

**PESTICIDE REGISTRATION NOTICE (PRN) 2017-2**

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDE PRODUCTS AND DEVICES; U.S. AND STATE DEPARTMENTS OF AGRICULTURE; COMMODITY AND GROWER GROUPS, GROWERS, AND OTHER INTERESTED PERSONS

ATTENTION: Persons Responsible for Initial and Continuing Registration of Pesticide Products

SUBJECT: Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship

**1. BRIEF OVERVIEW, PURPOSE AND APPLICABILITY**

Pesticides can be used to control a variety of pests, such as insects, weeds, rodents, bacteria, fungi, etc. Over time many pesticides have gradually lost their effectiveness because pests have evolved resistance – a significant decrease in sensitivity to a pesticide, which reduces the field performance of these pesticides. The agency is concerned about resistance issues and believes that managing the development of pesticide resistance, in conjunction with alternative pest-management strategies and Integrated Pest Management (IPM) programs, is an important part of sustainable pest management. To address the growing issue of resistance and preserve the useful life of pesticides, the agency is beginning to embark on a more widespread effort and several activities that are aimed at combating and slowing the development of pesticide resistance.

One of these activities is the concurrent but separate release of PRN 2017-1, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling*. PRN 2017-1, which revises and updates PRN 2001-5, applies to most conventional, agricultural pesticides (*i.e.*, herbicides, fungicides, bactericides, insecticides and acaricides). The updates in PRN 2017-1 focus on pesticides labels and are aimed at improving information about how pesticide users can minimize and manage pest resistance. PRN 2017-1 updates PRN 2001-5 with the following three categories of changes: (a) provides additional guidance to registrants and a recommended format for resistance-management statements or information to place on labels; (b) includes references to external technical resources for guidance on resistance management; and (c) updates the instructions on how to submit changes to existing labels in order to enhance resistance-management language. PRN 2017-1 is considered the baseline for all resistance labeling for conventional pesticides while this PRN provides additional guidance for herbicides specifically.

PRN 2017-2 communicates the agency's approach to address herbicide-resistant weeds by providing guidance on labeling, education, training, and stewardship for herbicides undergoing registration review or registration (*i.e.*, new herbicide active ingredients, new uses proposed for use on herbicide-resistant crops, or other case-specific registration actions). It is part of a holistic, proactive approach to slow the development and spread of herbicide-resistant weeds, and prolong the useful lifespan of herbicides and related technology. The agency is focusing on the more holistic guidance for herbicides first because: (1) they are the most widely used agricultural chemicals, (2) no new herbicide mechanism of action has been developed in last 30

years, (3) the number of herbicide-resistant weeds are rapidly increasing, and (4) the potential economic impacts of herbicide-resistant weeds on U.S. agriculture are significant. In the future, the agency plans to evaluate other types of pesticides (e.g., fungicides, bactericides, insecticides, and acaricides) to determine what guidance may be appropriate for these types of pesticides.

The guidance in this PRN is intended to provide herbicide users and registrants useful strategies that, when implemented, will slow the development of herbicide resistance and prolong the useful life of herbicides. The primary beneficiaries of this PRN will be growers of crops that are, or may be, affected by herbicide-resistant weed and the registrants of herbicides. The research on herbicide resistance-management may change through time and the reader is urged to check for additional sources of information.

It is important that multiple stakeholders be actively involved in developing and implementing herbicide resistance management strategies. Herbicide resistance evolves based on complex interactions of the chemical, pest, and agronomic practices. To address the economic and social factors that drive grower behavior, a collaboration of growers, crop advisors, academia, Federal and State regulators, registrants, and others is needed.

This Pesticide Registration Notice (PRN 2017-2) applies to end-use herbicide products used in agriculture and to some non-agricultural use sites. See Section 6 for a complete description. Implementation of this PRN is addressed in Section 5.

## **2. EFFECTIVE DATE**

This guidance is effective immediately.

## **3. BACKGROUND**

### **A. HERBICIDE RESISTANCE**

The development and spread of herbicide-resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide-resistant weeds have been known since the 1950s, the number of species and their geographical extent has been increasing rapidly in the last decade. As of May 2017, Heap<sup>1</sup> reports that there are over 250 weed species with confirmed herbicide resistance worldwide. There are 80 unique weed species with herbicide resistance to at least one herbicide in the U.S. Considering that some weed species have developed resistance to more than one mode of action (MOA) independently, there are 155 weed species/MOA combinations with confirmed resistance.<sup>2</sup> These 155 combinations have shown resistance to herbicides with 18 different

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<sup>1</sup> Heap, I. 2016. *op. cit.*

<sup>2</sup> Heap, I. 2016. International Survey of Herbicide-resistant Weeds. Accessed on March 11, 2016 at <http://www.weedscience.org>



MOAs. In the U.S., 48 states have reported the presence of herbicide-resistant weeds. And in the U.S. there are 46 crops and sites (e.g., roadsides, pastures, and railways) with herbicide-resistant weeds. Often only the first few confirmed cases are reported to the International Survey of Herbicide-Resistant Weeds website<sup>3</sup>, so the prevalence and geographical extent is underestimated.

