September 14, 2016

Ladies & Gentlemen:

The Environmental Protection Agency (EPA or the Agency) is seeking public comment on a draft Pesticide Registration Notice (draft PR Notice) entitled, “Determination of Minor Use under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 2(ll).” CropLife America (CLA) is pleased to comment on behalf of our members.

CLA is the national trade association that represents the manufacturers, formulators and distributors of crop protection products. CLA’s member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by farmers, ranchers, and landowners in the United States. CLA comments publicly on issues of general importance and concern to our member companies.

Comments on the Two Ways That FIFRA Provides to Define a Minor Use

Acreage definition of “minor use”
The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides two independent definitions of “minor use.” First, FIFRA §2(ll)(1) defines any crop grown commercially on less than 300,000 acres as a minor use. We understand this limit applies to production within a given year.

The draft PR Notice specifies USDA’s most recent Census of Agriculture\(^1\) as the source EPA will rely upon to determine crop acreage. Given the size and complexity of this publication, it would be helpful to indicate in the PR Notice the portions of the Census that spell out crop acreage, specifically Table 37 (Specified Crops by Acres Harvested); Table 38 (Vegetables, Potatoes, and Melons Harvested for Sale); and Table 39 (Specified Fruits and Nuts by Acres).

For the following reasons, we suggest that EPA consider other reliable sources of information as needed, particularly to address the timing limitations of the Census. The Census is compiled at

\(^1\) https://www.agcensus.usda.gov/Publications/2012/
5-year intervals. Furthermore, the report is generally not released until a few years after the most recent production data that it contains. A significant or precipitous reduction in production acreage for a particular crop might occur in that time period, making it newly qualified as a minor crop, but not eligible for FIFRA incentives for some years, until the next USDA report is published. Strict dependence on the USDA report might delay access to newer crop protection technology for producers of that crop. EPA should consider applications for such “new” minor crops, while the Census catches up, based on reliable information submitted with an application. Examples of crops with annual U.S. production acreage fluctuating around the 300,000-acre threshold are flaxseed and lentils.²

Economic conditions definition of “minor use”
Second, FIFRA provides that economic circumstances can define a minor pesticide use on a crop that is grown on more than 300,000 acres [FIFRA §2(ll)(2)]. A specific pesticide use can be considered minor if it “does not provide sufficient economic incentive to support initial registration or continuing registration …” Currently, PRN 97-2³ defines the economic incentive as insufficient if the “incremental costs to register” the specific use exceeds the “registrant's gross sales which are the additional sales projected at full market potential” for a single year. The draft PR Notice acknowledges that this standard can overestimate the economic incentive to the extent that gross revenues at full market potential exclude the cost of producing the pesticide or full market potential is not reached in a year. Alternatively, the standard can underestimate the economic incentive to the extent that the pesticide is marketed for more than a single year. Therefore, the draft PR Notice proposes replacing the current standard with a new one based on an investment paradigm. CLA agrees that an investment paradigm can provide a more accurate measure of the economic incentives faced by registrants and would like to offer some suggestions for improving use of the general method proposed in the draft PR Notice.

The draft PR Notice states that the benefit cost ratio (BCR; abbreviated B/C in the draft PR Notice) “can be helpful to determine how uncertainty in the future revenue stream influences the likelihood of an overall positive outcome (page 7).” It is not clear how the BCR can be used to assess uncertainty in general or how the EPA may use the BCR in this capacity. Therefore, CLA recommends removing this language or providing more information on how the EPA plans to use the BCR in this capacity.

The draft PR Notice also states that the internal rate of return (IRR) “measures the return on the investment as an annual average percentage growth (page 7)” and “can be useful to compare the value of the registration investment to other potential investment opportunities based on the rate of return over time (page 7).” The first statement’s interpretation of the IRR is not generally regarded as accurate and often leads to unreliable implications.⁵ In terms of the second

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⁴ A similar statement, “IRR for a particular use can be compared to IRRs of other registered uses to provide another measure of the incentive to register a chemical for a particular use,” is found on page 11.
statement, while there are circumstances where it is appropriate to compare the profitability of investments using the IRR, this generally is not the case. It is also generally not the case that an investment is profitable when the IRR exceeds the market rate of return, because the analysis depends on the specific characteristics of the stream of revenues and costs over time. Therefore, CLA recommends removing this language.

