



*Healthy Plants • Healthy World*

September 1, 2016

OPP Docket  
Environmental Protection Agency  
Docket Center (EPA/DC)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460-0001

**SUBJECT: The American Phytopathological Society (APS) on Draft Pesticide Registration Notice (PRN) 2016-X: Guidance for Pesticide Registrants on Resistance Management Labeling; EPA-HQ-OPP-2016-0242 and EPA ID # EPA-HQ-OPP-2016-0226**

On August 5, 2016 the Environmental Protection Agency (EPA, the Agency) issued an extension of time for comments on “Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling” and “Guidance for Herbicide Resistance Management Labeling, Education, Training and Stewardship” until September 1, 2016. The American Phytopathological Society (APS) appreciates the opportunity to comment on two Federal Register documents (81 FR 35766) (FRL-9946-52), (81 FR 35767) (FRL-9946-53) and documents associated with these draft guidance documents.

The American Phytopathological Society is a non-profit, professional scientific organization representing nearly 5,000 scientists and practitioners of plant pathology dedicated to the study and management of plant disease, especially as it relates to feeding the ever growing world population. APS is the premier society dedicated to high quality, innovative plant disease research and management. APS is driven by a distinctive community of scientists who come from academia, industry, government and private practice whose commitment is to the judicious use of sound science to shape public policy as it relates to management of plant diseases.

As a society that encompasses basic and applied scientific disciplines, the APS appreciates the EPA’s endeavors to aid in the ongoing efforts to address the management of pest resistance to crop protection products. We also value the working relationship that the APS has with the Agency, especially the opportunities we enjoy to directly communicate with EPA’s Biological and Environmental Analysis Division (BEAD). We believe that the BEAD and the APS have endeavored to enhance this relationship over the past decade.

### **General Comments**

Resistance management is of critical importance to maintaining optimal crop protection strategies for successful high-yield plant production. APS supports maintaining the Mode of Action (MoA) classification on the label to reduce the potential for resistance development, consistent with most current fungicide labels. The Fungicide Resistance Action Committee (FRAC) (<http://www.frac.info/>) maintains a current list of plant pathogens documenting fungicide resistant pathogens and the accepted classification scheme for listing the MoAs.

Certain other label language suggested in the EPA’s proposed guidelines delineated in these Draft PR Notices are noted by the APS to potentially be problematic. The APS is particularly concerned about the vague and unquantifiable language recommended in

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many sections of the draft PR Notices, since all label statements have the force of the law and anyone using a pesticide in a manner inconsistent with the labeling may be subject to civil and/or criminal penalties. Such language includes numerous uses of the following terms: “appropriate”, “significant”, “recommended”, “adopt” and “sustainable”. Additionally, the proposed requirements for “monitoring”, use of “predictive models” and “adoption of integrated pest management programs” are neither defined nor quantified, resulting in great uncertainty as to how those label statements might be interpreted and enforced.

Although the APS recognizes that such general terms can be useful when drafting basic guidelines appropriate to a wide array of crop protection products, we suggest that the documents would be less confusing, stronger and far more useful if they overtly recognized the vagueness inherent in this approach, provided the rationale for employing it as discussed above and encouraged registrants to customize the label language appropriate for their individual products. Although Draft PR Notices are intended to recommend “guidance”, on a number of occasions they have been used to assume the power of mandatory law for pesticide registrants and users. Indeed, many APS members have pointed out that the PR Notices indicate that they are “voluntary” guidance documents yet they contain provisions for compliance in two (2) years. The APS strongly recommends that the problems inherent to these issues be recognized in any subsequent efforts to improve (or initiate) resistance-management language on individual pesticide labels, so that what appears to be a well-intentioned initiative does not result in negative unintended consequences for registrants, users and advisor specialists.

