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GUIDE TO SUBMITTING DATA FOR 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.

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:	<p>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 eFile. APHIS protects and enhances U.S. agricultural and natural resources using a science-sound regulatory framework to ensure the safe movement – including importation, interstate movement, and confined environmental release – of organisms developed using genetic engineering. APHIS receives its regulatory authority from the Plant Protection Act, and implements regulations for certain organisms developed using genetic engineering (7 CFR part 340).</p>
DISCLAIMER:	<p>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.</p>

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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 movement and release of organisms developed using genetic engineering (modified organisms). Any person or organization who intends to perform a confined field release of modified organisms that are subject to 7 CFR part 340 or wishes to move that material between States or to import material into the United States requires a permit from BRS as outlined in 7 CFR 340.2. When BRS issues a permit, the applicant becomes responsible for submitting reports and/or notices about the status of the regulated material.

Permit holders use reports and notices to convey to BRS compliance-related information to fulfill permits conditions. Reports and notices have specific due dates and data requirements based on the modified organisms described in permits. BRS uses reports and notices for various purposes, such as initiating an inspection process or monitoring compliance.

BRS provides this Guide for Required Reports and Notices for Permits under 7 CFR part 340 to help stakeholders (responsible persons, agents, and the general public) understand the data requirements for reports and notices and process for completing them in eFile by their due dates.

TIPS FOR NAVIGATING THIS DOCUMENT

Using Hyperlinks

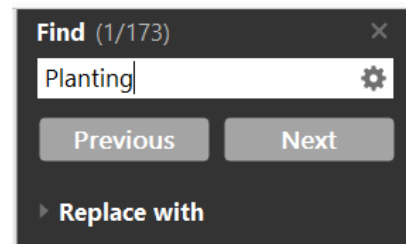
This document contains hyperlinks for items such as definitions throughout the document. A hyperlink will typically have a word in blue text with a line underneath it. To activate the hyperlink, click on the word/link. When you hover over the hyperlink, it will also provide you with the following directions.

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 left of the screen. Enter a word in the box to find in the document. In the example below 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 material. 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 permit applications, reports, and notices.

In this example below, the GPS provide 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 or click outside of the GPS Decimal Degree Format box to view your GPS coordinates.

<u>Latitude</u>				<u>Longitude</u>			
			Cardinal				Cardinal
Degrees	Minutes	Seconds	Direction	Degrees	Minutes	Seconds	Direction
<input type="text" value="38"/>	<input type="text" value="58"/>	<input type="text" value="8.65"/>	<input type="text" value="N"/>	<input type="text" value="76"/>	<input type="text" value="55"/>	<input type="text" value="31.60"/>	<input type="text" value="W"/>
GPS Decimal Degree Format				GPS Decimal Degree Format			
<input type="text" value="38.969069"/>				<input type="text" value="-76.925444"/>			

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 permit conditions, preferably as an electronic file in APHIS eFile (a web-based information management system), no later than the due date listed on your permit. If you are unable to use APHIS eFile, you may instead submit your report/notice via email to BRSCCompliance@usda.gov by providing the required data listed in your permit conditions no later than the due date listed on your permit.

- For step-by-step procedures and graphics specific to entering your data in APHIS eFile, please see our [Permit Application and Compliance Reporting Job Aid](#).

- APHIS eFile populates reports based on information you provide in your environmental release report (previously called planting report). Based on the locations you submit as planted on your environmental release report, eFile will create corresponding release site and volunteer monitoring reports for you to complete. If you omit a planted location from your environmental release report, you will not be able to submit release site reports or volunteer monitoring reports for that location using 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.

Certify and Submit

I, Demo Only BRS Applicant, hereby certify that the Pre-Harvest/Pre-Destruct Notices submitted to APHIS is true and accurate to the best of my knowledge and belief. If there are any changes to the information disclosed in this Pre-Harvest/Pre-Destruct Notices, I will contact APHIS. WARNING: Once you certify and submit, the report will no longer be editable.

- For specific information on what, when, and how to submit your reports and notices, refer to the standard and supplemental permit conditions (SPCs) in your permit.
- If reports or notices contain data claimed as Confidential Business Information (CBI), you must submit both CBI and CBI-deleted versions per 7 CFR part 340.7. When claiming CBI, use brackets [] to designate CBI information within the report. If CBI is involved, please submit both CBI and CBI-deleted versions. For more specific information please see [Guidance for Submitting Confidential Business Information](#).

What if my supplemental permit conditions require data elements or special reports/notices that are not identified in APHIS eFile?

For a small amount of information (e.g., 100 characters or less), use the eFile comment section in the applicable report/notice to add the information. This may commonly occur to include data around development stages of volunteers at the time of destruction or other similar information.

For a large amount of data, 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 [Permit Application and Compliance Reporting Job Aid](#). 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 [Appendix III – Example Template for Report Attachment](#).
- If you need assistance with this, please contact BRSCCompliance@usda.gov.

Submitting Reports via XML Upload

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

QUICK GUIDE TO DUE DATES FOR REPORTS AND NOTICES

This quick guide lists typical due dates for reports and notices. Please see your specific supplemental permit conditions (SPCs) to view your required reports and notices and due dates. Some reports and notices apply to only certain types of permits (denoted with an *), such as Plant-Made Pharmaceutical or Industrial (PMPI) permits, multi-year permits, etc. You must submit any required report or notice no later than the applicable due date listed in supplemental permit conditions for your permit(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 Permit Type (but not limited to)	Due Date	Example
Pre-Environmental Release Notice* (eFile or other documents may call this Pre-Planting 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 before May 3, 2022.
Environmental Release Report (eFile or other documents may call this Planting Report)	All permits for environmental release for each applicable site/location	Following an environmental release (e.g., planting or placement in greenhouse that does not meet the definition of a “contained facility” or shade house), you must submit an environmental release report to APHIS by the 15 th of the month following the month in which the release occurred.	You conducted your environmental release (planting) on June 6, 2022. You must submit your report on or before July 15, 2022. If you have multiple release sites, and you conducted your environmental releases on June 6, 2022, at Site1, on July 8, 2022, at Site2, and on July 20, 2022, at Site3, you must ensure that the releases for Site1 and Site2 are submitted by July 15, 2022. You should submit the release for Site3 in a new environmental release

