Defining “Economic” Minor Use

FIFRA 2(ll)(2)

FIFRA 2(ll) defines Minor Use

1) Total U.S. acreage for the crop is less than 300,000 acres, or
2) Use does not provide sufficient economic incentive and
   A. There are insufficient efficacious alternatives
   B. Alternatives pose greater risks
   C. Pesticide is/will be significant in managing resistance
   D. Pesticide is/will be significant in IPM program

Determine Economic Incentive

- Compare cost of registration to net revenue from sales of product
  - Do the returns justify the investment?
- Implement so that analysis is:
  - Rigorous and objective
  - Open and transparent to all stakeholders
  - Easy to implement (e.g., reasonable amount of data)

Example: Please Bear in Mind

- What registration costs should be included and how?
- What manufacturing/marketing costs should be included and how?
- What time frame should we use?
- What is the best measure to use to compare costs and revenues?
- What is/are the appropriate threshold(s) to distinguish “sufficient” and “insufficient” incentives?

Example: Herbicide in Soybean

- Herbicide targeting a resistant weed found in soybean in North Carolina
  - Relatively small area affected, but with potential to spread widely
  - Optimal policy would be to manage locally to avoid spread
- Candidate herbicide also registered on cotton and some other small-acreage crops

Example: Registration Costs for New Use

- Data generation costs $2.40 million
  - Residue data $2.20 million
  - Efficacy studies $0.20 million
- PRIA fee (additional food use) $0.06 million
- Other ?

- Total $2.46 million

Example: Gross Revenues for New Use

- Anticipated price is about $10/lb
- Expected application rate is 1 lb/acre
- Anticipated Acres and Gross Revenue by year

1. 125,000	$1.25 million
2. 275,000	$2.75 million
3. 325,000	$3.25 million
TOTAL Gross Revenue	**$7.25 million**

Example: Net Revenues for New Use

- Manufacturing, etc. cost?
  - Registrant claims costs including raw material, labor, power, shipping, advertising, etc
  - Claims CBI
- New use relatively small compared to existing use (cotton registration)
  - Let's say additional costs for new use are 50% of gross revenue
- Need to discount money spent/received in future

Example: Net Present Value of New Use

Year	Net Revenue Discounted (7%)
1	$0.58 million
2	$1.20 million
3	$1.33 million
Total	$3.11 million
Registration Cost	$2.46 million
NPV	**$0.65 million**
Return/Cost	**1.3**

Example: w/ Manufacturing Cost

Manufacturing Cost = 50% of Gross Revenue

Year	Net Revenue Discounted (7%)
1	$0.58 million
2	$1.20 million
3	$1.33 million
Total	$3.11 million
Registration Cost	$2.46 million
NPV	**$0.65 million**
Return/Cost	**1.3**

Manufacturing Cost = 80% of Gross Revenue

Year	Net Revenue Discounted (7%)
1	$0.23 million
2	$0.48 million
3	$0.53 million
Total	$1.24 million
Registration Cost	$2.46 million
NPV	**-$1.22million**
Return/Cost	**0.5**

Considerations

- Measure and Threshold(s) for ‘insufficient incentive’?
- Cost of manufacturing/marketing pesticide
  - Registrant-submitted data?
  - Qualitative categories with set cost as proportion of gross revenue?
  - Other options?
- Appropriate time period of analysis
  - Too short understates total return
  - Longer and predicted use is very uncertain

Questions/Comments/Ideas?

- Contacts
  - Jack Housenger housenger.jack@epa.gov
  - Tim Kiely kiley.timothy@epa.gov
  - T J Wyatt wyatt.tj@epa.gov

Registration Costs (C_0)

- Costs for final steps of bringing product to market
- Submission
  - Data required for registration
  - Registration fee for proposed use
  - Other costs? Potentially Confidential, and difficult to verify.

Revenue (R_t)

- Ideally, use Net Revenue
  - Gross Revenue (Price x Quantity of product)
  - minus Costs (manufacturing, distribution, etc)
- Submission
  - Actual/Anticipated Price (EPA may verify using proprietary data)
  - Actual/Anticipated Quantity based on acres treated (EPA may verify with USDA, proprietary data)
  - Costs? Likely CBI. Difficult to verify, not open or transparent

Comparing Revenue and Cost

- Can't simply compare cost and benefit
  - Need to compare over a period of years
  - Time value of money
  - Risk
- Proposed Approach: NPV
  - Commonly used to assess the profitability of an investment
  - OPP has discussed ideas with USDA

Net Present Value

- Proposed approach: Net Present Value

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

- Time frame (T = 3 years)
  - Too short and we understate total return
  - Too long and predictions become very uncertain
- Discount rate (r)
  - Reflects uncertainty, inflation, cost of money, etc.
  - May vary according to situation, economic conditions

Interpreting NPV

- NPV calculation provides difference in dollars
  - How much is enough
- Revenues/Cost [1 + NPV/C_0] provides benefit-cost ratio
- Internal Rate of Return [discount rate (r) to make NPV=0] tells you how fast your investment is growing