



Allergen and Gluten Free Options

Use the following steps to determine if you should pursue the allergen/gluten free market

Step 1: Watch the video, “A Food Manufacturer’s Guide to Allergens & Gluten”.

If you believe your company is interested in producing products for the allergen/gluten free market, answer some preliminary questions.

Q1: Does your company have the values and “culture” to fully commit to providing suitable products for the allergen/gluten free consumer?

- “Culture” includes a leadership style that empowers employees to consistently provide products that customers value.
- Without a **supporting** culture and values, it is unlikely that a company will be able to sustain the commitment necessary to meet the needs of this market.

Q2: Are you prepared to undertake a feasibility assessment and financial analysis?

- Be prepared to evaluate the size and location of potential markets to ensure the selected option properly aligns with your business goals and capabilities.
- Contact your New Venture Specialist or Development Officer for assistance.

If you can answer “yes” to both questions, continue to Step 2.

Step 2: Work through the “Allergen/Gluten Decision Tree Flow Chart” to determine which option fits your company.

Step 3: Go to the option that best fits your situation to find out more about the requirements.

Option 1: Dedicated facility with no allergens or gluten permitted within the facility (page 2)

Option 2: Physically segregated facilities with dedicated equipment for both allergen and non-allergen containing products (page 4)

Step 4: Complete a financial assessment.

Warning: It is very difficult to meet the requirements of an Allergen & Gluten Management program in a shared room or with shared equipment for the production of both allergen and non-allergen containing products.

Financials & Other

Complete a financial and resource assessment to determine the short and long term implications of meeting and sustaining the requirements of the option you have chosen.

Here are some things to consider:

- Costs may initially be higher to design and construct dedicated/segregated facilities and equipment.
- Be aware of the up front and ongoing costs involved with meeting the control requirements for each option.
- Be aware of any certification or program standards you are currently following or considering to develop your company and site specific Allergen & Gluten Management program.
- Contact your Safe Food Specialist for assistance.

Option 1

To pursue this option:

- All of your products *are* allergen or gluten free
- Market size aligns with your production capabilities **OR** you have a plan to achieve this which aligns with your business goals and financial means
- Market location is accessible with your distribution capabilities **OR** you have a plan to achieve this which aligns with your business goals and financial means



Option 1: Dedicated facility with no allergens or gluten permitted within the facility

This option focuses on **preventing the entry of allergens and gluten into the facility** by **verifying their absence** in the incoming ingredients and implementing preventive strategies for personnel.

There will likely be reduced ongoing monitoring of other operational elements once procurement, receiving, product development and employee controls have been validated and supported with ongoing training, monitoring, testing, verification and audits. Each company/facility must review the requirements and determine the best way to consistently meet the required outcomes.

Allergen/Gluten Management Policy

- The policy is a written management commitment to develop the control measures needed to maintain an allergen/gluten free processing environment
- Management fully understands the needs of the allergen/gluten free customer and has taken the steps and committed ongoing resources to fully manage these requirements
- The policy and commitment is reviewed and renewed annually

Option 1: Allergen & Gluten Management Program Components



The following are of some of the requirements in each area of your business.

Supplier Assurance & Procurement

- Check the source of each ingredient for potential allergens/gluten
- Confirm suppliers' allergen/gluten free status
- Implement supplier agreements to maintain allergen/gluten free status in their operations with no substitutions without prior approval
- Generate an approved supplier list, including secondary backup suppliers, for use by product development, procurement and receiving personnel who identify incoming ingredients approved for purchase and receiving

Product Development

- Develop a policy to exclude all allergens and gluten from new products
- Use an approved supplier list for acquiring new ingredients
- Work with quality assurance to identify new potential suppliers of ingredients for approved supplier list

Receiving

- Use approved supplier list for the receiving of all incoming ingredients
- Train employees on the use of approved supplier list and corrective measures to take when an ingredient or supplier isn't approved (including documentation)

Audits

- Internal audit of Allergen & Gluten Management program – annual review
- Supplier audits – initial approval, annual renewal and when a problem is identified
- Third party audit – component of a systems audit to demonstrate compliance to customers

Personnel & Training

- There is a no allergen/gluten policy for employees within the facility (may need to make alternative arrangements for lunches/breaks)
- Employees wear dedicated clothing within operational areas of the facility
- Train on allergens/gluten, allergen/gluten free policy, allergen/gluten management programs, personnel policy/good manufacturing processes as it relates to allergen management and specific job functions at the start of employment and on an annual basis for all employees

Monitoring & Testing

- Monitor employee practices daily to prevent entry of allergens/gluten into facility
- Monitor incoming ingredients – check approved supplier list and ingredient listing for each ingredient as received to prevent unintentional entry of allergens/gluten into facility
- Test incoming ingredients prior to approval to verify absence and on an annual schedule

