Pathogen Management Plan Guidance Material

Draft

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Table of Contents

1 Pathogen Management Plan Guidance Material

1.1 Introduction to this document:

Experience tells us that contamination of manufactured foods typically occurs during the manufacture process. That is, from the processing environment, or from inadequate process control. Therefore, effective management of pathogens can be achieved by controlling pathogens in the process environment, and by ensuring appropriate process controls. This document provides guidance to manufacturers for pathogen management. For some food industries a pathogen management plan is a regulatory requirement. For others, it is not mandatory, but all manufacturers are strongly encouraged to adopt these useful principles for ensuring food safety.

Pathogen Management will normally be a pre-requisite/supporting programme to the HACCP plan referenced by your overall food control plan. Alternatively these elements could be contained within your overall food control plan.

The key point is that pathogen management is an integral part of food safety and should form an integral part of any food control plan. The pathogen management plan needs to be carefully developed and adequately resourced to be effective.

Please note:

This document is currently in draft format only.

This document was originally written for use by the dairy product manufacturing industry, however it was soon recognised that much of the advice and most of the principles contained in this document are applicable to many other food sectors. Therefore this document is undergoing review to ensure the language, principles and examples are relevant to a wider range of food manufacturing situations.

If you wish to comment on the usefulness of this document, or make suggestions for improvement, please forward your comments to the contacts listed in section 4 of this document.

1.2 How to use this document:

These guidelines do not constitute an exhaustive list of control measures. Each processing operation is unique and you will need to evaluate your own operation to establish the pathogen management procedures that are most appropriate. For this reason it is recommended you read this document in its entirety before beginning to write and implement your own pathogen management plan.

1.3 Scope:

The business needs to define the scope of the Pathogen Management Plan e.g. "All activities from on-site management of incoming/raw ingredients through to the point of retail sale or the export of final product".

1.4 Regulatory Outcomes you will need to meet:

This guidance material may be of assistance in meeting the Regulatory outcomes that can be found at:

www.nzfsa.govt.nz/policy-law/legislation/index.htm

Dairy Products: www.nzfsa.govt.nz/dairy/

Animal Products: www.nzfsa.govt.nz/animalproducts/index.htm

Domestic and Imported Food: www.nzfsa.govt.nz/processed-food-retail-sale/index.htm

Wine: www.nzfsa.govt.nz/wine/index.htm

Plant Products: www.nzfsa.govt.nz/plant/index.htm

1.5 Definitions:

For the purpose of this document, the following expressions have the meaning stated:

At Risk Product – means product:

- Manufactured during a time of Zone 3 contamination (including the time period between a known positive result and a previous negative result).
- On the cusp either side of product with a positive pathogen result.
- Manufactured under abnormal processing conditions e.g. microbiological CCP failure, failure or uncertainty of control methods such as heat treatment controls or building integrity.

Outcome - means the expected level of control of a risk factor relating to food resulting from implementation of the management programme.

Food Control Plan – this term currently means either a Food Safety Programme (Food Act 1981), a Product Safety Programme (Dairy Regulations 1990), or a Risk Management Plan (Animal Products Act 1999).

Control – As per Codex definitions:

> ***Control (verb)****:* To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.
>
> ***Control (noun):*** The state wherein correct procedures are being followed and criteria are being met.
>
> ***Control measure***: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Process – includes kill, slaughter, dress, cut, extract, manufacture, pack, preserve, transport, and store.

Process Control Step – means a microbiological process control step.

Product – means any animal or plant material that has been processed (other than simply transported or stored in such a way as not to involve any alteration to its nature) for the purpose, or ultimate purpose, of consumption or other use by humans or animals.

Raw – means food material prior to any bacteriocidal Critical Control Point in the process.

2 Pathogen Management Plan Development

It is important to understand what a Pathogen Management Plan should contain. Elements of the Pathogen Management Plan should be determined using risk assessment principles. This section describes the process to identify and assess your pathogen hazards and risks. The rest of this document provides additional guidance to help you achieve an effective Pathogen Management Plan.

Draw together:

- Premises diagrams
- Process Flow(s)
- Product Description(s)
- HACCP Plan (where available)
- Any relevant and available pathogen history of the premises
- A person or persons that have a variety of skills and experience with the product, process and pathogens.

Using these resources answer the following questions (also note, an example worksheet/checklist is available in appendix 1 to provide additional assistance in ensuring completeness of your Pathogen Management Plan):

What pathogens are risks to your product/process?

Consider pathogens that commonly cause food-borne illnesses. These are the hazards to be considered for your product. Guidance is available in the relevant legislation and/or NZFSA information for your food business and market(s). For example, NZFSA Standard D107, NZFSA Microbial Pathogen Data Sheets, FSANZ Food Standards Code. Can these pathogens grow/survive in your product (use product descriptions to help determine this), or present a risk to your intended consumer groups?

Consider sources of pathogens, and how these pathogens could be carried into your process/product and pose a risk to consumers.

Consider all of the things that move on to your site or into your process, and any possible pathways for contamination of the process, for example, vehicles, waste, people (staff, maintenance and contract workers, visitors), animals, insects, services (water, air), ingredients/raw materials, equipment (cleaning or process).

Establish the risk these sources/pathways present to your process/product

If a source of bacterial contamination exists within a processing area, bacterial numbers will increase rapidly if there are:

- Suitable temperatures
- Enough time (between clean-ups)
- Ample nutrients and water

Understanding these concepts is an important tool in the development of effective control measures.

Consider each of the pathogens and each source identified above and determine the likelihood of in process or product contamination, This assessment of risk should only be carried out by competent technical people. If in doubt, food businesses are advised to seek suitably competent technical advice and/or contact the NZFSA.

Your programme should document the process you have used to assess risk.

What procedures and/or processing steps do you need to have in place to control these sources and pathways?

You may already have procedures and or processing steps in place that will address the sources and pathways you have identified, for example, during the development of a HACCP plan. The effectiveness of these procedures and or processing steps will need to be verified.

Note any procedures and/or processing steps you already have, and consider additional controls you may need to develop for inclusion in your Pathogen Management Plan.

Other Useful Resources:

NZFSA publications (see www.nzfsa.govt.nz)

Consultants/industry experts

Bad Bug Book (http://vm.cfsan.fda.gov/~mow/intro.html)

A Guide to Calculating the Shelf Life of Foods (http://www.nzfsa.govt.nz/processed-food-retail-sale/shelf-life/index.htm)

Predictive modelling programmes/software (before use consult a technical specialist)

3 Technical considerations for achieving an effective Pathogen Management Plan.

This section provides guidance to enable development of effective control measures. These will form the basis of your Pathogen Management Plan.

3.1 Buildings

3.1.1 Requirements

Can you demonstrate that your building meets minimum requirements for your type of food manufacture, or provide an approved/validated alternative?

