Code of Practice:

Rendering

Part 3: HACCP Application, and the Identification of Other Risk Factors and their Controls

Prelims

Amendment 0

September 2009

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Website

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1 Introduction

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1.1 Purpose of this document

Part 3 of this Code of Practice (COP) has been developed by the New Zealand Food Safety Authority (NZFSA), in consultation with industry, to provide guidance on the application of Hazard Analysis and Critical Control Point (HACCP) principles to rendering operations. It also covers the identification and control of risk factors related to the wholesomeness and labelling of products.

1.2 HACCP

HACCP is a systematic and science-based control system for assuring the safety of animal product. It is achieved by identifying and assessing hazards, and developing controls for them. HACCP focuses on preventative measures and avoids reliance on the traditional approach of endpoint product testing as a means of controlling the safety of animal product. It is internationally recognised as the foremost means of assuring food safety.

Operators must apply HACCP principles to their process when developing their risk management programme (RMP).

1.3 Definitions

The following definitions used in this document have been derived from the Codex HACCP guidelines.

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.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

2 Hazards and their sources

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2.1 Hazard

A hazard is a biological, chemical or physical agent in, or condition of, animal product with the potential to cause an adverse health effect.

- Biological hazards include micro-organisms (e.g. *Salmonella* spp., *E.coli* 0157:H7) and parasites (e.g. *Toxoplasma gondii)*.

  Micro-organisms that are non-pathogenic are not considered as hazards. For example, spoilage organisms that cause loss of quality in products but will not cause animal illness.

- Chemical hazards include heavy metals, pesticides and veterinary medicines. Some feed additives may also be hazardous if present in excessive or toxic amounts (e.g. nitrite).

- Physical hazards are foreign objects that may cause illness or injury. Examples of these hazards are glass and metal fragments.

2.2 Sources of hazards

The main sources of hazards are:

- inputs (e.g. raw material, additives, packaging);

- the process itself; and

- direct or indirect contamination from personnel and environmental sources (e.g. water, pests, wastes, equipment, internal and external environs).

The operator must ensure that identified hazards from these sources are adequately addressed in the RMP by control measures under Good Operating Practice (i.e. supporting systems) or at Critical Control Points.

3 Good Operating Practice

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Good Operating Practice (GOP) is the foundation for HACCP and RMPs. It covers the practices and procedures designed to ensure the consistent production of products that are safe and suitable for their intended purpose, and that meet relevant regulatory requirements. It includes several interacting components - good hygienic practices, effective processing operations and effective quality assurance systems.

The operator's GOP procedures should be documented in supporting systems (also known as prerequisite programmes) before the application of HACCP. The HACCP approach used in this document is based on the expectation that these supporting systems are effectively being implemented. The GOP supporting systems for rendering operations are covered in Part 2 of the COP.

4 Application of HACCP principles

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4.1 HACCP principles

The essential steps for the application of HACCP consist of:

- the establishment of the scope, the product description and intended purpose, and the process description; and
- the application of the seven HACCP principles.

The HACCP principles, as defined by Codex are:

1. Conduct a hazard analysis;
2. Determine the Critical Control Points (CCP);
3. Establish critical limits;
4. Establish a system to monitor control of the CCP;
5. Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control;
6. Establish procedures for verification to confirm that the HACCP system is working effectively;
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

The operator is required to apply these HACCP principles to the process, considering all inputs and process steps. The application must be documented, and supported using information such as historical company records, technical publications or information provided by the regulator. The person or people involved in this activity must have the appropriate knowledge and skills regarding HACCP, the product and the process.

The operator must reassess their HACCP application whenever changes in the product, process and/or premises are made.

Each of the HACCP principles is discussed in the following sections. An example of the step-by-step application of the HACCP principles for rendering is given in the Generic RMP Model.

4.2 Scope

The scope defines the accepted boundaries of the HACCP application. The scope should identify the product(s), and the start and endpoint of the process covered by the HACCP application.

4.3 Product description and intended purpose

The operator must give a full description of the product or products groups. When there are multiple products, they should be categorised into groups of products with similar characteristics, processing steps and/or intended use, in order to simplify the HACCP application.

The description should include the following information:

- product name(s);
- intended use of the product(s);
- intended consumer;
- any relevant regulatory limits;
- any operator-defined limit; and
- other product details (e.g. packaging specifications, shelf-life and storage requirements; labelling requirements).

This information will provide a profile of the product(s), which is necessary for setting criteria that make an important contribution to the safety of the product (e.g. operator-defined limit), and hazard identification and analysis.

