UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Jeffrey H. Birk, Ph.D.
Regulatory Manager
BASF
26 Davis Drive
Research Triangle Park, NC 27709

Subject: Registration Amendment – Amended Terms and Conditions, Amended Labeling Including Collateral Labeling
Product Name: ENGENIA HERBICIDE
EPA Registration Number: 7969-472
Application Date: 12/9/2022
Last Resubmission: 02/10/2023
Decision Number: 589343

Dear Dr. Birk:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. The labeling associated with this approval supersedes the previously approved labeling. This amendment does not affect any terms and conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them. This includes the stipulation that this registration remains time-limited and will automatically expire on December 20, 2025, unless amended by EPA.

BASF submitted a label amendment pursuant to 40 C.F.R. § 152.44 to change the directions for use on this product to further restrict use of this product when used in Iowa, Illinois, Indiana, and South Dakota. Subject to the additional terms and conditions of registration described in this letter, EPA approves the labeling proposed by BASF and has determined that the amendment meets the standard of registration. The amendment approved through this letter includes additional, state-specific application date restrictions intended to further reduce off-target movement of the active ingredient dicamba. The states incorporated in this amendment were proposed by the registrant because they accounted for a significant percentage of total off-target movement complaints reported to state lead agencies in the last 3 years and these states did not object in writing to these labeling changes being made.

The ecological risk assessment (available on www.regulations.gov in docket EPA-HQ-OPP-2020-0492) relied upon in the registration of the product on 10/27/2020 supports the use of measures to address off-target movement, such as application cut-off dates, to avoid applications of dicamba on days with temperatures favoring off-target movement. As discussed in that risk

assessment, ambient temperature has been demonstrated to be directly related to the volatility of dicamba, with higher temperatures leading to increased volatility. Restricting the application to a time when temperature is reduced both on the day of application and in the days following application is likely to reduce the potential for volatilization of dicamba. The registrants of three dicamba-based products registered for over-the-top use, including BASF, proposed a June 12th cut-off date for Iowa, Illinois, and Indiana. The registrants also proposed a June 20th cut-off date for South Dakota, as recommended by that state. A registrant-provided rationale for the June 12th date was based on a reduction in off-target movement as a result of decreased temperatures, reduced plant height earlier in the season, the opportunity for applications to be spread more evenly through the season, and indications of improvement in Minnesota during the 2022 season using the June 12th cut-off date. EPA views these dates as directionally correct to reduce temperatures at which applications are performed.

Because this amendment approves application cut-off dates earlier than the cut-off dates considered in the Agency's ecological risk assessment developed for the registration of the product on 10/27/2020, this amendment does not allow for exposures beyond what was considered in the Agency's previous ecological risk assessment.

If the terms outlined below are not complied with, the registration may be subject to cancellation in accordance with FIFRA section 6. BASF must comply with all the following terms and conditions:

1. To ensure that products are not misbranded or misused, and appropriate labeling is in the possession of users for the 2023 growing season, the following terms and conditions are required.

    a. For all existing product in the possession of BASF or released for shipment and are in the channels of trade prior to date of this letter, BASF must make the amended labeling available as described below.

        i. By three days after approval, BASF's website where existing collateral labeling is held must be updated to reflect the changes within this amendment where the user will be able to access all collateral labeling for this registration in a downloadable format.

        ii. By three days after approval, copies of the amended labeling must be announced and posted in a prominent location on all BASF websites that are part of this product's labeling and be retained until the expiration date of this registration unless superseded by subsequent approved labeling.

iii. By three days after approval, a non-closeable banner containing the following must be prominently displayed at the top of all BASF websites that are part of this product's labeling. This banner must be posted until the expiration date of this registration unless superseded by subsequent approved labeling.

1. "ATTENTION: YOU MUST HAVE ALL LABELING APPLICABLE TO YOUR LOCATION IN YOUR POSSESSION FOR ENGENIA HERBICIDE TO BE LAWFULLY APPLIED AFTER March 15, 2022."
2. A copy or link to a copy of the amended labeling with approval date unless prominent labeling links are visible upon reading banner.
3. "EPA has approved amended labeling for this product which must be followed."
4. "It is a violation of FIFRA Section 12 to use a registered pesticide in a manner inconsistent with its labeling."

b. BASF must communicate the availability of and requirement for users to follow the amended labeling in the annual ENGENIA HERBICIDE education and training program, including in written educational communications. This information must be incorporated into the training by three days after the approval of this amendment. The training course must provide users with the amended labeling, if applicable in the state covered by the training course and must discuss the requirement to visit the website listed on the product label. Materials must emphasize that:

i. Users must obtain a copy of the amended labeling, if applicable, which must be in possession of the user at the time of application.

ii. After March 15, 2022, users of this product must follow the amended labeling they receive during training, if applicable.

c. BASF must take the following actions to contact all users who have already completed the 2023 training in states where there are EPA-approved state-specific restrictions implemented through the amended labeling to communicate the amended labeling. This will be done by sending all users who have already completed the 2023 training either (1) an email requesting a response via certification statement acknowledging that they have read and understood the new requirements or (2) a physical letter containing a reply postcard acknowledging receipt stating they have read and understood the new labeling requirements. If BASF does not receive the email response or reply postcard within two weeks, BASF must contact that user two additional times. The second contact attempt must be made by repeating the initial method of contact. Next, if no reply is received one week after the second contact attempt, BASF must follow-up another time with an alternative reasonable means of

contact to receive documentation from the user acknowledging that they have read and understood the new labeling requirements. If a valid phone number is used as the method for making the third contact attempt, BASF must solicit the user during that phone call to either mail or email them an acknowledgement that they have read and understand the new labeling requirements. Records of these contact attempts and replies must be kept by BASF and shared upon request.

d. BASF must send a report to EPA by six weeks after date of this letter detailing its efforts to accomplish all of the above. A copy or a link to the copy of the training materials must be included with this report. BASF must maintain copies of any correspondence it sends to all sellers, distributors, and purchasers and make them available to EPA upon request.

2. BASF must communicate the availability and requirement to adhere to the amended labeling.

   a. BASF must add the amended labeling to its training and educational materials for the relevant states and have website links to copies of the current approved labeling.

   b. The educational and training materials supporting this labeling change must be disseminated to state pesticide authorities and state agricultural extension services in the relevant states to support those authorities in assisting users in their local area.

References to the company's website on the label becomes labeling under FIFRA and therefore the website is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA Section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to EPA's attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A stamped copy of the container and collateral labeling is enclosed. This labeling supersedes all previously accepted labeling. BASF must submit one printed copy of the final amended labeling for the record prior to adding the amended labeling to its website as required under 1.a.ii. If BASF fails to comply with these terms, BASF has agreed in prior written acceptance of these terms that EPA may cancel the registration under an expedited process under FIFRA 6(e).

You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved container labeling for 18 months from the date of this letter, noting that based on the above conditions the collateral labeling will be posted on the website and go into effect immediately. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions, please contact Lindsay Roe by phone at (202)566-2878, or via email at Roe.lindsay@epa.gov.

Sincerely,

Lindsay Roe, Chief
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs