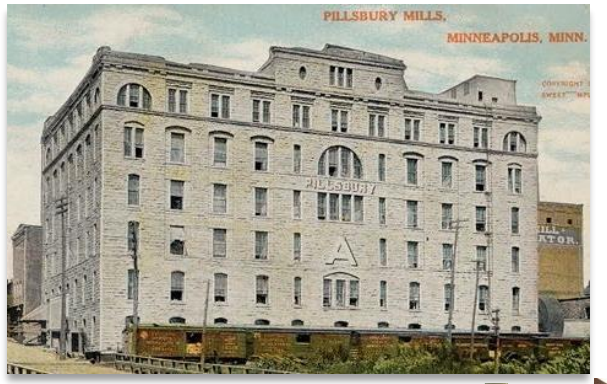
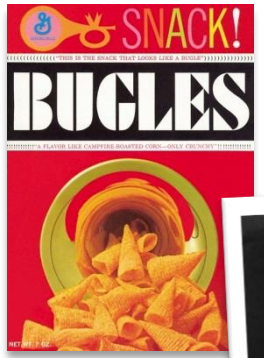
FSMA Supplier Preventive Controls and Audits

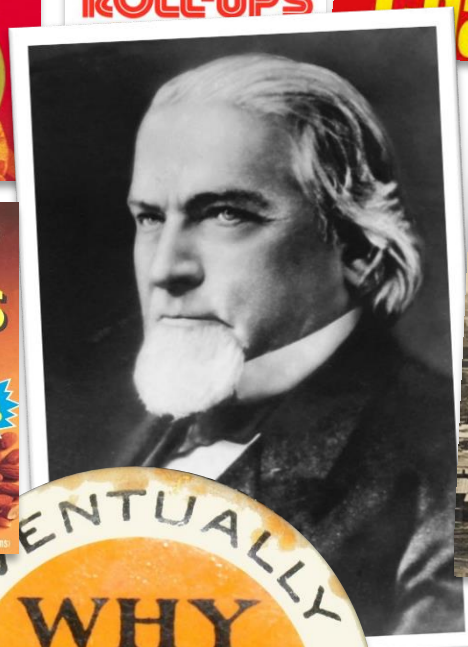
Scott Hood
June 2018

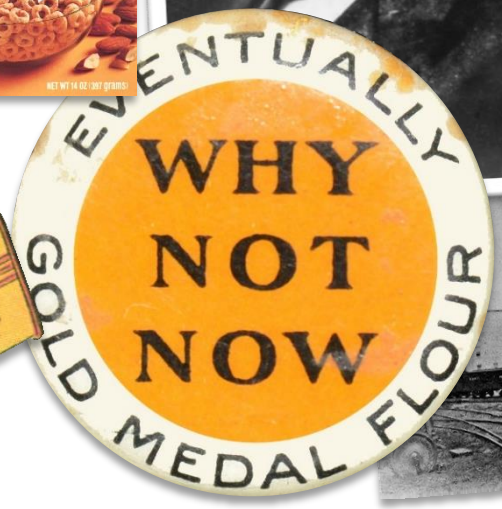
Our Legacy: 150 Years of Making Food People Love

