Ref: 1100-07-CG

Date: 1 December 1998

To: All holders of *Guide to HACCP* Systems in the Meat Industry (*Hazard Analysis Critical Control Point)*

Subject: Amendment 4: *Guide to HACCP* Systems in the Meat Industry (*Hazard Analysis Critical Control Point)*

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1. Changes with Amendment 4

The pattern of changes to *Guide to HACCP* Systems in the Meat Industry (*Hazard Analysis Critical Control Point)* which started with Amendments 1-3 has continued with Amendment 4.

1.1 The amendment will be housed in the two folders as follows:

- Volume I will contain the addition to the Contents pages;
- Volume II will contain the amendment to the further processing template (Appendix VIII.2) and the new generic HACCP plan (Appendix X.4).

1.2 The system for denoting amendments has been changed from a background screen over the amendment to a # symbol in the margin indicating the line on which a change has been made.

2. Procedure

Attached are updated pages for your *Guide to HACCP* Systems in the Meat Industry (*Hazard Analysis Critical Control Point)*.

Please **sign off** the Amendment Record, and file this update letter in the back of your manual for quick reference.

Remove old pages	Insert new pages
Volume I P.7-P.8	 P.7-P.8
Volume II P.1 VIII.2.8 ─ VIII.2.9	 P.1 VIII.2.8 ─ VIII.2.9 New white divider marked "Raw Beef Patties" after Page X.3.22 X.4.1 ─ X.4.31

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MAF Regulatory Authority

Volume II

Templates

Generic Plans

Page

Contents of Volume II Page

Templates

Generic Plans

7. Hazard Analysis and CCP Determination

7.1 Raw material hazard identification

Identify biological, chemical and physical hazards that are reasonably likely to occur in the raw material. Raw material may include meat (e.g. chilled beef carcass, trimmings) and non-meat ingredients (e.g. spices, vegetables, food additives).

Hazards need to be specifically defined (e.g. *Taenia saginata*, *Clostridium botulinum*, shotgun pellets) or may be identified as a class, based on their characteristics, when this is appropriate (e.g. enteric pathogens, spore forming organisms, metal objects).

To avoid repetition and simplify hazard identification and analysis, codes may be assigned to the different hazard categories. For example, hazards may be categorised by source (e.g. microbiological hazards from non-meat ingredients) as well as by type (i.e. biological, chemical, physical). Codes may be carried forward from a previous plan, particularly when this helps demonstrate continuity of the process and carry over of the relevant hazards (e.g. slaughter and dressing to cooling and boning). Codes must be clearly defined in the plan when used.

Identified raw material hazards are summarised in a generic form in Form 5a.

Form 5a: Hazard identification for raw material

Raw material	Biological hazard	Chemical hazard	Physical hazard

7.2 Hazard analysis and CCP determination (raw material, other inputs and process steps)

Record the identified raw material hazards from Section 7.1 in the appropriate column in Form 5b.

Identify any biological, chemical or physical hazards resulting from a process step requirement not being met (e.g. metal from equipment). Process step hazards are expected to be a sporadic occurrence. Frequent occurrence could indicate that a prerequisite programme is ineffective and needs to be improved. Process step hazards may be controlled under effective prerequisite programmes and/or dealt with at CCPs in the HACCP plan. Note that once these hazards are identified, they may become part of the raw material hazards at subsequent steps if immediate control is unavailable.

Identify any biological, chemical or physical hazards that are reasonably likely to occur in # association with other inputs at each process step (e.g. packaging, processing aids). Generally, # these hazards will be addressed by appropriate prerequisite programmes (e.g. Supplier Quality # Assurance (SQA) programme, food contact materials). For more complex processes, such as # those with multiple ingredients, a separate hazard identification for each input may be essential.

Hazards must be analysed for each process step. Record comments on the potential impact of a process step on hazards that are reasonably likely to occur (e.g. transfer or redistribution of raw material hazards, pathogen growth). **These comments can be recorded in the same column as process step hazards (see Form 5b for the presentation).** Careful consideration should be given to the effectiveness of the prerequisite programmes when evaluating the impact of a process step.

Consider whether each hazard could be present at an unacceptable level in relation to achieving the FSOs for the process (Question 1, Form 5b) and provide justification. Reference to the scientific literature, surveys, company experience and/or historical data will be helpful as supporting information. Record the outcomes of the hazard analysis.

When Question 1 is answered “yes” (i.e. a hazard could be present at an unacceptable level), then answer both questions 2 and 3 relating to control measures.

Even when there are control measures available at the step at which the hazard(s) is being analysed, previous process steps should also be considered for control of the hazard. The absence of adequate control measures at any step in the process means that redesign of the process/product should be undertaken so that the FSO can be achieved. If redesign is impossible, the hazard must be identified as unaddressed within the HACCP plan (or under GMP where it is the only identified hazard) for this product and process.

Appendix X.4: Generic HACCP Plan for the Manufacture of Raw Beef Patties

1. Prerequisite Requirements

The following are documented prerequisite programmes/sanitation standard operating procedures (SSOPs):

- sanitary design;
- potable water quality;
- sanitation and cleanup procedures for edible areas and food contact surfaces (preoperational and operational);
- personal hygiene (protective clothing requirements, personal equipment and use of amenities);
- hygienic processing (processing techniques and procedures, damaged carton procedure, dropped meat);
- rework procedures;
- supplier quality assurance (ingredient specifications, supplier audits, certifications, product testing);
- food contact materials (specifications, handling and storage);
- product testing procedures;
- training;
- repairs and maintenance of equipment;
- control of chemicals;
- vermin control;
- waste disposal;
- refrigeration management;
- handling and disposition of detained and nonconforming products;
- recall procedures.

