

CFSAN HEALTH HAZARD EVALUATION

HHE # 9420

RES# 75996

CLASS: III

Section A. Incident Summary (to be completed by requesting CSO)

1. PRODUCT INFORMATION (Include relevant lot information if appropriate.)

Starkey Spring Water, 16 fl oz. glass bottles, Produced **(b) (4)**

2. FIRM INFORMATION (Include supplier information if appropriate and note if domestic or foreign.)

Recalling Firm:
Starkey Water
102 Council Ave
Council, Idaho 83612
FEI#3010863196
(Domestic)

3. SOURCE OF PROBLEM

- Undeclared allergen:
- Presence of contaminant or impurities (specify): **arsenic**
- Microbial contamination (specify):
- Presence of foreign bodies:
- Other:

4. NATURE OF PROBLEM (What happened to create the hazard/ problem? What is the extent of the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)

Starkey Spring Water was sampled and found to contain arsenic. The arsenic level in lot# **(b) (4)** tested by the Florida Department of Agriculture and Consumer Services Laboratory # 2016/FL-18831 was at 11.7 ppb. The 11.7 ppb value exceeds the 10 ppb FDA permissible level of arsenic in water in accordance with 21 CFR 165.110.

5. Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

- No Yes

6. **PRECEDENT HHEs** (Using the CFSAN HHE database, please summarize any related precedents. Please include reference numbers or copies of supporting precedent cases.)

<u>HHE #</u>	<u>Date Signed</u>	<u>Hazard Identified</u>
9287	09/19/2016	Arsenic in apple nectar
8786	09/18/2014	Arsenic in apple juice
8257	07/20/2012	Arsenic in apple juice

Section B. Health Effects Review (to be completed by HHEB member)

7. ADVERSE REACTION INFORMATION

What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

In most drinking water sources, the inorganic form of arsenic tends to be more prominent than organic forms. At low levels of exposure, the primary concern from exposure to inorganic arsenic are effects that result from chronic exposure. The main adverse effects reported to be associated with long-term ingestion of inorganic arsenic in humans are cancer, skin lesions, cardiovascular disease, neurodevelopmental toxicity, adverse pregnancy outcomes, and diabetes. Of these, the greatest strength of evidence for a causal association is for cancers of the skin, bladder and lung and for skin lesions (hyperkeratosis, hyperpigmentation and hypopigmentation) that were observed in studies in which inorganic arsenic exposure was high due to inorganic arsenic in drinking water (e.g., >100 µg/L).

The level of 11.7 ppb arsenic in bottled exceeds the 10 ppb FDA allowable level for arsenic in water in accordance with 21 CFR 165.110, but is not likely to be a health concern from short term consumption.

8. AT RISK POPULATION

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

No – the general population is at risk

Yes – check all that apply

Infants

Children

Pregnant women, nursing women, or women of childbearing age

Elderly consumers

Individuals with allergy/intolerance to (food/product)

- Immunosuppressed individuals
- Medical conditions (e.g., diabetes, celiac disease)
- Other (please describe):

9. Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?

- No Yes

10. What is the hazard associated with use of the product? (Select one. If more than one is selected, please explain.)

- Life-threatening (death has or could occur)
- Results in permanent impairment of a body function or permanent damage to a body structure
- Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function
- Temporary or reversible (without medical intervention)
- Limited (transient, minor impairment or complaints)
- No adverse health consequences
- Hazard cannot be assessed with the data currently available

11. What is the probability of each adverse event occurring, as specified in Item 10? (If more than one item is selected below, specify the corresponding health hazard.)

- Highly likely to occur (every time the product is used)
- Likely to occur (reasonable probability of occurrence)
- Might occur (remote probability of occurrence)
- Unlikely to occur
- Unknown (please explain):
- Not applicable

Conclusion:

With prolonged use of the product for many years, a wide variety of adverse effects may occur. No significant effects are expected with short term use.

