Industry Product Safety Guidelines for Non-Ready-To-Eat (NRTE) Plant Based Meal Solutions in Australia and New Zealand

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1) Purpose

The purpose of this product safety guide is to provide support information to industry to consider when developing quality system requirements unique to chilled non-ready-to-eat (NRTE) plant-based meal solutions (PBMS).

This resource joins a growing number of industry guides developed by the Alternative Proteins Council (APC), including:

- Plant-Based Meat Alternative Product Labelling Guideline (Published June 2022, Revised April 2023)
- Plant-Based Dairy Alternative Product Labelling Guideline (in progress)

The Alternative Proteins Council (**APC**) is the peak industry representative group for Australia and New Zealand's alternative proteins sector. The APC provides a collective voice for the sector, including including plant-based meat alternatives, plant-based dairy alternatives, precision-fermentation and cellular agricultural sectors, and a platform to discuss shared issues and opportunities. The Council works to ensure the voice of the sector remains unified and represented on key industry issues.

2) Introduction

Non-ready-to-eat (NRTE) chilled foods include a vast range of food products, from pizza to plant-based meat analogues such as burgers, meatballs, sausages, nuggets; soups, sauces and doughs that require cooking prior to consumption.

It is important to consider all sections starting with food safety by design through the manufacturing process. These foods may include both raw and heat-processed ingredients. Further heat processing may or may not be used during the manufacturing process and by the consumer. For these reasons, chilled foods depend on refrigeration as the primary means of preservation. Chilled food manufacturers must aim to achieve less than 5°C in storage and distribution.

A key criterion for chilled foods is that they must be microbiologically safe at the point of consumption.

Pathogens such as *Listeria monocytogenes* that could result in food-borne illness when consumed must be controlled. Within this context, ensuring the safety and quality of chilled foods is

dependent on the integrity of the entire food chain, from production and harvesting of ingredients, through manufacturing and distribution and finally, storage and preparation by the consumer.

Listeria is a significant risk to PBMS products throughout the process, with its ability to survive and grow in chilled conditions as an opportunistic pathogen. *Listeria* can also be ubiquitous in the environment in which the plant-based meat analogue is manufactured. Raw materials out of specification, inadequate multi-hurdle design and/or execution, improper cleaning, poor zoning and much more can all contribute to contamination in the environment and the chilled products.

If the raw plant-based meat analogue is designed to be cooked by the consumer, then the cook step should result in at least a six (6) log reduction in *Listeria monocytogenes* in the food as consumed.

The task of setting up and managing a chilled food operation demands a high level of expertise to ensure that a facility is properly designed and that appropriate procedures are in place to achieve the production of safe foods. These procedures involve application of Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and implementation of a Hazard Analysis and Critical Control Points (HACCP) based systems.

3) Main Hazards

Chilled foods may be manufactured using a wide variety of ingredients, processes and packaging systems. Microbiological, chemical or physical hazards may be very different from one product to another. Control of hazards must be done through application of HACCP systems.

a) Microbiological Hazards

Chilled foods are very sensitive to microbiological contamination, growth and toxin development.

Table 1 lists the pathogenic microorganisms of concern along with their principal growth boundaries. While all these pathogens need to be taken into consideration, cold growing pathogens such as *Listeria monocytogenes*, *psychrotrophic Clostridium botulinum* and *psychrotrophic Bacillus cereus* are particularly relevant to chilled food.

If flour is used as a major raw ingredient or meat containing finished products are also made on the same lines used to manufacture NRTE PBMS products then Shiga Toxin producing *E.Coli* (STEC) as a pathogen should be considered if *E.Coli* limits exceed 10 cfu/g.

To control these microbiological hazards the adequate control measures must be in place for:

- Supplier selection, specifications and control of incoming raw material
- Appropriate raw material storage
- Process design and control measures
- Hygienic processing conditions, appropriate zoning principles
- Establishment of appropriate product shelf life and correct instructions for preparation/cooking
- Maintenance of the chill chain during distribution and sale

Control measures for each of the above steps must be done through the application of HACCP.

Table 1: Commonly accepted growth boundaries of pathogenic microorganisms[1]

Microorganism and growth boundaries[2]	**Min temp (°C)**	**Min pH**	**Min a_w**	**Aerobic / anaerobic[3]**
L. monocytogenes	-0.4	4.3	0.92	Facultative
B. cereus	4[4]	4.5[5]	0.93	Facultative
Campylobacter jejuni	32	4.9	0.99	Microaerophilic
Cl. botulinum Mesophilic/proteolytic	10-12	4.6	0.93	Anaerobic
Cl. botulinum Psychrotrophic/non-proteolytic	3.3	5.0	0.97 (5% NaCl)	Anaerobic
Cl. perfringens	12	5.5-5.8	0.935	Anaerobic
E. coli	7-8	4.4	0.95	Facultative
E. coli O157:H7	6.5	4.5	0.95	Facultative
Salmonella	6	4.0	0.94	Facultative
Staphylococcus aureus[6]	5.2[7]	4.5	0.86	Facultative
V. cholerae	10	5.0	0.97	Facultative
V. parahaemolyticus	5	4.8	0.94	Facultative
Y. enterocolitica	-1.3	4.2	0.96	Facultative

Other microorganisms of spoilage concern that can be considered for testing are lactic acid bacteria, psychrotrophic lactic acid bacteria, psychrotrophic plate count, yeast and mould.

b) Chemical Hazards

Chilled foods, like other food products, are also subject to contamination by environmental contaminants and residues from pesticides or veterinary drugs. Compliance of raw material with the relevant legislation is essential.

Supplier selection, evaluation and follow-up are the best control measures. Chemicals such as cleaning agents, lubricants and pest control materials may also present on-site chemical hazards. The correct use of food-grade chemicals, where appropriate, and application of GMP and GHP are the best control measures.

The specification and selection of ingredients need to assess the potential for chemical contaminants that may be introduced via solvents or intermediate processing such as mineral oil hydrocarbons (MOH). Mineral oil aromatic hydrocarbons (MOAH) present a long-term health

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[1] *References: Microorganisms in Foods. Vol. 5. Microbiological Specifications of Food Pathogens. (1995), ICMSF, Blackie Academic & Professional; ACMSF Report on Verocytoxin-Producing Escherichia coli (1995), HMSO, London, ISBN 0-11-321909-1.*

hazard with a carcinogenic and genotoxic effect. Mineral oil saturated hydrocarbons (MOSH) present a moderate long-term health hazard with accumulation in the liver.

MOH, MOAH and MOSH may be monitored by non-governmental organisations (NGOs) for products in the market, particularly PBMS. This can result in high attention of consumers and negative press around PBMS brands.

Chemical contaminants from packaging material such as mineral oil hydrocarbon transfer must also be assessed in HACCP.

c) Physical Hazards

Physical hazards might include foreign bodies such as metal, glass, wood, stone, insect fragments and bird feathers. Their control is ensured by raw material quality, specifications, supplier evaluation and provisions applied during processing, eg metal detectors after packaging and filters in line.

4) Control Measures

Food safety by design is essential in PBMS products. Design captures the holistic view from the raw materials to the multi-hurdle technology design and execution. Safety and quality by design enables success at the manufacturing facility and for the product's shelf life through intended distribution.

a) Raw Materials

Raw materials should be fit for purpose for PBMS products.

Materials should be assessed for their risk of microbial contamination, the process that will be used to remove and/or reduce the microbial contaminant load in finished product. Additionally, raw materials with high microbial loads, even if going through a validated kill step, can present a risk to the factory environment. Therefore, the factory must adhere to the strictest hygiene requirements for both NRTE and ready to eat (RTE) products.

For example, raw materials prepared and handled prior to the kill step in a medium hygiene zone of a factory still need to be of acceptable microbiological standards.

Proper onboarding and approval of raw materials is required for PBMS. A strong Supplier Quality Audit (SQA) must be performed and on-going supplier management must be applied to assure the utmost safety of the raw materials.

Most ingredients used for PBMS are ingredients that have been used historically in the food. However, as PBMS evolve, new, novel or non-traditional ingredients may be considered. It is important to assess all new ingredients, early in the development process for emerging or potential risks that are biological, chemical contaminants and/or of regulatory concerns.

There are also strict regulatory processes that must be followed for pre-approval and use of novel food/ingredients (see the Australia New Zealand Food Standards Code (ANZFSC)).

The following basic mandatory principles should apply to raw material and packaging materials used in the manufacture of NRTE PBMS products.

1. Raw materials and packaging materials must be purchased to agreed specifications and from suppliers who comply with GMP, HACCP and who can demonstrate compliance with all relevant legislation. Sourcing from global food safety initiative (GFSI) accredited suppliers ensures that the supplier has a quality management system in place.
2. Supplier evaluation should be done to ensure the supplier can consistently meet the quality and food safety requirements set in the specifications.
3. The specifications should be determined through application of HACCP, with expert advice used and validated through the product design phase. The specification should have critical limits outlined for microbiological, chemical (including possible contaminants), physical, allergen and organoleptic characteristics of the delivered materials. Storage and distribution handling must be specified.
4. Verification of supplier specifications and controls to be done via monitoring of received materials using approved laboratories and methods against the critical acceptance limits set.
5. Raw materials must be stored as quickly as possible after delivery in adequate, specifically designed, temperature controlled in hygienic conditions to prevent contamination of microorganisms, physical and chemical contaminations and allergen cross contamination.
6. Appropriate good warehousing principles such as traceability, first in first out (FIFO) must be in place.
7. The raw material preparation area must be hygienically designed and zoned to minimise any cross contamination or microbiological growth.
8. Raw material thawing is a critical process and must be considered in HACCP. Time and temperature must be selected to manage any risk of microbiological growth.
9. Prepared and thawed raw materials must be processed immediately. If this is not possible, then the materials must be held at specified conditions of time (limit) and temperature.
10. Only cleaned and steam-treated herbs and spices are used for manufacture of PBMS.

b) Processing

There is a potential for consumer misuse of NRTE plant-based products as consumers may consider the product to be safe (being made of plant materials) and could eat the products uncooked. The HACCP study must consider this potential consumer misuse and build appropriate control measures in all aspects of product design, handling, facility design and personnel GMP.

The following principles must be considered when processing NRTE PBMS.

1. Individual or multi hurdles such as aW, pH, preservatives, modified atmospheric packaging to be identified in product design stage to control pathogen growth, toxin formation or spoilage during storage and distribution.
2. Predictive modelling or challenge testing to be done to demonstrate the hurdles chosen are effective. If the operation does not have on site expertise on predictive modelling or challenge testing, then external expert advice should be sought.
3. Shelf-life protocol must be developed to assess organoleptic as well as spoilage organism growth for the entire chilled shelf life.
4. If any heat treatment is used in the process, the heat treatment must be validated and must be validated for worst case scenario, such as heat penetration to the centre of the product.

5. Hurdle verification to be done as critical control points/operational pre-requisite program (CCPs/OPRPs) for every batch produced. Calibration must be in place for any instrument used to monitor the hurdle in the process, such as extrusion temperature, acid addition, for example.
6. If raw materials don't all undergo the heat treatment step of >70°C / 2 minutes, all types of pathogens should remain a risk for HACCP and strong pre-requisite programs must be in place to minimise the risks from raw materials plus onsite contamination from poor GMP practices.
7. Instructions for consumer preparation and use must be validated for effectiveness and practicality.
8. Chilling of the product must commence as soon as it is practicable after heating or extrusion.
9. Temperature control of the product during processing to be below < 5°C to minimise potential opportunistic pathogenic growth.
10. Potential contamination from personnel movement to be minimised with personnel entering through a designated area and following specified GMP procedures. The personnel must understand the importance of maintaining appropriate hygiene conditions throughout the facility.
11. The operational teams are given thorough training in all aspects of processing and storage of chilled products as well as personnel hygiene and cleanliness.
12. Effective cleaning and sanitation program to be in place and must be reviewed when new products are introduced for its effectiveness. Chemicals to be rotated to prevent any resistant biofilm formation on site. Cleaning company experts should be requested to give assistance on developing effective cleaning and sanitation programs.
13. Environmental monitoring to be in place targeting *Listeria* as the hygiene indicator.

c) Storage and Supply Chain

To ensure that safety and quality of the products are maintained during its stated shelf life, it is essential that the product be kept continuously cold from the time it is packaged until it is consumed or prepared for consumption. The storage temperature should be that which will maintain product safety for the intended shelf life of the product. If the temperature of the product is the principle means of preservation, then the product should be kept at a temperature as low as possible.

In any case, validation of the selected temperature must be carried out.

- The storage and distribution temperature MUST be that which will maintain product safety for the intended shelf life of the product.
- Knowledge of the chill chain performance, in terms of temperature and time, as well as reasonable consumer handling must be considered when designing chilled products and establishing their shelf life.
- Maintenance of the chilled supply chain during storage, transport, distribution and sale.

Chilled:

- Refrigerated conditions <5°C must be maintained throughout storage and the supply chain.
- Refrigeration can substantially reduce the rate at which food will deteriorate. Low temperatures slow down the growth of microorganisms and the rate of chemical (including enzymic) changes in food.

