



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 28, 2023

Andrew Olson, Ph.D.
U.S. Regulatory Manager
BASF Corporation
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: PRIA (Pesticide Registration Improvement Act) Amendment – Convert seed increase registration to commercial use
Product Name: GMB151 Soybean
EPA Registration Number: 7969-434
EPA Receipt Date: 12/15/2021
Action Case Number: 00337375

Dear Dr. Olson:

The amendment referenced above, submitted in connections with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the updated terms and conditions as described in this letter.

1. Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. The subject registration will automatically expire at midnight on October 31, 2026.
3. The subject registration will be limited to *Bacillus thuringiensis* Cry14Ab-1 (vector pSZ8832) and the genetic material necessary for its production in GMB151 Soybean (OECD Unique Identifier: BCS-GM151-6).
4. GMB151 Soybean may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce soybean varieties with combined pesticidal traits.
5. BASF must submit the following data and/or information within the timeframe specified:
 - a. Grower stewardship materials with respect to *Heterodera glycines*, soybean cyst nematodes, including educational materials and the technology use guide for the product. These materials must be submitted within 90 days of the first commercial plantings of GMB151 Soybean.

- b. Baseline susceptibility data, sampling methods, and on-plant greenhouse bioassay methodology for detecting resistant populations. These methods and accompanying data must be submitted within one year of commercial plantings of GMB151 Soybean.
6. BASF must combine GMB151 Soybean (Cry14Ab-1) with soybean lines natively resistant to soybean cyst nematode, such as PI 88788.
 7. Resistance Management Program Elements. The required resistance management plan for GMB151 soybeans must have the following components:
 - a. BASF must implement an Integrated Pest Management (IPM)-based stewardship program for GMB151 Soybean;
 - b. Requirements for BASF to prepare and require GMB151 Soybean users to sign “grower agreements” which impose binding contractual obligations on the grower to comply with the RM requirements including best management practices for soybean cyst nematodes;
 - c. Requirements for BASF to develop, implement, and report to EPA on programs to educate growers about resistance management practices as well as tools to evaluate growers' adoption of the measures recommended under the resistance management program;
 - d. Requirements for BASF to develop, implement, and report to EPA on a resistance monitoring program for soybean cyst nematodes using sentinel plots and investigations of grower reports of unexpected damage;
 - e. Requirements for BASF to develop, implement, and report to EPA on a resistance confirmation bioassay to determine whether there are statistically significant and biologically relevant changes in susceptibility to Cry14Ab-1 protein in soybean cyst nematodes;
 - f. Requirements for BASF to develop, and if triggered, to implement a "remedial action plan" which would contain measures BASF would take in the event that any resistance was detected as well as to report on activity under the plan to EPA;
 - g. Requirements for annual reports on or before the time frames specified in the Annual Reports section below.

8. Resistance Management Plan Requirements

a. Integrated pest management (IPM) stewardship program

BASF must implement a best management practice (BMP)-based stewardship program for GMB151 Soybean. This program will be designed to reduce selection pressure for soybean cyst nematode resistance and prolong trait durability. Implementation of the IPM strategy can include grower education initiatives and outreach to extension and consultant groups. Key components of the stewardship program include:

- Non-host crop rotation after use of GMB151 Soybean;
- Eliminate non-crop host plants during non-host crop rotation;

- Monitoring for unexpected injury;
- Sanitation and dispersal limitation measures.

BASF must submit an annual report to the EPA documenting activities conducted under the IPM stewardship program. The report must include:

- A third-party anonymous survey of grower practices an assessment of grower practices;
- The level of IPM/BMP adoption by commercial growers of GMB151 Soybean growers in different regions of the country; and
- A discussion of the potential impact of non-adoption of IPM/BMP measures.

