



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

APR 23 2015

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

CERTIFIED MAIL RECEIPT RETURN REQUESTED

Rob Williams, President
Makhteshim Agan of North America, Inc., d/b/a ADAMA
3120 Highwoods Blvd., Suite 100
Raleigh, NC 27604

Re: FIFRA Section 13 ORDER
Makhteshim Agan of North America, Inc., d/b/a ADAMA

Dear Mr. Williams:

Enclosed is a Stop Sale, Use, or Removal Order ("Order") issued by the Environmental Protection Agency, Waste and Chemical Enforcement Division, concerning the pesticide product Fluensulfone 480EC, EPA Reg. No. 66222-243. This Order requires Makhteshim Agan of North America, Inc., d/b/a ADAMA, to immediately cease the sale, use and removal of the product Fluensulfone 480EC in accordance with the provisions of the Order. ***The Order is effective immediately upon receipt.***

Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), authorizes the EPA Administrator 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 on the basis of inspection or tests 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 FIFRA. EPA has reason to believe, based on tests performed by or for ADAMA, that Fluensulfone 480EC is a misbranded pesticide and that ADAMA has distributed or sold, or intends to distribute or sell, this misbranded pesticide in violation of FIFRA.

If you have any questions about this matter or wish to request an informal conference to discuss these alleged violations, you may contact Brian Dyer, Enforcement Case Officer, at (202) 564-4166, and for any legal matters, contact Tom Charlton, Attorney, at (202) 564-6960.

Sincerely,

Kenneth C. Schefski, Acting Director
Waste and Chemical Enforcement Division

Enclosure

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HEADQUARTERS**

In the Matter of:

**Makhteshim Agan of North
America, Inc., d/b/a ADAMA
3120 Highwoods Blvd., Suite 100
Raleigh, North Carolina 27604**

Respondent

**ORDER
SECTION 13(a)**

**FEDERAL INSECTICIDE, FUNGICIDE
AND RODENTICIDE ACT**

Docket No. FIFRA-HQ-2015-5009

I. AUTHORITY

1. This Stop Sale, Use, or Removal Order (“Order”) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency (“EPA”) by section 13(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (“FIFRA”), 7 U.S.C. § 136k(a), which authorizes the Administrator of the EPA to issue an order 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 that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
2. This authority has been delegated from the EPA Administrator to the Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, U.S. EPA.
3. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any State to sell or distribute to any person any pesticide that is misbranded.
4. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
5. 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.”
6. Section 2(gg) of FIFRA, 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.”

7. 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.” *See also* 40 C.F.R. § 152.15.
8. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a “pest” as “any insect, rodent, nematode, fungus, weed, or [] any other 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].” *See also* 40 C.F.R. § 152.5.
9. Section 2(bb) of FIFRA, 7 U.S.C. § 136(bb), defines “unreasonable adverse effects on the environment” to mean, “(1) any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 342(a)” (FFDCA).
10. Section 201(q)(1) of the FFDCA, 21 U.S.C. § 321(q)(1), defines “pesticide chemical” to mean, *inter alia*, “any substance that is a pesticide within the meaning of [FIFRA] . . . including all active and inert ingredients of such pesticide.”
11. Section 201(q)(2) of the FFDCA, 21 U.S.C. 321(q)(2), defines “pesticide chemical residue” to mean “a residue in or on raw agricultural commodity or processed food of -- (A) a pesticide chemical; or (B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.”
12. Section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F), provides that a pesticide is “misbranded” if such pesticide’s “labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements under section [3(d) of FIFRA], are adequate to protect health and the environment.”
13. Section 2(q)(1)(G) of FIFRA, 7 U.S.C. § 136(q)(1)(G), provides that a pesticide is “misbranded” if such pesticide’s “label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section [3(d) of FIFRA], is adequate to protect health and the environment.”
14. FIFRA’s implementing regulations require an applicant for pesticide registration to submit materials to enable the Administrator to make a determination that use of the pesticide will not generally cause unreasonable adverse effects on the environment.
40 C.F.R. § 152.50(f)(1).
15. Section 408(a)(1) of the FFDCA, 21 U.S.C. § 346a(a)(1), provides that any pesticide chemical residue in food is unsafe for purposes of section 402(a)(2)(B) of the FFDCA, 21 U.S.C. § 342(a)(2)(B), unless the quantity of the pesticide chemical residue is within the limits of an established tolerance or an exemption from the requirement of a tolerance for

those residues is in effect. The term food includes both raw agricultural commodities and processed foods. *Id.*

