



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 8

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EPA Region VIII  
Hearing Clerk

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**SENT VIA ELECTRONIC MAIL**  
**DELIVERY RECEIPT REQUESTED**

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

To: U.S. Department of Homeland Security  
Bureau of Customs and Border Protection  
Denver, Colorado 3307

Subject: Requested action to be taken regarding the Atlantium Hydro-Optic UV units in shipment with entry number 8SB-00128088 FIFRA-08-2022-0019

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 ACE by the EPA on January 10, 2022.

The following information pertains to the shipment:

- The importer and manufacturer is Atlantium Technologies Ltd., HaMelacha St 11, Bet Shemesh, Israel.
- The consignee is NOW Water LLC 40350 Brickyard Drive Madera, California 93636-9519.
- The broker is MH Logistics, [info@mhls.co](mailto:info@mhls.co).
- The bill number is 006-50164752-UFL00024776.
- The entry file date was January 4, 2022.
- The quantity is 6 Atlantium Hydro-Optic UV units, weighing approximately 84 pounds.
- The port of entry is Denver, Colorado 3307.
- The country of origin as entered in ACE is Israel.

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 accordance with 40 C.F.R. § 156.10(a)(5), a pesticide or a device is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

- A false or misleading statement concerning the effectiveness of the product as a pesticide or device. 40 C.F.R. § 156.10(a)(5)(ii).
- A false or misleading comparison with other pesticides or devices. 40 C.F.R. § 156.10(a)(5)(iv).
- Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government. 40 C.F.R. § 156.10(a)(5)(v).
- A true statement used in such a way as to give a false or misleading impression to the purchaser. 40 C.F.R. § 156.10(a)(5)(vii).
- Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”. 40 C.F.R. § 156.10(a)(5)(ix).

The “Guide to the Atlantium Hydro-Optic UV System RZ104 Series” document that accompanies the product includes the following claims:

- The Atlantium RZ104 Series systems guarantee water bio-security at optimized energy efficiency, and meet EPA criteria for providing bio-security.
- Water Disinfection - meets US Environmental Protection Agency (EPA) criteria for providing bio-security
- Chlorine Replacement - provides a chemical-free alternative to chlorine for treating source water. It easily inactivates microorganisms including those that are resistant to chlorine and heat.
- Guaranteed required dose for complete microbial inactivation.
- The specially designed short (Arc length 95mm / 3.74 inch) Medium Pressure High Intensity (MPHI) lamps deliver a broad spectrum disinfection that irrevocably damages deoxyribonucleic acid (DNA) and proteins in microorganisms.

Claims made for the product are also found on the website, <https://atlantium.com/>, which include the following:

- “A Proven Solution for Virus Inactivation”
- “Atlantium’s Hydro-Optic™ (HOD) UV technology is designed to achieve unmatched microbiological inactivation levels: hydraulic and fiber-optic principles are integrated with the simplicity and effectiveness of UV light disinfection.”
- “The ray’s long path inside the chamber combined with an optimally engineered flow of water in a controlled, defined pattern, creates a uniform UV dose distribution that reaches and inactivates microorganisms throughout all the water running through the chamber. This is one of the key elements to attaining high levels of microbial inactivation at efficiency electrical consumption.”

These Atlantium Hydro-Optic UV units are devices 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 Atlantium Hydro-Optic UV units are labeled with the EPA Establishment Number 99105-ISR-1 however, they are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there are no directions for use and no caution or warning statements on their label.

The Atlantium Hydro-Optic UV units are also misbranded because the labeling is false or misleading as defined by 7 U.S.C. § 136(q)(1) and 40 C.F.R. § 156.10(a)(5).

Therefore, these products are misbranded pursuant to 7 U.S.C. § 136(q)(1). 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 file reports required by the Act. As required by 19 C.F.R. section 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 8SB-00128088 can be allowed entry into the United States.

The Agency hereby notifies U.S. Customs and Border Protection that this merchandise has been refused admission and recommends that this merchandise be re-exported or destroyed within 90 calendar days from the date of this Notice.

On January 10, 2022, the Customs and Border Patrol unit chief in Denver, Colorado, was informed by the EPA 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](mailto:tokarz.christine@epa.gov) if you have any questions concerning this matter.