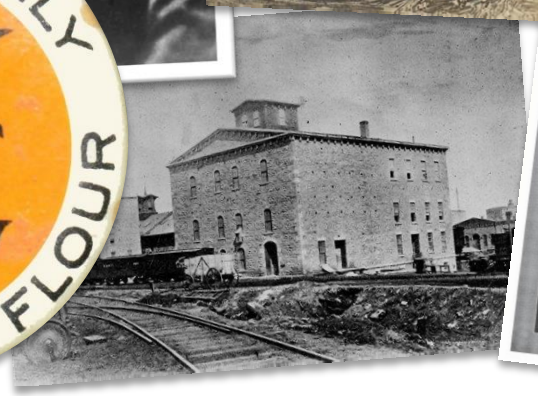
MAKING FOOD PEOPLE LOVE











Our Brands


Pillsbury


yoplait


Quality Foods
PROGRESSO


Cinnamon Toast Crunch


OLD EL Paso
SINCE 1938


Betty Crocker


NATURE VALLEY


Hamburger Helper


FOUNDED IN SKAGIT VALLEY, WA
Cascadian Farm
ORGANIC
SINCE 1972


MUIR GLEN
Organic


Annie's


Carolina
O melhor do leite para sua família


Yoki


Totino's


LATINA


Cheerios


KITANO


Häagen-Dazs


FIBER One


EPIC
100% GRASS FED PROTEIN


LÄRABAR


JUS-ROL


灣仔碼头

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OUR MISSION:

Be the source of scientific health, nutrition and food safety expertise that creates value and growth for General Mills

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Global Scientific & Regulatory Affairs

Global Scientific Research

Global Health & Wellness Communications

Global Food Safety

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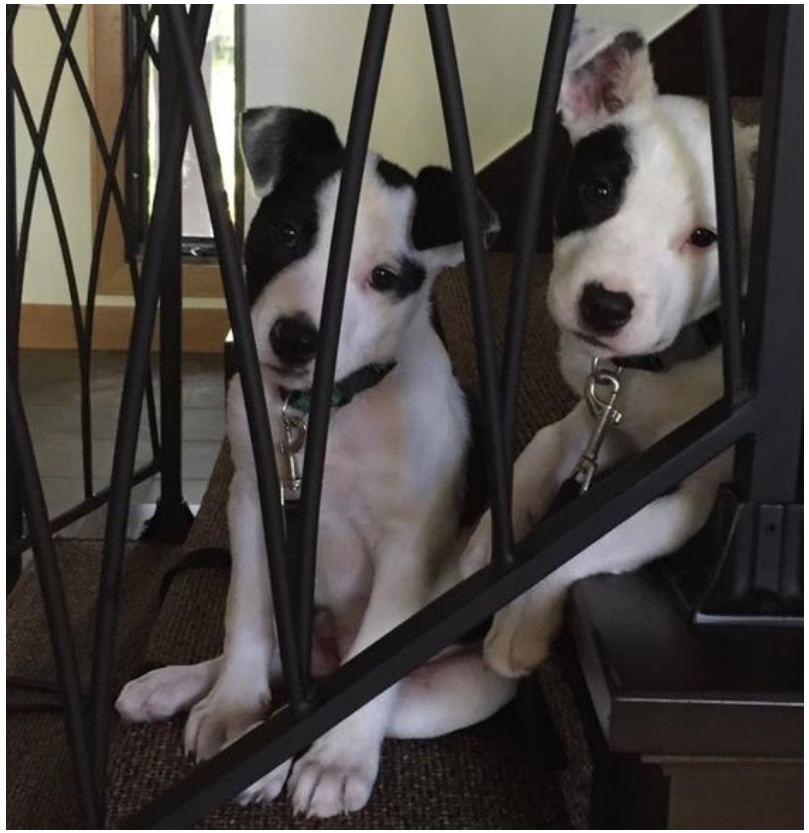


Before we begin…

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Summary Slide First

- Understand your supply chain
- Know your suppliers
  - Focus on FSMA compliant supply chain programs for those suppliers that require a supply chain control
- Documentation is important

External Engagement

FSMA Human Food Rule Structure

- CFR117 – Current Good Manufacturing Practice, Hazard Analysis and Risk-based Preventative Controls for Human Food
  - Subpart B: cGMP's
  - Subpart C: Food Safety Plan/Hazard Analysis
  - Subpart F: Records
  - **Subpart G: Supply Chain Program**
- Most Warehouses: Subparts C & G do not apply (solely managing unexposed food)

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Supplier Controls - Based on Who Controls The Hazard