16. Section 402(a)(2)(B) of the FFDCA, 21 U.S.C. § 342(a)(2)(B), provides that any food that contains any unsafe pesticide chemical residue shall be deemed adulterated and as such is prohibited by section 301(a) of the FFDCA, 21 U.S.C. § 331(a), from being introduced (or delivered for introduction) into interstate commerce.
17. Section 303(f)(2)(A) of the FFDCA, 21 U.S.C. § 333(f)(2)(A), provides for civil penalties for any person who introduces (or delivers for introduction) into interstate commerce food that is adulterated. Section 304 of the FFDCA, 21 U.S.C. § 334, further provides that adulterated food can be seized by the U.S. Marshall's Service at the direction of the Food and Drug Administration.
18. Section 408(b)(1) of the FFDCA, 21 U.S.C. § 346a(b)(1), authorizes EPA to issue regulations establishing general procedures and requirements for establishing, modifying, or revoking pesticide tolerances. Those regulations are found at 40 C.F.R. Part 180.
19. EPA's regulations regarding tolerance petitions require petitioners to submit full reports of tests and investigations made with respect to (1) the safety of the pesticide chemical and (2) the nature and amount of the pesticide chemical residue that is likely to remain in or on any food. 40 C.F.R. §§ 180.7(b)(5) and (6).
20. Section 408(a) of the FFDCA, 21 U.S.C. § 346a(a), and 40 C.F.R. § 180.1(e) of the EPA's regulations provide that where a pesticide chemical residue tolerance is established for a raw agricultural commodity, a separate tolerance for food processed from that commodity is not required if:
 - (a) The pesticide chemical was used on the raw agricultural commodity in conformity with the tolerance (40 C.F.R. § 180.1(e)(1));
 - (b) The pesticide chemical residues have been removed to the extent possible in good manufacturing practice (40 C.F.R. § 180.1(e)(2)); and
 - (c) The concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue on the raw agricultural commodity (40 C.F.R. § 180.1(e)(3)).
21. Section 180.40(f) requires that processing data be submitted before the Agency establishes a crop group tolerance. 40 C.F.R. § 180.40(f).

II. BACKGROUND

22. Makhteshim Agan of North America, Inc., d/b/a ADAMA ("ADAMA") is a corporation located and incorporated in the state of Illinois. ADAMA is a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).

23. This Order refers to ADAMA and all its divisions, offices and branches, collectively, as “ADAMA.”
24. ADAMA is the registrant for the pesticide product Fluensulfone 480EC, a nematicide containing the active ingredient Fluensulfone, which has been assigned EPA Registration Number 66222-243. Fluensulfone 480EC was given the alternate brand name, “Nimitz.”
25. Fluensulfone 480EC is a “pesticide” as that term is defined in section 2(u) of FIFRA, 7 U.S.C. § 136(u).
26. On April 16, 2012, EPA received a registration package from ADAMA for the product Fluensulfone 480EC which included a Tolerance Petition, dated April 13, 2012, requesting the establishment of tolerances for residues of Fluensulfone in or on cucurbits and fruiting vegetables. Those fruiting vegetables included, but were not limited to, tomatoes.
27. On September 11, 2014, EPA approved the registration for the product Fluensulfone 480EC. The registration provided for end-use application on cucurbits and fruiting vegetables, including tomatoes.
28. Concurrently, EPA established a tolerance for residues of Fluensulfone in or on cucurbits and fruiting vegetables. EPA did not establish a separate tolerance to cover concentrated residues of Fluensulfone in foods processed from treated raw agricultural commodities, e.g., tomato paste, because the data provided by the petitioner did not indicate that a tolerance on processed foods might be necessary.
29. On or about February 3, 2015, Health Canada, Government of Canada informed EPA that they had received from ADAMA a tomato processing study involving Fluensulfone. The study, completed on October 4, 2013 and identified as “Study Number AA120702” (“Study”), showed pesticide chemical residues of Fluensulfone concentrating in tomato paste.
30. Tests associated with the Study indicated that the concentration of the pesticide chemical residues for Fluensulfone in tomato paste and other tomato processed products would be greater than the tolerance established by EPA for residues of Fluensulfone in or on fruiting vegetables.
31. Where residues of Fluensulfone in processed tomato products exceed the established tolerance for residues of Fluensulfone in fruiting vegetables, a separate pesticide tolerance for processed tomato products is required in order for those products not to be considered unsafe or adulterated. 21 U.S.C. § 346a(a) and 40 C.F.R. § 180.1(e)(3).
32. The Study was not submitted by ADAMA as part of the original registration and tolerance petition application package or as an amendment to that application package prior to EPA approving the registration on September 11, 2014, as required under 40 C.F.R. §§ 152.50(f) and 180.7(b).

33. Since the registration was approved for the product Fluensulfone 480EC, ADAMA has not submitted a Tolerance Petition requesting a tolerance for processed tomato products.
34. The approved FIFRA label for the product Fluensulfone 480EC allows for its use on tomatoes without any specific restrictions for the product's use on tomatoes intended for processing.

III. BASIS FOR THE ORDER

35. Based on tests associated with the Study, EPA has reason to believe that the product Fluensulfone 480EC is in violation of FIFRA as a misbranded product whose distribution or sale violates section 12(a)(1)(E).
36. The EPA-approved end-use label permits the product Fluensulfone 480EC to be used on tomatoes and does not contain directions for use that would prohibit use on tomatoes destined for processing. The label does not provide any other warnings, precautionary language or relevant caution statement to limit its use to tomatoes not destined for processing.
37. EPA has reason to believe on the basis of the tests associated with the Study that the product Fluensulfone 480EC, as currently labeled, cannot be used on tomatoes without resulting in unsafe pesticide chemical residues of Fluensulfone in processed tomato products.
38. Processed tomato products containing unsafe residue levels would be considered adulterated food under section 402(a)(2)(B) of the FFDCA, 21 U.S.C. § 342(a)(2)(B), and as such, would be prohibited by section 301(a) of the FFDCA, 21 U.S.C. § 331(a), from being introduced (or delivered for introduction) into interstate commerce. A person who introduced such processed tomato products (or delivered them for introduction) into interstate commerce could be fined a civil penalty or have the products seized by the United States Government. FFDCA §§ 303(f)(2)(A) and 304(a), 21 U.S.C. §§ 333(f)(2)(A) and 334(a).
39. Dietary risk presented by adulterated food is inconsistent with the standard in section 408 of the FFDCA and presents an unreasonable adverse effect on the environment as defined at section 2(bb) of FIFRA. 7 U.S.C. § 136(bb).
40. The economic costs posed by any seizure of this food or by the imposition of civil penalties for introducing this food into interstate commerce presents an unreasonable adverse effect on the environment as defined at section 2(bb) of FIFRA. 7 U.S.C. § 136(bb).
41. Therefore, EPA has reason to believe that the pesticide Fluensulfone 480EC is misbranded as defined in section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F), because, as described in Paragraphs 34 and 36 above, the labeling accompanying it does not contain directions for use that are necessary for effecting the purpose for which the product is intended and, if complied with, is adequate to protect health and the environment.
42. EPA also has reason to believe the pesticide Fluensulfone 480EC is misbranded as defined in section 2(q)(1)(G) of FIFRA, 7 U.S.C. § 136(q)(1)(G), because, as described in Paragraphs

34 and 36 above, the label does not contain a warning or caution statement which may be necessary and if complied with, is adequate to protect health and the environment.

IV. ORDER

43. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders ADAMA to **immediately cease** the sale, use or removal of the product Fluensulfone 480EC under its ownership, control or custody, wherever such Fluensulfone 480EC products are located, except in accordance with the provisions of this Order.
44. This Order shall extend to all quantities and sizes of the product Fluensulfone 480EC, EPA Reg. No. 66222-243, intended for sale or distribution, including Fluensulfone 480EC products marketed under alternate brand names and any Fluensulfone 480EC stocks returned to ADAMA from its customers or other end-users.
45. Fluensulfone 480EC products shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, offered for delivery, moved or removed for disposal from any facility or establishment, for any reason, unless approved by EPA in writing. Any proposal for movement of the product Fluensulfone 480EC shall be submitted to James Miles, Chief, Pesticides and Tanks Enforcement Branch (2249A), United States Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and shall include:
 - (a) the purpose for which the movement is being requested;
 - (b) an accounting of the quantities of product to be moved, including location(s), quantities from each location and container size for the products to be moved; and
 - (c) the destination location to which the product will be moved.
46. Within 10 days of receipt of this Order, ADAMA shall submit to EPA an accounting of all Fluensulfone 480EC product subject to this Order. The report shall be submitted to James Miles, Chief, Pesticides and Tanks Enforcement Branch (2249A), United States Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and shall include:
 - (a) A description of all existing Fluensulfone 480EC product inventory, including the location(s) where the product is held, quantities, and container size. ADAMA must update the information on a weekly basis for four weeks, on a monthly basis for the following six months, and thereafter only upon further changes to the information;
 - (b) A complete list of its ADAMA distributors and direct-sale customers and records of all sales and distributions made to such entities; and
 - (c) Provisions to maintain records of the disposition (e.g., reformulation, repackaging, relabeling, disposal) of the product Fluensulfone 480EC and to make the records


available to EPA upon request. Such records must include information on the method, the quantity and the location of disposition and/or disposal.

47. Any agent, owner, or operator of ADAMA violating the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 136f.
48. 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.
49. This Order shall be effective immediately upon receipt by ADAMA or any agents of ADAMA.
50. This Order shall remain in effect unless and until revoked, terminated, suspended or modified in writing by EPA.
51. If any provision or provisions of this Order is/are subsequently held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

V. OTHER MATTERS

52. For any additional information about this Order, please contact Brian Dyer, Enforcement Case Officer, at 202-564-4166. For any legal matters concerning this Order, please contact Tom Charlton, Attorney, at 202-564-6960.

4/23/15
Date



Kenneth C. Schefski, Acting Director
Waste and Chemical Enforcement Division

Docket No. FIFRA-HQ-2015-5009
FIFRA § 13(a) ORDER