UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Minor Use Determination of Deltamethrin as a Mosquito Adulticide under FIFRA 2(ll)(2) (DP# 423118, DP# 427246)

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Product Review Panel: September 16, 2015

Summary

A pesticide registrant has requested exclusive use protection of data submitted to support registration of deltamethrin as a mosquito adulticide under FIFRA section 3(c)(1)(F)(vi). To be eligible for protection, the new registration must be for a minor use. The registrant asserts that the mosquito adulticide use of deltamethrin is a minor use as defined by FIFRA 2(ll)(2), *i.e.*, that the use does not provide sufficient incentive for registration. Bayer's proposed new use pattern for deltamethrin is as a ground-applied mosquito adulticide using primarily truck-mounted ULV sprayers and mist blowers. Being granted status as an economic minor use pesticide means that the registrant will have exclusive access to their data used for risk assessments and registration. Without this data protection, competing firms could cite the original registrant's data to obtain a similar registration. These competing products could make it difficult for the original data generator to recoup their investment. This would reduce the incentive of a firm to register a potentially useful product. In this case, the disincentive could limit the options available for mosquito abatement, an important public health use.

In this memo, the Biological and Economic Analysis Division (BEAD) evaluates whether the use of deltamethrin as a mosquito adulticide for wide area mosquito control should be classified as an economic minor use. To qualify as an economic minor use, a pesticide must not provide sufficient economic incentive to support the registration, and at least one of four other beneficial criteria must be met.

BEAD's conclusion is that the new use pattern for deltamethrin meets the requirements to be considered an economic minor use pesticide. BEAD concludes that this request meets the criterion that the new use can play a significant part in an integrated pest management (IPM) program. Whether the potential revenues from the new registration are insufficient depends on the assumptions about future sales and sales prices. However, for plausible values of sales and selling prices based on past market conditions for mosquito adulticides, the estimated revenues are not sufficient to justify the additional registration costs for a new product. Together, these findings mean that deltamethrin as a wide area mosquito adulticide qualifies for status as an economic minor use under FIFRA 2(ll)(2).

Background

In recognition of the high cost of generating required registration data and the potential for low returns, FIFRA provides certain incentives for the registration of pesticide products for "Minor Uses" – uses that are important to growers or to the environment (e.g., products which have lower risk to health or the environment, products which aid with resistance management, etc.) but are not supported by registrants because they have low expected returns. 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.

Under FIFRA Section 2(ll)(1), a crop that is grown on fewer than 300,000 qualifies as a minor use. BEAD relies on the United States Department of Agriculture's Census of Agriculture, published every five years, as the most complete source for data on the acreage in production. Under FIFRA section 2(ll)(2), a use that does not provide sufficient economic incentive to seek or maintain registration but does have important value for human health or the environment qualifies as a minor use.

Deltamethrin is currently being sold as an insecticide by multiple manufacturers. If the new use of deltamethrin for mosquito control is not classified as an economic minor use, other mosquito control producers who wish to compete would be able cite the original registrant's data when bringing their own products to market. Potential competitors would need to submit acute toxicity for their products but would be able to cite (with compensation) the product performance data of the first data-submitting firm, rather than generating their own data. This potential competition may reduce the incentive of the original registrant to undertake expensive data generation and pursue registering a new product. If a registrant were granted status as an economic minor use, they would be granted exclusive use of their data for a period of ten years, and potential competitors would have to do their own studies and submit the data, or wait for the exclusive use period to end. Either case would allow the data generating registrant to avoid competing for deltamethrin market share for at least a few years. Without exclusive use of data, the registrant will face competition in the deltamethrin market, which may have the effect of reduced sales, or forcing the registrant to lower the price to maintain market share.

Past EPA policy for evaluation of economic incentive for status as an economic minor use, was established in PR Notice 97-2. This Pesticide Registration notice (see Appendix A) considered there to be an insufficient economic incentive when cost of registration exceeded one year of gross revenue at "full market potential." The standard set in PR Notice 97-2 has rarely, if ever, been used, suggesting that it may fail to take into account important factors. In consultation with USDA, OPP/BEAD developed an approach to evaluate the economic incentive for registering a pesticide as an investment decision. This approach is based on the net present value (NPV) of registration as a business investment and uses several measures that characterize the magnitude of the benefits to the registrant to register deltamethrin as a mosquito adulticide.

This document is organized as follows. First, the biological characteristics of deltamethrin are examined to ensure that at least one of the four criteria demonstrating the value of the pesticide is met. Second, the approach used to evaluate the private incentives for a registrant to register this use for deltamethrin are described, and several measures are used to assess this investment. The

results of the analysis are discussed and interpreted in the context of the market for mosquito adulticides.

Biological Methodology and Analysis

To evaluate whether a pesticide has biological value to the user and/or society, FIFRA requires using the same criteria used to define a minor use pesticide, as described above (See FIFRA section 3(c)(1)(F)(ii)). These criteria are (1) whether there are insufficient efficacious alternative registered pesticides for this use, (2) the alternatives to the pesticide use pose greater risks to the environment or human health, (3) whether the chemical will play a significant part in managing pest resistance, and (4) whether it will play a significant part in an integrated pest management program. For this analysis, BEAD will not evaluate whether the new product presents lower risk to human health or the environment, but will consider the other three criteria, to determine if the new product meets one of those criteria necessary for minor use status, but also because these elements may provide insight into how much revenue might be generated from the new product.

BEAD reviews information submitted by the registrant on comparative efficacy, role in resistance management, IPM, *etc.* The information is verified by consulting (USDA-funded, extension service and/or grower-developed) crop profiles and pest management strategic plans. BEAD also consults technical literature (in scientific, peer-reviewed publications) and extension service literature from land-grant universities and USDA/ARS, USDA/APHIS, *etc.*

This deltamethrin formulation will be used for the wide area control of populations of adult mosquitoes of various species. In the supporting documentation provided by Bayer for this request, summaries of efficacy based on several trials were included. These compared deltamethrin against the following currently available alternatives: naled, permethrin, pyrethrin, resmethrin (soon to be voluntarily cancelled), and sumithrin (with and without phenothrin). Efficacy in terms of % mortality 24 hours after application, at three distances (100, 200, and 300 feet) was described separately for mosquito species that are considered to be less pesticide resistant (in the United States) and thus easier to control, vs. those with more widespread resistance to organophosphates and/or pyrethroids. "Easier to control" species included *Aedes aegypti*, *A.solicitans*, *A. taeniorhynchus*, and *C. pipiens*; "harder to control" ones included *Culex quinquefasciatus* and *Anopheles quadrimaculatus*.

While the summaries from Bayer did not include statistics, they show that at least two other alternatives, the organophosphate naled and the pyrethroid sumithrin (mixed with phenothrin) have almost 90% mortality against "easily controlled" mosquito species, as compared to 100 % for deltamethrin, even at 300 feet from the point of application. For "harder to control" species, at the same distance, only sumithrin+phenothrin had mortality close to that of deltamethrin (81 vs 83 %, respectively). While Bayer asserts that this difference is a significant advantage for deltamethrin's efficacy, BEAD cannot reasonably make such a conclusion given the summarized nature of the data and the arguably similar mortality provided by at least two of the listed alternatives.

In addition, BEAD notes that organophosphates, such as malathion and naled, and pyrethroids, such as permethrin and suithrin, are among those mentioned as useful adulticides in extension

literature (e.g., FCCMC 2009). As Bayer itself noted in its request documentation, proprietary data show that permethrin, malathion, naled, sumithrin, and etofenprox are among the most highly used adulticides in the U.S. While there are probably mosquito populations resistant or less susceptible to one or the other of these materials, BEAD could not locate clear evidence that lack of efficacy is a serious problem when the entire suite of available adulticides is considered. Therefore, BEAD cannot conclude that there are insufficient efficacious alternatives for the purpose that deltamethrin will be used.

The second biological benefits criterion requires BEAD to evaluate whether or not the new use will play a significant part in managing pesticide resistance. It is well documented that some mosquito species in the U.S. show resistance to selected organophosphates and pyrethroids. While it is unclear to what extent such resistance is common in the United States, there is no reason not to expect that it could develop in additional areas. It is possible that for populations showing only organophosphate resistance, deltamethrin could be used as a rotation partner in a season-long management program to control mosquitoes while delaying resistance.

However, there are other pyrethroids already available, and these could be used for the same resistance management purpose. Cross-resistance to pyrethroids, a phenomenon where pest resistance to one pyrethroid allows better survival against other pyrethroids, has also been documented for mosquitoes in the U.S. and elsewhere (Liu *et al.* 2004, Flores *et al.* 2013). In other parts of the world, resistance to deltamethrin itself has also been documented (e.g., Bisset *et al.* 2013). At least one study also showed that southern U.S. populations of the species *Culex quinquefaciatus* have the potential to develop resistance to deltamethrin (Liu *et al.* 2004). Given these factors, BEAD cannot conclude that deltamethrin will be a significant resistance management tool in mosquito control.

