BCW Food Products, Inc. 6000 Denton Drive Dallas, TX 75235	Document #619 Recall
	Approved by: Melissa Boris

1. **Purpose**
   1.1. The purpose of this procedure is to effectively withdrawal and recall products in which the safety, quality or legality may have been compromised.
2. **Scope**
   2.1. This document establishes a protocol for the market withdrawal and/or recall of products produced at BCW Food Products.

3. **Responsibilities**
   3.1. It shall be the responsibility of any employee who learns or suspects that a recall may be necessary, regardless of time of day, to notify the following:

Notification Priority List		
1. President	(469) 682-9066	campbellwilliams@bcwilliams.com
2. VP of Manufacturing	(425) 864-8403	dhoffman@bcwilliams.com
3. Executive Vice President	(214) 507-6227	tmarron@bcwilliams.com
4. Recall Coordinator	(817) 454-5585	mboris@bcwilliams.com
5. Food Safety/Quality	(817) 454-5585	mboris@bcwilliams.com

   3.2. It shall be the responsibility of the **President** to approve and initiate the recall.
   3.3. It shall be the responsibility of the **Recall Coordinator** to notify all individuals designated on the recall list.

Name	Title	24 Hr. Contact Number
Bowman Williams	Chairman / CEO	(214) 912-0239
Campbell Williams	President	(469) 682-9066
Tim Marron	Executive Vice President	(214) 507-6227
Dave Hoffman	VP of Manufacturing/ Strategic Development	(425) 864-8403
Candy Krywalski	Vice President of Purchasing	(469) 767-7163
Jia-Ching Li	Vice President of Regulatory & HR	(214) 718-7016
Steve Bolton	Production Manager	(469) 774-8593
Oscar Garcia	Shipping / Receiving and Sanitation Manager	(972) 998-0082
Daniel Hoenich	R&D Manager	(214) 769-8316
Melissa Boris	Sr. Quality Assurance Manager (Recall Coordinator)	(817) 454-5585 (469) 348-6895

3.4. It shall be the responsibility of the **President** for all communications outside the company, including initial notification to the FDA via the Reportable Food Registry (www.safetyreporting.hhs.gov) within 24 hours after a responsible individual determines that a food is reportable. A 619.7 FDA Notification of Product Recall form shall be submitted.

3.4.1. A product recall shall not take place without direct communication between the **President** and an **Executive Officer** of the recalling company.

3.4.2. Once identified, it shall be the responsibility of the **President** or **Executive Vice President** to notify the customer(s) of the recall. In addition, a Customer Recall Notification Letter shall be sent priority overnight by the **President** or **Executive Vice President** to notify and provide additional clarification to the customer.

3.5. The Certification Body issuing the current BRC Global Standard certification shall be notified within 3 working days of any significant food safety incidents, recalls or regulatory enforcement notifications. A 619.7 FDA Notification of Product Recall form shall be submitted.

3.6. The Certification Body issuing the current Gluten-Free Certification Program shall be notified within 24 hours from the date of release of the official recall or withdrawal notification for gluten-free products. A 619.7 FDA Notification of Product Recall form shall be submitted.

Certification Body			
FoodChain ID 504 N 4rd St. Fairfield, IA 52556	(641) 209-4500	(641) 209-3783	foodrecalls@foodchainid.com
AIB International			gfsi@aibinternational.com

3.7. BRC Global Standard shall be notified within 1 working day from the date of release of the official recall or withdrawal notification for gluten-free products.

BRCGS	
BRCGS	compliance@brcgs.com

3.8. It shall be the responsibility of the **Production Manager** to provide required production documentation.

3.9. It shall be the responsibility of the **Shipping/Receiving Manager** to provide all required shipping/receiving documentation.

3.10. It shall be the responsibility of the **Vice President of Purchasing** to assist with shipping/receiving documents and in supplying customer order information needed to contact customers.

3.11. It shall be the responsibility of the **Recall Coordinator** or designee to assist with document control in order to reconcile the product retrieved. The product shall be reconciled using the 699.5 Recall Reconciliation Log form.

3.12. It is the responsibility of the **Recall Coordinator** or designee to ensure that communication between executive and customers, certification body, and regulatory authorities are conducted in a timely manner.

4. Procedure

4.1. BCW Food Products shall follow all FDA guidelines.

4.2. Recalls shall be categorized into one of three classes, according to the level of hazard involved:

4.2.1. Class I: Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulinum toxin or food with undeclared allergens.

4.2.2. Class II: Products that might cause a temporary health problem or pose only a slight threat of a serious nature.

4.2.3. Class III: Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws. Examples include: a minor container defect and lack of English labeling in a retail food.

