Food Safety Audit Expectations
for
Costco Suppliers

Version 1.0

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General Audit Requirements

Costco's Food Safety Commitment

Food safety and food quality are interrelated objectives - both of which require deliberate planning, execution, and monitoring. Food safety audits are vital to maintaining the highest possible food safety and quality standards for food products. Audit reports provide accurate information on the compliance and overall food safety status of current and prospective suppliers, while also providing a framework for future improvements.

To ensure confidentiality, audit information will only be shared internally between the Costco Food Safety Audit Team and Costco Buyers. The Costco Food Safety Audit Team will review audits to identify opportunities for improvement and ensure that corrective actions are completed, while the Costco buying staff will use audit information to guide purchasing decisions.

Costco Audit Requirements – Food and Produce

- All locations/facilities that process, pack, warehouse, or distribute consumable products (e.g. food, beverages, supplements) or supply food-contact packaging materials to Costco are required to have an annual third-party food safety audit. Suppliers located in China must complete two food safety audits per year.

- Fresh produce suppliers that grow, harvest, pack, cool, process, store, and distribute produce items are required to have an annual third-party food safety audit. All produce suppliers in China must complete two food safety audits per year.

- To be accepted by Costco, audits must be performed by a Costco-approved audit company. The only exception is for new suppliers who wish to submit a previously-completed audit (within the past 12 months) for review. The full audit report must be submitted to Costco, in addition to corrective action responses for each deficiency. If a previously-completed audit report is accepted, the supplier's anniversary audit must be a Costco-approved audit scheme and shall be conducted by a Costco-approved audit company.

- Costco will only accept audits/certifications performed while the audit site is fully operational. While preferable, suppliers are not required to be producing product, cultivating or processing crops for Costco at the time of the audit. However, similar products and processes must be witnessed by the auditor.

Costco-Approved Audit Companies

Costco will only accept audits or certifications from the approved list of audit companies below. If a supplier ships to Costco in multiple countries, they must use an audit company that is approved-for-use by all countries they supply product to.

To ensure objectivity in the audit process, Costco requires audit companies to rotate their auditors every three years (at minimum).

Out of consideration to site employees, and to prevent auditor fatigue, Costco expects each audit day to be limited to no more than 10 hours.

United States
Acerta
AIB International
Asure Quality
AUS-MEAT / AUS-QUAL
BSI Group
Control Union
DNV-GL
Eagle Food Registrations
Eurofins
FoodChain ID (formerly Cert ID)
Food Safety Net Services
Intertek
LRQA
LSQA (GAP audits only. No facility audits.)
Mérieux
NSF International
PMC
Primus Auditing Operations (PAO)
Safe Food Certifications
SCS Global Services
SGS
TUV USA / TUV Nord
UL-STR
WQS-QIMA / QIMA (formerly Asia Food Inspection)
Validus

Australia - same as U.S. with the addition of:
Bureau Veritas

Canada - same as U.S. with the addition of:
Bureau Veritas
SAI Global

France - same as U.S. with the addition of:
Afnor
Bureau Veritas
Dekra

Japan - same as U.S. with the addition of:
Bureau Veritas
JFIC

Korea - same as U.S. with the addition of:
Bureau Veritas

Mexico - same as U.S. with the addition of:
Bureau Veritas
Global STD certification

Spain - same as U.S. with the addition of:
Aenor
Applus
Bureau Veritas

Taiwan - same as U.S. with the addition of:
Bureau Veritas

U.K. / Iceland - same as U.S. with the addition of:
Bureau Veritas
* U.K. will accept BRC Certifications or Salsa Audits regardless of audit company. The UK also accepts ISO Certifications.

Accepted Facility Audit Types and Scoring Requirements

GFSI (Global Food Safety Initiative) Audits

- Costco accepts **BRC, SQF, IFS, GFSI Global Markets Program Assessment**, and **FSSC 22000** audits (annual FSSC surveillance audit with Costco Addendum must be shared with Costco regardless of certification expiration date). All GFSI surveillance audits must be shared with Costco.

- A Costco GFSI Addendum must be completed for each GFSI scheme listed above. If the GFSI Addendum is not completed when requested by Costco, the audit company must return to the site and complete the Addendum at the audit company's expense. If a supplier cancels the addendum when one is required, the audit company will return to the site at the supplier's expense to perform the addendum.

All certification and recertification audits must be current (within the past 12 months). Costco will only accept GFSI certifications from Costco-approved audit companies (except for new suppliers). The audit company must post the preliminary audit results in the appropriate Costco audit database within 7 calendar days. Suppliers must notify Costco immediately via email or phone in the event their GFSI certification becomes suspended or cancelled.

Costco's GFSI Score Requirements	
BRC	Grade **B** or above
SQF	Total preliminary score of **85** or above
IFS	Total preliminary score of **85** or above
FSSC 22000	**Successful Certification** (audits are not scored)
Global Markets Program Assessment	**GFSI Global Markets Program Assessment for Primary Production** Initial Assessment must meet Basic Level at **90%** or above Second Year Assessment must meet Intermediate Level at **75%** or above Third Year Facility must obtain full **GFSI Certification** or complete a **GMP/GAP Audit** per Costco's requirements.

Global Markets Program Assessment	**GFSI Global Markets Program Assessment for Manufacturing** Initial Assessment must meet Intermediate Level at **80%** or above Second Year Assessment Facility must obtain full **GFSI Certification** or complete a **GMP Audit** per Costco's requirements. • Note: Costco prefers the assessments to be conducted by a Costco-approved audit company. In the rare event that Costco-approved audit companies are not available to the supplier, Costco will require that the chosen audit company be accredited against ISO/IEC 17065 and/or ISO/IEC 17021. The audit company shall be accredited by an IAF member Accreditation Body which can be found on the IAF website: www.iaf.nu. Suppliers must notify Costco in advance to verify that the audit company meets these requirements.

Primary Packaging Manufacturers (Food-Contact)

Costco accepts Packaging Audit reports (i.e. bag, film, clam shell) from a Costco approved Audit company. Costco will accept either a GFSI Certification or the audit company's unique Packaging Audit.