The final biological benefits criterion requires BEAD to examine whether or not the new use will play a significant part in an IPM program. While most of the alternatives are, like deltamethrin, designed to be used at very low application rates, deltamethrin is one of only a few that maintains its efficacy across distances up to 300 feet. Of the available adulticide alternatives, only naled and sumithrin are similar in this respect (see discussion above). As a broad spectrum organophosphate, naled has acutely toxic effects on non-target insects and is arguably not a high priority choice in an IPM program. A recent study (Chaskapoulou *et al.* 2014) found that both deltamethrin and phenothrin (a component of the sumithrin formulation) had virtually no non-target impacts when applied aerially for mosquito control in Greece. This study evaluated impacts on insects that act as biological control agents (e.g., ladybeetles and green lacewings) as well as honeybees and their hives, and this low impact on non-target species may be desirable for mosquito control districts.

The results lend support to their better suitability as significant components of an IPM program that seeks to minimize impacts to beneficial insects while still effectively controlling mosquito adults. While sumithrin/phenothrin formulations may be similar in this respect to deltamethrin, BEAD further notes that they are much more susceptible to rapid degradation in the typical environment (Cornine 2013). Thus, mosquito managers may need to reapply treatments with these or other adulticides more frequently than with deltamethrin, thus increasing the overall pesticide load in the treated area and the resulting non-target impacts over time. Therefore,

BEAD concludes that the new use of deltamethrin, as a long-residual, ultra-low volume formulation with good long-distance efficacy, reasonably provides a significant IPM component for mosquito management. Thus, BEAD concludes that the wide-area adulticide use of deltamethrin qualifies for the IPM criterion.

Economic Methodology and Data

Overview of Methodology

In this analysis, the cost to register a pesticide use is viewed as the investment which allows the pesticide to be legally marketed for such use. These costs, which include data generation and registration fees, are treated as the initial investment in a net present value (NPV) approach. The NPV approach is used to compare the cost of obtaining (and/or keeping) a registration to the returns to the sale of the product over some time period in the future. There are other costs which are relevant to registration, but these are difficult to quantify in a transparent manner and thus are not considered quantitatively in these analyses. Comparing the costs and estimated revenues will allow BEAD to determine whether future revenues are insufficient to justify the investment in registration costs.

The NPV of the investment in registration is calculated as:

$$NPV = \sum_{t=1}^{T} \left[\frac{Net\ Rev_t}{(1+r)^t} \right] - C_0$$

where,

$Net\ Rev_t$	=	Net revenue (revenue minus cost) at time t
C_0	=	Initial cash investment
r	=	Discount rate
t	=	Time of the cash flow (*e.g.*, one year, one quarter)
T	=	Time at the end of analysis

This approach lends itself to several measures and potential ways of determining whether registration of a pesticide product provides sufficient returns. First, using the calculated NPV, a positive value indicates that the investment is worthwhile. However, this measure does not necessarily capture the full decision since it ignores the size of the initial investment. Another measure is the benefit-cost ratio where $\frac{B}{C} = \sum_{t=1}^{T} \left[\frac{Net\ Rev_t}{(1+r)^t} \right] \Big/ C_0$. It can also be calculated as 1 + NPV/C_0. Typically, if the benefit-cost ratio is greater than one, the project is worthwhile (corresponding to a positive NPV). These measures also require an accurate measure of the discount rate, r, especially as it reflects the opportunity cost of capital. In isolation, it is possible to determine if an investment is worthwhile, but it is harder to judge whether returns are "insufficient." As a third measure, therefore, BEAD also calculates the internal rate of return (IRR), which is the value for the discount rate that makes the present value of future cash flows

exactly equal to the initial cash investment. The rate of return on an investment can be compared to potential returns on other ventures such as returns on the stock market in general or in particular sectors.

To calculate the NPV and benefit cost ratio, the analysis uses a seven percent discount rate based on the rate used by the Office of Management and Budget (OMB) to represent the private rate for the purpose of regulatory analysis. The rate may not conform to that used by an actual firm; it would depend on the availability of alternative investments, *i.e.*, the opportunity cost of capital. All measures are calculated over a time horizon (T) of five and ten years, based on discussions with registrants. Estimating revenues over a longer time horizon is subject to increasing uncertainty.