2. Scope of HACCP Plan

HACCP application: Food safety

Product: Raw beef patties

Process: Processing of raw beef patties from receiving raw materials and other inputs to loadout of packaged frozen products.

3. Product Description and Intended Use

Form 1: Product description and intended use

1. Product name(s)	Frozen raw beef patties
2. Important product characteristics	Product meeting company and regulatory specifications for sensory and microbiological quality, foreign objects, temperature and packaging.
3. How is it to be used: **a. By a further processor, retailer or food service outlet** **b. By the consumer**	a. Cooked in food service outlets b. Cooked
4. Intended consumer	General public ("high-risk" groups not specified for this plan)
5. Packaging	Company/regulatory specification
6. Shelf life and storage requirements	Company/regulatory specification
7. Where it will be sold **a. Export market** **b. Local market**	List countries, if applicable
8. Labelling instructions	Company/regulatory specification
9. Special distribution controls required	Refrigerated distribution as per company/regulatory specification

4. Initial Food Safety Objectives

(To be confirmed after hazard identification and analysis, and CCP determination. See Section 8 for confirmed objectives.)

To ensure that meat and non-meat ingredients are in compliance with agreed specifications, and that meat is sourced from suppliers that have an effective HACCP plan which achieves specified microbiological and chemical residue targets.

To minimise the transfer of microbiological hazards to the product, and their redistribution, so specific microbiological targets are met.

To minimise the growth of pathogens on the product, by the use of an effective refrigeration system, so specific microbiological targets are met.

To remove foreign objects so specific targets are met.

5. Process Flow Diagram

Form 2: Raw materials / other inputs

Product name: Frozen beef patties	
Raw material/other inputs	**Description/specification**
Beef cuts/trimmings [1]	Slaughtered, dressed and processed under a HACCP plan.
Non-meat ingredients, e.g. salt, spices[1]	As per company specifications and the New Zealand Food Regulations 1984
Food contact packaging materials[2]	Suitable for use as food contact materials.

1. These inputs and their hazards must be addressed by a prerequisite programme/SSOP (i.e. Supplier Quality Assurance (SQA) programme), or specifically considered during hazard identification in this HACCP plan.

2. Specifications and hygienic handling of these materials are covered by premises' prerequisite programme for food contact materials.

Form 3: Process flow diagram

Premises that allow rework of products must clearly reflect this practice in the process flow. The impact of rework at the relevant steps must be considered during hazard analysis and CCP determination. Strict compliance to documented rework procedures must be observed .

Process: Manufacture of raw beef patties

Inputs	Process steps		Edible outputs
Frozen and chilled beef cuts/trimmings, and non-meat ingredients	1. Receiving meat ▼ 2. Chilled/frozen storage of meat ▼ 3. Tempering meat ▼ 4. Weighing meat ▼ 5. Decartoning ▼ 6. Pre-grinding meat ▼ 7. Mixing ▼ 8. Final grinding ▼ 9. Forming ▼ 10. Perforation ▼ 11. Freezing ▼ 12. Metal detection ▼	1a. Receiving non-meat ingredients ▼ 2a. Storage of non-meat ingredients ▼ ▼ 3a. Weighing non-meat ingredients ▼ ▼ ▼ ▼	
Packaging materials	13. Packaging ▼ 14. Labelling and weighing ▼ 15. Storage of frozen products ▼ 16. Loadout		Frozen beef patties

6. Job Descriptions

Form 4 must be completed and confirmed for each step in the particular process.

Form 4: Template for job description

Job description
Process step no:
Summary list of food safety responsibilities of operator: *(confirm after HACCP plan completed)* **Reference:**

7. Hazard Analysis and CCP Determination

7.1 Raw material hazard identification

Form 5a: Hazard identification for meat and non-meat ingredients [1]

Raw material	Biological hazard	Chemical hazard	Physical hazard
Meat ingredients [2]			
Chilled /frozen beef cuts and trimmings	B1 – Enteric pathogens associated with contamination from faeces, ingesta, hides, e.g. *Salmonella* spp., *E. coli* O157:H7, *Campylobacter jejuni*, *Clostridium* spp.	C1[3] – Unidentified chemical residues, e.g. anthelmintics, antibiotics, environmental contaminants.	P1 – Bone P1 – Metal
Non- meat ingredients			
Food grade salt	None	None	None
Spices (decontaminated) [4]	B2 – Spore forming organisms e.g. *Bacillus cereus*, *Clostridium* spp.	C2[3] – Chemical residues, e.g. herbicides, pesticides, fumigant	None

1. The following codes are used in this generic plan:

   B – Biological
   - B1 – Microbiological hazards associated with meat ingredients
   - B2 – Microbiological hazards associated with non-meat ingredients
   - B3 – Microbiological hazards associated with other inputs
   - B4 – Microbiological hazards associated with contamination due to a process step requirement not being met (sporadic occurrence)

   C – Chemical
   - C1 – Chemical hazards associated with meat ingredients
   - C2 – Chemical hazards associated with non-meat ingredients
   - C3 – Chemical hazards associated with other inputs
   - C4 – Chemical hazards associated with contamination due to a process step requirement not being met (sporadic occurrence)