- Manufacturer, processor
- Raise the animal
- Grow the food

- Manufacturer, processor

- Manufacturer, processor or preparer

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Facility Requirements

Food Safety Plan

- Overseen by PQCI

Written Hazard Analysis

- Similar to HACCP Plan

Documented Preventive Controls

- Including Supply Chain Controls

Monitoring, Verification, Corrective Actions

Recall Plan

General Mills Complex North American Supply Chain

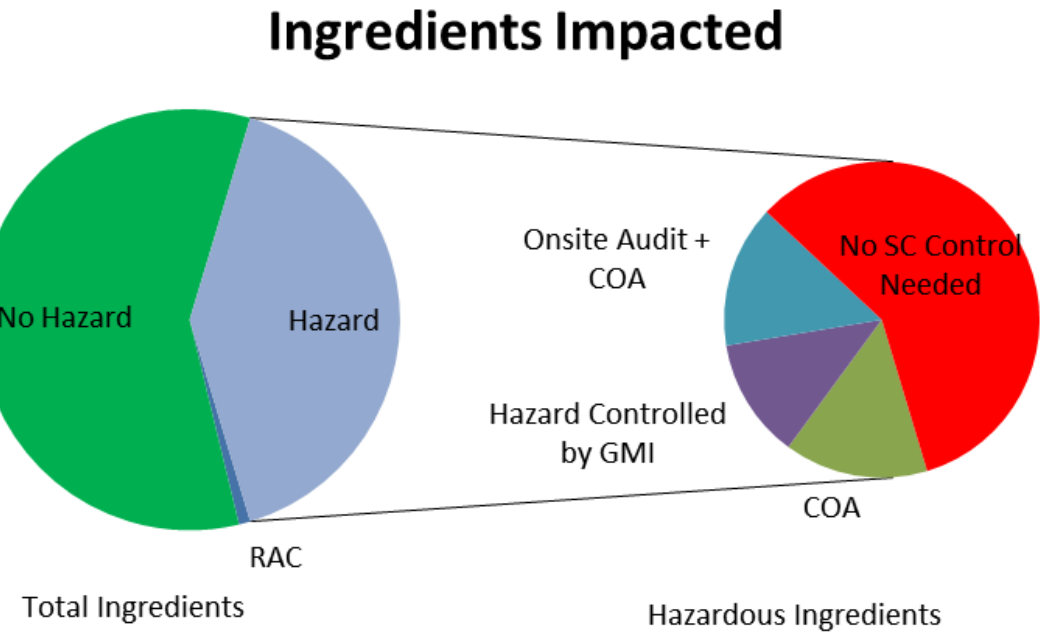
- 1000’s of ingredients
- Hundreds of ingredients purchased by contract locations

- 100’s of Vendors
- 1000’s of Vendor Production Locations

- Dozens of GMI Facilities
- 100’s of Contract Locations
- Large pilot plant facilities

Supply Chain Program - Where Did We Start?

- Start with all vendors supplying FDA registered facilities
- Perform hazard analysis based on where ingredients are used
- Determined which ingredients and suppliers require a supply chain applied control



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Facility Food Safety Plan GMI Requirements

- Copy of Supply Chain Program procedure that outlines:
  - Use of approved suppliers (corporate activity)
  - Determination of appropriate supplier verification activities (corporate activity)
  - Conducting supplier verification activities (corporate & plant activities)
- Facility specific written ingredient hazard analysis that identifies ingredients requiring a supply chain applied control
- Written procedure used if any raw material sampling and testing is performed at GMI/ESC facility
- Written procedures for receiving raw materials that require supply chain applied controls - including COA records under this program

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Supply Chain Controls

- The ingredient hazard analysis identifies hazards requiring a supply-chain-applied control
- An ingredient may not have a hazard requiring a preventive control; e.g., vinegar, salt, sugar
- A hazard requiring a preventive control that is associated with an ingredient or raw material **may not require a supply-chain program**; e.g.,
  - When the receiving facility controls the hazard (ex. Validated lethality step in the manufacturing process)
  - When a Customer or downstream entity provides written assurance that they control the hazard

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FDA Announces Enforcement Discretion Policy for Certain FSMA Regulations

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Constituent Update

January 4, 2018

The FDA announced today that it intends to exercise enforcement discretion for certain provisions in four of the rules that implement the FDA Food Safety Modernization Act (FSMA). This means that during the enforcement discretion period, the agency does not intend to enforce these provisions as they currently apply to certain entities or activities.

