



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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

Ref: 8ENF-UFO

NOV 14 2011

VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED
AND ELECTRONIC TRANSMISSION

Michael Manning, President
Pioneer H2O Technologies, Inc.
3225 South Wadsworth Blvd, Unit L
Lakewood, CO 80227

Michael Boucher
Counsel for Pioneer H2O Technologies, Inc.
McKenna Long & Aldridge LLP
1900 K Street NW
Washington, DC 20006-1108

Re: FIFRA Section 13 ORDER
Pioneer H2O Technologies, Inc.

Dear Mr. Manning and Mr. Boucher:

Enclosed is a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 13(a) Order concerning Pioneer H2O Technologies, Inc (Pioneer) unregistered pesticide products, Tru-Blu (sodium bromide) and copper ionizers (including but not limited to P-15, p-25, and P-50). ***The Order is effective immediately upon receipt.***

Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), authorizes the United States Environmental Protection Agency (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 has been or is intended to be distributed or sold in violation of FIFRA. As explained further in the enclosed Order, EPA has reason to believe that Pioneer distributed or sold violative pesticide products.

EPA has considered Pioneer's October 26, 2011 request to allow a limited sale of Tru-Blu to two of Pioneer's distributors while Pioneer seeks registration. EPA has denied Pioneer's request for the reasons set forth in the enclosed November 4, 2011 letter.

If you have any questions about this matter, you may contact Eduardo Quintana, Senior Enforcement Attorney by phone: 303-312-6924 or email: quintana.eduardo@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Stavnes', written over a light gray circular stamp.

Sandra A. Stavnes, Director
UFO Technical Enforcement Program
Office of Enforcement, Compliance
and Environmental Justice

Enclosures



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

NOV 4 2011

Mr. Michael Boucher
Counsel for Pioneer H2O Technologies, Inc.
McKenna Long & Aldridge, LLP
1900 K Street N.W.
Washington, DC 20006

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Dear Mr. Boucher:

Thank you for your October 26, 2011 letter to the United States Environmental Protection Agency (EPA). You request that the EPA provide Pioneer H2O Technologies, Inc. (Pioneer) with an assurance that it may sell or distribute unregistered pesticides to two customers while Pioneer completes the pesticide registration process. For the reasons set forth below, the EPA is denying this request.

The EPA has a longstanding policy against the exercise of enforcement discretion, which is described in a 1995 memorandum entitled "Processing Requests for the Use of Enforcement Discretion." That memorandum reaffirmed a 1984 policy statement. The EPA "recognized two general situations in which a no action assurance may be appropriate: where it is expressly provided for by an applicable statute, and in the extremely unusual circumstances where an assurance is clearly necessary to serve the public interest and which no other mechanism can address adequately." In making this evaluation, the Agency considers a number of factors, including the potential impact on human health and the environment and whether an adequate alternative exists.

Applying this policy to your request, the EPA finds that enforcement discretion is not expressly provided for by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Further, the EPA does not believe that you demonstrated an extremely unusual circumstance where an assurance is clearly necessary to serve the public interest. Even if your letter had done so, we conclude that there are other mechanisms that can address this situation adequately.

Once Pioneer submits a pesticide registration application for its unregistered sodium bromide product, the EPA will work with Pioneer to register the product as quickly as possible. As you know, the EPA considers Pioneer's pesticide registration as a high priority project which will expedite the registration process. The EPA's goal is to keep the amount of time it takes to register Pioneer's product to a minimum. EPA encourages Pioneer to continue its efforts to seek product registration and to engage with the EPA to facilitate that process.

Under FIFRA, it is unlawful for any person, including Pioneer's customers, to distribute or sell any pesticide not properly registered with the EPA. A product is deemed to be a pesticide if it kills, repels, or mitigates any pest and/or if the person selling the product makes any pesticidal claims for the product or has constructive knowledge that the product is or will be used for pesticidal purposes. It is clear from the EPA's investigation that Pioneer was making pesticidal claims for its Tru-Blu product and that Pioneer knew that the sole purpose of the product was to achieve a pesticidal effect. As such, Pioneer's sodium bromide product is a pesticide and requires registration with the EPA before it may lawfully be distributed or sold.



