



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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FIFRA-08-2023-0010

Received by
EPA Region VIII
Hearing Clerk

Ref: 8ENF-AT-P

SENT VIA ELECTRONIC MAIL
DELIVERY RECEIPT REQUESTED

From: David Cobb
Section Supervisor, Toxics Enforcement Section
Enforcement and Compliance Assurance Division

To: U.S. Department of Homeland Security
Bureau of Customs and Border Protection
Pembina, North Dakota 3401

Subject: Requested action to be taken regarding the Ozone Water Purification System in shipment with entry number AD1-08115610

By this memorandum, the U.S. Environmental Protection Agency, Region 8, is informing the Bureau of Customs and Border Protection of the U.S. Department of Homeland Security that the products in the import shipment described below should be **Denied Entry-Refused Delivery** into the United States pursuant to the authority of section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136o(c), and the implementing regulations at 19 C.F.R. section 12.114. The entry was marked "Hold Intact," "Refused," and "Re-Export" in the Automated Commercial Environment (ACE) by the EPA on December 13, 2022.

The following information pertains to the shipment:

- The consignee is Automotive Parts & Tools Inc., 3101 NW 32 Avenue, Unit 1078, Miami, Florida 33142.
- The importer and manufacturer is Mobetta Water Inc., PO Box 6051, Westlock AB T7P2P7, point of contact, stan@mobettawater.com.
- The broker is Carson Customs Brokers (USA) Inc., Megen Tuttle, LCB/CCS/BRANCH MANAGER, mtuttle@carsonintl.com.
- The bill number is KIDY900463141.
- The entry file date was December 13, 2022.
- The quantity is one Ozone Water Purification System.
- The port of entry is Pembina, North Dakota 3401.
- The country of origin as entered in ACE is Alberta, Canada.

Section 12(a)(1)(F) of FIFRA, 7 U.S.C. 136j(a)(1)(F) provides that it shall be unlawful for any person in any State to distribute or sell to any person any device which is misbranded.

Section 2(t) of FIFRA, 7 U.S.C. § 136(t) defines “pest” as “(1) any insect, rodent, nematode, fungus, weed, or (2) 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 136w(c)(1) of this title.”

Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines “label” as “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers” and 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 in literature accompanying the pesticide....”

Section 2(h) of FIFRA, 7 U.S.C. § 136(h), defines “device” as “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.” (See also 40 C.F.R. § 152.500(a)).

Under FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1), a device is misbranded and subject to enforcement action if, among other reasons:

- the labeling bears any statements, designs, or graphic representations that are false or misleading (see 40 CFR 156.10(a)(5) below);
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3) (as of 2010, such standards have yet to be established for devices);
- it is an imitation of, or is offered for sale under the name of another device;
- the label fails to bear the establishment number of the establishment where it was produced;
- any required information is not prominently displayed on the label;
- it lacks adequate directions for use; or
- it lacks an adequate warning or caution statement.

In a statement from the manufacturer dated December 13, 2022:

- “It is a system to mix ozone gas with water prior to bottling. As I am sure you know, ozone injection is the standard of the bottled water industry.”
- “The machine uses an ozone generator, oxygen generator and water pump all made by other companies. We assemble it in a package that is easy for our customer to install.”
- “We don't issue a serial number or affix a label to it on it because the individual components provided by others have their own labels”
- “As stated above, it is for mixing ozone gas with water prior to bottling to kill bacteria.”

This Ozone Water Purification System is a device under FIFRA section 2(h), 7 U.S.C. § 136(h), and 40 C.F.R § 152.500(a) because they fall within the definition of “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest, [which includes virus, bacteria, or other micro-organism,] or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.”

The Ozone Water Purification System is misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there is no EPA Establishment Number, there are no directions for use, and no caution or warning statements on their labels.

Importing these products in the shipment referenced above is a violation of FIFRA section 12(a)(1)(F), 7 U.S.C. § 136j(a)(1)(F), as a distribution or sale of a misbranded device.

The shipment that arrived at the border for import is also in violation of FIFRA section 12(a)(2)(N), 7 U.S.C. § 136j(a)(2)(N), because a registrant, wholesaler, dealer, retailer, or other distributor failed to correctly file reports required by the Act. As required by 19 C.F.R. § 12.114, a Notice of Arrival of Pesticides and Devices, EPA form 3540-1, and a copy of one product label must be submitted.

Therefore, none of the products referenced above in the shipment with entry number AD1-08115610 should be allowed entry into the United States.

The Agency hereby notifies U.S. Customs and Border Protection that this merchandise should be refused admission and recommends that this merchandise be re-exported or destroyed within 90 calendar days from the date of this Notice. On December 13, 2022, the EPA informed the Customs and Border Patrol unit chief in Pembina, North Dakota, that it would deny entry of this shipment.

Please contact Christine Tokarz, the import enforcement coordinator, by phone at (303) 312-6147 or by email at tokarz.christine@epa.gov if you have any questions concerning this matter.