UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 12, 2016

Laurent C. Mézin, Ph. D.
Manager, Regulatory Affairs
SePRO Corporation
11550 North Meridian Street, Suite 600
Carmel, IN 46032

Subject: Exclusive Use Data Protection – Fluridone on Cotton
Product Name: Sonar Technical
EPA Registration Number: 67690-6
EPA Finding: Data Protection Expiration Date: August 29, 2024
Protected Studies: MRID Numbers 49385701-49385716

Dear Dr. Mézin:

This letter addresses your request that data [MRID Nos. 49385701-49385716] associated with the minor use registrations(s) of fluridone on cotton each receive a ten year exclusive-use protection period. EPA is granting the request for an exclusive-use data protection of ten years to protect the requested data from August 29, 2014 to August 29, 2024 under EPA Registration No. 67690-6.

SePRO Corporation cited FIFRA section 3(c)(1)(F)(vi) as the authority for EPA to make such a determination. The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated this subsection under 3(c)(1)(F). FIFRA section 3(c)(1)(F)(vi) sets forth the criteria for establishing a new period of exclusive-use data protection. A new ten year period of exclusivity can be established for data exclusively used to support a minor crop use submitted after the expiration of the exclusive use period for the active ingredient under FIFRA 3(c)(1)(F)(ii).

FIFRA section 3(c)(1)(F)(vi) and its implementing regulations[1] specifically describe the set of

[1] 40 CFR §152.83(b) *Exclusive use period for certain minor use data.* A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met: (1) The study relates solely to a minor use of a pesticide. (2) The applicant or registrant at the time the new use is requested has notified the administrator that any exclusive use period for the pesticide has expired and that the study is eligible for exclusive use treatment. (3) Less than 10 years have passed since the study was submitted to EPA. (4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B). (5) The minor use supported by the data has not been voluntarily canceled nor have such data been used to support a non-minor use. See also, Federal Register 79, 6825.

data that are eligible for exclusive-use protection. A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all of the conditions are met. The following are our considerations for determining whether the data associated with the requested registration are eligible for a new ten year period of exclusive-use protection.

First, the data associated with this registration [MRID Nos. 49385701-49385716] do pertain solely to a registration of a minor use (BEAD. June 18, 2015. Minor Use Determination of Fluridone on Cotton under FIFRA 2(11)(2) (DP#423484)).

Second, the data were submitted after the exclusive-use period for the first registration of the new chemical had expired. The initial registration for fluridone was granted on March 31, 1986.

Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B).

Fourthly, the data was submitted concurrently with the application, in compliance with FIFRA section 3(c)(1)(F)(vi).

Finally, the data were not generated by IR-4. Data generated by IR-4 are not entitled to exclusive-use protection (see 40 CFR 152.94(b)).

DETERMINATION

The Agency concludes that the residue and environmental fate data [MRID Nos. 49385701-49385716] supporting the use(s) of fluridone on cotton do qualify for the requested new ten year period of exclusive-use protection. In consideration of the pest management niche, EPA concludes that cotton was found to qualify as an economic minor use under FIFRA 2(11)(2), lack of economic incentive, as confirmed by the attached assessment. EPA's review concludes that this use could play an important role in managing herbicide resistant Palmer Amaranth. Therefore, the Agency **GRANTS** your request for a new 10 year exclusive-use protection of these data [MRID Nos. 49385701-49385716]. If the Agency receives a me-too application for this pesticide and use combination during the new ten year exclusive-use data protection period citing SePRO's data [MRID Nos. 49385701-49385716], those applications will be denied. Exclusive-use protection for data, which complies with 40 CFR 152.83(b), submitted in support of these registration(s) will expire in 10 years (August 29, 2024). In addition, if the minor use registration which is supported by these data is voluntarily canceled or if such data are

subsequently used to support a non-minor use, the data shall no longer be subject to the exclusive use provision of FIFRA section 3(c)(1)(F)(vi).

Sincerely,

Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs

Attachment: BEAD. June 18, 2015. Minor Use Determination of Fluridone on Cotton under FIFRA 2(11)(2) (DP#423484)

cc: BC, Dan Kenny
PM, Kathryn Montague
Staff Reviewer, Sarah Meadows

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

JUN 18 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Minor Use Determination of Fluridone on Cotton under FIFRA 2(ll)(2) (DP# 423484)

FROM: Michelle Ranville, Economist
Economic Analysis Branch

Bill Chism, Senior Biologist
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Tim Kiely, Chief
Economic Analysis Branch

Arnet Jones, Chief
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Sarah Meadows, Risk Manager
Daniel Kenny, Chief
Herbicide Branch
Registration Division (7505P)

Product Review Panel: June 10, 2015

SUMMARY

SePRO has requested exclusive use protection of data submitted to support registration of cotton under FIFRA 3(c)(1)(F)(vi) based on economic minor use status under FIFRA 2(ll)(2). In this memo, the Biological and Economic Analysis Division (BEAD) evaluates the status of fluridone on cotton as an economic minor use.

BEAD has determined that the registration of fluridone on cotton does not have sufficient economic incentive for a registrant to pursue. The potential for fluridone to be used as a cotton herbicide has long been recognized (it is not suitable for use on other crops due to the possibility

of crop damage), but its cost relative to other cotton herbicides has precluded it from competing against other forms of weed control. Weed resistance to other herbicides has opened a market niche for fluridone, but the current market structure is comprised of several potential competing registrants, making it unlikely that any one firm to ensure sufficient returns to justify the costs of registration.

BEAD has also determined that fluridone can play a significant part in managing weed resistance because of its ability to control glyphosate resistant Palmer amaranth. It will also provide weed control in situations where effective alternatives are lacking. EPA has granted Section 18 emergency exemptions in six states (GA, NC, SC, TN, AR, and MO) allowing the use of fluridone for the control of Palmer amaranth in cotton.

Background

In recognition of the high cost of generating data and the potential for low returns, FIFRA provides certain incentives for the registration of products that are important to growers (e.g., products which aid with resistance management) or to the environment (e.g., products which have lower risk to ecological endpoints) but are not supported by registrants because they have low expected returns. Under FIFRA section 2(ll)(1), a crop that is grown on fewer than 300,000 acres in the United States qualifies as a minor use. BEAD relies on the USDA 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.

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.

To date, the 'economic' definition of a minor use has been defined by Pesticide Registration (PR) Notice 97-2, as one where the incremental costs of registration (additional data generation costs) are greater than the annual gross revenue from sales for the specific use at full market potential. However, this approach does not consider the costs of manufacturing the pesticide nor the difference in time between incurring the cost of registration and receiving revenue from sales. The criteria in the PR Notice may be overly strict and potentially deterred registrants from seeking the minor use designation and obtaining the incentives for registration that should be available to them. This, in turn, could limit the availability of pesticides for small acreages or important uses.

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 of registration as a business investment and uses several measures that characterize the magnitude of the benefits to the registrant to register fluridone on cotton for the control of glyphosate-resistant Palmer amaranth.

This document is organized as follows. First, the biological characteristics of fluridone 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 fluridone is 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 fluridone on cotton. The conclusion provides BEAD's findings and explains how other, qualitative factors influence the determination of insufficient incentive.

Biological Methodology and Analysis

To evaluate whether a pesticide has biological value to the user and/or society, BEAD uses criteria similar to those used to determine if the minor uses for which the pesticide is registered help to qualify the registrant for an extension of the period of exclusive use over the data (See FIFRA section 3(c)(1)(F)(ii)). BEAD considers the following three criteria: (1) whether there are insufficient efficacious alternative registered pesticides for this use, (2) whether the chemical will play a significant part in managing pest resistance, and (3) whether it will play a significant part in an integrated pest management program. OPP also can consider whether a new use can be considered 'reduced risk,' i.e., posing less risk than existing alternatives. 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.*