There are two common benchmarks for assessing an investment using an NPV, BCR, or IRR. Alternatively, there is the benchmark of whether the investment is more profitable than some alternative investment. Being clear about the benchmark is important. The majority of the draft PR Notice frames the investment as a standalone project and determining whether that project is profitable. However, there are statements in the draft suggesting a comparison of alternative investments and “competing uses for capital.” The standalone investment benchmark is more transparent and straightforward because there are many additional factors to consider when comparing two or more alternative investments: differential time frames in which revenues and costs accrue; differences in the riskiness of alternative revenue and cost streams; and overall magnitudes of alternative investment revenues and costs. CLA recommends clarifying that EPA will use a standalone project analysis.

In terms of implementation, three different types of costs are defined: the cost of registration \((C_0)\); the cost of manufacturing and distributing the pesticide that varies depending on how much pesticide is sold \((c(q_t))\); and the cost of registration maintenance, legal fees and other factors that does not vary with how much pesticide is sold \((\gamma_t)\). The proposed definition of the BCR includes the first of these as a cost, while including the second and third in revenues:

\[
BCR = \frac{\sum_{t=1}^{T} P_t \cdot q_t - c(q_t) - \gamma_t}{C_0}
\]

An alternative and arguably more accurate definition in this setting is:

\[
BCR = \frac{\sum_{t=1}^{T} P_t \cdot q_t}{C_0 + \sum_{t=1}^{T} (c(q_t) + \gamma_t)}
\]

There are two options to address this issue. The first is to eliminate the BCR from consideration, though it can provide useful information on the relative profitability of each dollar invested in the registration or the pesticide use. The second option is to use the second definition of the BCR, which more accurately reflects the actual investment revenue and cost streams faced by registrants for a registered pesticide use.

The current document assumes that the costs of registration \((C_0)\) all occur in an initial year. In actuality, the registration process extends over multiple years, which biases the cost estimate downward. CLA recommends appropriately discounting registration costs when (as usually is the case) the registration process extends beyond a year.

A primary motivation for calculating and using an IRR is to avoid having to make explicit assumptions about the discount rate. However, the IRR still makes implicit assumptions about the discount rate. These implicit assumptions make it a systematically biased estimate of the types of annual percentage rates (APRs) commonly reported for a variety of financial products (e.g., mortgages, certificates of deposit, and mutual funds). We also note that the EPA’s own
Guidelines for Preparing Economic Analyses⁶ (Chapter 6) do not reference or recommend the IRR. Therefore, in the interest in increased transparency, CLA recommends that the IRR not be used with the NPV and BCR when determining the economic incentives for registrants.

The NPV and BCR are both sensitive to the choice of a discount rate. Choosing a higher or lower discount rate can result in an increase or decrease in the NPV and BCR. While a 7-percent discount rate may be a reasonable place to start an NPV and BCR analysis, CLA recommends that EPA consider a range of values both above and below 7 percent. This type of analysis provides a transparent strategy for assessing how sensitive the profitability of an investment is to competing capital uses and uncertainty, as both of these factors often support the use of higher discount rates for calculating the profitability of an investment using the NPV.

It is important for EPA to acknowledge that individual registrants appropriately use different discount rates to evaluate potential registration investments, based on their respective company circumstances and requirements. It should make clear that it is not suggesting that any particular rate is the actual rate in any particular circumstance. Moreover, EPA should make clear that its use of surrogate rates here is for simplicity and for this purpose alone. Finally, EPA should be explicit that it is using such surrogate rates for this particular exercise only and is not offering them for nor should they be used for any purpose other than this exercise.

Extend minor use incentives to specialty crops
The Agency’s approach to designation of minor use status in the draft PR Notice should be consistent with its policy for IR-4 public interest findings, including specialty crops, as defined there.

In statutes and in practice, the definitions of minor use and specialty crop overlap.

• The 2014 Farm Bill amended the Competitive, Special, and Facilities Research Grant Act (7 U.S.C. 450i(e)) to expand the remit of the IR-4 Program “… to assist in the collection of residue and efficacy data in support of— (A) the registration or reregistration of pesticides for minor agricultural use and for use on specialty crops (as defined in section 3 of the Specialty Crops Competitiveness Act of 2004 (7 U.S.C. 1621 note)), under [FIFRA] …” (emphasis added).

• Under the 2004 Specialty Crop Competitiveness Act (7 USC §1621 note), “The term ‘specialty crop’ means fruits and vegetables, tree nuts, dried fruits, and horticulture and nursery crops (including floriculture).”