SIGNATURES

Requested By: Dehlia R. Young -S
Dehlia Young
Consumer Safety Officer

Digitally signed by Dehlia R. Young -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=2001401065,
cn=Dehlia R. Young -S
Date: 2017.01.13 15:28:29 -05'00'

Date: 12/29/2016

Deborah C. Smegal -S

Digitally signed by Deborah C. Smegal -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=2001346993,
cn=Deborah C. Smegal -S
Date: 2017.01.13 15:37:19 -05'00'

Date:

Deborah Smegal, M.P.H.
Branch Chief, Contaminant Assessment Branch
Health Hazard Evaluation Board Member

Linda M. Katz -S

Digitally signed by Linda M. Katz -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Linda M. Katz -S,
0.9.2342.19200300.100.1.1=1300040951
Date: 2017.01.18 09:49:23 -05'00'

Date:

Linda M. Katz, M.D., M.P.H.
Acting Chief Medical Officer
Chairperson, Health Hazard Evaluation Board

CFSAN HEALTH HAZARD EVALUATION

HHE # 9438

RES# 76172

CLASS: III

Section A. Incident Summary (to be completed by requesting CSO)

- 1. PRODUCT INFORMATION** (Include relevant lot information if appropriate.)
Starkey Spring Water, 16.9 fl oz. (550 ml), 15 Glass Bottles in a cardboard box,
Produced on (b) (4)
- 2. FIRM INFORMATION** (Include supplier information if appropriate and note if domestic or foreign.)
Starkey Water, Council, Idaho (Domestic)

3. SOURCE OF PROBLEM

- Undeclared allergen:
 Presence of contaminant or impurities (specify): Arsenic
 Microbial contamination (specify):
 Presence of foreign bodies:
 Other:

- 4. NATURE OF PROBLEM** (What happened to create the hazard/ problem? What is the extent of the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)

Starkey Spring Water was sampled and found to contain arsenic. The Florida Department of Agriculture and Consumer Services found 12 ppb arsenic level in lot# (b) (4). This level exceeds the 10 ppb FDA permissible level of arsenic in water in accordance with 21 CFR 165.110.

- 5. Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?**

No Yes

- 6. PRECEDENT HHEs** (Using the CFSAN HHE database, please summarize any related precedents. Please include reference numbers or copies of supporting precedent cases.)

<u>HHE #</u>	<u>Date Signed</u>	<u>Hazard Identified</u>
9287	09/19/2016	Arsenic in Apple Nectar
8786	09/18/2014	Arsenic in Apple Juice
8257	07/20/2012	Arsenic in Apple Juice
9420	01/04/2017	Arsenic in Bottled Water

Section B. Health Effects Review (to be completed by HHEB member)

7. ADVERSE REACTION INFORMATION

What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

In most drinking water sources, the inorganic form of arsenic tends to be more prominent than organic forms. At low levels of exposure, the primary concern from exposure to inorganic arsenic are effects that result from chronic exposure. The main adverse effects reported to be associated with long-term ingestion of inorganic arsenic in humans are cancer, skin lesions, cardiovascular disease, neurodevelopmental toxicity, adverse pregnancy outcomes, and diabetes. Of these, the greatest strength of evidence for a causal association is for cancers of the skin, bladder and lung and for skin lesions (hyperkeratosis, hyperpigmentation and hypopigmentation) that were observed in studies in which inorganic arsenic exposure was high due to inorganic arsenic in drinking water (e.g., >100 µg/L).

The level of 12 ppb arsenic in bottled water exceeds the 10 ppb FDA allowable level for arsenic in water in accordance with 21CFR 165.110, but is not likely to be a health concern from short term consumption.

8. AT RISK POPULATION

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

No – the general population is at risk

Yes – check all that apply

Infants

Children

Pregnant women, nursing women, or women of childbearing age

Elderly consumers

Individuals with allergy/intolerance to (food/product)

Immunosuppressed individuals

Medical conditions (e.g., diabetes, celiac disease)

Other (please describe):

9. Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?

No

Yes

10. What is the hazard associated with use of the product? (Select one. If more than one is selected, please explain.)

- Life-threatening (death has or could occur)
- Results in permanent impairment of a body function or permanent damage to a body structure
- Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function
- Temporary or reversible (without medical intervention)
- Limited (transient, minor impairment or complaints)
- No adverse health consequences
- Hazard cannot be assessed with the data currently available

11. What is the probability of each adverse event occurring, as specified in Item 10? (If more than one item is selected below, specify the corresponding health hazard.)

- Highly likely to occur (every time the product is used)
- Likely to occur (reasonable probability of occurrence)
- Might occur (remote probability of occurrence)
- Unlikely to occur
- Unknown (please explain):
- Not applicable

Conclusion:

With prolonged use of the product for many years, a wide variety of adverse effects may occur. No significant effects are expected with short term use.