Fluridone will be used for the control of glyphosate resistant Palmer amaranth (*Amaranthus palmeri S. Watson*) in cotton (*Gossypium hirsutum*). Palmer amaranth is a broad leaved herbaceous plant native to the southwest United States. Palmer amaranth is found in 30 states including all of the cotton producing states. A single Palmer amaranth plant can grow to 7.5 feet tall, with a dry weight of 3.5 pounds per plant, and stems over 1.5 inches in diameter which can cause stoppages of the cotton harvester (Horak et al, 2000). Glyphosate-resistant Palmer amaranth has seriously endangered conservation tillage and has increased herbicide costs by more than 70 percent (Smith, 2012). Hand weeding is very expensive and crews are not generally available when needed. Estimates from Arkansas indicate 5 percent of the growers experience 100 percent loss and 20 percent of the growers experience 20 to 40 percent yield loss (Smith, 2012). A total of 630,000 acres of cotton in the mid-south and southeastern U.S. is infested with glyphosate-resistant Palmer amaranth (Nichols et al., 2009). Palmer amaranth biotypes have also been found to be resistant to AcetoLactate Synthase (ALS) inhibiting herbicides and are tolerant to many other mechanisms of action (Whitaker et al, 2011). In addition most post-emergence herbicides registered in cotton are only effective when the weed is

3 inches tall or smaller (Culpepper et al. 2012). A Palmer amaranth plant can grow from seedling emergence to over 3 inches in under a week. Factors such as rain, broken equipment, or the inability to spray all of the cotton acres in a short amount of time can lead to the weed growing beyond the sensitive stage.

BEAD has reviewed the available efficacy data submitted by SePRO Corporation for this registration and the Section-18 package and determined that fluridone meets the FIFRA Section 2(ll)(2)(A), (C), and (D) criteria to manage pest resistance because it can be an effective tool for the control of glyphosate resistant Palmer amaranth. Fluridone herbicide is a carotenoid biosynthesis inhibitor (Weed Science Society of America (WSSA) Group 12 mode of action (WSSA, 2007)). With proper soil moisture, fluridone provides control of Palmer amaranth whereas available alternatives fail. This gives farmers a form of preemergence control where options are currently very limited. Fluridone uses a different mechanism of action than other herbicides, meaning that it is beneficial for a resistance management program to extend the effective life of existing herbicides. As a post-emergence herbicide, fluridone fits within an IPM program as an alternative to prophylactic, pre-emergence treatments.

Economic Methodology and Data

Overview of Methodology

In this analysis, the cost to register a new 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 PRIA 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. Other factors (see Appendix) are considered qualitatively in interpreting the results of the NPV analysis.

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

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.

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). Calculating NPV and $\frac{B}{C}$ require estimates of the initial cost investment and net revenue through time. 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 sufficient. 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.

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 returns, data include the expected sales price and projected sales. Sales price per acre was taken from SePRO's website where it advertises the price of Brake®, its products containing fluridone and fomesafen which are being used under Section 18 Emergency Exemption (SePRO Corp., 2015). Projected sales are based on the projected acreage to be treated and the useful life of the pesticide. The projected acreage is based on estimates of glyphosate-resistant palmer amaranth (GRPA). The useful life could be short, if for example, the target pests develop resistance or competing products are registered. Informal discussions suggest that registrants typically consider a three to seven year time horizon. See Appendix. EPA assesses three different scenarios in this analysis: five years, ten years, and twenty years.

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 of registration of fluridone on cotton 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 surveys of labs that generate registration data which EPA has conducted in support of rulemaking and data call-in requests over time.

The total data generation cost for registering fluridone on cotton is estimated to be $2.589 million, with residue chemistry 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 $32,275. Thus, the total cost for data and fees is estimated to be $2.635 million (Table 1).

