Dear Dr. Owens:

We are writing to initiate discussions with Bt corn registrants (via the Agricultural Biotechnology Stewardship Technical Committee) on improvements to corn rootworm resistance management. As you are aware, ABSTC and EPA share a common interest in preserving the durability of Bt corn traits to control corn rootworm. Along these lines, the Agency convened a Science Advisory Panel (SAP) meeting in December 2013 to address scientific uncertainties associated with corn rootworm resistance monitoring. These discussions will follow from the recommendations made by the panel in its report dated March 5, 2014.

To aid in starting the discussions, the Agency is enclosing a set of proposals developed by the Biopesticides and Pollution Prevention Division to enhance current resistance management and monitoring programs for corn rootworm. These proposals are consistent with the SAP’s guidance and cover five aspects of IRM, including the following:

- Integrated Pest Management (IPM) as a component of corn rootworm resistance management
- Responses to unexpected damage in Bt corn fields
- Elimination of the requirement for annual random sampling of corn rootworm from the Corn Belt
- Use of on-plant assays for resistance determinations
- Enhancements to current remedial action plans

The Agency’s goal is to have improvements in place for the 2015 growing season. To meet this goal, we are asking that you submit a response to the attached proposal by September 21, 2014. EPA would like to finalize the agreement/enhancements to the affected Bt corn products by October 31, 2014.
If you would like to schedule a meeting to discuss this further after you've responded to our proposal, or if you have any questions or concerns, please contact Alan Reynolds (reynolds.alan@epa.gov; 703-605-0515).

Sincerely,

[Signature]

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticide and Pollution Prevention Division

Enclosure
EPA Framework for PIP Registrants:
Proposal to Address Key SAP Recommendations for Corn Rootworm (CRW) IRM
Draft Date: 8/27/14

Overall Goal: BPPD has identified five areas of improvement for corn rootworm resistance management. These measures are needed to increase the durability of CRW Bt PIPs (so as to reduce the potential need for remediation), and to improve on current abilities to detect and respond to cases of resistance. BPPD is targeting these improvements to be in place for the 2015 growing season.

1) Utilize an IPM approach to CRW resistance management

- Rationale:
  o Given the documented cases of field resistance to some Bt traits, refuge alone has not been sufficient to manage CRW resistance to Bt corn;
  o The SAP concluded (and EPA agrees) that sound IPM practices may reduce the potential for resistance (and hence remediation).
- Goals:
  o IPM stewardship program. Registrants must supplement IRM (refuges) with IPM techniques. This can be implemented by registrants as a stewardship program as part of the terms of registration that must include the following specific IPM approaches:
    ▪ Crop rotation with no more than two consecutive years of Bt corn (preferably rotating to soybean). Rotation can be accomplished on a farm-wide basis or field-by-field within a farm;
    ▪ Use of multiple Bt modes of action for CRW control, preferably in pyramided varieties (4 Bt PIPs are currently registered: Cry3Bb1, Cry34/35, mCry3A, and eCry3.1Ab); AND
    ▪ Use of non-Bt (conventional) corn with insecticide use for CRW management;
  o Adoption targets. The stewardship program must establish adoption targets for the IPM elements (i.e., % of growers and total corn acres planted with each company’s seed using each IPM approach), as defined below. A two tier system is envisioned, with separate targets for high risk areas (i.e., the “Red Zone”) and lower risk areas (i.e., the “fringe” of the Corn Belt).

<table>
<thead>
<tr>
<th>Tactic</th>
<th>IPM Adoption (% of total acres)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Risk Areas</td>
</tr>
<tr>
<td>Overall Participation</td>
<td>70</td>
</tr>
<tr>
<td>Tactics to be used among IPM participants:</td>
<td></td>
</tr>
<tr>
<td>- Crop rotation</td>
<td>50</td>
</tr>
<tr>
<td>- Multiple modes of action/pyramids</td>
<td>25</td>
</tr>
<tr>
<td>- Non-Bt corn w/SAI</td>
<td>25</td>
</tr>
<tr>
<td>Use of single toxin PIPs</td>
<td>No more than 10%</td>
</tr>
</tbody>
</table>
- **Annual reporting.** The program would require annual reporting to EPA of success in meeting the IPM targets (i.e., how many growers chose to implement crop rotation, pyramids, etc.). Each company would report data individually based for their customers (surveys could be conducted similar to those done for refuge compliance). BPPD will analyze the reports and tabulate data across the industry as a whole;

- **Single trait PIPs.** The stewardship program and reporting must include information on progress towards replacement of single-trait CRW commercial PIP products;
  - Non-starter:
    - **Soil-applied insecticides (SAI).** SAI must be prohibited from use in combination with Bt corn for controlling corn rootworm. This can be done via bag tag language, grower guides, and terms of registration.
  - **Challenges to be addressed:**
    - Need for coordination between companies, particularly among growers who may purchase seed from more than one company (a program analogous to the existing compliance assurance program could address this challenge);
    - Need for means to address neighboring farms;
    - Implementation of SAI prohibition.

