

**Written Update for the October 14-15, 2009
PPDC Meeting on the
Plant-Incorporated Protectant (PIP) Data Requirements Proposed Rule**

EPA is preparing to propose a data requirements rule for plant-incorporated protectants (PIPs).

- Data requirements reflect the data and information necessary to support a regulatory decision on experimental use permits and commercial registrations for PIPs.
- This proposal is part of a larger effort to update and improve all of the data requirements for pesticide regulatory purposes.
- The Agency has updated data requirements for conventional (Oct 26, 2007), biochemical, and microbial pesticides in part 158 (Oct 26, 2007), and has proposed updated data requirements for antimicrobial pesticides in part 158 (Oct 8, 2008).

This rule will mostly codify existing data requirements that are currently applied on a case-by-case basis.

- These are not new data requirements, although new technologies and new methods to evaluate PIPs have been introduced since EPA began regulating these products in the 1980s.
- The Agency has been relying on the data requirements for microbial pesticides, mainly because the products we have seen to date have come from microorganisms (bacteria and plant viruses).
- The data requirements the Agency plans to propose will reflect current scientific knowledge and understanding and are also being written broadly enough to include consideration of what may be needed to assess a non-protein based PIP, such as RNAi.

The basic structure will encompass five categories of data and information: product characterization, human health, nontarget effects, environmental fate, and resistance management.

- Combination or stacked PIPs will be addressed through a synergy data requirement and guideline that was brought to the Scientific Advisory Panel (SAP) in February 2009.
- Gene flow will be receiving more attention, and we intend to ask the applicant to examine gene flow and weediness issues. Gene flow was also addressed at the February 2009 SAP.
- More information on the February SAP, including meeting minutes, can be found at <http://www.epa.gov/scipoly/sap/meetings/2009/022509meeting.htm>.

The Agency is also considering including a provision for a cisgenic PIP exemption.

- This provision would exempt from registration a PIP created by moving cisgenic genetic material between plants that can naturally interbreed.

BPPD is concurrently developing test guidelines that will go with the PIP data requirements.

- These guidelines will follow agreed upon international agreements, such as OECD and Codex.

- Some will also be based on existing EPA OPPTS harmonized guidelines as appropriate.
- The proposed data requirements and the guidelines will be available for public comment.

Schedule is as follows:

- A proposed rule is expected in late 2010.
- The Unified Agenda (also known as the Semiannual Regulatory Agenda) provides updates every six months (<http://www.gpoaccess.gov/ua/index.html>) on the status of this and other EPA rule makings.

Copies of pre-rule outreach the Agency has done on this rule will be available to the public by mid-October by visiting docket EPA-HQ-OPP-2009-0499.

- Access docket material through <http://www.regulations.gov>.