SIGNATURES

Requested By: Kerri Harris -S
Kerri Harris-Garner,
Ph.D.
Consumer Safety Officer

Digitally signed by Kerri Harris -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, cn=Kerri Harris -S,
0.9.2342.19200300.100.1.1=2000469569
Date: 2017.01.12 17:00:11 -06'00'

Date: 1/12/2017

Deborah C. Smegal -S

Digitally signed by Deborah C. Smegal -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=2001346993,
cn=Deborah C. Smegal -S
Date: 2017.01.12 18:13:16 -05'00'

Deborah Smegal, M.P.H.
Branch Chief, Contaminant Assessment Branch
Health Hazard Evaluation Board Member

Date:

Linda M. Katz -S

Digitally signed by Linda M. Katz -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Linda M. Katz -S,
0.9.2342.19200300.100.1.1=1300040951
Date: 2017.01.13 15:40:23 -05'00'

Linda M. Katz, M.D., M.P.H.
Acting Chief Medical Officer
Chairperson, Health Hazard Evaluation Board

Date:

Wilde, Samantha

From: kuntz.thomas@fda.hhs.gov
Sent: Thursday, January 12, 2017 9:11 AM
To: ORA HQ Recall SEA; ORA HQ CFSAN Class
Subject: Recall Classified for 75996 - Starkey Water

Recall Classified for [75996](#)

Comments - [75996](#)

- **Center Comments :**

Class III. CFSAN concurs with audit check strategy.

- **Email Comments :**

Recall Date Information - [75996](#)

Firm Awareness : 12/12/2016	Classification : 01/12/2017
Recall Initiation : 12/15/2016	Recall Completed :
District Awareness : 12/15/2016	Termination :
HHE Sent : 12/29/2016	State Press Issued :
Distribution Chain Notified : 12/16/2016	Firm Press Issued :
Alert : 12/16/2016	FDA Press Issued :
Recommendation : 12/21/2016	

Recall Firm Information - [75996](#)

- **Recalling Firm :**

Starkey Water
102 Council Ave
Council Idaho 83612
United States

- **Manufacturing Firm 1:**

Starkey Water
Confidential : N
102 Council Ave
Council Idaho 83612
United States

Product 1 - [75996](#)

- **Product Description :**

Starkey Spring Water, Item code STC.5, 16.9 FL oz. (500 mL) glass bottle. Product UPC 8 11904 02000 7. Case UPC 8 11904 02002 1.

- **Product Public Reason for Recall :**

Starkey Spring Water, 16.9 fl oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample.

- **Code Information :**

produced on (b) (4)

- **Industry-Product Code :**

29-RCY01

- **District Recommended Classification :**

Class II

- **Center Classification :**

Class III

- **Product Effect. Check Level / Percent :**

A / 100

- **Product Audit Check Level / Percent :**

B / 40

- **Recall Number :**

F-1179-2017

Recall Event Level Information - [75996](#)

- **Recall Status :**

Ongoing

- **Firm Recommended Recall Depth :**

Retail

- **Voluntary/Mandated :**

FDA Initiated

- **Voluntary/Mandated Date :**

12/16/2016

- **Effectiveness Check Level / Percent :**

A / 100

- **Audit Check Level / Percent :**

B / 40

- **Audit/Effectiveness Check Modification :**

SEA-DO recommends to call or visit two direct accounts and three sub-accounts per direct account.

- **Effectiveness Check Information :**

- **Audit Check Information :**

- **Section of Law Violated :**

- **Recall Strategy :**

The firm notified their consignees by telephone on 12/15/16 and sent the notification via email on 12/16/16. Distributors and retailers were instructed to destroy any remaining affected product. Customers with questions about recall can call Susan Drexel at 303-920-5441.

- **Distribution Pattern :**

distributed in (b) (4) .

- **Quantity Distributed :**

(b) (4)

- **List of Consignees or Comments :**

List of (b) (4) direct accounts: Allegro Coffee Manufacturer HQ 12799 Claude Court Thornton, CO (b) (4)

- **Number of Foreign Consignees :**

0

- **Number of Other Consignees :**

- **Number of VA Consignees :**

0

0

- **Number of DOD Consignees :**

- **Number of USDA Consignees :**

- **District Management Approval :**

- **District Management Approval Date :**

- **Class I Termination Recommendation :**

- **Firm Initial Notification :**

Combination

Event ID: **75996** Status: **Terminated** Updated: **09/07/2017** Role: **Center Recall Coordinator**

Recall Details

1. Event Information
2. Summary and Termination Information
3. Center Information
4. Product Information
5. Firm and Contact Information