Some populations of a weed species have confirmed resistance to multiple MOAs. In the U.S., eleven weed species have populations with confirmed resistance to two MOAs, three weed species have populations with confirmed resistance to three MOAs, and three weed species have populations with confirmed resistance to four MOAs. Some of the most troublesome and widespread weed species in U.S. agriculture include redroot pigweed, waterhemp, kochia, ragweed, wild oat, and Palmer amaranth. Cross resistance, where a weed is resistant to multiple MOAs, can be due to an alteration of the target enzyme or in a small number of cases due to enhanced detoxification. Enhanced detoxification can lead to herbicide failures the first time they are used without taking multiple generations to select for the resistance gene.

While the general resistance-management approach described in this PRN is applicable to all types of pesticides, the agency is primarily focusing on herbicides at this time for several reasons. First, herbicides are the most widely used agricultural chemicals. Over 285 million acres were treated on nearly 800,000 farm operations in 2012<sup>4</sup>. Second, unlike fungicides and insecticides, there have been no new herbicide MOAs developed in the last 30 years. Therefore, users do not have a new MOA to control herbicide-resistant weeds and it's important to protect the long term efficacy of these chemistries. Third, the number of herbicide-resistant weeds and the affected acreage infested is rapidly increasing. Finally, growers are facing severe economic impacts from herbicide-resistant weeds with up to 100% crop loss in some cases.

For example, in 1998 glyphosate was applied to about 80 million acres (multiple applications are counted separately) and by 2014, the total acreage had increased to nearly 300 million acres. In 2010, glyphosate-resistant weeds infested up to 33 million acres and this number had almost doubled to over 61 million acres infested by 2012.<sup>5</sup> The USDA reported that in 2010 growers with glyphosate-resistant weed problems received over \$67 per acre less for corn and over \$23 per acre less for soybeans due to increased costs to control weeds.<sup>6</sup> Cotton growers in Georgia spend between \$75 and \$100 per acre for adequate control of Palmer amaranth. With approximately 1.4 million acres grown annually in Georgia, the costs have exceeded \$1 billion in

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<sup>3</sup> Heap, I. 2016. *op. cit.*

<sup>4</sup> USDA. 2014. *2012 Census of Agriculture*. United States Department of Agriculture.

<sup>5</sup> Fraser, 2013. *Glyphosate resistant weeds intensifying*. Accessed online on July 23, 2015 at <http://stratusresearch.com/blog/glyphosate-resistant-weeds-intensifying>

<sup>6</sup> Livingston, et al., 2015. *The Economics of Glyphosate Resistance Management in Corn and Soybean Production*, ERR-184, U.S. Department of Agriculture, Economic Research Service, April 2015.

10-plus years.<sup>7</sup> Herbicide resistance in a particular weed species develops over time because of selection pressure placed on the population from the repeated use of a single mechanism of action. A few individuals with natural resistance to the herbicide survive an application of the herbicide. As these individuals reproduce and as each generation is exposed to the herbicide, the proportion of resistant individuals in the population increase and eventually the herbicide-resistant individuals dominate the population.<sup>8,9</sup> The speed at which this genetic shift occurs in the genetic frequency in the population depends on the intensity of the selection pressure. Variance in the intensity of selection pressure depends upon the interaction of characteristics of the chemical, characteristic of the weed species, and characteristics of the crop production system.

Table 1 identifies some of characteristics of herbicide, weed species, and production practices that influence the intensity of selection for the development of herbicide resistance. This table is provided to show several factors that influence selection pressure. Many of these factors cannot be integrated into an herbicide-resistance management approach, because they are inherent to the herbicide, the target weed, and the production practices.

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<sup>7</sup> Thompson, C. 2015. Glyphosate-resistant Palmer amaranth still a concern for Georgia cotton growers. 1/29/2015 Media Newswire. College of Agricultural and Environmental Sciences, University of Georgia.

<sup>8</sup> Vencill, et al., 2012. *Herbicide resistance: Toward an understanding of resistance development and the impact of herbicide-resistant crops*. Weed Science, 60, Special Issue: 2-30.

<sup>9</sup> Norsworthy, et al., 2012. *Reducing the risks of herbicide resistance: Best management practices and recommendations*. Weed Science 60 Special Issue: 31-62.