Minimum requirements may be defined by legislation or industry guidance e.g. Territorial Authority (council) building codes, Food Act 1981, Food Hygiene Regulations 1974, Animal Products Act 1999. Additional guidance can be obtained from the Operational Guideline: Design and Construction of Dairy Premises and Equipment (available on the NZFSA website at http://www.nzfsa.govt.nz/dairy/publications/guidelines/designandconstruction.htm).

3.1.2 Building Location:

What impact could your external environment have on food safety?

Consider things like:

- proximity to high risk operations (e.g. landfill, water treatment stations, pathogen lab, adjacent manufacturers)
- movement of vehicles on and off site,
- waste disposal (e.g. general rubbish and process waste), positioning, access, spill containment, frequency of removal.

3.1.3 Building Design:

Good building design is essential for effective pathogen control. For example, consider whether:

- Windows and doors are tight fitting and kept closed to exclude insects, pests and dust (which may carry bacteria).
- There is direct access to the outside environment.
- Floor, wall and ceiling materials are non-porous and easily cleaned.
- Floors are well drained to prevent ponding.
- Drains are away from the packaging area and well screened and trapped - especially where they pass through a wall.
- Raw products/ingredients are received in an area separate from processing and packaging areas.
- Processing areas flow naturally from raw/unprocessed food to final product.
- Amenities (toilets, changing areas, canteens) are located so employee movements to and from these areas do not give opportunities for cross-contamination between processing areas.
- Temperature is controlled in areas where such temperature control is necessary.
- Ventilation and air transport systems are appropriate.
- Microbiology laboratories are physically separated from the processing building.
- Waste storage areas are isolated so that leaking or spilled material cannot be tracked around the site and back into the processing areas.

3.1.4 Floors and Drains

- Floors are likely to become contaminated from foot and vehicular traffic, or from contaminated material falling on to them.
- Drains are likely to become contaminated because almost everything on the floor will find its way into the drain.

So assume that the floor and drains are always contaminated

Control of floors and drains:

- eliminate ponding of water and water leaks
- eliminate cracks and holes
- pipe waste directly into the drain
- ensure that drains have adequate capacity
- drain traps should be located outside
- drain traps should be cleaned regularly
- make floors as smooth as safety will allow
- clean and sanitise floors and drains daily
- use dedicated cleaning equipment
- use low pressure hosing (see section on cleaning)

Each business should develop an action policy for handling any equipment or product that falls on to the floor, e.g., equipment must be cleaned and sanitised before reuse, and product must be discarded. Ensure that all staff are intimately familiar with this policy.

3.1.5 Walls and Ceilings

- Walls and ceilings should be made of materials that can be easily cleaned and sanitised;
    - non-absorbent
    - no holes or cracks
    - no unflashed openings
    - no sills or high ledges
- Sealing the join between wall and floor minimises the build-up of water or other residues.

3.2 Equipment

3.2.1 Equipment selection & design

All equipment should be designed for easy cleaning and disinfection, and made of non-absorbent material, e.g.;

- stainless steel (with hygienic welds that are ground and polished)
- no hollow box sections that can trap food residues and contaminants
- no sandwiched surfaces
- free draining pipes and sections.

Conveyor belts have proven to be ideal places for pathogens to lodge and grow, especially belts with absorbent material, such as nylon reinforcing on the lower surface or running through the middle of the fabric.

Conveyor belts should:

- be made of hygienic, easily cleaned material
- be well above the floor
- never be allowed to touch the floor
- be made of non-absorbent material.
- have rollers that are completely sealed are used in critical hygiene areas.

Some equipment will need to be dismantled each day, so that each surface can be adequately cleaned and sanitised.

Boltholes and rivets will allow liquids to pass from one surface to another. Their positioning needs to be carefully considered when equipment is designed and built. It is recommended that rivets are not used in critical hygiene areas as they cannot be effectively cleaned. Ensure that bolts/bolt-holes are **not** positioned on or above any product contact surface.

3.2.2 Equipment Maintenance

Maintenance will normally be carried out by either company engineers or contracted tradespeople. It is important to ensure that the activities of maintenance personnel causes minimal contamination of the processing areas and that there is adequate clean-up upon completion of the work.

3.2.3 Access Restrictions

- The normal access restrictions that apply to all other personnel on site must also apply to site engineers, electricians, and other contracted service personnel (see also section 3.4).

3.2.4 Timing of Maintenance

- All normal maintenance should be timed to occur between normal processing runs. This will allow for a full clean up and sanitising before work resumes.
- If maintenance cannot be programmed between processing runs, it should occur at a normal work break so that:
    - product is not being processed at the time
    - the plant can be cleaned and sanitised afterwards.

3.2.5 Breakdowns

- Breakdowns that require immediate attention must also be followed up with cleaning and sanitising of those parts of the plant that have been worked upon.
- Product which is in-process at the time of the breakdown may be at risk from;
    - environmental contamination during repairs
    - temperature abuse.
- Product which is in-process will need to be assessed to determine the potential risk and each site should document guidelines for the disposition of product identified as at risk.

3.3 Services

Consider the impact that services have on the pathogen risk e.g. direct/indirect contact of services with product or product contact surfaces. What will you need to do to minimise the impact?

3.3.1 Water

Ensure that water used is effectively treated, e.g., by chlorination, U.V., ozone, or filtration.

- Manufacturers must meet relevant regulatory requirements (ref NZFSA Standard D113, DWSNZ 2000)
- Ensure that any water stored on site is protected from contamination, e.g., in covered holding tanks or covered header tanks.
- Water quality should be checked at regular intervals (e.g., turbidity, available chlorine, coliforms.)
- Hoses should be kept off the floor when not in use. **Remember**, the floor is probably contaminated.
- Frayed hoses should be replaced.
- Never let hose nozzles touch the floor.
- Equipment that generate aerosols, such as pumps, or washing equipment, should be well shielded to prevent aerosols spreading throughout the processing area.
- Eliminate leaks from hoses, taps, drains, steam lines, condensate pipes or any other source (to deprive pathogens of the moisture needed for growth).