Report Type	Applicable Permit Type (but not limited to)	Due Date	Example
			report due on or before August 15, 2022.
Environmental Release Report for Plant Backs*	All permits with SPCs that authorizes planting back to the same nonregulated species	After planting back to a nonregulated plant of the same species, you submit an environmental release report no later than 45 days.	You planted a nonregulated plant of the same species on June 29, 2022. You must submit your environmental release report on or before August 13, 2022.
Environmental Release Report of No Environmental Release. (eFile and other documents may refer to this as Report of No Planting in supplement permit conditions)	All permits for environmental release for each applicable site/location	For any Release Site listed in the permit where a release does not occur, you must submit a planting/release report that indicates “no planting/release” no later than 30 calendar days after the permit expiration date.	You elected to not plant/release a modified organism at one or more locations authorized in your permit. 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.	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 environmental release report and/or final environmental release report. See specific due dates below.	
Annual Environmental Release Report* (eFile or other documents may call this the Annual Field Test Report or Field	All multi-year permits	You must submit environmental release 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	<ul style="list-style-type: none"> The effective date of your permit is April 1, 2022, your annual environmental release 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

Report Type	Applicable Permit Type (but not limited to)	Due Date	Example
Test Report, Annual)		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 Release Site Report for the first year and a Final Release Site Report.	<p>additional report the following year on May 1, 2024. A final environmental release report will be due in 2025 even if you renew the permit.</p> <ul style="list-style-type: none"> • However, if you terminate during your first year, on March 15, 2023, you will be required to send us annual environmental release report no later than May 1, 2023, and a Final Release Site Report as required in your SPCs.
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.	You anticipate harvesting or terminating your field trial on October 8, 2022. You must submit your notice on or before September 17, 2022.
Environmental Release Report, Final (eFile or other documents may call this the Final Field Test Report or Field Test Report, Final)	All permits for environmental release	You must submit a final Environmental Release Report no later than 180 calendar days after the permit expiration date for each Release Site where a release occurred. You must submit this report even if APHIS issues a new permit for release at the Release Site.	The expiration date for your permit is April 8, 2022. You must submit your report on or before October 5, 2022.
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 environmental release report.	
Interim Post-termination Volunteer Monitoring Report*	For permits that include this requirement in SPCs, see your SPCs	If your post-termination volunteer monitoring requirement is longer than 12 months, you must submit an Interim Post-	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

Report Type	Applicable Permit Type (but not limited to)	Due Date	Example
<p>(Previously called Annual Volunteer Monitoring Report)</p>		<p>Termination Volunteer Monitoring Report (VMR) until volunteer monitoring concludes. Your first interim VMR is due no later than 13 months after harvest or termination of the field trial. Thereafter, you must submit an interim VMR on or before the yearly anniversary date of the first interim VMR, unless it is the final VMR for the field trial, in which case you must submit it no later than three months from the last volunteer monitoring interval required by your permit.</p>	<p>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 is due no later than July 2, 2024.</p>
<p>Post-termination Volunteer Monitoring Reports, Final</p>	<p>All permits for environmental release</p>	<p>A final VMR is due no later than 3 months following the end of the VMR period as described in section Volunteer Monitoring Requirements, Post-Termination of your SPCs.</p>	<p>Your last volunteer monitoring interval was March 15, 2022, your final report is due no later than June 16, 2022.</p>
<p>Volunteer Monitoring Report when Planting Back to Same Species, Regulated</p>	<p>For permits that include this as an option in SPCs, see your SPCs</p>	<p>If BRS authorizes all or part of a Release Site to be planted to an organism under permit of the same species for the next growing season:</p> <ul style="list-style-type: none"> 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 	<p>Your 2022 permit authorized you to plant modified corn at Site1. You decide to plant modified 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 modified 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</p>

Report Type	Applicable Permit Type (but not limited to)	Due Date	Example
		<p>planted area as described in the new permit.</p> <ul style="list-style-type: none"> You must continue to monitor any unplanted areas according to the monitoring requirements of this permit. 	<p>plant pack did not occur. You must continue to monitor this area for the remaining volunteer monitoring period noted in the original permit. In this example, you must volunteer monitor this site for 12 months, with your last volunteer monitoring interval ending around September 5, 2023.</p>
<p>Return to General Use Notice – Cleaning*</p>	<p>PMPI Permits or other permits that include this requirement in SPCs</p>	<p>You must submit a cleaning notice for equipment or facilities you wish to return to general use no later than 21 calendar days prior to the anticipated cleaning.</p>	<p>You wish to clean your combine so you can return it to general use by June 16, 2022. You must submit your notice on or before May 26, 2022.</p>
<p>Reporting of Possible or Actual Unauthorized Release</p>	<p>All permits</p>	<p>In the event of a possible or actual unauthorized release (whether intentional or accidental), you must contact BRS within 24 hours of discovery and, no later than 5 business days after discovery, you must submit a written statement of facts.</p>	<p>You discover regulated material 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.</p>

APPENDIX I – DEFINITIONS

Below is a list of definitions that are important to understanding the data requirements for the submission of reports and notices. Definitions that come from the regulations are referenced as 7 CFR § 340.3.

Agent. A person who is designated by the responsible person to act in whole or in part on behalf of the permittee to maintain control over an organism under permit during its movement and to ensure compliance with all applicable permit conditions and the requirements in 7 CFR part 340. Multiple agents may be associated with a single responsible person or permit. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States. 7 CFR § 340.3

Article. Any material or tangible object that could harbor plant pests. 7 CFR § 340.3

Authorization Number. APHIS eFile assigns an auto-generated number for your permit (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).

Contained facility. A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the organisms. Examples include but are not limited to laboratories, growth chambers, fermenters, and containment greenhouses.
7 CFR § 340.3

County. The county of the release site.

Destruction. The deliberate destruction of crops or agricultural products to render it useless for consumption or processing. It may be 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 a permit is valid for authorized activities (i.e., the start date for a permit).

eFile. A web-based system that allows users to apply for and receive import, interstate movement, transit, and release permits, 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.
7 CFR § 340.3

Environmental Release ID (Planting ID in 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 permit duration (e.g., different times or different release sites within the same location) under your permit, 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”.

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 (6) 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 (5) 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 one State into or through any other State or within the District of Columbia, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States. 7 CFR § 340.3

Location Address. Street address of the release site.

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

Location Unique ID. This is an alphanumeric code provided by the responsible person (during permit 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 permit. You must use the same Unique ID in the *Environmental Release Report* provided in the issued permit application submission.

Move (moving, movement). To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur. 7 CFR § 340.3

Notice. Mechanisms by which a responsible person communicates compliance-related information about the introductions of regulated materials 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.

Organism. Any active, infective, or dormant stage of 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. 7 CFR § 340.3

Permit. A written authorization, including by electronic methods, by the Administrator to move organisms regulated under 7 CFR part 340 and associated articles under conditions prescribed by the Administrator. 7 CFR § 340.3

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 bulb, a root, or a seed. 7 CFR § 340.3

Post-Termination. The time frame after you destroyed (terminated) the modified plants/organisms that were released as authorized by your permit.