Data Sources

Data requirements were identified in conjunction with OPP's Registration Division (RD), and costs for the required studies were taken from a database of estimated data generation costs maintained by EPA. RD also confirmed the registration fees levied under the Pesticide Registration Improvement Act (PRIA).

To estimate gross revenue, necessary data include the expected sales price and projected sales. There is a great deal of uncertainty for these assumptions, because the product is not yet on the market. Sales price is estimated from private sector market research data on prices of mosquito adulticides sold to mosquito abatement districts (MADs). Projected sales are based on the projected acreage to be treated with deltamethrin sold by Bayer.

Analysis of Incentives

Economic Criteria

As noted above, to evaluate the economic incentive, the applicant and BEAD must consider the costs of registration and the future sales of the product less manufacturing costs and other annual costs such as maintenance fees for the registration.

Cost of Registration (C_0)

The primary costs of registration are the cost of generating required data and the PRIA fees. For the purposes of this analysis, BEAD notes that the costs to register deltamethrin as a mosquito adulticide for wide area mosquito control include data required for the technical grade active ingredient (TGAI) and one product since these are both necessary to legally market the chemical to end users. The expected data required for registration and BEAD's estimated costs for fulfilling these data requirements are shown in Table 1. As mentioned above, the list of data requirements is based on consultation with OPP's Registration Division (RD). Estimated costs are based on various EPA conducted surveys of laboratories that generate registration data in support of rulemaking and data call-in requests over time.

The total data generation cost for registering deltamethrin as a mosquito adulticide is estimated to be $1.162 million, with product performance data being the most expensive component. There are also fees for registering a new pesticide use and for reviewing the request for exclusive use, which total to $64,450. Finally, BEAD adds in the cost of the paperwork burden for submitting a Section 3 reduced risk application, $48,700. Thus, the total cost for data and fees is estimated to be $1.274 million (Table 1).

Table 1. Data Requirements and Costs for Registration of Deltamethrin as Mosquito Adulticide for Wide Area Mosquito Control[1]

Study Title	Guideline[2]	Estimated Cost
Product Performance	810 Series	$ 352,500
Product Identity, Composition, and Analysis	830 series, Group A	$ 21,000
Physical/Chemical Properties	830 series, Group B	$ 81,500
Fate, Transport, and Transformation	835 series, Groups C, F	$ 219,000
Residue Chemistry	860 Series	$ 280,800
Acute Toxicity	870 series, Group A	$ 158,800
Total Data Costs		**$ 1,162,300**
PRIA Registration Fees[3]		$ 64,450
Section 3 Paperwork Burden[4]		$ 48,700
Total Registration Cost (C_0)		**$ 1,273,975**

[1] Data requirements based on consultation with OPP's Registration Division and include the cost of additional technical data as well as product data for one product. Estimated cost for data requirements is based on surveys of labs that generate registration data which EPA has conducted in support of rulemaking and data call-in requests over time.

[2] Not all tests in these groups were required.

[3] The registration fee for a new food use is $62,975 and the fee to review a request for exclusive use of data under FIFRA Sec. 3(c)(1)(F)(vi) is $1,575.

[4] Cost of paperwork burden to prepare and submit a Section 3 application for a reduced risk pesticide. (EPA, 2015)

There are other costs involved with registering a pesticide, most notably conferring with EPA/OPP, evaluating risk assessments for errors, submitting and revising labels, *etc.* These costs are difficult to quantify and verify; they are also potentially vary substantially across registration actions. Thus, these costs are not incorporated into a quantitative analysis of whether there is sufficient economic incentive to register a use.

Future Sales (*Net Rev$_t$*)

The returns to this "investment" are the revenues from sales of the pesticide. Annual net revenues will be total sales (the price of the chemical times the amount sold) less the costs of producing and distributing the pesticide each year.

$$NetRev_t = P_t \cdot q_t - c(q_t) - \gamma_t$$

where *NetRev$_t$* is net revenue in time t, P_t is the price of deltamethrin, q_t is the quantity sold, $c(q_t)$ is the cost of manufacturing and distributing the product and depends on the quantify sold, and γ_t are other costs that do not depend on the amount sold such as the registration maintenance fee. Gross revenue, or total sales, is calculated as P_t times q_t. In this case, the price (P_t) is measured as the cost per acre and the quantity (q_t) is the acres treated.