Scoring Requirement: Costco will defer to audit scheme scoring requirements.

N60 Addendum (Only Applicable to Suppliers of Raw Beef to Costco Facilities)

All suppliers that provide raw beef protein components to Costco's Tracy, CA and Morris, IL meat plants must also complete an N60 Addendum. Costco will accept both the Costco N60 Addendum as well as N60 audits developed and performed by Costco-approved audit companies.

Scoring Requirement: Costco will defer to audit scheme scoring requirements.

Distribution Center/ Warehouse Audits

Costco accepts Distribution Center/ Warehouse Audits when conducted by a Costco approved audit company. Costco will accept either a GFSI Certification or an audit company's unique Distribution Center / Warehouse Audit form.

Scoring Requirement: Costco will defer to audit scheme scoring requirements.

cGMP Audits (Supplements and Pharmaceutical Industry)

Costco accepts cGMP audits (Current Good Manufacturing Practice) when conducted by a Costco approved audit company. cGMP audits verify that manufacturing facilities and processes are designed, implemented, monitored, and controlled appropriately.

Scoring Requirement: Costco will defer to audit scheme scoring requirements.

Costco GMP Audit

Costco GMP audits are required to be unannounced. The audit must be conducted within a 90-day audit window from the date of the previous audit (45 days before/after audit anniversary date). Audit companies will contact suppliers to schedule audits within the specified timeframe.

During the scheduling process, the audit company will ask the site to provide blackout dates (if any). A blackout date is a period of time in which the site will not be operational or producing Costco product or like product. Blackout dates are strictly limited to non-production days and will not be granted for any other reason. Unless blackout dates are provided by the site, all days within the 90-day audit window will be considered "audit ready" dates. If a site is not operational on an audit-ready-date, the audit must be rescheduled within the original 90 day window at the supplier's expense. It is advisable to check with your audit company regarding their cancellation policy and associated fees.

The majority of Costco GMP audits can be completed in a single audit day, though certain audits may require a second day due to the size, complexity, and readiness of a facility.

Scoring Requirement: Minimum score of **85** in each category. No Critical Findings.

Costco Small Supplier Audit

Suppliers that have fewer than 25 employees and have not previously completed a third-party food safety audit are eligible for a Costco Small Supplier Audit. Unlike the Costco GMP Audit, Small Supplier Audits are always announced. Small Supplier Audits are intended as an introduction to Costco's food safety program and are to be performed on a one-time-basis only. All subsequent audits completed for Costco must be either a Costco GMP audit or GFSI Certification with Costco Addendum.

Scoring Requirement: Minimum score of **75** in each category. No Critical Findings.

Animal Welfare Audits

Facilities that slaughter, convert animals into food, or have an on-farm environment (i.e. laying hens, dairy cattle, etc.) are required to have an annual animal welfare or certification audit. Please refer to the Costco Animal Welfare Audit Expectations Document for further information.

Corrective Action Plans (CAPs) – All Audits and Costco Addendum

A Corrective Action Plan or Corrective Action Report (CAP or CAR) is an outline of all non-conformances found during the audit that should address the following:

o   Employee(s) responsible for corrective actions

o   Root Cause Analysis

o   Corrective Action

o   Preventive Plan

o   Completion Date (or estimated completion date)

Corrective Action Plans must be submitted to, reviewed, and approved by the third-party auditor or audit company. The CAP must be uploaded to the appropriate audit database within 14 calendar days of the audit being posted. During the anniversary or re-certification audit, the auditor will confirm that all corrective or preventive actions from the previous year's audit have been implemented.

GFSI certification and surveillance audit non-conformances must be addressed per scheme requirements.

Non-conformances identified in Costco GMP, Small Supplier, or Costco GFSI Addendum reports must be addressed with a corrective action response if the total score is below 98%. During the site's anniversary audit or re-audit, the auditor will verify that non-conformances from the previous audit have been satisfactorily addressed. If Costco GMP or Addendum non-conformances from the previous audit are not corrected by the time of the anniversary audit, each repeat non-conformance will be awarded a score of "0" points. Corrective actions will still be required for audits scoring 98% and above, but these do not need to be submitted to Costco for review. Scoring and corrective action requirements for Costco audits are listed in the table below.

Corrective Action Requirements		
Score	Rating	Action
98 - 100%	Excellent	Corrective Actions required, but do not need to be submitted to a Costco audit database
85 - 97%	Satisfactory	Corrective Actions required
< 85% total score for scored GFSI schemes; **Grade C** or below for BRC **Unsuccessful certification** for FSSC 22000 **< 85%** in any category: GMP audit **< 75%** in any category: Costco Small Supplier	Failed	Corrective Action and **Re-Audit Required within 60 days**

Re-Audit Criteria: GFSI and Costco Audits

Audit companies are required to notify Costco of all failed audits within 24 hours. A failed audit of any type will trigger an announced re-audit within 60 days of the initial audit date. All corrective actions identified in the original audit must be verified during the re-audit.

Failed GFSI audits will trigger a Costco GMP re-audit within 60 days, independent of GFSI requirements for maintaining Certification. For Costco GMP and Small Supplier audits, the re-audit completion date will become the new anniversary date.

Failing the Costco GFSI Addendum with a critical failure or a total score of less than 85 could result in a re-audit. Costco will make re-audit determinations on a case-by-case basis.

Costco will require re-audits under the following circumstances:

- Direct product contamination is observed by the auditor.

- The site does not take documented corrective actions when critical limits are not met.

- Employees with sores, infected wounds or other infectious illnesses are observed in direct contact with exposed food, primary packaging, or production / storage areas.

- Allergens are present in the facility, but an allergen control program has not been developed.

- A documented SSOP Program (Standard Sanitation Operating Procedures) has not been established and/or implemented.

- A documented Food Safety Plan or HACCP Plan has not been established (as per regulatory requirements).

- A written pest control program is inadequate or has not been established.

- Facility water is not from a potable source.

- The facility has been issued an FDA warning letter (Form 483).

- Water potability is not tested by a certified laboratory and records are not maintained (annual testing for municipal water sources and quarterly for well water).

