Glyphosate Update
PPDC Meeting Nov. 2, 2016 – Session 7g

Overview

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings. Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites, such as greenhouses, aquatic areas, and residential areas. Use of glyphosate in the United States and globally has increased overtime, particularly with the introduction of glyphosate-resistant crops; however, usage has stabilized in recent years due to the increased number of weed species becoming resistant to glyphosate. Glyphosate is currently undergoing Registration Review, which reviews all registered pesticides at least every 15 years as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Recently, EPA collected and analyzed a substantial amount of data informing the carcinogenic potential of glyphosate and utilized the draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment", which provides the foundation for evaluating multiple lines of scientific evidence. A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed. This includes epidemiological, animal carcinogenicity, genotoxicity, and absorption, distribution, metabolism, and excretion (ADME) studies. Guideline studies were collected for consideration from the toxicological databases for glyphosate and glyphosate salts. A fit-for-purpose systematic review was executed to obtain relevant and appropriate guideline and open literature studies with the potential to inform the human carcinogenic potential of glyphosate. Furthermore, the list of studies obtained from the toxicological databases and systematic review was cross-referenced with recent internal reviews, review articles from the open literature, and international agency evaluations.

Available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate according to the 2005 Guidelines for Carcinogen Risk Assessment. A total of 58 epidemiological studies, 20 animal carcinogenicity studies, and almost 200 genotoxicity assays were considered in the current evaluation. Additionally, multiple lines of evidence were integrated in a weight-of-evidence analysis using the modified Bradford Hill Criteria considering concepts, such as strength, consistency, dose response, temporal concordance, and biological plausibility. The totality of the data has been used by the agency to inform cancer classification descriptors according to the 2005 Guidelines for Carcinogen Risk Assessment. The agency originally planned to hold the FIFRA Scientific Advisory Panel (SAP) evaluation of human carcinogenic potential for the active ingredient glyphosate on October 18-21, 2016.

On October 14, 2016, EPA postponed the FIFRA SAP meeting due to recent changes in the availability of experts for the peer review panel. Given the importance of epidemiology in the review of glyphosate's carcinogenic potential, the agency believes that additional expertise in epidemiology will benefit the panel and allow for a more robust review of the data. As a result, the SAP meeting on glyphosate has been postponed. The agency will issue another announcement once the new date for the SAP meeting on glyphosate has been determined.