**Table 1. Some of the chemical and weed characteristics, and agronomic practices influencing the intensity of selection pressure for herbicide resistance.**

	Lower Selective Pressure	Higher Selective Pressure
Herbicide MOA	Multiple-site Mechanism of Action No cross resistance Not persistent Multi-genic resistance Metabolism difficult	Single-site Mechanism of Action Cross resistance Persistent Monogenic Resistance Metabolism relatively easy
Target Weeds	Long life cycle Few progeny / limited dispersal Low inherent genetic variability Metabolic pathway lacking No cross resistance Low fitness of resistant strains	Short life cycle / many generations per year High fecundity / widespread dispersal High inherent genetic variability Pathway for metabolism present Cross resistance already exists High fitness of resistant strains
Agronomic and Management Practices	Crop typically rotated Perennial crops with multiple weed management strategies Little weed control necessary No dominant Herbicide Resistant (HR) trait Many methods of weed control used (both chemical and nonchemical)	No rotation (mono-cropped) Widely grown crop with short rotations Multiple applications needed to obtain season long control Rotated with crops tolerant to same HR trait Reliance on single active ingredient Limited methods of control (lack of diversity)

## B. DEFINITIONS

The agency uses the following definitions for weed resistance in this document: <sup>10</sup>

Confirmed resistance – The agency considers a weed biotype to demonstrate confirmed resistance when it meets all of the following criteria<sup>11</sup>:

- Fulfillment of the Weed Science Society of America (WSSA) definition of resistance and the survey’s definition of an herbicide-resistant weed;
- Data confirmation using acceptable scientific protocols;
- The resistance must be heritable;
- Demonstration of practical field impact;
- Identification as a problem weed to species level, not the result of deliberate/artificial selection.

Herbicide resistance – The inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. Resistance may be

<sup>10</sup> Vencill, et al., 2012. *Ibid.* Norsworthy et al., 2012. *Ibid.* Heap, 2016. *op. cit.*

<sup>11</sup> Heap, 2016. *op. cit.*

naturally occurring or induced by such techniques as genetic engineering or selection of variants produced by tissue culture or mutagenesis.

Herbicide tolerance – The inherent ability of a species to survive and reproduce after herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant.

Lack of product performance – Failure of a product to perform as expected. The lack of performance may result from many conditions such as weather, incorrect timing of application, equipment malfunction, in addition to suspected herbicide resistance.

Suspected herbicide resistance – This term is synonymous to “likely resistance” in the draft PRN and “possible resistance”<sup>12</sup>. Suspected resistance is the situation where the following three indicators occur at a site or location:

- Failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds;
- A spreading patch of non-controlled plants of a particular weed species; and
- Surviving plants mixed with controlled individuals of the same species.

Mechanism of Action (MOA) – The biochemical mechanism within a plant that the herbicide detrimentally affects so that the plant succumbs to the herbicide. For example, the inhibition of an enzyme that is vital to plant growth or the inability of the plant to metabolize the herbicide before it has caused damage.<sup>13</sup> Site of action is sometimes used instead of mechanism of action.

## **C. REGULATORY BASIS FOR MANAGING SUSPECTED HERBICIDE-RESISTANCE**

### **1. Basis**

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for federal regulation of pesticide distribution, sale, and use. Section 3(a) of FIFRA requires that pesticides be registered to be sold or distributed in the U.S. To be granted a registration, the applicant must show, among other things, that using the pesticide according to specifications will not generally cause “unreasonable adverse effects on the environment.” FIFRA 2(bb) defines the term “unreasonable adverse effects on the environment” to mean: “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.” Herbicide-resistant weeds can reduce the efficacy of an herbicide application thus lowering the overall benefit to a grower which changes the overall balance

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<sup>12</sup> Norsworthy et al., 2012. *Ibid.* p. 39.

<sup>13</sup> Vencill, et al., 2012. *op. cit.*



between risk and benefit of that herbicide.

## **2. Reporting Under 6(a)(2)**

Section 6(a)(2) of FIFRA requires “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 [EPA].” The development of herbicide-resistant weeds (either confirmed or suspected resistance) changes the benefits of an herbicide and must be reported.

The agency has implemented the requirement to report resistance information under 6(a)(2) through regulations at 40 CFR Part 159. In particular, 40 CFR 159.188(c), states:

“(c) Development of pesticide resistance. Information must be submitted concerning substantiation of any incident of a pest having developed resistance to any pesticide (both public health and non-public health) that occurred under conditions of use, application rates and methods specified on the label if either of the following conditions is met:

- (1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions.
- (2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.”

The agency is here reiterating the requirements for reporting resistance (confirmed and suspected resistance as described above) in accordance with FIFRA 6(a)(2) and 40 CFR Part 159. The identification of any suspected resistant weed must be reported to the agency under 6(a)(2).

The schedule for reporting resistance is, described in PRN 98-4<sup>14</sup> as follows:

Reports may be accumulated for three months, and submitted to the agency by the end of the second month after the accumulation period. The first accumulation period will begin on 1 April of each year.