3.3.2 Air

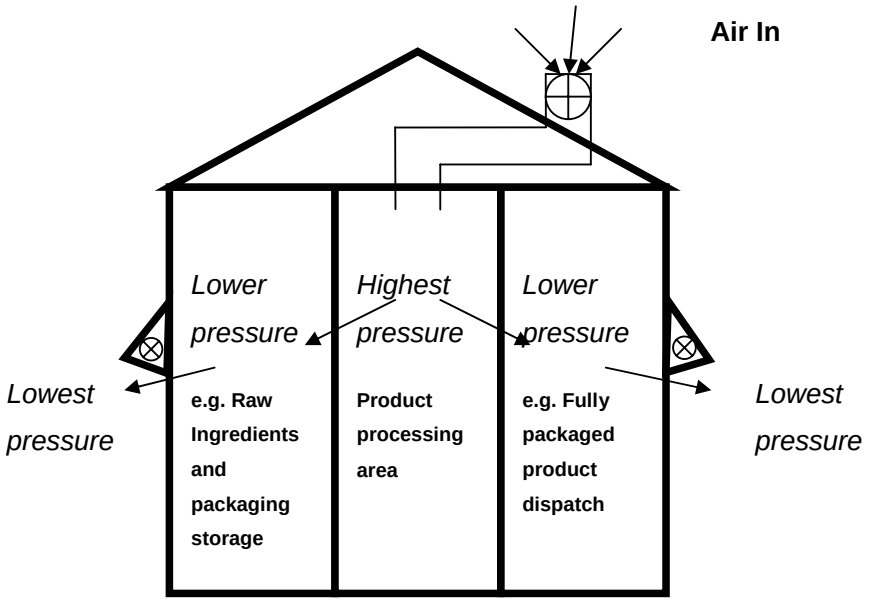
3.3.2.1 Ventilation Systems

It is desirable that food processing operations operate at a positive air pressure with respect to the outside environment, to prevent contamination being sucked into the building from outside. Critical hygiene areas should be at a higher pressure than areas where raw materials are handled or stored. Positive air pressure can be achieved by forcing fresh, clean air into the processing area. Refer to figure 1.

The volume of incoming air must be greater than the volume removed by exhaust vents and extractor fans to maintain a **positive pressure** in the processing area.

Condensation on walls and ceilings is an indication that the ventilation system is inadequate.

Figure 1:



3.3.2.2 Filtration Systems

Consider whether air needs to be filtered to remove contaminating particles. Where air filtration is included in your Pathogen Management Plan there should be a documented filter maintenance programme in place, with records kept of all filter maintenance carried out. Filters will need to be checked, cleaned and replaced at frequent intervals. Air intakes should be upwind from the prevailing wind, exhaust vents, inwards goods and rubbish disposal sites.

3.3.3 Cooling systems

Condensate can provide a moisture source that may allow pathogens to multiply.

Therefore, it is essential that all drainage ducting from air-handlers and condensers is piped directly into the drains and not on to the floor or ground.

Note: Cooling towers can produce aerosols and should be considered as a potential source of contamination.

3.4 Controlled access

The processing area is the most common source of contamination for processed foods.

For this reason, it is vital to ensure that the processing area is always protected from contamination.

Processing areas can be divided or defined based on risks such as potential product exposure or functional use of the area. It is useful to consider these as specific zones.

Zone 1 encompasses the **outside** environment of the processing area.

Zone 2 encompasses those **inside** areas where product is not normally exposed (standard hygiene area), e.g. stores, or where there is exposed raw product (ie prior to a microbiocidal critical control point) e.g. raw milk prior to pasteurisation. These areas should be seen as a **buffer** between the outside environment or other high risk area and the critical hygiene area (Zone 3).

Zone 3 encompasses those **inside** areas where product, particularly product after a microbiocidal critical control point, is normally exposed (critical hygiene areas).

An effective Pathogen Management Plan will identify and control pathogen transfer pathways between zones. This is particularly important between zones 2 and 3.
These pathways may include:

- people
- equipment
- tools
- vehicles
- pallets, crates and bins
- ingredients
- packaging

Note: 'Zones' often implies physical separation between areas. Where physical separation of areas is not possible controls should be identified to ensure incompatible activities are

somehow segregated (e.g. by time, space, designated equipment/operators, cleaning). Physical controls may occur at the boundaries of zones. If such a boundary is in place, everything within that boundary will normally be considered as one zone. If different zones are identified or desired within a physical boundary, there must be appropriate controls in place to control the pathogen transfer pathways between the different zones.

3.4.1 People (e.g. staff, visitors, contractors)

Access should be restricted only to the people who need to be there, and who have undergone appropriate induction/training.

Personal Health: People entering a processing area should be free of illness, or symptoms, that could put product (and ultimately the end consumer) at risk.

The NZFSA sickness policy template (http://www.nzfsa.govt.nz/processed-food-retail-sale/templates/sickness-template.pdf) provides more information on the types of communicable disease/illness that pose a threat to food safety and how a business might manage this.

Personal Hygiene: People entering the processing area should understand the role personal hygiene has in food safety (e.g. the potential for contamination of product/equipment with soiled hands).

3.4.2 Handwashing and sanitising

Hand-washing facilities should include a dedicated sink (piped directly into the drains), warm water, soap and suitable hand drying materials (e.g., paper towels). These facilities should be maintained in a clean and tidy condition.

Staff members must know when it is appropriate to wash their hands, e.g.:

- before starting work
- before and after work breaks
- after going to the toilet
- after working with raw product
- after working with raw product contact surfaces

- after rubbish removal and cleaning operations.

Hand disinfection facilities may also be provided. These can provide some additional protection but only if appropriate hand washing has been carried out first. Examples of hand disinfection available include:

- alcohol gel dispenser
- dipping in sanitiser

3.4.3 Watches, Rings, and other Jewellery

Watches, rings and other jewellery cannot be adequately cleaned and so are potential sources of contamination. Consider the risk jewellery presents to your process and whether it is appropriate to implement a jewellery policy outlining which jewellery items can or cannot be worn in processing areas.

3.4.4 Eating, Drinking and Smoking etc

There are some activities that should not be carried out in the processing environment e.g eating, drinking, smoking, spitting.

This is to protect the processing environment from the bacteria that live inside our mouths and on our faces. Food or drink items may also carry in additional pathogen contaminants, so should not be taken into processing areas.

3.4.5 Protective Clothing

As part of your risk assessment you will have determined whether protective clothing must be worn to protect the processing environment from contaminants on clothing and street shoes.

If required, any protective clothing policy applies to everyone (e.g. staff, visitors, managers, regulatory agents).

Protective clothing may include:

- overalls
- hairnets, hats, beard masks
- boots

- aprons
- gloves

Cleaned overalls and other protective clothing (e.g. boots, aprons) must be stored appropriately to minimise cross-contamination between clean and dirty items.

The wearer should keep protective clothing as clean as practically possible. Consideration should be given to the potential for transfer of contamination via protective clothing (e.g. during movement between zones, during change of activities).

3.4.6 Gloves

Gloves may be worn to protect your hands and to prevent bacteria on your skin from contaminating the product.

Gloved hands must also be washed and sanitised during the course of normal work.

Disposable gloves should be replaced regularly (e.g. when they become soiled/damaged, after breaks, between zones/activities)

Gloves must be washed and sanitised at regular intervals and stored in a hygienic manner when not in use.