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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 8

2011 NOV 14 PM 3:41

FILED
EPA REGION VIII
DENVER, COLORADO

<u>In the Matter of:</u>)	
)	
Pioneer H2O Technologies, Inc.)	STOP SALE, USE,
3225 S. Wadsworth Blvd.)	OR REMOVAL ORDER
Lakewood, Colorado 80227,)	
)	DOCKET NO: FIFRA-08-2012-0003
Respondent)	
)	

I. AUTHORITIES

1. The United States Environmental Protection Agency ("EPA") 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.
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), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide not registered in accordance with FIFRA Section 3, 7 U.S.C. § 136(a).
4. 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.
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), 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.”
8. 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].”
9. 40 C.F.R. § 152.5 states “An organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: ... (3) Any plant growing where not wanted, including any moss, alga, liverwort, or other plant of any higher order, and any plant part such as a root; or (4) Any fungus, bacterium, virus, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs ... and cosmetics...”
10. 40 C.F.R. § 152.15 states: “No person may distribute or sell any pesticide product that is not registered under the Act . . . A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if: (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise): (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or (2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or (b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

II. BACKGROUND

11. Pioneer H2O Technologies, Inc. is a corporation located at 3225 South Wadsworth Blvd., Unit L, Lakewood, CO 80227.
12. Pioneer is a “person” as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
13. On June 9, 2010, EPA inspected Pioneer’s facility at 3225 South Wadsworth Blvd., Unit L, Lakewood, Colorado 80227 as authorized under FIFRA.
14. On June 23, 2011, EPA Region 8 sent Pioneer a letter, clarifying that Tru-Blu was a pesticide requiring registration and notifying Pioneer that it was out of compliance with FIFRA.

15. On September 1, 2011, EPA Region 8 replied to a Pioneer letter, informing it again that EPA was concerned about Pioneer's continued non-compliance with FIFRA, and that sale or distribution of unregistered pesticides violates FIFRA.

16. As of November 8, 2011, Pioneer has not applied for or received registration for Tru-Blu.

III. BASIS FOR ORDER

17. The EPA inspection and subsequent investigation established that Pioneer distributes or sells Tru-Blu, a sodium bromide product, for the purpose of pool sanitization.

18. Sodium Bromide is an active ingredient in pesticide products, including pool sanitizers. EPA registered its first sodium bromide product in 1975.

19. Pioneer distributes and sells Tru-Blu for use in two bromine-generating systems that electronically create bromine via an electrolytic process device.

20. Pioneer claimed that Tru-Blu has a pesticidal purpose. For example:

- Pioneer stated on its website: "Sodium Bromide is added to your hot tub or spa water. When Sodium Bromide comes in contact with the Genesis Device it's electronically converted from Sodium Bromide (salt) into Bromine (sanitizer)."
- Pioneer states in several publications available on its website: "Bromine is the recommended sanitizer for hot tubs and spas. The Bromine sanitizes the spa's water then reverts back to Sodium Bromide, completing the perpetual cycle."¹
- Pioneer stated on its website: "The GENESIS Device is growing rapidly and quickly becoming the sanitation system of choice for many of the industries prime spa manufacturers."
- Pioneer states in several publications available on its website: "If your Bromine level exceeds 5ppm, the pH will rise and cause the following complications: Inability for Sanitizer to Kill Algae and Bacteria."²

21. The Tru-Blu product is a pesticide because Pioneer claims, states, or implies (by labeling or otherwise) that Tru-Blu, by itself or in combination with any other substance, can or will be used as a pesticide.

¹ See http://www.pioneerh2o.com/images/Genesis/Genesis_Owners_Manual_2007.pdf (last visited October 19, 2011), <http://www.pioneerh2o.com/Genesis-Manual-2008.pdf> (last visited October 19, 2011) and <http://www.pioneerh2o.com/Genesis-Canadian-Manual.pdf> (last visited October 19, 2011).

² See http://www.pioneerh2o.com/images/Genesis/Genesis_Owners_Manual_2007.pdf (last visited October 19, 2011), <http://www.pioneerh2o.com/Genesis-Manual-2008.pdf> (last visited October 19, 2011).