The EPA PR Notice states “Resistance-management labeling will provide pesticide users with easy access to important information regarding target-site resistance, the cornerstone of most resistance management programs”. As noted above, it also requires compliance with Integrated Pest Management (IPM) practices, including scouting and monitoring for target pest resistance, although these terms are not defined. The United States Department of Agriculture continues to make available a wealth of information on IPM tactics and strategies, as do local statewide and regional Cooperative Extension programs and industry groups such as FRAC, the Herbicide Resistance Action Committee (HRAC) and the Insecticide Resistance Action Committee (IRAC). The APS suggests that a number of the draft labeling statements on IPM with regard to identification of potential resistance should be referred to these experienced specialists.

One of the associated PR Notices includes the statement that “The Agency has found pesticide resistance to be an adverse effect, and the lack of appropriate resistance-management guidance on the label may become a factor that could strongly influence EPA’s regulatory conclusions on the risk and benefits of a pesticide.” The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), section (6)(a)(2) states that “If at any time after the registration of a pesticide the registrant has additional *factual* information regarding unreasonable adverse effects *on the environment* of the pesticide, the registrant shall submit such information to the, Administrator” (emphasis added). It is unclear how pesticide resistance could be categorized as an adverse environmental effect. The APS has continuously supported fungicide resistance management strategies, as the loss of a crop protection tool is not advantageous nor does such loss contribute to sustainable agriculture. Additionally, since one of these draft guidance documents requires an additional yearly reporting of resistance observations, it appears to the APS that this requirement is duplicative of FIFRA section (6)(a)(2) reporting and is unreasonable since the Agency will already be in possession of this information. Further, since this provision would consist of required reporting, it would (and should) be subject to rulemaking. And there are no guidelines with regard to what constitutes quantification of pesticide resistance. If field observations are used, shouldn’t these observations be verified with laboratory testing before reporting is required?

Resistance management is quite complicated within the plant pathogen realm. Thus utilizing the same regulatory language to address resistance management for plant pathogens as for insects and weeds is

more than ambitious, since pathogens can be haploid or diploid and subject to monogenic or polygenic inheritance, and should be considered cautiously by the Agency before recommending or requiring its incorporation into the label. For example, the proposed requirement to discontinue the use of a fungicide/bactericide if disease continues to progress after application is not appropriate since a diverse set of field conditions would need to be evaluated to determine if disease progression was truly due to fungicide/bactericide resistance. In our experience, factors such as poor weed management, poor insect vector control, erroneous application timing, poor application technology, adverse weather events, and various forms of operator error can be collectively responsible for a large number of plant disease control failures. Fungicide or bactericide resistance can also be a cause for disease control failures but often is not the primary cause.

### **Specific Comments**

EPA Docket ID # EPA-HQ-OPP-2016-0242

Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling

Fungicides/Bactericides (Pages 9-11):

The APS agrees with EPA's desire to steward active fungicide/bactericide chemistries to reduce the risk of resistance development in fungal and bacterial plant pathogen populations. Industry has proactively included most of the proposed label language suggested by EPA where appropriate. However, the APS is concerned that these guidelines are applying a broad brush to a very complex and nuanced issue. The document does not take all application types into consideration. The APS has been pleased with the current registration and labeling process as it allows for flexibility in different application types, crops, and diseases. Not all guidelines are applicable to all situations.

Bactericides are much more limited in available modes of action and disease control options. The APS feels strongly that bactericide management guidelines and label language should be considered separately from fungicides, as options for controlling bacterial diseases are significantly limited and will support fewer new restrictions while still maintaining effective options for disease management.

The APS also strongly suggests that nematicide management guidelines and label language be considered separately from fungicides and bactericides as management practices are much different.

### **Item 2 – additional resistance management labeling statements:**

The APS recommends to adjust opening statement to “To delay fungicide/bactericide resistance, *consider the following steps:*”

1. The APS supports rotating MoA within a growing season. However, MoA rotation among seasons is not consistent with typical recommendation practices.

BASF Priaxor – example of MoA rotation language

<p><b>Resistance Management.</b> To limit the potential for development of resistance, <b>DO NOT</b> apply more than 16 fl ozs of <b>Priaxor</b> per acre per season. <b>DO NOT</b> make more than two (2) sequential applications of <b>Priaxor</b> before alternating to a labeled <b>non-Group 7</b> or <b>non-Group 11</b> fungicide.</p>
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2. The APS agrees that use of fungicide/bactericide mixtures of different modes of action can contribute to resistance management. However, not all pathogens/diseases have another effective MoA available, and mixtures may be unnecessary when application is a component of an overall MoA rotation program or when only one fungicide application is required in a situation that is less likely to contribute to resistance (e.g. postharvest).