This report is due September 30th each year, beginning the first growing season of GMB151 Soybean commercial use.

b. Grower Agreements

- 1) Persons purchasing GMB151 Soybean must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current resistance management program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the resistance management program.
- 3) BASF must implement an approved system which is reasonably likely to assure that persons purchasing GMB151 Soybean will affirm annually that they are contractually bound to comply with the requirements of the resistance management program.
- 4) BASF must use a grower agreement for GMB151 Soybean. If BASF wishes to change any part of the grower agreement that would affect either the content of the resistance management program or the legal enforceability of the provisions of the agreement relating to the resistance management program, thirty days prior to implementing a proposed change, BASF must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this registration.
- 5) BASF shall maintain records of all GMB151 Soybean grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 6) BASF shall make available to the Agency upon request records of the number of units of GMB151 Soybean seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. BASF is required to submit reports within three months of the Agency’s request.
- 7) BASF must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that

confidential business information, including the names, personal information, and grower license number will be protected.

c. Resistance Management Education Program

BASF must implement the following resistance management education program:

- 1) BASF must design and implement a comprehensive, ongoing resistance management education program designed to convey GMB151 Soybean users the importance of complying with the RM program. The program shall include information encouraging GMB151 Soybean users to pursue elements of the resistance management program relating to best management practices. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each GMB151 Soybean grower separate from the grower agreement. BASF shall coordinate its education program with educational efforts of other organizations, such as the Soybean Cyst Nematode Coalition, American Soybean Association, and state extension programs. Education presentations will target growers, university extension, consultants, internal sales and technical teams, and other appropriate audiences.
- 2) Annually, BASF shall revise, and expand as necessary, its education program to take into account the information collected through the best management practices survey required under section 8.a and from other sources.
- 3) Within 90 days of request, BASF shall provide a report to EPA summarizing the activities it carried out under its education program for the prior year and its plans for its education program during the current year.

d. Resistance Monitoring

BASF must conduct an annual resistance monitoring program to assess the susceptibility of the soybean cyst nematode to the Cry14Ab-1 toxin. The resistance monitoring program must include sentinel plots for surveying for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following terms:

- 1) BASF will monitor for resistance in soybean cyst nematodes by the following methods:
 - a) Sentinel plots of GMB151 Soybean and comparative non-Bt soybean lines to monitor the abundance of soybean cyst nematodes in areas of expected high adoption and resistance risk.
 - b) Investigations of grower, extension specialist or consultant reports of less than expected results or control failures of GMB151 Soybean. BASF will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of soybean cyst nematode

damage occur. BASF must investigate all damage reports. See section 8.e (“Remedial Action Plans”) below.

- c) For both the sentinel plot and field damage report investigations, EPA defines “confirmed unexpected injury (UXI)” with the following triggers based on the number of cysts in 10 sampled plants:
 - i. An average of 20 cysts per symptomatic plant prior to 60 days after planting;
 - ii. An average of 50 cysts per symptomatic plant up to 90 days after planting;
 - iii. Any symptomatic plants documented after 90 days post-planting will be considered evidence as a confirmed UXI event;
 - iv. BASF must resample the confirmed UXI field at or after harvest;
 - v. BASF must implement remedial action measures in response to a confirmed UXI event – see section 8.e.

 - d) A confirmed UXI event will be considered “putatively resistant” if BASF samples the field again at or after harvest and collects 4000 eggs/100cm³ soil. If this egg threshold is obtained, BASF will conduct an on-plant greenhouse bioassay to compare the putatively resistant population of soybean cyst nematode to a susceptible population. If a significant difference in survival of these two colonies is observed in GMB151 soybeans, then the population will be deemed “confirmed resistant.”
 - i. For all cases of confirmed resistance, BASF must implement remedial action measures as required in section 8.e.

 - e) BASF is required submit the methodology for the on-plant greenhouse resistance confirmation bioassay within one year after commercialization of GMB151 Soybean.
- 2) Once resistance is first confirmed in a field collection of SCN, it will be reported to the Agency. BASF will further investigate to 1) Determine if the observed effect is heritable; 2) Demonstrate that the increased survival is due to resistance to Cry14Ab-1; 3) Characterize the soil properties in which resistance developed; 4) Determine the geographic extent of the resistance distribution; and 5) Determine the affected grower’s level of adherence to IPM best practices. BASF will report to the Agency on these findings and confer with the Agency regarding additional information needs.
 - 3) BASF must provide to EPA for review and approval any revisions to the soybean cyst nematode resistance monitoring plans prior to their implementation.
 - 4) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by September 30th each year for soybean cyst nematode for the duration of this registration. Additionally, BASF will meet with the Agency by February 28th of each year to discuss any damage incidents or resistance investigations from the previous year.

e. Remedial Action Plans

A specific remedial (mitigation) action plan for soybean cyst nematode is required for GMB151 Soybean for the purpose of containing resistance and perhaps eliminating resistance if it develops.

