



## Previous audit details

Audit Type		Surveillance - Announced	
Start Date	23/1/2019	End Date	24/1/2019
Non-conformances raised at previous audit have been closed?		Yes	No non-conformances raised for the head office at previous audit. All site level non-conformities have been addressed.
Please describe any changes since the previous audit		Generally, no significant changes noted within the last twelve months for activities facilitated by the head office except that the organization has elected to transfer certification of all sites to SGS.  Site: Aside from updates to organizational documentation to comply with FSSC v5, no significant changes to site management system, products, or processes have occurred in since the 2019 surveillance audit.	

## Executive Summary

Audit Summary	HQ: Head office activities were generally found to be in compliance with FSSC Ver 5 requirements.		
	Site: The audit resulted in a total of 5 minor non-conformances to include areas such as management review, employee practices, and food safety related training records. The General Mills Cincinnati site was built in 1959 and spans a total of 300,000 sq ft, including 90,000 sq ft of warehouse space, with the remaining 210,000 sq ft consisting of production space. Site products include varieties of Chex, Fiber One, Cinnamon Toast Crunch, and Cinnamon Toast Crunch Churros. Most products are packaged for retail sale, with some distributed in bulk for copacking at other General Mills or 3rd party facilities. Raw materials are received by rail, truck, and bulk tanker. Most products are shipped domestically with some products also distributed to Canada.		
Please confirm that the audit objectives have been fulfilled		Yes	

## Number of nonconformities

Critical Nonconformities	0
Major Nonconformities	0
Minor Nonconformities	5

Audit Recommendation	Certification maintained
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## Summarise any recalls or withdrawals since the last audit:

There were two reported recalls that occurred over the last twelve months: January 2019 – Gold Medal Unbleached Flour# 5 – Salmonella and September 2019 – Gold Medal Unbleached Flour# 5 06Sep2020 – E. coli. Recall procedures were executed as per FDA guidelines and effectiveness was reviewed during the audit. Previous certification body was also notified. Recovery is 100%.

## Legal compliance evaluation, statutory, regulatory and other requirements:

Scientific and regulatory affairs handled by General Mills Inc.'s Innovation, Technology and Quality division. All regions of distribution, manufacture and sale have been taken into account. Site registration and compliance are to be further verified during individual site audits.  
All aspects of facility operation reviewed by the auditor were found to be in compliance with relevant legislation.

## Use of logos

The organization does not use the FSSC logo or certification mark in any form.

## Key processing steps and Control measures:

During the audit the control of the following key processing steps and operational prerequisite programs (oPRPs) and CCP(s) were verified. All oPRPs and CCP's should be verified.

Control measure	Short description (process step)	Food safety hazards to be controlled	Monitoring procedure and critical limit	Verified during audit
CCP	Metal Detection - Cartons and bulk bags	Metallic foreign material	Metal detectors are challenged at startup and every 2 hours of production following. Units are challenged using 2.0 mm SS Stainless test pieces.	Yes
OPRP	Post Allergen Clean	Cross contamination/undeclared allergens resulting from shared equipment (wheat)	Visual verification that clean has been performed in accordance with validated cleaning SOP	Yes
OPRP	Sanitation/Environmental Cleaning Program	Post lethality pathogen contamination of product	In accordance with the documented arrangements for environmental monitoring; the limit is any positive finding discovered during environmental monitoring	Yes
OPRP	Receiving of Ingredients	Pathogen presence in raw materials	COA review prior to ingredient receipt; zero pathogens present	Yes