3. The APS also supports the integrated disease management statement as it is already consistent with current practice.

Bayer's Luna Experience – example of IPM language:

“IPM: Applications of fungicides should be integrated into an overall disease and pest management program. Cultural practices known to reduce disease development should be followed. Consult your local extension specialist, certified crop advisor and/ or manufacturer representative for additional IPM strategies established for your area. This product may be used in Agricultural Extension advisory (disease forecasting or risk assessment) programs, which recommend application timing based on environmental factors favorable for disease development”.

4. Predictive disease models are helpful for the implementation of fungicide applications but are not always the best tool to avoid resistance development. Predictive models vary greatly in their quality and utility in general, and even a model that is useful in one region may be much less useful and/or accurate in another. Furthermore, use of a particular fungicide within a model system will depend somewhat on the fungicide's physical mode of action, e.g., whether it is preventive (should be applied before a potential infection event) or curative (should be applied after a putative infection event). It is not possible to make a general statement about the use of predictive models beyond recommending that they be considered when trying to best time the need for and timing of a fungicide application, as per label recommendations. The APS recommends that applicators follow the label for subsequent applications but to include predictive models if useful and applicable.
5. The APS does not support the resistance monitoring statement. The end user should communicate his/her concerns to the manufacturer representative and/or university extension specialist. A trained professional can respond to those concerns and determine whether lack of performance is a potential resistance concern or something else (applicator error, poor application timing, weather). As a practice, manufacturers already provide a phone number on the label to report product performance concerns.
6. The APS does not support the disease continuation statement and believes that it should be removed entirely. We support the need to rotate MoA for resistance management, and that label language is already standard practice. Poor control in the field could also be caused by other factors including poor application, fungicide selection, timing of application, fast and multiple pathogen cycles, or pathogen reintroduction.

Syngenta Switch 62.5WG – example of resistance management language

## RESISTANCE MANAGEMENT

GROUP	9	12	FUNGICIDES
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Switch 62.5WG contains two fungicides with different modes of action. Cyprodinil is an anilino-pyrimidine in Group 9. Fludioxonil is a phenylpyrrole in Group 12. A disease management program that includes alternation or tank mixes between Switch 62.5WG and other labeled fungicides that have a different mode of action is essential to prevent pathogen populations from developing resistance to Switch 62.5WG. Do not alternate or tank mix this product with fungicides to which resistance has already developed. Switch 62.5WG may be applied in an alternating or blocking program.

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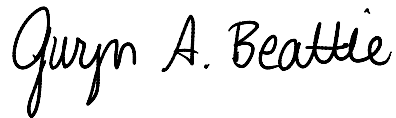
7. The APS supports the statement about contacting an extension specialist or certified crop advisors for resistance management and IPM recommendations.
8. For further information and to report suspected resistance, the APS supports the provision to provide contact information of the manufacturer (phone or internet site) but not the name of a company representative as the relevant personnel often change. Rather, the APS suggests the inclusion of general language to contact “a company representative”.

In conclusion, the APS would be encouraged if the Agency would engage us in a discussion of the ramifications and alternatives to those currently proposed in the PR Notices. We continue to have the highest degree of respect for our current relationship and look forward to continued advancement of our two-way communications and to contributing our Society’s knowledge towards improved management of plant pathogen resistance to crop protection products within regulatory policies that are based on sound science.

Sincerely,

A handwritten signature in black ink that reads "Timothy D. Murray". The signature is written in a cursive, flowing style.

Timothy D. Murray  
President, American Phytopathological Society

A handwritten signature in black ink that reads "Gwyn A. Beattie". The signature is written in a cursive, flowing style.

Gwyn A. Beattie  
APS Public Policy Board Chair