



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alex Martin, Chief Executive Officer
PuriCore Inc.
508 Lapp Road
Malvern, PA 19355

MAY 26 2016

Re: Federal Insecticide, Fungicide and Rodenticide Act
Stop Sale, Use or Removal Order
DOCKET NO: FIFRA-03-2016-0122SS

Dear Mr. Martin:

Enclosed is a Stop Sale, Use, or Removal Order ("Order on Consent") concerning violations of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. §§ 136 *et seq.* ("FIFRA"). The United States Environmental Protection Agency ("EPA") is issuing this Order on Consent under the authority of Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), for PuriCore's ProduceFresh product. The enclosed Order on Consent requires the immediate cessation of all sales and distribution of ProduceFresh. A violation of such an Order on Consent is an unlawful act under Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), and subject to civil and/or criminal penalties under Section 14 of FIFRA, 7 U.S.C. § 136l. It is my understanding that PuriCore has already submitted an application for ProduceFresh to become registered with EPA as a pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a. If ProduceFresh becomes registered with EPA as a pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a, such product will not be subject to this Order on Consent.

If you have any questions regarding this Order on Consent, please contact the enforcement officer for this matter, Evelyn Sorto, at (215) 814-2123 or sorto.evelyn@epa.gov, or have your counsel contact Jennifer M. Abramson, Senior Assistant Regional Counsel, at (215) 814-2066 or abramson.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Armstead".

John A. Armstead, Director
Land and Chemicals Division

Enclosures

cc: Evelyn Sorto, EPA
Jennifer M. Abramson, EPA
Cynthia Taub, Steptoe

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 ARCH STREET
PHILADELPHIA, PENNSYLVANIA 19103-2029**

IN THE MATTER OF)	DOCKET NO: FIFRA-03-2016-0122SS
)	
PuriCore Inc.)	Stop Sale, Use or
508 Lapp Road)	Removal Order
Malvern, PA 19355)	
)	Consented to by PuriCore Inc.
Respondent)	
_____)	

I. AUTHORITY

1. This Stop Sale, Use or Removal Order (“Order on Consent”) 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 on the basis of inspections or tests that the pesticide or device is in violation of any provision of FIFRA, the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA, or when the registration of the pesticide has been canceled by a final order. This authority was delegated to the Regional Administrator of EPA Region III, and was further re-delegated within EPA Region III to the Director of the Land and Chemicals Division and to the Associate Director for the Office of Toxics and Pesticides in the Land and Chemicals Division.

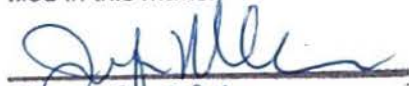
2. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), makes it unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136a, or whose registration has been canceled or suspended unless otherwise authorized by EPA under FIFRA.

3. Pursuant to Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), no person in any State may distribute or sell to any person any pesticide that is not registered under FIFRA.

4. Pursuant to Section 2(s) of FIFRA, 7 U.S.C. § 136(s), the term “person” means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

5. Pursuant to Section 2(gg) of FIFRA, 7 U.S.C § 136(gg), to “distribute or sell” means 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.

I hereby certify that the
within is a true and correct copy
of the original SSURD
filed in this matter.



Attorney for EPA

6. Pursuant to Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.3, the term “pesticide” includes “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”

7. Pursuant to 40 C.F.R. §§ 152.15(a)(1) and 152.15(c), the regulations implementing FIFRA give further guidance on what constitutes a pesticidal purpose, stating that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if, among other things, the person who distributes or sells the substance “claims, states or implies (by labeling or otherwise) . . . [t]hat the substance . . . can or should be used as a pesticide”, or “has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.”

8. Pursuant to Section 2(t) of FIFRA, 7 U.S.C. § 136(t) and 40 C.F.R. § 152.5, the term “pest” includes viruses, bacteria, or other micro-organisms, except viruses, bacteria, or other micro-organisms on or in living man or other living animals and those on or in processed food.

9. Pursuant to Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines “label” to mean the written, printed or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers; and defines “labeling” to include all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time, or to which reference is made on the label.

II. BACKGROUND

10. On May 21, 2015, a representative of the EPA, duly authorized to conduct inspections under the authorities of Section 8 and Section 9 of FIFRA, 7 U.S.C. § 136f and § 136g, conducted an inspection at the PuriCore facility located at 508 Lapp Road in Malvern, Pennsylvania.

11. As a result of EPA’s May 21, 2015 inspection and other information gathering activities deriving from that inspection, EPA collected information pertaining to a product that PuriCore distributes or sells under the brand name ProduceFresh, showing the following:

- (a) At least since 2005, PuriCore has been selling Sterilox Food Safety Systems to the supermarket retail market. These Systems, now marketed as Sterilox Fresh Systems, are located on-site at thousands of individual supermarket retailers and use water, salt and electricity to generate a hypochlorous acid solution known as Sterilox solution that is used in the crisping process for fresh produce as well as in produce-misting systems. PuriCore has described its Systems as being intended for food safety purposes, and as generating a sanitizing solution that eliminates pathogens and cross-contamination, reduces spoilage organisms and removes and prevents the growth of biofilms and harmful pathogens. PuriCore’s supermarket retail customers have recognized PuriCore’s Systems as providing value in reducing their food safety risk profile.
PuriCore’s Systems are not subject to this Order on Consent.

- (b) In or about 2013, PuriCore began selling a bottled concentrate version of its Sterilox solution for use in the supermarket retailer market in the form of ProduceFresh. PuriCore represents that (after dilution) ProduceFresh is the same Sterilox solution as that generated in its Systems and markets both its Systems and ProduceFresh under its Sterilox Fresh product line. As with its Systems, PuriCore markets ProduceFresh to supermarket retailers and sells it by the case either in 2.5 or 1 gallon-sized containers. ProduceFresh has been used by individual supermarket retailer locations across the United States, including locations associated with a top-three U.S. supermarket retailer.
- (c) During the time period beginning when it started selling ProduceFresh in 2013 until sometime in 2015, PuriCore made the following claims, statements or implications in connection with ProduceFresh:

- i. On its <http://www.steriloxfresh.com> website, the following language:

ProduceFresh [is] highly effective at killing a broad range of pathogens and spoilage organisms including:

<i>E.coli 0157</i>	<i>Yeast</i>
<i>Salmonella</i>	<i>Molds</i>
<i>Staphylococcus</i>	<i>Norovirus</i>
<i>Listeria</i>	<i>Human and animal influenza</i> <i>(including H5N1 avian influenza)</i>

ProduceFresh offers your store many benefits for fresher, safer produce without the capital investment.

Use Producefresh in your produce operation to: Protect your brand against cross-contamination.

- ii. In its marketing/promotional materials, the following language:

Reduce harmful pathogen growth and biofilm buildup inside your misting system.

Using ProduceFresh in your daily crisping operation provides food safety protection for your customers by preventing cross contamination in the produce wash water.

Sterilox Solution Protects the Produce Wash Water. A study was conducted in November 2013 by UC Davis comparing 5 different sanitizer options and plain tap water. Sanitizers are absolutely critical for food safety because they are effective in reducing pathogens in the wash water itself. Researchers found that chlorine-based treatments were "significantly more effective than water alone" at reducing the E.coli in the wash water.

Jensen Farms Cantaloupe Recall (Listeria). 147 people sickened and 33 deaths. Jensen Farms \$2.5 Million in insurance exhausted, company bankrupted. Criminally negligent charges – each received 5 years probation, 100 hours of community service and a fine of \$150,000 as restitution to the victims. Claims estimated from \$1-1.3MM Per Claim x 55 = \$75-80M. 66 pending lawsuits settled

for an undisclosed amount of money from the Kroger Co. and Frontera Produce, Ltd. Could it have been prevented? How much insurance is enough? FDA officials were "highly critical of the processing methods used at Jensen Farms," and emphasized two probable causes of the contamination: a change in processing equipment and a decision not to chlorinate cantaloupe wash water.

iii. On ProduceFresh labels, the following language:

Produce Safety and Quality Solution

To prevent the risk of cross contamination and improve produce freshness, always use ProduceFresh during the produce washing process

www.steriloxfresh.com



- (d) Following EPA's May 21, 2015 inspection, PuriCore revised its website, marketing/promotional material, and labels so as to remove claims, statements or implications made in connection with ProduceFresh, including many of those identified in paragraph 11(c), above. On or about this time, PuriCore began marketing the product to supermarket retailers solely as a "freshness enhancer" using the same brand name, ProduceFresh, and continued selling ProduceFresh to the same customers it sold to prior to May 21 2015. PuriCore continued to market ProduceFresh as a bottled concentrate version of the Sterilox solution generated in its Systems and stills sells both under its Sterilox Fresh product line.
- (e) In August 2015, PuriCore submitted an application for ProduceFresh to be registered with EPA as a pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a. As of the date of this Order on Consent, the ProduceFresh application is currently pending with EPA.
- (f) In a news article dated October 27, 2015, an official from one of PuriCore's national supermarket retail customers of ProduceFresh described Sterilox as an "anti-microbial agent approved for food and designed to keep the [misting] line free of bacteria."
- (g) PuriCore currently makes the following claims, statements or implications in connection with ProduceFresh:
- i. On its <http://www.steriloxfresh.com> website, PuriCore provides links to informational resources specific to food safety, as well as news articles, press releases and industry awards describing the antibacterial properties and food safety benefits of the sanitizing solution produced in PuriCore's Systems. See e.g., <http://www.steriloxfresh.com/news-resources/overview>

- (d) ProduceFresh is being used at individual supermarket retailer locations across the United States, including locations associated with a top-three U.S. supermarket retailer, based, at least in part, on such representations.
- (e) Though PuriCore revised its website, marketing/promotional materials and product label following EPA's May 21, 2015 inspection, it continues to distribute or sell the product to supermarket retailers using the brand name ProduceFresh and still markets it as a bottled concentrate version of the Sterilox solution generated in PuriCore's Systems under its SteriloxFresh product line.
- (f) In August 2015, PuriCore submitted an application for ProduceFresh to be registered with EPA as a pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a.
- (g) In October 2015, subsequent to PuriCore's revisions to its website, marketing/promotional materials and label, an official from one of PuriCore's supermarket retail customers of ProduceFresh acknowledged Sterilox as having pesticidal properties.
- (h) PuriCore currently is making claims, statements or implications that ProduceFresh can or should be used as a pesticide (see paragraph 15, below).

15. EPA has reason to believe that PuriCore is claiming, stating, or implying that ProduceFresh can or should be used as a pesticide under 40 C.F.R. § 152.15(a)(1).

- (a) PuriCore sells ProduceFresh under its SteriloxFresh product line, and with labels that include the SteriloxFresh trademark and a reference to www.steriloxfresh.com.
- (b) The term Sterilox is a derivative of the word "sterile" which according to Merriam-Webster is an adjective meaning 1: not able to produce fruit, crops, or offspring: not fertile or 2: free from microscopic living things and especially germs (as bacteria and viruses).
- (c) The ProduceFresh label references www.steriloxfresh.com and information on this website is therefore part of the product's "labeling" under Section 2(p) of FIFRA, 7 U.S.C. § 136(p), including specific informational resources related to food safety as well as news articles, press releases and industry awards describing the antibacterial properties and food safety benefits of the sanitizing solution generated in PuriCore's Systems.
- (d) As PuriCore markets ProduceFresh as a bottled concentrate version of the Sterilox solution produced in its Systems, representations made by PuriCore in connection with its Systems implicitly also apply to ProduceFresh.
- (e) Language about ProduceFresh, similar to that identified in paragraph 11(c), above, is still publically accessible and can easily be found online.

16. For the reasons stated above and based on the administrative record for this Order on Consent, EPA has reason to believe that ProduceFresh is a pesticide under 40 C.F.R. § 152.3, and therefore must be registered under Section 3 of FIFRA, 7 U.S.C. § 136a, in order to be lawfully distributed or sold.

17. ProduceFresh is not registered with EPA as a pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a, nor has ever been so registered. As a result, EPA has not had an opportunity to review the efficacy and risks associated with ProduceFresh, which is currently being used on produce at thousands of individual supermarket retailer locations across the United States

18. PuriCore owns, controls and/or has custody of ProduceFresh and has sold or distributed or intends to sell or distribute these products to other persons in violation of Sections 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

IV. ORDER ON CONSENT

19. Pursuant to the authority of Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders PuriCore to stop the sale, use or removal of ProduceFresh under its ownership, control or custody, wherever such products are located, except in accordance with the provisions of this Order on Consent, or any subsequent modifications to this Order on Consent.