Checklist	Section	Summary
ISO 22000:2018 - Food Safety Management Systems	4	<p><b>Context of the organization</b></p> <p><i>Understanding the organization and its context (4.1)</i>  <i>Understanding the needs and expectations of interested parties (4.2)</i>  HQ: General Mills is a company engaged in the manufacture of food products under the following categories: cereal, snacks, convenient meals, yogurt, ice cream and pet food intended for either retail or institutional distribution. The company has defined its purpose as to serve the world by making food people love. The company is 150 years old serving 100+ markets globally with net sales of about 16.9 B in 2019. There are 38,000 employees worldwide and is also considered as the second largest natural and organic manufacturer in the US. Identification of internal and external issues as well as needs and expectations of interested parties is handled by the organization's corporate communications team. Documented information retained on company Sharepoint. Interested parties include customers, consumers, employees, regulatory bodies, vendors, welfare groups and competitors among others. Internal and external issues looked into at the time of visit include those in relation to food safety and labour relations. Company position on these issues have been identified as well as relevant parties involved. (Reference document: Policy 1 – Product Regulatory Compliance)</p> <p><i>Site:</i>  These clauses were covered at the audit of the corporate office.</p> <p><i>Determining the Scope of the FSMS (4.3)</i>  <i>Scope of the Management System</i>  The scope of the site's food safety management system has been properly documented in the facility's food safety manual, as verified by the auditor.</p> <p><i>Food safety management system (4.4)</i>  Measurable objectives have been defined and documented and were found to properly</p>
ISO 22000:2018 - Food Safety Management Systems	5	<p><b>Leadership</b></p> <p><i>Leadership and commitment (5.1)</i>  Evidence of management commitment to the implementation of the FSSC 22000 standard was present throughout the audit via demonstration of adequate resource allocation to support product safety, performance of management review, and the measurement of site performance against measurable objectives in place to support product safety. The corporate support teams of General Mills develop the targets and measurable objectives to support product safety.</p> <p><i>Food Safety Policy (5.2)</i>  Document Cincinnati Food Safety Policy, CI-QRO-POL-014, 8.27.20, serves as the facility's food safety policy. The policy is communicated in the following ways:</p> <ul style="list-style-type: none"> <li>• Posting in high visibility areas – conference rooms, above handwashing sinks, timeclocks, hallways, employee break room, etc.</li> <li>• Reviewed in quarterly management review meetings</li> <li>• As an element of onboarding and annual refresher training</li> </ul> <p>Per this policy, the General Mills Cincinnati facility is committed to compliance with all applicable laws and regulations, the General Mills Corporate Food Safety and Regulatory Matters Policies and Standards, as well as the production of safe and wholesome food.</p> <p><i>Organizational roles, responsibilities and authorities (5.3)</i>  HQ:  The ITQ Global CIE – Food Safety and Quality is headed by Jodi Benson, EVP Chief Innovation and Technology with Mark Fryling as the Vice President. They head a group of quality directors handling the following activities: Labelling and Regulatory Compliance, External Quality Management (Raw Materials and Packaging Materials), External Supply Chain (Co-Manufacturers), Food Safety Center of Excellence (Internal Audits, Sanitation, Hazard, Regulatory Compliance, Zero Lost Culture). For each segment of the business,</p>

ISO 22000:2018 - Food Safety Management Systems	6	Planning	<p><i>Actions to address risks and opportunities (6.1)</i></p> <p>HQ: Food safety risks are managed by the organization through the hazard assessment, food fraud assessment and food defense assessment. Further, the head office (through the VCOE group) manages the food safety management system risk grid calibration based on the results of internal audit, external audit, microbiology and regulatory. A GMI Facility Risk Ranking Tool has been developed.</p> <p>Opportunities are considered as plant controllable risk and used to build improvement targets. Note that the risk ranking tool have been revised recently and 2020 has been considered as a baseline year.</p> <p>Site: Auditor verified that the site has properly identified controllable risks related to the interest parties identified, such as compliance with relevant legislation, compliance with customer requirements etc. The assessment was completed using the GMI Risk Rating Tool referenced above.</p> <p><i>Objectives of the food safety management system (6.2)</i></p> <p>HQ: At the site level, a FSRA (Food Safety Regulatory Assessment) scorecard is being maintained. This is composed of three components: Self-assessment: inspections, verification, environmental monitoring, 4 Quarter Risk Reduction Plan and External Events (plant controllable events) such as recalls, withdrawals, results of audits, regulatory , etc. Objectives are monitored quarterly based on fiscal year. Below objectives relate to the sites directly:</p> <ol style="list-style-type: none"> <li>1. Zero FDA 483 observations at GM facilities</li> <li>2. No loss of GFSI certification</li> </ol>
ISO 22000:2018 - Food Safety Management Systems	7	Support	<p><i>Resources (7.1)</i></p> <p>HQ: Adequacy of provision of resources, infrastructure and work environment are to be assessed for each site.</p> <p>Site: Adequate resource allocation to support effectively implemented food safety and quality management systems was observed throughout the audit. It should also be noted that the facility was able to demonstrate evidence of signification resource allocation to address flaking paint observed by the auditor in several areas of production, as well as roof repairs. At present, the facility currently addresses roof leaks via the placement of plastic tarps with drainage hoses underneath known leak locations. The number of these devices in use has been significantly reduced in recent years (74 total in January 2019 to 38 as of the date of audit.) due to repairs made to the roof, as demonstrated to the auditor. Both the roof and flaking paint repairs are long term capital projects that are directly related to the age of the facility.</p> <p><i>Control of Externally Provided Process, Products, and Services</i></p> <p>HQ: Control of externally provided processes, products or services - Supplier management is a head office controlled function. An initial assessment on the material and supplying location through documentation is performed. Supplier surveys are sent out and assessment is made on the following parameters: regulatory compliance, product control, recall and traceability, third party audit, GMP and sanitation, transportation, product identity and labelling. HACCP, allergens, microbiological controls, thermal processing, ingredients, packaging and premiums, pesticide management, physical hazard detection and control, food defense, process controls, training and quality management. Third party</p>