Release into the environment (environmental release). The use of an organism outside the physical constraints of a contained facility. 7 CFR § 340.3

Report. Mechanisms by which a responsible person communicates compliance-related information about the introductions of regulated materials covered by permits. 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 individual responsible for maintaining control over a GE organism under permit during its movement and for ensuring compliance with all conditions contained in any applicable permit as well as with other requirements in 7 CFR part 340 and in the Plant Protection Act (7 U.S.C. 7701 *et seq.*). This individual must sign the permit application, must be at least 18 years of age, and must be a legal resident of the United States. 7 CFR § 340.3

State. The state of the release site.

Termination. To destroy or devitalize the modified plants/organisms that were grown as authorized by your permit. Termination of the field trial must occur on or before the expiration date of the permit, or as specified in the permit, unless the permit has been renewed.

Unauthorized release. The intentional or accidental movement of an organism under a permit issued pursuant to 7 CFR part 340 in a manner not authorized by the permit; or the intentional or accidental movement without a permit of an organism that is subject to the regulations in 7 CFR part 340.
7 CFR § 340.3

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

“Permit conditions. The standard conditions listed in this [paragraph \(i\)](#) will be assigned to all permits issued under this section. The Administrator may assign supplemental permit conditions as deemed necessary to ensure confinement of the GE organism. Prior to issuance of a permit or an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the permit, as described in this [paragraph \(i\)](#). If the responsible person does not agree to the conditions, the amendment will be denied.” (7 CFR 340.5(i))

“Records related to activities carried out under the permit must be maintained by the responsible person and must be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part. APHIS must be allowed access to all records, to include visual inspection and reproduction (e.g., photocopying, digital reproduction). The responsible person must submit reports and notices to APHIS, containing the information specified within the permit, at the times specified in the permit.” (7 CFR 340.5(i)(6))

“Following an environmental release, environmental release reports must be submitted for all authorized release locations where the release occurred. Environmental release reports must contain details of sufficient accuracy, quality, and completeness to identify the location, shape, and size of the release and the organism(s) released into the environment. In the event no release occurs at an authorized location, an environmental release report of no environmental release must be submitted for all authorized locations where an environmental release did not occur. Unauthorized releases must be reported in accordance with [paragraph \(i\)\(9\)](#) of this section.” (7 CFR 340.5(i)(6)(i))

“When the environmental release is of a plant, reports of volunteer monitoring activities and findings must be submitted for all authorized release locations where an environmental release occurred. If no monitoring activities are conducted, a volunteer monitoring report of no monitoring must be submitted indicating why no volunteer monitoring was done.” (7 CFR 340.5(i)(6)(ii))

*“In the event of a possible or actual unauthorized release, the responsible person must contact APHIS as described in the permit within 24 hours of discovery and must subsequently supply a statement of facts in writing no later than 5 business days after discovery.”
(7 CFR 340.5(i)(9))*

APPENDIX III – EXAMPLE TEMPLATE FOR REPORT ATTACHMENTS

APHIS eFile accepts different documents formats for report attachments including pdf, word files, excel files, PowerPoint, and photos. Below is just one simple way you can provide the data requirement for your reports.

In this example, the developer found several data requirements listed in our supplemental permit conditions were not available to answer in eFile for our 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 [Permit Application and Compliance Reporting Job Aid](#) located on the [APHIS eFile Training](#) 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 Release Site Report, Annual 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 E 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, including dates, taken to remove or destroy flowers.
- I. Indicate if you have submitted a report of any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occurred.

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
- 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/A
 - 1. Date of Action: N/A
 - I. Have we ever submitted a report of any unusual flowering, early flowering, out-of-season flowering, 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 of any unusual flowering, early flowering, out-of-season flowering, 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 of any unusual flowering, early flowering, out-of-season flowering, or overabundance of flowering occurred: No

APPENDIX IV – REPORTS AND NOTICES IN DETAIL

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

PRE-ENVIRONMENTAL RELEASE NOTICE

If you hold a BRS permit for the environmental release of a modified organism, you may be required to submit a *Pre-Environmental Release Notice* for all release site locations authorized in your permit.

Your permit’s supplemental permit conditions will indicate whether a Pre-Environmental Release Notices (formerly referred to as “Pre-planting notice”) 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-Environmental Release Notice (Pre-Planting/Pre-Release Notice in eFile); see [pages 2 and 3](#).

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

Typical Data Requirements for Pre-Environmental Release Notice:

You must submit a Pre-Environmental Release Notice, for each site listed on your permit, no later than 7 calendar days before the environmental release (planting). The list below describes the data requirements for a Pre-Environmental Release Notice, the information eFile will populate in the notice, and the information you should have on hand when submitting your notice.

Applicable Regulation [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

Authorization Number
Organism Under Permit (species) – In eFile this is called Organism
Location Unique ID
Release Site Name – In eFile this is called Release Site
County
State
Location Address
Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Planned Release start date	You must provide the date on which the modified organism(s) releases is (are) expected to be released into the environment (planted).
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 eFile record (e.g., total acres planted, including borders, cumulative acres planted).

ENVIRONMENTAL RELEASE REPORT AND REPORT OF NO PLANTING/ENVIRONMENTAL RELEASE

If you hold a BRS permit for the environmental release of a modified organism, you must submit an Environmental Release Report for all release sites/locations authorized in your permit.

BRS uses information from Environmental Release Reports to track where and when regulated material 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 permit: 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 an 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 modified organism into the environment, and you must submit an 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 replace modified plants that have died).

How to Submit Your Environmental Release Report (Planting/Environmental Release Report in eFile): see [pages 2 and 3](#).

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

For Multiple Environmental Releases

When multiple releases occur under a single permit, you must submit an 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. 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 separate Environmental Release Reports. All Environmental Release Reports, including multiple releases, must be submitted no later than the 15th of the month following the environmental release.

Typical Data for Requirements for Environmental Release Report:

After planting at any authorized release site locations, you must submit an Environmental Release Report by the 15th of the following (next) month.

