

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NOV 22 2011

Dr. J. Austin Burns
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63137

Subject: MON 89034 x TC1507 x MON 88017 x DAS-59122-7 and MON 89034 x TC1507 x MON 88017 x DAS-59122-7 RIB Complete™ June 10, 2011 and October 27, 2011 Applications to Amend the Expiration Date for Monsanto SmartStax Products EPA Registration Nos. ~~524-581~~ and 524-595

Dear Dr. Burns:

The amendments referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable subject to the following terms and conditions.

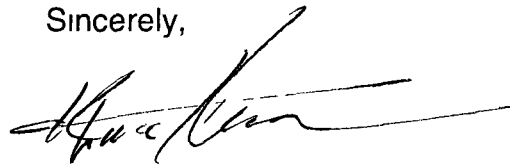
- 1) The expiration date for these products is November 30, 2013.
- 2) The Agency recognizes that large corn rootworm populations, environmental conditions, and protein expression levels can influence corn root damage and may affect the definition of suspected CRW resistance. The Agency plans to work with the registrants to refine the definition of suspected resistance based on these factors. Until such time that the Agency accepts a modified definition of suspected resistance to corn rootworm, resistance will be suspected in cases where the average root damage in the SmartStax field is > 0.5 on the nodal injury scale (NIS) and the frequency of SmartStax with > 0.5 nodes destroyed exceeds 50% of the sampled plants.
- 3) Within 90 days of this amendment, you must submit an enhanced rootworm resistance monitoring plan for SmartStax that accounts for reports of suspected and/or confirmed resistance. The rootworm resistance monitoring plan and the revised definitions for suspected and confirmed resistance for SmartStax must be found acceptable to BPPD by May 1, 2012 and utilized by Monsanto beginning in the 2012 season. This enhanced monitoring program should:

- o Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to SmartStax;
 - o Be focused on areas where the potential for resistance is greatest for SmartStax and for the corn rootworm active single event components of SmartStax (Cry3Bb1 and Cry34Ab1/Cry35Ab1), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g. crop rotation versus continuous corn), and academic and extension publications on Bt corn field performance;
 - o Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, other registrants of SmartStax, and other registrants of similar products, as appropriate;
 - o Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient(s), as well as to publicly available reports of suspected or confirmed resistance to other *Bt* protein toxins in SmartStax.
- 4) Within 90 days of this amendment, you must submit an enhanced remedial action plan for SmartStax that includes actions to be taken in response to both suspected and confirmed resistance. This remedial action plan must include a description of steps to be taken in response to customer product performance inquiries and annual reporting to the agency on the outcomes of investigations into any such inquiries that might indicate potential resistance. The program must include revised definitions of unexpected damage to SmartStax corn that could indicate potential suspected resistance. The enhanced remedial action plan must be found acceptable to BPPD by May 1, 2012.
- 5) The Grower Guide or its supplements must include language directing the user to contact a company representative if they observe unexpected insect feeding damage to their SmartStax corn. As part of its follow up on reports of unexpected damage to SmartStax corn, the registrant must determine the nodal injury scale (NIS) of affected corn. If the NIS results fall within the definition of suspected resistance for SmartStax, then until such time as the Agency accepts a modified remedial action plan, the registrant must provide specific guidance to affected growers in managing corn rootworms in the affected fields. This will include 1) providing specific grower guidance to control the adult stage of corn rootworms, where adult beetles are still present and

laying eggs during the season that unexpected damage meets the suspected resistance definition, and 2) where the grower continues to be an existing customer of the registrant or seed company licensee into the following season, providing specific grower guidance and assistance to use an additional or alternative pest control method during the season following the initial finding that unexpected damage meets the suspected resistance definition

- 6) Monsanto will submit additional modeling, scientific literature, and other scientific information addressing the impact of pyramid PIP use in areas of confirmed resistance to one of the rootworm-active components of the pyramid by August 30, 2012
- 7) Should resistance to any of the constituent toxins of SmartStax be confirmed (from target pest populations collected in 2012 or prior growing seasons) in accordance with the existing definition of "confirmed resistance" for the appropriate toxin, EPA will reassess and, if EPA concludes it is necessary, Monsanto will revise the refuge/seed blend requirements for SmartStax. The registrants may independently submit updated definitions of confirmed resistance for their respective SmartStax active proteins for EPA's consideration in order to harmonize and/or keep definitions current with scientific standards, any such submission must be found acceptable to BPPD by May 1, 2012. EPA will incorporate all relevant scientific information (including the data required above) in its reassessment of the refuge/seed blend requirements. The revised refuge/seed blend requirements will be effective for the following growing season (after resistance confirmation) in the geographic areas in which resistance was confirmed. The geographic area of confirmed resistance could be less than a single county, a single county, or multiple counties, depending on EPA's analysis of the collected data.
- 8) For the SmartStax block refuge products, submit a revised Compliance Assurance plan by February 28, 2012

Sincerely,



Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure