

APHIS Determination Decision regarding the Petition for Partial Non-Regulated status for Monsanto/KWS glyphosate tolerant (Roundup Ready®) H7-1 sugar beets (a “Partial, i.e., Conditional, Deregulation”)

Introduction and Summary of Decision

The Animal and Plant Health Inspection Service (APHIS) is issuing a Determination Decision to partially deregulate H7-1 sugar beets with conditions for root crop production and to allow seed production under 7 C.F.R. Part 340 (Decision). This decision is in response to a petition for partial deregulation submitted to APHIS by Monsanto Company and KWS SAAT AG (Petitioners) on July 29, 2010.

Monsanto/KWS’ event H7-1 sugar beet is unlikely to present a plant pest risk when it is grown for commercial root production under the specific mandatory conditions required and imposed by APHIS in this Decision. Therefore, APHIS has determined that H7-1 commercial root crop, if grown under these specific mandatory conditions, should be granted “non-regulated status in part” pursuant to 7 CFR 340.6. As a result of this determination, the H7-1 root crop will not be considered a regulated article under APHIS’s biotechnology regulations at 7 CFR part 340 and will not be subject to the requirements of those regulations for the duration of this interim action, as long as the activities pertaining to root crop production are conducted in compliance with the mandatory conditions that are imposed and enforced by APHIS in this Decision. This Decision and agency action represents an interim measure and will not extend beyond December 2012.

Background

In 1987, APHIS promulgated its biotechnology regulations (7 CFR Part 340, referred to hereafter as the Part 340 regulations) under the authority of the Federal Plant Pest Act (FPPA) and the Plant Quarantine Act (PQA) to address potential risks that certain genetically engineered (GE) organisms might pose as plant pests.¹ The Part 340 regulations refer to such GE organisms as "regulated articles." A "regulated article" is defined as: "Any organism which has been altered or produced through genetic engineering, if the

¹ The FPPA and PQA were consolidated along with other statutory authorities into the Plant Protection Act of 2000 (PPA), in which Congress found that: “it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests . . . in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests . . . ; decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science”

The PPA defines a plant pest as:

PLANT PEST.—The term “plant pest” means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

- (A) A protozoan.
- (B) A nonhuman animal.
- (C) A parasitic plant.
- (D) A bacterium.
- (E) A fungus.
- (F) A virus or viroid.
- (G) An infectious agent or other pathogen.
- (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

7 U.S.C. §7702(14).

donor organism, recipient organism, or vector or vector agent belongs to any genera taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." 7 CFR 340.0.

The Part 340 regulations were amended in 1993 to provide a procedure for the release from regulation of plants which do not present a plant pest risk. 7 CFR 340.6, which is entitled: "Petition for determination of nonregulated status," describes the petition process, the data requirements, and actions that the Administrator may take in response to a petition. It is under this procedure that APHIS received the petition to grant partial non-regulated status with conditions to event H7-1 sugar beets.

Monsanto Company and KWS SAAT AG submitted a petition (dated 7/29/2010 and posted on APHIS-BRS' website at: http://www.aphis.usda.gov/brs/aphisdocs2/03_32301p_a1.pdf) pursuant to 7 CFR 340.6. The petition specifically requested a "partial deregulation" or similar administrative action regarding Petitioners' genetically engineered Roundup Ready® sugar beet (RRSB) event H7-1.

In a draft Environmental Assessment for the Partial Deregulation of event H7-1 sugar beets issued by APHIS on November 4, 2010 (Draft EA), APHIS stated that Monsanto/KWS' petition to partially deregulate their genetically engineered event H7-1 sugar beets did not clearly explain what the Petitioners meant and envisioned by their petition for a "partial deregulation." See Draft EA at p. 4. APHIS explained that the Petitioners did not identify any specific mechanism(s) that could or would be used to impose the mandatory conditions to prevent any potential plant pest risks that might result from the complete cultivation process (seed development and research, producing seed for root production, root and seed planting, harvesting and processing, etc.) for event H7-1 sugar beets. APHIS also explained that petitioners did not identify specific parties or entities who would be subject to those mandatory conditions, or how compliance with those mandatory conditions would be ensured. APHIS stated that it interpreted the Petition for Partial Deregulation to be a request that event H7-1 sugar beets would no longer be regulated under 7 CFR Part 340 provided that they are cultivated under the mandatory conditions and interim measures that APHIS had proposed to the United States District Court in previous litigation related to event H7-1 sugar beets.

