Evaluation of Compliance Agreement Request for Consistency with APHIS' Determination Decision regarding Monsanto/KWS' Petition for Partial Non-Regulated Status for glyphosate tolerant (Roundup Ready®) H7-1 sugar beets, the Final Environmental Assessment and the Finding of No Significant Impact.

Monsanto Company and KWS SAAT AG Supplemental Request for Partial Deregulation of Sugar Beet Genetically Engineered to be Tolerant to the Herbicide Glyphosate

United States Department of Agriculture
Animal and Plant Health Inspection Service

In a notice published in the Federal Register (75 FR 67945-67946, Docket No. APHIS-2010-0047) on February 8, 2011, the United States Department of Agriculture (USDA) and the Animal and Plant Health Inspection Service (APHIS) announced its determination to partially deregulate Roundup Ready® sugar beets developed by the Monsanto Company (Monsanto) and KWS SAAT AG (KWS), designated as event H7-1. Under this partial deregulation, H7-1 sugar beet seed production activities remain subject to all of the procedural and substantive requirements of 7 CFR 340 and all H7-1 sugar beet root production activities must be conducted pursuant to a compliance agreement and pursuant to enforceable mandatory conditions.

As specified in the February 8th Determination Decision to approve, in part, on an interim basis, a conditional Partial Deregulation of H7-1 sugar beets, in its Final EA and FONSI, APHIS notified the public of its intent to evaluate each request it receives to enter into a compliance agreement for consistency with the final EA, FONSI, and Determination Decision prior to issuing the compliance agreement. Specifically, APHIS indicated that prior to issuing any compliance agreement, APHIS would evaluate and make a determination about whether the compliance agreement corresponds with all of the required conditions and provisions as mandated by APHIS' Determination Decision and as described and evaluated in the Final EA and the FONSI.

This document serves as the formal documentation of APHIS' review and evaluation process to ensure that the compliance agreement request corresponds with all of the required conditions and provisions as mandated by APHIS' Determination Decision and as described and evaluated in the Final EA and the FONSI.

Consistency with APHIS' Determination Decision and the Scope of the Final EA. As identified in the PPRA, the Final EA and FONSI, and pursuant to APHIS' February 8th Determination Decision regarding all H7-1 sugar beet root crop production activities, such root production activities can be "released into the environment" (planted/grown/harvested, transported, etc.) for an interim period of time pursuant to a compliance agreement authorized by the PPA when grown under specific mandatory conditions imposed and enforced by APHIS. Pursuant to the Determination Decision, compliance agreements with mandatory conditions and restrictions may be issued for the environmental release (planting) of the H7-1 sugar beet root crop in the states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming; and for the importation and interstate movement of H7-1 sugar beets associated with root production activities (seeds and roots) within and into the

US. The environmental release of H7-1 sugar beets will be limited to sites that have been in agricultural production for a minimum of 3 years.

APHIS 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. Such organizations or entities include, but are not limited to, seed companies shipping H7-1-derived sugar beet seed for root production, and 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, or other agents of the entity). The root production cooperatives or other root production entities that enter into a compliance agreement with APHIS are required to ensure that all of the respective entity's employees, members or associates that are under the entity's compliance agreement and subject to it (like farmers, growers, transport drivers, and/or other individuals) will adhere to all of the mandatory requirements and conditions of the compliance agreement. Accordingly, both the root production cooperatives or other entities that enter into a compliance agreement with APHIS, as well as all persons engaging in root crop production activities in association with or on behalf of the respective entity are legally obligated and required to abide by all the mandatory requirements and conditions imposed by the compliance agreement and all of them collectively and/or individually can be held responsible and accountable by APHIS for any non-compliance or other violation of any of the mandatory requirements and conditions imposed by the compliance agreement.

General Administrative Requirements/Conditions of Root Production Activities. As identified in the Final EA and FONSI, the following mandatory administrative requirements and conditions will be imposed on H7-1 sugar beet root crop production activities under the compliance agreement:

1. *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.
2. *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. 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.

3. *Third Party Inspections and Audits.*
    a. Third Party Inspections: The responsible entity will have fifteen business days after APHIS notifies the entity of its approval of third party inspectors to retain the services of the third party inspector(s). APHIS officials will contact the third party inspectors to schedule inspection training. 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. 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.
    b. Third Party Audits: The responsible entity will have fifteen business days after APHIS notifies the entity of its approval of third party auditors to retain the services of the third party auditor(s). 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.
4. *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).
5. *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.
6. *Duration of Compliance Agreement.* The compliance agreement is valid and effective from the date of issuance until December 31, 2012, unless revoked or superseded by APHIS/BRS.
7. *Cancellation or revocation of Compliance Agreement.* In the event of a finding of noncompliance 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 the 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.

Mandatory Restrictions/Conditions for Planting of the Root Crop. As identified in the Final EA and FONSI, the following mandatory conditions and restrictions will be imposed on the planting of the H7-1 sugar beetroot crop production activities pursuant to the mandatory compliance agreement:

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 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 bolters, and provide a description of the location and action taken by the field personnel. The responsible entity shall ensure that all records of inspection and bolter removal and records are maintained for the duration of this compliance agreement.
5. Third party inspectors procured by the responsible entity 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.

Mandatory Conditions/Restrictions for Movement of the Seed for Root Crop Production. As identified in the Final EA and FONSI, the following mandatory conditions and restrictions will be imposed on the interstate movement and importation of H7-1 seeds associated with root production activities pursuant to the compliance agreement:

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.
2. 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.
3. 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.
4. 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.
5. 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).

Mandatory Conditions/Restrictions for Movement of the Root Crop for Processing. As identified in the Final EA and FONSI, the following mandatory conditions and restrictions will be imposed on the interstate movement and importation of the H7-1 sugar beet root crop pursuant to the compliance agreement:

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.

Compliance Agreement Request. APHIS has received a request to enter into a compliance agreement from Holly Seed, LLC to authorize the environmental release/movement of H7-1 sugar beet seeds/roots for H7-1 root production activities in Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, and Wyoming.

Determination of Consistency with APHIS' Determination Decision, Final EA and FONSI. APHIS has reviewed the information submitted by the applicant and has determined that the request to enter into a compliance agreement and the signed compliance agreement submitted by

applicant is consistent with all of the required conditions and provisions required by APHIS' Determination Decision and identified within the scope of and evaluated by the Final EA and FONSI. Therefore, APHIS has determined that approving this compliance agreement request is consistent with APHIS' Determination Decision, its Final EA and FONSI, and it is not necessary for APHIS to supplement or revise the Final EA or FONSI, or prepare any other additional NEPA documentation or analysis prior to issuing this compliance agreement.

Sidney W. Abel CEO
Assistant Deputy Administrator
(NAME and TITLE of APHIS-BRS Official)

3/16/2011
DATE

Done at :(City, State) Riverdale, MD