Intended use and consumer

The intended use should be based on the expected uses of the product by the end user or consumer. In some cases, it may also be important to identify whether the product is intended for any specific consumer group, particularly vulnerable groups of the population.

Regulatory requirements

Regulatory requirements are mandatory requirements under the Animal Products Act and can be found in the Act, Regulations and Specifications and relate to the management of food safety and suitability. These can be non-measurable (e.g. requirements for premises, personnel hygiene), which are largely addressed under Good Operating Practice, or measurable.

Regulatory limit

A regulatory limit is a measurable regulatory requirement that is critical to fitness for intended purpose of animal material or animal product. They are set by the regulator, and may be based on quantitative risk assessments or on best available science. **At present no regulatory limit has been established for any rendered product.**

Operator-defined limit

An operator-defined limit is a measurable limit that an operator has established to manage the fitness for purpose of animal material or animal product. Examples of operator-defined limits are:

- intrinsic parameters of the final product (e.g. moisture content of meat & bone meal);
- microbiological criteria related to the safe consumption of the product (where regulatory limits are not yet established);
- levels of chemical hazards (e.g. maximum residue limits for certain chemicals);
- levels of physical hazards (e.g. limit for metal fragments in meat & bone meal); and
- parameters related to wholesomeness (e.g. level of defects, indicators of spoilage).

The operator should first check relevant legislation for any regulatory requirements that are appropriate for their specific product(s) and the hazard(s) of concern. When no regulatory limit has been specified and if necessary for the safe consumption of the product, the operator should define their own operator-defined limit. For example, NZFSA has not established a moisture content limit for meat & bone meal, but since this is an important characteristic related to the stability and suitability of the product, it is expected that the operator will define an appropriate moisture content limit for the product.

The operator must have evidence to show that the operator-defined limit they have set is appropriate to the product considering its intended use and consumer. The types of evidence which could be used include:

- published information from approved codes of practice, guidelines produced by government and reputable industry organisations;
- peer-reviewed scientific information;
- outcomes of validated predictive models;
- scientific information from a person or organisation known to be competent; and/or
- data from the company's monitoring and verification programmes, trials and experiments.

Operator-defined limits may be achieved by GOP or CCPs. For raw products, which have not undergone any lethal processing treatment (e.g. cooking), any identified operator-defined limits are likely to be achieved by applying controls under GOP. For further processed products any identified operator-defined limit that is essential for the safety of the product should be considered at CCP determination and may result in a CCP.

4.4 Process description

An accurate description of the process is necessary to be able to do a proper hazard analysis. The simplest way to describe the process is to develop one or more process flow diagrams showing all inputs, process steps, and outputs. These diagrams provide a basis for a systematic (i.e. step-by-step) hazard analysis.

The main steps in the process should be shown, including any rework or recycling of materials. Inputs should include all raw materials, additives and other ingredients, and packaging that will form part of the end product.

The process flow diagram should be confirmed by a person or persons with sufficient knowledge of the operation to ensure that it is accurate and reflects what is actually happening.

4.5 Hazard analysis

4.5.1 Hazard identification

Hazards that are “reasonably likely to occur” should be considered in hazard identification. Reasonably likely to occur means that:

- the particular hazard is known to occur in the particular animal material or product based on scientific reports, industry or company results, codes of practice, and information from the NZFSA; and
- the hazard is known to occur in New Zealand (care should be taken when considering overseas information).

Hazards should be identified to the level necessary to enable identification of specific controls for the particular hazard/product combination.

For certain hazard/product combinations, it may be acceptable to identify hazards as a group based on their common characteristics, source and/or control.

Vague descriptions of hazards should be avoided. For example, “foreign objects in meat & bone meal” could mean metal, glass, or plastic. These objects should be identified specifically as they are from different sources, have different characteristics, and would have different control measures.

4.5.2 Identification of hazards from inputs

The operator should identify the hazards that are reasonably likely to occur in each input, considering any supplier assurances, agreed specifications and supplier performance.

In most cases, the best option for the operator is to require that the supplier controls the hazard to acceptable levels in incoming raw materials and ingredients. This may be addressed under a supplier quality assurance programme which may include; having agreed material specifications, provision of certificates of analysis, conducting supplier audits, and testing of incoming materials.

4.5.3 Identification of hazards at the process steps

The operator should identify the hazards that are introduced or transferred to the product as a consequence of applying the process step itself. The potential impact of the process step on any existing hazard (e.g. microbiological growth, toxin formation) should also be considered during hazard analysis. Hazard analysis should be done for each step.