Event Information

Recall Event ID	75996	EON ID	
Recall Number(s)	F-1179-2017		
District	Seattle District Office	Coordinator	Anh T Nguyen
Firm Awareness Date	12/12/2016	District Awareness Date	12/15/2016
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Dehlia Young
Recalling Firm FEI	3010863196	Name (Int)	Starkey Water
Manufacturer FEI	3010863196	Name (Int)	Starkey Water
Responsible Firm FEI	3010863196	Name	Starkey Water
Public Reason for Recall	Starkey Spring Water, 16.9 fl oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample.		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	FDA Initiated	Date (Int)	12/16/2016
Firm Recommended Recall Depth	Retail	Date Distribution Chain Notified	12/16/2016
Recall Initiation Date (Int)	12/15/2016	Firm Initial Notification	Combination
Determination Date		Center Coordinator Assigned Date	12/29/2016
Classification Date	01/12/2017	FDA Sample Number	none

Complete Reason for Recall	<p>Starkey Spring Water, 16.9 FL oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample. The sample of lot # (b) (4) was collected on 07/07/16 and the results were included in a report dated 12/09/16 by the Florida Department of Agriculture and Consumer Services (FDACS). The arsenic level in lot# (b) (4) tested by the FDACS Laboratory # 2016/FL-18831 was at 11.7ppb. On 12/12/16, according to the firm, testing result was provided to Whole Foods Market store in Florida by Florida Department of Agriculture and Consumer Services (FDACS). On 12/13/16: SEA-DO became aware of bottled water sample result provided by FDACS (11.7 ppb of arsenic) and consulted with CFSAN Recalls. On 12/14/16: CFSAN Recalls responded and stated that 11.7 ppb value exceeds the 10 ppb FDA permissible level of arsenic in water (21 CFR 165.100) and is a health concern. It would be a class 2 recall. On 12/14/16 and 12/15/16: SEA-DO notified the firm of sample result, notified the firm about a potential class II result, and asked for the firm plan on distributed product. On 12/15/16: the firm agreed to recall. On 12/16/16: the firm submitted the Attachment A information. On 12/21/16: the firm submitted the Attachment B information.</p>	
Root Cause	Other	
Root Cause Narrative	unknown. The firm reported that the testing from the (b) (4) for this week of production was at 10 ppb.	
Center Comments	Class III. CFSAN concurs with audit check strategy.	
Type Of Injury	none reported to date	
Quantity Manufactured	(b) (4)	
Quantity Distributed (Int)	(b) (4)	
Number of Domestic Consignees	(b) (4)	
Number of Foreign Consignees	0	
Distributed From	(b) (4)	
Distribution Pattern (Int)	distributed in (b) (4)	
Manufactured From	(b) (4)	
Public Summary of Recall Strategy (Int)	<p>The firm notified their consignees by telephone on 12/15/16 and sent the notification via email on 12/16/16. Distributors and retailers were instructed to destroy any remaining affected product. Customers with questions about recall can call Susan Drexel at 303-920-5441.</p>	
Recall Strategy	<p>The firm notified their consignees by telephone on 12/15/16 and sent the notification via email on 12/16/16. Distributors and retailers were instructed to destroy any remaining affected product. Customers with questions about recall can call Susan Drexel at 303-920-5441.</p>	
Effectiveness Check Level	A Percent 100	
Audit Check Level	B Percent 40	
Audit/Effectiveness Check Modification	SEA-DO recommends to call or visit two direct accounts and three sub-accounts per direct account.	
RAC Assignment Date Issued	12/28/2016	RAC Assignment Date Completed
District RAC Assignment Needed?	Yes	District Justification for No Audit Check
District Recommendation for No Audit Check Comments		Center Concur with District RAC Recommendation

Center RAC Assignment Needed?

Center Justification for No Audit

Check

Center Recommendation

Center Entering Recall

Justification Comments

What Consumers Should Do (Int)

Expanded Comments for

What Consumers Should Do (Int)

Firm Press Issued (Int)

URL (Int)

State Press Issued (Int)

URL (Int)

FDA Press Issued (Int)

URL (Int)

Additional Medical Product Information (Int)

URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments

List of five direct accounts: Allegro Coffee Manufacturer HQ 12799

Claude Court Thornton, CO (b) (4)
[Redacted]
[Redacted]
[Redacted]

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	0	Direct Accounts	(b) (4)
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected

No inventory remained at the consignees

Product Disposition

None remaining

Number of Consignees Responding to Notification

The (b) (4) consignees have one point of contact and did respond to the recall notification. Allegro Coffee was visited by the recalling firm

