UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

December 22, 2021

Ray S. McAllister
Senior Director, Regulatory Policy
CropLife America
4201 Wilson Blvd.
Arlington, VA 22203

Kristen R. Spotz
Senior Director, Regulatory Affairs
RISE, Responsible Industry for a Sound Environment
4201 Wilson Boulevard, Suite 700
Arlington, VA 22203

Dear Mr. McAllister and Ms. Spotz:

This letter is in response to your letter of November 19, 2021, in which CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) requested that the Office of Pesticide Programs (OPP) extend the December 31, 2021, deadlines for use of the following in pesticide formulations as provided for in the in-kind substitutions for ethylene oxide- and propylene oxide-derived inert ingredients (Phase 1 response of 4/29/2021), and the not-in-kind substitutions for propylene glycol (Phase 2 response of 7/1/2021) for a period of 12 months.

In conjunction with that request, a number of CLA and RISE member companies provided information to OPP to further document the continuing circumstances that have adversely impacted supplies of these inert ingredients, including significant supply chain disruptions. This documentation included force majeure declarations and supply control notices sent to registrants by suppliers of propylene glycol and ethylene oxide- and propylene oxide-derived inert ingredients--evidence of the continued disruption in supplies of these inert ingredients faced by registrants.

Based on our evaluation of the information provided in support of the extension request and affirmation of the safety of the substitutions, it has been determined that the time-limited processes described in the agency's responses of April 29, 2021 (Phase 1), and July 1, 2021 (Phase 2), should be extended. Therefore, the agency will permit registrants to continue to utilize the processes described in the Phase 1 and Phase 2 responses through December 31, 2022.

Sincerely,

for

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS

April 29, 2021

Ray S. McAllister
Senior Director, Regulatory Policy
Crop Life America

Kristen R. Spotz
Senior Director, Regulatory Affairs
RISE, Responsible Industry for a Sound Environment

Gary Halvorson
Interim President
Council of Producers & Distributors of Agrotechnology

Komal K. Jain
Executive Director
Center for Biocide Chemistries

Dear Mr. McAllister, Ms. Spotz, Mr. Halvorson, and Ms. Jain:

This letter is in response to your letters dated March 30, 2021, informing the agency of a disruption in the supply chain for certain inert ingredients derived from ethylene oxide (EO) and propylene oxide (PO) feedstocks. Your letters noted that EO and PO production has been unexpectedly interrupted by weather events that occurred in the U.S. Gulf Coast in February 2021, with each letter including industry proposals for regulatory mechanisms that could be utilized by EPA to help alleviate these supply chain issues, which are characterized in the letters as urgent in nature. Additional information regarding the genesis and significance of this supply chain disruption to the pesticide industry was provided to the agency on April 23, 2021, in a document entitled "Supplemental Information on Shortage of Inert Ingredients Derived from Ethylene Oxide and Propylene Oxide Chemical Feedstocks."

Specifically, this letter addresses the set of industry proposals identified as "Phase 1 – "In-Kind Substitution Mechanism." Those proposals included the following:

A. expanding the designation of inert ingredients already on the Environmental Protection Agency's (EPA) Commodity Inert Ingredient List to include all non-food uses of List N-only inert ingredients; and

B. updating the Commodity Inert Ingredient List to include additional EO- and PO-based Alkoxylates beyond those already on the list; and

C. allowing registrants to substitute inerts on the Commodity Inert Ingredient List in food-use products, provided that appropriate self-certifications concerning data rights are made.
The agency has considered this set of proposals and determined that there is sufficient flexibility in our current regulatory scheme to allow for a temporary process to address these supply chain issues. The details of that process are given below.

Commodity Inert Ingredient List Designation. The agency has determined that an expansion of the designation of "For List N products only" to "For List N products and other nonfood-use products only" in the Commodity Inert List at https://www.epa.gov/pesticide-registration/commodity-inert-ingredients is appropriate and will adopt this proposal on a permanent basis by making the appropriate revision to the Commodity Inert List website. This determination is based upon the fact that the "For List N products only" designation in the Commodity Inert List was established to provide for additional flexibilities in the production of List N pesticides, specifically as related to the ability to source certain inert ingredients for these disinfectants used against the novel coronavirus. Since data rights obligations under FFDCA §408(i) do not apply, EPA is comfortable expanding the list, at this point, to "For List N products and other nonfood-use products only." This expansion will not affect the interests of data submitters.

Use of Additional Sources of Certain EO- and PO-based Alkoxylates. While the proposal to expand the Commodity Inert Ingredient List to include additional EO- and PO-based alkoxylates has merit, as noted in our 4/9 email response to Ray McAllister, the process required to fully validate each proposed addition and to perform quality control needed to ensure proper chemical names and CAS Reg. Nos. associated with each addition is a resource-intensive process. This process likely would not be able to be completed in the timeframe needed to provide the full relief sought under this element of the proposal. However, PR Notice 98-10, Section III.B., does, under certain circumstances, allow registrants to change the source of inert ingredients in a formulation from the current source without notification to the agency. The agency has determined that, based on the supply-chain interruptions impacting EO and PO production, a change or addition of source for the inert ingredients listed in Attachment 1 can be accomplished without notification to the agency during this period of significant supply disruption. Therefore, for the period of time from the date of this letter until December 31, 2021, the agency has concluded that changes or additions of sources for the inert ingredients listed in Attachment 1 are permitted via non-notification.

Addition or Change in Suppliers of Inert Ingredients in Food-Use Pesticides. The industry proposal included a self-certification process for ensuring compliance with data compensation rights under FFDCA §408(i) and FIFRA §3(c)(1)(F) if sources of EO- and PO-derived ingredients are to be substituted in pesticide formulations that have food-use patterns. To be clear, the current process utilized by registrants and suppliers of inert ingredients for use of inert ingredients with associated data compensation rights is to: 1) source such inert ingredients from the data owner(s), or 2) provide the agency with documentation that an offer to pay for the use of

such data has been made to the appropriate data submitter/owner or agent thereof. As these current procedures for addressing inert ingredient data compensation rights do not require a registrant to obtain agency approval prior to sourcing inert ingredients with associated data compensation rights, a self-certification process to ensure compliance with data compensation rights is unnecessary. We believe that, along with the flexibilities provided above, the current process for ensuring inert ingredient data compensation rights addresses this aspect of the industry proposal and no further change is needed.

Sincerely,

MARIETTA ECHEVERRIA

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Date: 2021.05.03 08:49:22 -04'00'

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs

Anita Pease, Director
Antimicrobials Division
Office of Pesticide Programs

ATTACHMENT 1

A. α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons

(CAS RN 9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 34398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 61791–13–7, 39587–22–9, 85422–93–1; 68154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 72854–13–8, 73049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)

B. Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives

1. α-Alkyl (minimum C6 linear, branched, saturated and or unsaturated)-ω-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; minimum oxyethylene content is 2 moles; minimum oxypropylene content is 0 moles.

(CAS RN 9046-01-9, 37280-82-3, 39464-66-9, 42612-52-2, 50643-20-4, 52019-36-0, 58318-92-6, 60267-55-2, 61837-79-4, 67711-84-6, 68070-99-5, 68071-35-2, 68071-17-0, 68130-47-2, 68186-37-8, 68186-36-7, 68311-02-4, 68425-73-0, 68458-48-0, 68511-37-5, 68610-65-1, 68585-36-4, 68649-29-6, 68815-11-2, 68908-64-5, 68891-13-4, 73038-25-2, 78330-24-2, 108818-88-8, 154518-39-5, 317833-96-8, 873662-29-4, 936100-29-7, 936100-30-0)

2. [α]-Alkyl(C6-C15)-[ω]-hydroxypoly(oxyethylene) sulfate, and it ammonium, calcium, magnesium, potassium, sodium, and zinc salts, poly(oxyethylene) content averages 2-4 moles.

(CAS RN 3088-31-1, 9004-82-4, 9004-84-6, 13150-00-0, 25446-78-0, 26183-44-8, 32612-48-9, 50602- 06-7, 62755-21-9, 68424-50-0, 68511-39-7, 68585-34-2, 68611-55-2, 68891-38-3, 73665-22-2)

C. Alkyl Amine Polyalkoxylates

1. N,N-Bis-a-ethyl-w-hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2–60 moles

(CAS RN 10213–78–2, 25307–17–9, 26635–92–7, 26635–93–8, 288259–52–9, 58253–49–9, 61790–82–7, 61791–14–8, 61791–24–0, 61791–26–2, 61791–31–9, 61791–44–4, 68155–33–9, 68155–39–5, 68155–40–8,70955–14–5, 73246–96–5)

2. N,N–Bis-a-ethyl-w-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2–60 moles

(CAS RN 68213–26–3, 68153–97–9, 75601–76–2)

D. α-[p-(1,1 ,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of p-(l,1,3,3- tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70

(CAS RN 9036-19-5, 9002-93-1)

E. Methyl poly(oxyethylene)C8–C18 alkylammonium chlorides where the poly(oxyethylene) content is n=2–15 and where C8–C18 alkyl is linear and may be saturated or unsaturated

(CAS RN 3010–24–0, 18448–65–2, 70750–47–9, 22340–01–8, 67784–77–4, 64755–05–1, 61791–10–4, 28724–32–5, 28880–55–9, 68187–69–9, 68607–27–2, 60687–90–3)

F. Nonylphenol Ethoxylates, Phosphates, and Sulfate Derivatives

1. α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and mono hydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles or 30 moles CAS RN 51811-79-1, 59139-23-0, 67922-57-0, 68412-53-3, 68553-97-9, 68954-84-7, 99821-14-4, 152143-22-1, 51609-41-7, 37340-60-6, 106151-63-7, 68584-47-4, 52503-15-8, 68458-49-1)

2. α -(p-Nonylphenyl)- ω - hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is propylene trimer isomer and the poly(oxyethylene) content averages 4 moles

(CAS RN 9014-90-8, 9051-57-4, 9081-17-8, 68649-55-8, 68891-33-8)
G. N,N,N,N-Tetrakis 2-hydroxy propyl ethylene diamine

(CAS RN 102-60-3)

H. Ethylene Oxide Adducts of 2,4,7,9 - Tetramethyl - 5 -Decyndiol

(CAS RN 9014-85-1)

I. Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether

(CAS RN 69029–39–6)

J. Oxirane, polymer with methyloxirane, block

(CAS RN 106392-12-5)

K. Poly(oxyethylene) p-nonylphenol

(CAS RN 26027-38-3)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS

May 3, 2021

Ray S. McAllister
Senior Director, Regulatory Policy
Crop Life America

Kristen R. Spotz
Senior Director, Regulatory Affairs
RISE, Responsible Industry for a Sound Environment

Gary Halvorson
Interim President
Council of Producers & Distributors of Agrotechnology

Komal K. Jain
Executive Director
Center for Biocide Chemistries

Re: Addendum to the Phase 1 Response Letter dated April 29, 2021

Dear Mr. McAllister, Ms. Spotz, Mr. Halvorson, and Ms. Jain:

This letter is an addendum to the Phase 1 response letter dated April 29, 2021.

In addition to the inert ingredients listed in Attachment 1 of that letter, changes or additions of sources for the inert ingredients listed below are also permitted via non-notification for the time period specified in that letter.

Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(dodecyloxy)-, ammonium salt (CAS Reg. No. 32612-48-9)
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(dodecyloxy)-, potassium salt CAS Reg 50602-06-7)
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(dodecyloxy)-, magnesium salt (CAS Reg. No. 62755-21-9)
Fatty acids, tall-oil, C12-15-alkyl esters, sulfated, sodium salts (CAS Reg. No. 68424-50-0)
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C12-15-alkyl ethers (CAS Reg. No. 68511-39-7)
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C10-16-alkyl ethers, sodium salts ethers (CAS Reg. No. 68585-34-2)

Sulfuric acid, mono-C10-16-alkyl ester ethers (CAS Reg. No. 68611-55-2)
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C12-14-alkyl ethers, sodium salts ethers (CAS Reg. No. 68891-38-3)
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C6-10-alkyl ethers, sodium salts ethers (CAS Reg. No. 73665-22-2)

Sincerely,

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 1, 2021

Ray S. McAllister
Senior Director, Regulatory Policy
Crop Life America

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RISE, Responsible Industry for a Sound Environment

Gary Halvorson
Interim President
Council of Producers & Distributors of Agrotechnology

Komal K. Jain
Executive Director
Center for Biocide Chemistries

Dear Mr. McAllister, Ms. Spotz, Mr. Halvorson, and Ms. Jain:

This letter is in response to your letters dated March 30, 2021, informing the agency of a disruption in the supply chain for certain inert ingredients derived from ethylene oxide (EO) and propylene oxide (PO) feedstocks. Your letters noted that EO and PO production has been unexpectedly interrupted by weather events that occurred in the U.S. Gulf Coast in February 2021, with each letter including industry proposals for regulatory mechanisms that could be utilized by EPA to help alleviate these supply chain issues, which are characterized in the letters as urgent in nature. Additional information regarding the genesis and significance of this supply chain disruption to the pesticide industry was provided to the agency on April 23, 2021, in a document entitled "Supplemental Information on Shortage of Inert Ingredients Derived from Ethylene Oxide and Propylene Oxide Chemical Feedstocks."

Specifically, this letter is in response to the industry proposal identified as "Phase 2 – "Not In-Kind" Substitution Mechanism" as related to non-antimicrobial pesticide products. A separate response to the industry Phase 2 proposal will be provided for antimicrobial pesticide products.

Under your proposal, registrants would be allowed to substitute one or more pre-approved alternate inert ingredients for specified inert ingredients that are in short supply through a self-certification process. Based on the initial Phase 2 proposal and a subsequent email of April 7, 2021, in which the document "Assessment of Potential Substitutes for Propylene Glycol" was included, the specifics of the proposed substitution would be to permit registrants to substitute glycerin (CAS Reg. No. 56-81-5); diethylene glycol (CAS Reg. No. 111-46-6), ethylene glycol

(CAS Reg No. 107-21-1); and/or 1,3-propanediol (CAS Reg. No. 504-63-2) for the inert ingredient propylene glycol.

Your proposal would permit an end-use or manufacturing-use product registrant to substitute some combination of the substitutes listed above for propylene glycol, including cases where propylene glycol is directly added to the formulation or is part of a brand name mixture in which the full composition is known to the registrant. Additionally, the proposal included further constraints on the substitutions, including self-certifications that the substitute inert ingredients serve the same function in the product as propylene glycol, and that the change: 1) would not impact the validity of any product-specific data submitted in support of the registration; 2) would not change the product's acute toxicity category or physical/chemical characteristics such that label modifications are necessary; and 3) would not affect the product's fitness for its intended purposes in terms of efficacy, phytotoxicity, or otherwise.

Following a full consideration of the proposal, the agency has determined that, subject to certain prescribed limitations, a time-limited expedited process for formulation amendments. This analysis included a review of publicly-available acute toxicity data and physical/chemical characteristics data for propylene glycol and each of proposed substitute inert ingredients (glycerin, diethylene glycol, ethylene glycol, and 1,3-propanediol) in which it was determined that the overall acute toxicity profile and physical/chemical characteristics of the substitute inert ingredients was comparable to that of propylene glycol and therefore would not impact the validity of any product-specific data submitted in support of the affected registrations. The specific details of this process, including limitations, are given as an attachment to this letter.

Sincerely,

MARIETTA ECHEVERRIA

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Date: 2021.07.01 14:44:49 -04'00'

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs

ATTACHMENT

Use of Streamlined Minor Formulation Amendment Process with Self Certification for Non-Antimicrobial Products—Changes from Propylene Glycol to Glycerin, Diethylene Glycol, Ethylene Glycol and/or 1,3-Propanediol

PR Notice 98-10, Section V. allows for the accelerated review of certain changes in product formulation via the submission of an application for amended registration identified as minor formulation amendments. The type of amendment that would fall under the category of minor formulation amendments is given in Section V.A.3 of PR Notice 98-10 and includes the following limitations:

a) the nominal concentration of active ingredient does not change;
b) the change does not invalidate any product-specific data submitted in support of the initial registration which causes additional data to be required;
c) the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;
d) if the product is registered for food use, the inert ingredient is considered to be exempt from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e);
e). any change is for inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and
f). the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.

PR Notice 98-10 further states that such formulation amendments will not be considered for accelerated review if they: 1) change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or 2) affect the product's efficacy so that supporting data are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact surface sanitizers, and liquid or aerosol insecticides intended for household use).

The agency has determined that a change in product formulation proposed to address the supply disruptions involving propylene glycol that meet each of the following conditions would meet the criteria as given in PR Notice 98-10, Section V.A.3. Specifically:

1) The formulation change is specific to the substitution of the inert ingredient propylene glycol with a combination of one of more of the following inert ingredients: glycerin; diethylene glycol; ethylene glycol; and 1,3-propanediol;

2) The specific weight percentages of any of the propylene glycol substitutes given in paragraph (1) are clearly provided and the combined weight percentage of the propylene glycol substitutes does not exceed the concentration of propylene glycol as listed in the product’s CSF;

3) The product(s) that is/are the subject of an application for amended registration do not include antimicrobial pesticide products; and

4) The product(s) that is/are the subject of an application for amended registration is not a bait product labeled for use against pests included in the list of *Pests of Significant Public Health Importance.* https://www.epa.gov/insect-repellents/list-pests-significant-public-health-importance.

The agency has further concluded that, in the case of minor formulation amendments meeting the criteria given above, a streamlined minor formulation amendment process temporarily provides sufficient information to satisfy the agency's regulatory needs. Therefore, given the temporary nature of the propylene glycol supply disruption, the agency has determined that for a period from the date of this letter through December 31, 2021, it will allow registrants of pesticide products containing propylene glycol as an inert ingredient to use a streamlined self-certification process for the minor formulation amendments conforming to the criteria given above. In lieu of the standard review process for minor formulation amendments described in PR Notice 98-10, Section V.B., EPA will allow for a streamlined minor formulation amendment process whereby such change may be submitted in the form of a single submission for amendment of multiple impacted products. The registration amendment submission should include an attachment to EPA Form 8570-1 specifically identifying the products (by EPA Registration No.) for which minor formulation amendments are being sought along with the following self-certification statement:

"*The change in formulation for EPA Registration No. [xxx-xx, etc.] is limited to a substitution of propylene glycol with a combination of one of more of the following inert ingredients: glycerin; diethylene glycol; ethylene glycol; and 1,3-propanediol and no other changes to the product formulation have been made. Additionally, this substitution: 1) does not materially affect the validity of any product-specific data submitted in support of the registration; 2) does not change the product's acute toxicity category such that label modifications are necessary; 3) does not change the product's physical/chemical characteristics such that label modifications are necessary; and 4) does not affect the product's fitness for its intended purposes in terms of efficacy, phytotoxicity, or otherwise. This self-certification is consistent with the provisions of PR Notice 98-10 and no other changes have been made to the confidential statement of formula or labeling of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this self-certification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under section 12 and 14 of FIFRA*."

Following receipt of such streamlined minor formulation amendments, the agency will review the submission to ensure that the products are within the scope of the streamlined minor formulation amendment process described above, confirm that the self-certification statement is included, and provide a response in writing granting or denying the amendment.

EPA intends to allow this expedited process for these minor formulation amendments until December 31, 2021. If a registrant has determined that, for any impacted product, they seek to

continue production/formulation with inert ingredients as described in paragraph (1) above, the registrant must submit an amendment for each impacted product, including an application (EPA Form 8570-1) and CSF for the proposed formulation to the agency for additional review prior to December 31,2021. Stocks of product approved under the present program that have been released for shipment by December 31, 2021, would be allowed to be sold and distributed after December 31, 2021.