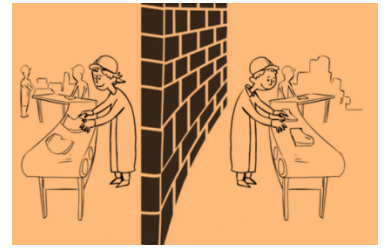
Verification & Validation

- Verify procurement practices – monthly record review
- Verify approved supplier list – annually or whenever a new supplier is added or a change is made
- Verify training records for allergens – complete and current
- Validate Allergen & Gluten Management Program - initial assessment and then annual review/reassessment to ensure program controls for allergens and gluten are still effective

Option 2

To pursue this option:

- You have products that **do not contain ANY** allergens/gluten and products that **do contain** allergens/gluten
- You operate **physically segregated facilities with dedicated equipment** for allergen and non-allergen containing products with the **ability to control cross contamination**
- Market size for each product line aligns with your production capabilities **OR** you have a plan to achieve this which aligns with your business goals and financial means
- Market location for each product line is accessible with your distribution capabilities **OR** you have a plan to achieve this which aligns with your business goals and financial means



Option 2: Physically segregated facilities with dedicated equipment for both allergen and non-allergen containing products

This option focuses on identifying allergens and gluten at the *point of entry* and **physically segregating** their *storage and processing*. Dedicated equipment and utensils are maintained in each segregated area. Management focuses on maintaining segregation and controlling cross contamination.

For this option you need to clearly **define** where your **segregation starts and ends** in order to control cross contamination.

Allergens in use must present a low risk of air borne contamination and may require separate HVAC systems in segregated areas.

There will likely be ongoing monitoring for operational elements within transition zones and at entry/exit points to segregated areas with the focus on identifying allergens/gluten to prevent and control cross contamination. All operational controls need to be validated and supported with ongoing training, monitoring, testing, verification and audits.

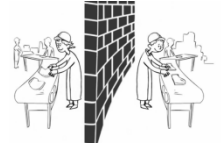
Each company/facility must review the requirements and determine the best way to consistently meet the required outcomes.

Allergen/Gluten Management Policy

- Get written commitment from management to develop and maintain control requirements for segregating allergen/gluten free from allergen/gluten products and processing and maintaining the use of dedicated equipment and utensils within segregated areas
- Management fully understands the needs of the allergen/gluten free consumer and has taken the steps and committed ongoing resources to be able to fully manage these requirements
- Policy and commitment reviewed and renewed annually

Option 2: Allergen & Gluten Management Program

Components



The following are of some of the requirements in each area of your business.

Supplier Assurance & Procurement

- Check the source of each ingredient for potential allergens/gluten
- Confirm suppliers' allergen/gluten free status
- Implement supplier agreements to maintain current allergen/gluten free status in their operations with no substitutions without prior approval
- Generate an approved supplier list, including secondary back up suppliers, for use by product development, procurement and receiving personnel who identify the incoming ingredients approved for purchasing and receiving

Product Development

- Develop a policy to formulate new products without allergens/gluten when possible
- Develop a policy to identify all allergens and gluten sources in ingredients for new products or when making changes to existing products
- Develop a policy to formulate new products with same sources of allergens/gluten currently in use within the segregated allergen/gluten areas of the facility
- Develop a policy to use approved supplier list for sourcing new ingredients
- Work with quality assurance to identify new potential suppliers of ingredients for approved supplier list

Storage

- Implement protocols for moving allergen and non-allergen ingredients and products in segregated storage areas to prevent cross contamination
- Train employees on corrective measures to take if an ingredient is in the wrong location or is damaged in a transition zone (to control cross contamination)

Receiving

- Use an approved supplier list for the receiving of all incoming ingredients
- Train employees on the use of approved supplier list and corrective measures to take when an ingredient or supplier isn't approved (including documentation)
- Train employees on protocols for receiving allergen/gluten ingredients and non-allergen/gluten-free ingredients to prevent potential cross contamination

Personnel & Training

- Implement a no allergen/gluten policy for employees working within the allergen/gluten free segregated facility (may need to make alternative arrangements for lunches/breaks)
- Make employees wear visually-distinct and dedicated clothing within operational areas of each segregated facility including segregated changes areas
- Train employees on allergens/gluten, allergen/gluten free policy, allergen/gluten management programs, personnel policy/GMPs as it relates to allergen management and specific job functions at the start of employment and on an annual basis for all employees

Facility Layout

- Plant schematic clearly identifying segregated areas, dedicated equipment, operational areas, employee welfare areas, transition zones, approved employee traffic patterns and HVAC

Option 2 Cont'd.