• The Pesticide Registration Improvement Act of 2004 [PRIA; FIFRA Section 33(b)(7)(E)] exempts “… an application from the registration service fee if the Administrator determines that — (i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR–4) …; and (ii) the exemption is in the public interest.”

• In 2014, EPA published a policy on Factors for IR-4 Public Interest Finding,⁷ unifying these legislative concepts and equating “specialty crop” with minor use, for purposes of qualifying

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⁷ https://www.epa.gov/pria-fees/guidance-ir-4-exemptions
for the IR-4 PRIA minor use fee exemption, without need of a further demonstration of economic minor use.

Thus a number of specialty crops that exceed 300,000 acres of annual U.S. commercial production could qualify *a priori* for the IR-4 PRIA fee exemption, and should also be afforded the other incentives allowed by FIFRA.

Table 1. Vegetables and fruits exceeding 300,000 acres of commercial U.S. production in 2012. Data from USDA’s 2014 *Census of Agriculture*, Tables 38 and 39.

<table>
<thead>
<tr>
<th>Crop</th>
<th>Acreage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lettuce, all</td>
<td>323,359</td>
</tr>
<tr>
<td>Potatoes</td>
<td>1,168,199</td>
</tr>
<tr>
<td>Sweet corn</td>
<td>572,068</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>397,656</td>
</tr>
<tr>
<td>Apples</td>
<td>384,237</td>
</tr>
<tr>
<td>Grapes</td>
<td>1,139,146</td>
</tr>
<tr>
<td>Citrus fruit</td>
<td>877,701</td>
</tr>
<tr>
<td>Almonds</td>
<td>936,248</td>
</tr>
<tr>
<td>Pecans</td>
<td>543,486</td>
</tr>
<tr>
<td>Walnuts, English</td>
<td>332,045</td>
</tr>
</tbody>
</table>

**Data and costs that are included or excluded**

The draft PR Notice states that “… since some data … may support multiple uses … such basic data should not be claimed to be part of the cost of registering an additional use.” However, if the use of an active ingredient is expanding into a new category for the first time (such as the first terrestrial crop use for an aquatic pesticide), some general or basic studies may be needed for that active ingredient the first time to support that economic minor use. They should be considered part of the minor use support costs, even though they may be used subsequently to support other uses.

The draft PR Notice states (p. 9):

“EPA maintains a database of test costs for most studies listed in the CFR. The test costs are obtained by EPA from independent laboratories and the averages of the costs are publicly available and should be used for the purpose of estimating the cost of generating the data required for registering the purported minor use. The use of this cost information will ensure consistency and transparency.”

It is our understanding, however, that the cost estimates are not, in fact, available to the public.

First, even if these figures are made available for public review, EPA should explicitly acknowledge that these estimates are not the actual costs for any specific studies or data package. The Agency should also acknowledge that the actual costs of data can vary significantly, depending on the guidelines at the time of the study, the specific attributes of the test substance, and the nature of the particular testing facility (for instance, contract laboratory or in-house laboratory of the applicant/registrant), among other factors. Also, for studies conducted by contract laboratories, there are additional costs by the applicant or its consultant to oversee and support the work.
Second, it is important for EPA to be explicit that such estimates are surrogates being used for simplicity and for this purpose alone, and that they are not being offered for nor should they be considered reliable for any other purpose.

In the draft PR Notice, EPA has left research and development out of the applicant’s/registrant’s total costs, which we assume would include studies on product efficacy and crop phytotoxicity. While the Agency does not typically call in or review such studies, they are indeed essential for support of minor uses, and their costs can be a significant and major portion of the required resources. This is particularly so in the instances in which the field residue work is largely covered by a crop group tolerance. Such studies should be considered as part of the registrant’s costs to support a minor use.

An Alternative Approach

The proposed economic analysis is quite an onerous process. In addition, it could require submission of confidential and sensitive business information, with uncertainty about whether such information would be protected from disclosure to competitors who could in turn seek to use or misuse the information for competitive advantage. Furthermore, as the Agency acknowledges in the draft PR Notice, “… a burdensome process to demonstrate [low incentive] would simply be an added deterrent to registration.”