Animal Food), Foreign Supplier Verification Programs rule (FSVP), and Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (Produce Safety) and how they apply to:

- facilities that would be farms except for certain factors and activities,
- written assurances provisions in all four rules related to the control of identified hazards or microorganisms that are a potential risk to public health
- the animal food preventive controls requirements for certain manufacturing/processing activities performed on human food by-products used as animal food, and
- FSVP requirements for importers of food contact substances.

Issuing this enforcement discretion guidance is consistent with other actions the FDA has taken to ensure that the

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Ingredient Hazard Analysis Guidance

Ingredients that need a SC applied control[1]:
Q1 = Yes (ingredient has a hazard)
Q2 = No (hazard not controlled by manufacturing, foodservice customer, validated consumer cook instructions or ingredient/product design)

SAHCODHA level hazards (SC Control = COA and Onsite Audit)[++]:

- Shiga-toxin producing E. coli
- L. Mono
- Salmonella
- C. Botulinum

Example:

List the name and code of each ingredient in this HACCP plan		List the specific hazard reasonably forseeable in this ingredient. If no hazard exists, state "none."				CRITICAL INGREDIENT?	Supply Chain Control Required		Summarize the rationale describing the control
Ingredient Name	Hazard Type	Hazard	Q1	Q2	Q3	*(Yes/No)*	*(Yes/No)*	*Describe the SC control*	Rationale
206070 Wheat Flakes	Biol	Salmonella	Yes	No	NA	**Yes**	**Yes**	**Onsite Audit/COA Review**	Hazard is controlled by Supply chain control, CoA verification is required for each load
	Chem	Allergen - Wheat	Yes	No	Yes		**No**		Plant Allergen control plan controlls allergen hazard
	Phys	None	No	NA	NA		**No**		No hazard reasonably foreseeable to occur

FYI: Biological hazards that have validated cooking step (Q1=Y, Q2=Y, Q3=NA) are not flagged as a critical ingredient

SAHCODHA level hazards – Heat Treated Wheat Flour (SC Control = COA, Onsite Audit, Annual Food Safety Record Review):

- Shiga-toxin producing E. coli
- Salmonella

Supplier Verification Activities

- PCHF Rule subpart G section 117.410:
  - Onsite audits
  - Sampling and testing of raw material or other ingredient
  - Review of the supplier's relevant food safety records
  - Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient

Supplier Verification Activities

- When a hazard….will be controlled by a supplier….will result in a *serious adverse heath consequences or death to humans* (SAHCODHA):
  - The appropriate supplier verification activity is an onsite audit of the supplier (before using the raw material and annually thereafter)
  - For GMI – will be a 3rd party audit (GFSI/AIB)

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Who does the audit?

Customer

External Party

- GFSI is widely recognized
- Other groups do audits

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Supplier Verification – COA Program

Monitoring

- Review for each lot

Verification

- Periodic review of the COA program

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Supplier Verification: Other

- Some hazards will require an “other” supplier verification activity
  - Ex: Mycotoxins (vomitoxin/aflatoxin) – Grains
  - Heat treated flour (cookies) food safety record reviews
- Annual letters and food safety record reviews will be maintained & managed by corporate