3.4.7 Footbaths and/or Boot Exchanges

Boot exchanges are the preferred barrier between zones, particularly into dry areas, where control of moisture on the floor is important to prevent pathogen growth. However, if your risk assessment has determined that a footbath is necessary the following should be considered:

Footbaths should:

- be too wide to jump
- be 50-70mm constant depth
- contain suitable sanitiser at recommended strength
- be changed at least daily

(Note: Check sanitiser strengths periodically throughout the day to determine how often sanitiser must be changed).

3.4.8 Equipment/Materials

Consideration should be given to the impact incoming equipment/materials has on the pathogen risk.

Assume everything entering the processing area is contaminated

Specific consideration should be given to the following:

- Transfer systems
    - large equipment / pallets etc through air lock
    - small items conveyers with air curtains or similar
- Removal of outer packaging before entry into processing area
- Cleaning/Sanitising incoming goods/containers
- Restriction of vehicle movements
- Appropriate storage of equipment/materials/ingredients/final product
- Restriction of access of certain materials (either into the processing area or between areas) e.g. wood, porous materials, cleaning equipment, high risk foods, tools
- Use of separate equipment for raw and processed product, including:
    - Bins, crates
    - Knives, utensils
    - conveyors
    - tables
    - cleaning equipment
    - tools

3.5 House-keeping

Consideration should be given to the internal environment and routine activities that may affect movement or growth of pathogens. Routine 'house-keeping' activities may impact pathogen control in many ways.

3.5.1 Cleaning and Sanitising

Cleaning = physical removal of visible soil.
Sanitising = inactivation of most bacteria left on cleaned surfaces.

3.5.1.1 Cleaning

What needs to be cleaned?

Not only do all equipment and processing areas surfaces need to be adequately cleaned and sanitised on a regular basis, but particular attention should also be given to areas where potentially hazardous materials accumulate and present a pathogen risk, such as:

- Waste accumulation areas
- Drains
- Fat traps,
- Water traps
- Vacuum cleaners / central vacuum systems
- Laundry

3.5.1.1.1 Cleaning Procedures

Before a formalised cleaning programme can be developed you should determine standardised operating procedures for your processing steps/areas.

- **Every** procedure needs a specific cleaning and sanitising programme. This should state;
    - what has to be cleaned
    - with what
    - how
    - by whom

- how to monitor effectiveness.

- Cleaning procedures should also be in place to cover items not directly related to processing, including electrical boxes, power cables and plugs.

- Supervision and records of cleaning and sanitising operations will provide a high level of assurance that they have been carried out correctly. This could include checklists for operators to indicate areas cleaned, and pre-processing peer inspections to visually assess cleanliness of critical areas or equipment.

- Environmental monitoring for hygiene indicators, such as *coliforms*, *total plate count*, or ATP (an indicator of biological material present) can assist in determining whether the cleaning systems are effective.

3.5.1.1.2 Cleaning Frequencies

Almost everything will need to be cleaned and sanitised at least daily.
Remember ... bacteria can grow very fast so mid-shift clean-ups may be necessary.

- Many items in the processing area will need to be cleaned and sanitised whenever they become soiled, e.g., a knife that falls on to the floor, or an emptied bin before reuse.

- Consider whether the processing area will be washed down before breaks. Or, whether product remains in-process over breaks. You may consider it better practice for staff to stagger breaks or to ensure that a batch of product has been fully processed before starting a break.

- Some items or areas tend to be overlooked. These also need to be included in a regular programme of cleaning and sanitising. Examples include:

  - chillers
  - freezers
  - light fittings
  - doors/doorways
  - forklifts
  - soap dispensers.

3.5.1.1.3 Cleaning Equipment

Cleaning equipment can be a breeding ground for bacteria.

Separate cleaning equipment could be used for each hygiene zone to ensure that cross-contamination between zones cannot occur. Ensure that relative cross-contamination risks between the following have been considered when establishing cleaning programmes:

- Inside vs Outside
- Raw product areas vs Process areas
- Product contact vs Non-product contact

Equipment used to clean the floor and drains be should dedicated to this task and not be used for any other purpose.

- Use only easily cleaned, non-absorbent cleaning equipment, for example:
  - plastic brushes
  - nylon bristles
  - rubber squeegees.
- Don't use cleaning equipment with wooden handles, wooden heads or fibrous bristles, as these porous materials can harbour pathogens.
- Clean and sanitise all cleaning equipment after every use.
- Ensure that all cleaning equipment is stored in such a manner that it will not pose any risk to the processing operation, and so that the cleaning equipment is protected from environmental contamination.

  For example, store all cleaned cleaning equipment in a well separated cupboard or room.

Note: High pressure hoses create aerosols that can spread bacteria throughout your processing area. Use other cleaning options whenever possible! For example, low pressure/high volume hosing, brushing, sweeping.

3.5.1.2 Sanitising

- Sanitising will only be effective if the surface being sanitised has already been thoroughly cleaned to remove all product or other residue (sanitisers are effective on surfaces, residual product can hide pathogens from the surface and protect them from sanitisers).
- Sanitisers must only be used at the concentration recommended by the manufacturer and be allowed to stay in contact with the surface for the recommended time.
    - Increasing the concentration of the sanitiser will not compensate for inadequate cleaning.
    - Combination detergent/sanitisers typically do not produce an effective kill of pathogens. Consider whether specific areas will require that each cleaning operation is followed-up with a stand alone sanitiser.
    - Fast acting sanitisers will be necessary for sanitising plant prior to short breaks, e.g., quaternary ammonium compounds. Slower acting sanitisers may be suitable for longer breaks, such as over night.

3.5.2 Control of Absorbent Materials

Pathogens will survive and grow in **any** absorbent material including;

- wood
- foam
- cloths
- scourers
- cardboard
- rope
- nylon fabric
- conveyor fabric

These materials **cannot** be effectively sanitised and any found in processing areas should be replaced with sanitary, easily cleaned, non-absorbent alternatives. It may be useful to include a regular check of processing areas for absorbent materials, documenting any found and corrective action taken.

3.5.3 Waste Control

Every food business produces waste and stores it temporarily before disposal. This poses some potential problems:

- Food scraps will attract hungry pests, e.g. insects, rodents and birds, that are likely to be carrying pathogens.
- Food scraps provide a good growth medium for bacteria, including pathogens. Note, if the food scraps produce an offensive odour, this is usually due to bacterial growth and can be indicative of increased risk of pathogens.
- Pathogens may grow on discarded packaging material, e.g cardboard boxes or crates, particularly if it is wet.

3.5.3.1 Recommended Waste Control Guidelines

3.5.3.1.1 Inside:

- Wherever possible, waste should be discarded to designated areas/bins as it is produced,
- All waste bins should be covered.
- Clearly differentiate waste bins from product bins
- Waste bins used in food preparation areas should be emptied and cleaned at least daily.
- Dispose of all packaging used for raw food materials immediately after opening
- Do not reuse any raw material packaging (e.g.cartons used for raw chickens).
- Use bins with foot-operated lid openers to reduce the risk of contaminating hands.

