DRAFT

OPP Docket
Environmental Protection Agency
Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave NW
Washington, DC 20460–0001


Ladies & Gentlemen:

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA’s member companies produce, sell and distribute virtually all of the vital and necessary crop protection and biotechnology products used by farmers, ranchers and landowners. CLA is committed to working with the Environmental Protection Agency (EPA or the Agency) to encourage practical, science-based regulation of its members’ products.

Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber, and fuel. CLA members support science based regulation, using a comprehensive risk assessment approach to ensure crop protection products can be used without causing unreasonable harm to either human health or the environment. CLA appreciates the opportunity to comment on the Draft Pesticide Registration Notice (PR Notice or PRN) 2016-X, “Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling” (EPA-HQ-OPP-2016-0242) and on Draft PR Notice 2016-XX, "Guidance for Herbicide-Resistance Management, Labeling, Education, Training and Stewardship" (EPA-HQ-OPP-2016-0226) (Draft Guidance) scheduled to close on September 1, 2016.

The average time from first laboratory synthesis to first product sales for a new agricultural pesticide active ingredient in world markets now exceeds 11 years. The results of the testing

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culminate in the production of a product label, which is approved by the EPA, and stipulates the conditions under which the product may be used, such that its use will not cause unreasonable adverse effects on the environment. The registrant may not make claims that substantially differ from the EPA-approved label and use of the product not compliant with its label is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

CLA and its members have a long history of education and outreach on resistance issues through their own work and also through participation in organizations dedicated to resistance stewardship, including the North American Fungicide Resistance Action Committee (NAFRAC), Herbicide Resistance Action Committee-United States (HRAC-US) and Insecticide Resistance Action Committee-United States (IRAC-US). These organizations have developed educational, science-based initiatives to address fungicide, herbicide and insecticide resistance in agricultural pest control systems. CLA is, therefore, uniquely qualified to comment on the subject Draft Guidance documents (PRNs, or PR Notices).

Below we offer some general comments and observations on the Agency's approach to resistance management. We then comment on some of the more technical aspects of the Agency's resistance management recommendations and, in closing, we explain why pest resistance is a benefit consideration under FIFRA's "unreasonable adverse effects" standard but not an adverse effect and urge that the Agency confirm in its final PRNs that its resistance management recommendations are voluntary, thereby confirming PR Notice 2001-5.

CLA'S GENERAL RECOMMENDATIONS AND OBSERVATIONS ON RESISTANCE MANAGEMENT:

CLA welcomes EPA’s updating of PRN 2001-6. We are concerned, however, that resistance management does not lend itself to prescriptive regulatory measures, such as mandatory labeling. We are uncertain whether "one size fits all" is the best approach to take when it comes to resistance management. Below we urge the Agency to consider the amount of mandatory information already on the label and suggest some ways the Agency can more effectively support resistance management than through prescriptive labeling measures.

Resistance Management Does Not Lend Itself to Prescriptive Regulation by EPA, Look Instead to Existing Resistance Management Resources: A pest's development of resistance to a pesticide is the product of complex agronomic and biological processes over time. For this reason, CLA respectfully submits resistance management does not lend itself to prescriptive regulations and labeling requirements. The Weed Science Society of America (WSSA) and organizations like HRAC should continue to provide the basic elements for herbicide resistance management

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2 See, e.g., 7 U.S.C. § 136(a) et seq., 40 C.F.R. 156.10.
3 7 U.S.C. § 136l.
practices and related product labeling. Product labels should refer users to their local cooperative extension/consultant/adviser to access Best Management Practices (BMPs). Registrants may elect to insert the Herbicide Resistance Management and BMPs on their labels if they are concerned about stewardship issues. This minimizes the impact on product labels and relieves the resource strain on both registrants and EPA to make and review label changes. We urge EPA to look to professional weed science societies and academic institutions to expand and improve existing stewardship and training programs for resistance management. EPA should not try to reinvent the resistance management wheel, particularly when the greatest expertise on resistance management already resides in the university community and not in governmental regulatory agencies.

