

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 8 1595 Wynkoop Street DENVER, CO 80202-1129 Phone 800-227-8917 http://www.epa.gov/region08

JUN 3 0 2016

Ref: 8ENF-UFO

VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED AND ELECTRONIC TRANSMISSION

Joni Casper, Registered Agent Bioxy USA, LLC 626 Treven Place Draper, Utah 84020

> Re: STOP SALE, USE OR REMOVAL ORDER Bioxy USA LLC FIFRA-08-2016-0006

Dear Ms. Casper:

Enclosed is a Stop Sale, Use or Removal Order (Order) issued by the United States Environmental Protection Agency Region 8 to Bioxy USA LLC (Bioxy) for producing, distributing or selling unregistered pesticide products as described in the Order. *The Order is effective immediately upon receipt by you, as registered agent for Bioxy*.

Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136k(a), authorizes 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 the pesticide is in violation of any provision of FIFRA or such pesticide has been or is intended to be distributed or sold in violation of FIFRA. As explained further in the enclosed Order, Bioxy has been and is producing, distributing, or selling unregistered pesticide products.

If you or Bioxy have any questions about this matter, you may contact Dan Webster of my staff at 303-312-7076, or by email at webster.daniel@epa.gov. For any legal questions, please contact Brenda Morris, Senior Enforcement Attorney by phone (303-312-6891) or by email at morris.brenda@epa.gov.

Sincerely,

David Cobb, Acting Unit Chief Technical Enforcement Program Office of Enforcement, Compliance and Environmental Justice

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

2016 JUN 30 AM 11:25

FILED EPA REGION VIII HEARING CLERK

In the Matter of:

Bioxy USA, LLC 626 Treven Place Draper, UT 84020

Respondent

STOP SALE, USE, OR REMOVAL ORDER FIFRA-08-2016-0006

I. AUTHORITIES

- 1. The United States Environmental Protection Agency issues this Stop Sale, Use, or Removal Order (Order) pursuant to the authority vested in the Administrator of the EPA by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. § 136k(a), which authorizes the Administrator of the EPA to issue orders prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe the pesticide or device is in violation of any provision of FIFRA, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration has been cancelled by a final order.
- 2. Supervisors in the Technical Enforcement Program and the Legal Enforcement Program have been jointly delegated the authority to issue such orders.
- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states "it shall be unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered under section 136a of this title or whose registration has been cancelled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter."
- 4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states "it shall be unlawful for any person in any State to distribute or sell to any person any pesticide, which is adulterated or misbranded."
- 5. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), states it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 6. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 7. Section 2(gg), 7 U.S.C. § 136(gg) defines "to distribute or sell" as "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."

- 8. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a "pesticide", in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."
- 9. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part as "any form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1) [of FIFRA]."
- 10. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), states that 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."
- 11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "labeling" in part as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or literature accompanying the pesticide or device."
- 12. As stated at 40 C.F.R. § 152.15, with certain exceptions not applicable in this circumstance, "[n]o person may distribute or sell any pesticide product that is not registered under [FIFRA]."

II. BACKGROUND

- 13. Bioxy USA, LLC (Bioxy) is a corporation organized under the laws of the State of Utah and is authorized to do business in the State of Utah.
- 14. Bioxy is an official affiliate of Arlington Scientific, Inc., both of which companies are located at 1840 North Technology Drive, Springville, Utah 84663.
- 15. Bioxy is a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- 16. Arlington Scientific, Inc. is a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- 17. Arlington Scientific Inc., attempted to register Bioxy Plus with EPA on behalf of its affiliate Bioxy on December 1, 2015. The EPA Office of Pesticide Programs (OPP) rejected the application due to insufficient data.
- 18. Bioxy Plus is a pH neutral powdered product that generates peracetic acid when mixed with water. It is advertised as an environmentally safe and non-toxic peracetic acid disinfectant capable of killing superbugs.
- 19. The Bioxy Plus product is making pesticidal claims and this product is not registered with the EPA.
- 20. OPP discovered that Bioxy USA's website, bioxyusa.com, appears to advertise and offer Bioxy Plus for sale in the U.S.