- 1) BASF must take the following actions for cases of confirmed UXI or confirmed resistance:
 - a) For confirmed UXI or confirmed resistance cases, BASF must hold discussions with the relevant grower(s) and recommend the following best management practices:
 - Rotate to a non-host crop the season after GMB151 Soybean;
 - Eliminate non-crop host plants during the non-host crop rotation;
 - Mitigate against soil movement out of the UXI field through sanitation.
 - b) For confirmed UXI or confirmed resistance cases, BASF must hold discussions with grower(s) of GMB151 Soybean within the county of the mitigation action area and recommend the following best management practices:
 - Rotate to non-host crop season after GMB151 Soybean;
 - Mitigate against soil movement from fields outside of the grower's control (e.g., sanitation of shared equipment);
 - BASF must cease sales of GMB151 Soybean to growers with fields exhibiting confirmed resistant populations of SCN as well as surrounding fields.
 - Monitor GMB151 for UXI, report to BASF if observed.
 - c) After remediation, BASF must hold discussions with the relevant grower(s) and recommend the following best management practices:
 - Monitor GMB151 Soybean for UXI, report to BASF if observed;
 - Plant soybean with alternative genetic source (QTL) of host plant resistance if resistance confirmation finds virulence to QTL in UXI soybean crop;
 - Use nematocidal seed treatments in subsequent years.
- 2) BASF must take the following measure for confirmed resistance cases:
 - Affected customers and extension agents must be notified regarding confirmed resistance within 30 days;

f. Reports for Sales, Grower Education, and Resistance Monitoring

- 1) BASF must provide to EPA within 90 days of request:
 - a) Annual sales reported and summed by state (county level data will be made available by request);

- b) A report summarizing any substantive changes to the grower education program completed the previous year.
- 2) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by September 30th each for the duration of this registration. BASF will also discuss any cases of putative resistance with the Agency prior to the subsequent field season by January 31st. The report will contain information such as:
 - a) Number of UXI reports and subsequently confirmed UXI cases in GMB151 Soybean fields, including state and county information.
 - b) Number of confirmed UXI cases that were assessed to have resistant populations of soybean cyst nematode.
 - c) Detailed results and discussion of the resistance confirmation bioassay.
 - 3) A report must be submitted to EPA by September 30th annually documented the results of the best management practice survey in section 8.a.

Please note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 11/24/2021

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this 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 labeling for 18 months from the date of this letter. 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.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Matt Weiner by phone at (202) 566-1509 or via email at weiner.matthew@epa.gov.

Sincerely,

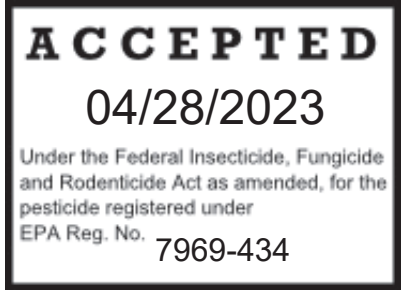
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Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

Proposed Plant-Incorporated Protectant Label

GMB151
Plant-Parasitic Nematode-Protected Soybean
(OECD Unique Identifier BCS-GM151-6)



Active Ingredient:

Bacillus thuringiensis Cry14Ab-1 protein and the genetic material necessary for its production (vector pSZ8832) in GMB151 soybean (OECD ID BCS-GM151-6)..... < 0.016622%*

Inert Ingredient:

4-hydroxyphenyl pyruvate deoxygenase (HPPD-4) and the genetic material necessary for its production (vector pSZ8832) in GMB151 soybean (OECD ID BCS-GM151-6)..... < 0.001271%*

*Maximum percent (wt/wt) of dry grain

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration Number: 7969-434
EPA ESTABLISHMENT NUMBER: 7969-NC-1
NET CONTENTS: _____

BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

GMB151 soybean may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce soybean varieties with combined pesticidal traits.

Soybean has been transformed to express *Bacillus thuringiensis* Cry14Ab-1 protein for the control of soybean cyst nematode (*Heterodera glycines*).

There are no refuge requirements for planting GMB151 soybean.

INTEGRATED PEST MANAGEMENT:

Best management practices are recommended when using Plant-Parasitic Nematode protection. Examples of appropriate BMPs include but are not limited to:

- Non-host crop rotation after use of Cry14Ab-1 soybeans
- Eliminate non-crop host plants during non-host crop rotation
- Monitoring for unexpected injury
- Sanitation and dispersal limitation measures