Carefully Consider What Resistance Management Measures EPA Recommends The Registrant To Place On Pesticide Labels: Information on pesticide labels related to pesticide resistance must be clear and concise. We urge EPA to recommend only labeling that clearly enhances the safe and efficacious use of the pesticide. We are concerned that pesticide applicators may overlook portions of current labels because of the volume of information and number of pages. The more text that is added to labels, the more likely it is to cause confusion and frustration for applicators. BMPs may be very specific to crop, pest, climatic conditions, and geographic location. Following them is essential for successful resistance management, but there is simply not room on the pesticide label to include them all. Labels are not training guides.

The proposed resistance management PR Notices will only add pages of “recommended practices” and “management” information that are already available on the web sites of commodity groups, the crop protection industry, and university extension. It would be more appropriate for the label to refer to authoritative information on the registrant’s web site and similar resources of academic institutions, Extension Service, Resistance Action Committees (HRAC, IRAC, FRAC), and professional societies (e.g., WSSA, APS, ESA). Labels should simply refer the user to existing web links for resistance management practices instead of listing those practices on labels. Since these websites already exist, there is no reason for EPA to create and/or maintain its own web site for this information.

The proposed categorization scheme of PRN 2016-XX introduces unnecessary complexity that will create confusion for users, cause disputes among registrants, and be misleading for premix products containing multiple active ingredients with different MOAs. For example, more categories for insect resistance management guidance have created more confusion and led to reduced implementation of resistance management by growers across the entire program. We urge EPA to adopt a single consistent program for all products, without subcategorization.

EPA’s proposal to use herbicide-tolerant crops and new or novel MOAs as factors in determining “high concern” is not appropriate. There is no scientific basis for presuming susceptibility to resistance issues, based on novelty alone. And resistance development can only be a product of herbicide use, not the cultivation of herbicide-tolerant crops.
It is impractical for applicators and growers to effectively “Monitor treated pest populations for resistance development.” A more appropriate statement might be: “Monitor treated fields after application for unexpected survival of [target pests]. Consult [the registrant] and Extension specialists if resistance is apparent after application in accordance with the label.” Specific pest species might be listed there, if they are known or suspected to be prone to resistance development. Survival of pest populations after treatment can also be attributable to improper application technique, low application rate, adverse weather conditions, improper pesticide selection, particularly high pest populations, or new pest populations moving into the field after treatment. None of these conditions constitutes resistance development.

Consider The Impact of Registration Actions on Resistance: Traditionally, EPA has not considered the potential impact of Agency-initiated registration or labeling conditions or changes on the development of pest resistance. The Agency will serve as a more effective resistance management partner with registrant and users by systematically assessing the potential effect of pesticide registration decisions on the development of pest resistance. Cancelling a pesticide or forcing a registrant to remove a use during registration review may remove a mode of action, placing more pressure on the remaining active ingredients registered for the same use. Presently, the Agency considers the cost and efficacy of alternative pesticides as an element of the candidate pesticide's "benefits," but EPA unfortunately does not consider whether the removal of the candidate pesticide may accelerate the development of resistance to other pesticides in the pests controlled by the candidate pesticide. In short, we urge the Agency to develop appropriate weighting techniques in risk assessments to balance the potential resistance management benefit of a product and its MOA against the product's risks to non-target organisms when deciding whether to restrict, cancel or place conditions on the product and its uses.

Similarly, we urge EPA not to impose restrictions on the use of a pesticide that run counter to good pesticide resistant management practices (e.g., limiting tank-mix flexibility; imposing unrealistic no-spray buffer zones that will harbor resistant populations; and others).

EPA Should Encourage Registration of Products That Will Assist Resistance Management: We urge EPA to accelerate the registration of new products and new active ingredients that will assist resistance management. Streamlining the application and review process to allow pesticide products with new/unique modes of action to enter the marketplace at an accelerated pace is far and away the most important way that the Agency can contribute to resistance management. One of FIFRA's requirements for minor use status is how the use will contribute to resistance management. CLA fears that the high costs of implementing EPA-regulated resistance-management measures will reduce the incentives to register new products, which in turn reduces the arsenal of tools and MOAs available for successful resistance management.

