

PEER REVIEW PLAN

Title:

Human health and ecological risk assessments for SmartStax PRO (MON 89034 x TC1507 x MON 87411 x DAS-59122-7), a plant-incorporated protectant intended to control corn rootworm through ribonucleic acid (RNA) interference

Purpose/Objective:

Earlier this year, EPA received applications from Monsanto Company and Dow AgroSciences, LLC, requesting registration of commercial release RNAi PIPs expressing DvSnf7 dsRNA and known by the name SmartStax PRO. SmartStax PRO also expresses several Bt insecticidal Cry proteins.

Product Completion Date (Projected):

06/08/2017

OMB Category:

Influential

Peer Review Leader:

Anna Lowit
email: lowit.anna@epa.gov

External Peer Review Mechanism:

FIFRA Science Advisory Panel (SAP)

Peer Review Expected to Begin:

4th Quarter, Fiscal Year 2016

EPA's Fiscal Years run from October to September.
Quarters for Fiscal Year 2016:
1st: October - December, 2015
2nd: January - March, 2016
3rd: April - June, 2016
4th: July - September, 2016

Was a deferral to peer review invoked?

No

Will an alternative peer review process be employed?

No

Number of Peer Reviewers

more than 10

Primary Disciplines needed in the review:

Biology-Entomology, Biology-Molecular,
Risk Assessment-Ecological, Risk
Assessment-Human Health

Who will select the reviewers?

EPA

Will the public, including scientific or professional societies be asked to nominate peer reviewers?	Yes
Will public nominations be allowed through the Peer Review Agenda?	No
Will there be opportunity for public comment on the product?	Yes
Describe How and When	<p>The Agency encourages written comments be submitted on or before September 13, 2016, to provide adequate time for the FIFRA SAP to review and consider the comments. The Agency encourages requests for oral comments be submitted on or before September 20, 2016. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after September 13, 2016, should contact the Designated Federal Official (DFO). Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2016-0349, by one of the following methods:</p> <ul style="list-style-type: none"> â€ Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. â€ Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001. â€ Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.
Will the Agency provide significant and relevant public comments to the peer reviewers before they conduct their review?	Yes
Will the review be a panel, conducted in public?	Yes
Will public comments be allowed at the panel review?	Yes