   P – Physical
   - P1 – Physical hazards associated with meat ingredients
   - P2 – Physical hazards associated with non-meat ingredients
   - P3 – Physical hazards associated with other inputs
   - P4 – Physical hazards associated with contamination due to a process step requirement not being met (sporadic occurrence)

2. Hazards listed for meat are those that have been identified in the *Generic HACCP Plan for Cooling and Boning of Beef* as food safety hazards that may be reasonably associated with beef cuts and trimmings. Note that new codes have been used in this generic plan. Biological hazards associated with beef are discussed in Sections 1 and 2 of the *Annex to Appendix IX.2: Background Information to the Generic HACCP Plan for Slaughter and Dressing of Cattle.*

3. If a supplier can give an assurance that there are adequate controls for chemical hazards in their HACCP plan (e.g. by providing producers' or manufacturers' guarantees whereby compliance can be verified under the SQA programme), then these hazards need not appear in this raw material hazard identification.

4. Powdered spices used in commercial processing of beef patties are generally decontaminated to reduce microbiological contaminants. Included in their specifications is that they are free from foreign objects. Compliance to these specifications should be verified under the SQA programme.

7.2 Hazard analysis and CCP determination (raw material, other inputs and process steps)

Hazard analysis may result in changes in the initial food safety objectives set in Section 4. See Section 8 for confirmed objectives.

Form 5b: Hazard analysis and CCP determination (raw material, other inputs and process steps)

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
Receiving and preparation of non-meat ingredients										
1a. Receiving non-meat ingredients	Salt									
	Spices	B2. Spore forming organisms				No				
		C2. Chemical residues				No				
2a. Storage of non-meat ingredients	Salt									
	Spices	B2. Spore forming organisms				No				
		C2. Chemical residues				No				
3a. Weighing non-meat ingredients **(To step 7)**	Salt									
	Spices	B2. Spore forming organisms				No				
		C2. Chemical residues				No				

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
Main process										
1. Receiving meat	Beef cuts/ trimmings	B1. Enteric pathogens				No				
		C1. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	
		P1. Metal				Yes	Refer to Annex, Section 4.1.	No	No	
2. Chilled/ frozen storage of meat	Beef cuts/ trimmings	B1. Enteric pathogens				No				
		C1. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	
		P1. Metal				Yes	Refer to Annex, Section 4.1.	No	No	
3. Tempering meat	Beef cuts/ trimmings	B1. Enteric pathogens				No				
		C1. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
		P1. Metal				Yes	Refer to Annex, Section 4.1.	No	No	
4. Weighing meat	Beef cuts/ trimmings	B1. Enteric pathogens				No				
		C1. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	
		P1. Metal				Yes	Refer to Annex, Section 4.1.	No	No	
5. Decartoning	Beef cuts/ trimmings	B1. Enteric pathogens				No				
		C1. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	
		P1. Metal				Yes	Refer to Annex, Section 4.1.	No	No	
6. Pre-grinding of meat	Beef cuts/ trimmings	B1. Enteric pathogens			(ii) Transfer and redistribution	No				
		C1. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
		P1. Metal				Yes	Refer to Annex, Section 4.1.	No	No	
					(i) P4. Metal	Yes	Refer to Annex, Section 6.2.	No	No	
7. Mixing	Ground beef and non-meat ingredients	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Section 4.1.	No	No	
		P1/P4. Metal				Yes	Refer to Annex, Sections 4.1 and 6.2.	No	No	
8. Final grinding	Mixture	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
		P1. Bone				Yes	Refer to Annex, Sections 4.1.	Yes – bone eliminator Refer to Annex, Section 6.2.	No	1

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
		P1/P4. Metal				Yes	Refer to Annex, Sections 4.1 and 6.2.	No	No	
					(i) P4. Metal	Yes	Refer to Annex, Section 6.2.	No	No	
9. Forming	Mixture	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
		P1/P4. Metal				Yes	Refer to Annex, Sections 4.1 and 6.2.	No	No	
10. Perforation	Patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
		P1/P4. Metal				Yes	Refer to Annex, Sections 4.1 and 6.2.	No	No	
11. Freezing	Patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
		C1/C2. Chemical residues				No				
		P1/P4. Metal				Yes	Refer to Annex, Sections 4.1 and 6.2.	No	No	
12. Metal detection	Frozen patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
		P1/P4. Metal				Yes	Refer to Annex, Sections 4.1 and 6.2.	Yes – metal detector. Refer to Annex, Section 6.3.	No	2
13. Packag-ing	Frozen patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
			Packaging materials	None						

Process step	Inputs				(i) Process step hazards (ii) Potential impact of process step on existing hazards	Q1. Could the hazard be present in or on the product[1] at unacceptable levels[2] at this step? If yes, answer Q2 and Q3.		Q2. Is there a control measure at this step that would prevent unacceptable levels of the hazard? If yes, then this step is a CCP. If no, not a CCP.	Q3. Is there a control measure available at a previous step? If yes, retrospectively assign the previous step as a CCP.	CCP No.
	Raw material		Other inputs							
	Component	Hazards	Component	Hazards		Yes/No	Justification			
14. Labelling and weighing	Packed frozen patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
15. Storage of frozen products	Packed frozen patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				
16. Loadout	Packed frozen patties	B1. Enteric pathogens				No				
		B2. Spore forming organisms				No				
		C1/C2. Chemical residues				No				

1. Product is defined as the edible component of final product.

2. Unacceptable – as demonstrated by data (scientific literature, applied research or on-site experience) associated with achieving the FSOs established for the process. In the determination of unacceptability, hazards should be considered in terms of level, frequency, transfer and redistribution, and severity of effect on consumer.

