UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 9, 2021

George Sabbagh
Bayer Crop Science
801 Pennsylvania Ave, NW
Suite 900
Washington, DC, 20004

Subject: Information Concerning Dicamba That Must Be Reported Pursuant to FIFRA section 6(a)(2)

Dear Dr. Sabbagh:

As you are aware, dicamba has appeared in news reports[1] during this growing season, indicating that dicamba products approved for use over-the-top of dicamba-tolerant cotton and soybeans with the more restrictive label and registration requirements from October 2020 appear to continue to be associated with reported alleged adverse incidents. We are sending this letter to you as a registrant of products containing dicamba for post-emergent uses on crops genetically engineered to be resistant to dicamba in order to highlight dicamba-specific information subject to reporting under FIFRA section 6(a)(2) and its implementing regulations at 40 CFR Part 159. This letter is being sent to ensure EPA has all the relevant information to make its decisions relating to these registrations.

EPA has had discussions with researchers who have conducted studies related to these uses. Those discussions alluded to studies that have not been submitted to EPA. Some of this information may fall within a registrant's obligation under FIFRA section 6(a)(2) and its implementing regulations. EPA has also received dicamba-related incident reports for the 2021 growing season from non-registrant parties. As a reminder, most adverse effects information must be reported to EPA within 30 days of its receipt by a registrant or its agents. Additionally, EPA is aware of lawsuits against certain parties related to the use of these products. Any information described in this letter that has been developed or provided in connection with a lawsuit must be reported under FIFRA section 6(a)(2) and its implementing regulations.

FIFRA section 6(a)(2) requires that "[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects of the pesticide, the registrant shall submit such information to the Administrator." EPA's implementing regulations at 40 CFR part 159 specify the types of information required to be submitted pursuant to FIFRA section 6(a)(2).

[1] For example, this article by NPR: https://www.npr.org/2021/07/23/1019746945/a-drift-prone-weedkiller-still-damages-crops-and-trees-despite-attempts-to-stop-.

EPA's regulations at 40 CFR 159.195(a) require submission of adverse effects information if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product. In addition, the 2020 post-emergent dicamba registrations identify certain requirements for enhanced reporting of adverse effects information. As noted in the terms and conditions of registration for your product, this information must be submitted annually by January 15 (beginning January 15, 2022) and final report with all then available information due September 30, 2025. Accordingly, I am writing to remind you of your specific obligations under 40 CFR 159.165-159.188 and your general obligations under 40 CFR 159.195(a), and to inform you in accordance with 40 CFR 159.195(c) of certain specific types of information that EPA considers reportable pursuant to FIFRA section 6(a)(2).

Any of the information listed below, in the possession or control of Bayer (and previously Monsanto) or any of its consultants, attorneys, or agents, that has not previously submitted to EPA must be reported to EPA under section 6(a)(2) and under the registration requirements for the post-emergent dicamba registrations on dicamba tolerant cotton and soybean:

1) Information (studies, incident reports, etc.) not already provided to EPA by your company regarding adverse effects, including allegations of non-target plant damage resulting from the use of, or contact with dicamba, including non-lethal effects, which occurred in any country at any time after October 2020. Adverse effects include but are not limited to 10% visual injury (i.e., cupping) and/or 5% reduction in height, biomass, or yield. Reportable information includes all information described in 40 CFR 159.158, and includes complaints, memos, investigations, reports, or other documents arising from incidents or studies. EPA is particularly interested in information on the locations of adverse effects, the distance between the damage location and any dicamba product applications to label-authorized or unauthorized sites, and any quantitative measurements of damage including visual injury, plant height, and plant yield.

2) All information regarding the sensitivity of non-target plant species (both crop and non-crop plants) to dicamba exposure, including qualitative assessments of relative sensitivity. EPA is especially interested in any data that may indicate plant species (both crop and non-crop plants) may be more sensitive to dicamba than soybeans.

3) Annual total quantities sold, nationally in the United States and per state, for each dicamba-containing product registered to your company. These sales data must be provided both for dicamba-containing products approved for over-the-top use and those approved for uses other than over-the-top use. Data must be reported at the product level for each product for each year from 2014 through 2021 and be provided in a searchable Excel spreadsheet format.

4) The Agency has received reports of seed breeding programs and research plots being impacted by exposure to dicamba. EPA has not received such reports from your company. Provide all information regarding the impact of dicamba on seed research and breeding programs. In addition to research and breeding plots, provide all reports of adverse effects to seed plots for commercial seed production; however, you may omit reports of adverse effects to crops modified to increase dicamba tolerance. Submit all available information on the nature of any damage to these plots as well as on the distance between the possible sources of the damage and the damaged crop.

5) EPA has received allegations that some registrants have not submitted reports of leaf "cupping" of soybean plants on the grounds that cupping can be caused by drought and/or exposure to herbicides other than dicamba (e.g, glufosinate, group 15 herbicides) in certain varieties that are of "poor plant genetics". EPA considers this assertion speculative, and insufficient grounds to rule out dicamba exposure as a cause of cupping. Accordingly, leaf cupping is considered an adverse effect of dicamba exposure and must be reported irrespective of plant genetics, although genetic information considered relevant may be included in the report. EPA requires all information on incidents related to "cupping," regardless of plant genetics, be included in the incident reports (i.e., do not exclude reports of "cupping" on varieties that have "poor plant genetics").