Scheduling

- Receive allergen and non-allergen ingredients
- Ship allergen and non-allergen products
- Move allergen and non-allergen ingredients from segregated storage through transition zones to segregated processing areas
- Schedule staggered breaks and lunches for employees working in allergen and non-allergen segregated areas to avoid unintentional cross contamination in transition zones
- Implement staggered start times for employees working in allergen and non-allergen segregated areas to avoid unintentional cross contamination in transition zones

Formulation Control

- Develop procedures for transferring non allergen/gluten ingredients or work in progress from designated storages into processing to avoid cross contamination
- Implement procedures for measuring correct ingredients in processing
- Implement procedures to double check each batch to ensure there have been no ingredient substitutions (ensure what's in the recipe is what's on the product label)

Cross Contamination Controls

- Adhere to all relevant policies in other Allergen & Gluten Free Management Programs

Handling

- Ensure personnel working with allergens or gluten are visually identified and do not handle non allergen/gluten ingredients or products
- Develop a policy requiring ongoing monitoring of personnel to ensure adherence to handling policies

Labelling Control

- Assign designated storage for pre-printed labels for allergen and non-allergen finished products
- Develop a policy for visually differentiated labels for allergen and non-allergen finished products
- Implement procedures to check all ingredients in the product are listed on the product label

Shipping/Distribution

- Implementing protocols and training for scheduling, handling and documenting separate and combined allergen and non-allergen containing products for customer orders and loading in shipping area

Equipment & Maintenance

- Monitor the use of designated equipment, utensils and tools within each segregated area of the facility
- Develop a policy to restrict or control the movement of maintenance personnel, equipment and tools between segregated areas including adherence to cross contamination protocols
- Monitor maintenance activities including adherence to employee traffic patterns and visual uniform policy for each segregated area

Sanitation

- Designate cleaning areas for each segregated area or protocols for accessing a common use cleaning area
- Display visual identification of cleaning tools and utensils for each segregated area
- Implement protocols for adherence to cross protocols and scheduling of cleaning if done by a dedicated sanitation crew with responsibility for cleaning and sanitizing the entire facility

Option 2 Cont'd.

Monitoring & Testing

- Monitor employee practices daily to prevent entry of restricted allergens/gluten into facility
- Monitor incoming ingredients – check approved supplier list and ingredient listing for each ingredient as received to prevent entry of unintentional allergens/gluten into facility
- Test incoming ingredients – prior to approval and on an annual schedule
- Monitor all Allergen & Gluten Management Program practices and procedures

Verification & Validation

- Verify all relevant Allergen & Gluten Management Program components and records
- Validate Allergen & Gluten Management Program – do an initial assessment and annual review/reassessment to ensure program controls are still effective

Audits

- Conduct an internal audit of Allergen & Gluten Management Programs—review annually
- Conduct supplier audits – for initial approval, annual renewal and when a problem is identified
- Conduct a third party audit – a component of a systems audit to demonstrate compliance to customers

If your responses to the decision tree questions ended up at *'Allergen & gluten free market is likely not a valid option at this time'* and you are still interested in positioning your products for these markets, see Page 8.

Should I make it allergen/gluten free?

If your responses to the decision tree questions ended up at 'Allergen & gluten free market is likely not a valid option at this time' and you are still interested in positioning your products for these markets, keep reading.

How can you meet the requirements to directly market your products to the allergen and gluten-free consumer?

Many processors operate in facilities and with equipment that is used to manufacture products that contain both allergen and non-allergen ingredients or contain different allergen ingredients. The presence of undeclared allergens in products without allergens or with different allergens is done operationally through the implementation of Allergen Management programs.

If you are a processor in these circumstances, certain consumers with gluten intolerance or food allergies may decide to still purchase your products based upon the information you provide on your product label and website. Even with rigorous allergen management programs the potential for cross contamination exists which makes it risky to directly market products produced in these facilities to consumers with gluten intolerance or food allergies.

If you believe this could be a significant market for your products you can start by using the decision tree and checklist to determine where there is an opportunity to move towards meeting the requirements for option 1 or 2. If you are able to reformulate your products to exclude allergens or gluten or if you are able to effectively segregate and manage the processing of non-allergen products from those that contain allergens this may provide the opportunity to directly position these products to allergen and gluten-free consumers.

Next Steps

If you have questions or need more information please contact your Safe Food Specialist for assistance.

For more information

Janice Futz, Safe Food System Specialist, janice.futz@gov.ab.ca 1-403-601-8217

Kellie Jackson, Development Officer, Crop Extension Branch kellie.jackson@gov.ab.ca 1-403-948-8538