Applicable Regulations [7 CFR 340.5\(i\)](#), [7 CFR 340.5\(i\)\(6\)](#), and [7 CFR 340.5\(i\)\(6\)\(i\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

Authorization Number
 Organism Under Permit (species) – In eFile this is called Organism
 Location Unique ID
 Release Site Name – In eFile this is called Release Site
 County
 State
 Location Address
 Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Environmental Release ID (Unique ID) In eFile this is called Planting ID	This is your release identifier. If you replant a location previously identified with an ID, you must provide a different ID for the new planting.
Release Start Date In eFile this is called Start Date	You must provide the date each environmental release occurred in the relevant release site(s) location.
Anticipated Harvest/Destruction Date	Provide the date on which the modified organism(s) releases is (are) expected to be harvested or terminated prior to harvest.
Total Acreage of Released Organism(s) Under Permit In eFile this is called Quantity (Acres)	Report the total size (in acres) of the release based on the area occupied by the released organism(s) under permit. Do not include border rows when calculating the size, even though they are usually 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. If, for some reason, your reported size includes border rows, please use the comment section to indicate your size includes border rows.
Constructs Released Click on Save, after entering the information above to enter construct and GPS coordinate information	After entering the above information, click on Save and prompts for Constructs will appear: Under Constructs click on Add Construct <ul style="list-style-type: none"> • Click inside of the Construct box and add one construct from the list provided. <ul style="list-style-type: none"> ○ You may add Lines/Events, but this is optional. • Click on Save and repeat the process to add any additional constructs released. List all constructs approved on permit that you released for each location unique ID; you may add Lines/Events to your report, but this is optional.
GPS Coordinates (in Decimal Degrees)	After entering the above information, click on Save and prompts for Constructs and GPS coordinates will appear:

Data Requirements	Description
Click on Save, after entering the information above to enter construct and GPS coordinate information	Under GPS coordinates click on Add GPS Coordinates: <ul style="list-style-type: none"> • Enter the Latitude and Longitude of your released organism under permit. Please provide up to six (6) 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 (5) decimal places.
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 Report of No Planting/Environmental Release:

For any Release Site listed in the permit where a release does not occur, you must submit a planting/release report of “no planting/release” no later than 30 calendar days after the permit expiration date.

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)\(i\)](#)

Do not identify sites as “no planting/no environmental release” in your environmental release reports in eFile if you will, or will likely, release at these locations prior to the expiration date of your permit. Only note a site as “no planting/no environmental release” in an *Environmental Release Report* if you are certain no releases will occur at a given site before the permit expires. If you have inadvertently reported a “no planting/no environmental release” for a site you intend to plant, contact BRSCCompliance@usda.gov so we can correct your report in 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 eFile for that site, which could cause you to have a compliance issue due to late reporting or not reporting an environmental release.

Core Data Requirements listed in your SPCs that eFile Self-Populates:

Authorization Number

Organism Under Permit (species) – In eFile this is called Organism

Location Unique ID

Release Site Name – In eFile this is called Release Site

County

State

Location Address

Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Environmental Release ID (Unique ID) In eFile this is called No Planting ID	This is your release identifier. If you replant a location previously identified with an ID, you must provide a different ID for the new planting.
Report of No Planting/Release Date In eFile this is called Report of No-Planting Date	Provide the date a decision was made not to plant (a particular release site) in the relevant release sites location.
Explanation	Treat this as a comments box if you wish to add any additional information about this no planting/environmental release report, for example, an explanation of why the site was not used.

ENVIRONMENTAL RELEASE REPORT FOR PLANT BACKS, SAME SPECIES, NONREGULATED

If your permit authorizes you to plant back a field trial with a nonmodified plant or modified, nonregulated plant of the same species (for example, to increase insect or disease pressure or for soil nutrient studies) in mainland/non-tropical locations or tropical locations during the post-termination volunteer monitoring period of your permit, you must submit a report for such planting. You must treat the plants as regulated and the planting as a regulated environmental release, complying with all permit conditions and following all associated SOPs submitted with the permit.

How to Submit Your Environmental Release Report for Plant Backs, Same Species, Nonregulated Report:

Currently, permit holders cannot enter this report into eFile. These reports must be sent to the BRS Compliance Inbox at BRSCompliance@usda.gov. BRS staff will enter these reports into eFile. Please include the information listed below in the section Typical Data Requirements for Report for Plant Backs, Same Species, Nonregulated in your report.

If you need assistance with submitting your Environmental Release Report for Plant Backs, Same Species, please contact BRSCompliance@usda.gov.

Typical Data Requirements for Report for Plant Backs, Same Species, Nonregulated:

If you are replanting back to a nonregulated plant of the same species during the volunteer monitoring period and after the expiration date of the permit, submit the Environmental Release Report no later than 45 days after the replanting occurs to BRSCompliance@usda.gov.

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

Authorization Number
 Organism Under Permit (species) – In eFile this is called Organism
 Location Unique ID
 Release Site Name – In eFile this is called Release Site
 County
 State
 Location Address
 Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Environmental Release ID (Unique ID) In eFile this is called Planting ID	If you replant a location previously identified with an ID, you must provide a different ID for the new planting. You must indicate if you are replanting back to a nonregulated plant of the same species.
Release Start Date In eFile this is called Start Date	You must provide the date of each environmental release occurrence in the relevant release site location.
Anticipated Harvest/Destruction Date	Provide the date on which the organism(s) releases is(are) expected to be harvested or terminated prior to harvest.
Total Acreage of Released Organism(s) Under Permit In eFile this is called Quantity (Acres)	Report the total size of the release, including only the area occupied by the released organism(s) under permit. You must submit the size in acres; use no more than five decimal places. BRS 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 collective acres released (including border rows) must 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 note this in the comments section of the report.
GPS Coordinates (in Decimal Degrees) Click on Save, after entering the information above to enter construct and GPS coordinate information	After entering the above information, click on Save and prompts for Constructs and GPS coordinates will appear: Under GPS coordinates click on Add GPS Coordinates: <ul style="list-style-type: none"> • Enter the Latitude and Longitude of your released organism under permit. Please provide up to six (6) 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 (5) 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.
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).

PRE-FLOWERING NOTICE

If you have been approved and issued an BRS permit for the environmental release of a modified organism, 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 modified organism is authorized to flower.

How to Submit Your Pre-Flowering Notice: see [pages 2 and 3](#).

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

Typical Data Requirements for Pre-Flowering Notice:

For any plants allowed to flower, you must submit a Pre-Flowering Notice no later than 7 calendar days prior to the first anticipated flowering of the field trial.

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

- Authorization Number
- Organism Under Permit (species) – In eFile this is called Organism
- Location Unique ID
- Release Site Name – In eFile this is called Release Site
- County
- State
- Location Address
- Release Site Agent Name and Contact Information
- Environmental Release ID (Unique ID) - In 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.
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).
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ANNUAL ENVIRONMENTAL RELEASE REPORT

For multi-year permits, you are typically required to submit an Annual Environmental Release Report (formerly referred to as “Annual Field Test Report”) for each year the permit is authorized, except for the last year when you are required to submit a Final Environmental Release Report (see Final Environmental Release Report in this document for more information).