Table 1. Data Requirements and Costs for Registration of Fluridone on Cotton[1]

Study Title	Guideline[2]	Estimated Cost
Product Identity, Composition, and Analysis	830 series, Group A	$ 56,100
Physical/Chemical Properties	830 series, Group B	$ 39,500
Description of production process	835 series, Groups A, B, D, F	$ 946,300
Residue Chemistry	860 Series	$ 1,494,100
Acute Toxicity	870 series, Group A	$ 53,000
Total Data Costs		**$ 2,589,000**
PRIA Registration Fee[3]		$ 32,275
Section 3 Paperwork Burden[4]		$ 14,000
Total Registration Cost (C_0)		**$ 2,635,275**

[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 rule-making 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. Small businesses are entitled to a 50 percent fee waiver on both fees. (EPA, 2013)

[4] Cost of paperwork burden to prepare and submit a Section 3 application for a new food use (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 somewhat difficult to quantify and verify, particularly for an individual registration action. Thus, these costs are not incorporated into a quantitative analysis of whether there is sufficient economic incentive to register a use. For the purposes of this analysis, BEAD notes that the registration of fluridone on cotton is the sole action under consideration. Thus, in contrast to a situation where multiple registration actions are packaged together and the marginal cost of an additional action would be rather low, all unquantified registration costs would apply to the cotton registration of fluridone. This will need to be considered in the interpretation of the results of the analysis.

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 fluridone, q_t is the quantity sold, $c(q_t)$ is the cost of manufacturing and distributing the herbicide 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. Alternatively, we can measure total sales as the cost per acre for a treatment, measured as the cost per pound times the application rate, multiplied by the acres treated. This approach is likely to be somewhat easier because it focuses on the target pest and the acres it infests.

Price or Cost per Acre

Fluridone is currently marketed for control of aquatic weeds in irrigation systems. Based on an internet search of producers and distributors of the aquatic product and application rates from Section 18 requests (Chism and Faulkner, 2012), BEAD previously estimated that the product would sell for between $67 and $128 per acre on cotton. The range depended on generic or brand name and application rate. BEAD estimated at the low end of the range ($70) given the lower-priced competitors. However, the product is currently being marketed at an even lower price of approximately $35 per acre (SePRO Corp., 2015). However, this is still expensive relative to other cotton herbicides used to treat palmer amaranth, which generally cost less than $10 per acre (maximum $20 per acre).

Quantity or Acres Treated

We now consider the acres treated with fluridone, the primary use of which will be for control of glyphosate resistant Palmer amaranth (GRPA) in cotton production. GRPA is a growing problem in U.S. cotton production. In 2009, Nichols *et al.* estimated that about 630,000 acres of cotton was infested with GRPA of which about 15 percent (approx. 100,000 acres) was severely

infested. Given its higher per acre cost relative to other cotton herbicides, only the severely infested acres are those likely to be treated with fluridone. Less severely infested acres may be cheaper to treat with currently available herbicides and/or cultural practices like hand weeding. Moreover, fluridone will be used on cotton that will be planted back to cotton (due to restrictions to avoid damage to following crops) and in areas where adequate soil moisture is assured for the herbicide to provide effective control (Culpepper, 2012). Based on the requirements for fields to be planted back to cotton and the need for an adequate supply of soil moisture, BEAD's analysis estimates the acres planted to be based on cotton followed by cotton in irrigated fields. There are over 10 million acres of cotton grown in the U.S. (USDA/Census, 2007) and 2.7 million acres of irrigated cotton following cotton (USDA, 2007). If 15 percent of this area is ultimately severely infested with GRPA, the area treated with fluridone would be just over 400,000 acres. This is relatively close to an estimated 500,000 acres made by USDA (Coble, personal communication, 2012).

At the end of 2014, fluridone had been approved for use in five states under Section 18 Emergency Exemptions. Table 2 shows the approved acreage by state and the reported use. Despite its efficacy, fluridone was only used on around 50% of the acres for which it was approved, suggesting that the price is an important factor in its adoption. However, the Section 18 reports also indicate that fluridone, currently treating close to 100,000 acres, will already have some market penetration when it obtains a Section 3 registration.