Ingredient Hazard Review									
List the name and code of each ingredient in this HACCP plan		List the specific hazard reasonably forseeable in this ingredient. If no hazard exists, state "none."				CRITICAL INGREDIENT?	Supply Chain Control Required		Summarize the rationale describing the control
Ingredient Name	Hazard Type	Hazard	Q1	Q2	Q3	*(Yes/No)*	*(Yes/No)*	*Describe the SC control*	Rationale
215990 Flour Hard Spring Whole Wheat	Biol	Salmonella,E. coli O157:H7	Yes	Yes	No	Yes	No		Hazard is either fully controlled by thermal activation in our facility or foodservice facility
	Chem	Allergen - Wheat	Yes	No	No		No		Hazard is full controlled through Allergen control program
	Chem	Pesticide residue	No	NA	NA		No		Hazard is fully controlled through prerequisite programs, must meet EPA standards, and is unlikely to occur.
	Chem	Vomitoxin	Yes	No	NA		Yes	Supplier Program	Annual review of Supplier Control Program
	Phys	Foreign material	No	NA	NA		No		Hazard is fully controlled through prerequisite programs and is unlikely to

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Supplier Controls - Allergens

- Allergens are identified as chemical hazards in the ingredient hazard analysis
- Manufacturing plants cannot eliminate or reduce allergens but do manage them using allergen labeling, separation, allergen cleaning and other allergen preventive controls

Supplier Control Allergen Scenarios

	No Allergens in Facility	All Like Allergens in Facility	Unlike Allergens in Facility	Unlike Allergens on Same Line/ Cross-Labeled	Unlike Allergens on Same Line/ Not Cross-Labeled
Supplier Allergen PC	No	Yes – labeling	Yes – labeling	Yes – labeling	Yes – Preventing Cross Contact & Labeling
Manufacturer Supply Chain Control	No	No	No	No	Yes - Annual Onsite Audit

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Know Your Suppliers

FDA Resources Online

Secure | https://datadashboard.fda.gov/ora/index.htm

FDA U.S. FOOD & DRUG ADMINISTRATION
DATA DASHBOARD

https://datadashboard.fda.gov/ora/index.htm

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DATA DASHBOARD

Compliance Dashboards

Inspections ▪ Compliance Actions ▪ Recalls ▪ Imports

FSMA Data Search

Firm/Supplier Evaluation Resources

Secure | https://datadashboard.fda.gov/ora/fd/fser.htm

Firm Legal Name

Enter Firm Name or FEI Number

Clear/Reset

** If the results are different from your search parameters, the firm name and/or FEI was merged with one of the firms in the search results. **

Search Results: 50

FEI Number	Legal Name	Street Address	City Name	Firm State
1000520786	General Mills, Inc		Le Sueur	Minnesota
1000221024	General Mills LLC		Superior	Wisconsin
1000306701	General Mills Chanhassen Plant		Chanhassen	Minnesota
3003893038	General Mills India Pvt. Ltd.	8th Floor, Main Street	Mumbai	-
3004270111	General Mills - Landes	519 route Royale	Labatut	-
3004271291	General Mills - Nasik	F - 11 Midc	Malegaon	-
3004339290	General Mills - Elevator T		Minneapolis	Minnesota
3006531114	General Mills- Gigante Verde S de RL de CV		Irapuato	-
3007715506	Namdhari Rice & General Mills	Sri Jiwan Nagar	Sirsa	-
3007853132	Devgan Rice & General Mills	Devgan Rice & General Mills, Tarn Taran Rd, Sangrana Sahib	Amritsar	-
3008223637	General Mills India Pvt Ltd	902, Ventura, Hiranandani Business Park, Powai	Mumbai	-
3008736211	General Mills - Burzaco		Burzaco	-
3008802753	General Mills - Ad Warehouse		Minneapolis	Minnesota
3009555931	General Mills Inc. - Linder Location		Milwaukee	Wisconsin
3011084470	General Mills Brazil Alimentos Ltda.		Sao Bernardo do Campo	-

