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How to Report an Unauthorized or Accidental Release

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As specified in regulations, persons engaging in regulated activities must notify APHIS of any possible or actual unauthorized movements or releases of the regulated materials, including accidental releases or those caused by flooding or other weather events. Time frames for reporting depends upon the type of incident or observation.

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HOW to Report an Incident

By Phone

Describe the incident, date, location (county and state/territory), crop or organism, developer's name and contact information, APHIS permit/notification number, and initial corrective actions. Please call one of the following numbers at BRS headquarters:

- The dedicated reporting line of Biotechnology Regulatory Services: 301-851-3935.
- If you cannot get through to the dedicated reporting line, call the main line of BRS: 301-851-3877. Please state that you wish to report an incident to the Compliance Evaluation and Enforcement Branch.

IN CASE OF AN EMERGENCY AND YOU ARE UNABLE TO REACH HEADQUARTERS CONTACT:

- Eastern Region Biotechnologist (states east of Mississippi River, plus Minnesota, Puerto Rico, and the American Virgin Islands): 919-855-7622 or 919-855-7624.
- Western Region Biotechnologist (states west of Mississippi River including Alaska, Hawaii, and Pacific Territories (Guam, Northern Marianas, American Samoa), except Minnesota): 970-494-7513 or 970-494-7573.

In Writing

Describe the incident in detail, and provide the date, location (county and state/territory), crop or organism, developer's name and contact information, APHIS permit/notification number, and initial corrective actions by one of the following

methods:

- Sending an email to the dedicated reporting address: BRSCompliance@usda.gov
- Sending a letter to the BRS Compliance, Evaluation and Enforcement Branch using the address below. (BRS encourages using an overnight carrier service, but it is not required.)

USDA APHIS BRS
ATTN: Compliance Evaluation and Enforcement Branch
4700 River Road, Unit 91
Riverdale, MD 20737

The written report should provide incident information regarding who was involved, what occurred, where, when, how, and why it occurred. The report should indicate whether an unauthorized release resulted in loss of containment. It should include any corrective actions, preventive actions, and/or mitigating actions already taken. When applicable, it should include a statement regarding who can provide information to APHIS about the incident, and who can receive information from APHIS about it. It should also include any necessary authorization statement for such discussions to occur. For example, an responsible person may designate a site researcher or regulatory compliance lead as the point-of-contact for APHIS.

WHAT and WHEN You Need to Report

APHIS regulations require responsible persons to report the following:

1. **Unauthorized Release:** If a regulated article is accidentally released into the environment, or is released without authorization. The responsible person must ***orally report the incident immediately upon discovery AND in writing within 24 hours.*** *Note:* Unauthorized releases include releases made before the effective date, or after the expiration date, of a permit or notification. They also include importations and interstate movements made without valid permits or notifications. Planting at or moving regulated material to sites other than those described on the permit or notification qualify as noncompliance. These are only examples of possible incidents, and other similar incidents

qualify.

2. **Substantially Different Characteristics:** When the regulated article or host organism (such as a microbial organism, and the host organism is substantially different) shows features substantially different from those listed in the permit or notification. The responsible person must ***report the occurrence in writing as soon as possible but no later than 5 working days after discovery***. BRS also encourages reporting orally before sending the written report, but it is not required.
3. **Any Unusual Occurrence:** When any unexpected result or event (excessive mortality or morbidity, or unanticipated effects on non-target organisms) affects the regulated article or host, or its controlled release into the environment. The responsible person must ***report the occurrence in writing as soon as possible but no later than 5 working days after discovery***. BRS also encourages reporting orally before sending the written report, but it is not required.

WHO Should Report

- Responsible persons who possess permits or acknowledged notifications are required by regulations to report certain incidents to BRS (see your authorization and **WHAT and WHEN You Need to Report** - below).
- Third parties, including members of the public, who have knowledge or evidence of biotechnology-related noncompliance incidents are encouraged to voluntarily report them to BRS. Third parties do not need to have all of the requested information (see **How to Report** tab below) to report an incident.

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