- Finished products are not properly coded for traceability.

- Evidence of <u>decomposed</u> pests in the interior of the facility (including <u>decomposed</u> pests in traps).

- Pests or evidence of pests (such as fecal matter) on, or in any food ingredient, food contact surface, packaging material, or finished product (common pests include, but not limited to: insects, spiders, rodents, amphibians, mammals or birds).

- A product recall, serious incident, or Costco concern will initiate an immediate Costco GMP audit. These audits will be conducted independent of the anniversary audit timeline and will not impact GFSI Certification, if applicable.

Note: – Applicable to Suppliers that Manufacture In, or Import to, the United States

- The facility cannot provide proof of FDA registration for the Bioterrorism Act, or are not in compliance with USDA requirements.

- A Hazard Analysis has not been established per FDA Preventive Controls requirements or USDA regulations. A **hazard analysis** is a systematic review that identifies, evaluates and controls hazards which are significant for food safety.

Audit Databases

Audit reports and corrective actions will be uploaded to a Costco audit database by the audit company and must be translated to a language accepted by that country – i.e. English for the U.S. (please e-mail your Costco food safety contacts for country-specific requirements). Audit companies are required to upload Costco audit reports (GMP, Small Supplier, Distribution/Warehouse and Packaging audits) and preliminary GFSI certification reports within 7 calendar days from the date an audit is completed. Each facility is required to submit their corrective action plan (CAP) to the audit company within 14 calendar days of the audit report being posted to a Costco audit database. For Certification audits, the final version of the GFSI audit will be posted upon issuance. GFSI audits will follow the Certification Program owners' timetable for posting.

EFA (Enterprise Facility Audit) Database

With the exception of fresh produce operations, all facilities are required to be registered in the EFA (Enterprise Facility Audit) database. As of the publication date of this document (11/30/2018), only the U.S. and Canada are active within the EFA database – though all Costco countries will eventually join EFA. For now, suppliers to other Costco countries should clarify their database registration requirements with a member of the respective Costco food safety team or their Costco buyers.

Facilities that supply the U.S. can request registration forms by e-mailing fsa@costco.com. Facilities that supply Canada can e-mail cnfsa@costco.com. If a facility supplies product to both Costco U.S. and Costco Canada, completed registration forms should be sent to the Costco U.S. team. Costco food safety staff will complete the actual registration process in the system.

Because EFA is designed to hold audit documents for Costco's internal reference only, facilities will not have access to the EFA system. Only suppliers (the business that receives purchase orders from Costco) will be credentialed in the system. Credentialing is a process in which Costco grants EFA access to verified supplier contacts. Credentialed users will have visibility to the status of audits, but will not have access to the documents themselves. Suppliers who need access to audit documents can request these from the facility that paid for the audit, or from the audit company if a data-sharing agreement is in place. Credentialed supplier contacts can access the EFA database by following the link below.

https://bpm.costco.com/ProcessPortal/login.jsp

TraQtion

All facilities currently registered in the TraQtion database will be transitioned to EFA as their TraQtion registrations expire. New and prospective Costco suppliers will be required to register in EFA, not TraQtion. Costco audit coordinators will contact each facility when they are eligible for EFA onboarding. If you have questions on the transition from TraQtion to EFA, please send an e-mail to the Costco Food Safety Team: fsa@costco.com.

Azzule Systems (Fresh Produce)

Costco is using Azzule Systems to manage Fresh Produce audit information (i.e. audit reports, corrective actions, and certificates). Suppliers in Azzule are expected to maintain complete supply chain transparency for all product(s) sold to Costco. To that end, suppliers and audit companies should adhere to the following requirements.

1. Suppliers should instruct their audit company to submit their Costco Addendum(s) using the Azzule Auditing Software.

2. Additionally, audit companies should submit 3rd party food safety audits using the Azzule Auditing Software or audit company Supply Chain Program (CB SCP), depending upon audit scheme. This submission process will post the audit to the auditee's Supply Chain Program (SCP).

3. Costco suppliers can then access their SCP to transfer the audit to Costco's Azzule site. If the supplier is not the auditee, they can retrieve the audit and then send to Costco's Azzule site.

The most current Costco Food Safety Audit Expectations and Addendum documents can be found through this link on the Azzule website:

http://www.azzule.com/services/costcoaddendumsandexpectations.aspx

For Azzule related questions please contact Azzule Support by email at support@azzule.com or by phone:

U.S.A +1 805-354-7127

Mexico +52 66 77 16 50 37

Chile +56 32 3325045

Costco-Specific Food Safety Requirements

Costco Auditor Evaluations (Shadow Audits)

Auditor evaluations are a key component of Costco's Food Safety Audit Program because they enable us to determine auditor competency. This process, known in the industry as a Shadow Audit, takes place during audits at our suppliers' facilities. During a shadow audit, a member of the Costco Food Safety staff will accompany the auditor for the entire duration of the audit. Once the audit is completed, the Costco employee will complete a written auditor evaluation, which will be submitted to the audit company.

During the evaluation, the Costco employee will examine all documentation reviewed by the auditor and will also walk the entire facility during the inspection (interior and exterior). In addition, the Costco evaluator will take notes during the audit on any observations that may have been overlooked in the audit - though these items are not discussed until after the auditor is finished with the closing meeting. At no time are the Costco observations used for audit purposes, nor do they impact audit scoring. To ensure that Costco's concerns are addressed, facilities must provide Costco with an e-mailed corrective action response for each observation.

Costco appreciates supplier cooperation with this important program.

Country-Specific Requirements for Costco International Regions

All of the countries that Costco does business in have unique legal requirements that suppliers must follow. Questions on country-specific requirements for international regions should be directed to the appropriate Costco food safety team(s).

HACCP and Preventive Controls (FSMA)

HACCP Defined (Hazard Analysis Critical Control Point)

According to the FDA, "HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles."

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the Critical Control Points (CCPs).

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

Preventive Controls Defined

FSMA (Food Safety Modernization Act) – A U.S. Food Safety Act passed into law in 2011. The Act places emphasis on the prevention of foodborne illness rather than reacting to outbreaks of foodborne illness. The Act contains 7 rules: **Preventive Controls for Food for Humans**; Preventive Controls for Food for Animals; Sanitary Transport of Human and Animal Food; Produce Safety; Foreign Supplier Verification; and Accredited Third-Party Certification (used for the Voluntary Qualified Importer Program (VQIP)).

Preventive Controls Rule takes HACCP a step further by requiring suppliers to become more proactive instead of reactive. Preventive Controls are those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis. These controls must be consistent with the current scientific understanding of safe food manufacturing, processing, packaging or holding at the time of the analysis.

USDA & FDA HACCP Programs

- Seafood, Juice and low acid canned foods fall under FDA HACCP regulations and must operate a HACCP plan for their operation.
- USDA Regulations apply to beef, pork, poultry, catfish and egg products. Items that are regulated by the USDA are required to operate under a HACCP Program
- All other food types will require a preventative controls plan

Costco's HACCP/Preventive Control Requirements

- Processing facilities that do not supply Costco product to the U.S., but do supply Costco's international regions, must operate under a HACCP Program or Preventative Control Plan.

- Each facility must have a written Food Safety Plan that includes a detailed risk assessment. The facility should use the results of the risk assessment to determine whether Critical Control Points or Preventive Controls are necessary. This is a Costco requirement, independent of regulatory guidelines.

- Facilities that do not have an established HACCP Plan or Preventive Control Plan at the time of their initial Costco audit must implement one prior to their anniversary audit. Failure to comply will result in an automatic failure of the anniversary audit.

- The person or persons responsible for the HACCP program or Preventative Control Plan must successfully complete formal HACCP or PCQI training by a credible agency in a classroom environment. If a person is already HACCP trained in classroom, the PCQI training could be taken either in classroom or on-line.

- The person or persons responsible for the Preventive Controls Plan must be a recognized PCQI (**P**reventive **C**ontrol **Q**ualified **I**ndividual – aka "**Q**ualified **I**ndividual") per the FDA requirements. A **qualified individual (QI)** is a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

- HACCP and PCQI certifications must be current within 5 years. For recertification only, Costco will accept in-class or online courses conducted by a credible agency.

Microbiological Testing

Environmental Sampling Program Requirements

Facilities that are producing Kirkland Signature products or high risk items must have a documented Environmental Sampling Program to detect pathogens of concern. High risk items are foods or food-products with inherent characteristics that heighten the risk of microbiological growth, physical hazards, or chemical contamination that may be injurious to consumers. High-risk-product is also that which is deemed high risk by Costco or declared high risk by a regulatory body due to previous foodborne illness outbreaks.

The Environmental Sampling Program should be robust and must include sample frequency, site selection, test results and corrective actions. Sampling frequency and site selection must be based on a risk assessment of the facility and product involved. A validation study must be completed to demonstrate the effectiveness of the program. If positive test results are obtained (presence/indicator of target organism), full details of the cause analysis, corrective actions and retesting results must be available for review by Costco Food Safety upon request.

The following items are an example of what are identified as high risk:

- Fresh produce suppliers with production and storage facilities where water is introduced (wash step, high humidity storage, wet cleaning processes, etc.).

- Suppliers producing foods that are ready to eat (cut produce and foods that don't require further cooking) or foods that are naturally susceptible to bacterial growth (i.e. sliced lunch meats, dairy products, cooked meat and fish, frozen fruits and vegetables, cut salad mixes, baby leaf salads, cut fruit, prepared vegetable trays, and cantaloupe – page 19).

Test and Hold Requirements

Costco suppliers of high risk items must have a documented Finished Goods Microbial Test and Hold Program in place to detect pathogens of concern. The test and hold program should include a robust sampling plan developed by the food safety staff that is designed to detect the organisms of concern.

An example of an appropriate sampling plan in a high risk ready to eat food processing facility would include at a minimum an N=60 sampling plan. The sampling plan should utilize a grab sample with hourly composite sampling and have appropriate lot definition with hourly test results.

For more information on microbiological sampling and testing programs, please review the list of references below. Please contact your Costco buyer if you are unsure of the test and hold requirements for your item(s).

○   ICMSF (International Commission on Microbiological Specifications for Foods)

- ○ (2005) Microorganisms in Foods, 6, Microbial Ecology of Food Commodities, Kluwer Academic/Plenum Publishers, New York, U.S.A

- ○ (2002) Microorganisms in Foods, 7, Microbiological Testing In Food Safety Management, Springer, New York, U.S.A MIL Standard 105

Water Testing Requirements

Water used in any processing operation must be from a microbiologically potable source. Costco requires this to be confirmed through testing by a certified third-party laboratory. Costco requires any municipal water source to be tested annually and well water to be tested quarterly. Samples must be drawn from various sites throughout the facility and test records are to be maintained. Water used for either processing or sanitation purposes must be tested for generic E.coli.

Allergens

Costco requires that all facilities have a documented allergen control program that addresses all countries they produce product for. The table below lists the allergens and labeling requirements for all countries that Costco currently operates in.

United States	Crustacean Shellfish, Egg, Fish, Milk, Peanut, Soy, Tree Nuts, Wheat *(Gluten)*, Sulfites *(≥10mg/kg)*
Canada	Crustacean Shellfish, Egg, Fish, Milk, Peanut, Soy, Tree Nuts, Wheat or Triticale, Cereals w/ Gluten, Molluscan Shellfish, Mustard, Sesame, Sulfites *(directly added or equal to 10mg/kg)* CFIA Link
EU / UK / Iceland	Crustacean Shellfish, Egg (any farmed animal), Fish, Milk (any farmed animal), Peanut, Soy, Tree Nuts, Cereals w/ Gluten *(including Wheat or Triticale)*, Celery, Lupin, Molluscan Shellfish, Mustard, Sesame, Sulfites *(≥10mg/kg)* EU Regulation Regulation (EU) No 1169/2011 Annex II update
Mexico	Crustacean Shellfish, Egg, Fish, Milk, Peanut, Soy, Tree Nuts, Cereal Grains w/ Gluten, Sulfites *(≥ 10mg/kg)* ESHA Research Link FARRP Link

Australia	Crustacean Shellfish, Egg, Fish, Milk (any product containing milk from an animal source), Peanut, Soy, Tree Nuts, Wheat, Cereal Grains w/Gluten *[(A) where these substances are present in beer and spirits; or (B) glucose syrups that are made from wheat starch and that: (a) have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and (b) have a gluten protein content that does not exceed 20 mg/kg; or (C) alcohol distilled from wheat]*, Lupin, Molluscan Shellfish, Sesame, Sulfites *(≥10mg/kg)*, Bee Pollen / Propolis, Royal Jelly **Note:** if a food is or includes as an ingredient royal jelly, the following warning statement is required: 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers' Australia Food Code Link Section 1.2.3, subsections 2, 3, & 4 list mandatory advisory statements, warning statements, and declaration of foods or substances.
China	Crustacean Shellfish, Egg, Fish, Milk *(including milk sugar)*, Peanut, Soy, Tree Nuts, Wheat, Grains containing gluten and their products *(suah as wheat, rye, barley, oats, spelt or their cross breeding strains)* *China disclosed draft regulation for GB 7718 (Standard for general labeling for prepackaged food) and GB 28050 (Standard for nutritional labeling for prepackaged food) in November 2018, am unable to pull the draft documents. There will be changes made to the labeling regulations for allergens, however, it is not clear if the list itself is changing.
Japan	**Mandatory:** Crab, Shrimp/Prawn, Egg, Dairy Products, Peanut, Wheat, Buckwheat **Recommended**: Abalone, Mackerel, Squid, Salmon, Salmon Roe, Cashew nut, Walnut, Matsutake Mushroom, Sesame, Soybean, Yam, Apple, Banana, Kiwifruit, Orange, Peach, Beef, Chicken, Gelatin, Pork. CAA Japan Link **Note:** recommended allergen labels are mandatory unless facilities can prove that cross-contamination is not a factor.

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Korea	Crab, Shrimp/Prawn, Egg *(confined to those from Poultry)*, Mackerel, Milk, Peanut, Soy *(including highly refined oils)*, Walnut, Wheat, Buckwheat, Squid, Clam *(including Oysters, Abalone, Mussel)*, Peach, Pork, Tomato, sulfurous acid *(confined to cases where sulfurous acid is added and the final product includes 10mg/kg or more SO2)*, Chicken, Beef, Squid, MFDS Labelling Requirements Link "May contain" statements are mandatory for Korean products that have a shared manufacturing process (workers, utensils, production line, storage of ingredients, etc.) with allergens, regardless of sanitation procedures.
Taiwan	Crustacean Shellfish, Conch, Eggs, Milk, Peanuts, Mango, Kiwi, Soy, Tree Nuts, Sulfites *(≥ 10mg/kg)*, Cereals containing Gluten , Sesame, Fish, Mollusks, Buckwheat, Celery, Lupin and Mustard The warning information prescribed in Article 3 shall be labeled as either way: (1) Labeling on the package with the term of "This product contains _____", "This product contains _____, unsuitable for susceptible individuals", or other synonymous terms. (2)The product name claims _____ , label in this way, all the allergic substances of product should be included in the product name. Taiwan FDA Link

Foreign Material Detection

All Costco suppliers are required to have a comprehensive foreign material control program in place to control known and likely hazards. Effective foreign material control can only be achieved when the singular elements of a food safety plan are coordinated to minimize, detect, and eliminate physical hazards. Mindful of the great variability in the products and production environments found at food facilities, Costco requires that individualized programs be created on the framework outlined below.

Among these requirements are:

- Facilities must complete a comprehensive and documented risk assessment of all processes and inputs. A risk assessment is a systematic review of processes and inputs that identifies and evaluates the severity and likelihood of hazards in order to determine appropriate process controls.
- Facilities must establish and maintain a supplier approval program that establishes foreign material parameters for incoming ingredients and components.

- Facilities must perform documented and thorough inspections of incoming materials to detect foreign material hazards

- Facilities must establish controls on the proper storage and transport of all ingredients and product

- Facilities must conduct employee training on foreign material hazards for each employee at the facility, as well suitable awareness training for visitors and contractors.

- Facilities must institute all appropriate policies and procedures to control the risk of wood, metal, glass, plastic, and other known foreign material contaminants.

- Facilities must conduct regular and documented inspection of equipment and likely sources of foreign material, and have a reporting mechanism in place for employees to report concerns.

- All facilities (other than low-risk operations with a documented and accurate risk assessment) must have a properly installed and calibrated foreign material detection device for finished product (metal detector or x-ray). Note: Industries with alternative prevention measures in place (screens, filters, etc.) may be exempt from the requirement to operate with foreign material detection devices (i.e. shell eggs, any fluid processing, whole muscle meat processors, whole raw agricultural commodities (RACs) that are not processed).

- Facilities must have a customer complaint procedure in place, which must also include periodic trending of complaint data

Foreign Material Detection Devices

Foreign material detection devices, such as x-ray and metal detectors, are an important final step to ensuring that product which has been manufactured under appropriate controls is free of physical contaminants. If you are considering purchasing a foreign material detection device, Costco would like you to weigh the benefits of x-ray over metal detection for your facility. X-ray can not only pick out metal, but also is able to determine densities of rubber, plastics, bone fragments, along with sticks or twigs.

To ensure that all detection devices are operating correctly, Costco requires facilities to perform documented detector challenges at an interval of two hours or less. Detector challenges should also be performed at the beginning and end of production. When checking metal detection devices, the auditor will ask plant staff to demonstrate that all devices in the facility are operational and calibrated to the proper sensitivity using certified test pieces (Ferrous, Non-Ferrous, and Stainless Steel). Challenge materials must conform to the manufacturer's recommendations (i.e. metal, glass, plastic, wood, etc.), and reflect the known and likely contaminants of the product or production process.

Costco requires auditors to witness challenges to foreign material detection devices, regardless of whether these devices are being used for Costco product during the audit period. In facilities with 5 or fewer detection devices, all units must be challenged. When the device count exceeds 5 units, Costco will expect 5 devices be challenged in addition to 30% of the remaining devices.

All foreign material detection devices must have a proper rejection mechanism i.e. belt stops, air-jet etc. A written procedure must be in place to control product rejected by a foreign material detection device and to segregate that product from general production (this action must be documented). Site

employees must demonstrate appropriate knowledge of foreign material detector procedures and product disposition.

If processors do not have a foreign material detection device in place at the time of their Costco audit, they will be required to justify their decision with a detailed risk assessment that demonstrates that the product and production-process are low-risk. If foreign material controls are not in place at the time of the audit **and** no risk assessment has been completed, the auditor will consult with Costco personnel to analyze the risk level. If the risk is considered low, a device will not be required, though the facility must complete a documented risk assessment. If the risk is medium or high, the site will receive an audit non-conformance. In addition, the site will be required to implement foreign material controls and/or install a foreign material detection device (preferably x-ray, as this technology can detect physical hazards other than metal) as soon as possible. Facilities that have not installed a detection device by the time of their Costco anniversary audit will receive an automatic audit failure.

Pest Control

Facilities must have and maintain an integrated pest management program (IPM) that manages both the interior and exterior of the facility (to include storage areas for both product and packaging). The IPM must list the designated/trained/licensed pest control officer(s) (PCO) responsible for the program. Pest control programs must be developed and implemented/performed by licensed and certified pest control personnel. In countries without a licensing requirement, pest control personnel must be trained and should maintain a written pest control program that demonstrates their understanding of pest control and it's alignment with food safety operations. The pest control program must outline responsibilities for both in-house personnel and contractors.

At a minimum, the Integrated Pest Management Program must meet the following requirements:

- The IPM must establish a scheduled frequency of service for all interior and exterior devices. Complete records of all services must be kept.

- The PCO must maintain a current map (updated at least annually) that shows the location and type of all interior and exterior pest control devices.

- All pest control devices must be numbered/identified. Corresponding placards should also be placed above devices to enable personnel to confirm that the devices are in their designated locations per the current pest control map.

- Pest control devices, including Insect Light Traps, must be located away from exposed food products, packaging and raw materials. Chemical usage logs and current SDS information must be maintained.

- Bait stations and other pesticides are limited to outside use unless country laws require otherwise. Interior devices (i.e. tin cat or Ketch-Alls) must be placed on both sides of all doors leading to exterior of the facility and properly identified with placards unless country laws require otherwise. In the case of a country without a licensing requirement, pest control personnel must be trained and have written protocol to demonstrate their understanding of pest control as it applies to food safety. Monthly trend catch records must be maintained if facility is operating in house pest control.

- It is recommended that interior devices (i.e. tin cat, glue boards, or Ketch-All) be placed on both sides of all doors leading to the exterior of the facility. In countries that do not mandate this, they must

have at least one. Monthly catch records must be maintained and a trend analysis performed by the PCO at least annually. Costco does not allow snap traps to be used.

Good Manufacturing Practices

Good Manufacturing Practices (GMP) are defined as the deliberate coordination of management and manufacturing practices to ensure that food safety and quality standards are met (both customer specifications and legal requirements).

To safeguard food products, Costco has established the following rules concerning glove-use, hand washing sinks and hair restraints.

Gloves: No Bare-Hands Contact

Gloves must be worn when where there is direct hand contact with ready-to-eat products, regardless of the risk level. Prior to wearing gloves, employees must thoroughly wash and dry their hands. A written glove policy must be kept, which defines the type of gloves to be worn, the proper use of gloves for food handling tasks, and replacement frequency.

Single-use gloves must be latex-free and powder-free. If fabric gloves are used when hands are in contact with food, they need to be covered with latex-free / powder-free gloves.

Reusable food-safe gloves must be washed and sanitized frequently – at the start of a shift, after breaks, and after handling potential contaminants (at a minimum). They should always be clean and in good condition.

Where it can be demonstrated, through scientific validation studies, that the wearing of gloves is impractical or less hygienic than bare hands, Costco may offer an exemption to the glove requirement. These are rarely issued, and are only granted when the product, processes, risk-level, and validation evidence support an exemption.

Hand Washing Sinks

Designated and well-stocked hand washing sinks (**must** be hands-free) shall be located at every regular employee entrance to the processing area, and in a manner that allows employees to go directly from the hand sink to their work-station without the risk of contamination. Processing area hand sinks must have warm water, liquid soap, hands-free towels (or other sanitary drying devices), and a hands-free waste container. Hand wash signage must be posted near the station and shall be translated as needed to reflect the languages spoken by workers. Employees must wash their hands prior to starting work, after a break, after using the restroom, and any time hands become contaminated.

Hand sinks must be available inside restroom facilities and shall be used for that purpose only. Once an employee exits a restroom, they must re-wash their hands at a designated production area hand-sink before returning to work.

Hair Restraints

All employees must wear a hairnet when working around exposed product. Workers with a beard and/or mustache must wear a hair restraint that fully covers all hair. Costco does not view a ball cap as a hair cover or hair restraint. If a ball cap or other head covering is worn, it must be covered by a hair net.

Product Traceability

For year-round operations, Costco suppliers must complete at least two self-administered annual traceability exercises to verify the effectiveness of the product recall program. Trace exercises must track the distribution of specific product lots of finished-goods, raw ingredients, and primary packaging (one step forward, one step back). Each separate exercise must focus on different topics, which include: (1) a finished goods item, (2) a raw ingredient, or (3) primary packaging. The remaining topic not addressed by the facility's two self-administered trace exercises will be the subject of an onsite exercise initiated by the auditor during the annual audit. If the facility is not yet producing for Costco, an item similar to what would be supplied to Costco should be chosen. The recall/traceability system must be able to account for 100% of the product in a two-hour timeframe.

For non-year-round operations, Costco requires facilities to conduct a single mock recall/traceability exercise. A second exercise will be completed by the auditor during the annual food safety audit.

Companies with corporate generated recall systems in place need only provide the auditor with a copy of their program and a sample mock recall or trace back exercise.

Product Code Dates

At a minimum, all product sold to Costco must be marked with a use-by, sell-by or best-before date that can be used for traceability/recall purposes. Produce items should also include a packed-on-date or scannable barcode/QR-code that can provide information for traceability and recalls. Julian code dating is not acceptable for any Costco product.

All bagged salads and leafy green products must be labeled with the Harvest region and the pack date.

Approved Supplier Program

Facilities must have an Approved Supplier Program in place to monitor and evaluate all raw material, ingredient and primary packaging suppliers. Raw material and ingredient suppliers must be operating under a HACCP/Preventive Controls program, as per regulatory requirements. Facilities must maintain records on their ingredient/component suppliers, which should include: a current third-party food safety audit (full report), evidence of an established recall/traceability program, and a detailed product specification sheet.

Primary packaging manufacturers must have a documented monitoring program to evaluate finished-goods and ensure their compliance to all applicable regulations and customer requirements. These facilities must complete an annual third-party audit and also maintain a robust traceability program that can identify and account for specific lot numbers of packaging material.

Produce Audit Requirements

Produce (fresh, frozen, dried, canned, etc.) continues to be an important part of Costco's business. Due to the nature of produce commodities, Costco has established produce-specific requirements that are better tailored to the farms, harvesters, packinghouses, coolers, and processors that handle the produce sold to Costco members.

Produce audits are comprised of three major categories, which include:

- **Grower Audits** - A food safety assessment of a Ranch or Greenhouse environment.
  Note: When product is Field Packed it must follow follow the "Costco Produce Addendum for Field Pack Commodities".

- **Harvest Crew Audits** - A food safety assessment of the Harvest Crew practices and environment.
  Note: When product is Field Packed it must follow the "Costco Produce Addendum for Field Pack Commodities".

- **Facility Audits** – A food safety assessment of operations at a Packinghouse, Processor (all product types), Cooler/Cold Storage and Distribution Centers.

To ensure that effective food safety practices are in place for all produce operation types, Costco has established the following requirements.

1. Food safety audits must be shared with Costco Azzule Data Management or Costco's EFA system. Costco will continue using Azzule for data management, but will now allow suppliers to use the SCP (Supply Chain Program) for third-party audits. To ensure Supply Chain Transparency, Costco suppliers must share all audits in the supply chain via Azzule.

2. Suppliers and facilities are responsible for monitoring their growers' third-party audits - including audit review and corrective action oversight. Growers and Harvest Crews must pass an annual Food Safety Audit, which shall be conducted during the active harvest season.

3. Field-packed commodities must adhere to Costco's audit scheme and audit company requirements (page reference). Field-packed refers to product that is harvested and packed into final retail packaging in the field (i.e. clamshell, cartons wrapped product etc.).

4. Growers and Harvest Crews for non-field-packed commodities may now use the third-party audit company and audit scheme of their choosing.

5. Produce facility audits will continue to have Costco-specific requirements, as defined in the General Audit Requirements section of this document.

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6. Costco requires irrigation water to meet or exceed the requirements of the U.S. FDA Produce Safety Rule. The Produce Safety Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

Facilities and Field-Packed Commodities – Accepted Standard Audit Types

Costco will accept the following non-GFSI audit schemes (see table below). These audits must be completed by a Costco-approved audit company. The Costco Addendum will not be required for these audit schemes, as Costco's food safety requirements are satisfactorily addressed within each audit.

Produce Audit Types Accepted by Costco

Audit Scheme Owner	Audit Type
Azzule	Standard GAP GMP Audit
SCS	GMP Audit
SGS	GMP Audit

Corrective Action Requirements – Standard Audits

98 – 100%	Corrective Actions required, but do not need to be submitted to a Costco audit database
85 – 97%	Corrective Actions required
< 85%	Corrective Action and **Re-Audit Required**

Facilities and Field-Packed Commodities – GFSI Certifications

Field Pack Audits

All produce items that are field-packed will require an annual Ranch and Harvest Crew Audit. If the operation grows multiple crops with different harvesting practices, separate audits will be required. Field pack audits must be uploaded to Azzule and will be directly reviewed by Costco. Ranch and harvest crew audits for non-field-packed items also need to be uploaded to Azzule.

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Facility Audits – Supplier Approval and Monitoring

During audits, facilities will be required to provide evidence (e.g., third-party audits, certificates of analysis, reviews of supplier records, etc.) that they are monitoring all applicable Grower and Harvest Crew Audits for commodities being supplied to Costco. A registry of approved growers must be maintained, which should include criteria for grower approval, suspension, and termination. Grower and harvest crew audits must meet minimum passing score/grade per the Certification Program/audit requirement. Corrective actions and re-audits for grower and harvest crew audits must be completed as required. Growers may choose any Certification Program or audit company that is acceptable to the facility.

All GAP/GMP audits must be current (within the past calendar year). Costco requires the audit company performing your audit to post the results in the appropriate Costco audit database within 7 calendar days (review to ensure that this timing is accurate for all schemes).

Costco will accept the following GFSI certifications for facilities and field-packed commodities:

BRC – Minimum Grade B Costco Addendum required for facilities BRC audits apply to facilities only	**PrimusGFS** – Minimum score 90% Costco Addendum is **not** required
CanadaGAP – Minimum score 85% Costco Addendum required for field-packed commodities and facilities Costco accepts Group/Multi-Site Audits	**SQF** – Minimum score 85% Costco Addendum required for field-packed commodities and facilities Costco accepts Group/Multi-Site Audits
GlobalG.A.P. – Passing (GAP only) Costco Addendum required for field-packed commodities GlobalG.A.P. schemes accepted for Field-Packed Commodities are IFA, PSS and HPSS. Costco accepts Group/Multi-Site Audits GLOBALG.A.P. Certification audits will not be accepted for any type of Facility, including packinghouses, processing, coolers, cold storage, distribution centers, etc.	Note: Costco does not accept the Harmonized Audit for Facilities or Field-Packed Commodities

Corrective Actions – Certification Audits and Costco Addendum

Corrective Actions – All Audit Schemes and Costco Addendum (when applicable)

Corrective Actions are an integral part of the audit process and a requirement of doing business with Costco. Auditees with an audit scoring below 98% must post a Corrective Action Report to Azzule within 14 days of the audit being posted or according to scheme requirements. Auditees must contact thei

r audit company for instructions on submitting CARs to Azzule.

Re-Audits: GFSI, GMP, GAP

If a GFSI audit does not meet Costco's scoring requirements, Costco will require a re-audit to be conducted. Because Costco's re-audit timeline and scoring varies from GFSI requirements, the re-audit may be a Costco approved, non-GFSI audit scheme. The re-audit will not count towards the GFSI Audit Scheme Certification, nor will it impact the GFSI audit anniversary date. The re-audit will be conducted in addition to any/all GFSI scheme requirements.

Re-audits for Packinghouse, Cooler, Cold Storage, Storage and Distribution and Processing Audits must be conducted within 60 days of the original audit date, when allowed by scheme requirements.

Re-audits for Grower, Harvest Crew and Greenhouse Audits must be conducted within 30 days of the original audit date.

If the growing season is finished or if the Facility is non-operational, a re-audit must take place within the first 30 days of the next growing season. Costco reserves the right to suspend orders for product in the interval between a failed audit and the submission of re-audit results.

A product recall or other serious incident will initiate a requirement for a new food safety audit.

Sanitation Verification (Facilities)

There must be a written program in place to verify sanitation effectiveness for food contact surfaces. The program should be based on a risk assessment of the operation and validated. Examples of acceptable verification include ATP monitoring or swabbing for TPC (Total Plate Count).

Test and Hold Requirements

Costco has a test and hold policy in place for all ready-to-eat and at-risk produce. This includes items such as, but not limited to, cut salad mixes, baby leaf salads, cut fruit, frozen fruits and vegetables, and prepared vegetable trays. Costco considers cantaloupe an at-risk produce item (both whole melon and sliced/cut). Costco does not consider other whole fruit ready-to-eat produce. Testing requirements are outlined on the Costco product specifications.

Facilities that supply frozen fruits and vegetables should contact their Costco buying team for specific testing requirements.

All test and hold data and purchase order information must be uploaded to Azzule prior to shipment of goods to Costco. For questions on test and hold, please e-mail fsa@costco.com.

Costco specifications for ready-to-eat and at-risk produce are defined below.

Fresh Produce Testing Requirements

Bacteria of Concern	Target	Maximum Level
Total Plate Count (TPC)	**< 100,000** cfu/gram	**1,000,000** cfu/gram
Generic E. coli	**<10** cfu/gram	**50** cfu/gram
EHEC *Contact Costco Food Safety if you have questions.*	**Negative** Note: test method must detect for Stx1 or Stx2 and EAE genes at a minimum. Note: There are now test kits available that detect more than these genes or that detects a group of markers that include the EAE, stx1 and 2 genes. These kits are also acceptable for use on Costco products.	
Salmonella	**Negative**	

Field Packed Produce Testing Requirements

Bacteria of Concern	Target	Maximum Level
Total Plate Count (TPC)	**< 1,000,000** cfu/gram	**10,000,000** cfu/gram
Generic E. coli	**<10** cfu/gram	**100** cfu/gram
EHEC *Contact Costco Food Safety if you have questions.*	**Negative** Note: test method must detect for Stx1 or Stx2 and EAE genes at a minimum. Note: There are now test kits available that detect more than these genes or that detects a group of markers that include the EAE, stx1 and 2 genes. These kits are also acceptable for use on Costco products.	
Salmonella	**Negative**	

Cantaloupe-Specific Testing Requirements		
Bacteria of Concern	**Target**	**Maximum Level**
Total Plate Count (TPC)	**< 1,000,000** cfu/gram	**10,000,000** cfu/gram
Generic E. coli	**<10** cfu/gram	**100** cfu/gram
EHEC *Contact Costco Food Safety if you have questions.*	**Negative** Note: test method must detect for Stx1 or Stx2 and EAE genes at a minimum. Note: There are now test kits available that detect more than these genes or that detects a group of markers that include the EAE, stx1 and 2 genes. These kits are also acceptable for use on Costco products.	
Salmonella	**Negative**	
Listeria	**Negative** An Environmental Sampling Plan must be provided to Costco outlining sampling that will be conducted at the processing facility to minimize the potential of contamination of product with *Listeria monocytogenes*. The plan must identify *Listeria* spp. growth areas and harborages and how each area will be sampled and responded to in the event of positive findings.	

Produce-Specific Good Agricultural Practices (GAP)

Good Agricultural Practices (**GAP)** are defined as food safety practices for farm activities related to risk mitigation of water, soil amendments, land use (previous and adjacent), animal access (domestic/wild), equipment, tools and buildings, worker health & hygiene practices.

To ensure that safe handling of produce, Costco has established the following GAP requirements.

- A minimum of one working field sanitation unit (clean and well-stocked toilet and hand wash stations) is required for every 20 employees. Toilet and hand washing facilities must be within a 5-minute walking distance for all employees -driving time/distance will not be considered. Hand wash stations must be located outside portable restroom facilities in order for hand washing activities to be observed/verified by supervisors.

- Picking bags, gloves, knives and aprons must be controlled and monitored by equipment storage & control procedures. These items should be on a documented cleaning schedule. The site is responsible for the condition, cleanliness, and upkeep of all equipment and garments. Harvesting equipment must be on a documented cleaning and sanitizing program.

- Cloths, towels and other cleaning materials that pose a risk of contamination and/or adulteration shall not be used to remove dirt and debris from product. Workers must not handle product in a manner that results in contamination or adulteration.

- With the exception of commodities for which wooden harvest bins are the industry standard, product must not come in contact with surfaces that cannot be properly cleaned and sanitized. Similarly, materials that are prone to creating foreign material contamination must be avoided. These materials include - but are not limited to - foam rubber, any type of carpet, wood, non-food grade plastic, cardboard, tape, etc.

- Employees must not consume or store personal food, candy, gum, tobacco or beverages (including water) on the packing line or processing floor. Facilities should instead ensure that employees have adequate access and opportunity for water breaks in a non-production area (employees must wash hands after breaks).

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