

New Orleans, LA - NAICC 2014 Mock Biotech Worksheet

Worksheet 1: NOTIFICATION INSPECTION WORKSHEET

Section 1

A. BRS Inspection Number (BRS IN) <input style="width: 90%;" type="text" value="14-985"/>	B. Notification Number <input style="width: 90%;" type="text" value="13-999-104N"/>
C. Inspector's name <input style="width: 90%;" type="text" value="Sarah Allely"/>	D. Inspector's phone <input style="width: 90%;" type="text" value="970-494-7512"/>
E. Cooperator at site <input style="width: 90%;" type="text" value="Peggie N. Robinson"/>	F. Applicant & Organization <input style="width: 90%;" type="text" value="Peggie N. Robinson, Our Gang Biotech"/>
G. Cooperator's mailing address <input style="width: 90%; height: 40px;" type="text" value="323232 Biotech Lane
London, Alaska 99546"/>	H. Cooperator's phone <input style="width: 90%;" type="text" value="703-292-6000 ext 6286"/>
I. Field Trial Site Location Information:	
GPS coordinates at one corner: (use decimal degree format)	County & State:
<input style="width: 90%;" type="text" value="NA"/>	<input style="width: 90%;" type="text" value="Douglas County, Alaska"/>
J. Inspection date <input style="width: 90%;" type="text" value="1/30/2014"/>	K. Crop/organism <input style="width: 90%;" type="text" value="Corn"/>

Instructions for completing above items:

- A/B. See the Inspection Assignment Memo for the BRS IN and Notification Number.
- C/D. Provide Lead Inspector information including cell phone number.
- E. The name of the responsible person at the site who may receive follow up information about inspection outcomes (may not be the same person who accompanies you during the inspection).
- F. The name of the applicant (person) on the Permit.
- G. The responsible party's/cooperator's exact mailing information (where BRS may send follow up correspondence).
- H. Provide Cooperator's phone number
- I. Determine GPS coordinates for at least one corner of the field trial site; indicate County/State of site.
- J. The date(s) inspection occurred.
- K. The crop/organism type that you inspected.

Methods of Verification

Inspectors should answer the questions by using a variety of methods to verify compliance. After each worksheet question, method(s) of verification are indicated by a capital letter or letters.

Methods of verification: O = Observation, R = Records review, I = Interview

When two verification methods are listed after a question, the first method should be used whenever possible but the secondary verification method is acceptable. A combination of methods may be ideal.

Circle Yes, No or N/A after each question. Add comments for any questions answered **No or N/A**.

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Section 2

Inspection Questions:

1. List all parties in attendance during the inspection, including name, affiliation/organization and job title or duties associated with the trial.*(I)
Sarah Allely, Compliance Specialist, APHIS-BRS and Peggie N. Robinson, Site Cooperator, Our Gang Biotech
2. Do the **notification** (application and acknowledgement letter) **and design protocols** you received from BRS match those held by the cooperator on site? (R)
[Yes or No] Yes, I inspected the Cooperator's design protocols, application, and acknowledgement letter and verified that they matched those provided to me by BRS.

Shipping and Packing

3. Do the **shipping and packing containers** used for this field trial prevent dissemination of viable regulated plant material while **in transit to the destination facility**? (O/I)
[Yes, No or N/A] Yes, the Cooperator stated that the seeds were double-bagged and contained within a cardboard box during shipping.
4. Were **containers or methods used** sufficient to fully contain the regulated material during **transport to the field trial location**? (O/I)
[Yes or No] Yes. The Cooperator did not report any issues with the integrity of the plastic bags or cardboard boxes used in shipping. The one box I inspected was intact.
5. Were shipments sent and received **within the authorized dates** for this notification and shipping **dates properly recorded**? (R)
[Yes or No] Yes. I inspected the shipping log provided by the Cooperator and verified that the shipment was received within the authorized date range.
6. **Were shipping and packing materials** used for this field trial **cleaned out and/or disposed of** to prevent dissemination of the regulated article? (O/I)
[Yes, No or N/A] Yes, the Cooperator reported cleaning out one of the boxes before disposing of it. She presented a second shipping box, which was clean and free of regulated material.
7. Were **storage containers or areas sufficient to** properly identify and **fully contain** the regulated material at the facility to prevent release into the environment? (O/I)
[Yes, No or N/A] Yes. The regulated seed was stored in a labeled plastic bag within a locked GLP chemical storage room. There is a shelf within that room designated just for storage of USDA regulated corn.

Regulated Articles

8. Did the cooperator/responsible party **maintain identity of the regulated material** at all times during handling (seed storage, shipping, etc.)? (O/I)
[Yes or No] Yes. The seed is being stored in a plastic bag within a locked cabinet and the bag is labeled. During shipping it was double-bagged and contained in a cardboard, labeled box.
9. Does the cooperator/responsible party **have a record-keeping system** (e.g. log, inventory or notebook), to record all incoming and outgoing shipments? (R/I)

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[Yes or No] Yes. The Cooperator provided a log that included shipping forms that listed the date the shipment was received, the quantity received, the permit number, and initials of who received the shipment.

10. Did your inspection find that this field trial is **free of any potential non-compliance** issues? (O/R/I/M)

[Yes or No] Yes. I did not find any potential non-compliance issue.

Section 3

Additional Notes/Findings:

The Cooperator provided me their shipping log. It is stated in the design protocols that, "a data sheet will be compiled on each construct of modified plants or received by personnel upon receipt of regulated material. **Data will include 1) the construct transformed, 2) number of plants, 3) location & labeling, and fate of seeds or plants after analysis.** These data sheets will be archived to ensure chain-of-custody of the genetically modified, regulated material." **The shipping log provided to me did not include the construct transformed, or the fate of seeds after analysis.**

The Cooperator keeps the seeds locked in a GLP chemical storage room, and designates one shelf for storing USDA-regulated corn. The corn is kept double-bagged, sealed and labeled. Reference chemicals are also stored in this room and the temperature was monitored and logged starting when these chemicals arrived.