All information submitted to the agency under 6(a)(2) is not entitled to confidential treatment, based on Class Determination 99-1, available at 64 FR 70019.

## **3. Labeling**

Another aspect of the registration process is EPA’s review of the pesticide’s labeling. In granting a registration, EPA must determine that the pesticide’s “labeling” complies with the requirements of FIFRA (FIFRA § 3(c)(5)(B)). In Section 2(p)(2)(A), FIFRA defines “labeling” to include all written, printed, or graphic matter accompanying the pesticide at any time. One of FIFRA’s requirements for labeling is that it not be false or misleading in any particular. (See definition of

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<sup>14</sup> PRN 98-4: Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants w/Attachment (PDF). Accessed April 2017 at <https://www.epa.gov/pesticide-registration/prn-98-4-additional-guidance-final-fifra-section-6a2-regulations-pesticide>

“misbranding” in FIFRA § 2(q)(1)). Should an herbicide label lack information described herein, it could be misleading to users of the pesticide and if so therefore could not be approved by the EPA. Further, for labels that had previously been approved before resistance became a concern, the development of resistance could cause the pesticide’s outdated labeling to be misleading making the product misbranded and unlawful for sale or distribution. See FIFRA §§ 2(q)(1) and 12(a)(1)(E). Flaws or inadequacies in the labeling could also lead EPA to cancel the product under FIFRA § 6(b).

#### **D. STAKEHOLDER INPUT**

The agency discussed the new herbicide resistance-management approach with stakeholders including registrants, grower groups, crop consultants, non-governmental organizations, retailers, scientists, USDA, and the Weed Science Society of America, which helped inform its decision to provide these recommendations to registrants and other interested persons. The agency first consulted USDA/APHIS (Animal and Plant Health Inspection Service) and USDA/OPMP (Office of Pest Management Policy) about herbicide-resistance management in July 2013 and presented the draft proposal to USDA/OPMP in October 2015.

In September 2014, the Weed Science Society of America sponsored an international meeting, the Herbicide Resistance Summit II, hosted by the National Research Council<sup>15</sup>. This meeting was organized to facilitate a more unified understanding of the herbicide-resistance issues across the country, understanding of differences of viewpoints, and approaches to solutions. The meeting was attended in person or via webinar by participants from approximately 100 locations across the United States, Australia, Canada and Germany, underscoring the significance and widespread nature of this problem and its impact on agricultural productivity. The EPA announced at this meeting that it would take a more proactive role in developing regulatory approaches for managing resistant weeds<sup>16</sup>. Shortly after this meeting, the Secretary of Agriculture announced USDA’s herbicide-resistance actions that were developed in collaboration with EPA and are complementary to this strategy<sup>17</sup>.

In February 2016, the EPA described this herbicide-resistance management strategy at the Regulatory Aspects Section of the WSSA annual meeting, which was held jointly with the Southern Weed Science Society (SWSS). Discussions with various stakeholders at this meeting

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<sup>15</sup> WSSA, 2014. Herbicide Resistance Summit II. Weed Science Society of America. Accessed April 2017 at <http://wssa.net/wssa/weed/resistance-summit-ii/>.

<sup>16</sup> Housenger, 2014. *EPA’s Perspective on Herbicide Resistance in Weeds*. USDA Stakeholder Workshop on Coexistence March 12, 2015. Accessed April 2017 at: <https://www.aphis.usda.gov/stakeholders/downloads/2015/coexistence/Jack-Housenger.pdf>

<sup>17</sup> USDA, 2014. *USDA Announces Measures to Help Farmers Diversify Weed Control Efforts*. United States Department of Agriculture. Accessed April 2017 at: [www.usda.gov/wps/portal/usda/usdamediafb?contentid=2014/10/0227.xml&printable=true&contentidonly=true](http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2014/10/0227.xml&printable=true&contentidonly=true).



provided important insight into how herbicide resistance can be managed and most stakeholders were receptive to the overall approach.

Between June and September of 2016 the agency issued for public comment a draft guidance aimed at combating and slowing the development of pesticide resistance entitled “*PR Notice 2017-XX Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship.*” The final document also incorporates changes based on some of the public comments received in regards to the labeling PRN (“*PRN 2017-X, Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling*”) and to herbicide specific docket comments. After considering these comments, the agency is finalizing today’s version of the herbicide-resistance management guidance as *PRN-2017-2*.

All of the commenters agreed with the basic goals of the PRN and most parts of the PRN are similar to the draft proposal. The EPA received general comments on the document, terminology, clarification questions, as well as comments on the individual resistance management elements. Based on public comments, this PRN recommends that most herbicides address all elements of the PRN. While the draft PRN recommended registrants develop tables of resistant weeds for all of their herbicide active ingredients, the final PRN has replaced those tables with label language to remind users to check for herbicide-resistant weeds in their area. The final PRN also clarifies what use sites are covered. The EPA has provided examples of label language and explained what information can be added by notification. A detailed response to the public comments received on this PRN is available in EPA Docket ID: EPA-HQ-OPP-2016-0226.