4.2.4. If a cause cannot be readily determined, production shall be stopped.

4.3. Recall procedures shall allow for 24/7 enactment if necessary.

4.3.1. Finished Product Recall:

- Determine the BCW manufacturing date(s), batch number(s), and the quantity of suspect product produced.
- If a BCW batch is recalled, the batch produced immediately before and after the contamination shall be recalled.
- If a BCW batch is recalled, the entire product run immediately before and after shall be re-verified by the Quality Department using previously acquired retained samples.
- Suspect finished product in inventory shall be immediately isolated and placed on hold and listed on the Hold Log. A determination will be made as to how the finished product on hold will be returned, destroyed, or disposed of.
- If finished product has entered commerce, **Purchasing** shall locate all shipped products.
- Review the 606.6 Finished Product Reject Log for rejected finished product left on hold.
- If outside testing is required, an approved certified laboratory shall be used.
- The 622 Post-Recall Procedure must be performed and followed.

4.3.2. Raw Material (Primary Packaging) Recall:

- Determine from receiving records the quantity of suspect lot(s) received and receiving date(s): 299.4 Inbound Shipment and Inspection form and 299.2 Flour Receiving Log and the supplier receivers serve as a record of all incoming ingredients.
- Suspect raw material not entered into production shall be immediately isolated and placed on hold and listed on the Hold Log. A determination will be made as to how the raw material on hold will be returned, destroyed, or disposed of.
- The **QA Department** shall submit a product specification, a certificate of analysis and a physical sample for the lot in question to an outside laboratory for analytical testing, if necessary.

- If the raw material is a major or minor bin ingredient, use ingredient lot numbers from: 499.14 Major Bin Report, 499.15 Minor Bin Report forms and batch pull sheets to determine when a suspect raw material was used and how much was used. In order to provide assurance of recovering all suspect material from the major and minor bins, an assessment shall be performed to determine the amount of material that may have come in contact immediately before and immediately after the suspect lot.
- If the raw material is a weigh-up ingredient, use batch sheets to isolate when a suspect raw material was used and how much was used. Any weigh-up(s) containing a suspect ingredient will result in recall of batches scaled for the product run.
- If the raw material is flour, use 499.16 Daily Flour Usage Report sheets and Batch Pull Sheets to isolate when the suspect raw material was used and how much was used. In order to provide assurance of recovering all suspect material from the silos, an assessment shall be performed to determine the amount of material that may have come in contact immediately before and immediately after the suspect lot.
- If the raw material is primary packaging, identify the used material with the following:
  - Bags: 499.11 Bag and Lot Number Verification
  - Totes: 402.1 Product Changeover Verification 300 Line
- Record all BCW affected product by item number(s), manufacturing date(s), batch number(s) and yields.
- Locate where any scrap was carried over and used.
- Review the Hold log for currently held raw materials.
- Verify that all suspect raw material has been accounted for.

4.4. Conduct a physical count of the BCW affected product in the facility. BCW affected product in the facility shall immediately be isolated and placed on hold and listed on the Hold Log.

4.5. Using shipping records, determine when the BCW affected product was shipped from the facility. The Shipping Pick Sheets provided with each Bill of Lading re-confirm the item number and document the manufacturing date(s), and batch number(s) of each shipment.

4.6. Cross check to account for all BCW affected product produced.

4.7. The supplier of the raw material must be contact by the **VP of Purchasing.**
  - Request a 606.2 Supplier Corrective Action with a 2-week due date.
  - If a Supplier Corrective Action form is not completed within 2-weeks, the supplier will be evaluated for continued use.

4.8. Prior to contacting the customer(s), a determination shall be made as to how the BCW affected product will be returned or where and how the affected product will be destroyed or disposed of by the customer.

4.8.1. A 619.6 Product Return/Destruction Confirmation Form shall be sent to the appropriate customers by the **President** or **Executive Vice President.**

4.9. Returned product shall be tagged with a Hold Tag and listed on the Hold Log.

4.10. The **President** shall determine if legal counsel shall be contacted

4.11. **Dallas District FDA Contact Numbers:**
Dallas (DAL-FO), 4040 North Central Expressway, Suite 900, Dallas, TX 75204

FDA Contact	Phone	Fax	Email
Karen Daugherty, Director Investigations Branch	(214) 253-5228	(214) 253-5314	Karen.Daugherty@fda.hhs.gov
Jessica Havranek, Director Compliance Branch	(913) 495-5183		Jessica.Havranek@fda.hhs.gov
Casey L. Hamblin, Recall Coordinator	(214) 253-5222	(214) 253-5314	Casey.Hamblin@fda.hhs.gov
Jane Broussard, Emergency Response Coordinator	(214) 253-4925	(214) 253-5318	Jane.Broussard@fda.hhs.gov
Edmundo Garcia, District Director	(214) 253-5201	(214) 253-5201	Edmundo.garcia@fda.hhs.gov

4.12. A 619.3 Recall Status Report shall be submitted to the FDA. It shall be the responsibility of the **Executive Vice President** to communicate with the customer and maintain up to date Recall Status Reports. Recall Status Reports shall be discontinued when the FDA terminates the recall.

