provide an
	estimate of the number.
	If you have wellking sites to requite a few isolation distance field twist)
	If you have multiple sites to monitor (ex; isolation distance, field trial) add this information in Actions Taken or in an attached document
	uploaded
	into the Annual Field Test Report for each site.
	into the Annual Field Test Report for each site.
	Example:
	- Isolation Distance: 20 flowers found, visible flower buds, found
	May 1, 2022, removed by hand on May 1, 2022.
	- Field Trial: 10 flowers found, visible flower buds, found May 1,
	2022, removed by hand on May 1, 2022.
	If you have a lot of information to add to the report BRS suggests you
	upload the information into the report as a Word, PDF, Excel, or
	PowerPoint document. For more information about uploading
	documents into your report, see Appendix III.
The developmental stage	Under Comments or In an Attachment:
of any flowers at time of	Provide the developmental stage of flowers at time of destruction
destruction	(e.g., reproductive structures, visible flower buds, open flowers, pollen
	or seed) If you have multiple sites to monitor (ex, fallow zone, field
	trial, equipment cleanout area) add this information in Actions Taken
	or in an attached document uploaded into the Annual Field Test Report
	for each site.
	• Example:
	- Perimeter Zone: 20 flowers found, visible flower buds,
	found May 1, 2022, removed by hand on May 1, 2022.
	- Field Trial: 10 flowers found, visible flower buds, found May 1,
	2022, removed by hand on May 1, 2022.

	- Fallow Zone: 0 volunteers found.
	If you have a lot of information to add to the report BRS suggests you upload the information into the report as a Word, PDF, Excel, or PowerPoint document. For more information about uploading documents into your report, see Appendix III .
Any actions, including	Under Comments or In an Attachment:
dates, taken to remove or	Dravida actions taken to remove or destroy flavors for each site
destroy flowers	Provide actions taken to remove or destroy flowers for each site, ensuring you reference your SPCs to ensure you are following any specific flower removal or destruction methods.

PRE-HARVEST/PRE-TERMINATION NOTICE

Pre-Harvest/Pre-Termination Notices are specified but not limited to PMPI one-year and multi-year permits. Please see your specific supplemental permit conditions to see if your specific permit requires a Pre-Harvest/Termination Notice(s).

How to Submit Your Pre-Harvest/Pre-Termination Notice

See the How to Submit Your Reports and Notices in this document for more information.

If you need assistance with submitting your Pre-Harvest/Pre-Termination, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Pre-Harvest/Pre-Termination Notice

You must submit a Pre-Harvest/Pre-Termination Notice no later than 21 calendar days prior to the initial anticipated harvest or termination date of the field trial and include. Please see your specific supplemental permit conditions to see if your Notice has a different due date.

Applicable Regulations: 7 CFR § 340.4(f).

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the permit:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)
- Environmental Release ID (Unique ID) (in APHIS eFile this is called "Planting ID")



Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
The earliest planned harvest/termination	Under Anticipated Harvest/Termination Date:
start date. For multiple harvests, submit the notice prior to the initial harvest	 Provide the date on which you anticipate you will harvest or terminate the regulated article(s) under permit. For multiple harvests, submit the notice prior to the initial harvest.
Comments	Provide as text any comments or miscellaneous information relating to the release. Examples of such information include data elements that you provided in past reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

FINAL FIELD TEST REPORT

If you have been approved and issued an APHIS BRS permit or notification for the environmental release of a regulated article, and conducted an environmental release, you must submit a Final Field Test Report for all release site locations authorized in your authorization.

Submission of environmental release information within a *Final Field Test Report* supports two critical APHIS regulatory functions: (1) compliance verification through inspections and (2) monitoring and response to regulatory incidents and emergency management situations, such as severe weather events.

How to Submit Your Final Field Test Report [Field Test Report (Annual or Final) in APHIS eFile]: See the <u>How to Submit Your Reports and Notices</u> in this document for more information.

If you need assistance with submitting your Final Field Test Report, please contact BRSCompliance@usda.gov.

Data Requirements for Final Field Test Report

Field Test Report. You must submit a field test report within 6 months after the termination of the field test.

• BRS is deferring this requirement such that you must submit a final field test report no later 180 calendar days after the permit expiration date for each planted Release Site. You must submit this report even if APHIS issues a new permit for release at the release site.

Applicable Regulations <u>7 CFR § 340.4(f)</u>, <u>7 CFR § 340.4(f)(9)</u>, and <u>(7 CFR § 340.3(d)(4))</u>.