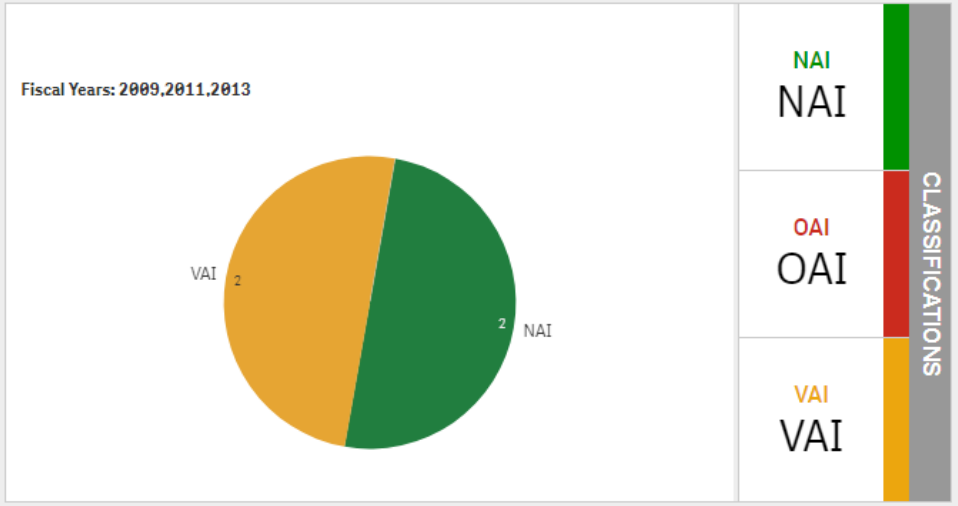
How to Use the Dashboard | Glossary

FEI Number	PROFILE		Country
1000139677		General Mills, Inc. Albuquerque New Mexico 87113	United States

Compliance Trend Data | Import Alerts & Warning Letters

INSPECTIONS

Inspections	Classifications
3	4



Project Area	Inspection ID	Inspection End Date	Product Type	Classification
Food Composition, Standards, Labeling and Econ	713064	03/08/2011	Food/Cosmetics	NAI
Foodborne Biological Hazards	572423	03/31/2009	Food/Cosmetics	VAI

FDA U.S. FOOD & DRUG ADMINISTRATION
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Data Dashboard