Management of herbicide-resistant weeds, both in mitigating established herbicide-resistant weeds, and in slowing or preventing the development of new herbicide-resistant weeds is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are necessary to address this problem.

#### **4. HERBICIDE RESISTANCE MANAGEMENT PROGRAM**

EPA’s Office of Pesticide Programs (OPP) is providing this herbicide resistance management program to registrants of herbicides and other stakeholders in order to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide-resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves. The approach also provides elements that are focused on labeling, education, training, and stewardship strategies. In addition to these elements, the agency and the registrants may identify additional case-specific measures that are deemed appropriate to reduce the risk of development and spread of herbicide-resistant weeds during registration review or registration actions. This could include such measures as disallowing reapplication of the herbicide on the same crop in the following year or time-limited registration among others.

These elements may be on the label, the technical use agreement for the seed trait, or as a reporting requirement.

**A. Herbicide-Resistance Elements**

The agency considers that all herbicides present some risk of developing herbicide-resistant weeds. Therefore, the agency has determined that the following three groups of resistance-management elements be addressed: (1) elements for the label, (2) elements and terms of registration, and (3) elements for education, training, and stewardship.

**Elements for Label**

Place the MOA, using the WSSA Groupings (as described in PRN 2017-1), on the label. This provides critical information to growers and crop advisors when developing herbicide programs and following best management practices for weed resistance. It allows the user to rotate between effective MOA's to reduce the buildup of resistant weeds.

Clearly express all currently required application parameters and product information on the label, including: maximum dose per application, maximum dose per crop cycle or per year, maximum number of applications per crop cycle or per year. This information is critical to allow the user to know how many applications and the amounts that can be applied in order to develop an effective Integrated Pest Management (IPM) plan for the season and the entire year.

Example Label Statements:

*Apply [X] oz. of product per acre ([X] pounds active ingredient per acre).*

*Do not apply more than [X] oz. of product per acre per season ([X] pound active ingredient per acre per season).*

*Do not apply more than [X] pounds active ingredient per acre per year.*

*Do not make applications less than [X] days apart.*

Recommendations (not requirement) that the field should be scouted both before and after a pesticide application (as described in PRN 2017-1). This recommendation reminds the user to scout to help ensure that the proper herbicide is applied based on the weed species and growth stage. This recommendation also helps the user determine if the herbicide applied has provided effective control.

Example Label Statements:

*Fields should be scouted prior to application to identify the weed species present and their growth stage to determine if the intended application will be effective.*



*Fields should be scouted after application to verify that the treatment was effective.*

Label statement defining suspected resistance<sup>18</sup>. This element provides critical information for the user, and the registrant or their representative, to identify suspected resistant weeds.

Example Label Statement:

*Suspected herbicide-resistant weeds may be identified by these indicators:*

- \* Failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds;*
- \* A spreading patch of non-controlled plants of a particular weed species; and*
- \* Surviving plants mixed with controlled individuals of the same species.*

Label statement that the user should report lack of performance to the registrant or their representative and proactively take action before escaped weeds become widespread in their fields. EPA expects that the registrant or their representative will investigate to determine if the situation meets the criteria of suspected resistance. By reporting and investigating these incidents, cases resulting from suspected resistant weeds may be distinguished from lack of performance from other causes (e.g., equipment malfunction, weather events, etc). This allows early action to be taken to control these weeds before resistance becomes widespread in their fields. The prevention of the development of herbicide-resistant weeds should be the first priority of a weed resistance plan (Appendix I). However, when suspected resistant weeds are identified, the highest priority is to achieve control of these weeds over any sampling to confirm herbicide resistance.

Example Advisory Label Statements:

*Report any incidence of non-performance of this product against a particular weed species to your [registrant]retailer, representative or call XXX-XXX-XXXX. If resistance is suspected, treat weed escapes with an herbicide having a different mechanism of action and/or use non-chemical means to remove escapes, as practical, with the goal of preventing further seed production.*

Label statements describing best management practices for resistance management based on PRN 2017-1. Best Management Practices from WSSA, and the Herbicide Resistance Action Committee (HRAC) proposed guidance. Registrants should include statement that are appropriate to the labeled use sites.