3.5.3.1.2 Outside:

- Locate bulk waste bins away from food preparation and storage areas.
- Store wet waste in metal or plastic containers with tight-fitting lids

- Wet waste should be removed from the premises every working day
- Clean bins regularly to prevent build-up of pathogen-containing residues
- Wash bins in a well drained yard area
- Store dry waste in enclosed containers
- Yard areas should be kept clean and tidy.

3.5.4 Pest Management

Pathogens may be carried into the environment by animals other than humans. Just as you have given consideration to access controls for people, also consider access controls for other animals (e.g. rodents, insects, birds).

3.6 Process Control

It will be necessary for each business/plant to identify the manufacturing process steps where some form of control over pathogens can be established, and then to ensure that effective control is always maintained at these steps. For many businesses this will occur during the development of a HACCP plan.

A process control step should be considered as a step that is designed to eliminate, or at least significantly reduce, the total number of contaminating bacteria, e.g., *heat treatment, pH, addition of salt or sugar (reducing water activity of the product)*.

For each process control step identified - the operating criteria will need to be established. Note, when these process control steps are identified as critical control points (in a HACCP plan) they must be documented, verified and checked regularly. Where several 'hurdles' are required for appropriate control, but each individually does not meet the requirement for a CCP, you should document the hurdles used and ensure that each hurdle is regularly checked and verified and records/logs kept.

For example, a heat treatment will require a defined time/temperature combination, a schedule for verifying that this time/temperature combination is achieved all the time and the keeping of appropriate records/logs.

3.6.1 Prior to processing

- Raw/processed materials should be stored appropriately – eg chilled or frozen as soon as possible after receipt, or kept in a dry and clean environment.
- Processing of raw materials should commence as soon as possible after receipt (minimising delays)
- Unnecessary handling of materials prior to processing should be minimised.

3.6.2 During processing

- Appropriate time and temperature combinations should be determined for each operation.
- The temperatures of processing operations must be carefully controlled to achieve the desired result.
- Control of temperature in the processing environment should be reviewed to restrict the growth of pathogens

3.6.3 During storage

- Products should be stored appropriately – eg chilled or frozen as soon as possible after processing, or kept in a clean dry environment This will minimise the likelihood of pathogen growth in product.
- The temperature of chillers and freezers used for product storage should be monitored and controlled constantly. (Remember that the rate of cooling or freezing will also determine the likelihood of significant pathogen growth.)
- Ensure that all product contact surfaces, such as spiral belts or racks/shelves are kept clean and sanitary, e.g. the product contact surfaces in chillers and freezers will accumulate product residues if not cleaned regularly.

Note: Some pathogens are capable of growing at refrigeration temperatures but they prefer to grow at higher temperatures. It is important to control the temperature during all phases of processing of high moisture foods to ensure the potential pathogens are not provided with an opportunity for significant growth.

3.7 Monitoring and Surveillance

Regulatory requirements may specify environmental surveillance and/or final product testing.

3.7.1 Environmental surveillance

The environmental monitoring programme provides verification that the pathogen control systems in place are effective. Environmental or final product monitoring cannot in itself be considered a control.

3.7.1.1 General Considerations

- Contamination of product from the processing environment is the most common source of contamination for processed foods.
- For this reason, it is vital to ensure that the processing environment is always protected from contamination using the measures previously described.
- Monitoring of the processing environment (and final product) provides the processor with an assurance that the control measures are effective.
- When using environmental monitoring as a verification activity each premise should develop documented sampling procedures. In general these should describe;
    - Sampling responsibilities
    - Site plan showing sampling sites
    - Sampling procedures
    - Required follow-up action.

3.7.1.2 Sample Site Selection

The selection of suitable sample sites should be based upon the perceived risk to the process. Processing areas can generally be maintained in a sanitary condition. However, contamination may be brought into processing areas, e.g. on items such as raw ingredients, water, equipment or people. Alternatively, pathogens may enter the process environment more discretely, e.g. on pests, through roof leaks.

A risk assessment should have determined what control measures are necessary to prevent entry by these, or any other identified means. The sampling plan for the environmental surveillance programme should be developed to confirm the effectiveness of these controls.

In general, surveillance can occur at three discrete levels of risk, based on the principle of zones described earlier.

- **Zone 1** encompasses the **outside** environment of the processing area.
- **Zone 2** encompasses those **inside** areas where product is not normally exposed (standard hygiene area), e.g. stores, or where there is exposed raw product (ie prior to a microbiocidal critical control point) e.g. raw milk prior to pasteurisation. These areas should be seen as a **buffer** between the outside environment or other high risk area and the critical hygiene area (Zone 3).
- **Zone 3** encompasses those **inside** areas where product, particularly product after a microbiocidal critical control point, is normally exposed (critical hygiene areas).

Zone 1: Samples from this area provide some indication of the risk to the process from the immediate surrounds. This is useful information as it enables the business to manage potential problem areas. Examples of suitable sampling sites include:

- Access-ways
- Puddles
- Rubbish areas
- Roofs
- Gutters
- Doorways

Samples may be in the form of swabs, wet material, or dry material (sweepings, scrapings, rubbish, product residues).

Zone 2: Examples of suitable sampling sites include:

- Raw material stores
- Materials stores
- Product stores
- Floors
- Service areas
- Wet areas
- Forklifts

Samples may be in the form of swabs, wet material or dry material (sweepings, scrapings, rubbish).

Zone 3: It is important to know that this environment is free from contamination at all times. Examples of suitable sampling sites include:

- Processing areas
- Packaging areas
- Chillers/Freezers
- Forklifts/trolleys
- Drains
- Floors
- Cleaning equipment
- Walls/ledges
- Hard to clean equipment
- Wet areas
- Product contact equipment
- Benches
- Conveying systems/belts

- Utensils, e.g. knives
- Gloves
- Product contact water
- Shelving
- Packaging material
- Bins/crates

Samples may be in the form of swabs, wet material or dry material (scrapings, product residues).

3.7.1.3 Sample Collection

The purpose of the surveillance programme is to test the effectiveness of pathogen control measures. Therefore it is in the best interests of the business to maximise the effectiveness of the surveillance programme. As a general rule, the bigger the sample taken, the more likely you are to detect environmental contamination.

Samples may be in the form of swabs, wet material or dry material (eg scrapings, product residues).