Quantity or Acres Treated

To estimate revenue for the applicant, we need to estimate the quantity of deltamethrin that will be sold, without the luxury of knowing how well it will perform in the marketplace. To estimate the market for Bayer's deltamethrin product, BEAD uses information from private sector market research on the mosquito adulticide market. There is obviously a great deal of uncertainty around these estimates, however.

The overall market for ground applied adulticides in 2010 was about 62 million acre treatments (Kline, 2013). About 5,023,000 acre treatments of resmethrin, a mosquito adulticide, were applied in 2010 (Kline, 2013). The resmethrin product is no longer being marketed. The applicant for the new use of deltamethrin is also the producer of resemethrin. It is possible that deltamethrin will capture all of the resmethrin market, but also possible that existing competing products will take some of that market share. At the same time, deltamethrin, a new pyrethroid product for this use, may be able to compete with existing products for some of the total market for ground-applied mosquito control. It is softer against non-target insects, and the Bayer formulation may have greater efficacy at larger distances from the application. For our estimate, we assume that the full market potential for deltamethrin is 50% of the current market for resmethrin, plus 5% of other ground applied products. Excluding resmethrin, the market for ground applied adulticides was about 58 million acre-treatments (Kline, 2013). Five percent of the 58 million acre-treatment is about 2.9 million acre-treatments. Combined with 50% of the total resmethrin acre-treatments (about 2.5 million acres), BEAD estimates the total market for deltamethrin to be about 5.4 million acre-treatments.

The applicant's concern is that, without the exclusive use of data, they will be subject to competition from other mosquito control producers, who will cite the initial registrant's data when bringing their own products to market. The original period of exclusive use of data has expired; another competing firm would only need to submit acute toxicity for its product and cite (with compensation) the product performance data of the first data-submitting firm. It should be noted, however, that Bayer has 100% market share for resmethrin, which indicates an ability to compete effectively against generic manufacturers. For the purposes of this analysis, BEAD assumes that, because of their current distribution and marketing network, a new product and use

pattern that they are bringing to market, and technological advantages that allow the initial registrant's formulation to maintain efficacy at greater distances than other water-based products, Bayer will maintain a relatively large share of the market for deltamethrin. As a starting point, BEAD assumes that the initial registrant will have 39% of the deltamethrin market, which is equal to the market share of Univar for ground-applied permethrin. Univar's market share for permethrin is the largest market share for any one company of any of the ground applied pyrethroids. An alternative would be the largest market share of any active ingredient among ground applied pesticides, which would be Cheminova's share of ground applied malathion, at 92%; BEAD considers that to be the high end of the range for plausible market share.

If the total market for deltamethrin is 5.4 million acre-treatments, and Bayer captures 39% of the total, the market for Bayer's new product is about 2.1 million acre-treatments per year. We use that estimate as the low point of the range for sales, but acknowledge that sales may be higher. If we consider the large market share, such as Cheminova, 92% of the total market of 5.4 million is about 5.0 million acre treatments.

Whatever the market for deltamethrin, a period of years may pass before Bayer gains market acceptance among mosquito abatement districts, who may require a few years to fully accept deltamethrin as a substitute for resmethrin or other products. For the purposes of this analysis, we assume that Bayer can use their existing distribution and marketing network to grow sales of deltamethrin for mosquito control, so they will be able to achieve full market potential after three years, with a straight-line interpolation between years one and three. Table 2 presents the market share and revenues for the registrant of the new deltamethrin product with a maximum total market of 2.1 million acre-treatments, although we consider higher values (see Figure 1).

Price or Cost per Acre

A difficulty in this analysis is determining the price at which deltamethrin will be sold. As a starting point, BEAD will assume that the price of deltamethrin is $0.43 per acre treated, which is the average cost of mosquito adulticide treatments in 2010, according to proprietary data on industry pest control practices (Kline, 2013). This is substantially lower than the price per acre for resmethrin, which was $1.43 - $2.85 per acre, based on market research data (Kline, 2013). We consider a range of prices, however. Deltamethrin is currently registered for control of insects, primarily as a residential product. Bayer currently sells a deltamethrin product (Suspend SC). The price of $0.43 is within the range of prices calculated from the purchase price of Suspend SC: based on an internet search of the price for Suspend SC, and using the rates that would be applied as a mosquito adulticide, the per acre cost of deltamethrin would be $0.31 per acre at the low rate, and $0.93 at the high rate. Mosquito abatement districts may face different prices than homeowners, however.

Gross and Net Revenue

With estimates of cost per acre, acres treated, and market share, future gross revenues can be calculated for the use of deltamethrin as a mosquito adulticide.

