Appendix D. Sample Compliance Agreement

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE BIOTECHNOLOGY REGULATORY SERVICES	**COMPLIANCE AGREEMENT**
1. RESPONSIBLE ENTITY NAME AND ADDRESS	2. AUTHORIZED REPRESENTATIVE NAME AND ADDRESS

3. ARTICLE(S)

H7-1 Sugar Beet Root Crop

4. APPLICABLE FEDERAL STATUTES OR REGULATIONS

Plant Protection Act of 2000, as amended

5. I/WE AGREE TO THE FOLLOWING:

This compliance agreement is required as a condition for partial deregulation of the H7-1 sugar beet root crop and is a legally binding and enforceable agreement that authorizes root crop production activities by the Responsible Entity named above and all persons engaging in root crop production activities in association with or on behalf of the Responsible Entity. By signing this compliance agreement, the authorized representative of the Responsible Entity confirms his/her authority to sign the agreement on behalf of the Responsible Entity named above and all persons engaging in root crop production activities in association with or on behalf of the Responsible Entity. The Responsible Entity confirms its understanding of the requirements/conditions set forth in the agreement and confirms that the Responsible Entity and all persons conducting root crop production activities under this compliance agreement will comply with the requirements/conditions of the agreement. The mandatory requirements/conditions under this agreement are outlined and attached as Appendix A and incorporated into this agreement by reference. The Responsible Entity named above designates XXXXXXXXXXXXXXX XXXXXXXXXXXXXX as an Authorized Representative and a point of contact in connection with the performance of this agreement.

6. SIGNATURE	7. TITLE	8. DATE SIGNED
The affixing of the signatures below will validate this agreement which shall remain in effect until canceled, but may be revised as necessary or revoked for noncompliance.		9. AGREEMENT NUMBER 10. DATE OF AGREEMENT
11. BRS OFFICIAL (NAME AND TITLE)		12. ADDRESS
13. SIGNATURE		
14. US GOVERNMENT/STATE AGENCY		15. ADDRESS
16. SIGNATURE		

Appendix A

The following mandatory requirements/conditions apply to the responsible entity and any person conducting root crop production activities (from obtaining/shipping seed for planting to the transportation of the root crop to the processing facility) in association with or on behalf of the responsible entity under this compliance agreement. The term person in this paragraph includes any individual, partnership, corporation, association, joint venture, or other legal entity.

General Administrative Requirements/Conditions:

Information Required: The responsible entity, through its authorized representative, shall submit to APHIS/BRS, no later than 28 days (emailed or postmarked) after the first day of planting under this compliance agreement and every 28 days thereafter until all planting is completed, a planting report (refer to "RRSB _example planting report") that must include the following information: the names and addresses of all growers, the county and state where each release (planting) occurred, at least one GPS coordinate for each release site and the location of the GPS coordinate (e.g., NW corner of the field), confirmation that the release site has been in agricultural production for at least the past three years, the exact planting date(s) for each release site, and the actual acreage planted at each site. Each report shall include plantings occurring during the prior 28 days (to extent such information is reasonably available at the time of the report) and information for plantings occurring in prior reporting periods for which information was not available at the time the prior report was submitted. The reports may be submitted electronically via email at RRSB.BRS@aphis.usda.gov or via mail at: USDA/APHISIBRS Attn. RRSB Planting Reports, 4700 River Road Unit 91, Riverdale, MD 20737; please for an example of a planting report.

The responsible entity through its authorized representative shall notify APHIS/BRS (via email at RRSB.BRS@aphis.usda.gov, via phone at (301) 734-5690), within 48 hours, of any change in the information provided to APHIS/BRS, either upon application for a compliance agreement or at anytime thereafter, regarding planting and/or movement/importation activities (e.g., changes/updates to planting locations, GPS coordinates, shipping addresses for seed and/or root movement).

Reporting of Incidents of Noncompliance: The responsible entity through its authorized representative shall notify APHIS/BRS, verbally (301-734-5690) and in writing via email (RRSB.BRS@aphis.usda.gov), within 24 hours, after becoming aware of unauthorized releases and/or movements. In addition, the responsible entity through its authorized representative shall notify APHIS/BRS, verbally (301-734-5690) and in writing via email (RRSB.BRS@aphis.usda.gov), within 48 hours, after becoming aware of any instance of noncompliance with the conditions of the compliance agreement. In incidents involving unauthorized releases and/or noncompliance, growers shall give notice immediately to the responsible entity so that the responsible entity may notify APHIS/BRS. When contacting APHIS/BRS, the authorized representative shall describe the incident, the date it occurred, the location (including county and state and GPS coordinate(s) of release site), name and address of grower, and field personnel associated with the incident. The authorized representative shall also provide immediate or short term corrective actions and, if necessary and available, long-term plans to return the situation to compliance and prevent similar incidents from occurring in the future. APHIS/BRS will review the information provided by the authorized representative and request additional information, if necessary, within 24 hours of the receipt of the notice. APHIS/BRS may require additional corrective actions if APHIS/BRS deems it necessary. The responsible entity and all persons engaged in root crop production activities in association with

or on behalf of the responsible entity must cooperate with APHIS/BRS until the situation is resolved and the incident brought back to compliance. APHIS/BRS will record the incident and submit a response in writing, summarizing the incident and corrective measures, as per APHIS standard procedure in handling noncompliance incidents, to the authorized representative, no later than 10 days of the receipt of the notice.

Third Party Inspections and Audits

Third Party Inspections**:** APHIS/BRS will evaluate the third party inspectors' credentials provided by the responsible entity through its authorized representative in the request for the compliance agreement. The credentials will be evaluated for information such as, prior experience with biotechnology inspections, general experience in conducting inspections, and overall experience/background in agriculture. After evaluating the inspectors' credentials, APHIS will notify the authorized representative which third party inspectors it believes are qualified to conduct H7-1 sugar beet root crop inspections on behalf of the Agency. The responsible entity will have fifteen business days, from the date of the notice, to retain the services of the third party inspector(s). The responsible entity may choose to retain the services of one or more of the APHIS approved inspectors. Upon retaining the services of the third party inspector(s), the authorized representative shall supply the name(s) of the third party inspector(s) to APHIS/BRS. APHIS officials will contact the third party inspectors to schedule inspection training. (APHIS will provide an inspection form to be used by inspectors to capture inspection data.) The third party inspectors will schedule and conduct inspections according to APHIS' instructions. APHIS/BRS will coordinate with a third party inspector to randomly choose a statistically representative sample of fields, from those fields designated by APHIS to inspect, to conduct inspection for bolters (to satisfy condition 5 under Requirements/Conditions for Planting of the Root Crop). The third party inspectors will submit inspection reports directly to APHIS and APHIS will work directly with the inspectors if the reports require additional information. A large number of the root production fields and facilities will be inspected by the third party inspectors, sufficient to give statistically significant conclusions ($p=0.05$) on overall compliance. If the Compliance Agreement only covers seed movements, no third party inspectors are required.

Third Party Audits: APHIS/BRS will evaluate the third party auditors' credentials provided by the responsible entity through its authorized representative in the request for the compliance agreement. The credentials will be evaluated for information such as, prior experience with biotechnology inspections, general experience in conducting inspections, and overall experience/background in agriculture. After evaluating the auditors' credentials, APHIS will notify the authorized representative which third party auditors it believes are qualified to conduct H7-1 sugar beet root crop audits on behalf of the Agency. The responsible entity will have fifteen business days, from the date of the notice, to retain the services of the third party auditor(s). The responsible entity may choose to retain the services of one or more of the APHIS-approved auditors. Upon retaining the services of the third party auditor(s), the authorized representative shall supply the name(s) of the third party auditor(s) to APHIS/BRS. APHIS officials will contact the third party auditors to schedule audit training. APHIS will provide an audit form to be used by auditors to capture audit information. The third party auditors will schedule and conduct audits according to APHIS' instructions. APHIS will require third party auditors to review shipping records and/or grower records and to submit auditing reports directly to APHIS for review. APHIS will work directly with the auditors if the reports require additional information.

All Activities conducted by the responsible entity and any person engaging in root crop production activities in association with or on behalf of the root crop entity to comply with compliance agreement requirements/conditions may be either inspected or audited by APHIS or third party inspectors or auditors or both.

Access to Records, Planting Locations, and Facilities: The responsible entity shall ensure that all persons conducting root crop production activities under this compliance agreement provide access to all records required to be maintained under this compliance agreement and provide access, during regular business hours, to inspect planting locations, facilities, and transport vehicles, upon request by APHIS/BRS or its authorized representative(s).

Training: The responsible entity shall ensure that all persons conducting root crop production activities under this compliance agreement receive a copy of this compliance agreement and are trained in the processes and procedures necessary to comply with the terms of this compliance agreement. In addition, the responsible entity shall ensure that written documentation of the training is maintained and that all training records are maintained for the duration of this compliance agreement.

