June 5, 2019

Environmental Protection Agency Docket Center
1200 Pennsylvania Ave., NW
Washington, DC 20460–0001
Submitted Via http:// www.regulations.gov

Re: Petition to Modify the Tolerance and Product Labels for Glyphosate with Regard to Oats; Notice of Filing; 84 FR 19783; May 6, 2019; Docket No. EPA–HQ–OPP–2019–0066.

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to provide comments regarding the petition from Environmental Working Group (EWG) and others to the U.S. Environmental Protection Agency (EPA or the Agency) to reduce the glyphosate tolerance in oats from 30ppm to 0.1ppm and require labels of glyphosate products to prohibit preharvest use on oats in the U.S. [Docket ID No. EOA-HQ-OPP-2019-0066].

Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA represents the interests of its registrant member companies by, among other things, monitoring legislation, federal agency regulations and actions, and litigation that impact the crop protection and pest control industries; and participating in such actions when appropriate. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

EPA regulates pesticides under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC §136 *et seq.*, and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 USC §346(a). Both FIFRA and the FFDCA were amended in 1996 by the Food Quality Protection Act (FQPA), which provides the legal standard under which EPA establishes tolerances, or maximum residue levels of pesticides allowed in food.

To implement the risk assessment standard established by the FQPA, EPA developed new science policies, working with stakeholders from industry, academia, civil society, other members of the public, and EPA's FIFRA Science Advisory Panel. These include guidelines regarding: the establishment of safety factors; dietary exposure and risk assessment; threshold of regulation; drinking water exposure; residential exposure; aggregate exposure and risk assessment; cumulative risk assessment for pesticides with a common mechanism of toxicity; and use and pesticide usage information (see list at https://www.epa.gov/laws-regulations/significant-guidance-documents-chemical-safety-and-pollution-prevention). In the years since the enactment of the FQPA, these policies have been updated and refined as necessary. The data criteria and methodologies required to establish tolerances for pesticide residues are set forth in 40 CFR §158.1410. Tolerances established prior to the FQPA have been reevaluated and modified as necessary during Tolerance Reassessment (FFDCA §408(q)) and Registration Review (FIFRA §3(g)), according to these FQPA policies.

Tolerances for residues of glyphosate in numerous plant commodities, established using the procedures and methodologies administered by EPA, are set forth in 40 CFR §180.364. The tolerance established for glyphosate by EPA in oats is harmonized with the maximum residue level (MRL) established for cereal grains by Codex Alimentarius, or "Food Code" which is a collection of standards, guidelines and codes of

practice adopted by the Codex Alimentarius Commission (CAC). See 73 FR 29463, 5/21/2008 and 73 FR 52607, 9/10/2008. The CAC is the Food Standards Program established jointly by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations to protect consumer health and promote fair practices in food trade.

In its recent Proposed Interim Decision (PID, April 2019; https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361), EPA evaluated the residue chemistry database for glyphosate to determine if the established tolerances conform to current practices (including FQPA policies) and to determine whether updates were necessary to accommodate current crop-group/subgroup definitions. The Agency laid out its intended revisions, but noted no changes required to address safety concerns, stating: "EPA thoroughly assessed risks to humans from exposure to glyphosate from all uses and all routes of exposure and did not identify any risks of concern. . . . The agency has determined that glyphosate is not likely to be carcinogenic to humans and therefore a quantitative cancer assessment was not conducted." PID at 19

The Agency further concluded: "Due to its widespread use, trace amounts of glyphosate residues may be found in various fresh fruits, vegetables, cereals, and other food and beverage commodities. However, these trace amounts are below maximum residue levels established by the agency for those commodities and are not expected to pose risks of concern to consumers." Additionally, "EPA evaluated dietary exposure to all population subgroups, including children, infants, and women of child-bearing age. There were no dietary risks of concern for glyphosate using an unrefined analysis, which (1) assumes that all food commodities contain maximum legal residues (i.e., tolerance-level residues) and all registered food crops have been treated with glyphosate, and (2) uses high-end estimates of glyphosate in drinking water." In its dietary exposure assessment, EPA included pre-harvest desiccant use at the maximum level in cereal products and concluded that the aggregate exposure to glyphosate is below the agency's level of concern.

EPA's regulation of pesticides includes statutorily-required regular review to ensure that products meet Congressionally-mandated safety standards using the best available science, based on established methodologies recognized by regulators and stakeholders as protective of public health. EPA has established tolerances for glyphosate, as for many other pesticides, based on this standard. Further, EPA's risk assessment of glyphosate is consistent with other global regulatory authorities and international organizations, including the Canadian Pest Management Regulatory Agency, the Australian Pesticide and Veterinary medicines Authority, the European Food Safety Authority, the European Chemicals Agency, the German Federal Institute for Occupational Safety and Health, the Joint FAO/WHO Meeting on Pesticides Residues, the New Zealand Environmental Protection Authority, the Korean Rural Development Authority, and the Food Safety Commission of Japan.

To summarize, EPA has established and implemented a scientifically robust regulatory process for setting tolerances and determining label uses when approving the use of a crop protection technology. Tolerances and label use for glyphosate has been established after thorough scientific evaluation based on the current standards. In its petition, EWG fails to justify a departure from EPA's well-established existing standards and the standards of virtually every regulatory body around the world. We therefore, request the agency to deny EWG's petition.

Sincerely,

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