- 5°C or below is necessary to minimise the growth of infectious or toxigenic microorganisms in the food so that the microbiological safety of the food will not be adversely affected for the time the food is at that temperature.

Frozen:

- Frozen potentially hazardous food must be kept at a temperature that ensures the food remains completely frozen (-18°C to -25°C).

General:

Particular attention should be paid throughout storage and distribution to:

- Periods of defrosting of refrigeration units at each point of the distribution chain
- Temperature abuse
    - Chilled product – maximum temperature
    - Frozen product – Freeze / thaw cycles and maximum temperature
- Avoid overloading the cold storage facility.
- Appropriate packaging to ensure the product is protected through the distribution chain.

Refrigerated product display:

- Products should not be stacked higher than the maximum level indicated in display cases, in front of air ducts or too close to heat generating lamps. There should also be a good circulation of air.

Validation:

- Temperature abuse microbiological trials to ensure the product will maintain food safety across the validated shelf life.

Monitoring:

- Regular and effective monitoring of temperature of storage areas, transport vehicles and the store display cases should be carried out.
    - This monitoring should take place, in particular, when the transport vehicle is loaded or unloaded.
    - The temperature probes must be part of the site calibration program.
    - Alarm and visual alert setup with trigger levels if temperature goes out of specification.

Traceability:

- Traceability allows tracking of the history, application and location of products under consideration.
- Traceability can relate to:
    - The origin of ingredients and packaging materials
    - The processing history
    - The distribution and location of the product through the supply chain
- Traceability requires documented procedures looking at product identification from purchasing of the raw materials throughout the whole process and shipment.

d) Labelling to position as NRTE and for Cooking Instructions

Finished products should be clearly positioned as NRTE.

Information related to microbiological safety eg describing the product as ‘Raw’ or ‘Uncooked’,

storage conditions and product usage, must be given appropriate placement and prominence on packaging.

Where appropriate, uncooked components must be made visible and evident to the consumer. Packaging and images on the packaging must be aligned with NRTE status of the product to avoid consumer misinterpretation as RTE. High risk raw materials, such as uncooked plant-based meat analogues, require specific and clear labelling to make clear the nature of the ingredient as packaged.

Front of pack statements such as 'Cook Before Serving' can improve communication to consumers to indicate that the product requires a heat step prior to consumption.

Finished product must be properly labelled with validated cooking instructions.

Serving instructions and suggested recipes must be clearly written to prevent any misuse.

Communication to the consumer, through different channels eg written cooking instructions, written or displayed serving instructions/recipes, advertisements, images or other means, must be fully aligned and understandable by the consumer.

Establishing Consumer Cooking Instructions

Cooking is an essential means to control microbial hazards. Cooking instructions communicate to consumers or others on the producers behalf (catering facilities, service stations, etc), how to prepare and/or cook NRTE products to ensure microbiological safety.

HACCP must assess:

- Consumer understanding of preparation instructions and consumer behaviour in product handling /preparation for NRTE foods.
- Variance in consumer use of NRTE products, including innovated product concepts.
- Assess the risk of consumption without or non-adherence to the application of cooking instructions.

Consumer misuse, non-adherence of consumers to cooking instructions, misleading or confusing cooking instructions of food products, expected or normal use of products not accounted for, and variability of product and cooking appliances, need to be taken into consideration when developing cooking instructions. Cooking instructions communicated to the consumer must be established and validated prior to the launch of the product to ensure microbiological safety.

Verification of cooking instructions must be completed to ensure they meet expected or intended microbiological safety limits when changes are made such as renovation to the recipe, changes to product/process design that may impact original validation or additional product uses based on marketing communications or consumer feedback.

5) Other Considerations

These guidelines are provided for information purposes only. Additional independent professional advice is recommended to ensure care and judgement with respect to use of any material provided.

6) References

The European Chilled Food Federation (ECFF) Recommendations for the Hygienic Manufacture of Chilled Foods 2005 (formerly ECFF Guidelines 1996) provide a reference for the production of a wide spectrum of chilled foods, outlining the fundamental principles that should be considered when designing safe manufacturing operations. *https://www.ecff.net/wp-content/uploads/2018/10/ECFF_Recommendations_2nd_ed_18_12_06.pdf*

Codex Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life, CAC/RCP 46-(1999)

FSANZ Safe Food Australia – 3rd Edition, November 2016 – A guide to the Food Safety Standards
Mineral oil hydrocarbons.pdf (foodstandards.gov.au)

Australia New Zealand Food Standards Code