Do Not Impose the PRNs' "Recommendations" On Registrants Before Their Finalization: In several recent regulatory actions, unfortunately, the Agency has already attempted to implement provisions of these two draft PR Notices, while the PRNs is still in draft form and the Agency is
soliciting comments. EPA in 2016 has issued Proposed Interim Registration Review Decision documents (PIDs) for bentazon, sodium acifluorfen, sulfonylureas, and others, that required label changes including herbicide resistance management practices similar to those described in the draft PR Notices 2016-X and 2016-XX. We urge the Agency not to short-circuit the PRN comment process, and to wait for the PR Notices to be finalized before applying their "recommendations" to regulatory actions. The original PR Notice on resistance management, PRN 2001-5, reminded registrants that the Agency's resistance management recommendations were voluntary, not mandatory. It is confusing when the Divisions of OPP mandate that applicants and registrants implement "voluntary" resistance management recommendations from the draft PRNs.

TECHNICAL COMMENTS

CLA commends EPA for recognizing the need to have the agricultural community continue to elevate concerns for pests developing resistance to crop protection products. As noted, we believe that more education, training, and outreach programs utilizing existing institutions with resistance expertise will more likely promote successful resistance management than extensive additional labeling. Below we comment on some of the technical features of PRNs 2016-X and 2016-XX.

Application to End Use Agricultural Products: Good stewardship principles include placing prudent resistance management measures on all agricultural labels designated for end-users, including applicators in the field and others on the front line of resistance management. EPA's final guidance should advise registrants that its recommendations are not applicable to manufacturing use or technical labels. PR Notice 2016-X (pp. 2, 3) is clearly meant to address “end-use … products that are intended for agricultural use” but is “… not generally intended to apply to products labeled for the general consumer, such as residential or home-use pesticides.” By implication, the scope of PR Notice 2016-XX is similar (p. 2): “The beneficiaries of this PR Notice will be growers of crops … and the registrants of herbicides.” Nevertheless, PRN 2016-XX states: “This PR Notice is applicable to all herbicides regulated by the Agency.” (Emphasis added)

CLA understands that registrants of sulfonylurea (SU) herbicides were recently informed by OPP’s Pesticide Reevaluation Division (PRD) that the Biological and Economic Analysis Division (BEAD) intends to extend the resistance management measures in PR Notice 2016-XX to non-ag uses (e.g. residential use, turf uses, landscape ornamental products, and products used for rights of way/vegetation management purposes). CropLife America opposes this extension because it is inconsistent with the PRN 2016-X. EPA must clearly and specifically propose and seek public comment on applying resistance management measures to non-agricultural products, so that all stakeholders are fully aware of the Agency’s intent, and have the opportunity to evaluate and offer feedback. It would be more appropriate to specifically limit PRN 2016-XX to agricultural uses of herbicides for the time being, and gain a few years of field experience before
considering expansion of its scope to non-agricultural uses. Homeowners lack the understanding and training to follow the complex resistance management measures EPA is proposing and would become easily confused.

Registrants With Existing Labeled Resistance Management Should Not Be Required To Amend Their Labels: Amending labels (through notification or formal amendment) to add the Agency-recommended boilerplate resistance management statements may not be appropriate for all registered herbicides. Weeds have not developed resistance to certain herbicidal modes of action. The Agency must grant registrants some flexibility to use resistance management approaches other than those recommended in PRN 2016-XX or none at all, as appropriate.

In reference to the mode of action (MOA) grouping and identification symbols, CLA recommends that EPA use the information as recommended in the Draft Guidance for fungicides and insecticides (PRN 2016-X). For herbicides, CLA recommends that EPA continue to use the MOA designation of the Weed Science Society of America (WSSA) for the identifier codes, rather than the HRAC-US codes. Subject to granting the registrant some discretion in what resistance management labeling will work best for its products, as noted above, CLA is also supportive of the “notification” and “amendment” methods suggested in PRN 2016-X to revise labeling of existing products, as well as encouraging applicants of new products to address resistance management in their applications for registration. MOA information is straightforward and allows a choice of routes to put resistance management information on the label.

We disagree that “revising product labels with resistance management label language are largely one-time activities for each herbicide.” Some CLA members are skeptical that revising labels is a "one-time activity," because they have previously revised their labels, and now the Agency is asking that they revise their labels again to incorporate the Agency's proposed PRN recommendations. After the close of the comment period on the resistance management PRNs and before 2018, CLA recommends that the Agency fix a date, after which it will recommend that the labels for all new products bear the MOA “box” in the upper right hand corner of the front panel. In addition, for quickest review of the new product label, EPA should recommend that product-specific resistance-management language that is included in this Draft Guidance be included on the newly submitted labels, as appropriate.