8. Confirmed Food Safety Objectives (FSOs)

FSO1: To ensure that meat and non-meat ingredients are in compliance with agreed specifications, and that meat is sourced from suppliers that have an effective HACCP plan that achieves specified microbiological and chemical residue targets.

FSO2: To minimise the transfer of microbiological hazards to the product, and their redistribution, so specific microbiological targets are met.

FSO3: To minimise the growth of pathogens in the product so specific microbiological targets are met.

FSO4: To prevent and/or remove foreign objects from the product (e.g. bone pieces, metal) so specific targets are met.

9. Completion of the HACCP Plan

Full documentation is required for the remaining elements of the HACCP plan:

- critical limit setting;
- monitoring procedures;
- corrective action procedures;
- verification procedures including validation;
- documentation and record keeping procedures.

Refer to Sections 9-13 of the *Template for Establishing a HACCP Plan for Further Processing of Meat and Meat Products* for detailed requirements.

Form 6 provides a summary of the plan. References to documented procedures located elsewhere should be shown on this form.

10. Verification of the HACCP Plan

10.1 Validation of the HACCP plan

Validation of the HACCP plan involves the initial confirmation that the HACCP plan is complete and will achieve each of the FSOs. Identified CCPs should be evaluated to ensure that the control measure applied at that particular process step will achieve or contribute to the achievement of the relevant FSO. Some FSOs may be dependent on prerequisite programmes rather than the HACCP plan itself.

An example of how this generic HACCP plan may be validated is given below:

FSO1: To ensure that meat and non-meat ingredients are in compliance with agreed specifications, and that meat is sourced from suppliers that have an effective HACCP plan that achieves specified microbiological and chemical residue targets.

FSO1 is expected to be primarily achieved by implementing an effective Supplier Quality Assurance programme. Supplier compliance to agreed specifications may be verified by testing meat/non-meat ingredients (e.g. microbiological analysis), reviewing suppliers' processing data and inspection of ingredients at receiving. Reviews of incoming material records and supplier HACCP plan audits could be used to validate that meat is sourced from preferred suppliers that have an effective HACCP plan.

FSO2: To minimise the transfer of microbiological hazards to the product, and their redistribution, so specific microbiological targets are met.

FSO2 is expected to be achieved by effective prerequisite programmes (e.g. sanitation and cleanup procedures, personal hygiene, hygienic processing, rework procedures). Prerequisite programmes should be validated in accordance with the requirements in IS 8. Microbiological testing of products may also be used to validate this FSO.

FSO3: To minimise the growth of pathogens in the product so specific microbiological targets are met.

FSO3 is expected to be addressed by an effective prerequisite programme on refrigeration management which should be validated in accordance with the requirements in IS 6 and IS 8. Microbiological testing of products may also be used to validate this FSO.

FSO4: To prevent and/or remove foreign objects from the product (i.e. bone pieces, metal) so specific targets are met.

FSO4 is expected to be achieved by the removal of bone chips at CCP1 (final grinding), the removal of metal objects at CCP2 (metal detection), and effective prerequisite programmes (e.g. the SQA programme, repairs and maintenance, personal hygiene and hygienic processing).

The performance of the metal detector to consistently detect and reject specified metal objects should be evaluated against the target set for the FSO. It is important to take into consideration the types of metal likely to occur in the product, the capability of the machine, and the characteristics of the product. The processor will need to establish a detailed test methodology for checking the performance of the detector. This should include specifying how the test piece is mounted and passed through the search head with or without product being present, examination procedure for reject material, frequency and interval for testing.

The effectiveness of the bone eliminator should be evaluated against the target set for the FSO. A method for the analysis of bone chips in meat mixtures is mentioned in the Annex, Section 6.2.

Prerequisite programmes should be validated in accordance with the requirements in IS 8.

10.2 Ongoing verification

Ongoing verification activities confirm whether the HACCP plan is operating effectively and according to documented procedures. Examples of these activities are internal and extrinsic audits, HACCP review, and product testing programmes.

10.3 Revalidation

A revalidation of the HACCP plan is required, whenever changes are made (e.g. changes to premises, product, process, intended use of the product) or process failure that may compromise product safety occurs.

Form 6: HACCP plan summary spreadsheet for the manufacture of raw beef patties

Process step	Hazard ID	CCP no.	Critical limits	Monitoring procedures/tools (consider who, what, when and how)	Corrective actions[1]	Verification procedures[2]	HACCP records[3]
Receiving and preparation of non-meat ingredients							
1a. Receiving non-meat ingredients							
2a. Storage of non-meat ingredients							
3a. Weighing non-meat ingredients **(To step 7)**							
Main process							
1. Receiving meat							
2. Chilled /frozen storage of meat							
3. Tempering meat							
4. Weighing meat							
5. Decartoning							
6. Pre-grinding meat							
7. Mixing							