2) **Implement a proactive strategy to detect unexpected damage (UXD) in Bt corn fields**

- **Rationale:**
  - UXD is the first real indicator of potential resistance;
  - Cases of resistance to date have been documented by collecting CRW from damaged fields;
  - Effective and timely responses to UXD may aid remediation (if resistant CRW are responsible).
- **Goals:**
  - **Damage thresholds.** Revise terms and conditions to require the use of damage thresholds to trigger CRW sampling for resistance determinations: 1.0 Node Injury Score (NIS) for single traits and 0.5 NIS for pyramids;
  - **Adult collection.** Revise term and conditions to require collection of adults from the damaged site (or same field if collections are delayed that season) and that those adults be tested for resistance with on-plant assays (see #4 below);
  - **Immediate implementation of BMPs.** Revise terms and conditions to require, in cases of UXD, that BMPs be implemented immediately (i.e., before resistance confirmation) to mitigate the spread of a potentially resistant population. BMPs are essentially the same IPM practices that were detailed in #1 above but may include beetle bombing to reduce egg laying the next year.
  - **Target adoption level for BMPs.** At least 75%, similar to the IPM targets for high risk areas in #1 above.
- **Challenges to be addressed:**
  - Many elements are currently in place (e.g., damage triggers and BMPs for UXD) but there is a need for standardization across the industry;
o Need for improvement of detection capabilities in high risk areas - better scouting, possibly involving crop consultants, university extension personnel, company representatives (registrants currently rely solely on growers to report UXD);

o Mechanism for reporting UXD cases and their resolution to EPA. One possible tool could be to use EPA’s Central Data Exchange (CDX). CDX is a secure means to report information to EPA (used in the Air program) and could be used to tabulate UXD damage reports by toxin and geographic location. This information could be used in inform remedial action strategies (see #5 below).

3) Remove requirement for annual monitoring of CRW populations randomly sampled from the Corn Belt

- Rationale:
  o EPA has concluded that data aren’t meaningful unless populations are tracked over time;
  o Panel recommended tracking individual populations or discrete geographic locations based on high risk factors, but such tracking will be inefficient and unlikely to detect resistance before field failure;
  o BPPD believes it will be more effective to focus instead on proactive detection and response to UXD (#2 above).

- Goals:
  o Industry to modify terms of registration to remove annual sampling requirements (coupled with improvements to UXD scouting detailed in #2 above).

4) Improve resistance confirmation process by replacing artificial diet bioassays with “on-plant” assays

- Rationale:
  o EPA has concluded that diet bioassays have not been helpful for regulatory purposes – data are too variable to reliably draw conclusions about resistance;
  o EPA believes that on-plant assays represent a more realistic exposure scenario and can serve as a diagnostic tool;
  o EPA understands that two on-plant assays have been developed (with methodology in the public literature) to confirm resistance: single on-plant assay (Gassmann) and Sublethal Seedling assay (Pioneer).

- Goals:
  o Industry to modify terms of registration to mandate the use of an on-plant assay and resistance confirmation criteria;
  o Resistance is confirmed by comparing a population’s response on Bt vs. non-Bt corn and/or with a susceptible control population (2 statistically significant comparisons are needed to confirm resistance);

- Challenges to be addressed:
  o How to ensure consistent resistance determination standards with two separate assays (single on-plant vs. SSA);
  o Adaptation of the on-plant assays for the different registered Bt toxins, particularly the SSA which was developed for Cry34/35 corn;
5) Enhance current remedial action (RA) plans (in the event of documented resistance)

- **Rationale:**
  - The panel recommended that specific, implementable RA plans be developed prior to resistance confirmation (currently registrants are required to work with EPA to develop a plan ex post facto);
  - The goals of RA are to 1) contain (and extirpate if possible) resistant populations, and 2) preserve the durability of Bt CRW traits in areas where they are still effective.

- **Goals:**
  - **Remedial action plans.** Registrants must develop and submit RA plans to be in place prior to resistance development;
  - **Standards.** Remedial action plans must identify industry-wide standards as follows:
    - Timing: RA plan must ensure action (IPM-based BMPs from #2 above) occurs immediately in response to UXD (i.e., within the growing season) and should continue in subsequent seasons unless resistance is disconfirmed;
    - BMPs: RA plan must require the following specific steps taken for UXD and/or resistance:
      - Adult CRW treatment ("beetle bombing") in UXD damage fields (same season);
      - Crop rotation (preferred), use of alternate Bt modes of action, use of pyramided varieties, or non-Bt corn (with insecticides) in subsequent seasons;
    - Geography: RA plan must describe how to define the scope of RA. The RA area as defined in the plan must include not just the affected field but surrounding fields and farms within the dispersal range of CRW. (This could also be informed by UXD reports received by CDX – see #2 above).
  - **Data needs.** Additional research is needed to improve RA including CRW dispersal in simulation models to assess the potential spread of resistant populations and would entertain revised plans based on the results of any such research;
  - **Notification system.** RA plan must require cases of documented resistance to be publicly reported on web site (either by ABSTC, the individual company, or EPA). This would help growers make informed decisions about CRW management options.

- **Challenges to be addressed:**
  - Defining the remediation zone, which could involve multiple farms and customers from different registrants;
  - Need for coordination between companies;
  - Need for additional research to scientifically delineate remediation areas (the SAP also proposed a number of techniques to do this);
  - Encouraging growers to implement effective measures (e.g., crop rotation) that may differ from their farming practices.