



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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DELIVERY RECEIPT REQUESTED

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

To: U.S. Department of Homeland Security
Bureau of Customs and Border Protection
Port of Sweetgrass, Montana 3310

Subject: Requested action to be taken regarding the Miele AirClean Filters in the Section 321 shipment described below FIFRA-08-2024-0034

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 (CBP) 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. §12.114. On April 24, 2024, the EPA inspected this shipment and informed CBP of their recommendation for refusal.

The following information pertains to the shipment:

- The manufacturer is Miele USA Headquarters, 9 Independence Way, Princeton, New Jersey 08540.
- The file date was April 24, 2024.
- The quantity is 24 Miele AirClean Filters, weighing 50 pounds.
- The port of entry is Sweetgrass, Montana, 3310.

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 also 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3);
- 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.

The labeling for the Miele AirClean Filters had the following language:

- “HEPA Air Clean Filter”
- “Allergy XL Pack”
- “99.9% Filtration”

These statements demonstrate a pesticidal intent pursuant to the definitions above. The Miele AirClean Filters 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 Miele AirClean Filters are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there is no EPA Establishment Number, no directions for use, and no caution or warning statements on their labels.

Therefore, these products are misbranded pursuant to 7 U.S.C. § 136(q)(1). Importing the products in the shipment(s) 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 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 FIFRA. As required by 19 C.F.R. § 12.113 a Notice of Arrival of Pesticides and Devices, EPA form 3540-1, and a copy of one product label must be submitted.

The EPA hereby notifies CBP that the Miele AirClean Filters in the shipment referenced above should be refused admission pursuant to the authority of FIFRA § 17(c), 7 U.S.C. § 136o(c), and the

implementing regulations at 19 C.F.R. § 12.114. The importer should export this merchandise or dispose of the products under supervision of the CBP within ninety calendar days from the date of this memorandum or within such additional time as the District Director of CBP specifies. Failure to do so may result in either the destruction of the merchandise as authorized by the FIFRA or in any action necessary to enforce the terms of any bond under which the shipment has been released to the consignee. Alternatively, CBP may elect to seize the products as a prohibited importation pursuant to their authorities as set out at 19 U.S.C. § 1595a(c)(2)(A).

On April 24, 2024, the EPA informed the CBP Cargo Chief in Sweetgrass, Montana 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.