Process step	Hazard ID	CCP no.	Critical limits	Monitoring procedures/tools (consider who, what, when and how)	Corrective actions[1]	Verification procedures[2]	HACCP records[3]
8. Final grinding	Bone pieces	1	Bone eliminator functioning as per specifications. Refer to Annex, Section 6.2.	Operator to visually check performance of bone eliminator at predetermined frequency.	(a) Stop grinding and notify supervisor. (b) Retain affected ground meat until cleared by Supervisor. (c) Disassemble and clean bone eliminator and/or correct setting of bone eliminator.	FSO validation Product testing for bone chips Calibration of bone eliminator Internal audit Extrinsic audit (e.g. regulator, client) Customer complaints HACCP review	Validation record Daily monitoring record Product testing record Corrective action report Calibration record Internal audit report Extrinsic audit report Customer complaints file HACCP review record
9. Forming							
10. Perforation							
11. Freezing							

Process step	Hazard ID	CCP no.	Critical limits	Monitoring procedures/tools (consider who, what, when and how)	Corrective actions[1]	Verification procedures[2]	HACCP records[3]
12. Metal detection	Metal	2	Metal detector functioning as per specifications. Product characteristics (e.g. temperature) as per specifications for which detector sensitivity has been adjusted. Refer to Annex, Section 6.3.	Daily calibration checks of detector against test pieces at predetermined frequency. Examination of all rejected products.	(a) Hold products produced since last satisfactory check of the metal detector. (b) Correct metal detector or product characteristics affecting machine sensitivity. (c) Repass the product through functioning detector. (d) Hold any noncomplying product for further analysis. (e) Identify source of metal and take preventive action.	FSO validation Calibration of metal detector Internal audit Extrinsic audit (e.g. regulator, client) Customer complaints HACCP review	Validation record Daily monitoring record Calibration record Corrective action report Internal audit report Extrinsic audit report Customer complaints file HACCP review record
13. Packaging							
14. Labelling and weighing							
15. Storage							
16. Loadout							

1. Corrective actions should reflect an escalating response when ongoing noncompliance occurs.

2. Verification procedures apply to all aspects of the HACCP plan.

3. HACCP records apply to all aspects of the HACCP plan. Refer to IS 8, Section 4 regarding requirements for documentation and record keeping.

Annex to Appendix X.4: Background Information to the Generic HACCP Plan for the Manufacture of Raw Beef Patties

The processes covered by the *Generic HACCP Plan for the Manufacture of Raw Beef Patties* continue on from where cooling and boning end. The raw material hazard identification for this plan is based on the assumption that the beef was processed under a HACCP plan which covers slaughter and dressing, and cooling and boning. Hazards identified in the *Generic HACCP Plan for Cooling and Boning of Beef* as those that may be reasonably associated with beef cuts and trimmings are carried through to the manufacture of beef patties.

1. Foodborne Illness Associated With Ground Beef Products

Salmonella, Staphylococcus aureus and *Clostridium perfringens* are the main aetiological agents associated with foodborne illness attributed to ground meat, including hamburger meat (Varnam and Sutherland, 1995). In recent years, *E. coli* O157:H7 in ground beef products, hamburger in particular, have been implicated in a number of outbreaks of human illness in several countries (Doyle *et al*., 1997).

Twenty-five percent of beef-related foodborne outbreaks in the USA, from 1968 to 1977, were attributed to ground beef products (Bryan, 1980), whereas 21% of beef-related incidents of foodborne illness in Canada in 1983 were attributed to hamburger (Todd, 1989). In New Zealand, there is no evidence that ground beef or beef patties is a common cause of illness.

Beef patties are usually cooked at, or shortly before, the point of consumption. Foodborne illness associated with beef patty consumption is therefore only likely to occur as a result of conscious raw consumption, undercooking or contamination of the cooked product.

2. Biological Hazards

2.1 Meat

Enteric pathogens, such as *Salmonella* spp., *E. coli* O157:H7, *Campylobacter jejuni* and *Clostridium* spp. are the biological hazards of major food safety concern that may be present on beef cuts and trimmings, the raw material commonly used in the manufacture of beef patties.

Pathogens associated with meat that can grow at chiller temperatures, such as *Listeria* and *Yersinia*, have also been identified in recent years. Although these cold-tolerant pathogens may pose some health risk, this has not been quantified and is considered by Gill (1993) to be insignificant.

Biological hazards associated with the consumption of beef patties are briefly discussed below. Refer to *Annex to Appendix IX.1: Background information to the Generic HACCP Plan for the Slaughter and Dressing of Cattle* for more details on these biological hazards.

Salmonella spp.

Salmonella spp. is the primary bacterial aetiological agent responsible for beef-related foodborne outbreaks in the USA and Canada (Bryan, 1980; Todd, 1989; Bean and Griffin, 1990). Examples of beef products that have been implicated in outbreaks are roast beef, jerky and ground beef. Raw hamburger meat has been identified as a vehicle for outbreaks of human salmonellosis in the United States (Fontaine *et al*., 1978; Bryan, 1980). Contamination of the raw beef combined with improper food handling practices were found to be important factors in a substantial proportion of the *Salmonella* cases (Bryan, 1980).

E. coli O157:H7

E. coli O157:H7 was first recognised as a foodborne pathogen after two outbreaks of haemorrhagic colitis in the USA in 1982, attributed to the consumption of undercooked hamburgers from a fast-food restaurant chain. Since then, several beef-related outbreaks caused by *E. coli* O157:H7 have been reported in other countries, including the USA (Bean *et al*., 1990; Tarr, 1994), Canada and the UK (Chapman *et al*., 1993). The principal vehicle implicated in outbreaks has been ground beef and evidence suggests that in most instances the meat was undercooked (Doyle, 1991; Doyle *et al*., 1997). One of the notable outbreaks, affecting 16 people in the USA in July 1997, resulted in the recall of 25 million pounds of hamburger meat. Evidence suggests that the pathogen came from any one of 10 slaughterhouses that supplied the raw material to the manufacturing plant.