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<sup>18</sup> 2 (Norsworthy et al., 2012. Ibid. p. 39

Example Label Statements:

*Plant into weed-free fields and keep fields as weed-free as possible.*

*To the extent possible, use a diversified approach toward weed management. Whenever possible incorporate multiple weed-control practices such as mechanical cultivation, biological management practices, and crop rotation.*

*Fields with difficult to control weeds should be rotated to crops that allow the use of herbicides with alternative mechanisms of action or different management practices.*

*To the extent possible do not allow weed escapes to produce seeds, roots or tubers. Manage weed seeds at harvest and post-harvest to prevent a buildup of the weed seed-bank.*

*Prevent field-to-field and within-field movement of weed seed or vegetative propagules. Thoroughly clean plant residues from equipment before leaving fields.*

*Prevent an influx of weeds into the field by managing field borders.*

*Identify weeds present in the field through scouting and field history and understand their biology. The weed-control program should consider all of the weeds present.*

*Difficult to control weeds may require sequential applications of herbicides with differing mechanisms of action.*

*Apply this herbicide at the correct timing and rate needed to control the most difficult weed in the field.*

*Use a broad spectrum soil-applied herbicide with a mechanism of action that differs from this product as a foundation in a weed-control program. Do not use more than two applications of this or any other herbicide with the same mechanism of action within a single growing season unless mixed with an herbicide with another mechanism of action with an overlapping spectrum for the difficult-to-control weeds.*

*If resistance is suspected, treat weed escapes with an herbicide with a different MOA or use non-chemical methods to remove escapes.*

Label statements on local resistant weeds. Knowing what herbicide-resistant weeds have been found in your local area allows the user to proactively address herbicide resistance based on the local circumstances. In general, the purpose of using multiple herbicides in a single product is to increase the spectrum of weeds controlled and not for herbicide-resistance management. Some products may contain one or more active ingredients at less than the optimal rate for control on a given weed species. Without clarification, the user may use a product with multiple herbicides and assume that multiple MOAs are being used for a specific herbicide-resistant weed species. This element will allow the user to make informed decisions about the need for additional control measures.



Example Label Statement:

*[For products formulated as a single active ingredient.] Contact your local sales representative, crop advisor, or extension agent to find out if suspected resistant weeds to this MOA have been found in your region. If resistant biotypes of target weeds have been reported, use the application rates of this product specified for your local conditions. Tank mix products so that there are multiple effective mechanisms of actions for each target weed.*

*[For products that are mixtures of herbicides.] Contact your local sales representative, crop advisor, or extension agent to find out if suspected resistant weeds to these MOAs have been found in your region. Do not assume that each listed weed is being controlled by multiple mechanisms of action. Co-formulated active ingredients are intended to broaden the spectrum of weeds that are controlled. Some weeds may be controlled by only one of the active ingredient in this product.*

### **Elements and Terms of Registration (Registrant Responsibilities)**

In addition to the advisory label statements, the agency recommends additional actions involving registration terms that will help provide users with information necessary to help reduce the evolution and spread of resistance.

Registrant(s) report new cases of suspected and confirmed resistance to EPA and users. This will allow all stakeholders access to information about suspected and confirmed resistance in a timely manner so they are aware of and can proactively address the problem. The agency expects reporting of confirmed and suspected resistance to be in compliance with 6(a)(2) requirements.

Unique terms and conditions of registration. In some cases, it may be appropriate to place other conditions on the registration (e.g., apply only with another MOA, apply every other year, statements about pollen flow for herbicide resistant crops with weedy relatives, or concern about non-target site resistance).

### **Elements for Education, Training, and Stewardship**

Provide educational and training materials for growers and users. It is critical that multiple stakeholders participate in this effort. The most successful strategies for herbicide resistance management will be tailored for local conditions. Moreover, crop advisers, extension agents, commodity groups and registrants need to work collaboratively to design effective educational and training materials.

Educational materials should include a resistance-management plan that includes best management practices and other proactive measures to reduce likelihood of resistance. Another aspect of the educational outreach should involve a remedial-action plan which is instrumental in the early identification and remediation of the first signs of suspected resistance. Stakeholders may also choose to develop collaboratively other educational

and training materials on herbicide resistance and its management. These materials should be applicable to local conditions and adaptable to changes in the scope of the weed problem. The agency recommends that these materials be developed with input from the following groups: registrants, agricultural extension, crop consultants, individual crop associations, the Herbicide Resistance Action Committee, or and local, state, and Federal governmental agencies. The materials could be developed by a single stakeholder or collaboratively with other stakeholders. See Appendix 1 for example outlines for a resistance management and remedial action plan. The agency is available to consult and discuss the development of these educational materials. However, EPA does not intend to review or approve these materials because that would make them more difficult to modify or adapt to meet local and changing conditions.

#### **B. Related Information**

The agency is also issuing a Pesticide Registration Notice, PRN-2017-1, providing guidance to pesticide registrants regarding labels and labeling for pesticide resistance. That PRN updates and supersedes the guidance provided in PRN 2001-5.

### **5. IMPLEMENTATION**

OPP is beginning to implement herbicide-resistance measures for existing chemicals during registration review. In registration review, EPA will include herbicide-resistance elements in every herbicide proposed decisions and proposed interim decisions and in final decisions and interim decisions. For registration, OPP is implementing herbicide-resistance measures for all end-use herbicide products described in Section 6.