APHIS further stated that it interpreted Monsanto/KWS' Petition for Partial Deregulation to request that the mandatory conditions imposed on the cultivation and production of event H7-1 sugar beets would be complied with and enforced by the responsible parties who cultivate event H7-1 sugar beets. In other words, the major entities, associations, and cooperatives that produce and/or grow H7-1 sugar beets seed and root crops would be responsible for overseeing implementation and monitoring of the mandatory conditions for such cultivation.

In response to Monsanto/KWS' Petition for Partial Deregulation, APHIS explained that in its view an interim partial deregulation would mean that event H7-1 sugar beets would no longer be regulated under 7 CFR Part 340 and that the cultivation of event H7-1 sugar beets (both root and seed production activities) would be allowed under mandatory conditions imposed by Monsanto/KWS (and/or other entities) through

technology stewardship agreements, contracts, or other legal instruments between Monsanto/KWS or any other entity, association, or cooperative involved in the business of producing or growing event H7-1 sugar beets root or seed crops.

Monsanto sent APHIS a four-page explanation response (response) on November 18, 2010, which was received within the 30 day public comment period for the draft EA.² In its November 18, 2010 response, Monsanto explained:

We submit this initial comment to address an apparent misimpression by APHIS that, under a “partial deregulation” (deregulation “in part” with conditions), APHIS would rely for enforcement on the terms of existing agreements between Monsanto/KWS and growers or seed companies. To the contrary, we contemplate (and have previously proposed) that APHIS would have direct authority over growers of Roundup Ready® sugar beets (RRSB) under partial deregulation, as set forth below. This is consistent with the Supreme Court’s 2010 opinion in *Monsanto Co. v. Geertson Seed Farms* and would allow APHIS to exercise its statutory authority to require and enforce the types of cultivation requirements discussed in its Draft Environmental Assessment (EA). We continue to believe that a partial deregulation is the best and most practical option for addressing the continued cultivation and use of Roundup Ready sugar beets, which will be critical to ensure a sufficient supply of domestic sugar.

See Monsanto’s November 18, 2010 response at page 1.

In light of Petitioners’ clarification of their Petition for a Partial Deregulation of both the root and seed crop production activities and their explanation of what they view as a Partial Deregulation of event H7-1 sugar beets, APHIS has decided to grant the Petition as requested “in part” pursuant to 7 CFR 340.6(d)(3)(i).

It is important to note that in choosing the Preferred Alternative, APHIS has decided only to grant the Petition for Partial Deregulation “in part.” With regard to seed crop production activities, APHIS chooses Alternative 2, and, with regard to root crop production activities, APHIS chooses Alternative 3 with a modification. This Decision is fully described and explained in the Final EA, the FONSI, and this Determination Decision. Finally, it is important to note that this Determination Decision is conditional in nature. In other words, the APHIS Administrator reserves her authority to revoke, withdraw, or revise any part of this Decision in the event that commercial root production activities are not carried out in full compliance with the mandatory conditions imposed in this Decision or for any other reason within the Administrator’s authority and discretion. Likewise, the APHIS Administrator reserves her authority to revoke, withdraw, or revise any part of this Decision in the event that commercial seed production activities are not carried out in full compliance with the mandatory conditions imposed by Part 340 regulations pursuant to this Decision or for any other reason within the Administrator’s authority and discretion.

APHIS’ Decision With Respect to the interim Partial Deregulation of the H7-1 Root Crop

Monsanto/KWS’ event H7-1 sugar beet is unlikely to present a plant pest risk when it is grown for commercial root production under the specific mandatory conditions required and imposed by APHIS in this Decision. As a result of this determination, the H7-1 root crop will not be considered a regulated article

² The public comment period for the draft EA concluded on December 6, 2010.

under APHIS's biotechnology regulations at 7 CFR part 340 and will not be subject to the requirements of those regulations for the duration of this interim action as long as the activities pertaining to the root crop production are conducted in compliance with these mandatory conditions which will be enforced by APHIS. Accordingly, permits or acknowledged notifications that were previously required for release into the environment, interstate movement, or importation under APHIS' part 340 biotechnology regulations will not be required for the cultivation/production of Monsanto/KWS H7-1 sugar beet root crop grown under these mandatory conditions for the duration of this interim action, that is, no longer than December 2012.

