UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

SENT VIA ELECTRONIC MAIL DELIVERY RECEIPT REQUESTED (*jtorrents@matholding.com*)

June 20, 2023

INDUSTRIAS QUIMICAS DEL VALLES, S.A. Attn: Joana Torrents, General Counsel Rafael Casanova 81 08100 Mollet del Vallès, Spain

Re: Stop Sale, Use, or Removal Order (SSURO) to Industrias Quimicas del Valles, S.A.

Enclosed is a Stop Sale, Use, or Removal Order (SSURO) issued by the U.S. Environmental Protection Agency (EPA) to Industrias Quimicas del Valles, S.A. (IQV), concerning AmeriCop 40 DF (EPA Reg. No. 35484-4). The enclosed SSURO requires that IQV stop all distribution and sale of AmeriCop 40 DF except as permitted by this SSURO, which is effective immediately upon receipt.

Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136k(a), authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal of any pesticide by any person who owns, controls, or has custody of such pesticide whenever there is reason to believe that the pesticide is in violation of any provision of FIFRA or has been or is intended to be distributed or sold in violation of any provision of FIFRA.

EPA has reason to believe that IQV has distributed or sold misbranded AmeriCop 40 DF, an unlawful act under section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E). The current label includes the statement "For Organic Production" and EPA's three-leaf logo, indicating that it may be used for organic production under the United States Department of Agriculture's (USDA) National Organic Program (NOP). An inert ingredient used in AmeriCop 40 DF contains an ingredient not permitted under 7 C.F.R. pt. 205, making the product ineligible for use in organic production under USDA's NOP and misbranded under FIFRA.

The issuance of this Order shall not act as a waiver by EPA of any available lawful authority, enforcement or otherwise, including authority to seek civil penalties for alleged violations contained in this Order under section 14(a) of FIFRA, 7 U.S.C. § 136l(a).

Questions concerning this matter may be directed to Haley Todd via email at todd.haley@epa.gov.

Sincerely,

Gregory Sullivan, Director Waste & Chemical Enforcement Division Office of Civil Enforcement Office of Enforcement & Compliance Assurance U.S. Environmental Protection Agency

Enclosure(s): SSURO to Industrias Quimicas del Valles, S.A.

Cc: Hume Ross, Wiley Rein LLP (*hross@wiley.law*) Jordi Crespi Juanola, MAT Holding (*jcrespi@matholding.com*) Lisa Setliff, Landis International, Inc. (*lsetliff@landisintl.com*) Timothy Joseph, Landis International, Inc. (*tjoseph@landisintl.com*) Tracy Heinzman, Wiley Rein LLC (*theinzman@wiley.law*)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

IN THE MATTER OF:

Industrias Quimicas del Valles, Mollet del Vallès, Spain

Respondent

STOP SALE, USE, OR REMOVAL ORDER Docket No. FIFRA-HQ-2023-5009

I. <u>AUTHORITY</u>

 The Environmental Protection Agency (EPA) regulates pesticides and pesticide devices pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"), 7 U.S.C. §§ 136-136y.

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2. Section 13(a) of FIFRA authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal or any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe, on the basis of inspection or tests, the pesticide or device is in violation of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA. 7 U.S.C. § 136k(a).

3. This authority has been delegated from the EPA Administrator to the Director and Associate Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance.

II. <u>APPLICABLE LAW</u>

4. Section 12(a)(1)(E) of FIFRA provides that it is unlawful for any person in any State to distribute or sell to any person any pesticide that is adulterated or misbranded. 7 U.S.C. § 136j(a)(1)(E).

5. "Person" means "any individual, partnership, association, corporation, or any organized group or persons whether incorporated or not." 7 U.S.C. § 136(s).

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6. "Registrant" means a person who has registered a pesticide under FIFRA. 7 U.S.C. § 136(y).

7. "Pesticide" is defined in part as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u).

8. "To distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. 7 U.S.C. § 136(gg); 40 C.F.R. § 152.3.

 A pesticide is misbranded if its "labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A).

10. "Label" means "the written, printed, or graphic matter on, or attached to, the pesticide or device or any ot its containers or wrappers." 7 U.S.C. § 136(p)(1).

11. "Labeling" includes "all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time, or to which reference is made on the label or in literature accompanying the pesticide or device." 7 U.S.C. § 136(p)(2).

12. For a pesticide product to meet the requirements of the National Organic Program (NOP), in addition to other requirements, each active and inert ingredient used in the product must be permitted under the National List of Allowed and Prohibited Substances, codified at 7 C.F.R. pt. 205.