Duration of Compliance Agreement: This compliance agreement is valid and effective from the date of issuance (i.e. the date signed by APHIS/BRS) until December 31, 2012, unless revoked or superseded by APHIS/BRS. (The December 31, 2012 date does not preclude the responsible entity from ensuring that monitoring for volunteers continues through the end of the three-year monitoring period as set forth in the compliance agreement).

Cancellation or Revocation of Compliance Agreement: A violation of the requirements/conditions of this compliance agreement is a violation of the Plant Protection Act. In the event of a finding of noncompliance or violation of the requirements/conditions of the compliance agreement, APHIS may, at its discretion, revise, suspend, revoke, or otherwise withdraw the compliance agreement. APHIS may also, at its discretion, use the full range of the Plant Protection Act authorities to impose, as appropriate, criminal and/or civil penalties against any person conducting root crop production activities in violation of this agreement and may take remedial measures including seizure, quarantine, and/or destruction of any H7-1 sugar beet root crop production that is found to be in violation of the conditions set forth in the compliance agreement.

Requirements/Conditions for Planting of the Root Crop:

1. Planting of H7-1 sugar beet seed for root production is not allowed in the state of California, and the following counties in Washington State: Clallam, Clark, Cowlitz, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, Pacific, Pierce, San Juan, Skagit, Skamania, Snohomish, Thurston, Wahkiakum, and Whatcom.

2. The planting of H7-1 sugar beet seed for root crop production is only allowed in the following states: Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming.

3. The planting of H7-1 sugar beet seed for root production is only allowed in sites that have been in agricultural production for at least three years prior to planting.

4. Root growers shall ensure that root crop fields are surveyed to identify and eliminate any bolters before they produce pollen or set seed. Fields shall be surveyed at least once every 3-4 weeks beginning April 1. Root growers shall ensure that field personnel maintain

records of their field observations and removal of bolters. Reports where bolters are not observed must be maintained as well. If bolters are found, the responsible entity through its authorized representative shall ensure that APHIS/BRS is notified (via email at RRSB.BRS@aphis.usda.gov, via phone at (301) 851-3867), within 48 hours after finding the bolters, and provided a description of the location and action taken by the field personnel to remove them. The responsible entity shall ensure that all records of inspection and bolter removal are maintained for the duration of this compliance agreement.

5. Third party inspectors procured by the responsible entity (see **Third Party Inspections and Audits** above) will coordinate with APHIS/BRS to randomly choose a statistically representative sample of fields, from those fields designated by APHIS to inspect, to conduct inspection for bolters. (This third party inspection is in addition to the requirement in paragraph 4 above that root growers survey their fields at least once every 3-4 weeks.) If bolters are identified, the root grower shall be notified immediately and those bolters must be removed.

6. Planting/cultivating/harvesting equipment that might be used in chard/red beet production shall not be used or shared for regulated GE material in the same growing year.

7. The responsible entity shall ensure root crop fields are monitored for volunteers for three-years (at least twice per year during the growing season) following harvest, and any volunteer plants must be destroyed. If the same land is used for crop cultivation during the volunteer monitoring period, that crop shall be visually distinct from sugar beets or the fields must be left fallow. The responsible entity shall ensure that records of observations are maintained for the volunteer monitoring period.

8. The responsible entity shall ensure that root growers maintain records of all the activities being carried out under the compliance agreements to demonstrate adherence to the mandatory conditions and restrictions.

Requirements/Conditions for Movement of the Seed for Root Crop Production:

1. The responsible entity shall ensure that, during transport of seed for root crop production, chain of custody and records (such as manifests or receipts) are maintained for the duration of this compliance agreement. Sugar beet seeds shall be transported in a sealed plastic bag(s), envelope(s), or other suitable container(s) (primary container) to prevent seed loss.

2. The primary container for transporting seeds shall be placed inside a sealed secondary container that is independently capable of preventing spillage or loss of seed during transport.

3. Each set of containers (primary and secondary) for transporting seeds shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength. Each container shall clearly identify that the seed contents within shall only be used for the planting of sugar beet root crop.
4. The shipping containers for transporting seeds shall be transported in enclosed trucks or trailers with closed sides (unless the seed is already packaged with sufficient levels of packaging as described above).

Requirements/Conditions for Movement of the Root Crop for Processing:

1. The responsible entity shall ensure that, during transport of the root crop to a processing facility or any intermediate holding area, chain of custody and records (such as manifests or receipts) are maintained for the duration of this compliance agreement.

2. Trucks used for the movement of root crop from field to storage/processing shall be loaded in a manner to minimize loss of beets during transport or equipped with a retaining device.