Effectiveness Check Information

100%

Recall Audit Check Count

Audit Count Summary : Not Available

Audit Check Information	SEA-DO sent RAC assignment to MIN-DO and PHI-DO. PHI-DO responded with 1 E D and 2 E S MIN-DO responded with 1 E D (submitted 3177 on 3/2/17). E=effective D=direct account S=sub account
Section of Law Violated	403(a)(1)
Preventive Action Taken by Firm	Lower the internal testing threshold of acceptability for arsenic to 9 ppb. Hold and re-test all lots over the 9 ppb threshold Retrain and reinforce requirement to re-test any lots above the threshold. Only lots passing the threshold may be released for distribution. Increases holding period from (b) (4) .
District Follow-Up	SEA-DO recalls received notification from Florida Dept. of Ag. regarding high arsenic levels in the bottled water. SEA-DO recalls worked with the firm to collect Attachment B information, document the recall and review the documents to verify the recall is effective and complete.
District Review	Recall appears effective and complete.
Legal Action	None
Class I Termination Recommendation	
Recommended/Prepared By	Jean R McCurry
District Management Approval	Jean R McCurry Date 03/03/2017
Center Concurrence	
Recall Completed Date	01/23/2017
Termination Letter Date	03/03/2017

CFSAN Center Information

Docs Rcvd at Ctr Date	12/21/2016
HHE Sent	12/29/2016
HHE Signed	01/04/2017
HHE Precedent	9420
Outbreak Associated	N

Outbreak Event Number

Product Information

Product : 1

Industry-Product Code	29-RCY01
Precedent Recall	9420
Precedent Policy	
Precedent Policy Comment	
Product Description (Int) (Label/Packaging)	Starkey Spring Water, Item code STC.5, 16.9 FL oz. (500 mL) glass bottle. Product UPC 8 11904 02000 7. Case UPC 8 11904 02002 1.
Trade Name (Int)	Starkey Spring Water
Generic Name (Int)	
Product Usage	human consumption
Product Quantity Distributed (Int)	(b) (4)

Recall Number (Int)	F-1179-2017
Product Public Reason for Recall (Int)	Starkey Spring Water, 16.9 fl oz. glass bottles, are recalled because 11.7 ppb of arsenic was detected in water sample.
Field Recommended Classification	Class II
Center Determination/Classification (Int)	Class III
Center Recommended Depth	Retail
Product Effectiveness Check Level	A Percent 100
Product Audit Check Level	B Percent 40
Code Information (Int)	produced on (b) (4)
Expected Life	
Shelf Life	
CFSAN Reason	Chemical contaminant

Recalling Firm Information

FEI	3010863196
Firm Name (Int)	Starkey Water
Address (Int)	102 Council Ave
City (Int)	Council
State/Province (Int)	Idaho
Country (Int)	United States
Postal Code (Int)	83612
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	Jeff Teter
Title	President/General Manager
Firm Name (Int)	Starkey Water
Address (Int)	102 Council Ave
City (Int)	Council
State/Province (Int)	Idaho
Country (Int)	United States
Postal Code (Int)	83612
Telephone	Ext Country Code
Facsimile	303-920-5468 Ext Country Code
E-mail Address	Jeff.Teter@allegrocoffee.com
Comment	Company headquarters is located in Thornton, Colorado

Manufacturer Information

FEI 3010863196

Firm Name **(Int)** Starkey Water

Address **(Int)** 102 Council Ave

City **(Int)** Council

State/Province **(Int)** Idaho

Country **(Int)** United States

Postal Code **(Int)** 83612

Telephone **Ext Country Code**

Comment

Responsible Firm Information

FEI 3010863196

Firm Type Manufacturer

Firm Name **(Int)** Starkey Water

Address **(Int)** 102 Council Ave

City **(Int)** Council

State/Province **(Int)** Idaho

Country **(Int)** United States

Postal Code **(Int)** 83612

Telephone **Ext Country Code**

Comment

Recall Contact

Official's Name Susan Drexel

Title Director of Plant Operations and Purchasing

Firm Name **(Int)** Starkey Water

Address **(Int)** 102 Council Ave

City **(Int)** Council

State/Province **(Int)** Idaho

Country **(Int)** United States

Postal Code **(Int)** 83612

Telephone **Ext Country Code**

Facsimile 303-920-5468 **Ext Country Code**

E-mail Address susan.drexel@allegrocoffee.com

Comment

Public Contact

Official's Name Tara Cross

Title	Director of Marketing
Firm Name (Int)	Starkey Water
Address (Int)	102 Council Ave
City (Int)	Council
State/Province (Int)	Idaho
Country (Int)	United States
Postal Code (Int)	83612
Telephone	Ext Country Code
Facsimile	303-920-5468 Ext Country Code
E-mail Address	Tara.Cross@allegrocoffee.com
Comment	

WARNING! Sensitive/critical information. This information is proprietary and confidential. It should not be disclosed to unauthorized parties and should be maintained in a secure environment.

