

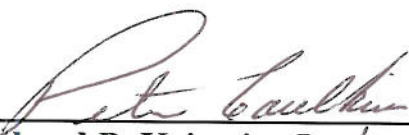


# Glyphosate Final Work Plan (FWP)

Registration Review Case No. 0178

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Approved by:

  
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Director  
Pesticide Re-evaluation Division

Date:

12/29/09

## **Introduction**

This is the Environmental Protection Agency's (EPA or the Agency) *Final Work Plan* (FWP) for the registration review of glyphosate. This FWP includes the expected registration review timeline. The FWP also addresses public comments received concerning the *Preliminary Work Plan* (PWP) in the *Summary Document*, which was posted in the glyphosate review docket (EPA-HQ-OPP-2009-0361), and any other comments concerning the initial docket postings. The *Summary Document* provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Agency is implementing the new registration review program and will review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at: [http://www.epa.gov/oppsrrd1/registration\\_review/](http://www.epa.gov/oppsrrd1/registration_review/).

Glyphosate (case #0178) is a non-selective, phosphonomethyl amino acid herbicide which is among several other active salt compounds that will be considered together, with glyphosate acid as the common stressor. Other forms of glyphosate included in this case include: isopropylamine salt (103601); glycine, *N*-(phosphonomethyl)- sodium salt (sodium glyphosate) (103603); glyphosate, ammonium salt (103604); glyphosate ethanolamine salt (103605); glyphosate, diammonium salt (103607); glyphosate, dimethylammonium salt (103608); glycine, *N*-(phosphonomethyl)- potassium salt (103613); and glyphosate-trimesium (128501). Glyphosate is widely used to control weeds in agricultural crops and non-agricultural site and is registered for use on a variety of fruit, vegetable, and field crops as well as for aquatic and terrestrial uses. Glyphosate is also registered for use on glyphosate-resistant (transgenic) crop varieties such as canola, corn, cotton, soybeans, sugar beets, and wheat. Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-food sites including forestry, greenhouse, non-crop, and residential.

The Pest Management Regulatory Agency (PMRA) of Health Canada is currently in the process of developing its re-evaluation of glyphosate. The Agency is coordinating with PMRA on glyphosate in an effort to harmonize the assessments and scheduling.

## **Comments Received on Preliminary Work Plan**

The glyphosate registration review docket received 27 comments, one of which contained 33 signatures, during the 60-day public comment period, which began on July 22, 2009. The Agency believes that the comments received do not change the data and risk assessment needs or the timeline detailed in the Glyphosate PWP. An overview of

comments is presented in the “Summary of Comments and Agency Responses” section of this document.

### **Anticipated Risk Assessment and Data Needs**

#### *Ecological Risk:*

- The most recent risk assessment for all registered uses was conducted in 1993 for the Glyphosate Reregistration Eligibility Decision (RED). The assessment did not include a complete endangered species determination for glyphosate.
- The primary glyphosate degradate amino methyl phosphonic acid (AMPA), has not been evaluated for the ecological risk assessment except as detailed below for some endangered species. However, the Agency anticipates considering the AMPA degradate in the ecological risk assessment during registration review.
- The Agency completed endangered species assessments evaluating the potential effects of glyphosate on several species, consistent with court orders and settlements addressing risks to Pacific Northwest salmon and steelhead and the California red-legged frog.
- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether glyphosate’s use has “no effect” or “may affect” federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide’s use “may affect” a listed species or its designated critical habitat, the Agency will consult with the Services, as appropriate.
- Because the surfactant polyethoxylated tallow amine (POEA) is more toxic than glyphosate to aquatic organisms, glyphosate formulations containing POEA will be identified and considered in the ecological and endangered species risk assessment to be conducted for registration review.
- In order to conduct a complete ecological risk assessment for the registration review of glyphosate, the following data are needed:
  - GLN 850.2100 - Acute avian oral toxicity study (passerine species).
  - GLN 850.1025 - Acute toxicity estuarine/marine mollusk.
  - GLN 850.1035, 850.1045, and 850.1055 - Acute toxicity estuarine/marine invertebrate.
  - GLN 850.1075 - Acute toxicity estuarine/marine fish species.
- Please refer to the document, *Registration Review Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments*

for *Glyphosate and Its Salts*, found in the docket EPA-HQ-OPP-2009-0361, for a detailed discussion of the anticipated ecological risk assessment needs.