ISO 22000:2018 - Food Safety Management Systems	8	Operation	<p><i>Operational Planning and Control (8.1)</i>  The site has planned, implemented, controlled, maintained, and updated the processes necessary to ensure ongoing conformity and safety of end products as documented in the relevant sections below. Key hazard control measures to demonstrate effective process control have been defined and implemented as described in sections 8.2, 8.5, and 8.8. In addition, changes to site processes and system documentation are managed in accordance with the processes outlined in section 6.3.</p> <p><i>NC# 4</i>  8.1  Finished product checkweighers are challenged once per shift using a known failure sample. During demonstration of the challenge of the line 15 checkweigher, the sample failed to reject twice and had to be manipulated by the operator to achieve a passing result.</p> <p><i>PRPs (8.2)</i>  HQ:  Prerequisite Programmes - Sites are expected to manage their own specific prerequisite programmes in accordance with FSSC Ver 5 requirements and 18 GM global policies.</p> <p>Site:  Adequate and effective pre-requisite programs have been documented and implemented as described in sections 4-18 of the ISO/TS 22002-1 portion of the report below.</p> <p><i>Traceability (8.3)</i>  To verify the effectiveness of site traceability processes, auditor requested that a traceability exercise be performed during the audit based on the purchase of a product at</p>
ISO 22000:2018 - Food Safety Management Systems	9	Performance evaluation	<p><i>Monitoring, Measurement, and Evaluation (9.1)</i>  The determination of the data that needs to be collected, measured, and evaluated has been adequately defined and documented. Examples of documented monitoring and measuring evidence reviewed by the auditor include product and process measurements outlined in the verification and calibration sections of the report, feedback from customers described in the communication section, the requirements for supplier monitoring, etc. All relevant data collected from monitoring and measurement was observed to be included as input to management review.</p> <p><i>Internal audit (9.2)</i>  HQ:  All internal audits are conducted by the VCOE group, unannounced to all GM facilities. Note that head office audits are more of audits against GM internal procedures. Sites are still expected to execute internal audits against FSSC standard. There are currently five qualified internal auditors from the head office. Verified qualification of internal auditors assigned through auditor on-boarding checklist. Latest sign-off was made for Shanna Morrisette last October 29, 2018. FSSC LAC was completed September 2017. Latest sign off was made for Michelle Sandy dated January 2, 2019. FSSC LAC was completed in 2008. Audit frequency is based on the risk grid. Latest audit plan was updated Nov 13, 2019. Head office audits consists of the following stages: Stage 1 – programs and documentation and Stage 2 – physical inspection of the plant and record review.</p> <p><i>Nonconformances classified as per G-GAP as of June 1, 2018</i>  1. Critical finding – corrective action due to 30 days, food safety or regulatory condition leading to likely contamination  2. Finding – corrective action due to 30 days, does not reach critical finding status but can lead to it  3. Observation – no formal corrective action needed</p>

ISO 22000:2018 - Food Safety Management Systems	10	Improvement	<p><i>Continual Improvement (10.2)</i></p> <p><i>HQ:</i></p> <p><i>Each site is expected to execute continual improvements activities based on the results of the food safety regulatory assessment.</i></p> <p><i>Site:</i></p> <p><i>Evidence of continual improvement was observed through signification resource allocation to address flaking paint observed by the auditor in several areas of production, as well as roof repairs. At present, the facility currently addresses roof leaks via the placement of plastic tarps with drainage hoses underneath known leak locations. The number of these devices in use has been significantly reduced in recent years (74 total in January 2019 to 38 as of the date of audit.) due to repairs made to the roof, as demonstrated to the auditor. Both the roof and flaking paint repairs are long term capital projects that are directly related to the age of the facility.</i></p> <p><i>The facility also routinely trends customer complaint performance, as well as a number of food safety and quality related KPIs to identify areas for continual growth and improvement.</i></p> <p><i>Updating the FSMS (10.3)</i></p> <p><i>The FSMS was observed to be properly updated in all cases in which qualifying events had occurred; i.e., following receipt of customer feedback, discovery of process deviations, an</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	4	Construction and layout of buildings	<p><i>All site production processes were found to be performed on equipment suitable to prevent provision of potential contamination sources.</i></p> <p><i>No potential sources of contamination were observed as a result of the facility location or conditions of the facility environment.</i></p> <p><i>The facility is located in a slightly industrial area with no neighbors that may potentially present a potential source of contamination.</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	5	Layout of premises and workspace	<p><i>The movement patterns of materials, products and people were found to be designed in such a way to prevent potential cross contamination.</i></p> <p><i>The flows of traffic and production were observed to be suitable to facilitate adequate separation between raw and processed areas.</i></p> <p><i>Most internal structures and fittings, including ceilings, walls, floors, windows, etc., were observed to be constructed of cleanable materials and maintained in suitable condition.</i></p> <p><i>All facility equipment was observed to be located in such a manner as not to present a risk to product or packaging materials.</i></p> <p><i>The analytical/chemical laboratories are located outside of the processing area,</i></p>