Printed by: **Thomas Kuntz**

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Wilde, Samantha

From: Harris-Garner, Kerri L.
Sent: Thursday, January 19, 2017 6:17 PM
To: ORA HQ CFSAN Class; ORA HQ Recall SEA
Subject: Recall Classified for 76172 - Starkey Water

Recall Classified for [76172](#)

Comments - [76172](#)

- **Center Comments :**

Class III. CFSAN concurs with audit check strategy.

- **Email Comments :**

Recall Date Information - [76172](#)

Firm Awareness : 01/04/2017	Classification : 01/19/2017
Recall Initiation : 01/04/2017	Recall Completed :
District Awareness : 01/05/2017	Termination :
HHE Sent : 01/12/2017	State Press Issued :
Distribution Chain Notified : 01/04/2017	Firm Press Issued :
Alert : 01/05/2017	FDA Press Issued :
Recommendation : 01/11/2017	

Recall Firm Information - [76172](#)

- **Recalling Firm :**

Starkey Water
102 Council Ave
Council Idaho 83612
United States

- **Manufacturing Firm 1:**

Starkey Water
Confidential : N
102 Council Ave
Council Idaho 83612
United States

Product 1 - [76172](#)

- **Product Description :**

Starkey Spring Water, 16.9 FL oz. (500 mL) glass bottle. packed 15 bottles in cardboard box. Product UPC 8 11904 02000 7. Case UPC 8 11904 02002 1.

- **Product Public Reason for Recall :**

12 ppb of arsenic was detected in water sample

- **Code Information :**

Produced On (b) (4)

- **Industry-Product Code :**

29-RCY01

- **District Recommended Classification :**

Class II

- **Center Classification :**

Class III

- **Product Effect. Check Level / Percent :**

B / 50

- **Product Audit Check Level / Percent :**

B / 25

- **Recall Number :**

F-1333-2017

Recall Event Level Information - [76172](#)

- **Recall Status :**

Ongoing

- **Firm Recommended Recall Depth :**

Retail

- **Voluntary/Mandated :**

Firm Initiated

- **Voluntary/Mandated Date :**

01/04/2017

- **Effectiveness Check Level / Percent :**

B / 50

- **Audit Check Level / Percent :**

B / 25

- **Audit/Effectiveness Check Modification :**

SEA-DO recommends level B (25%) or 2 distribution centers (DC) and two sub-accounts per DC for the RAC assignment. They can be done by telephone.

- **Effectiveness Check Information :**

- **Audit Check Information :**

- **Section of Law Violated :**

- **Recall Strategy :**

The firm notified their consignee(s) on 1/4/17 by email. Customers are advised to destroy product with this lot number. Customers with questions can call the firm at 303-920-5441 office or 720-470-1739 cell.

- **Distribution Pattern :**

distributed in (b) (4) .

- **Quantity Distributed :**

(b) (4)

- **List of Consignees or Comments :**

No VA or DoD consignees. No foreign consignees. Product distributed to (b) (4) distribution Centers in the US: (b) (4)

[Redacted]

- **Number of Foreign Consignees :**

0

- **Number of Other Consignees :**

- **Number of VA Consignees :**

- **Number of DOD Consignees :**

- **Number of USDA Consignees :**

- **District Management Approval :**

- **District Management Approval Date :**

- **Class I Termination Recommendation :**

- **Firm Initial Notification :**

E-Mail

Event ID: **76172** Status: **Terminated** Updated: **09/07/2017** Role: **Center Recall Coordinator**

Recall Details

1. Event Information
2. Summary and Termination Information
3. Center Information
4. Product Information
5. Firm and Contact Information

Event Information

Recall Event ID	76172	EON ID	
Recall Number(s)	F-1333-2017		
District	Seattle District Office	Coordinator	Anh T Nguyen
Firm Awareness Date	01/04/2017	District Awareness Date	01/05/2017
Center (Int)	Center for Food Safety and Applied Nutrition	Coordinator	Kerri Harris-Garner
Recalling Firm FEI	3010863196	Name (Int)	Starkey Water
Manufacturer FEI	3010863196	Name (Int)	Starkey Water
Responsible Firm FEI	3010863196	Name	Starkey Water
Public Reason for Recall	Starkey Spring Water, 16.9 fl oz. glass bottles, is recalled because 12 ppb of arsenic was detected in water sample.		
Edit Mode	Viewable	Recall Status (Int)	Terminated
Voluntary/Mandated (Int)	Firm Initiated	Date (Int)	01/04/2017
Firm Recommended Recall Depth	Retail	Date Distribution Chain Notified	01/04/2017
Recall Initiation Date (Int)	01/04/2017	Firm Initial Notification	E-Mail
Determination Date		Center Coordinator Assigned Date	01/12/2017
Classification Date	01/19/2017	FDA Sample Number	none

