DRAFT

November 19, 2021

Michael Goodis
Acting Deputy Director of Programs
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Marietta Echeverria
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Chemistry, Inerts and Toxicology Assessment
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Dear Mr. Goodis, Ms. Echeverria, and Mr. Leifer:

CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment) request that the Office of Pesticide Programs (OPP) extend the December 31, 2021 deadlines for use of the following in pesticide formulations:

(1) in-kind substitutions for ethylene oxide- and propylene oxide-derived inert ingredients (Phase 1 response of 4/29/2021); and
(2) not-in-kind substitutions for propylene glycol (Phase 2 response of 7/1/2021).

Extenuating circumstances continue to adversely affect supplies of these essential ingredients and will continue to restrain manufacture of pesticide products for the 2022 growing season. These include lingering effects of the extreme February storms on chemical manufacturing capacity in the Gulf states; disruptions caused by hurricanes during the summer months; supply chain distribution problems exacerbated by the pandemic; and others. We believe that extending the deadlines by 12 months would provide the needed regulatory relief.

The data and information needed to justify such extensions generally involve confidential business information (CBI). Therefore, we are asking our member companies to submit supporting information directly to the Agency to insure proper CBI protection. We are asking that this input be provided through the Pesticide Submission Portal (PSP) by Friday, December 3, 2021.

We emphasize that the formulation flexibility requested here does not in any way affect safety of the products. In-kind substitutions involve using alternate sources for the same identical

ingredients already approved. The few specified not-in-kind substitutions for propylene glycol have been carefully assessed to determine that they do not cause any increases in toxicity of the respective products.

We are learning of looming shortages for other active and inert ingredients, attributed to regulatory and manufacturing difficulties in China and elsewhere. We are working with colleagues across the registrant trade associations to propose generalized regulatory approaches for handling such shortages as they arise.

We look forward to a prompt response to this request, so that registrants can properly plan for formulation and manufacturing to meet needs of the coming growing season.

Sincerely,

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