You must submit Annual Environmental Release 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 Environmental Release 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 Environmental Release Report for the first year and a Final Environmental Release Report.

Other Reports Embedded in the Annual Environmental Release Report in 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 reports are required for your specific permit. In addition, these reports may have data requirements that do not appear in eFile, if this is the case, this information should be included as an attachment to your report.

How to Submit Your Annual Environmental Release Report (Field Test Report (Annual or Final) in eFile): see [pages 2 and 3](#).

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

Typical Data Requirements for Annual Environmental Release Report:

The Annual Report must reflect the current status and observations to date and the following information for each authorized trial site:

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

Authorization Number

Organism Under Permit (species) – In eFile this is called Organism

Location Unique ID

Release Site Name – In eFile this is called Release Site

County

State

Location Address

Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
<p>Indicate if any of the released organism under permit was destroyed before harvest.</p> <p>eFile Question: Was any planted material destroyed before harvest?</p>	<p>If yes, answer the following in eFile:</p> <p>When you answer Yes, the following appears:</p> <ul style="list-style-type: none"> • Pre-harvest destruction date <ul style="list-style-type: none"> ○ Enter your pre-harvest destruction completion date. • Pre-harvest destruction description, add the following: <ul style="list-style-type: none"> ○ Reason for termination ○ Plant stage at the time of termination (e.g., flowering, seed set) ○ Locations and methods of termination, including devitalization (e.g., burning, autoclaving) and disposition of regulated material (e.g., tilled under, landfill)
<p>Indicate if any organism under permit was harvested.</p> <p>eFile Question: Was any plated material harvested?</p>	<p>If yes, answer the following:</p> <ul style="list-style-type: none"> • Provide the harvest completion date.
<p>Indicate whether regulated material was left in field, taken off field, or both.</p> <p>eFile Questions: How was it terminated?</p> <ul style="list-style-type: none"> • All terminated in-field, • All terminated off-field, • Both <p>Choose the appropriate response for your trial.</p> <p>How was off field terminated material disposed?</p> <ul style="list-style-type: none"> • All stored or contained, • All destroyed, 	<p>If the organism under permit was destroyed at the Release Site (choose All terminated in-field for How was it terminated), provide the following information:</p> <ul style="list-style-type: none"> • Under In-field termination completion Date: <ul style="list-style-type: none"> ○ Provide the date the field trial was completely terminated. • Under In-field termination description box add the following: <ul style="list-style-type: none"> ○ Describe the methods taken to destroy/devitalize regulated material (e.g., burned, hammer-milled) and ○ Describe how you disposed of the material (e.g., tilled or disked under, left untilled in the field) <p>If the organism under permit 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:</p> <ul style="list-style-type: none"> • Under Off-field destruction date: <ul style="list-style-type: none"> ○ Provide the date, • Under Off-field destruction description: <ul style="list-style-type: none"> ○ location, and methods taken to destroy/devitalize organism under permit (e.g., burned, ground up) and

Data Requirements	Description
<ul style="list-style-type: none"> Both (some of each) <p>Choose the appropriate response for your trial.</p>	<ul style="list-style-type: none"> Where you disposed of the material (e.g., landfill) <p>If organism under permit was removed from the field and placed in storage (choose All terminated off-field or Both for How was it terminated, and All stored or contained or Both for How was off-field terminated material disposed) (Regulated material may be removed from the field and stored. You must store viable regulated material so that it is securely contained, and its identity maintained.) provide the following information:</p> <ul style="list-style-type: none"> Under Stored or contained quantity and Stored Units: <ul style="list-style-type: none"> The approximate amount of viable organism under permit that was stored and Under Stored Material Type: <ul style="list-style-type: none"> Enter what type of organism under permit is being stored (e.g., seed, ears) Under Description of storage location and material placed in storage: <ul style="list-style-type: none"> 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 address, and a description of the storage location.
<p>Indicate if any organism under permit remains growing at the release site.</p> <p>Question in eFile: Is any planting material still growing in the field?</p>	<p>If yes, answer the following: How much planted material is still growing in the field, in acres:</p> <ul style="list-style-type: none"> Report the total size of the remaining release, including only the area occupied by the organism(s) under permit. If nothing has been devitalized, this will be the same as the Total Acreage of Modified Plant(s) (Quantity (Acres)” in eFile) you recorded for your Environmental Release Report. 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. <p>Description of material still growing in the field:</p> <ul style="list-style-type: none"> Provide a description of the material, Provide the APHIS BRS authorization number authorizing you to continue the release.
<p>Indicate if you have submitted any of the following reports:</p>	<p>Under Comments provide the following information as needed:</p> <ul style="list-style-type: none"> A report on the unauthorized release of the organism under permit; A report that characteristics of the organism under permit are substantially different from those listed in the permit;

Data Requirements	Description
<p>Indicate if annual in-season monitoring for volunteers is required.</p> <p>Question in eFile: Is monitoring for volunteers during the field test required?</p>	<ul style="list-style-type: none"> • A report of any unusual occurrence. <p>If yes, answer the following:</p> <p>Under Monitoring Start Date:</p> <ul style="list-style-type: none"> • Indicate start date(s) of in-season volunteer monitoring for each field trial (environmental release (planting) date of field trial) <p>Under Monitoring End Date:</p> <ul style="list-style-type: none"> • Indicate end date(s) of in-season volunteer monitoring interval for each field trial. <p>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 environmental release report, after you Save the annual environmental release report, an Observations prompt will appear. To enter annual in-season volunteer monitoring information click on Add Observations. See the section In-season Volunteer Monitoring Report, Annual below for requirements.</p>
<p>Indicate if annual in-season monitoring for any flowering/anthesis is required.</p> <p>Question in eFile: Is monitoring for flowering during the field test required?</p>	<p>If yes, answer the following:</p> <p>Did Flowering Occur?</p> <ul style="list-style-type: none"> • Indicate if flowering occurred. If Yes, • Is flowering authorized under your authorization? <ul style="list-style-type: none"> ○ Indicate if flowering is authorized under this permit. If Yes, • Are you required to submit a flowering report? <ul style="list-style-type: none"> ○ Indicate if you are required to submit a flowering report. <p>If flowering occurred and you are required to submit a flowering report with your annual environmental release report after you Save the document, an Observations prompt will appear. To enter a flowering report information, click on Add Observations. See the section Flowering below for requirements.</p>
<p>Comments</p>	<p>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).</p>

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 eFile:

Once you have completed entering your data for the Annual Environmental Release Report and click on save an observation prompt will appear for you to enter your data requirements, see [pages 2 and 3](#) for more information.