If commercial root production activities are not carried out in full compliance with these mandatory conditions, the APHIS Administrator has the authority to return any such non-compliant root production activity to regulation under the Part 340 regulations or impose any other measures or restrictions as the Administrator considers appropriate and necessary. Any root production activities that are brought back under the Part 340 regulations pursuant to an order or other administrative action by the Administrator shall be subject to the regulations and requirements of Part 340 or any other measures or restrictions as the Administrator considers appropriate and necessary. In addition to having the authority and discretion to return to regulated status any "non-compliant" root production activity (i.e., any root production activity that is contrary to or in violation of any of the mandatory terms and conditions of the interim Partial Deregulation as enumerated in the compliance agreements described below), the APHIS Administrator has the ability to impose any of the enforcement and remedial authorities available in the PPA in response to non-compliant root production activities, including the authority to seek criminal and civil penalties, or to order the seizure, quarantine, and/or destruction of plants, plant products, or articles.

APHIS' Decision With Respect to the interim Partial deregulation of the H7-1 Seed Crop

APHIS has also determined that, at this time, the cultivation/production of the H7-1 sugar beet seed crop (seed production activities) must remain regulated under the APHIS Part 340 regulations and shall not be in the interim "partially deregulated with or without conditions." Thus, the Petition for the Partial Deregulation of event H7-1 sugar beets is *not* granted in reference to seed production activities. The event H7-1 sugar beets seed production activities shall remain subject to the Part 340 regulations and must be permitted or acknowledged (notifications) as required by Part 340 since APHIS has decided that seed crop production activities must remain regulated under the Part 340 regulations. Additionally, the importation of seeds and other propagative material will still be subject to APHIS foreign quarantine notices under other APHIS regulations.

Bases for Decision

This Determination Decision for the "Partial Deregulation with conditions for root production but not for seed production" is based on APHIS' reviews, evaluations, and analyses of field, greenhouse, and laboratory data, references provided in the original petition (03-323-01p), information provided by Monsanto in its July 2010 request for Partial Deregulation and other data or information or comments submitted by Monsanto, other relevant information and data as described in the Plant Pest Risk Assessment (PPRA) for H7-1 sugar beet, the Final Environmental Assessment, the FONSI, and in APHIS's Response to Public Comments on the Draft EA. All of these materials with their data, analyses, evaluations, and conclusions indicate that event H7-1 sugar beets, when grown commercially for root production under mandatory, enforceable, conditions, is unlikely to pose a plant pest risk in the interim while APHIS prepares an Environmental Impact Statement (EIS) for its Determination on whether or not to grant a Full Deregulation for Event H7-1 sugar beet.

The Plant Pest Risk Assessment (http://www.aphis.usda.gov/brs/not_reg.html) concluded that glyphosate tolerant H7-1 sugar beet, when grown in commercial beet fields for root production under mandatory conditions, is not likely to pose a plant pest risk and should accordingly be granted an interim nonregulated status for the following reasons:

(1) H7-1 sugar beets exhibit no plant pathogenic properties. Although a plant pathogen was used in the development of H7-1 sugar beets, these plants are not infected by this organism nor do they contain genetic material from pathogens used as a donor organism that can cause plant disease. No new protein other than the intended CP4 EPSPS was produced and there was no unintended change in the genome of H7-1 sugar beet as a result of the insertion.

(2) H7-1 sugar beets exhibit no characteristics that would cause them to be weedier than the non-transgenic parent sugar beets or other cultivated sugar beets and several control options besides glyphosate are available for control of feral or volunteer plants.

(3) Gene flow and introgression from H7-1 root crop to introduced or naturalized *Beta* species in the United States, when grown under mandatory conditions contained in compliance agreements is extremely unlikely and even if it were to occur, is not likely to increase the weediness potential of any resulting progeny any more than would introgression from other cultivated *Beta* species. Prohibitions on growing H7-1 in several counties in Washington State where sexually compatible relatives, Swiss chard and table beets, are grown for and/or produce seed and in California where sexually compatible relatives may produce seed, preclude this from occurring. Additionally, removal of bolters in commercial fields, as required under the mandatory compliance agreements, eliminates the possibility of pollen production.

(4) Horizontal gene transfer from the H7-1 root crop is highly unlikely to occur, and is not expected to pose a plant pest risk.

(5) Disease and pest susceptibility and compositional profiles of H7-1 are similar to those of the parent variety and other sugar beet cultivars grown in the United States; therefore, pest and disease control methods are expected to be similar and no direct or indirect plant pest effect on raw or processed plant commodity is expected.