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the authorization:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID

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- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
Indicate if you rendered the regulated article nonviable (i.e., not able to develop, grow, or survive) prior to harvest Question in APHIS eFile: Was any planted material destroyed before harvest?	If yes, answer the following in APHIS eFile: Was any planted material destroyed before harvest: if Yes, answer the following: • Pre-harvest destruction date - Enter the date you rendered the regulated article nonviable • Pre-harvest destruction description, add the following: - Destruction methods (e.g., mowing, burning, soil cultivation, herbicide application, disposition at authorized landfill); - Actual stage of plant development when rendered nonviable (e.g., vegetative or reproductive); and
Indicate if you harvested the regulated article and any viable material Question in APHIS eFile: Was any planted material harvested?	 Destruction location If yes, answer the following: Harvest Completion Date Provide the harvest completion date.
For the following requirements you must choose "All terminated in-field", "All terminated off-field", or both for the APHIS eFile question "How was it terminated?" See section below for more details.	
Indicate if you retained or destroyed the harvested regulated article and any viable material	If you retained the regulated article, choose "All terminated off-field" for, "How was it terminated?", and choose "All stored or contained" or "Both (some of each)" for, "How was off-field terminated material disposed?" and provide the following information:
APHIS eFile Questions: How was it terminated? • All terminated infield, • All terminated offfield	 Under Description of storage location and material placed in storage add; The location (including address and description) of contained facility where you stored the regulated article and any variable material, Under Stored Material Type A description of what you stored at that location, and

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Data Requirements	Description
Both Choose the appropriate	Under Stored or contained quantity Quantity of stored regulated article
response for your trial How was off field terminated material	 If destroyed material, choose "All destroyed" or "Both (some of each)" for, "How was off field terminated material disposed?" and provide the following information:
disposed?All stored or contained,All destroyed,	 Under Off-field Destruction Description Describe the method of destruction or disposal (e.g., burned, ground, authorized landfill) and
Both (some of each) Choose the appropriate	Under Off-field Destruction DateDate of destruction
response for your trial	
Indicate if you rendered the regulated article or associated viable material	If you rendered your regulated article or associated viable material nonviable at the release site (choose "All terminated in-field" for, "How was it terminated?"), provide the following information:
nonviable at the release site.	 Under the In-field termination completion Date: Provide the date you rendered the regulated article and associated material nonviable in the field.
APHIS eFile Questions:	
 How was it terminated? All terminated infield All terminated offfield 	 In the In-field termination description box add the following: Describe how you rendered the regulated article nonviable in the field to include the method of destruction (e.g., burned, hammer-milled) and/or disposition method(s) (e.g., tilled, remained untilled).
• Both	If the regulated article under permit was removed from the field and destroyed/devitalized or disposed of off-site (choose "All terminated off-
Choose the appropriate response for your trial	field" or "Both (some of each)" for, "How was it terminated?" and "All destroyed" for "How was off field terminated material disposed?"), provide the following information under the question:
How was off field terminated material disposed? • All stored or	 Under Off-field destruction date: Provide the date,
contained • All destroyed • Both (some of each)	 Under Off-field destruction description: location, and methods taken to destroy/devitalize the regulated article under permit (e.g., burned, ground up) and Enter the location (including address and description) of the
Choose the appropriate response for your trial.	contained facility where the material is stored. Provide the location the material is stored including address and a



Data Requirements	Description
	description of the storage location.
Indicate if you have observed any unexpected effects.	 Under Unexpected Effects: This field in eFile is defaulted to "No". If you have observed any unexpected effects, change the field to "Yes" and provide the following information:
	 Under Explanation: Describe any observations and data of excessive mortality or morbidity, or unanticipated effect on non-target organisms.
Describe any deleterious effects on plants, non-target organisms, or the environment.	 Under Deleterious Effects: This field in eFile is defaulted to "No". If you have observed any deleterious effects, change the field to "Yes" and provide the following information:
	 Under Deleterious Effects Data: Describe any deleterious effects on plants, non-target organisms, or the environment to include any relevant methods of observations, observations on other crops, and resulting data and analyses.
Comments	Optional Information: Provide as text any comments or miscellaneous information relating to the release. Examples of such information include data elements that you provided in past reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

POST-TERMINATION VOLUNTEER MONITORING REPORTS, INTERIM AND FINAL

You must submit a post-termination volunteer monitoring report (VMR) for each release at a release site and locations requiring monitoring under this permit, even if APHIS subsequently issues a new permit for a field trial. If you did not conduct volunteer monitoring, the volunteer monitoring report must specify "no monitoring" and explain why monitoring did not occur, as noted below.

How to Submit Your Post-Termination Volunteer Monitoring Report, Interim and Final (Volunteer Monitoring Report in APHIS eFile)

See the How to Submit Your Reports and Notices in this document for more information.

