DEFINING "ECONOMIC MINOR USE" UNDER FIFRA 2(ll)(2)—Session VI

The Food Quality Protection Act (FQPA) of 1996 mandated a more coordinated approach for managing minor crop pesticides. Minor uses of pesticides are of 'major' significance in agricultural production and for protecting public health from disease vectors. Without these comparatively small-scale but vital pesticide uses, many of the fruits, vegetables and ornamentals enjoyed in the U.S. and valued at billions of dollars could not be grown successfully.

Minor uses of pesticides are those for which the total U.S. acreage for a particular crop/commodity is less than 300,000 acres - or- where the crop/commodity is grown on more than 300,000 acres and for which the pesticide use does not provide sufficient economic incentive to the registrant to support its registration. Thus, a minor use of a pesticide is not always economically attractive to the pesticide industry because the amount of pesticide sold for the use is limited and revenues may be low, while the costs to obtain and maintain registration are substantial. However, EPA – working cooperatively with the USDA – recognizes that a variety of pest management tools are needed in order to: produce and maintain a safe, dependable supply of fruits and vegetables; implement integrated pest management (IPM) programs; manage pest resistance; allow U.S. crop producers to compete effectively in a global food market; and, minimize global spread of pest-vectored public health diseases.

While the acreage part of the minor use definition is self-explanatory and requires no guidance, the economic incentive part of the definition is not. EPA's Office of Pesticide Programs (OPP) is now proposing guidance for how it will apply the FIFRA 2(ll)(2) part of the minor use definition to identify an *economic* minor use and establish a framework (described below) for making economic minor use determinations. OPP is also proposing to provide guidance on the data/information that OPP will need to receive/review and how requests for an economic minor use determination will be evaluated. [A copy of that draft guidance is attached.]

The goal of the minor use designation under FIFRA 2(ll)(2) is to provide incentives and/or reduce obstacles to the registration of pest control products that have low expected returns but that are important to growers, subject (of course) to meeting mandated safety findings. At least five areas of OPP's pesticide regulatory programs rely on the definition of a minor use and could be affected by this guidance.

♦Requests for exclusive use of data decisions (extension period or new period of exclusive use of data protections)
♦Requests from IR-4
♦Public Interest Findings required for conditional registration of a new AI
♦Requests for minor use PRIA fee waivers
♦Requests for low volume/minor use data waivers

To date OPP has made one economic minor use determination, which involved a registration by a non-profit organization.

FIFRA Section 2(ll) defines a minor use of a pesticide as one where:

(1) the total United States acreage for the crop is less than 300,000 acres… **or**

(2) …the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use **and**–

(A) there are insufficient efficacious alternative registered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

(C) the minor use pesticide plays or will play a significant part in managing pest resistance; **or**

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

- OPP has an approach for evaluating parts (A) - (D), which demonstrate benefits to growers/society.
- However, to date there has been no identified approach to defining '[in]sufficient economic incentive.'

Benefits of Defining Minor Use under 2(ll)(2)

Helps to address niche uses on major crops that have low expected returns (*e.g.*, 'orphan' pests impacting few growers and/or few acres in/of major crop acreage; tools to control resistance; alternatives for older, broad-spectrum controls, *etc.*)

The full intent of defining minor use under FIFRA 2(ll) will come to fruition

A good approach should be:

- Rigorous enough to provide supportable results with reasonable amount of data
- Open and transparent to the public

Current Status

OPP has discussed our proposed approach/methodology with the USDA and a representative of grower organizations and is now ready to present the approach for broader/public comment.

Proposed Approach

EPA is proposing a Net Present Value (NPV) approach to evaluate a registrant's (lack of) incentive to register a pesticide use on a major crop. NPV is commonly used to assess the profitability of an investment. The approach will compare the cost of registration (investment) to the revenue received from sales over time (return on investment).

$$\text{NPV(registration)} = \sum_{t=1}^{T} \left[{R_t}/{(1+r)^t} \right] - C_0$$

The approach adds up annual revenue (R_t) over some time period (T) and compares that to the cost of registering that use. EPA is thinking about a time period of three to five years. A shorter time span understates total revenue, but a longer time span means increased uncertainty in the relevancy of data from past sales or the accuracy of predicted sales.

Future revenue is discounted at a rate (r) to make the comparison to investments taken today (C_0). This is because people value money now more than the promise of money at some future time. This observed phenomenon is due to a number of factors including, for example, the uncertainty of receiving the money at a later date and the lower buying power of money in the future because of inflation. EPA isn't sure what rate to use or even if a single rate is appropriate for all situations. Possible options include: OMB's discount rate of 7% used for rulemaking, the prime interest rate, the Dow Jones average rate of return on investments.

Other issues to discuss with stakeholders include:

- What and how to measure registration costs and revenue?
- What threshold(s) to use for determining "[in]sufficient economic incentive"?

What/How to measure?

Revenue

Revenue **(R_t)** for the registrant is sales minus cost of producing the pesticide over some time period.

- Quantity sold could be calculated as application rate time acres treated in a given year where acres treated could depend on the estimated extent of the target pest. Verified by USDA or other sources?
- Price of the pesticide, which is already being sold for other uses or would be provided by the registrant. Verified by comparing to prices of potential competitors?
- If /when necessary, how to account for manufacturing costs? Other costs (*e.g.*, distribution, advertising, *etc.*)?
    - Registrant submissions? Likely CBI; Difficult to verify.
    - Qualitative categories?
        - Small new use in comparison to current market implies 'low' additional costs
        - Large new use in comparison to current market implies 'high' additional costs

Registration Cost

Registration cost **(C_0)** is the cost of registering the product for a particular use and would include data generation costs and registration fees, etc.

What threshold(s) determines "[in]sufficient economic incentive" is still an open question, and is to a great extent company dependent (i.e., how much return on investment a given company is accustomed to making). OPP is proposing a range to allow flexibility.

At the PPDC meeting (May 3-4, 2012) OPP plans to walk members through how the proposed approach might work – with a couple of potential examples – and seek members' input on the approach and identified variables/options in question.

Please also review the draft guidance document and the Questions and Answers on Exclusive Use Data Protection for Minor Use Registrations OPP has provided (attached to this paper).