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

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

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

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

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	You must provide the date(s) you started your in-season monitoring for each field trial. (This information is entered into the annual environmental release report, before adding the observation information)
Indicate end date(s) of in-season monitoring for each field trial	You must provide the end date(s) of in-season monitoring for each field trial (This information is entered into the annual environmental release report, before adding the observation information)
Indicate the dates you monitored the field trial. In eFile this is called Observation Date	To start adding volunteer monitoring observation information click on Add Observation. Under Observation Date: <ul style="list-style-type: none"> • Enter a single observation date. For each new observation date, you must add a new observation. 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.
Indicate the location(s) you monitored.	Under Action Taken or in an Attached Document: <ul style="list-style-type: none"> • Indicate locations monitored, including the field trial (with any perimeter zone and border row areas), and any other areas where in-season monitoring is required (see, for example, Equipment Cleaning)

Data Requirements	Description
	<p>If you are entering information on multiple locations for one observation date, either add this data to Actions Taken box or to an attached document and include data below for each location.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Provide the number of in-season volunteers or sexually compatible relatives observed.</p> <p>In eFile this is called Number of Volunteers.</p>	<p>Under Number of Volunteers or in an Attached Document:</p> <ul style="list-style-type: none"> • Provide the number of volunteers observed (number only). If you found more than 100 in-season volunteers or sexually compatible relatives, follow an estimation strategy, and provide an estimate of the number. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Provide the developmental stage of the in-season volunteers found</p>	<p>Under Action Taken or In an Attached Document:</p> <ul style="list-style-type: none"> • Add the development stage of volunteer observed. Some examples of developmental stages include but are not limited to seedling, vegetative, or flowering. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example:

Data Requirements	Description
	<ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Provide a description of spatial distribution</p>	<p>Under Action Taken or In an Attached Document:</p> <ul style="list-style-type: none"> ● Add the spatial distribution of volunteers observed. Some examples of spatial distribution include but are not limited to localized/clustered, widespread, clustered in the southeast corner of the field. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> ● Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Any actions, including dates, taken to remove or destroy in-season volunteers</p>	<p>Under Action Taken or In an Attached Document:</p> <ul style="list-style-type: none"> ● Add actions taken. Please review your permit conditions, there may be specific or approved methods listed for your specific permit. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> ● Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found.

Data Requirements	Description
	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 A.
Indicate any dates upon which you identified in-season volunteers (if different than dates monitored)	Under Comments: Please provide any observation dates that you found volunteers that were not part of your scheduled observation dates.

FLOWERING REPORT

As part of the Environmental Release Report, Annual, 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 organism 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 Environmental Release Report, Annual in eFile: Once you have completed entering your data for the Annual Environmental Release Report and click on save an observation prompt will appear for you to enter your data requirements, see [pages 2 and 3](#) for more information.

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

Typical Data Requirements for Flowering Report:

You must submit a Flowering Report as part of the Environmental Release Report, Annual that provides a detailed report on flowering.

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Important Note: Currently the Add Observation section for adding your flowering report says volunteers in 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 Document <ul style="list-style-type: none"> Indicate 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 Appendix A.

Data Requirements	Description
<p>Indicate end date(s) of flower monitoring for each field trial</p>	<p>Under Comments or In an Attached Document</p> <ul style="list-style-type: none"> • Indicate the end date(s) for each field trial. <p>Reference your supplemental permit conditions to determine your end date for your flowering report.</p> <p>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 A.</p>
<p>Indicate the dates you monitored the field trial.</p> <p>In eFile this is called Observation Date.</p>	<p>Under Observation Date:</p> <ul style="list-style-type: none"> • To start adding flower monitoring observation information click on Add Observation. Enter a single observation date. For each new observation date, you must add a new observation. <p>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.</p>
<p>Indicate the location(s) you monitored,</p>	<p>Under Actions Taken or In an Attached Document:</p> <p>Indicate the locations you monitored, including the field trial (with any perimeter zone and border row areas), and any other areas where flower monitoring is required.</p> <p>If you have multiple sites to monitor (e.g., fallow zone, field trial, equipment cleanout area) add this information in Actions Taken or in an attached document uploaded into the annual environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ 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. <p>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.</p>
<p>Indicate any dates upon which you identified flowers (if different than dates monitored)</p>	<p>Under Comments:</p> <p>Please provide any observation dates that you found flowers that were not part of your scheduled observation dates.</p>

Data Requirements	Description
<p>The number of flowers observed.</p>	<p>Under Number of Volunteers:</p> <ul style="list-style-type: none"> • Enter the number of flowers observed. If more than 100 flowers were identified, follow an estimation strategy and provide an estimate of the number. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ 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. <p>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 A.</p>
<p>Whether any unusual flowering occurred</p>	<p>Under Comments or In an Attachment:</p> <p>Indicate if you found any unusual flowering such as, but not limited to, early flowering, out-of-season flowering, or overabundance of flowering occurred.</p> <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ 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. <p>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 A.</p>
<p>The developmental stage of any flowers at time of destruction</p>	<p>Under Comments or In an Attachment:</p> <p>Provide the developmental stage of flowers at time of destruction (e.g., reproductive structures, visible flower buds, open flowers, pollen or seed)</p> <p>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</p>

Data Requirements	Description
	<p>document uploaded into the annual environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ 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. <p>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 A.</p>
<p>Any actions, including dates, taken to remove or destroy flowers</p>	<p>Under Actions Taken or In an Attachment: How did you remove or destroy the observed flowers? Please reference your specific supplemental permit conditions to ensure you are following any specific flower removal or destruction methods.</p> <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ 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. <p>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 A.</p>

PRE-HARVEST/PRE-DESTRUCT NOTICE

Pre-Harvest/Pre-Destruct Notices (previously known as Pre-Harvest/Pre-Termination Notice) 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/Destruction Notice(s).

How to Submit Your Pre-Harvest/Pre-Destruct Notice: see [pages 2 and 3](#).

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

Typical Data Requirements for Pre-Harvest/Pre-Destruct Notice:

You must submit a Pre-Harvest/Pre-Destruct 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 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

- Authorization Number
- Organism Under Permit (species) – In eFile this is called Organism
- Location Unique ID
- Release Site Name – In eFile this is called Release Site
- County
- State
- Location Address
- Release Site Agent Name and Contact Information
- Environmental Release ID (Unique ID)- In eFile this is called Planting ID

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Release Site Agent and Contact Information	Name, address, phone number (cell and office), and email of responsible person and agent on-site (if any). (This information is automatically generated in the notice from the eFile system.)
The earliest planned harvest/destruct start date. For multiple harvests, submit the notice prior to the initial harvest	Under Anticipated Harvest/Destruct Date: <ul style="list-style-type: none"> • Provide the date on which you anticipate you will harvest or terminate the organism(s) under permit.
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 ENVIRONMENTAL RELEASE REPORT

If you have been approved and issued an APHIS BRS permit for the environmental release of an organism under permit, and conducted an environmental release, you must submit a *Final Environmental Release Report* for all release site locations authorized in your permit.