4.5.4 Identification of control measures

The operator should identify any control measures for each identified hazard.

A control measure is any action or activity that is applied to:

- control the initial levels of hazards (e.g. supplier assurances, testing and rejection of unacceptable ingredients);
- prevent an unacceptable increase of the hazard (e.g. hygienic processing techniques); and
- reduce or eliminate the level of the hazard (e.g. thermal processing, use of antimicrobial agents).

Most control measures are likely to be covered by GOP.

If control measures do not exist or are inadequate, the operator should consider the need for redesign of the process, the implementation of new control measures or leaving the hazard as uncontrolled (if appropriate).

4.6 CCP determination

A critical control point (CCP) is a step at which control can be applied and is essential for the safety of the product as defined by a regulatory limit or an operator-defined limit. The operator should determine whether there are any CCPs for the process.

Some points to consider when determining if control at the particular step is essential include: the degree of hazard control that is achieved at the step; likelihood of failure; consequence of control failure considering the intended use and consumer (i.e. risk to health). Generally, essential steps are those that are specifically designed to eliminate or reduce the hazard to an acceptable level.

The operator should use a systematic approach to hazard analysis and CCP determination for each process covered by the RMP. This must be documented, and any decisions made must be justified using information such as historical company records, technical publications, codes of practice or information provided by the NZFSA.

CCP determination can be facilitated by the use of a decision tree (e.g. Codex decision tree) or a table that provides a series of questions to guide the user through the decision-making process. The table currently used in the Generic RMP Model is a combined hazard analysis and CCP determination table that has been developed to suit the needs of the industries under the Animal Products Act. A template of this hazard analysis and CCP determination table is shown in Table 1.

When a CCP is identified, the remaining HACCP principles must be applied. When there are no CCPs identified, the other principles related to CCPs (i.e. critical limits, monitoring and corrective action) are not required, however, verification, documentation and record-keeping still need to be applied as part of GOP.

Table 1: Hazard analysis and CCP determination template

Process step	**Inputs**	**Hazard reasonably likely to occur on or in the product at this step**	**Justification**	**Q1. Is there a control measure(s) for the hazard at this step?** **If yes, identify the control measure and answer Q2.**	**Q2. Is the control measure at this step essential to product safety as defined by a regulatory limit or an operator-defined limit?** If yes, this step is a CCP. **If no, this step is not a CCP.**	**CCP no.**

To clarify the use of Table 1, the meaning of each column is explained. The operator should go through the series of questions for each step in the process. The hazard analysis must show any hazard that is uncontrolled at the end of the process. The Generic RMP Model shows how this table can be used for rendering operations.

Column 1 - Process step

Each process step should be written in column 1 in the order shown in the process flow diagram.

Column 2 – Inputs

All inputs at the particular step should be indicated in column 2. This should align with the process flow diagram.

Column 3 – Hazard identification

The hazards reasonably likely to occur at each process step should be identified considering:

- hazards introduced by inputs at that step;
- hazards introduced or transferred as a consequence of applying the process step itself (e.g. metal from pre-breakers);
- hazards carried over in the product from the previous step; and
- adverse impact of process step on existing hazards (e.g. growth of micro-organisms).

Column 4 – Justification

A brief justification for the hazard identified in the previous column should be given in column 4. Justification may be based on company experience and records, scientific literature, surveys, industry reports, Codes of Practice, generic RMP models and other guidance documents provided by the NZFSA.

Column 5 – Question 1: Identification of control measures

Question 1 requires the operator to identify any control measure for the identified hazard(s). Procedures for the control measure(s) must be documented in a supporting system of the RMP. The reference document title or number of the particular supporting system should also be cited.

Any hazard that is not completely eliminated at a step should be considered at the next step to ensure that the impact of succeeding steps on the existing hazard is considered during the analysis. In particular, bacterial pathogens should be carried over to succeeding steps since there is potential for their growth.

Hazards that are unlikely to be adversely affected by succeeding steps in the process (i.e. will not grow or increase), such as chemical residues and parasites, do not need to be carried over each succeeding step in the hazard analysis table to reduce repetition. However, the hazard must be reintroduced at the step where it is controlled or, if the hazard is considered to be uncontrolled, it must be shown at the last step of the process.

If a control measure for an identified hazard does not exist in the process or is inadequate, the operator should consider process redesign, the implementation of new control measures or leaving the hazard as uncontrolled (if appropriate).