If you need assistance with submitting your Post-Termination Volunteer Monitoring Report, Interim and Final, please contact BRSCompliance@usda.gov.

Typical Data Requirements for All Post-Termination Volunteer Monitoring Reports

After you terminate the environmental release at each planted release site, you must monitor for, remove, and devitalize or destroy any volunteer plants to prevent the regulated article from being released without authorization, spreading, dispersing, and/or persisting in the environment. A final VMR

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is due no later than three months following the end of the volunteer monitoring period as described in your "Post-Termination Volunteer Monitoring" of your SPCs.

For VM periods longer than 1-year, Interim VMRs are due annually as follows:

- The first interim VMR is due no later than 13 months after you terminated the environmental release;
- Subsequent Interim VMRs are due one year after the date you submitted the previous interim VMR;
 and
- The final year of volunteer monitoring is reported as a final VMR and is due no later than three months following the end of the volunteer monitor period listed in the "Post-Termination Volunteer Monitoring" section of your SPCs.

Applicable Regulations: 7 CFR § 340.4(f).

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the permit:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)
- Environmental Release ID (Unique ID) (in APHIS eFile this is called "Planting ID")

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
If you did not conduct volunteer monitoring, choose "No Monitoring Occurred" for the appropriate release site(s) on the "Location Detail" page and include all of the following:	
No Monitoring Occurred Report requirements*	When submitting a No Monitoring Occurred Report, provide the following:
	 Under "No Monitoring Date": The date of your no monitoring (optional). Reason for No Monitoring Provide a reason you did not monitor this location on the observation date you provided
	You do not need to address items below for the field trial for which you did not conduct volunteer monitoring
site(s) on	r monitoring, choose "Add Monitoring" for the appropriate release and include all of the following:

Data Requirements	Description
Start date(s) of volunteer monitoring period for each volunteer monitoring area	 Provide the date you started monitoring for volunteers for each terminated release site. Typically, the post-termination volunteer monitoring period for each environmental release begins at the termination of your environmental release.
End date(s) of volunteer monitoring period for each volunteer monitoring area (only required for Final VMR)	 Under Monitoring End Date: Interim Post-Termination Volunteer Monitoring Report Provide your estimated anticipated final volunteer monitoring period (optional). Final Post-Termination Volunteer Monitoring Report You must provide the date you stopped monitoring for volunteers
	for each field terminated. To start adding volunteer monitoring observation information click "Save" and then click on "Add Observation".
Observation Date(s) Enter the following data for each observation date	 Under Observation Date: Enter a single observation date. For each new observation date, you must add a new observation. Provide the dates you monitored the field trial and other monitored locations, as applicable. Please reference your specific supplemental permit conditions to determine your duration (period) and frequency (intervals) for volunteer monitoring. You should have a date for each time you monitored your trial. For example, if you are to monitor every 30 days and you started monitoring on April 1, 2022, your next volunteer monitoring should be around May 1, 2022. If weather or field conditions are not conducive for monitoring (e.g., rain, flood), you may undertake this monitoring up to two days earlier or two days later.
Provide the number of volunteers In APHIS eFile this is called "Number of Volunteers"	 Under Number of Volunteers or in an Attached Document: If no volunteers were observed, indicate "no volunteers observed" by adding the number zero. If volunteers were observed, indicate: Number of volunteers observed (if more than 100 in number, follow an estimation strategy and include an estimate number) If you have a lot of information to add to the report, BRS suggests you upload the information into the report as a Word, PDF, Excel, or PowerPoint document. For more information about uploading documents into your report, see Appendix III.



Data Requirements	Description
Any actions taken to destroy volunteers	Under Action Taken or in an Attached Document:
·	 Add actions taken to destroy volunteers. Please review your permit conditions, there may be specific or approved methods listed for your specific permit.
	If you have a lot of information to add to the report, BRS suggests you upload the information into the report as a Word, PDF, Excel, or PowerPoint document. For more information about uploading documents into your report, see Appendix III .
If the interval requirement noted in "Post- Termination Volunteer Monitoring" were not met, include an explanation of deviance (optional)	Under Comments: Please add an explanation for the deviation of your monitoring interval.
Comments (optional)	Provide as text any comments or miscellaneous information relating to the release. Examples of such information include data elements that you provided in past reports or desire to add to the APHIS eFile record (e.g., total acres planted, including borders, cumulative acres planted).