For this analysis, net revenue is assumed to be 35 percent of gross revenue, corresponding to production and marketing costs of 65 percent of the sales price. That is, $c(q_t) = 0.65 \cdot P_t = \$0.28$, given a price of $0.43. This relatively low assumption of 65 percent is based on the fact that deltamethrin is already manufactured as insecticide by Bayer, and the addition of the mosquito use does not appear to represent a large increase in production (not a large increase in marginal cost), and Bayer already has a successful marketing network in the mosquito control industry, meaning no additional investments are needed to support the distribution and sale of deltamethrin.

Table 2 presents BEAD's projections of acres treated (q_t) and gross and net revenue using the market share scenarios from Table 2. The estimates use the following parameters:

- $P_t = \$0.43$,
- $c(q_t) = \$0.28 \cdot q_t$, and
- $\gamma_t = 0$.

Also shown in Table 2 is the discounted cumulative gross and net revenue over five and ten years based on a seven percent discount rate. The discount rate was chosen because the Office of Management and Budget (OMB) uses seven percent to represent the private rate for the purpose of regulatory analysis. The rate may not conform to that used by an actual firm.

Table 2. Estimated Gross and Net Revenue of Data-Submitting Firm

Year	Bayer Deltamethrin Total Acre Treatments (Thousands)	Price per Acre (Dollars per Acre)	Gross Revenue (Thousands)	Cost (Dollars per Acre)	Net Revenue (Thousands)
2016	703	$0.43	$302	$0.28	$106
2017	1,406	$0.43	$605	$0.28	$212
2018	2,109	$0.43	$907	$0.28	$317
2019	2,109	$0.43	$907	$0.28	$317
2020	2,109	$0.43	$907	$0.28	$317
2021	2,109	$0.43	$907	$0.28	$317
2022	2,109	$0.43	$907	$0.28	$317
2023	2,109	$0.43	$907	$0.28	$317
2024	2,109	$0.43	$907	$0.28	$317
2025	2,109	$0.43	$907	$0.28	$317
Cumulative 2026 – 2035	21,090	$0.43	$9,069	$0.28	$3,174
Discounted cumulative revenue projections (7% discount rate)					
5 year (2016-2020)			$2,889		$1,011
10 year (2016-2025)			$5,540		$1,939

Source: EPA calculations

Incentive Measures

Table 3 presents the several different measures of economic value to the registrant. These measures of economic value highlight the difficulty in ascertaining whether a potential registrant has sufficient economic incentive to register a new use. The measures included provide conflicting results, depending on which measure is used, which estimate of revenue is used, and the length of run for the analysis.

Table 3. Economic Incentives

1	2015 Cost of Registration	$1,274,000
	Annual Revenue at Full Market	$907,000
2	5 Year NPV	-$263,000
	10 Year NPV	$665,000
3	5 Year Benefit/Cost Ratio	0.79
	10 Year Benefit/Cost Ratio	1.52
4	5 Year IRR	-
	10Year IRR	20%

Source: EPA calculations

The first section of Table 3 applies the standard from PR Notice 97-2 (see Appendix A), which is the difference between registration cost and returns "at full market potential." In this case, full market potential is estimated to be 2.1 million acres based acreage treated with resmethrin. This measure compares the registration cost of $1,274,000 with estimates of annual gross revenue. Deltamethrin meets the standard from the PR notice, because annual revenues are estimated to be $907,000 after year four, below the registration costs. This measure ignores important issues, of course, including the time value of money and non-registration costs of production.

The second part of Table 3 shows the estimated net present value of the investment under different time scenarios. These NPVs are estimated assuming that registration costs are the only costs incurred at the beginning of the analysis and that revenues from sales of the pesticide begin at the end of the first year. The NPV estimates, using a discount rate of seven percent, are positive for a ten year horizon but negative for a five year horizon.

The third part of Table 3 shows the estimated benefit-cost ratio. A value greater than one indicates, as does a positive NPV, that the net returns of the investment are higher than the cost. In this case, the benefit-cost ratio is above one for the ten year horizon, but below one for the five year horizon.

The fourth section of Table 3 shows estimates of the internal rate of return (IRR) under different time scenarios. Because the returns were negative for the five year horizon, the IRR is not calculated. The IRR is 20% without data protection for the ten year time horizon.