Complete Reason for Recall	<p>Starkey Spring Water, 16.9 fl oz. glass bottles, is recalled because 12 ppb of arsenic was detected in water sample. The water sample from the lot # (b) (4) 9:06 NV AC-51-2866 was collected on 12/12/2016 and the result was included in a report dated 12/29/16 by the Florida Department of Agriculture and Consumer Services (FDACS). The arsenic level in the sample tested by the FDACS Laboratory # 2016/FL-22279 was found at 12 ppb. The firm's private samples conducted by (b) (4) for this lot was at .010 mg/L. (b) (4) uses testing method EPA 200.8 and provided a valid test showing the product met the regulatory limit; consequently the product was released for distribution. On 1/4/17: according to the firm, testing result was provided to Whole Foods Market representative by Florida Department of Agriculture and Consumer Services (FDACS). On 1/5/17: the firm submitted the Attachment A information to SEA-DO. On 1/9/17: the firm submitted the Attachment B information to SEA-DO.</p>	
Root Cause	Other	
Root Cause Narrative	unknown	
Center Comments	Class III. CFSAN concurs with audit check strategy.	
Type Of Injury	none has been reported to date	
Quantity Manufactured		
Quantity Distributed (Int)	(b) (4)	
Number of Domestic Consignees	(b) (4)	
Number of Foreign Consignees	0	
Distributed From	(b) (4)	
Distribution Pattern (Int)	distributed in (b) (4)	
Manufactured From	(b) (4)	
Public Summary of Recall Strategy (Int)	The firm notified their consignee(s) on 1/4/17 by email. Customers are advised to destroy product with this lot number. Customers with questions can call the firm at 303-920-5441 office or 720-470-1739 cell.	
Recall Strategy	The firm notified their consignee(s) on 1/4/17 by email. Customers are advised to destroy product with this lot number. Customers with questions can call Susan Drexel at 303-920-5441 office or 720-470-1739 cell.	
Effectiveness Check Level	BPercent 50	
Audit Check Level	BPercent 25	
Audit/Effectiveness Check Modification	SEA-DO recommends level B (25%) or 2 distribution centers (DC) and two sub-accounts per DC for the RAC assignment. They can be done by telephone.	
RAC Assignment Date Issued	01/11/2017	RAC Assignment Date Completed
District RAC Assignment Needed?	Yes	District Justification for No Audit Check
District Recommendation for No Audit Check Comments		Center Concur with District RAC Recommendation
Center RAC Assignment Needed?		Center Justification for No Audit Check
Center Recommendation Justification Comments		Center Entering Recall
What Consumers Should Do (Int)		

Expanded Comments for
What Consumers Should Do (Int)

Firm Press Issued (Int) URL (Int)

State Press Issued (Int) URL (Int)

FDA Press Issued (Int) URL (Int)

Additional Medical Product
Information (Int) URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments No VA or DoD consignees. No foreign consignees. Product distributed to (b) (4) distribution Centers in the US: (b) (4)

[Redacted]
[Redacted]
[Redacted]
[Redacted]

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	(b) (4)	Repacker/Relabeler	0
Retailer	0	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

Summary/Termination Information

Quantity Recovered/Number of Units Corrected No recalled product remained at the consignee level.

Product Disposition No recalled product remained at the consignee level

Number of Consignees Responding to Notification (b) (4) These centers represent the (b) (4) to which product was distributed. Both regional centers replied that they had no remaining stock on hand.

Effectiveness Check Information 100% response.

Recall Audit Check Count Audit Count Summary : Not Available

Audit Check Information SEA-DO issued RAC to DEN-DO and DAL-DO on 1/11/17. DAL-DO submitted 3177 on 2/9/17 and it was found Effective (endorsed on 1/19/17). DEN-DO: Requested 3177 on 3/2/17. DEN-DO provided FDA 3177 to SEA-DO on 3/3/17. It was conducted on 1/26/17 and endorsed on 3/3/17. It was found to be effective.