Table 2. Acreage Approved and Utilized under Section 18 Exemptions for Fluridone, 2014

	Georgia	North Carolina	South Carolina	Tennessee	Arkansas	Total
Approved	35,000	45,000	60,000	7,500	20,000	167,500
Utilized	18,426	11,084	49,520	7,489	0	86,519
Percent of Approved Acreage being Utilized						**52%**

In order to determine the future sales of the product BEAD assumes a simple linear increase in sales from 100,000 in the year immediately following registration to the maximum of 400,000 acres in the fifth year of sales. Increasing sales are a function of both increasing acres severely affected by GRPA and time for farmers to try and adopt the chemical.

Gross and Net Revenue

Given estimates of cost per acre and acres treated, future gross revenues can be calculated for the cotton market. Given current market structure, however, it is unlikely that one registrant could capture the entire market because fluridone was first registered in 1986, and the original period of exclusive use of data has expired. Thus, any applicant obtaining a registration for a new use could be subject to immediate competition from other applicants which could cite (with compensation) the data of the first data-submitting firm. Two scenarios were evaluated, one in which the registrant captures 60 percent of the market and one in which the registrant captures 35 percent of the market. This range is based on the observed market shares for the brand name product of seven cotton herbicides that have generic competitors, which range from 35 to over 90 percent of the acres, according to proprietary market survey data. BEAD does not use the full range in assessing potential outcomes because the cases analyzed are all situations where the

brand name product had nearly a decade to establish the market while this situation represents a nearly new market with several potential entrants competing for shares immediately. It is also worth noting that there is an inverse relationship between the brand name market share and the difference in the price of the brand name compared to generic competitors. That is, if the brand name lowered the price to near the generic price, it seems to maintain a larger market share, but if the brand name maintained a price above the generic price, it ceded more market share.

For this analysis, net revenue is assumed to be 15 percent of gross revenue, corresponding to production and marketing costs of 85 percent of the sales price. That is, $c(q_t) = \$29.75 \cdot q_t$, given a price of $35.00. The net margin is an uncertainty in the analysis, so the analysis also considers a much higher margin of 40 percent. There are reasons, however to think the supply cost of fluridone will be relatively high compared to the sales price. First, fluridone currently has only a small market in aquatic sites while the market in cotton will be a relatively large site, implying a potentially large movement along the marginal cost (supply) curve. In contrast, imagine an herbicide with a large market in corn considering a move into a niche use in sorghum where there would be a relatively small movement along the supply curve. Second, fluridone is moving from aquatic to terrestrial sites meaning the registrants have to build a new distribution system which comes with fixed costs. In contrast, an expansion from corn into sorghum would be relatively costless because the distribution system would be substantially the same.

Table 3 presents BEAD's projections of acres treated (q_t) and gross and net revenue under two scenarios for market share, 60% and 35%. The initial registrant is assumed to capture the full market in the first year, both in recognition of the delay that may be required before a competitor can reach the market and in consideration that the registrant has been able to sell some product under emergency exemptions to the full registration requirements. We assume the registration process will take 15 months as specified under the Pesticide Registration Improvement Act (PRIA III). Thus, sales of fluridone could begin for the 2016 season. To summarize, we use the following parameters:

- $P = \$35$,
- $c(q_t) = \$29.75 \cdot q_t$, and
- $\gamma_t = 0$.

Table 3 presents the cumulative future gross and net revenue over various time periods using 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 3. Estimated Gross and Net Revenue of Data-Submitting Firm

Year	Total Acres Treated	Gross Revenue ($1000) 60% Market Share	Gross Revenue ($1000) 35% Market Share	Net Revenue ($1,000) 60% Market Share	Net Revenue ($1,000) 35% Market Share
2016	100,000	$3,500	$3,500	$525	$525
2017	175,077	$3,677	$2,145	$551	$322
2018	250,153	$5,253	$3,064	$788	$460
2019	325,230	$6,830	$3,984	$1,024	$598
2020	400,306	$8,406	$4,904	$1,261	$736
2021	400,306	$8,406	$4,904	$1,261	$736
2022	400,306	$8,406	$4,904	$1,261	$736
2023	400,306	$8,406	$4,904	$1,261	$736
2024	400,306	$8,406	$4,904	$1,261	$736
2025	400,306	$8,406	$4,904	$1,261	$736
2026 – 2035	400,306	$8,406	$4,904	$1,261	$736
Discounted cumulative future revenue $\sum_{t=1}^{T}\left[\frac{Net\ Rev_t}{(1+r)^t}\right]$, $r = 7\%$					
5 year (2016-2020)		$10,771	$7,646	$3,296	$2,127
10 year (2016-2025)		$37,704	$23,357	$6,982	$4,278
20 year (2016-2035)		$72,068	$43,402	$11,485	$6,904