13. Pesticide products that are not NOP compliant and are labeled "For Organic Production," "For Organic Gardening," contain the EPA three-leaf logo, or that contain the Organic Materials Review Institute (OMRI) logo are considered false and misleading and therefore misbranded under sections 2(q) and 12(a)(1)(E) of FIFRA, 7 U.S.C. §§ 136(q), 136j(a)(1)(E). *See also* Labeling of Pesticide Products under the National Organic Program, Pesticide Registration Notice 2003-1, 68 Fed. Reg. 10477 (Mar. 3, 2003).

III. BASIS FOR THE ORDER

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14. Industrias Quimicas del Valles (IQV) is a person under FIFRA, with its principal place of business in Mollet del Vallès, Spain, and is the registrant for AmeriCop 40 DF (EPA Reg. No. 35484-4) ("AmeriCop").

15. AmeriCop was first registered by EPA in August 2012 with an accepted label containing the "For Organic Production" statement and EPA's three-leaf symbol.

16. In March 2023, EPA's Office of Pesticide Programs (OPP) conducted an NOP review of AmeriCop. During this review, OPP noted that the producer of an inert ingredient used in AmeriCop changed its formula. The amended formula contained a constituent that was not listed under 7 C.F.R. pt. 205, rendering the product not compliant with NOP requirements, and therefore misbranded.

17. EPA collected import records and sales information from Respondent indicating that AmeriCop is currently held for distribution or sale within the United States.

18. Based upon the information described above, EPA has reason to believe that Respondent distributed misbranded pesticides in violation of section 12(a)(1)(E) of FIFRA when it sold or distributed AmeriCop containing ingredients that are not NOP compliant but labeled "For Organic Production" and containing EPA's three leaf symbol. 7 U.S.C. §136j(a)(1)(A).

19. Respondent filed an application with EPA to amend the AmeriCop formula, as registered, to replace the previous inert ingredient with one that is NOP compliant. Respondent also proposed to EPA that it be allowed to consolidate its misbranded stocks of AmeriCop already in commerce and relabel them to remove the false or misleading claims ("Rework Plan"). EPA has accepted the proposed Rework Plan and incorporates its terms as provided in this Order.

IV. ORDER

20. This Order shall be effective immediately upon receipt by Respondent or an authorized agent and shall remain in effect until revoked, terminated, suspended, or closed in writing by EPA.

21. Respondent is ordered to immediately cease the distribution, sale, offer for sale, holding for sale, shipping, delivering for shipment, receipt, delivery, offer for delivery, movement, use, or removal of all

misbranded AmeriCop products that are within its ownership, custody, or control, wherever located ("Subject Products"), except in accordance with this Order, including any future modifications.

- 22. Distribution or sale of the Subject Products is permitted only as follows:
 - (A) All Subject Products may be moved to locations identified in the Rework Plan for relabeling.
 - (B) Relabeling shall consist of the removal or covering of the false or misleading label elements identified in the Rework Plan, and replacement of the false or misleading label with a label approved by the EPA, including the incorporation of the appropriate registered establishment number of the pesticide producing establishment where the relabeling is being conducted, as approved by EPA.
 - (C) The Subject Products may be released for distribution in commerce on a rolling basis upon confirmation that the products have been relabeled as specified in the Rework Plan, are no longer misbranded, and may be lawfully sold or distributed in compliance with FIFRA.
 - (D) The sale, distribution, and use of products relabeled according to the Rework Plan shall not be a violation of this Order, provided that the products are otherwise compliant with FIFRA.

23. Respondent will document and report all movement and relabeling activities to EPA according to the terms set forth in the Rework Plan.

24. Respondent shall provide a copy of this Order to all persons, including contractors, whose duties might reasonably be expected to include compliance with any provision of this Order or Rework Plan.

25. All reporting to EPA provided by this Order and the Rework Plan shall be submitted to Haley Todd via email at todd.haley@epa.gov.

V. OTHER MATTERS

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26. Respondent may seek judicial review of this Order pursuant to section 16 of FIFRA. 7 U.S.C.§ 136n.

27. Any violation of this Order may result in civil or criminal penalties pursuant to section 14 of FIFRA. 7 U.S.C. § 136l.

28. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.

29. Respondent may assert a business confidentiality claim (CBI claim) covering all or part of the information provided as part of this Order if such information meets the requisite criteria and is submitted according to 40 C.F.R. § 2.203(b). Information properly subject to a CBI claim may be made available to the public only in accordance with 40 C.F.R. Part 2, Subpart B. Otherwise, information submitted to EPA may be made available to the public without further notice.

30. For any additional information about this Order, please contact Haley Todd at todd.haley@epa.gov.

Date

Gregory Sullivan, Director Waste & Chemical Enforcement Division Office of Civil Enforcement Office of Enforcement & Compliance Assurance U.S. Environmental Protection Agency