Section of Law Violated 403(a)(1)

Preventive Action Taken by Firm Lower the internal testing threshold of acceptability for arsenic to 9 ppb. Hold and re-test all lots over the 9 ppb threshold Retrain and reinforce requirement to re-test any lots above the threshold. Only lots below the threshold may be released for distribution. Increases holding period from (b) (4) Purchase order has been written and deposit paid for an arsenic removal filtration system from (b) (4) .

District Follow-Up Florida Department of Agric. provided information regarding high levels of arsenic in the bottled water. SEA-DO Recalls obtained Attachment B information, documented the recall and reviewed the records to verify the recall is effective and complete.

District Review Recall appears effective and complete. Awaited RAC prior to termination.

Legal Action None

Class I Termination

Recommendation

Recommended/Prepared By Jean R McCurry

District Management Approval Jean R McCurry **Date** 03/03/2017

Center Concurrence

Recall Completed Date 01/31/2017

Termination Letter Date 03/03/2017

CFSAN Center Information

Docs Rcvd at Ctr Date 01/11/2017

HHE Sent 01/12/2017

HHE Signed 01/13/2017

HHE Precedent 9438

Outbreak Associated N

Outbreak Event Number

Product Information

Product : 1

Industry-Product Code 29-RCY01

Precedent Recall 9438

Precedent Policy

Precedent Policy Comment

Product Description (Int) Starkey Spring Water, 16.9 FL oz. (500 mL) glass bottle. packed 15 bottles in cardboard box.
(Label/Packaging) Product UPC 8 11904 02000 7. Case UPC 8 11904 02002 1.

Trade Name (Int) Starkey Spring Water

Generic Name (Int)

Product Usage human consumption

Product Quantity Distributed (Int) (b) (4)

Recall Number (Int) F-1333-2017

Product Public Reason for Recall (Int) 12 ppb of arsenic was detected in water sample

Field Recommended Classification	Class II
Center Determination/Classification (Int)	Class III
Center Recommended Depth	Wholesale
Product Effectiveness Check Level	B Percent 50
Product Audit Check Level	B Percent 25
Code Information (Int)	Produced On (b) (4)
Expected Life	
Shelf Life	
CFSAN Reason	Chemical contaminant

Recalling Firm Information

FEI	3010863196
Firm Name (Int)	Starkey Water
Address (Int)	102 Council Ave
City (Int)	Council
State/Province (Int)	Idaho
Country (Int)	United States
Postal Code (Int)	83612
Telephone	Ext Country Code
Comment	

Most Responsible Individual

Official's Name	Jeff Teter
Title	President/General Manager
Firm Name (Int)	Starkey Water/Allegro Coffee
Address (Int)	12799 Claude Court
City (Int)	Thornton
State/Province (Int)	Colorado
Country (Int)	United States
Postal Code (Int)	
Telephone	303-920-5400 Ext Country Code
Facsimile	303-920-5468 Ext Country Code
E-mail Address	Jeff.Teter@allegrocoffee.com
Comment	Starkey Water is owned by Allegro Coffee and the company headquarters is located in Thornton, Colorado

Manufacturer Information

FEI	3010863196
Firm Name (Int)	Starkey Water

Address **(Int)** 102 Council Ave
City **(Int)** Council
State/Province **(Int)** Idaho
Country **(Int)** United States
Postal Code **(Int)** 83612
Telephone 303-920-5400 **Ext** **Country Code**
Comment

Responsible Firm Information

FEI 3010863196
Firm Type Manufacturer
Firm Name **(Int)** Starkey Water
Address **(Int)** 102 Council Ave
City **(Int)** Council
State/Province **(Int)** Idaho
Country **(Int)** United States
Postal Code **(Int)** 83612
Telephone **Ext** **Country Code**
Comment

Recall Contact

Official's Name Susan Drexel
Title Director of Plant Operations and Purchasing
Firm Name **(Int)** Starkey Water/Allegro Coffee
Address **(Int)** 12799 Claude Court
City **(Int)** Thornton
State/Province **(Int)** Colorado
Country **(Int)** United States
Postal Code **(Int)**
Telephone 303-920-5441 **Ext** **Country Code**
Facsimile 303-920-5468 **Ext** **Country Code**
E-mail Address susan.drexel@allegrocoffee.com
Comment

Public Contact

Official's Name Tara Cross
Title Director of Marketing
Firm Name **(Int)** Starkey Water/Allegro Coffee
Address **(Int)** 12799 Claude Court

City (Int)	Thornton
State/Province (Int)	Colorado
Country (Int)	United States
Postal Code (Int)	83612
Telephone	Ext Country Code
Facsimile	303-920-5468 Ext Country Code
E-mail Address	Tara.Cross@allegrocoffee.com
Comment	

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