6) Information not already provided to EPA by your company regarding the herbicidal and toxicological effects of any and all dicamba isomers, as well as the concentrations of the dicamba isomers in dicamba-formulated products, both those approved for over-the-top use and those approved for uses other than over-the-top use.

7) Information regarding tank mixes containing the aforementioned over-the-top dicamba products found to be or suspected of being incompatible or reactive.

8) Any information, including, but not limited to deposition transcripts, responses to interrogatories, expert reports, other discovery documents (including internal company correspondence), and trial exhibits or transcripts, that was generated as a result of or in anticipation of lawsuits filed in any country, indicating that use of or contact with dicamba, directly or indirectly, resulted or may have resulted in adverse effects to non-target plants.

9) All studies and associated data (raw and summary) not already provided to EPA by your company, completed, incomplete, or in progress, conducted or sponsored by or for your company[2] [3] regarding dicamba pertaining to:

   a) Off-target movement of dicamba, through direct application (with or without drift reduction technologies such as hooded or layby sprayers or volatility reduction agents), volatilization, off-site spray drift, potential for long-range transport, runoff, leaching to groundwater, or rainfall. Include any study summary or test that pertains to off-site transport that was discontinued because of damage either confirmed or suspected to be from dicamba exposure to controls or test plots, damage beyond the treated area, or dicamba contamination of workspaces (indoor or outdoor) during or after the dicamba application.

   b) Dicamba's potential toxicity to target or nontarget plants via any presence of dicamba/residues detected in rain water, concentrations of dicamba in the air (including but not limited to that moved via long-range transport), runoff, or leaching to groundwater that were commenced by you or by others on your behalf, including those where no written reports or summaries were submitted to you. Include both indoor (greenhouse studies) and outdoor (field or plot studies), as well as reports from efficacy studies and/or incidents.

   c) Development of plants' resistance to dicamba, or diminished control of weeds by dicamba., including conventional dicamba uses in addition to OTT uses.

If Bayer (and previously Monsanto) or any of its subsidiaries, or any consultant, attorney, or agent who acquired such information while acting as a consultant, attorney, or agent, posesses or controls any information relating to dicamba that falls into the categories identified above, you must submit such information pursuant to FIFRA section 6(a)(2) as well as the terms and conditions of your registration. Please note that EPA is not asking attorneys to provide any opinions or conclusions rendered as the professional legal judgment of an attorney as part of this letter. However, any factual information in the possession of attorneys that attorneys acquired while working for Bayer (and previously Monsanto) that falls into the categories identified in this letter, including any applicable expert opinions of non-attorneys, must be submitted pursuant to this letter. Any information that has previously been submitted to EPA's Office of Pesticide Programs is excluded and need not be provided to the Agency again in response to this letter.

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[2] This includes all studies and associated data conducted by BASF, Bayer (and previously Monsanto), Corteva, or Syngenta as well by others for BASF, Bayer (and previously Monsanto), Corteva, or Syngenta, including but not limited to university and weed scientists, regardless of the stage of the study (e.g., study began, but not completed). In addition, this includes but is not limited to studies that were terminated due to suspected or confirmed dicamba injury.

[3] Identify any studies conducted by outside parties but funded by your company or a subsidiary thereof, in which the scope was narrowed in order avoid capturing the full range of adverse effects that could reasonably be anticipated or studies that were terminated due to suspected or confirmed dicamba injury. Also provide contact information for the principal investigator(s) for those studies and authorization for the researchers to fully discuss matters pertaining to the studies.

In addition to supplying the information required by section 6(a)(2), EPA would greatly appreciate that the information be accompanied by a master index in order to expedite the Agency's review of information submitted in response to this letter. The Agency suggests that this master index should encompass the total body of information being submitted and should include fields, such as but not limited to, the category of information (e.g., incident report, internal company email, final study report, antagonism, development of resistance, etc.) and the date of the creation of each record. This index should be provided to the Agency in a readily searchable format, such as an Excel spreadsheet or Access database.

Because of the current situation with COVID-19, I am sending you this letter by email rather than certified mail. Please acknowledge receipt of this letter to me via email at echeverria.marietta@epa.gov within 2 days from the date of this letter. I am asking that all the information specified in this letter be submitted no later than 10 days from the date of this letter. To the extent the information specified in this letter is subject to a reporting deadline in 40 CFR 159.155, the deadline for submitting the information is either 10 days from the date of this letter or the applicable deadline in 40 CFR 159.155, whichever is sooner. All information must be submitted as provided in 40 CFR 152.125 and part 159. I recognize that the deadline for submitting this information could be challenging under current circumstances, and I am available to discuss with you alterations to the proposed schedule should you find that necessary.

Sincerely,

MARIETTA ECHEVERRIA

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Date: 2021.09.09 12:53:46 -04'00'

Marietta Echeverria, Acting Director
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