In addition, APHIS has completed a Final Environmental Assessment (EA) and has determined that this Decision granting the Petition on an interim basis “in part” (partial deregulation of root production activities but not seed production activities) as described herein will have no significant impact, individually or cumulatively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitat (http://www.aphis.usda.gov/brs/not_reg.html). APHIS also concludes that under the mandatory conditions of the partial deregulation for root crop production activities, H7-1 sugar beets are unlikely to exhibit new plant pest properties, different from any observed for conventional sugar beet varieties not considered regulated articles under 7 CFR part 340.

APHIS-BRS, in its PPRA, has resolved any potential plant pest risk issues associated with commercial event H7-1 root production activities conducted under the mandatory, enforceable conditions described in this Decision. APHIS-BRS will ensure that the conditions imposed by APHIS on event H7-1 sugar beets root production activities are enforced through written, enforceable compliance agreements. The use of these compliance agreements with mandatory conditions will ensure that the interim partial deregulation of root crop activities will not have any significant environmental impacts on the human environment.

Further, APHIS has determined that the granting of the partial deregulation of the H7-1 root production activities conditioned upon the use of enforceable compliance agreements with mandatory conditions will effectively prevent the potential economic or marketing impacts raised as a possible concern by the United States District Court for the Northern District of California in its decision dated September 21, 2009 (*Center for Food Safety et al. v. Thomas Vilsack et al.*), during the interim period that this Decision remains in effect, namely, no longer than December 2012. Only after APHIS completes its EIS and more completely and fully analyzes the potential environmental impacts of Petitioners' request for a Full Deregulation of event H7-1 sugar beets, along with the Final PPRA for a Full Deregulation of event H7-1 sugar beets, will APHIS ultimately decide the appropriate agency action on whether or not to grant the Petition for a Full Deregulation to H7-1 sugar beets.

APHIS' Preferred Alternative is an interim Partial Deregulation – a Combination of Alternatives 2 and 3.

APHIS has determined that its Preferred Alternative is to partially deregulate H7-1 sugar beet root production activities but impose mandatory conditions on those activities and not to partially deregulate seed crop production activities but rather to allow seed production activities to be conducted under the regulatory requirements of 7 C.F.R. Part 340. This Preferred Alternative combines the administrative aspects of Alternatives 2 and 3 as described in detail in the Draft EA. So, with regard to seed crop production activities, APHIS chooses Alternative 2 and, with regard to root crop production activities, APHIS chooses Alternative 3 with a modification. This Preferred Alternative represents a rational and reasonable choice that was suggested by commenters and is a logical outgrowth of Alternatives 2 and 3. The Preferred Alternative simply incorporates specific aspects of both Alternatives 2 and 3. All of the specific aspects of Alternatives 2 and 3 were fully evaluated and analyzed for any potential environmental impacts that might result from their possible implementation in the draft EA. The environmental analyses for Alternatives 2 and 3 in the draft EA are fully and completely applicable to those same aspects now incorporated into the Preferred Alternative.

APHIS has completed a Plant Pest Risk Assessment and determined that H7-1 sugar beet root production activities, if conducted under mandatory conditions, and conducted as an interim action until an EIS is completed, do not pose a plant pest risk and, therefore, should not be subject to the procedural and substantive requirements of 7 C.F.R. Part 340 for the duration of this interim action. APHIS has determined that its use of compliance agreements under its PPA authorities is an appropriate and effective regulatory mechanism to enforce the conditions for partial deregulation of root crop production activities and also to ensure complete compliance with those mandatory conditions. A compliance agreement is a regulatory mechanism to authorize actions and to enforce compliance with those actions under the PPA, similar to a permit. Compliance agreements will authorize root crop production activities under the PPA and impose mandatory conditions that must be followed as a condition of the granting of the partial deregulation for root crop production activities. Compliance agreements are well established in APHIS regulatory programs as an effective and efficient regulatory mechanism to authorize and ensure compliance with activities allowed under the PPA and they are used to maintain regulatory oversight by imposing conditions on those authorized activities. APHIS expects that sugar beet cooperatives and processors (or other associations or organizations that conduct Event H7-1 sugar beet root crop production activities) will be the only entities that will enter into compliance agreements and do so on behalf of their respective members/farmers.