*Human Health Risk:*

- The most recent comprehensive human health risk assessment for glyphosate was conducted in 2006 entitled “*Glyphosate Human Health Risk Assessment for Proposed Use on Indian Mulberry and Amended Use on Pea, Dry.*”
- In accordance with new data requirements under 40 CFR Part 158 (food and non-food uses) and because data regarding effects of glyphosate on neurologic and immune parameters is limited, additional data are needed. Therefore, the Agency anticipates requiring the following data for glyphosate:
  - GLN 870.6200 - Acute and subchronic neurotoxicity study.
  - GLN 870.7800 - Immunotoxicity study.
- Please refer to the document, *Glyphosate – Human-Health Assessment Scoping Document in Support of Registration Review*, found in the docket EPA-HQ-OPP-2009-0361, for a detailed discussion of the anticipated human health risk assessment needs.

**Timeline:**

EPA has created the following estimated timeline for the completion of the glyphosate registration review.

<b>Registration Review for Glyphosate – Projected Registration Review Timeline</b>	
Milestone	Date
<b>Opening the Docket</b>	
Open Docket & Public Comment for Preliminary Work Plan	July 2009
Close Public Comment	Sept. 2009
<b>Case Development</b>	
Final Work Plan	Dec. 2009
Issue DCI	July - Sept. 2010
Data Submission	July - Sept. 2012
Open Public Comment for Preliminary Risk Assessment	Jan.- March 2014
Close Public Comment Period	April - June 2014
<b>Registration Review Decision</b>	
Open Public Comment for Proposed Registration Review Decision	July - Sept. 2014
Close Public Comment	July - Sept. 2014
Final Registration Review Decision & Begin Post-Decision Follow-up	2015
<b>Total</b>	<b>6 years</b>

As noted above, the Agency plans to require a number of ecological fate and effects studies, an acute and subchronic neurotoxicity study, and an immunotoxicity study through a data call-in, which is expected to be issued in 2010. The new information will be used to conduct a comprehensive ecological risk assessment, including an endangered species assessment, as well as a revised occupational human health risk assessment, for all glyphosate pesticidal uses.

### **Summary of Comments Received During Docket Opening:**

The registrant submitted proposed corrections to technical terms, rates, toxicity endpoints, molecular weights, and concentrations, suggesting that they be consistently expressed in terms of acid equivalents (a.e.). The registrant also noted that none of the Monsanto formulations registered for use in aquatic environments in the United States contain POEA-type surfactants.

The Agency received comments opposing the use of glyphosate from the Center for Food Safety (CFS) and recommending that the Agency expand its risk assessments to include effects to amphibians, aquatic plants, and soil biota, as well as the toxicity of glyphosate formulations that include non-POEA surfactants. CSF commented on glyphosate's usage trends, ecological effects, and human health effects.

The Agency received comments on the toxicity of formulated products containing glyphosate from Beyond Pesticides, in a letter with 33 signatures. Beyond Pesticides commented that the Agency should reinstate the 10X safety factor for glyphosate and cited studies on human risk from glyphosate exposure.

The Agency received several comments addressing potential human health effects from the inert ingredients used in glyphosate formulations.

The Agency received comments and published documents opposing the use of glyphosate from Professor Seralini of the University of Caen (France), voicing concerns about the potential endocrine disruption effects from carbofuran, and from Professor Huber of Purdue University, who cited literature and personal experiences on secondary short- and long-term ecological effects from glyphosate use. The Agency also received two comments from an oyster farmer in Washington regarding the toxicity of glyphosate to oysters, its contribution to global warming, and its potential synergistic effects with other pesticides in aquatic environments.

The Agency received comments in support of glyphosate registration from the Farm Bureau offices of 11 states (OH, MS, KY, MI, SD, AR, NE, HI, IL, TX, PA), the American Farm Bureau Federation, and a retired member of Congress from Illinois. The Agency also received comments on the benefits of glyphosate from agricultural interest groups, including the Georgia Cotton Commission, the National Cotton Council, the American Sugarbeet Growers Association, and representatives of the Hawaiian Commercial and Sugar Company.