As noted, for registered products that already include the MOA designation and resistance management information on their labels, EPA should not necessarily seek to have those registrants revise their labels to mirror the recommendations of the PRNs. Updating existing labels that already bear MOA designations and resistance management measures should be at the registrant’s discretion. Many companies have spent a significant amount of effort over the past 5 years updating the MOA box and changing label language to support EPA’s current resistance management recommendations, and the Agency has approved those labels relatively recently. It
seems repetitive and unfair to ask them to again amend their labels over a 2-year period following issuance of a final PR Notice.

RESISTANCE IS A BENEFIT CONSIDERATION UNDER THE "UNREASONABLE ADVERSE EFFECT" BALANCING STANDARD; EPA'S FINAL PRN NOTICE SHOULD REMIND REGISTRANTS THAT ITS RECOMMENDATIONS ARE VOLUNTARY:

The primary benefit of pesticides is to control pests. To recognize a pesticide's benefit, Congress established in FIFRA a registration standard under which EPA is required to weigh a product’s potential to cause adverse effects on the environment, including non-target organisms, against its benefits. This is commonly referred to as FIFRA's "unreasonable adverse effects on the environment" standard.

A pesticide may only be registered, and may only remain registered, if, inter alia, “it will perform its intended function without unreasonable adverse effects on the environment.” It is the product’s benefits — its ability to perform its intended function — that make some potential level of risk “reasonable.” Indeed, FIFRA § 2(bb) defines “unreasonable adverse effects on the environment,” in pertinent part, to mean: “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits on the use of any pesticide.” (Emphasis added.) Congress has thus authorized EPA to take benefits into account when determining whether a risk posed by pesticide use is unreasonable. A pest's development of resistance to a pesticide, while it may reflect on the pesticide's benefits, is not an adverse effect on the environment.

The Agency recognized the distinction between risk and benefit when promulgating its current adverse effects (FIFRA § 6(a)(2)) requirements for reporting of substantiated instances of pesticide resistance. In that rule, EPA required registrants to submit substantiated information concerning incidents of pest resistance. EPA’s rationale then for including pest resistance incidents within the scope of reporting requirements under FIFRA § 6(a)(2) was that “… pest resistance is a very significant factor in determining the benefits of specific pesticides…” The preamble continues: “Section 2(bb) of FIFRA defines unreasonable adverse effects on the environment as including the consideration of information on benefits as well as risks.”

Finally, CLA notes that FIFRA also prohibits the sale or distribution of a misbranded pesticide, defined to include a pesticide the labeling of which is false or misleading, including a false or misleading statement concerning the effectiveness of the pesticide. In general, a pesticide is misbranded if its labeling claims that it will control a pest when the registrant has well

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4 FIFRA § 3(c)(5).
5 See 62 Fed. Reg. 49370 (Sept. 19, 1997) (finalizing 40 C.F.R. 159.188(c)).
6 Id. at 49385.
7 Id. at 49386.
8 FIFRA §12(a)(1)(E); 40 CFR §156.10(a)(5)(ii).
documented and substantiated, conclusive evidence that the pest has developed complete resistance to the pesticide.

In conclusion, CLA supports the voluntary adoption of clear and consistent information and resistance strategies on product labels to help users manage resistance. CLA requests that EPA clarify the nature of its updates to PR Notice 2001-5, including plans for implementation, particularly in light of the requirements Congress has set forth in FIFRA § 33 regarding timelines for agency decision-making. While the Draft PR Notice states that the requirements set forth are “not binding on either EPA or any outside parties,” it also includes language more mandatory in tone, including a timeline for implementation.

The Draft PR Notice appears to mandate these stewardship measures by referring to pesticide resistance as an “adverse effect.” PR Notice 2001-5, which EPA plans to update through the Draft PR Notice, however, makes no mention of resistance as an adverse effect. CLA supports final PR Notices 2016-X and 2016-XX reminding registrants that their resistant management recommendations are voluntary, consistent with PR Notice 2001-5.

We would be happy to further discuss and clarify any aspects or details of these comments. Please feel free to contact me at 202-872-3874 or rmcallister@croplifeamerica.org.

Respectfully submitted,

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Senior Director, Regulatory Policy

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9 See, e.g., Draft PR Notice 2016-X at 2 of 19.