E. coli O157:H7 infection was first identified in New Zealand in 1993. Between then to the end of June 1998, there have been a total of 61 reported cases of infection by the pathogen (ESR, 1998). A source of infection has not been reported for any of these cases.

Campylobacter

In New Zealand, the most significant factors associated with cases of campylobacteriosis are the consumption of raw or undercooked foods (notably poultry, but also unpasteurised dairy products) and the consumption of untreated drinking water (ESR, 1996). *Campylobacter* is far less frequently associated with red meat. This appears to be due to the lower carriage rate of mammals compared to birds and the fact that the bacteria appear to die off on the dry carcass surface (Hasell, 1994). Freezing also significantly reduces the number of viable organisms (Hasell, 1994). There has been one reported outbreak associated with undercooked hamburger meat in the Netherlands (Blaser *et al*., 1983).

A survey of 27 retail outlets in New Zealand showed that campylobacter was not detected in 50 samples of commercially ground beef obtained over a period of two months (Gill and Harris, 1984). Failure to detect *C. jejuni* in commercial ground meat was expected based on the low incidence and degree of *Campylobacter* contamination of red meat carcasses. Freezing to -18 °C for 7 days reduced numbers of *C. jejuni* in artificially contaminated hamburgers by one log cycle. Minimal cooking, even when meat at the centre of hamburgers remained raw, rapidly eliminated the organism. The absence of campylobacter in retail samples of ground beef and the minimal cooking requirements for the destruction of the organism led Gill and Harris (1984) to conclude that under New Zealand conditions, ground meat dishes are unlikely vectors for human *Campylobacter* enteritis.

Staphylococcus aureus

Staphylococcal food poisoning results from the ingestion of food containing the enterotoxin produced by certain strains of *Staphylococcus aureus*. The organism competes poorly with other bacteria and thus seldom causes food poisoning in raw meat products (ICMSF, 1996). Foodborne illness due to *S. aureus* enterotoxin is primarily a result of contamination by food handling personnel and is generally associated with temperature abuse of cooked products (Bryan, 1980; Bergdoll, 1989). Animal strains of *S. aureus* have rarely been associated with outbreaks of staphylococcal food poisoning in man (Wilks and Humble, 1997).

There is little manual handling of product during semi-automated, large scale production of beef patties. Product is also kept at low temperatures (< 3 °C) during the whole process. The presence of unacceptable levels of *S. aureus* in frozen raw beef patties is therefore likely to be due to contaminated incoming raw material rather than from contamination during the manufacturing process.

2.2 Non-meat ingredients

Spices

Spices are not major contributors to foodborne disease; however, they occasionally contain bacteria that can cause foodborne infections (ICMSF, 1998).

Spore-forming organisms that are capable of causing gastroenteritis when ingested in large populations are found in spices, but usually in small populations. Out of 110 of various spices tested for prevalence and levels of *Bacillus cereus*, the organism was found in 53% of the samples (Powers *et al.*, 1976). A recent survey on several spices found *B. cereus* in all samples at levels of 1×10^2 to 1×10^6 cfu/g (Giffel *et al*., 1996). A relatively high incidence of *Clostridium perfringens* has also been found in several spices (Powers *et al*., 1975).

Spices have also been implicated in several outbreaks of salmonellosis (ICMSF, 1998). The New Zealand microbiological reference criteria for *Salmonella* in herbs and spices (Ministry of Health, 1995) is zero in 25 g. Commercial suppliers of treated spices in New Zealand normally provide a guarantee that their products meet this criteria.

As bacterial spores may survive cooking temperatures and will grow in many foods at temperatures of 3-50 °C, spices harbouring these spores must be considered as a potential health hazard if the foods in which the spices are added are not properly prepared and handled (ICMSF, 1998). Under normal operations of beef patty manufacture and GMP, where the temperature of the product is unlikely to rise above 3 °C, bacterial spores are unable to grow and form toxins.

If the introduction of pathogens from spices is of concern, then the use of spices that have been treated to reduce microbiological levels may be advisable. The effectiveness of decontamination methods such as fumigation or irradiation is dependent on the initial microbial load of the spices and the treatment parameters. Alternatively, the use of essential oils and oleoresin can avoid spices being a source of microbial contamination.

The above points stress the importance of sourcing spices from preferred suppliers, setting of correct quality specifications and managing the procurement of spices under an effective Supplier Quality Assurance (SQA) programme.

3. Chemical Hazards

3.1 Meat

Chemical hazards that could be present in beef and meat products include agricultural chemicals (i.e. pesticides, herbicides, veterinary drugs) and environmental contaminants (i.e. heavy metals, organochlorines). New Zealand MAF maintains a National Residue Testing programme that monitors the residue status of animals slaughtered for human consumption.

Chemical hazards associated with identified chemical residues (e.g. suspect lines) are addressed under the *Generic HACCP Plan for Slaughter and Dressing for Cattle*. Carcasses and products from chemically suspect animals are sampled and detained according to MAF Reg specifications. Suspect products are stored separately until their disposition is determined by the regulator.

Chemical hazards associated with unidentified chemical residues (e.g. antibiotics, environmental contaminants) are addressed outside the HACCP plan, under the National Residue Testing programme. Sporadic chemical residues at some level will always occur, but recent results from the programme indicate that residue levels in meat are generally in compliance with national requirements.