Finally, in the Preliminary Work Plan, EPA solicited comments on three specific topics: environmental justice, water body impairment, and trade irritants. No comments or information were received during the comment period concerning these issues.

Comments relevant to human health have been addressed by the Health Effects Division's document, *Public Comments Regarding the Health Effects Division's (HED's) Human-Health Assessment Scoping Document in Support of Registration Review of 3-JUN-2009. HED's Response to Public Comments.* (12/28/09). Comments regarding the ecological fate or effects of glyphosate have been addressed by the Environmental Fate and Effects Division's document *Response to Public Comments on Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and Its Salts* (12./03/09). Comments regarding the use patterns of glyphosate have been addressed by the Biological and Economic Analysis Division's document, *Bead Responses to Selected Glyphosate Comments* (12/16/09). All of these documents are available in the docket (EPA-HQ-OPP-2009-0361).

### **Comments on Policy and Process and EPA Responses**

#### ***Comment***

The Agency received an anonymous comment opposing the manufacture and use of glyphosate due to potential risk to human health and the environment. The commenter cited a number of toxicity studies in the open literature on glyphosate and the inert ingredients used in glyphosate products.

#### ***EPA Response***

The Agency thanks the commenter and is aware of the studies cited. EPA conducts a review of the open literature in every pesticide registration review. The Agency's risk assessment process is continually updated to reflect the most current scientific methodologies and protect human health and the environment. Agency policies on risk assessment are vetted to independent Scientific Advisory Panels and opened for public comment. The Agency plans to re-evaluate risks from glyphosate and certain inert ingredients to humans and the environment during the registration review process.

#### ***Comment***

The Golf Course Superintendents Association of America submitted comments that described a report which they plan to submit to the Agency in 2010. The report will include data from comprehensive surveys conducted over a five-year period, which they conducted on pesticide use for weed control on golf courses.

#### ***EPA Response***

The Agency thanks the commenter and looks forward to the data to be submitted in 2010.

#### ***Comment***

The Agency received a comment from the Washington Department of Agriculture asking whether EPA intends to make recommendations or requirements on labels regarding adjuvants that have been approved for aquatic use by state lead agencies.

### ***EPA Response***

The Agency commends the state of Washington for its vigilance in assessing and registering adjuvants for use with pesticides. EPA has no authority to regulate adjuvants added separately to a tank mix of pesticides, but registrants routinely add warnings to labels for liability reasons if there is a risk from certain adjuvants. EPA will be assessing glyphosate products registered for use in aquatic environments, including the adjuvants and inerts which are an intrinsic part of the formulations.

### ***Comment***

Monsanto asked that EPA comment on its role in the NEPA process for other federal agencies, such as in deregulation decisions made by the U.S. Department of Agriculture Animal Plant Health and Inspection Service (APHIS) in the preparation of Environmental Impact Statements under the requirements of the National Environmental Policy Act (NEPA).

### ***EPA Response***

The Agency regulates the licensing of pesticide products under the FIFRA, and in accordance with its responsibilities under this statute, the Agency conducts human health and ecological risk assessments to ensure that the use of a pesticide product does not result in unreasonable risk to human health or the environment. While the Office of Pesticide Program's ecological risk assessments may be useful to other agencies, it is not for the Agency to comment on how its assessments are used, or should be used, by any other federal agency to fulfill its respective statutory obligations, such as those responsibilities under NEPA or any other statute.

The Office of Pesticide Programs regulates the licensing of pesticide products. In this capacity, OPP conducts assessments to determine whether the direct risks to non-target organisms outweigh the economic benefits of the use of a particular product. While OPP is charged with assessment of indirect effects as defined under the Endangered Species Act for endangered plants and animals, we generally do not conduct the type of cumulative assessments pursuant to NEPA. While OPP's assessments can be used as a portion of an Environmental Impact Statement, OPP's assessments should not be considered to address cumulative impacts under NEPA.

### **Next Steps**

The Agency plans to develop a Data Call-In Notice for this pesticide and expects to issue it in July 2010.