Source: EPA calculations.

Incentive Measures

Table 4 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 4. Analysis of Economic Incentive

		Gross Revenue ($1,000)		Net Revenue ($1,000)	
		60% market	35% market	60% market	35% market
1	2015 Cost of Registration	$2,635	$2,635		
	Annual Revenue at Full Market Potential	$8,406	$4,903		
2	5 Year NPV			$661	- $508
	10 Year NPV			$4,347	$1,642
	20 Year NPV			$8,849	$4,269
3	5 Year Benefit/Cost Ratio			1.25	0.81
	10 Year Benefit/Cost Ratio			2.65	1.62
	20 Year Benefit/Cost Ratio			4.36	2.62
4	5 Year IRR			15%	0%
	10 Year IRR			30%	18%
	20 Year IRR			32%	22%

Source: EPA calculations

The first part of Table 4 shows the analysis of economic incentive based on the standard from the current OPP policy, established in 1997 PR notice 97-2 – the difference between registration cost and returns "at full market potential," in this case, the year 2020 and beyond, after the maximum treated acreage of 400,000 acres is reached. This measure compares the registration cost of $2.635 million with estimates of gross revenue. The use does not meet the standard from the PR notice; revenues are $4.9 to $8.4 million per year, $2 to $6 million higher than registration costs. This measure does not account for the time value of money and non-registration costs of production.

The second part of Table 4 shows the 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 in the first year. Normally, sales of a pesticide would not begin in Year 1, but because nearly 100,000 acres are already treated with fluridone under Section 18 exemptions, the analysis reflects this. The NPV estimate, using a discount rate of seven percent, is negative for the low market share scenario over five years but slightly positive under the high market share scenario. The other time periods are positive under both market share scenarios.

The third part of Table 4 shows the benefit-cost ratio. Results indicate that the benefits are 80 to 125 percent of the costs for the 5-year time period depending on the market share the initial registrant obtains. This demonstrates the degree of uncertainty in the value of the investment. With longer time horizons, the benefit cost ration becomes more attractive, with benefits about 60 to 160 percent greater than costs if the revenue stream is secure over ten years.

The fourth section of Table 4 shows estimates of the internal rate of return (IRR) under different time scenarios. The return on the investment ranges ranging from essentially zero for the 5-year scenario with small market share to 32 percent for the scenario where the firm captures 60 percent of the market for 20 years. At 10 years, the small market share scenario provides an estimated return of 18 percent, which may not be a bad return.

Uncertainties

As with any prediction, there are a number of uncertainties in this analysis which may crucially influence the results. As can be seen from the analysis above, the time period is one such variable. If the time period over which registrants can recoup their costs is short, because resistance develops, other technologies develop, other chemistries can be made to work more cheaply, or for any other reason, the ability of the registrant to recoup registration costs becomes more difficult. As previously noted, informal discussions with registrants suggest that they tend to use a rather short time horizon of three to seven years in their decision making. See the Appendix.