Note: **Swabbing is an important mechanism for gathering environmental samples, particularly in areas where there is not enough loose material to pick up. Large gauze swabs (50 x 50mm 8-ply), moistened in suitable sterile diluent, are recommended, as they can cover a large area Additionally, the use of sterile stainless steel forceps to hold gauze swabs means that some considerable force can be applied to lift material stuck to surfaces.**

3.7.1.4 Compositing

Compositing is the combining of a number of samples prior to testing. This can reduce test costs while encouraging companies to take more samples. Compositing using gauze swabs is a particularly effective way of sampling large areas.

One disadvantage of compositing is that further traceback work will have to be undertaken to isolate a contamination point when a composite is positive, resulting in

a longer timeframe required to isolate the problem. However, for companies with effective controls and a good surveillance history, compositing is a cost effective option.

Compositing rules

- Only composite samples within a zone (don't mix samples from different zones).
- Do not composite wet samples with dry samples.
- Do not include swabs that smell of sanitiser in a composite.
- Document the sample sites for all areas that make up a composite.

3.7.2 Product Testing

Final product testing is not a pathogen control measure but may provide some limited form of verification. In most cases this is unlikely to be statistically significant. Therefore final product testing should never be considered as a substitute for pathogen control during processing. As a part of product verification it is recommended that a representative sample of finished product, in its final packaged form, be submitted for testing at regular intervals. Include samples of each product type and processing line.

Note: It is the operators responsibility that regulatory outcomes with respect to food safety are met.

3.7.3 Corrective actions

Just as selection of sample sites is based on perceived risk to the process, predetermined corrective actions when pathogens are isolated should be commensurate to the risk. The following are suggested actions in response to isolation of pathogens from each of the hygiene zones.

3.7.3.1 Positive Results from Zone 1 and 2

- Positive results from zones 1 and 2 are to be expected from time to time. These provide you with;
    - Confidence that your sample site selection is adequate
    - Knowledge with which to manage the situation.

3.7.3.1.1 Recommended Actions for Positive Results in Zone 1

- Use this positive result as an early warning. That is, pathogens are in the environment but not yet in processing areas.
- Reassess:
    - Cleaning and sanitising programmes for zone 2 areas
- You may wish to intensify sampling in zone 2 to ensure that access controls are intact and effective.

3.7.3.1.2 Recommended Actions for Positive Results in Zone 2

- Use this positive result as an early warning. That is, pathogens are in the environment but not yet in critical processing areas.
- Resample individual zone 2 sites in order to pinpoint the source of contamination.
- Reassess:
    - Access restrictions to zone 3
    - Trends of Zone 1 results to identify any areas that may require control reassessment.
    - Cleaning and sanitising programmes
    - Manufacturing and product handling procedures
- You may wish to intensify sampling in zone 3 to ensure that zone 3 barriers have not been breached.
- Clean and sanitise the affected area, if appropriate, to minimise the risk of contamination spreading.
- Resample the affected area, and adjacent areas, daily until you are sure that the source of contamination has been eliminated. Generally, this means predetermining a clearance schedule requiring a number of days of negative results. The number of days should depend on the area in question and the perceived risk, or regulatory requirement.

3.7.3.2 Positive Results from Zone 3

- Positive results in zone 3 mean that the zone 1 and zone 2 barriers have been breached and contamination has entered the critical hygiene area.

Note: It should be considered that product is 'at risk' of having been contaminated.

3.7.3.2.1 Recommended Actions For Positive Results in Zone 3

Sources of contamination in the critical hygiene area are not likely to be isolated in one discrete area. It may be necessary to hunt for sources of contamination in areas that do not form part of the normal monitoring programme.

Remember, the objectives of any follow-up action are to:

1. Identify the source of contamination.
2. Determine the extent of the problem, this includes prevalence in product and contamination of the environment
3. Eliminate this source of contamination.
4. Prevent any re-occurrence.

Specific follow-up action should include the following:

- Reassess:
    - Access restrictions to zones 2, 3.
    - Cleaning and sanitising programmes
    - Manufacturing and product handling procedures
    - Sanitary design of equipment.

- Intensify sampling in critical hygiene areas to pinpoint the source of contamination. (Individual samples will be needed for test.)
- Clean and sanitise zone 3.
- Resample all environmental sites in zone 3 verify cleaning and sanitising efficiency.

- It is recommended that batch-by-batch sampling and testing of product be carried out of all product in store processed since the date of the last **negative** test result for product, using a statistical approach e.g. ICMSF in consultation with the recognised authority (See ***Recommended Actions for Positive Product Results*** below for sampling and follow-up actions in the case of product positive results.)
- If product is not available for testing, you should contact your recognised agency or regulator.

3.7.3.2.2 Recommended Actions for Positive Product Results

- Product that exceeds, or is suspected to exceed, safety limits for pathogens poses a risk to public safety and must not be offered for sale.
- Each site should have in place a documented procedure for **recalling product** from the market place.
- All product in store that is "at risk" must be segregated from other product and clearly labelled to indicate its' status. For example, mark each package with **hold** labels.
- Product disposition options should be outlined in your Food Control Plan in accordance with regulatory requirements.
- Reassess the environmental sampling programme, access restrictions and processing procedures to determine possible causes of the product contamination.

3.8 Records

Efficient and accurate record keeping is essential to the application of a Pathogen Management Plan. Pathogen Management procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation, and the regulatory environment it is operating within.

3.9 Reporting

Regulatory requirements may specify reporting requirements with respect to pathogen management within a business.

Your pathogen management should document reporting requirements, ie. Who has to be notified, either internally or externally, if pathogens are isolated (note, it is strongly

recommended that your verifier or regulator be notified in the event of isolation of pathogens in zone 3 or in product).

3.10 Reviewing the Pathogen Management Plan

The pathogen management plan should specify the periods for review and who will be responsible for this. The plan should be examined for omissions or errors, particularly in light of any changes in the company's products or processes.

It is recommended that the pathogen management plan is reviewed:

- internally at least once a year
- externally/independently on a regular basis or as per regulatory requirements
- following an isolation of pathogens in zone 3 or in product.

Procedures and schedules for these reviews should be documented and held as part of the pathogen management plan itself.

3.11 Check-Back Tool

The decision tree in Appendix 2 can be used as a quick reference tool to clarify whether you have considered the key pathogen control measures, or whether you need to revisit/review your pathogen management plan to provide additional control measures.

3.12 Examples

A worked example of a pathogen management plans is available at http://www.nzfsa.govt.nz/dairy/publications/guidelines/pathogen/model/

Note: Further examples are being developed for small businesses and will be added as they are completed.