The measure of economic incentives are mixed with this set of assumptions, depending on the length of the time horizon used for analysis. However, it should be noted that the returns from introducing the new product are low. For example, the benefit/cost ratio estimate at ten years is 1.52. That is above one, but a firm might require a higher return than that before initiating an investment, because investments are risky and cannot be undone, and the time horizon for the firm may be shorter than ten years. In addition, the revenues under discussion, at least with the

assumptions here, are small, which means that a company may not find the investment worthwhile, even if the projected returns are higher than anticipated costs. New projects within a firm compete for resources and funding, and a low revenue product like deltamethrin for mosquito control may not be worthwhile from the point of view of the company. On the other hand, when considering a longer time horizon, the returns on the investment are more positive – although uncertainties grow over a longer time frame: for example, other competing chemistries may come to market, or deltamethrin may lose effectiveness due to mosquitoes developing resistance. There are also non-financial marketing reasons Bayer may wish to develop a new market to service their customers in the mosquito control abatement industry. Deltamethrin is a new chemistry that is softer against non-target insects, which might be desirable to mosquito control districts, and it can help replace resmethrin, which will no longer be available for mosquito control.

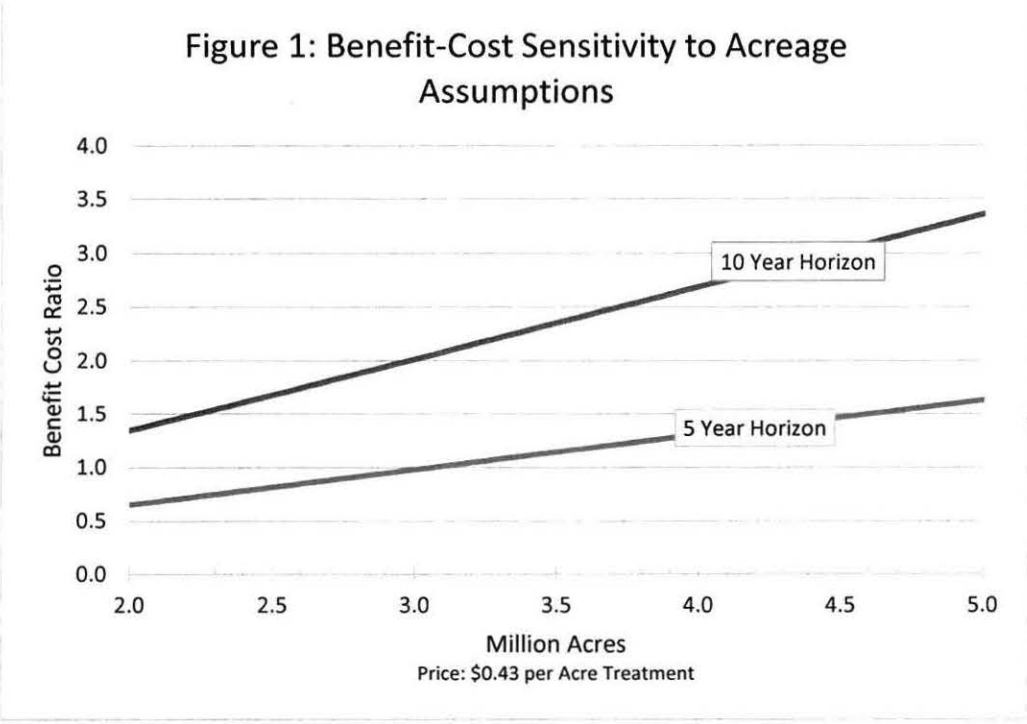
Discussion and Uncertainties

As with any prediction, there are a number of uncertainties in this analysis which may influence the results. In this case, the most important assumptions are probably the acre-treatments for Bayer's deltamethrin products, and the price for which they can sell deltamethrin. Figure 1 shows the benefit-cost ratios for five and ten year horizons at different levels of acre-treatments sold. Recalling that a benefit-cost ratio greater than one indicates a potentially profitable investment, the figure shows that the outcome is not sensitive to assumptions about sales volume for the ten year horizon. The lower benefit-cost curve, which corresponds to the shorter time horizon, is greater than one for sales above 3.1 million acres in a mature market, which corresponds to the initial registrant controlling about 58% of the total market for deltamethrin, instead of our low-end estimate of 39% here.

Related is the size of the overall mosquitocide market. If demand for mosquito control increases dramatically, then the market for deltamethrin is likely to be higher as well. Industry monitors predict little change in the overall mosquitocide market (annual growth of 0.2% for the next few years), although slightly negative growth for adulticides (negative 2.4%) as concerns over West Nile Virus diminish (Kline, 2013).

For the purposes of this analysis, we assumed that it takes three years for the market to reach its full potential, which means lower acre treatments in the early years. The results are sensitive to this assumption, because revenue in early years is discounted less than later years, and because we assume that the registrant is the sole supplier of deltamethrin for the first three years. If the market reached full potential in year one, the benefit/cost ratio over five years would be 1.3.

The results are sensitive to price. If deltamethrin sells at a higher price, then Bayer would require less acreage to reach a benefit/cost ratio greater than one, but the relationship between revenue and price is linear. For example, if Bayer were able to sell enough deltamethrin to treat 2.1 million acres, the critical price for a benefit/cost ratio greater than one over five years is about $0.41.



Conclusions

BEAD concludes that the new use of deltamethrin as a ground-applied mosquito adulticide meets the definition of an economic minor use. Using a reasonable set of assumptions about the future market for the product, BEAD concludes that it is plausible that the company faces insufficient incentive to undertake the investment in the new product and market. This conclusion could be in error. If the actual costs, selling price, market share are different from those modeled here, then the potential revenues might be sufficient to justify the cost.

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Private Pesticide Market Research

APPENDIX A – MINOR USE DEFINITION FROM PR NOTICE 97-2

Pesticide Registration (PR) Notice 97-2 (Dated April 18, 1997)

SUBJECT: New Chemical, New Use, EUP, Non-Fast Track Amendments and Inert Ingredient Registration Priorities for Conventional Pesticides

VII. MINOR USE DEFINITION

For the purpose of addressing the Food Quality Protection Act in this PR notice, the legislation defines "minor use" to mean the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where--

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; 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; or

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

(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.

The Food Quality Protection Act defines "minor use" of a pesticide on an animal, a commercial agricultural crop or site, or for public health purposes in two different ways. The first definition identifies minor use crops as those with less than 300,000 total U.S. acres. The second definition requires an economic determination that a registrant does not have the market revenues or sufficient economic incentive to support pesticide registration for a use site.

MINOR USE CROPS

A pesticide use on a crop with less than 300,000 acres of total U.S. production is a minor use. This definition applies to numerous fruits, vegetables, spices, and horticulture and nursery crops. As an alternative to listing all minor use crops, a list of crops with more than 300,000 acres of U.S. production is provided below. Pesticide uses on commercial agricultural crops that do not appear on the list will automatically be considered minor uses. Because the first definition applies only to crop uses of less than 300,000 acres, non-crop uses or sites (such as animal uses, aquatic weed control, and rights-of-ways) are not evaluated under the first definition.

Agricultural Crops Grown on More Than 300,000 Acres

Almonds	Pecans
Apples	Popcorn
Barley	Potatoes
Beans, dry	Rice
Beans, snap	Rye
Canola	Sod Farms
Corn (sweet & field)	Sorghum
Cotton	Soybeans
Cottonseed	Sugarbeets
Grapes	Sugarcane
Hay (alfalfa & other)	Sunflower
Oats	Tobacco
Oranges	Tomatoes
Peanuts	Turf

Wheat

MINOR USE ECONOMIC DEFINITION

A pesticide use on an agricultural crop grown on more than 300,000 acres or on a non-agricultural site may qualify as a minor use, provided the registrant can demonstrate that the use does not provide sufficient economic incentive to support registration. For purposes of this PR notice this economic determination can be made by using the equation:

(a) costs > gross revenues for 1 year for the specific site.

where:

Costs = incremental costs to register the site which are the costs of the additional data requirements to register the specific site. If registration costs are shared by more than one registrant, the costs should represent the registrant's share of the data requirement.

Revenues = registrant's gross sales which are the additional sales projected at full market potential for the specific site. EPA, in consultation with USDA, will make this determination based on the following information provided by the registrant:

Registrants that choose to submit priorities based on the economic definition for a minor use must provide the following:

1. A list of the registration data requirements and the estimated cost to generate the data for the specific site.

2. The Annual Domestic Sales or Revenues for the Specific Site: Provide the actual, annual value and quantity of domestic sales of the pesticide for the specific site. This value should be calculated as the average of the most recent 3 years. For the registration of a new site, annual revenues should be projected on the basis of full market potential.

3. A written summary addressing at least one of the criteria described in section VII(2)(A-D).

For a minor use priority that is determined to be a minor use as a result of the economic criteria specified above, the one year time frame for completion of reviews does not begin until after the economic determination has been completed.