10-348-107r

Evaluation of Permit Application 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, 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, all H7-1 sugar beet seed production activities remain subject to all of the procedural and substantive requirements of 7 CFR Part 340.

As specified in our February 8th Final EA, FONSI, and Determination Decision, in reference to seed production activities, APHIS decided to deny the Petition for a Partial Deregulation of H7-1 sugar beets seed production activities and instead decided to allow all seed productions activities to be conducted pursuant to APHIS' Part 340 regulations. APHIS also notified the public of its intent to evaluate each complete Part 340 permit application or notification prior to issuing the permit or acknowledging the notification for consistency with the Final EA, FONSI, and Determination Decision. Specifically, APHIS indicated that prior to issuing any Part 340 permit or notification, APHIS would evaluate and make a determination about whether the requested permit or notification 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 requested permit or notification 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 seed crop production activities, such seed production activities can be "released into the environment" (planted/grown/harvested, transported, etc.) pursuant to a Part 340 permit with specific mandatory conditions and requirements. Moreover, the importation into the United States and/or the interstate movement within the United States of H7-1 sugar beets associated with seed production activities (H7-1-

derived sugar beets, seeds, stecklings, and/or other plant material) can be allowed pursuant to a Part 340 notification. Thus, Part 340 permits may be issued for the environmental release (planting, etc.) of H7-1 sugar beets associated with all seed production activities in the States of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming. 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. Moreover, Part 340 notifications may be "acknowledged" for the importation and/or interstate movement of H7-1 sugar beets associated with seed production activities (H7-1-derived sugar beets, seeds, stecklings, and/or other plant material). These Part 340 permits and/or notifications required by APHIS' Determination Decision for all RRSB seed production activities will be enforced pursuant to APHIS' Part 340 regulations and the PPA.

APHIS may issue a Part 340 permit and/or notification for any seed production activity to any organization, association, corporation, institution or any other entity that is in the business of growing and/or producing H7-1 sugar beets. This includes, but is not limited to, seed companies producing H7-1-derived sugar beets, seeds, stecklings, and/or other plant material. These entities that apply for a Part 340 permit or notification for seed production activities will likewise be applying for the permit on behalf of all their respective members, farmers, transport drivers, etc. The entities producing sugar beets that apply for a Part 340 permit or notification for seed production activities are required to add to their respective "growers' and/or transport contracts" a legally binding contractual requirement whereby the respective farmers, growers, transport drivers, and/or other individuals must adhere to all the mandatory requirements and conditions imposed by APHIS' Part 340 permit and/or notification. Accordingly, both the seed production entities that that are issued a Part 340 permit and/or notification as well as all their respective members, farmers, transport drivers, etc. are legally obligated to abide by all the mandatory requirements and conditions imposed by the permit and/or notification and all of them collectively and/or individually can be held responsible and accountable by APHIS for any non-compliance or other violation of all the mandatory requirements and conditions imposed by the permit and/or notification. Because of the logistical impossibilities of dealing with the huge number of potential individuals involved in growing and transporting H7-1 sugar beets, APHIS does not envision issuing Part 340 seed production permits and/or notifications to individual farmers, transport drivers, or other individuals.

The Specific Mandatory Conditions/Restrictions Imposed on Seed Production Activities.

The following mandatory conditions and restrictions will be imposed on H7-1 sugar beets intended for seed production activities. As identified in the Final EA and FONSI, the following mandatory permit conditions will be imposed on plantings of H7-1 sugar beets intended for seed production via permit conditions where the seed producer (permit holders) will acknowledge and adhere to these mandatory conditions:

1. Planting of H7-1 sugar beets 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. A four-mile separation distance shall be maintained between male *fertile* H7-1 sugar beets and all other commercial *Beta* seed crops (i.e., table beets, Swiss chard) US wide.
3. An inventory of H7-1 male *fertile* planting locations shall be provided to APHIS within two weeks of planting.
4. A four-mile separation distance shall also be maintained between male *sterile* H7-1 sugar beets and all other commercial *Beta* seed crops US wide. During flowering, fields shall be scouted for male sterile H7-1 plants that shed pollen and such plants shall be destroyed.
5. A visual identification system, such as labeling, that accompanies the regulated material (e.g. basic seed, stock seed, stecklings, and commercial seed) throughout the production system, is required.
6. A companion seed-lot based tracking and tracing system that is fully auditable shall be maintained. Records must be retained for five years.
7. Other than non-GE *Beta* seed material used in the production of hybrid-seed, all H7-1 material shall be physically separated from non-regulated material to prevent commingling at all points throughout the production process.
8. Planting, cultivation, and harvesting equipment shall be cleaned to prevent H7-1 stecklings or seed from being physically transferred out of production areas or mixed with non-GE *Beta* material by inadvertent means.
9. All unused H7-1 stecklings shall be treated as regulated articles until devitalized and discarded.
10. All H7-1 seed and steckling material shall be moved in contained transport systems to avoid inadvertent release into the environment. Vehicles or movement containers shall be thoroughly cleaned after transport and any regulated material recovered shall be devitalized.
11. Sexually compatible varieties (e.g. chard/red beet) cannot be planted or produced in the same location (the same field) as H7-1 in the same growing year.
12. Planting/cultivating/harvesting equipment that might be used in chard/red beet seed production shall not be used for regulated GE material in the same growing year.
13. Measures to force same year sprouting of H7-1 seed left in production fields are required. Any seed which sprout from such leftover seed shall be destroyed. Fields shall be monitored for three years and any volunteer beet plants shall be destroyed. If the same land is used for crop cultivation during the three-year volunteer monitoring period, that crop shall be visually distinct from sugar beets or the fields left fallow.
14. A management plan shall be submitted and followed. The management plan will set forth best practices for oversight of the movement, transportation, and confined field production of H7-1 seed. The management plan shall include, but not be limited to, required resources, training of relevant personnel, monitoring of growers, record keeping, and verifying compliance with the permit conditions. The applicant shall also provide the SOPs that will be utilized to conduct the field trials and comply with the permit and permit conditions.
15. No H7-1 seed shall be cleaned or processed in any processing facility that also cleans and processes red beet or Swiss chard seed.
16. Interstate movement of H7-1 sugar beet stecklings and seed may only be authorized with a movement notification or permit consistent with regulations described in 7 CFR 340.

17. The applicant shall ensure that all site cooperators/growers have received the permit conditions and are trained in all the processes and procedures.
18. The applicant shall maintain records of all the activities authorized under the permit to demonstrate adherence to 7 CFR 340, the permit, and the permit conditions. These records shall be made available to APHIS/BRS.

Specific Permit Request.

APHIS has received a permit application from American Crystal Sugar Company is requesting APHIS to authorize the environmental release of H7-1 sugar beet seeds/stecklings for H7-1 seed production in Oregon.

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 for a Part 340 permit and/or notification for seed production activities submitted by the applicant is consistent with all of the required conditions and provisions required by APHIS' Determination Decision and indentified within the scope of and evaluated by the Final EA and FONSI. Therefore, APHIS has determined that approving this part 340 permit application and/or notification is consistent with APHIS' Determination Decision, 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 permit and/or notification.

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

2/18/2011
DATE

Done at :(City, State) Riverdale, Maryland