



MEMORANDUM

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

TO: Biotechnology Notification Holders

DATE: November 9, 2009

SUBJECT: Clarification Regarding Notification Planting Reports

ISSUE

This memorandum clarifies and describes planting information BRS requires for environmental releases conducted under the notification requirements of 7 CFR § 340.3.

BACKGROUND

On January 24, 2005, Biotechnology Regulatory Services (BRS) issued a memorandum to all notification holders describing planting report information to be submitted. BRS has recently reviewed the information contained in that memorandum as well as the regulatory requirements for notifications. We now wish to provide further clarification of the regulatory requirement for planting information in accordance with 7 CFR parts 340.3(d)(2)(iii) and 340.3(d)(2)(iv).

SUBMISSION OF ENVIRONMENTAL RELEASE INFORMATION

Environmental releases under notification are of three types: plantings of seed, transplanting of plants, or the placement or burial of pots containing plants. For each of these release activities, defined here as "planting" events, a "planting report" is required so that the location, size, and duration of all regulated environmental releases are known.

This information supports three critical BRS regulatory functions. It is used to (1) perform a risk assessment for the planned environmental release, (2) to verify compliance, and (3) to monitor and respond to emergency management situations, such as severe weather events.

As stated in regulation, BRS requires three types of information related to the environmental release of plants under notification. They are the location, size of planting, and date of the environmental release. This information must be provided when the notification is submitted to BRS prior to environmental release. However, most notifications are submitted many months prior to the expected date of release, which has made it difficult for responsible persons to predict, and for USDA to know, exact field location, size, and release date at the time of notification. In order to meet this requirement, BRS allows this information to be provided in two stages.



In the first stage, the outer boundaries of any location, a maximum planted area, and the period of release duration provided with the notification are sufficient for BRS to review.

In the second phase, following acknowledgement of the notification, the actual location, size of the planting (which must be situated within the boundaries in the acknowledged notification) and planting date must be submitted within the required time frame.

Notifications submitted without this information will not be acknowledged.

Subsequent planting reports must include the following required data:

- The location must be in the form of at least one GPS coordinate for the field or release site, and a coordinate location descriptor (such as, center, SW corner, etc.), or the legal location descriptor of sufficient resolution that the site can be readily located on a map.
- The date of each planting event in a given field location must be provided.
- The total area occupied by the regulated article in that planting event for the associated date must be provided.

Planting information must be provided in a written report no later than the end of the month following the month in which the planting has occurred.

When multiple plantings are made under a single notification, a planting report must be submitted no later than the end of the month following the month in which each planting has occurred.

Multiple notification holders may submit one monthly report listing information for all notifications in which planting has occurred.

Submit only previously unreported planting information. Do not submit previously reported plantings on the same site unless it is a new planting.

Identify in planting reports any sites included in the notification that will not be planted.

COMPLIANCE ACTIONS

LATE REQUIRED REPORT. If APHIS does not receive a planting report containing the required information by the due date (within the end of the month following the month in which the planting has occurred), the requirements specified in 7 CFR parts 340.3(d)(2)(iii) and 340.3(d)(2)(iv) have not been met. Furthermore, BRS identifies as late any type of required report that is submitted within 30 calendar days after the due date. For example, a report due May 31 would be deemed late if it was delivered to BRS June 1 through June 30.

REQUIRED REPORT NOT PROVIDED. If APHIS does not receive a planting report containing the required information more than 31 days after the due date, the requirements specified in 7 CFR parts 340.3(d)(2)(iii) and 340.3(d)(2)(iv) have not been met and will be considered a compliance infraction. BRS identifies as not provided, any type of required report that is submitted more than 31 calendar days following the due date. For example, a report due May 31 would be deemed “not provided” if it was delivered to BRS on or after July 1, or not delivered to BRS.

INCOMPLETE REQUIRED REPORT. If APHIS receives a planting report that does not contain required information, then the requirement specified in the requirements specified in 7 CFR parts 340.3(d)(2)(iii) and/or 340.3(d)(2)(iv) have not been met.

Late and/or missing reports are subject to enforcement actions including the issuance of a notice of non-compliance and/or a warning letter and the potential assessment of a civil penalty.

REPORT DELIVERY

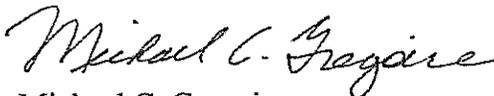
Please mail or deliver reports to:

Compliance and Inspection Branch
USDA, APHIS, Biotechnology Regulatory Services
4700 River Road, Unit 91
Riverdale, MD 20737

OR

Planting reports may be submitted via email at: BRSCompliance@aphis.usda.gov

Sincerely,



Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services