ISO/TS 22002-1:2009 - Food Manufacturing	6	Utilities – air, water, energy	<p><i>The design and distribution routes of plant utilities were found to be acceptable to minimize risk of product contamination. Proper controls were found to be in place to manage all utilities.</i></p> <p><i>Water Supply:</i>  <i>Water is supplied to the facility by the City of Cincinnati and is a product ingredient in the form of steam at the extrusion step. Auditor reviewed records of annual water testing to include testing for coliform and HPC, as performed on 2.17.20. All results were found to be within specification.</i></p> <p><i>Boiler Chemicals:</i>  <i>Steam is used as a product contact and is treated using chemicals from vendor Nalco. The chemicals in use at the site have been documented on the Boiler House Master Chemical List, CI-QRO-FOR-123.6, 9.18.20:</i>  <i>Nalco 22341</i>  <i>TriAct 1820</i>  <i>Nalco 1720</i>  <i>Letters or guarantee for food contact applications were able to be provided for all boiler chemicals in use by the site.</i></p> <p><i>Atmospheric Air:</i>  <i>Air and dust filters are in place in processing to maintain the atmospheric air in suitable condition.</i></p> <p><i>Compressed Air and Other Gases</i>  <i>Compressed air is used as a product contact and is generated using oil free compressors. In addition, all compressed air is filtered at the discharge of the air compressor via the use</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	7	Waste disposal	<p><i>Dedicated waste containers are in use at the facility, with waste removed from processing areas at an adequate frequency to prevent significant accumulation. Waste containers are color coded in accordance with the SOP Color Coding Policy for Tools and Containers:</i></p> <ul style="list-style-type: none"> <li><i>-Red Tools: Roof/Construction</i></li> <li><i>-Orange Containers: Maintenance use only</i></li> <li><i>-White or Stainless Tools &amp; Containers: Food Contact</i></li> <li><i>-Yellow Container &amp; Tools: Non-food Contact, Certa</i></li> <li><i>-Black Brushes: Drains only</i></li> <li><i>-Blue Brushes: Pipes, Non-Food contact only</i></li> <li><i>-Gray Containers: Trash, Bakery Feeds</i></li> <li><i>-Blue Containers: Recycling, Metal Detector Reject</i></li> </ul> <p><i>Waste management and removal practices were observed to be suitable to support an environment conducive to the prevention of significant accumulation. All facility drains were found to be of suitable design and condition to allow for the proper removal of all liquid waste from the facility.</i></p> <p><i>Packages bearing trademarked information are managed in accordance with SOP Waste</i></p>