22. Pioneer's Tru-Blu is a pesticide because Pioneer has actual or constructive knowledge that the Tru-Blu is intended to be used for a pesticidal purpose, specifically, for hot tub and spa sanitization.
23. Pioneer distributes and sells its Tru-Blu product without FIFRA registration.
24. Pioneer distributes and sells various copper ionizer products under the name of Natural Mineral Purification Systems including but not limited to the "P-15," "P-25," and "P-50" (hereinafter, "P-15," "P-25," and "P-50").
25. Pioneer claims that the copper ionizer products, P-15, P-25, and P-50, are "for the purpose of controlling micro-organisms and algae while avoiding the hazards of high level chemical dosing."³ Pioneer also claims, "The Natural Mineral Purification Systems micro-computer provides a constant mineral (Copper) sanitizer which devastates bacteria, yeast, mold, and all forms of algae."⁴
26. EPA clarified in 2007 that ion-generating equipment is a "pesticide" under FIFRA and published a public notice in the Federal Register containing detailed compliance instructions for the regulated community. The Federal Register Notice addresses "ion generators that incorporate a substance (e.g., silver or copper) in the form of an electrode, and pass a current through the electrode to release ions of that substance for the purpose of preventing, destroying, repelling, or mitigating a pest (e.g., bacteria or algae)." The Notice explains, "Because these items incorporate a substance or substances that accomplish their pesticidal function, such items are considered pesticides for purposes of FIFRA, and must be registered prior to sale or distribution." 72 Fed. Reg. 54039 (September 21, 2007). This notice and associated factsheet are available to the public on the EPA website.⁵
27. Pioneer's P-15, P-25, and P-50 copper ionizers work by utilizing an advanced electrolytic process device that "emits small amounts of Copper ions into water systems for the purpose of controlling micro-organisms and algae."⁶
28. Pioneer's P-15, P-25, and P-50 copper ionizers are pesticides because Pioneer claims, states, or implies (by labeling or otherwise) that P-15, P-25, and P-50 copper ionizers can or should be used as a pesticide and because Pioneer has actual or constructive knowledge that P-15 and P-50 copper ionizers are intended to be used for a pesticidal purpose.
29. Pioneer distributes or sells the copper ionizers P-15, P-25, and P-50 without FIFRA registration.

³ See http://www.pioneerh2o.com/Natural_Mineral_Technology.php (last visited October 12, 2011).

⁴ Owner's Manual and Installation Instructions for the Pioneer P-15 and P-50 Natural Mineral Purification Systems, available at: http://www.pioneerh2o.com/P_Manual.pdf (last visited October 12, 2011).

⁵ See http://www.epa.gov/oppad001/ion_gen equip.htm (last visited October 12, 2011)

⁶ *Id.*

30. Therefore, EPA has a reason to believe that Pioneer has been and is distributing or selling the pesticide products Tru-Blu, P-15, P-25, and P-50 without EPA registration in violation of FIFRA section 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A).

IV. ORDER

31. EPA hereby orders Pioneer to stop the sale, use, or removal of Tru-Blu and the copper ionizers including but not limited to the P-15, P-25, and P-50, EFFECTIVE IMMEDIATELY.
32. This Order pertains to all quantities and sizes of Tru-Blu and all types of copper ionizers including but not limited to the P-15, P-25, and P-50, within the ownership, control, or custody of Pioneer or any other entity producing Tru-Blu and/or P-15, P-25, and P-50, on behalf of Pioneer. These 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 Tru-Blu and the copper ionizers P-15, P-25, and P-50.
33. By November 30, 2011, Pioneer must submit a written inventory for the unregistered pesticides, Tru-Blu and the copper ionizers P-15, P-25, and P-50, within its custody or control and subject to this Order. The inventory shall list the quantity and location of all products and include plans for product storage or disposal. The products subject to this Order shall not be moved, destroyed or disposed of without prior written consent from EPA. This inventory must be submitted to the following person or to such other person as EPA designates in writing:


Eduardo Quintana
US EPA Region 8 (ENF-L)
1595 Wynkoop Street
Denver, CO 80202

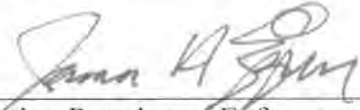
34. Any violation of the terms or provisions of this Order by an officer, agent, or other person acting for or employed by Pioneer may subject the violator as well as Pioneer to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136l.
35. The issuance of this Order shall not 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.
36. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by Respondent.

37. If any provision(s) of this Order 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. The terms of this Order shall remain in effect unless and until EPA modifies or terminates either the Order or certain provisions of the Order in writing.

11/14/11
Date

11/14/11
Date


Sandra Stavnes, Director
Technical Enforcement Program
Office of Enforcement, Compliance
and Environmental Justice


Acting Regulatory Enforcement Unit Chief
Legal Enforcement Program
Office of Enforcement, Compliance
and Environmental Justice