Chemical hazards associated with visible injection site lesions (ISLs) are usually addressed at post mortem inspection and at cutting and boning. Deep-seated ISLs may remain undetected in some cuts, but this is expected to be a rare occurrence.

3.2 Spices

Chemical residues of pesticides, herbicides and fumigants may be present in herbs and spices. Of particular concern are residues of methyl bromide, a fumigant used to control insect infestation in spices, and ethylene oxide, a chemical used for reducing microbial contamination. The SQA programme should ensure that chemical residue levels in non-meat ingredients are below the maximum permissible levels specified in New Zealand and importing country regulations.

4. Physical Hazards – Foreign Objects

4.1 Meat

The presence of foreign objects, such as metal and bone pieces, is of major concern to meat manufacturers (Archibald *et al.*, 1993; 1995) because of their potential for causing injury such as cuts, broken teeth, choking (Rhodehamel, 1992), and intestinal perforation (Gunn, 1966).

Manufacturers in Japan, the United States and New Zealand have reported finding metal objects in manufacturing meat produced in New Zealand. These objects included shotgun pellets, a MAF stamp, knives, hooks, bolts and nuts. There is agreement among manufacturers that meat suppliers should install a preventive programme for physical contamination, and a metal detection system to address the metal hazards.

One major New Zealand manufacturer now insists that their meat suppliers have an effective metal detection system in place. They claim that their problem with metal contaminants has been greatly reduced since they instituted this policy.

Although the use of metal detectors in boning premises may greatly reduce metal contaminants in beef cuts and trimmings, it probably will not completely remove metal objects that would be of concern to patty manufacturers. This is because metal detectors used in cutting and boning premises are generally set at limits higher than those used in patty manufacturing plants. Therefore, metal pieces with sizes smaller than the detection limit of the machine can still be present in beef cuts and trimmings.

Bone chips are a frequent problem in ground beef. According to Sebranek *et al*. (1989), about 0.1% of raw meat ingredient weight is likely to be bone or hard particles. These result from normal deboning operations where knives occasionally scrape or knick bone surfaces and result in bone particles in the meat. Unfortunately these bone chips are unlikely to be picked up by controls available under a cooling and boning HACCP plan because of their size, and they are frequently carried through to the finished product. Legal litigation by consumers concerning dental damage from hard particles in meat is not an unusual event in the US (Sebranek *et al*., 1989) .

4.2 Salt and spices

The New Zealand Food Regulations 1984 requires that salt shall be free of dirt, and that spices shall not contain foreign organic and inorganic matter, or any other unsuitable or inferior material. Specifications for commercially available spices normally include a requirement that they be free from foreign objects. Powdered spices are generally sieved and sometimes undergo metal detection to remove foreign objects. The SQA programme should ensure that non-meat ingredients are free from foreign objects which may pose a food safety hazard.

5. Supplier Quality Assurance (SQA) Programme

The microbiological quality of patties is largely affected, if not wholly determined, by the microbiological levels of the manufacturing beef from which the patties have been prepared (Gill *et al*., 1997). When patties are manufactured from raw material from multiple suppliers, the microbiological level of the product is probably determined by the raw material from the supplier having the poorest hygienic performance, i.e. raw material with satisfactory microbiological levels will not adequately dilute out raw material with unsatisfactory microbiological levels.

In order to make safe products, it is important that the hazards associated with raw materials are clearly understood and controlled to acceptable levels. The raw materials should either contain no hazards at unacceptable levels, or any hazards must be controllable by the process. In the case of raw patty manufacture where there is no destruction step for microorganisms, manufacturers should place special focus on receiving raw materials and ingredients from preferred suppliers and having an effective SQA programme in place.

Some of the elements which form part of an effective SQA programme include having agreed specifications, auditing suppliers and certificates of analysis (Mortimer and Wallace, 1994). Manufacturing plants should also have procedures in place for the verification of compliance to agreed specifications, such as physical inspection and microbiological testing of incoming materials based on statistically valid sampling plans.

6. Key Process Steps: Hazards and Potential Impact on Existing Hazards

It is assumed that the quality of incoming materials are adequately addressed under the SQA programme. Therefore, control measures applied during the manufacture of patties are primarily aimed at preventing the redistribution and uncontrolled growth of mesophilic pathogens in the product; and the prevention and/or removal of foreign objects to specified targets.

6.1 Receiving

Beef used for patty manufacture may be chilled, frozen or a combination of both. Large scale patty manufacture commonly involves the grinding of manufacturing beef from two or more sources for each batch. Chilled product is usually obtained in bulk bins from premises which are geographically convenient to the manufacturing plant. Frozen product is usually obtained in New Zealand in 27 kg boxes.

Meat temperature is commonly measured as part of incoming material inspection. A slight increase in temperature of frozen products during transport and handling prior to receiving, although undesirable, is not expected to compromise product safety. However, temperature increases in chilled products above 7 °C for a sufficient amount of time may allow mesophilic pathogen growth. Measuring the temperature of chilled beef at receiving may not be sufficient on its own to indicate whether temperature abuse occurs during transport. Transit time may also need to be considered. The use of temperature recorders may help in verifying temperature profiles during transport and this could be made part of the SQA programme.

Aside from temperature measurements, most manufacturing plants also inspect incoming raw materials for compliance with other agreed specifications such as package integrity, odour and appearance of chilled meat, age of product, and the presence of foreign objects.