4 For more information or comments on this guideline

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Appendix 1 – Pathogen Management Plan Elements

Self-Assessment Worksheet/Checklist

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	Systems Considerations		
1.0	**General**		
1.1	Scope of plan is defined		
1.2	Regulatory outcomes to be met are identified		
1.3	Management commitment to this pathogen management plan is demonstrated		
1.4	Responsibilities for the implementation and maintenance of this plan are defined		
1.5	Internal audit systems are defined		
1.6	Procedures for review of this plan are defined		
1.7	A corrective action system is described		
1.8	Relevant documents are subject to document control		
1.9	Documents and records are clear and legible		
2.0	**Risk Assessment**		
2.1	Pathogens that could be a risk to your products/processes are described		
2.2	Potential sources of these pathogens have been considered, including:		
	• Vehicles		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	• Waste		
	• Staff		
	• Visitors		
	• Contractors		
	• Animals		
	• Insects		
	• Birds		
	• Ingredients		
	• Water		
	• Air		
	• Equipment		
	• Packaging materials		
2.3	Potential pathways of contamination have been considered for each of the identified pathogens		
2.4	Parts of the process suitable for pathogen growth have been identified:		
	• Suitable temperatures		
	• Time between cleanups		
	• Food and moisture availability		
2.5	The likelihood of process or product contamination has been determined for each pathogen / source		
2.6	Control measures have been identified and		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	implemented as appropriate		
2.7	Rationale used for assessing risk has been documented		
3.0	**HACCP**		
3.1	Full documentation of HACCP for each process as per Codex Alimentarius.		
3.2	HACCP team make-up is appropriate.		
3.3	Flow diagrams are prepared for each main type of food produced.		
3.4	All hazards to the food have been identified.		
3.5	A hazard analysis has been carried out.		
3.6	Control measures have been identified for all hazards.		
3.7	Critical Control points have been identified.		
3.8	Critical limits have been identified.		
3.9	Monitoring activities have been documented for each critical control point.		
3.10	Corrective actions have been identified for situations where critical limits are exceeded.		
3.11	Verification actives have been documented.		
3.12	All documents and records relating to the HACCP plan have been identified.		
3.13	The HACCP process has been fully validated.		
3.14	Testing of product takes place to verify that food is safe. Testing and testing frequencies need to be defined. Follow-up/corrective action		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	systems are in place.		
4.0	**Raw Materials**		
4.1	Approved suppliers or equivalent are used		
4.2	Specifications for all incoming supplies		
4.3	Acceptance criteria for raw materials and ingredients based upon risk assessment of the raw materials and ingredients and of the suppliers.		
4.4	All incoming goods checked on receipt (condition, identification and labelling, temperature, quantity) and placed into storage as soon as practical or used immediately in the process.		
4.5	Ingredients / additives / processing aids are approved for use under the Food Standards Code.		
	Technical Considerations		
5.0	**Buildings**		
5.1	Buildings meet regulatory and local authority requirements		
5.2	Impact of building location has been considered, including: • Proximity to other high risk operations (eg. Landfill, waste water treatment, pathogen lab, contaminating neighbours) • Movement of vehicles on and off site		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	• Waste disposal (eg. Location of bins, access for removal, spill containment)		
5.3	Building design has been considered: • Windows and doors exclude pests • No direct access from critical processing areas to outside • Floor, wall, and ceiling materials are non-porous and easily cleaned • Process flow minimises opportunity for cross-contamination • Amenities located to minimise opportunity for cross-contamination • Temperature control as required • Air systems appropriate • Microbiology laboratories physically separated from processing building • Waste handling areas appropriately designed and located		
5.4	Appropriate consideration of floors and drains: • Designed to minimise ponding • Cracks and holes eliminated • Waste is piped directly to drain • Drains have adequate capacity • Drains are trapped • Traps are cleaned regularly		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	• Floors are smooth without being slippery • Floors and drains are cleaned daily • Cleaning equipment used for floors and drains are not used for any other purpose • Low pressure hosing only is used on floors and drains • Product contact equipment is not cleaned on the floor • Product that falls onto the floor is sent to waste		
5.5	Walls and ceiling are made of non-absorbent, easily cleaned material: • No holes or cracks • No unflashed openings • No sills or high ledges • Wall/floor junctions are appropriately flashed and sealed		
5.6	Equipment is designed and constructed for easy cleaning and disinfection: • Non-absorbent, non-corrosive, eg. Stainless steel • No hollow box sections • No sandwiched surfaces • Free draining pipes and sections, no		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	dead ends • Components likely to perish or discolour should be regularly replaced		
5.7	Conveyor belts: • Are made of hygienic, easily cleaned material • Are non-absorbent • Are never allowed to touch the floor • Have completely sealed rollers		
5.8	Equipment that needs to be dismantled for cleaning has been identified		
5.9	Maintenance is planned and carried out to minimise risk to product: • Maintenance personal observe normal access restrictions • Timing is appropriate • There is adequate clean-up after maintenance, including: removal of waste, cleaning and sanitising of the area		
5.10	There is appropriate control at breakdowns to ensure that product is not put at risk, or that product so identified is appropriately handled		
6.0	**Services**		
6.1	Water meets current regulatory requirements, DWSNZ 2000		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
6.2	Water is treated and handled appropriately: • Treated by local authority, or on-site, eg. by chlorination, ozone, UV, or filtration • Stored to prevent contamination • Quality checked regularly at point of use • Records of water treatment and checks are maintained		
6.3	Ventilation air is used to maintain positive air pressure inside the processing areas		
6.4	Ventilation air is filtered to remove insects and dust		
6.5	There is a documented filter maintenance programme		
6.6	Air intakes are up-wind of exhaust vents, cooling towers, inwards goods and rubbish disposal sites		
6.7	Condensate from cooling systems is piped directly into drains		
7.0	**Controlled Access**		
7.1	Critical hygiene areas have been adequately differentiated from other areas (eg. Zones or levels 1,2,3)		
7.2	Transfers between areas are controlled to minimise cross-contamination by, eg: • Redline		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	• Boot exchange • Footbath • Airlock		
7.3	Transfer areas are carefully monitored to ensure that controls are effective		
7.4	Access is restricted to those who need to be there		
7.5	People entering the critical hygiene area are free of illness		
7.6	People entering the critical hygiene area maintain appropriate level of person hygiene		
7.7	Hand washing facilities: • Are appropriately located • Have warm water • Soap • Suitable hand drying material, eg. Paper towels		
7.8	Staff wash hands at appropriate times		
7.9	Hand sanitation facilities are provided as appropriate		
7.10	Jewellery policies are adhered to		
7.11	Eating, drinking, smoking, spitting do not occur in processing areas		
7.12	Protective clothing is worn as appropriate		
7.13	The use of gloves is carefully monitored		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
8.0	**Housekeeping**		
8.1	Cleaning programmes have been documented: • What has to be cleaned • What cleaning equipment • How • By whom • How is effectiveness monitored		
8.2	Cleaning programmes include infrequently cleaned (out of the way) items or areas		
8.3	Records of cleaning and cleaning effectiveness are maintained		
8.4	Frequency of cleaning has been determined based on risk		
8.5	Cleaning equipment is dedicated to particular areas or items to minimise cross-contamination		
8.6	Cleaning equipment is easily cleaned and sanitised after use (No wooden handles or fibrous bristles)		
8.7	High pressure hosing is restricted to minimise the spread of contaminated aerosols		
8.8	Sanitising occurs only after effective cleaning		
8.9	Sanitiser strength and contact times are as per manufacturers instructions		
8.10	Combination detergent/sanitisers are not used		
8.11	Absorbent materials such as wood have been removed from processing areas		