In order to support the policy goals of this PRN, EPA encourages registrants to add the appropriate resistance-management statements through any of the agency's regulatory mechanisms. In particular, the addition of these statements will be permitted on existing products by (1) notification, (2) amendment or (3) as part of an application for a new product. The addition of the statements identified in this PRN, without other changes, will not result in the imposition of fees in association with the Pesticide Registration Improvements Act (PRIA).

#### **A. New Product Submissions**

Registrants should include the resistance management labeling described in this PRN, as appropriate, as part of new product submissions. EPA intends to consult this guidance when reviewing the resistance-management labeling sections for pending applications for registration of a new pesticide product before making a determination on registration.



## **B. How to Revise Labeling for Existing Products**

### **1. Notification**

Registrants who adopt the wording set forth in this PRN, as appropriate to their particular product, and who only make changes permitted by notification may submit a revised label via notification.

The registrant should submit one copy of the label (with changes clearly marked in a way that can be photocopied) along with a completed Application for Registration (EPA Form 8570-1). Registrants can utilize the Web-based Pesticide Submission Portal (PSP) described in the section below. Unless the registrant specifies that it has made any other changes to the labeling, the agency will assume the ONLY labeling changes made are to incorporate the resistance management language, or, in addition, other changes permitted via notification. If other changes not allowed by notification have been made to the labeling without written notice, EPA will consider referring such submission to the proper authorities under 18 U.S.C. 1001. Under 18 U.S.C. 1001, it is unlawful to knowingly and willfully make false statements to the government. Lastly, if labeling changes through notification under this PRN are not consistent with the procedures established in this PRN and the requirements of 40 CFR Part 156, the product may be in violation of FIFRA and may be subject to enforcement action and penalties. The application form should bear the following statement:

"Notification of label change per PRN 2017-2. This notification is consistent with the guidance in PRN 2017-2 regarding resistance management and the requirements of EPA's regulations at 40 CFR Part 156. Only changes that are permitted via notification are made on the submitted label. I understand that it is a violation of 18 U.S.C. Sec. 1001 to knowingly and willfully make any false statement to EPA. I further understand that if this notification is not consistent with the guidance of PRN 2017-2 and the requirements of 40 CFR Part 156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

EPA will review the Notification and determine whether the changes fall within the scope of PRN 2017-2. Registrants will be notified in writing of the agency's decision.

### **2. Amendment**

An amendment is appropriate for labeling changes that cannot be implemented via notification. If the registrant wishes to propose alternative wording from that set forth in this PRN or if the registrant wishes to use the wording in this PRN but also make other label changes not allowed by notification, then the revised label must be submitted as an Amendment. Service fees called for under the Pesticide Registration Improvement Act may apply if other labeling changes are proposed. The registrant should submit a completed Application for Registration (EPA Form 8570-1), as provided in 40 CFR §152.50, along with proposed labeling.

The registrant should submit a completed Application for Registration (EPA Form 8570-1), as provided in 40 CFR §152.50, along with proposed labeling.

## **6. SCOPE**

This PRN communicates the agency's approach to address herbicide-resistant weeds. It is germane to end-use herbicide products used in agriculture, including commercial turf and sod farms, ornamental production in the open. It also applies to non-agricultural use sites such as golf courses, aquatic vegetation, rights-of-way and vegetation management along roadways. This PRN does not apply to herbicide products labeled for use by the general consumer, such as residential use pesticides. Technical and manufacturing use products are expressly excluded.

While the requirements in FIFRA and agency regulations are binding on EPA and applicants, this PRN is not binding on EPA personnel, pesticide registrants and applicants, or the public. EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide applicants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or decision. Registrants and applicants may propose alternatives to the guidance provided in any application to the agency.

## **7. PAPERWORK REDUCTION ACT (PRA) NOTICE**

Under the PRA, "burden" means the total time, effort or financial resources expended by persons to generate, maintain, retain or disclose or provide information to or for a Federal agency. The registrant/applicant may incur a burden from the following activities associated with this PRN:

- 1) reading and understanding this PRN,
- 2) incorporating information into labels or making revisions to pesticide product labels consistent with the recommended resistance-management elements,
- 3) reporting cases of suspected and confirmed resistance, and
- 4) providing growers with a pesticide resistance management plan and remedial action plan.

The information collection activities associated with the activities described in this PRN are consistent with activities that are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., under several Information Collection Request (ICR) documents.

Reading and understanding this PRN is not expected to be a recurring burden for applicants. Similarly, revising product labels with resistance management elements and developing resistance management/remedial action plans are largely one-time activities for each herbicide. In many cases labels may be amended to include resistance management elements by notification (Section 5). As indicated in Section 5, Implementation, these activities are expected to occur as part of the section 3 registration and reevaluation processes. Reporting cases of resistance (activity 3) may be a recurring burden.