III. BASIS FOR ORDER

21. On June 22, 2016, an EPA credentialed inspector with the Utah Department of Agriculture and Food conducted an inspection at the Bioxy facility located in Springville, Utah.

- 22. The inspector requested copies of distribution records that support that Bioxy has been distributing the Bioxy Plus product since September 22, 2015.
- 23. The distribution records also show that Bioxy has been distributing two additional unregistered pesticide products called Bioxy H and Bioxy +, both of which are from a Canadian company called Bioxy AFD Inc. Neither of these pesticide products is registered in the United States.
- 24. Bioxy has been and is producing, distributing, or selling an unregistered pesticide in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 25. An EPA inspector conducted a review of the Bioxy website, at bioxyusa.com. The Bioxy Plus label contains a link to the company website, which makes the website a part of the Bioxy Plus labeling. False and misleading statements are considered misbranding. Several false and misleading statements were identified as part of the website review, including the statements below:
 - a. multiple claims as to the safety of the pesticide or its ingredients
 - i. "non-corrosive"
 - ii. "non-toxic"
 - iii. "are safe"
 - iv. "safe to handle"
 - v. In reference to healthcare associated infections (HAI) . . . "Will stop this!"
 - vi. "Environmentally friendly"
 - vii. "non-hazardous"
 - b. inappropriate comparisons with other active ingredients of other products:
 "advantages over conventional quaternary ammonium and chlorine based products"
- 26. Bioxy has been and is producing, distributing, or selling a misbranded pesticide in a violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

IV. ORDER

- 27. The EPA hereby orders Bioxy to stop the sale, use, or removal of all pesticide products subject to this Order: Bioxy H, Bioxy +, and Bioxy Plus, EFFECTIVE IMMEDIATELY.
- 28. The EPA hereby orders Bioxy to stop the advertising of and for the use of all Bioxy products subject to this Order, EFFECTIVE IMMEDIATELY.
- 29. This Order pertains to all quantities and sizes of Bioxy products distributed within the ownership, control, or custody of Bioxy or any other entity producing the products. The Bioxy products shall not be sold, used, or removed other than in accordance with the provisions of this Order or any further Stop Sale, Use, or Removal Order that may be issued in connection with such pesticide products.
- 30. The EPA hereby orders Bioxy to remove all false and misleading statements from their website and any other forms of advertising media.
- 31. No later than two weeks from receipt of this Order, Bioxy must submit a list of each person, as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s), to whom Bioxy has transferred any Bioxy products from July 1, 2014, to the date of submittal.

- 32. No later than two weeks from receipt of this Order, Bioxy must submit a written inventory for all Bioxy products within its custody or control and subject to this Order. The inventory shall list the quantity and location of all pesticide products subject to this Order and include plans for product storage or disposal. The pesticide products subject to this Order shall not be moved, destroyed or disposed of without prior written consent from EPA.
- 33. The list described in paragraph 31 and the inventory described in paragraph 32 must be submitted to the following:

Dan Webster US EPA Region 8 (ENF-UFO) 1595 Wynkoop Street Denver, CO 80202

- 34. Any violation of the terms or provisions of this Order by an officer, agent, or other person acting for or employed by Bioxy may subject such person as well as Bioxy to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 136*l*.
- 35. The issuance of this Order shall not constitute a waiver by the 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.
- 36. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by Respondent.
- 37. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
- 38. If any provisions of this Order are subsequently held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not be affected in any way or impaired thereby and shall remain in full force and effect. The terms of this Order shall remain in effect unless and until the EPA modifies or terminates either the Order or certain provisions of the Order in writing.

David Cobb, Acting Unit Chief Toxics Enforcement Program Office of Enforcement, Compliance and Environmental Justice

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James H. Eppers, Supervisory Attorney Legal Enforcement Program Office of Enforcement, Compliance and Environmental Justice