We understand that IR-4 has found that registrants are reluctant to seek the exemption or partial waiver of the PRIA fee for a minor use under FIFRA §33(b)(7)(E), because of the effort needed to demonstrate eligibility. A complex process developed by EPA for demonstrating eligibility would be less likely to be used, and would fail to achieve the Agency’s goals of “… providing more safe and effective tools to control pest problems.”

With all this in mind, CLA proposes an alternative to EPA’s economic analysis approach for determining when a pesticide use on a major crop would qualify as a minor use for the registration incentives available under FIFRA. Congress has set the 300,000-acre threshold for production of a particular crop as an a priori definition of minor use. By doing so, Congress implicitly assumes a limit on “anticipated revenues from the proposed use.” In defining economic minor use, EPA could establish a similar 300,000-acre limit on the U.S. major-crop production area that is affected by the pest, disease or weed problem(s) that would be controlled by a particular crop protection product, to qualify as an economic minor use.

EPA proposes to rely on USDA’s most recent Census of Agriculture as the source of acreage production figures (see comments above about considering additional information as well). Unfortunately, there is not a corresponding, regularly updated “Census of Pest, Disease, and Weed Infestations.” However, this information is particularly important to USDA, Land Grant colleges and universities, Extension Service, and grower organizations. This broad network gears up quickly to address any new crop protection problem, whether it is Asian soybean rust or brown marmorated stinkbug or citrus greening. Reliable, current information on the geographic extent of a crop protection problem could be provided fairly readily to accompany the application for approval of an economic minor use.
It is possible that a pest problem occurring on limited acreage in a crop could spread substantially to exceed 300,000 acres, after an economic minor use is registered. But that should not be reason to deprive growers of products to combat smaller infestations and to diminish the possibility of the pest problems spreading.

- The chances of significant geographic spread of the pest problem should be reduced by registering the use to keep the problem in check.
- The situation is similar to the potential fluctuations in crop production acreage around the 300,000-acre threshold.
- The simpler administrative requirements would help ensure availability of tools more promptly and on a favorable timeline, vis-a-vis potential broad-scale changes in pest infestation.

There might still be circumstances when an economic analysis would be appropriate to determine an economic minor use. Under Section V.B of the draft PR Notice, a second paragraph could be inserted to state: “If the applicant requests a designation of economic minor use under FIFRA §2(ll)(2) on the basis of geographic limitation of the target pest problem, the applicant should include reliable information describing the current geographic extent of the pest problem.”

Another situation that might effectively limit use of a pesticide product on a major crop to “minor crop” acreage is varietal sensitivity or tolerance to the pesticide. For example, if a potato variety grown on limited acreage is tolerant of a particular pesticide, while other varieties are susceptible, use of the pesticide limited to that variety could be considered a priori a minor use.

Why Seek Minor Use Status?

The draft PR Notice focuses on the first reason below for seeking minor use status, but there are other reasons that should be mentioned.

1. Qualifying for additional years of exclusive use of data under FIFRA §3(c)(1)(F)(ii).
2. Becoming eligible for IR-4 participation in producing data required for registration, which exempts the application from the corresponding PRIA fee under FIFRA §33(b)(7)(E). Furthermore, EPA counts minor uses supported by IR-4 data toward the number of minor uses necessary to extend the exclusive use period for new active ingredients.8
3. Obtaining an exemption from or partial waiver of the PRIA fee for the minor use under FIFRA §33(b)(7)(D).
4. Continuing support for a registered use during registration review that might now qualify as a minor use if it were an initial registration. [FIFRA §2(ii)(2)]
5. Continuing support for a registered use, if new label language or new data requirements imposed during review of peripherally related or unrelated label amendments might jeopardize the minor use, whether or not it previously was registered as or qualified as a minor use. [FIFRA §2(ii)(2)]

Revising PRN 97-2

The draft PR Notice would update only Section VII of PRN 97-2. To reduce or avoid the potential for confusion among registrants, the entire PRN 97-2 should be updated at this time to clarify which portions are still in effect. This may involve splitting it into two new PR Notices, with little or no change to the portions unrelated to minor uses.

In the draft PR Notice, page 1, footnote 1, the hyperlink to PRN 97-2 is obsolete. It should read: https://www.epa.gov/sites/production/files/2014-04/documents/pr97-2.pdf.

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We would welcome the opportunity to discuss these comments with the Agency. Please feel free to contact me directly at 202-872-3874 or ray@croplife.us.

Sincerely,

Ray S. McAllister
Senior Director, Regulatory Policy