*Herbicide Resistance Management PRN 2017-2*

The ICR document for the Application for New and Amended Pesticide Registration has been assigned EPA ICR Number 0277.16 and is approved under OMB control number 2070-0060. This ICR captures the burden of activities 1, 2, and 4 above for registrants implementing herbicide resistance measures for new chemicals and uses at the time of registration. The ICR document for the Pesticide Data Call-In Program has been assigned EPA ICR Number 2288.02 and is approved under OMB control number 2070-0174. This ICR captures the burden of activities 1, 2, and 4 above for registrants implementing herbicide resistance measures for registered herbicides at the time the chemical undergoes registration review. Given the relatively few number of actions involving these resistance management plans for registration and registration review; EPA is not revising the overall average burden estimate.

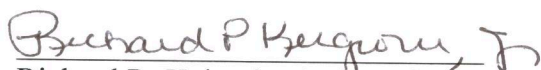
The ICR document for Submission of Unreasonable Adverse Effects Information under Section 6(a)(2) has been assigned EPA ICR Number 1204.12 and is approved under OMB control number 2070-0039. This ICR captures the burden associated with activity 3, reporting cases of resistance. The paperwork burden consists of processing and reviewing the information about the incident and submitting the report to EPA. This PRN does not expand or alter the burden estimates associated with information collection regarding Unreasonable Adverse Effects Information under Section 6(a)(2). Investigation of the incident is not considered paperwork.

The ICR document for Submission of Unreasonable Adverse Effects Information under Section 6(a)(2) has been assigned EPA ICR Number 1204.12 and is approved under OMB control number 2070-0039. This ICR captures the burden associated with activity 3, reporting cases of resistance. The paperwork burden consists of processing and reviewing the information about the incident and submitting the report to EPA. Investigation of the incident is not considered paperwork.

**8. FOR FURTHER INFORMATION**

If you have general questions about this PRN or about resistance management labeling, please contact:

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Richard P. Keigwin, Acting Director  
Office of Pesticide Programs  
U.S. Environmental Protection Agency

Date: 8/24/2017



## **APPENDIX 1.**

### **RESISTANCE MANAGEMENT PLANS and REMEDIAL ACTION PLANS**

The research on herbicide resistance-management may change through time and the reader is urged to check for additional sources of information. The agency recommends the following for resistance management plans and remedial action plans.

#### **Herbicide Resistance Management Plans<sup>19 20</sup>**

Based the comments received, discussions with agronomists and weed scientists, and the published literature, the following three categories are needed for the resistance management plans:

1. Develop a resistance management plan addressing the following elements:
  - a. Field assessment and /scouting pre- and post-treatment.
  - b. Weed identification
  - c. Weed control methods
    - i. Biological
    - ii. Chemical
    - iii. Cultural
    - iv. Mechanical
  - d. Sanitation
  - e. Reporting
  - f. Evaluation of control measures and follow-up, including herbicide resistance remedial action plan if weed resistance is suspected.
2. Discuss the role that local conditions and grower needs play in the development of resistance management plans.
3. Discuss the effects of herbicide resistant Best Management Practices on stewardship and other production issues, such as:
  - a. Conservation compliance programs.
  - b. Surface water and groundwater quality including elements of the Clean Water Act and its relation to resistance management.
  - c. Endangered, threatened, sensitive or special concern species.
  - d. Reduction/mitigation of off target impacts to pollinators and natural enemies.

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<sup>19</sup> American Society of Agronomy. 2016. Resistance Management Specialist Exam. Performance Objectives. Effective January, 2016. Accessed on April 2017 at <https://www.certifiedcropadviser.org/files/certifiedcropadviser/rms-performance-objectives.pdf>

<sup>20</sup> Norsworthy et al., 2012. *Ibid.* p. 39

The agency also recommends that the developers of these plans refer to Norsworthy et al. (2012) for additional detail on best management practices and recommendations. Many of these recommendations have been incorporated into the revised PRN as example label language.

### **Herbicide Resistant Remedial Plans**

Herbicide resistance remedial plans should emphasize, as much as practical, preventing seed production or other propagule production by the resistant weeds. The following items should be considered and recommended in the herbicide resistance remedial plan, as appropriate for local conditions:

- Mechanical controls, including hand weeding.
- Additional herbicide treatments, particularly using herbicides with a different MOA(s) than those already applied. The use of a different MOA(s) than the initial products must be emphasized.
- Use non-selective herbicides (i.e., glyphosate, glufosinate, paraquat) to control small isolated suspected resistant weed patches.
- Long-term measures to increase diversity of weed control methods, such as crop and herbicide rotation, use of tillage and/or planting of cover crops.