Under this Preferred Alternative, H7-1 sugar beet seed crop production activities are not partially deregulated but rather, they remain regulated pursuant to Part 340 and subject to Part 340 permit and notification requirements for importation, interstate movement and release into the environment.

Under this Preferred Alternative, pursuant to 7 C.F.R. Part 340.6, APHIS would, on an interim basis, partially deregulate H7-1 sugar beets by removing the H7-1 sugar beet root production activities from regulation under the 7 CFR Part 340, but only if the root crop is grown under mandatory conditions enforceable by APHIS. In other words, if the H7-1 sugar beet root crop is grown under certain conditions, it shall not be considered a regulated article under 7 C.F.R. Part 340 and will not be subject to the permitting and notification or other requirements for interstate movement and release into the environment for the duration of this interim action, namely, no longer than December 2012. Accordingly, the H7-1 sugar beet root production activities conducted pursuant to the APHIS conditions will be deregulated because APHIS, in its plant pest risk assessment of the H7-1 sugar beet root crop, has evaluated, analyzed, and concluded that the interstate movement and the environmental release of root production activities (e.g., the planting, harvesting, storage, and moving for processing into sugar) under mandatory conditions imposed by APHIS-BRS are unlikely to pose a plant pest risk (USDA-APHIS 2011).

The conditions that must be complied with in order to be granted a partial deregulation of event H7-1 sugar beets root production activities will be clearly listed in the compliance agreements. By means of these written compliance agreements, APHIS will formalize and impose the mandatory conditions under which the root production activities will be considered partially and conditionally deregulated for the duration of this interim action. By means of these compliance agreements APHIS will require conditions on the import, movement or environmental release of root production activities. These compliance agreements will be a signed, legally binding agreement between APHIS and a person who wants to import, move, and/or do an environmental release in conjunction with H7-1 sugar beet root production activities. APHIS expects that sugar beet cooperatives and processors (or other associations or organizations that conduct Event H7-1 sugar beet root crop production activities) will enter into compliance agreements on behalf of respective members/farmers. APHIS wants the public to understand that the movement and the environmental release of root production activities include the entire production cycle of the H7-1 sugar beet root crop activities, including, among other things, obtaining seed for planting, planting, harvesting, storage, and movement to be processed into sugar; and also that the terms “person,” “import,” and “move,” and “movement” used above have the meanings as they are so defined in the PPA.

Under this Preferred Alternative, the mandatory conditions and restrictions are quite similar to and consistent with the conditions that APHIS had previously proposed to the Court in litigation challenging the 2005 deregulation of H7-1 sugar beets. These conditions must be complied with in order for someone to be allowed to carry out H7-1 sugar beet root production activities with nonregulated status. APHIS inspections and/or third party inspections/audits will be required to ensure that persons importing, moving, and/or doing an environmental release (planting, etc.) in conjunction with H7-1 sugar beet root crop production activities comply with the conditions and restrictions imposed by APHIS’ granting of the partial deregulation and identified in the compliance agreements. Under the Preferred Alternative, the compliance agreements will be enforced under the authority of the PPA and 7 CFR Part 340. If APHIS determines that any of the mandatory conditions of the partial deregulation set forth in the compliance agreements are not complied with, APHIS has the discretion as its determines is necessary and appropriate to revoke, withdraw, or

otherwise cancel the conditional partial deregulation for commercial root crop production activities. Further, APHIS may use the full range of its PPA authorities to seek, as appropriate and necessary, criminal and/or civil penalties, and to take remedial measures including seizure, quarantine, and /or destruction of any root crop or root crop production activity that is in violation of the mandatory conditions of the partial deregulation.

The Action decided, authorized, and taken by APHIS under the Preferred Alternative is only an interim action which is limited in scope and duration and will terminate by December 2012. APHIS has determined that this interim action will neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS for a determination on whether or not to grant a Full Deregulation of H7-1 sugar beets.

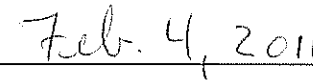
APHIS Administrator's Conclusion

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Comments received in reference to the Draft EA, the FONSI, and my knowledge and experience as the Administrator of APHIS, I have determined and decided that the Preferred Alternative as described and explained in the Final EA, the FONSI, and in this Determination Decision is the most scientifically sound and regulatory appropriate alternative in response to Monsanto/KWS' Petition for a Partial Deregulation with Conditions imposed and enforced by APHIS.

Signed this Date in Washington, DC



Cindy J. Smith
Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture



Date