Submission of environmental release information within a *Final Environmental Release 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 Environmental Release Report (Field Test Report (Annual or Final) in eFile):
see [pages 2 and 3](#).

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

Typical Data Requirements for Final Environmental Release Report:

Environmental Release Report, Final (formerly referred to as “Field Test Report, Final”). You must submit a final Environmental Release Report no later than 180 calendar days after the permit expiration date for each Release Site where a release occurred. You must submit this report even if APHIS issues a new permit for release at the Release Site.

Applicable Regulations [7 CFR 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

- Authorization Number
- Organism Under Permit (species) – In eFile this is called Organism
- Location Unique ID
- Release Site Name – In eFile this is called Release Site
- County
- State
- Location Address
- Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Indicate if regulated material was destroyed before harvest. Questions in eFile: Was any planted material destroyed before harvest?	If yes, answer the following in eFile: Was any planted material destroyed before harvest: if Yes, answer the following: <ul style="list-style-type: none"> • Pre-harvest destruction date <ul style="list-style-type: none"> ○ Enter your pre-harvest destruction completion date. • Pre-harvest destruction description, add the following: <ul style="list-style-type: none"> ○ Destruction methods (e.g., burning, autoclaving, tilled-under; disposition at authorized landfill); ○ Reason for destruction; ○ Actual stage of plant development at destruction (e.g., vegetative or reproductive); and ○ Destruction location
Indicate if regulated material was harvested. Question in eFile: Was any planted material harvested?	If yes, answer the following: Harvest Completion Date <ul style="list-style-type: none"> • Provide the harvest completion date. For the following requirements you must choose All terminated off-field or both for the eFile question “How was it terminated?” See section below for more details.

Data Requirements	Description
	<ul style="list-style-type: none"> • Location (including address and description) of contained facility where material is stored (To answer this question you must choose All terminated off-field or both for the eFile question How was it terminated? See below*) <ul style="list-style-type: none"> ○ Type and amount of stored regulated material; and • If destroyed, provide Off-field destruction (or disposal) description (e.g., burned, ground, authorized landfill) and date.
<p>Indicate whether your organism under permit was left in field, taken off field, or both.</p> <p>eFile Questions: How was it terminated?</p> <ul style="list-style-type: none"> • All terminated in-field, • All terminated off-field, • Both <p>Choose the appropriate response for your trial.</p> <p>How was off field terminated material disposed?</p> <ul style="list-style-type: none"> • All stored or contained, • All destroyed, • Both (some of each) <p>Choose the appropriate response for your trial.</p>	<p>If the organism under permit was left in the field (choose All terminated in-field for, “How was it terminated?”), provide the following information:</p> <ul style="list-style-type: none"> • Under the In-field termination completion Date: <ul style="list-style-type: none"> ○ Provide the date the field trial was completely terminated. • In the In-field termination description box add the following: <ul style="list-style-type: none"> ○ Describe the methods taken to destroy/devitalize regulated material (e.g., burned, hammer-milled) and ○ Describe how you disposed of the material (e.g., tilled or disked under, left untilled in the field). <p>If the organism under permit 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:</p> <ul style="list-style-type: none"> • Under Off-field destruction date: <ul style="list-style-type: none"> ○ Provide the date, • Under Off-field destruction description: <ul style="list-style-type: none"> ○ location, and methods taken to destroy/devitalize organism under permit (e.g., burned, ground up) and ○ Where you disposed of the material (e.g., landfill) <p>If organism under permit was removed from the field and placed in storage (choose All terminated off-field or Both for, How was it terminated, and All stored or contained or Both for, How was off-field terminated material disposed), provide the following information (Regulated material may be removed from the field and stored. You must store viable regulated material so that it is securely contained, and its identity maintained.):</p> <ul style="list-style-type: none"> • Under Stored or contained quantity and Stored Units: <ul style="list-style-type: none"> ○ The approximate amount of viable organism under permit that was stored and • Under Stored Material Type: <ul style="list-style-type: none"> ○ Enter what type of organism under permit is being stored (e.g., seed, ears) • Under Description of storage location and material placed in storage:

Data Requirements	Description
	<ul style="list-style-type: none"> ○ 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 address, and a description of the storage location.
<p>Indicate if any organism under permit remains growing at the release.</p> <p>Question in eFile: Is any planting material still growing in the field?</p>	<p>If yes, answer the following:</p> <p>How much planted material is still growing in the field, in acres?</p> <ul style="list-style-type: none"> ● Report the total size of the remaining release, including only the area occupied by the modified organism(s). If nothing has been devitalized, this will be the same as the Total Acreage of Modified Plant(s) (Quantity (Acres)” in eFile) you recorded for your Environmental Release Report. 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. <p>Description of still growing material:</p> <ul style="list-style-type: none"> ● Description of the remaining planted organism under permit ● Provide the APHIS BRS authorization number authorizing you to continue the release.
<p>Deleterious Effects and Unexpected Effects</p>	<p>Under Deleterious Effects Choose Yes or No</p> <ul style="list-style-type: none"> ● If choose Yes, you will also be required to add information to the Deleterious Effect Data field and an Explanation. <p>Under Unexpected Effects Choose Yes or No</p> <ul style="list-style-type: none"> ● If choose Yes, you will be required to add information under Crop Observation.
<p>Comments</p>	<p>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).</p>

POST-TERMINATION VOLUNTEER MONITORING REPORTS, INTERIM AND FINAL

You must submit post-termination volunteer monitoring reports for all field trials where an environmental release occurs (i.e., planted field trials) 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 eFile): see [pages 2 and 3](#).

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:

You must submit a final post-termination volunteer monitoring report (VMR) to APHIS no later than three months from the last volunteer monitoring interval described in this permit. If the post-termination volunteer monitoring period for any field trial in the permit is longer than one year, you must submit an interim VMR for the field trial until volunteer monitoring ceases.

- You must submit the first interim VMR no later than 13 months post-termination of the environmental release.
- Thereafter, you must submit subsequent interim VMR on or before the yearly anniversary date of the first annual VMR, unless it is the final VMR for the field trial, in which case you may submit it no later than three months from the last volunteer monitoring interval required by this permit.