6.2 Mincing, mixing and forming

Potential impact on existing microorganisms

Grinding is the most common and traditional comminution method for patty making. Meat is usually ground through a coarse plate (about 8-12 mm), followed by a fine plate (about 2.5-6 mm). Mixing may take place after grinding or alternatively grinding can be carried out in two stages, with an intermediate mixing stage.

During the grinding process, the temperature of the product tends to rise. For tempered meat, the latent heat of melting limits temperature rise (Varnam and Sutherland, 1995). Any temperature increase in chilled meat should not pose a problem because the temperature is immediately brought down during mixing.

Mixing temperature is very important for proper forming and is generally kept at about -3 to 0 °C (Mikkelsen, 1993). The required low mixture temperatures are achieved by using frozen meat in the formulations, or adding ice or CO_2 snow to the mixture. Mixing times for patties are very short; just sufficient for the mechanical action during mixing, sometimes together with NaCl, to bind the product before and after cooking. Beef patties are quick-frozen immediately after forming and perforation.

Therefore, normal temperature conditions during the manufacture of beef patties do not favour microbial growth.

Bone chips

Bone chips are a potential problem with all methods of comminuting meat, and some mincers are fitted with bone removal systems (Varnam and Sutherland, 1995). These exploit differences in the density of bone and meat to force the bone into separate channels at the exit plate. Meat temperature should be adequately controlled to within the range that will allow the bone removal system to function effectively. Several systems are currently available with varying effectiveness. Consequently, it is useful to be able to determine hard particle content in a particular mixture. Sebranek *et al*. (1989) provides a method for the analysis of bone chips and connective tissue in meat mixtures.

Metal

The presence of metal fragments in meat patties is not an unusual occurrence. These can come from incoming raw material or can be produced as a result of metal-to-metal contact, specially during grinding or mixing. Metal parts that can break loose from equipment, such as moving wire mesh belts, can also contribute to metal contaminants in the finished product.

Preventive measures, such as regular repair and maintenance of equipment and periodic checking of equipment for damage and missing parts, can help reduce the occurrence of metal objects in the product.

6.3 Metal detection

Most patty manufacturers, if not all, have metal detectors for 100% inspection of finished products prior to packaging.

When installing a metal detection system, it is important to take into consideration the types of metal likely to occur in the product, the capability of the machine, and the characteristics of the product. The limitations of the detector should be clearly understood and reflected in the food safety objective set for metal objects. The detection capability of metal detectors is generally influenced by the type, size and shape, and orientation of the metal, and the characteristics of the product (e.g. moisture content, temperature) (Shapton and Shapton,1991). Some processors set their critical limits for metal based on the limit of detection of the machine.

The processor will need to establish a detailed test methodology for checking the performance of the metal detector. This should include specifying how the test piece is mounted and passed through the search head with or without product being present, examination procedure for reject material, frequency and interval for calibration and testing.

6.4 Freezing

The extensive research carried out by MIRINZ on microbial growth at sub-freezing temperatures, clearly indicates that meat or meat products stored at product temperatures below -8 °C will not support any microbial growth (Winger, 1984). However, if present, some pathogens will survive freezing temperatures.

The different pathogens that could be present on meat and meat products prior to freezing show different sensitivities to freeze damage. Freezing causes damage to *Salmonella*, but it does not guarantee its destruction in food. *Salmonella* has been detected in products that have been stored frozen for years (ICMSF, 1996). Staphylococci are relatively resistant to freezing temperatures. Vegetative cells of *C. perfringens* are very sensitive to freezing, but its spores are highly resistant to cold. *E. coli* survives well in frozen food. Little change was observed in the numbers of *E. coli* O157:H7 in beef patties during 9 months storage at -20 °C (Doyle and Schoeni, 1984). It is therefore important that meat products are within acceptable microbiological levels prior to freezing.

7. Cooking Beef Patties

Although the cooking step is outside the scope of this HACCP plan, a brief discussion is given because of the major importance of proper cooking in the destruction of pathogens, such as *E. coli* O157:H7, in beef patties. In the case of any meat product that is not marketed as a ready-to-eat product, the food preparer has to use responsible precautions to ensure that the food is properly and safely prepared.

The primary method for destroying pathogens, such as *E. coli* O157:H7, in hamburger patties is by cooking them to a proper internal temperature (Singh *et al*., 1997). A number of recommendations for cooking beef patties have been made after disease outbreaks were caused by *E. coli* O157:H7 in ground beef. During a large outbreak in 1992-93 in the US, the FDA issued interim advice to cook all parts of hamburgers to 68.3 °C. Later in 1993, the USDA-FSIS issued an order requiring specified cooking times and temperatures for uncured meat patties (e.g. 66.1 °C for 41 s, 68.2 °C for 16 s, 69.4 °C for 10 s). Advice in the UK is to cook to a minimum internal temperature of 70 °C for 2 minutes, or equivalent (Desmarchelier and Grau, 1997). Factors which should be considered when establishing cooking time and temperatures include composition of patties (e.g. amount of fat), cooking method (i.e. equipment, procedure), and patty shape and thickness.

Consumers have been advised that the absence of internal pink colour can be an indicator of thorough cooking. However, studies have shown that this is not reliable (Van Laack *et al*., 1996; Warren *et al*., 1996). Expressible juice colour is considered to be a more reliable visual indicator of thorough cooking than internal colour (Warren *et al*., 1996).

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