

**United States Department of Agriculture  
Animal and Plant Health Inspection Service (APHIS)  
Biotechnology Regulatory Services (BRS)**

**Compliance Agreement Request – *Scope***

**On February 8, 2011, APHIS, BRS, issued a decision which partially deregulated H7-1 sugar beet root crop, provided that the root crops were grown under mandatory conditions and under compliance agreements.**

Pursuant to that decision, APHIS/BRS may issue a compliance agreement to any organization, association, corporation, institution, or any other entity that is in the business of growing and/or producing H7-1 sugar beets. These include, but are not limited to, seed companies shipping H7-1 derived sugar beet seed for root production, sugar beet cooperatives receiving and/or shipping seed, growers planting and/or shipping seed and shipping roots, and processors shipping and/or receiving roots for processing. These entities may enter into a compliance agreement with APHIS on behalf of all its members and/or employees (e.g., growers, contractors, transport drivers). APHIS will not issue compliance agreements to individual growers, contractors, or transport drivers.

**Compliance Agreement Request – *Administrative Requirements***

Responsible entities seeking a compliance agreement must appoint an authorized representative who is approved by the entity to request, legally bind and obligate, and sign the compliance agreement on behalf of the entity and its members, growers, contractors, etc. The authorized representative must submit a request, in writing, to USDA-APHIS-BRS, Regulatory Operations Programs (by email at: [RRSB.BRS@aphis.usda.gov](mailto:RRSB.BRS@aphis.usda.gov); by fax at: (301) 734-8910; or by mail at: 4700 River Road Unit 91, Riverdale, MD 20737, RE: Compliance Agreement Request) in advance of the shipment (import/movement) and/or planting (environmental release) of H7-1 sugar beets (seeds and roots) associated with the H7-1 sugar beet root production activities.

An authorized representative will be the primary contact with APHIS/BRS unless in the request, a second person who can serve as the alternate authorized representative for questions related to the compliance agreement and/or reporting instances of noncompliance is identified. The compliance agreement will name both authorized representatives, but only one will sign the agreement on behalf of the responsible entity.

An authorized representative shall submit the following information with their request for a compliance agreement: the name and address of the responsible entity, the nature of the responsible entity (e.g., cooperative, seed producer), the number and type of members (e.g., growers), the states where activities under the compliance agreement will be conducted, the type of activities that will be conducted under the compliance agreement (e.g. environmental release, seed movement, root crop movement), and the names and credentials of at least two third party

inspectors and two third party auditors (for releases) and the names and credentials of at least two third party auditors (movement of seed only) to potentially conduct third party inspections and third party audits on behalf of the Agency. APHIS/BRS will approve the third party inspectors and auditors after evaluating the third party inspectors' and auditors' credentials provided by the responsible person in the request for the compliance agreement. The credentials will be evaluated for information such as, prior experience with biotechnology inspections and/or audits, general experience in conducting inspections and/or audits, and overall experience/background in agriculture.

In addition, the authorized representative shall submit the following information with their request for a compliance agreement: For Importation and Movement: the name(s) of the company(ies) responsible for shipping (origin) H7-1 seed and/or the root crop and the name(s) of the company(ies)/organization(s) receiving (destination) H7-1 seed and/or the root crop, approximate (total) quantity of H7-1 seed and/or the root crop to be shipped, when the movement of H7-1 seed and/or the root crop will be conducted (i.e., start and end dates), and the county(ies) and state(s) where the movement will take place. For Environmental Release: the county(ies) and state(s) where the release will occur and the approximate acreage(s) to be planted. In addition, state if the release site has been under agricultural production for the past three years. (Please note: additional information will be required to be submitted by the authorized representative in a planting report 28 days after the first day of planting.)

Refer to page 3 for a template of the request letter and required information to be submitted in the request. For additional information on the request and/or the compliance agreement, please call (301) 851-3867 or email [RRSB.BRS@aphis.usda.gov](mailto:RRSB.BRS@aphis.usda.gov)

### **Compliance Agreement Request – *Review and Approval***

If APHIS/BRS approves the request, the compliance agreement will be sent via fax or mail to the authorized representative for their review and signature. The authorized representative will sign and return the compliance agreement to APHIS/BRS by fax or mail. In turn, APHIS/BRS will sign the agreement and return a copy of the agreement to the authorized representative within 24 hours of receipt.

No root crop production activity can occur under the compliance agreement until APHIS has signed and issued the compliance agreement.

**COMPANY LETTERHEAD**

**DATE**

**TO:** United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Biotechnology Regulatory Services  
**Attn:** Natalia Weinsetel, Ph.D.  
4700 River Road Unit 91  
Riverdale, MD 20737

**FROM:** Responsible Entity (name and address)  
Authorized Representative (name/address/email/phone number)  
Alternate Authorized Representative (name/address/email/phone number)

**SUBJECT:** Compliance Agreement Request

This letter serves as the formal request for company X to be the responsible entity and enter into a compliance agreement with APHIS/BRS in advance of the shipment (import/movement) and/or planting (environmental release) of H7-1 sugar beets (seeds and roots) associated with the H7-1 sugar beet root crop production activities. I, AAA, am the authorized representative approved by company X, the responsible entity, and authorized to request, legally bind and obligate, and sign the compliance agreement on behalf of company X and its members, growers, contractors, etc.

Company X wishes to import/move/plant (*select all that apply*) H7-1 sugar beet (seeds and roots) associated with sugar beet root production activities. The required information is provided below. *Note: please indicate (fax or mail) the method you would like APHIS to utilize to send you the compliance agreement for your review and signature.*

**Business Information:** *the name and address of the responsible entity, the nature of the responsible entity (e.g., cooperative, seed producer), the number and type of members (e.g., growers), the states where activities under the compliance agreement will be conducted, the type of activities that will be conducted under the compliance agreement (e.g, environmental release and/or movement).*

**Third Party Inspector and Third Party Auditor Information:** *the names and credentials of at least two third party inspectors and two third party auditors (for releases) and the names and credentials of at least two third party auditors (for movements of seed only). Please indicate attachment(s) (e.g., curriculum vitae, resume, etc.).*

**For Importation and Movement:** *the name(s) of the company(ies) responsible for shipping (origin) H7-1 seed and/or the root crop and the name(s) of the company(ies)/organization(s) receiving (destination) H7-1 seed and/or the root crop, approximate (total) quantity of H7-1 seed and/or the root crop to be shipped, when the movement of H7-1 seed and/or the root crop will be conducted (i.e., start and end dates), and the county(ies) and state(s) where the movement will take place.*

**For Environmental Release:** *the county(ies) and state(s) where the release will occur and the approximate acreage(s) to be planted. In addition, state if the release site has been under agricultural production for the past three years.*

If you have any questions regarding the above information, do not hesitate to contact me.  
Sincerely,

Authorized Representative