Typical Data Requirements for Volunteer Monitoring if Planting Back to a Regulated Material of the Same Species Under a New Permit

Plant backs: If APHIS authorized all of a field trial location to be planted back to a regulated material of the same species under a new permit and the planting under the new permit occurs, you must follow the volunteer monitoring requirements for the plant-back area as described in the new permit and submit a report of no monitoring under this permit for only the plant-back field trial location that identifies:

- 1. The field trial (Environmental Unique ID) that has been planted back under a new release permit
- 2. The release date for the new field trial
- 3. The new authorization number authorizing the plant back

When volunteer monitoring is complete for an authorized release site (final VMR), you must indicate the report is the final volunteer monitoring report.

RETURN TO GENERAL USE NOTICE

For certain authorized trial dedicated equipment and storage facilities are required. Prior to this dedicated equipment or storage facility being returned to general use (i.e., before moving to or using on

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any plants or release sites NOT authorized by an APHIS permit for the same species), APHIS must be notified using a Return to General Use Notice at least 14 calendar days in advance of the cleaning so that APHIS may schedule an inspection to ensure cleaning is done appropriately. The Return to General Use Notice is specified but not limited to PMPI one-year and multi-year permits. Please see your specific supplemental permit conditions to see if your permit requires a Return to General Use Notice(s).

How to Submit Your Return to General Use Notice (Cleaning (Return to General Use) Notice in APHIS eFile)

See the How to Submit Your Reports and Notices in this document for more information.

If you need assistance with submitting your Return to General Use Notice, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Return to General Use Notice

Return to General Use Notice – Cleaning. You must submit a cleaning notice no later than 21 calendar days prior to the anticipated return to general use of dedicated equipment and/or facilities.

Applicable Regulations: 7 CFR § 340.4(f).

Core Data Requirements listed in your SPCs that APHIS eFile auto-populates from the permit:

- Authorization Number
- Regulated Plant (species) (in APHIS eFile this is called "Regulated Article")
- Location Unique ID
- Release Site Name (in APHIS eFile this is called "Release Site County")
- State
- Location Address or GPS Coordinates of the authorized release site
- Release Site Agent Name and Contact Information (telephone number and email address)

Data Requirements You Must Include for Each Authorized Release Site

Data Requirements	Description
Add the location of the	Click on Add on the Location Details Page
Return to General Use	
for each equipment,	To add the location:
facilities, or both	Click inside of the "Location" box, and
equipment and	Choose the proper location from the list under that appears
facilities	
Add the Description of	Under Description:
equipment and	Add a description of equipment or facility to be returned to general use
facilities to be returned	and include how many pieces of equipment and number of facilities.
to general use	
	For example, the brand of planting/harvesting equipment (John Deere Grain
	Drill, Year: 2000, Model #333, Serial #123456). Quantity 1.
Cleaning Date	Indicate the proposed Return to General Use Cleaning Date



Comments	Provide as text any comments or miscellaneous information relating to the
	release. Examples of such information include data elements that you
	provided in past reports or desire to add to the APHIS eFile record (e.g., total
	acres planted, including borders, cumulative acres planted).

REPORTING OF POSSIBLE OR ACTUAL UNAUTHORIZED RELEASE

Reporting a Possible or Actual Unauthorized Release. In the event of a possible or actual unauthorized release (whether intentional or accidental), you must contact APHIS within 24 hours of discovery and must subsequently supply a statement of facts in writing no later than five business days after discovery. Examples of unauthorized releases include unauthorized flowering; dispersal of regulated articles due to a weather event (e.g., flooding, high winds); release of an unauthorized construct; any incursions of domestic (farm) animals when a regulated article is present; and the unauthorized removal of viable regulated articles by humans or wild animals, including accidental removal.

Applicable Regulations: 7 CFR § 340.4(f), 7 CFR § 340.4(f)(10)(i), and (7 CFR § 340.3(d)(5)).

You must notify APHIS of a possible or actual unauthorized release through its Compliance Staff by phone (301-851-3935) or email (<u>BRSCompliance@usda.gov</u>). If your call advances to voicemail, please ensure you leave a message describing the discovery. For additional information on notifying APHIS, please visit our <u>website</u>.

REPORTING OF REGULATED ARTICLE WITH CHARACTERISTICS SUBSTANTIALLY DIFFERENT OR IF IT SUFFERS ANY UNUSUAL OCCURRENCE

In the event of an unusual occurrence (excessive mortality or unanticipated effects on non-target organisms) or substantially different characteristics of the plant from those listed in this permit, you must report the discovery to APHIS Compliance staff via email (BRSCompliance@usda.gov) within 5 working days of discovery.

Applicable Regulations: 7 CFR § 340.4(f), 7 CFR § 340.4(f)(10)(ii), and (7 CFR § 340.3(d)(5)).

You must notify APHIS Compliance Staff via <a href="mailto:ema

For additional information on notifying APHIS, please visit our website.