20. This Order on Consent shall pertain to all quantities (in all packaging types and sizes) of ProduceFresh owned, controlled, or in the custody of PuriCore or of any parties acting as agents for PuriCore wherever they may be located. The product covered by this Order on Consent shall not be distributed, sold, offered for sale, held for distribution, held for sale, held for shipment, shipped, delivered for shipment, released for shipment, received and (having been so received) delivered or offered for delivery, moved, used or removed for any reason, other than in accordance with the provisions of this Order on Consent or any such further order as may be issued by EPA in connection with the pesticide product identified in this Order on Consent.

21. Failure to comply with this Order on Consent is a violation of Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), which provides that it shall be unlawful for any person to violate any order issued pursuant to Section 13 of FIFRA, 7 U.S.C. § 136k. Violation of the terms or provisions of this Order on Consent may subject PuriCore and/or any responsible individuals to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136l.

22. This Order on Consent shall take effect immediately upon receipt by PuriCore of a fully executed copy, whereupon it will remain in effect unless and until revoked, terminated, suspended, or modified, in writing, by EPA.

23. The issuance of this Order on Consent shall not act as a waiver by EPA of any enforcement or other authority available to EPA under FIFRA or any other federal statute. Nothing in this Order on Consent shall prevent EPA from assessing any penalties, or otherwise affect or limit the United States' authority to enforce other provisions of the FIFRA, or affect any person's obligations to comply with FIFRA or its implementing regulations. Further, nothing in this Order on Consent shall limit or otherwise preclude the United States from taking criminal or

additional civil judicial or administrative enforcement action against Respondent or any third parties pursuant to any federal enforceable law or regulation.

24. For technical assistance regarding any matter addressed in this Order on Consent, please contact:

Evelyn Sorto
Pesticides and Asbestos Programs Branch (3LC62)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029
Phone: (215) 814-2123
Fax: (215) 814-3114
E-mail: Sorto.Evelyn@epa.gov

25. For questions regarding legal matters relating to this Order on Consent, PuriCore, or if represented by counsel, PuriCore's attorney may contact:

Jennifer M. Abramson, Esq.
Office of Regional Counsel (3RC50)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029
Phone: (215) 814-2066
Fax: (215) 814-2603
E-mail: Abramson.Jennifer@epa.gov

26. Respondent waives any and all remedies, claims for relief and otherwise available rights to judicial or administrative review that Respondent may have with respect to any issue of fact or law set forth in this Order on Consent, including any right of judicial review under Section 16 of FIFRA, 7 U.S.C. § 136n.

27. PuriCore has voluntarily consented to withdraw ProduceFresh from the market as part of the resolution of this proceeding. This Order on Consent does not impact any other PuriCore products. PuriCore consents to this Order, but neither admits nor denies the specific allegations set forth herein.

5/23/16
Date



Alex Martin, Chief Executive Officer
PuriCore Inc.

5.26.16
Date



John A. Armstead, Director
Land and Chemicals Division

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

IN THE MATTER OF)	DOCKET NO: FIFRA-03-2016-0122SS
)	
PuriCore Inc.)	Stop Sale, Use or
508 Lapp Road)	Removal Order
Malvern, PA 19355)	
)	Consented to by PuriCore Inc.
Respondent)	
_____)	

CERTIFICATE OF SERVICE

I certify that the foregoing STOP SALE, USE OR REMOVAL ORDER in the above referenced matter was sent this day in the following manner to the below addressees.

Original and one copy by hand-delivery:

Lydia Guy, Regional Hearing Clerk

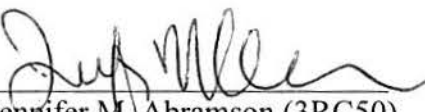
Copy by Certified Mail

Cynthia L. Taub, Esq.
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036

Alex Martin, CEO
PuriCore Inc.
508 Lapp Road
Malvern, PA 19355

MAY 26 2016

Date



Jennifer M. Abramson (3RC50)
Senior Assistant Regional Counsel
U.S. EPA, Region III