Another crucial determinant is market size. However, the spread of GRPA is subject to considerable uncertainty as is the portion of infested acres for which fluridone would be the preferred control option. The sales price of cotton will also influence growers' choices for weed control options. Moreover, this analysis does not consider any potential negative effects that investments in a new market may have in the company's existing market for aquatic weed control

This analysis also depends on data availability and certain BEAD assumptions. We know we have not accounted for all the costs associated with bringing a pesticide to market, which will bias upward the estimated measures of the overall return on the investment. As for returns, BEAD assumed that the unit manufacturing and distribution costs are 85 percent of the sale price in order to characterize net revenue. If costs are 70 percent of the sale price, the NPV of the investment over five years with only 35 percent of the market is $1.6 million, implying a benefit-cost ratio of 1.6 and an IRR of 26 percent, which would be a much more attractive investment. However, moving from a small aquatic market into a large terrestrial market is likely correlated with high manufacturing and distribution costs.

Conclusions

There are a number of qualitative considerations that suggest a registration of fluridone on cotton constitutes a minor use under FIFRA 2(ll)(2), lack of economic incentive. The potential for fluridone to be used as a cotton herbicide has long been recognized, but registration has not been pursued until recently. Weed resistance to other herbicides has opened a market niche, but the economics of cotton production still limit the price at which fluridone can be sold, which suggests a small per-unit return over manufacturing costs in comparison to other possible scenarios for a new herbicide use. Moreover, fluridone is not suitable for use on other crops due to the possibility of crop damage, further limiting its market potential. Together, these factors suggest that a registrant may not consider that it is economically feasible to register fluridone. BEAD's economic analysis supports this conclusion. The quantitative analysis suggests that returns on the registration costs are highly uncertain over a five-to-ten year time horizon and may be negative if the initial registrant cedes significant market share to generic competitors.

The current policy, established in PR Notice 97-2, has rarely, if ever been used, suggesting that it may fail to take into account important factors. One of the reasons for the analysis above is to consider other ways to determine whether there is a "lack of incentive" to register minor uses. Under current policy, a registrant would demonstrate a lack of incentive for a registration by showing that the costs of data generation exceed gross revenue from sales on that use at full market potential. Even accounting for competition, using the PR Notice policy as guidance, BEAD estimates that a registrant could have gross sales of $4.6 to $8.4 million at full market, substantially higher than the $2.6 million in data generation costs and registration fees. However, this measure of incentive does not consider the costs of manufacturing and distribution, which could be a substantial proportion of sales. Nor does is consider the rate of return on competing investments. BEAD believes these missing factors are vital to a more accurate economic analysis.

In consultation with USDA, BEAD developed a new approach that examines the registration decision as an investment. Registration costs are an investment and future net revenues represent the return on the investment. The analysis considered various measures to compare discounted future revenues over various lengths of time against the costs of registration (data and fees). These measures include the net present value (NPV) of the investment (discounted future revenues minus the cost of registration), the benefit-cost ratio (discounted future revenue divided by the cost of registration), and the internal rate of return (IRR) (a measure of how rapidly an investment grows over time). A key assumption in the qualitative analysis is that production and marketing costs are 85 percent of the sales price of the herbicide. This assumption is supported by certain characteristics of the market, especially the expansion of fluridone from a small, aquatic uses into a large, terrestrial use that involves substantial increase in production and the development of new distribution systems and marketing expertise. BEAD further acknowledges that all registration costs have not been quantified for this analysis and that these costs are important in this case because fluridone is only being registered for a single use site.

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Appendix

The following list of factors is based on a discussion between US EPA and pesticide registrants on the subject of minor use, June 14, 2012.

Factors Companies Consider Before Pursuing a Registration
COST FACTORS (not in order of priority)

- Registration costs
  - Data generation
  - other
- Manufacturing costs
  - Product support, product marketing
  - New company FTE to support new product, new market, new geography
  - New retailer program
  - Packaging, formulation, or manufacturing process changes
- Liability from damage to a high value crop or customer complaints
- Cannibalism of existing products - the registration of a new product that will reduce the sales of an existing product
- Post product introduction
  - Product monitoring
  - Stewardship programs

PROFIT FACTORS (not in order of priority)

- Percent market share – sales
- Percent return on investment
- Years for return – 3 to 5 to 7 years depending on company, market, and liability
- MRL – more food products are globally traded, even U.S. to Canada trade

Other Factors

- Size of the risk cup