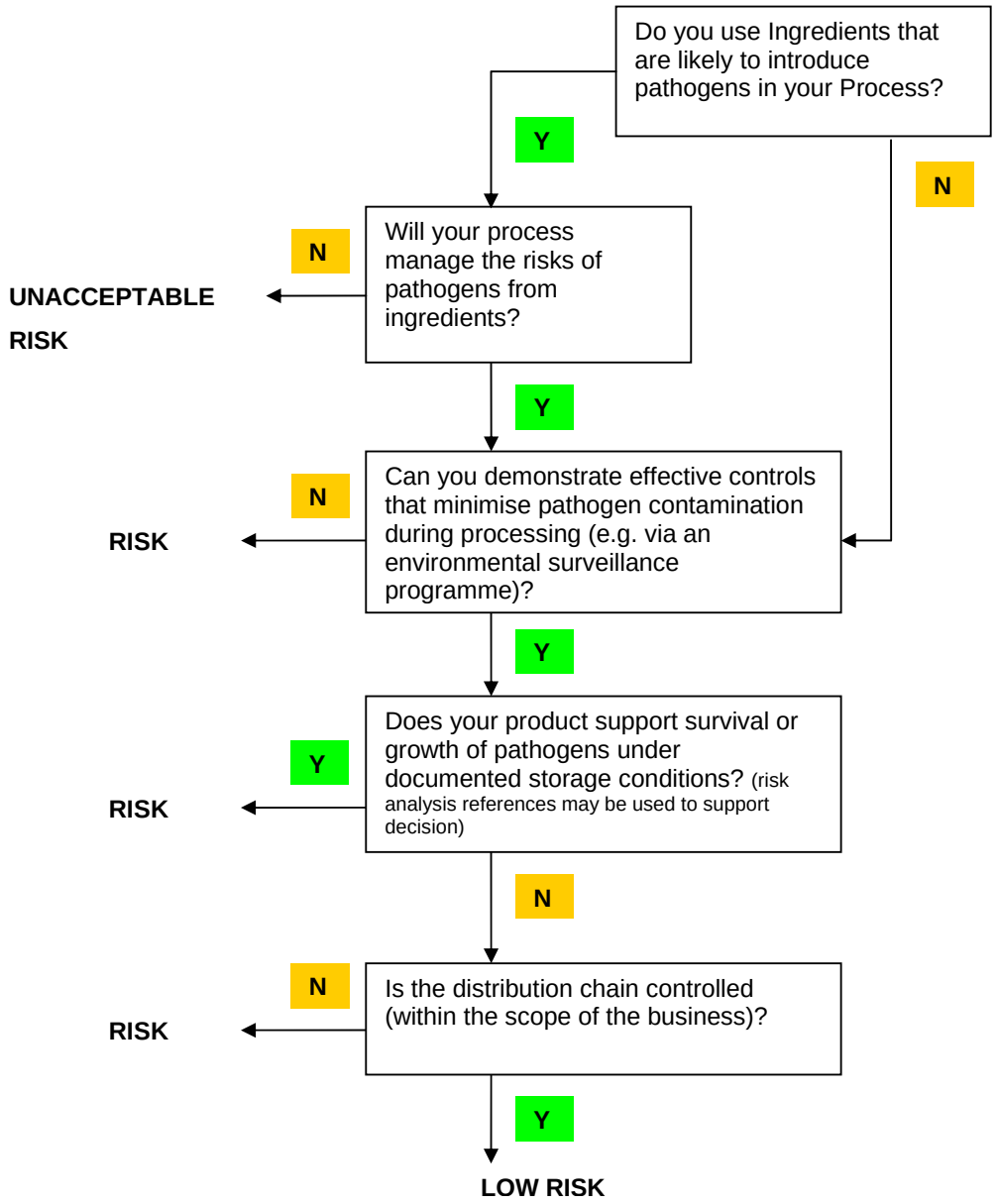
#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
8.12	Inside waste is stored and handled appropriately: • In dedicated areas • Covered bins • Clearly identified bins or bags • Bins emptied and cleaned daily • Raw material packaging disposed of immediately • Raw material packaging is not reused		
8.13	Outside waste is stored and handled appropriately: • Bulk waste bins away from storage or preparation areas • Wet waste is contained • Bins are cleaned regularly • Bin areas are well drained • Waste areas are clean and tidy		
8.14	A documented pest management programme is implemented and records are maintained		
9.0	**Process Control**		
9.1	Process control steps have been identified and implemented, eg through application of HACCP		
9.2	Control ***prior to processing*** minimises risk to product safety: • Appropriate storage		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	• Minimise delays • Minimise handling		
9.3	Control ***during processing*** minimises the risk to product safety: • Time / temperature • Temperature of process environment		
9.4	Control ***after processing*** minimises the risk to product safety: • Appropriate storage ASAP after processing • Temperature control and monitoring • Housekeeping in storage areas, especially chillers and freezers		
10.0	**Monitoring and Surveillance**		
10.1	Regulatory requirements for environmental surveillance are met.		
10.2	The environmental surveillance programme verifies that pathogen control systems are effective.		
10.3	Sampling procedures are documented.		
10.4	Sample site selection is based on perceived risk.		
10.5	Surveillance is based on a tiered approach to risk, eg. levels or zones 1,2,3 etc.		
10.6	Sample type is appropriate: • Large gauze swabs		

#	Pathogen Management Plan Requirement	Do you have this? ✓ / X	Reference
	• Sweepings • Scrapings • Product residues		
10.7	Samplers are trained appropriately: • Aseptic technique • Sample handling • Sample selection		
10.8	Samples are handled, stored and despatched to the laboratory in an appropriate manner.		
10.9	Documented corrective actions are described for each level or zone.		
10.10	Records of all results and any corrective actions taken are maintained.		
10.11	Corrective actions include tracing the source of the contamination.		
10.12	Product testing is carried out to verify the effectiveness of control measures and surveillance programme.		

Appendix 2 – Check Back Tool

Decision Tree for Ready To Eat Foods
To be used in conjunction with relevant HACCP and Microbiological Limits Standards (e.g D107, D110, ANZ FSC)



Where Risk is indicated, additional control will need to be included in the Pathogen Management and/or HACCP Plan.

Note: If there is more than one product process flow in the same environment the highest risk factor determined applies to all products in that environment.