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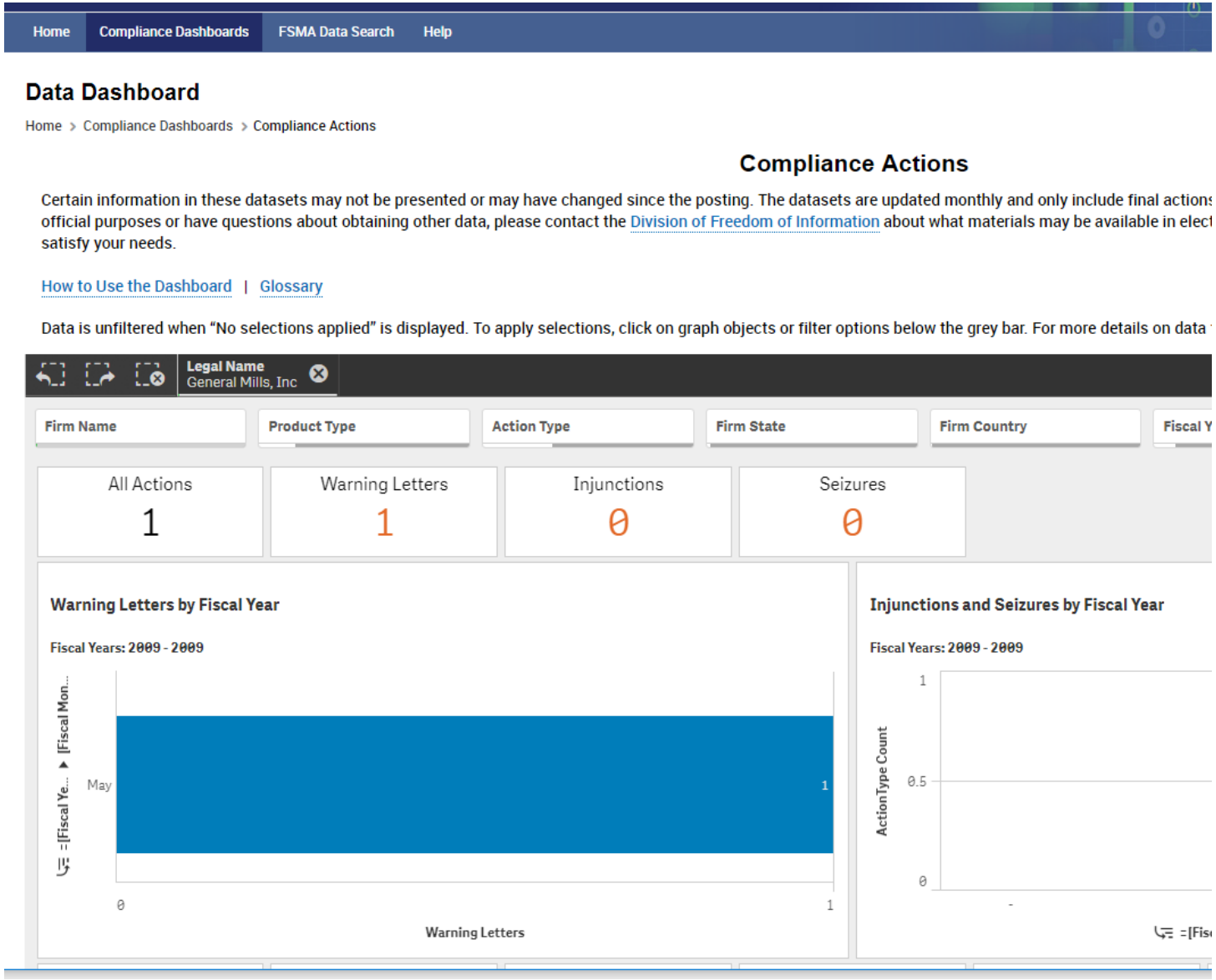
Compliance Dashboards

About the Data

The underlying data used to generate the dashboard graphs are based upon transparency datasets and other data already available to the public through the FDA.gov website. The datasets and data
Database, and selected data elements from the compliance and enforcement related information on FDA.gov. Additional data will be included in future releases of the Dashboard. You may find the loc
information about each dataset and other data sources by clicking on the links below:


Home
Compliance Dashboards
FSMA Data Search
Help
Data Dashboard
Home > Compliance Dashboards > Compliance Actions
Compliance Actions
Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated monthly and only include final actions
official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in elect
satisfy your needs.
How to Use the Dashboard | Glossary
Data is unfiltered when "No selections applied" is displayed. To apply selections, click on graph objects or filter options below the grey bar. For more details on data
Legal Name
General Mills, Inc
Firm Name
Product Type
Action Type
Firm State
Firm Country
Fiscal Y
All Actions
1
Warning Letters
1
Injunctions
0
Seizures
0
Warning Letters by Fiscal Year
Fiscal Years: 2009 - 2009
=[Fiscal Ye... ▸ [Fiscal Mon...
May
1
0
1
Warning Letters
Injunctions and Seizures by Fiscal Year
Fiscal Years: 2009 - 2009
ActionType Count
1
0.5
0
-

Working with FDA

- Continued understanding of role for written assurances
- Corporate level programs
  - Audit at facility
  - Audit at HQ
- Working with co-manufacturers
  - Who specs/purchases the ingredients?
- Role of 3rd party audits
  - Are the criteria acceptable?
  - We have seen very little focus on this by FDA

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Summary

- Understand your supply chain
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  - Focus on FSMA compliant supply chain programs for those suppliers that require a supply chain control
- Documentation is important

Thank You