Applicable Regulations [7 CFR 340.5\(i\)](#), [7 CFR 340.5\(i\)\(6\)](#), and [7 CFR 340.5\(i\)\(6\)\(ii\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

- Authorization Number
- Organism Under Permit (species) – In eFile this is called Organism
- Location Unique ID
- Release Site Name – In eFile this is called Release Site
- County
- State
- Location Address
- Release Site Agent Name and Contact Information
- Environmental Release ID (Unique ID) - In 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 Details Page and include all of the following	
No Monitoring Occurred Report requirements	When submitting a “No Monitoring Occurred” Report, provide the following: <ul style="list-style-type: none"> • Under No monitoring Date: <ul style="list-style-type: none"> ○ The date of your no monitoring • Reason for No Monitoring <ul style="list-style-type: none"> ○ Provide a reason you did not monitor this location on the observation date you provided.

Data Requirements	Description
	<ul style="list-style-type: none"> ○ Indicate whether the report is interim or final. <p>You do not need to address items below for the field trial for which you did not conduct volunteer monitoring</p>
<p>If you did conduct volunteer monitoring, Choose Add Monitoring for the appropriate release site(s) on the Location Details Page and include all of the following</p>	
<p>Start date(s) of volunteer monitoring interval for each volunteer monitoring area</p>	<p>Under Monitoring Start Date:</p> <ul style="list-style-type: none"> ● You must provide the date you started monitoring for volunteers for each field harvested/terminated. Typically, the post-termination volunteer monitoring period for each environmental release begins at release termination.
<p>End date(s) of volunteer monitoring interval for each volunteer monitoring area</p>	<p>Under Monitoring End Date:</p> <ul style="list-style-type: none"> ● You must provide the date you stopped monitoring for volunteers for each field harvested/terminated. If this is an interim post-termination volunteer monitoring report, please provide your anticipated final volunteer monitoring interval.
<p>Observation Date(s)</p> <p>Enter the following data for each observation date.</p>	<p>To start adding volunteer monitoring observation information click Save and then click on Add Observation.</p> <p>Volunteer Monitoring Dates for each Volunteer Monitoring area include:</p> <ul style="list-style-type: none"> ● Completed VM dates as prescribed in section (B)(ii)(2) of condition “Volunteer Monitoring, Post-Termination”; and ● Any other dates on which volunteers were observed outside of scheduled observations. <p>Under Observation Date:</p> <ul style="list-style-type: none"> ● 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. <p>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.</p>
<p>Volunteer Monitoring Locations</p>	<p>Under Action Taken or in an Attached Document:</p> <ul style="list-style-type: none"> ● Indicate all areas, including each Release Site, as described in section (A) of condition “Volunteer Monitoring, Post-Termination. <p>Review your supplemental permit conditions under “Volunteer Monitoring, Post-Termination” to view where you are required to volunteer monitor.</p>

Data Requirements	Description
	<p>If you are entering information on multiple locations for one observation date, either add this data to Actions Taken box or to an attached document and include data below for each location.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Provide the number of volunteers.</p> <p>In eFile this is called Number of Volunteers.</p>	<p>Under Number of Volunteers or in an Attached Document:</p> <ul style="list-style-type: none"> • If no volunteers were observed, indicate “no volunteers observed” by adding the number zero. • If volunteers were observed, indicate: <ul style="list-style-type: none"> ○ Number of volunteers observed (if more than 100 in number, follow an estimation strategy and include an estimate number) <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Provide the developmental stage of volunteers</p>	<p>Under Action Taken or in an Attached Document:</p> <ul style="list-style-type: none"> • Add the development stage of volunteer observed. Some examples of developmental stages include but are not limited to seedling, vegetative, or flowering. <p>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</p>

Data Requirements	Description
	<p>document uploaded into the annual environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Provide a description of spatial distribution</p>	<p>Under Action Taken or in an Attached Document:</p> <ul style="list-style-type: none"> • Add the spatial distribution of volunteers observed. Some examples of spatial distribution include but are not limited to localized/clustered, widespread, clustered in the southeast corner of the field. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example: <ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
<p>Any actions taken to destroy volunteers</p>	<p>Under Action Taken or in an Attached Document:</p> <ul style="list-style-type: none"> • Add actions taken to destroy volunteers. Please review your permit conditions, there may be specific or approved methods listed for your specific permit. <p>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 environmental release report for each site.</p> <ul style="list-style-type: none"> • Example:

Data Requirements	Description
	<ul style="list-style-type: none"> ○ Fallow zone: 20 volunteers found, V2 stage (vegetative), distributed widespread on the SW side of the trial, hand rogued and returned to the field to decompose. ○ Field Trial: 0 volunteers found. ○ Equipment Cleanout Area: 0 volunteers found. <p>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 A.</p>
Indicate any dates upon which you identified volunteer (if different than dates monitored)	<p>Under Comments: Please provide any observation dates that you found volunteers that were not part of your scheduled observation dates.</p>
If interval requirement of sections (B)(ii)(2) of conditions “Volunteer Monitoring, Post-Termination” were not met	<p>Under Comments: Please add an explanation for the deviation of your monitoring interval.</p>
Comments	<p>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).</p>

Typical Data Requirements for Volunteer Monitoring if Planting Back to a Modified Plant 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 modified plant 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 that has been planted back under a new permit
2. The planting 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 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 21 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 eFile): see [pages 2 and 3](#).

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 340.5\(i\)](#) and [7 CFR 340.5\(i\)\(6\)](#)

Core Data Requirements listed in your SPCs that eFile Self-Populates:

- Authorization Number
- Organism Under Permit (species) – In eFile this is called Organism
- Location Unique ID
- Release Site Name – In eFile this is called Release Site
- County
- State
- Location Address
- Release Site Agent Name and Contact Information

Data Requirements You Must Include for Each Authorized Release Site:

Data Requirements	Description
Add the location of the Return to General Use for each equipment, facilities, or both equipment and facilities	Click on Add on the Location Details Page To add the location: <ul style="list-style-type: none"> • Click inside of the Location box, and • Choose the proper location from the list under that appears.
Add the Description of equipment and facilities to be returned to general use	Under Description: <ul style="list-style-type: none"> • Add a description of equipment or facility to be returned to general use and include how many pieces of equipment and number of facilities. 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 5 business days after discovery. Examples of unauthorized releases include unauthorized flowering; dispersal of regulated material due to a weather event (e.g., flooding, high winds); release of an unauthorized construct; any incursions of domestic (farm) animals when regulated material is present; and the unauthorized removal of viable regulated material by humans or wild animals, including accidental removal.

Applicable Regulations [7 CFR 340.5\(i\)\(9\)](#)

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

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/compliance-and-inspections/how-to-report/report-a-release>