4.13. After the recall is deemed to be complete, the **President** shall submit a letter to the FDA along with the last status report.

4.14. Post evaluation of the recall shall take place and shall include:

- Checking all documentation for accuracy
- Re-evaluating the root cause of the problem that resulted in the recall
- Taking steps to prevent reoccurrence and future recalls
- Providing feedback to all parties involved for the purpose of achieving continuous improvement.
- Completing 619.2 Recall Summary with recorded key activities.
- It shall be the responsibility of the **Sales Representative** to contact the customer and complete the 619.5 Recall Follow-Up Form for recall effectiveness and ensure that the 619.4 Customer Recall Notification Letter and 619.6 Product Return/Destruction Confirmation Form were received by the customer.

5. Verification

5.1. Management shall review this procedure for compliance annually.

6. Revision History

01/04/1970 – New
08/05/2005 – Updated Recall Procedures
12/12/2006 – Updated FDA Contact Numbers
01/31/2008 – Updated Director of Manufacturing and Quality Assurance
03/20/2012 – New format; consolidated Recall Procedures with FDA Contact Numbers; Added Document numbers; Updated Director of Supply Chain, Vice President of

Operations and Technical Manager.

11/18/2013 – Changed Vice President of Operations to Vice President; changed Technical Team to QA Department.

03/04/2015 – Remove reference to Corrective Action form.

03/15/2016 – Remove reference to using AFL lab for testing. Remove reference to 606.2 and 606.3. Updated FDA contacts.

11/29/2016 – Remove the minor and major bin 10,000 lbs. additional recovery. Remove the silo 50,000 lbs. additional recovery. Added recall classifications.

12/02/2016 – Added 499.6 Production Time Sheet 300 Line. Added certification body contact information.

03/02/2017 – Update contact information. Update template.

03/30/2018 – Update header. Update CERT ID contact email. Update Dallas FDA contact information based on 3-14-18 mock recall. Change Stock Reconciliation Form to 699.5 Recall Reconciliation Log form. Update job titles. Replace 299.3 Receiving Ledger form with 299.4 Inbound Shipment and Inspection form. Remove batch sheet numbers. Update job titles. JC

07/13/2018 – Update form names. Update certification body name. JC

09/28/2018 – Update FoodChain ID email address. Added responsibility to 'Recall Coordinator to keep track of the timing of key activities'. Added notifying the CB 'any significant food safety incidents, recalls or regulatory food safety non-conformities'. JC

10/24/2018 – Updated Certification Body Information. LS

09/26/2019 – Change regulatory food safety non-conformance to regulatory enforcement notifications. Minor grammar fixed. JC

12/13/2019 – Update FDA Director of Compliance Branch contact. JC

04/30/2020 – Add 'BRC Global Standard shall be notified within 24 hours for gluten-free product'. JC

09/02/2020 – Updated regulatory contacts. KR

09/25/2020 – Added 619.1, removed section 4.3. Reorganized contacts in order. KR

10/21/2020 – Added Dave Hoffman to Recall list. Added Finished Product Reject log to 4.3.1. Primary packaging procedures added. Added recall effectiveness procedure. KR

11/09/2020 – Added contacting the supplier in 4.14. Included the 622 Post-recall procedure in section 4.3.1. KR

01/07/2021 – Updated sections 3.1. and 3.3. to remove Kathleen Rosgen name as the "Recall Coordinator". MB

01/27/2021 – Updated section 3.7. to change requirement of recall notification from 24 hrs. to "1 working day from date of release". Clause 3.12 of Issue 3 of the Gluten-Free Certification Program Global Standard updated the requirement for recall notifications. Added section 3.6. to include the CB (AIB) recall information and email for the Gluten-Free Certification Program. MB

05/18/2021 – Added Recall Coordinator contact information in the Priority Contact List. Added Hannah West title and contact information in the recall list. HW

09/28/2021 – Added form# in section 4.14 for the Customer Recall Notification Letter (619.4) and Product Return/Destruction Confirmation (619.6). MB

10/20/2021 – Removed Hannah West from the Priority Contact List. Added Melissa Boris contact information for the Recall Coordinator. HW