ISO/TS 22002-1:2009 - Food Manufacturing	8	Equipment suitability, cleaning and maintenance	<p><i>Piping and other processing equipment in the facility were found to be constructed of durable and cleanable materials</i></p> <p><i>Product contact surfaces in the facility are constructed from stainless steel and other materials approved for use in food manufacturing applications.</i></p> <p><i>Maintenance:</i></p> <p><i>Preventive maintenance in the facility is managed in accordance with SOP Preventive Maintenance, 8.5.1, 1.1.18, and executed using a combination of Maximo maintenance software. Work order print out on a weekly basis in accordance with the PM timeframes that have been programmed into Maximo for each piece of equipment. To facilitate scheduling, a daily meeting takes place amongst the maintenance staff to organize tasks according to priority.</i></p> <p><i>Priority is given to food safety related work orders based on a work type designation that is provided in Maximo. Maintenance requests are given priority based on their criticality, with work orders that affect food safety, quality, human safety, and production capability given priority. The work type in Maximo lists those work orders potentially affecting food safety by designating them as "GMP."</i></p> <p><i>To verify the effectiveness of site PM execution arrangements, the facility maintains the following KPIs:</i></p> <p><i>PM Completion % - # of work orders completed vs # due date</i></p> <p><i>Target: 80%</i></p> <p><i>YTD (by process area):</i></p> <p><i>-Cinnamon Toast Crunch: 109.86%</i></p> <p><i>-Fiber One: 85.32%</i></p> <p><i>-Rice: 80.76%</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	9	Management of purchased materials	<p><i>Supplier Approval:</i></p> <p><i>This was covered at the corporate audit; please see section 7 of the ISO 22000 portion of the report.</i></p> <p><i>Receiving:</i></p> <p><i>Raw materials are received at the Cincinnati site both in bulk and via tractor trailer. In accordance with SOP Raw Material Handling Procedure, CI-LOG-Sop-001, 9.18.20, all incoming delivery vehicles are inspected upon arrival at the facility and prior to receiving materials. Auditor verified the following receiving processes through employee interview:</i></p> <p><i>Bulk (silo storage) Materials</i></p> <p><i>Bulk materials received at the facility include wheat, rice, and sugar by rail, rice flour corn bran, and wheat starch by bulk truck, and molasses, sucrose, and canola oil by tanker truck. The inspection of delivery vehicles prior to receipt is documented on the Bulk Clean Certificate Inspection Form, CI-LOG-FOR-005, 4.9.20, a document that considers such aspects as ensuring that a wash ticket is present for liquids, that dry ingredients have been delivered by a vendor that utilizes dedicated delivery vehicles only, etc. Seals on incoming vehicles are verified to be intact with records maintained via the placement of a stamp on the BOL stating that "seals have been verified and are intact."</i></p> <p><i>COAs on these materials are reviewed by receiving personnel, as well as passed onto QA personnel for verification of conformance.</i></p> <p><i>Tractor Trailer (warehouse storage) Materials</i></p> <p><i>Materials that arrive via tractor trailer include packaging materials, sugar, salt,</i></p>



ISO/TS 22002-1:2009 - Food Manufacturing	10	Measures for prevention of cross contamination	<p><i>Microbiological contamination:</i>  Site products are ready to eat and not microbiologically sensitive based on having a water of activity that is unsupportive of microbiological growth, as demonstrated through presentation of the Process Lethality Validation Summary – Cincinnati Twin-Screw Extruders.</p> <p><i>Physical Contamination:</i>  Metal detectors are employed in packaging designated as CCP. Please see section 8.5 of the ISO 22000 section of the report for more information on these control measures. Several magnets and sifters are also present throughout site processes.  SOP Glass, Brittle Plastic, and Ceramic Policy, CI-QRO-POL-008, 3.18.20, is in place surrounding the handling and inspection of essential glass and brittle plastic in the facility, to include a requirement that no new glass or brittle plastic is permitted in the facility without the approval of management. This procedure also outlines steps to be taken in the event of glass breakage. In accordance with this SOP, annual audits are conducted to verify the condition of glass and brittle plastic in the facility. Auditor reviewed records of this audit from October 2019, as recorded on the Glass and Brittle Plastics CI-QRO-FOR-024C and found all records to be adequately completed, including records of response to address an identified instance of needed repair.</p> <p><i>Allergen Management:</i>  Allergens in the facility are handled in accordance with SOP Allergen Control, CI-QRO-POL-</p>
ISO/TS 22002-1:2009 - Food Manufacturing	11	Cleaning and sanitizing	<p>The plant was observed to be overall clean and well maintained. Routine housekeeping is accomplished in accordance with SOP MSS Documentation Importance and Expectations, CI-SAN-OPL-006, 5.21.19. Per this policy, the facility has defined written schedules for cleaning, with documented information retained as evidence.</p> <p>Chemicals, tools, and procedures for cleaning have been documented in various cleaning SOPs, such as the following reviewed by auditor:</p> <p>-Sanitation Standard Operating Procedure, 5-3, Enrober, CI-SAN-SSP-031, 6.26.19</p> <p>Records of cleaning are maintained on various forms that have been designed for such, to include the following process areas:</p> <p>Mill  Rail/Truck Shed  Liquid Room  Warehouse  Various Processing Areas (Chex, Cinnamon Toast Crunch, etc.)  Packing Areas</p> <p>Auditor reviewed records of housekeeping for all areas of the facility for the months of August 2020 (time period congruent with the product chosen as the subject of the traceability exercise) and found all records to be adequately completed.</p> <p>Auditor also reviewed records of a post allergen clean that was conducted on 9.4.20 when the facility transitioned from running Fiber One (contains wheat) to Rice Chex. Records were indicative of all necessary equipment being cleaned in accordance with the validated protocol for this task, as described in section 10 above.</p>

ISO/TS 22002-1:2009 - Food Manufacturing	12	Pest control	<p><i>Pest control in the facility is managed in accordance with SOP Integrated Pest Management Program, CQ-SAN-POL-002, 10.22.18. In accordance with this policy, all pest control is managed by the site, and at least one employee of the facility that is involved in the management, supervision, and execution of management duties must be trained and licensed according to Ohio State Law.</i></p> <p><i>Auditor reviewed evidence that 5 employees in the facility are licensed to apply pesticides and fumigate accordingly.</i></p> <p><i>As specified in the site pest control policy, rodents, insects, birds, and wildlife are included in the scope of the service. Up to date maps of pest control devices - bait stations, pheromone traps, light traps, and tin cats - in use at the facility are maintained in the pest control binder and were last verified on 6.24.19.</i></p> <p><i>Interior traps ( tin cats and light traps) are monitored on a weekly basis, with exterior traps monitored on a monthly basis. The facility uses U-Trap-It software to document the monitoring of traps. Employees in the facility are also able to report pest activity through the use of the Pest Incident Tracking form on the site's local intranet. The personnel responsible for pest control are then able to comment directly on this form with a response. Auditor reviewed records of a form submitted on 9.18.20 to report a raccoon near a dock door.</i></p> <p><i>Plant storage practices are designed and aligned with the goal of minimizing availability of food and water to pests. A list of pesticides approved for use in the establishment has been documented on the Pest Control Approved Master Chemical List, CI-QRO-FOR-123.2,</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	13	Personnel hygiene and employee facilities	<p><i>Effective implementation of the established procedures and protocols outlined in the site personnel hygiene policies Personnel Hygiene and Employee Facilities, CI-QRO-PRP-013, 12.6.19, as well as Cincinnati GMP Policy, CI-QRO-POL-002, were observed during the site audit.</i></p> <p><i>Hand washing stations were observed to be equipped with soap and paper towels. A suitable number of toilets that do not open direct to the production, storage or packing areas is provided</i></p> <p><i>An employee lunchroom equipped with a refrigerator, microwaves, chairs and tables was found to be well maintained and in clean condition</i></p> <p><i>Uniforms are provided and laundered by Aramark. All employees were observed to be wearing clean uniforms during the audit.</i></p> <p><i>Per the site personnel hygiene policy, employees who suffer or may suffer from any transmissible illness are required to report said condition to their immediate supervisor. Employees who suffer or may suffer from any transmissible illness are required to report said condition to their immediate supervisor. Those with any cuts or other open wounds are required to wear bandages.</i></p> <p><i>To control the spread of Covid 19, temperature scanning prior to facility entry has been implemented, all employees must wear masks, meetings are conducted virtually when</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	14	Rework	<p><i>Rework in the facility is accomplished in accordance with Hold Process, Hold Sampling, Rework, and Refeed, CI-QRO-SOP-002, 8.28.20. Per this policy, when rework into a product is incorporated as an "in-process" step, the product is fed only into a formula of product that is "like into like." All hold rework must also be labeled in a manner that associates it with hold number, product, and lot reasons. Traceability of rework is maintained by reworking product in isolation and printing the original best by date on the box of the new (revised) production run. Lots are therefore not mixed during rework events.</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	15	Product recall procedures	<p><i>As described in the ISO 22000 8.9.5 section of the report</i></p>

ISO/TS 22002-1:2009 - Food Manufacturing	16	Warehousing	<p><i>All aspects of the site warehouse were found to be adequate to provide an environment free of potential contamination sources.</i></p> <p><i>FIFO:</i>  <i>FIFO is managed electronically through the use of Red Prairie Inventory Management Software – this WMS automatically selects the oldest products for shipment when generating pick lists. Once per week, the Freshness Report for Raw and Finished Goods is generated, therefore allowing warehouse personnel visibility to goods that may be expiring soon. Auditor reviewed an example of this report from 8.31.20; for those products that were observed to be expired, auditor reviewed evidence that these materials had been placed on block status and handled accordingly. It should also be noted that some raw materials receive approval status from corporate personnel in order to avoid discarding the materials. These decisions are made based on inspection of material condition by site personnel, as well as discussion with product development personnel.</i></p> <p><i>No issues related to containers and conveyances were observed during the audit. All fork trucks are battery powered, and all storage containers for product are assigned a designated, solitary product use.</i></p>
ISO/TS 22002-1:2009 - Food Manufacturing	17	Product information/consu	<i>Labelling is handled at the corporate level; however, auditor verified that all site products are labelled with proper information to enable consumer knowledge, such as ingredients</i>
ISO/TS 22002-1:2009 - Food Manufacturing	18	Food defense, biovigilance and bioterrorism	<i>As documented under the FSSC requirement below. Auditor also verified through employee interview that seals are placed on outbound deliveries with the # recorded on the BOL, as well as verified to be present prior to accepting incoming deliveries of</i>
FSSC 22000 - Additional Requirements	2.5.1	Management of services	<p><i>HQ:</i>  <i>Sites do not typically have full service laboratories and have limited testing capabilities. Accredited methods indicated in Global PLM or Interspec for sites to refer to. Testing is usually outsourced to an external provider. The sites can opt to send samples for analysis to Medallion Laboratories which is a part of General Mills Inc.'s external phasing business and is a shared service between facilities. The laboratory has a valid ISO 17025 Accreditation valid until June 30, 2021. Medallion Laboratories also set-up internal reference materials for sites to use. However, due to geographical location, sites would have to utilized local laboratories which are ISO 17025 accredited as expected by the head</i></p>
FSSC 22000 - Additional Requirements	2.5.2	Product labelling	<p><i>HQ:</i>  <i>The labelling and regulatory compliance group is in charge of managing all product labelling requirements. The site uses a system called Interspec to generate labels. Ingredients used are prepopulated on the system and will allow the site to determine which are used, restrictions, allergens, addition and grouping, component label settings. An ingredient allergen report can also be generated. Associated formulas and nutrition information are also linked to Interspec. Label information for a cereal product (Cheerios) was sampled for this visit. BMN Series 33628101, 3388634101. Ingredients: whole grain oats, sugar, corn syrup, corn starch, salt, trisdodium, natural flavor, Vitamin E, added to preserve freshness, etc. Contains: Coconut. Gluten Free Claim was made for this product. All ingredients have been marked as gluten free as per ingredient claims and certification report. Further verified through Medallion Labs – Aug 22, 2019 – 12 boxes 22AUG2019 – Gluten average 2.2 ppm Ridascreen Total Gluten R47041. An Electronic Comprehensive Labelling Information and Product System (ECLIPS) is used by the sites. As the new packaging arrives in the facility, the site compares the information declaration versus the approved keyline (pdf version of approved packaging). The site also verifies the base</i></p>

FSSC 22000 - Additional Requirements	2.5.3	Food defense	<p>HQ:  <i>Sites are prescribed to use the FDA Food Defense Builder for the food defense assessment. Sites are expected to conduct the food defense assessment review annually. Head office also conducts the review annually during VCOE audits. The site is to document the facility food defense team, training, policies and procedures that support personnel, food safety and physical security and incident response programs and procedures. Each facility is to have their own self-assessment, risk mitigation action plan, emergency contacts, facility profile and food defense members.</i></p> <p>Site:  Threat Assessment:  <i>Food defense is accomplished in accordance with the arrangements listed in the Cincinnati Food Defense Policy, CI-QRPO-POL-014, 9.14.20. The policy includes identification of the food safety team, training requirements, a description of facility security controls, etc. The facility has conducted a food defense risk assessment using the FDA Food Defense Plan Builder. The assessment was conducted in January 2020, and includes documentation of the routine security measures that are in place to mitigate any food defense risks in the following areas:</i></p> <p><i>Outside Security  General Inside Security  Logistics and Storage Security  Management</i></p> <p><i>The facility has conducted a food defense risk assessment using a HACCP style methodology for each of the site's key processes that constitute the focus of their Food Safety Plan. The risk assessment performed includes the process steps depicted in the flow</i></p>
FSSC 22000 - Additional Requirements	2.5.4	Food Fraud mitigation	<p>HQ:  <i>Food fraud/ vulnerability assessment is managed by the head office's Food Fraud Mitigation Team. Global Food Fraud Prevention Plan was last revised March , 2019. Food Fraud Initial Screening is made through horizon scanning which involves reviewing external media reports, peer reviewed journal publications, regulatory documents, internal discussions with legal and corporate security. Food Fraud Vulnerability Assessment is made through SSAFE tool listing fifty question which cover opportunity, motivation, and control measures to food fraud. Horizon scanning strategy includes the following information sources: RASFF alerts, USFDA recall notifications and organic certifications, selerant email alerts, EU knowledge center for food fraud and quality, trello food fraud databse, Europol, Food track Inc., scopus alerts of peer reviewed journals related to food fraud. The food fraud team collects relevant information and reviewed periodically over the course of the year. Latest review dated Jan 6, 2020 for horizon</i></p>
FSSC 22000 - Additional Requirements	2.5.5	Logo use	<p><i>The site does not use the FSSC logo in any way.</i></p>
FSSC 22000 - Additional Requirements	2.5.6	Management of allergens (Only for categories C, E, FI, G, I & K)	<p><i>Potential allergen cross contamination in the facility in the was observed to be properly risk assessed in the site HACCP plan. In accordance with this Allergens in the facility are handled in accordance with SOP Allergen Control, CI-QRO-POL-009, 9.15.20. In accordance with this policy, a list of allergens handled at the facility has been documented on the Cincinnati Allergen/Organic Changeover Matrix, CI-QRO-FOR-048, 4.14.20. Per this document, the facility handles wheat and lecithin; this document provides a listing of all product handled at the facility, as well as an indication of type of cleaning that is required to be performed between product changeovers, such as those documented in SOP Line 15 6-2 Distribution Allergen Clean, CI-SAN-SSP-002, 2.1.15; this policy was observed to</i></p>

FSSC 22000 - Additional Requirements	2.5.7	Environmental monitoring (Only for categories C, I & K)	<p><i>Environmental monitoring is accomplished in accordance with SOP Pathogen Environmental Monitoring Program for GMI Cincinnati, CI-QRO-POL-006-002. Per this policy, the facility has been broken down into 4 zones for the purposes of this program:</i></p> <p><i>Zone 1: Direct product contact surface</i></p> <p><i>Zone 2: Non-product contact surfaces in close proximity to product contact</i></p> <p><i>Zone 3: Peripheral areas of production that if contaminated with a pathogen, could lead to contamination of zone 2 via movement of humans or machinery</i></p> <p><i>Zone 4: Non-production areas</i></p> <p><i>Sampling arrangements have also been assigned defined criteria as follows:</i></p> <p><i>Routine Fixed</i></p> <p><i>Routine Variable</i></p> <p><i>Non-Routine Positive Mitigation / Investigation</i></p> <p><i>Non-Routine Event Based</i></p> <p><i>During Production</i></p> <p><i>Before Start Up</i></p> <p><i>Not Running</i></p> <p><i>In accordance with these SOP defined arrangements, a monthly sampling schedule has been created, as documented in the PEMP Sites Excel file. The target organisms of the site's environmental monitoring program have are listeria and salmonella, with the organism being dependent upon the area. Proper corrective actions to be taken in the event of failure have also been defined in the site SOP. The site has not had 3 instances</i></p>
FSSC 22000 - Additional Requirements	2.5.8	Formulation of products (Only for category D)	NA

Checklist	Section	Clause	Requirement	Con	Grade	Finding details	Remark	Acceptance date
ISO 22000:2018 - Food Safety Management System	Support	7.2	Competence	No	Minor	Records of onboarding food safety / GMP training are not clearly documented.  During review of a completed JTA/QIT checklist, a form used to document job specific competency verification, it was observed that the form was not dated or signed by the learner or evaluator. In addition, none of the fields intended to be initiated by the learner to verify understanding of each individual task had been completed.		2-Oct-20
ISO 22000:2018 - Food Safety Management System	Operation	8.1	Operational planning and control	No	Minor	Finished product checkweighers are challenged once per shift using a known failure sample. During demonstration of the challenge of the line 15 checkweigher, the sample failed to reject twice and had to be manipulated by the operator to achieve a passing result.		2-Oct-20
ISO 22000:2018 - Food Safety Management System	Operation	8.5	Hazard control	No	Minor	The Product Description document for RTE cereals does not include the biological, chemical, and physical hazards relevant for food safety (i.e. water activity/moisture, allergen content, etc.).  The intended use statement for site products does not include consideration of groups of consumers/users known to be especially vulnerable to specific food safety hazards (i.e., allergenic consumers)		2-Oct-20
ISO 22000:2018 - Food Safety Management System	Operation	9.3	Management review	No	Minor	Records of management review were observed to have action items identified as output. Not documented however were the identification of owners and timeframes in accordance with arrangements provided in the Assigned Action Item table included on the minutes templates, Management Review Met, CI-QRO-FOR-054, 6.8.20.		2-Oct-20
ISO 22000:2018 - Food Safety Management System	Performance evaluation	13.7	Personal cleanliness	No	Minor	An employee was observed to be entering the facility to begin work at shift change. Auditor witnessed this individual wash his hands for approximately 2-3 seconds. This period of time is not adequate to ensure proper cleaning of hands before beginning any food handling activities.		2-Oct-20
ISO/TS 22002-1:2009 - Food Manufacturing	Personnel hygiene and employee facilities							