Column 6 - Question 2: CCP determination

The operator will need to decide whether or not the step is a CCP by determining if control at that step is essential, by itself or in combination with other steps, to achieve any regulatory limit or operator-defined limit related to the safety of the product.

Points to consider when determining if control at the particular step is essential include:

- the degree of hazard control that is achieved at the step;
- likelihood of failure;
- consequence of control failure (i.e. risk to health) considering the intended use and consumer.

4.7 Establish critical limits

Critical limit means a criterion which separates acceptability from unacceptability at a critical control point. The operator must define and justify critical limit(s) for each CCP. In some cases, more than one critical limit may be needed at a particular step. Parameters often used include temperature, time and moisture level.

Critical limits must be measurable and should be linked to the achievement of a regulatory limit or operator-defined limit related to safety of the product. They should be appropriate to the specific operation and product. They should be parameters that can be monitored on an on-going basis to ensure consistent effectiveness of the particular process step to achieve a specified level of control.

The operator should document:

- the parameters that are to be checked;
- the limit for each parameter; and
- justification for each limit.

4.8 Establish CCP monitoring

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The operator must document monitoring procedures for each critical limit. The monitoring procedures must be able to detect loss of control at the CCP quickly to allow immediate corrective actions to be taken.

Monitoring procedures should include the:

- person responsible for monitoring;
- monitoring method;
- monitoring frequency and sampling regime; and
- records to be kept.

The monitoring frequency selected must ensure adequate and consistent control. Monitoring may be continuous or be based on a statistical sampling plan. Other factors to consider for determining monitoring frequency include: the nature of the product, the likelihood of failing the limits, the cost of monitoring, the consequence of failure (including risk to animal health), the corrective actions expected (especially with respect to product disposition), and other relevant matters.

4.9 Establish corrective action

The operator must document corrective action procedures to be implemented when a critical limit is not met. Corrective action procedures should include the following information:

- person responsible for taking corrective action;
- procedures for restoration of control;
- procedures for control and disposition of non-conforming product, including checking of product back to the last acceptable result, where possible;
- action to prevent the problem from happening again;
- escalating response if preventative action fails; and
- records to be kept.

4.10 Establish verification procedures

The operator must establish and document operator verification procedures to ensure that the HACCP system continues to work effectively. The frequency of verification should be sufficient to confirm this.

Whenever possible, verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions.

Examples of verification activities include:

- review of the HACCP system and its records;
- review of deviations and product dispositions; and
- confirmation that CCPs are kept under control.

The verification procedures should include the following information:

- person responsible for operator verification;
- frequency or schedule for operator verification activities;
- verification methods and procedures;
- follow-up action to be taken if non-compliance occurs; and
- records to be kept.

4.11 Establish documentation and records

The operator must document all matters relating to the application of HACCP to the operation. Documentation and record keeping should be appropriate to the nature of the size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Examples of record that are expected to be generated when implementing HACCP are:

- CCP monitoring observations;
- deviations to critical limits and associated corrective actions;
- results of verification procedures; and
- modifications to the HACCP application.

4.12 Confirming the application of HACCP

The operator should check the application of HACCP after completing the initial hazard analysis and CCP determination. The following points should be considered:

- Are the operator-defined limits appropriate and achievable or are new ones needed?
- Are the identified CCPs essential to complying with the regulatory limit(s) or operator-defined limit(s)?
- Are the critical limits appropriate and achievable? Can the critical limits be monitored effectively?
- Are all the identified hazards adequately controlled by GOP and/or a CCP(s), or by controls outside the HACCP plan (e.g. regulated control scheme)? If not, does the process need to be modified or are additional control measures needed?
- Are there any uncontrolled hazards? If so, is it required by legislation to be controlled to a specified level? Does the operator need to consider redesigning the process/product? Does the operator need to inform the further processor or consumer about the uncontrolled hazard so that safety of the product can be assured prior to consumption of the product (e.g. by providing feedback to suppliers; or product specifications to customers / consumers).

5 Identification and control of risk factors related to wholesomeness and labelling of products

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5.1 Identification and control

The operator must identify any risk factor, that is reasonably likely to occur, that could:

- negatively affect the wholesomeness of the product: and/or
- lead to false or misleading labelling of the product.

Identification of risk factors should be done systematically for each step of the process, for each animal product or group of products. It should be based on:

- guidance given in other parts of this COP;
- operator knowledge / experience of their product and process (including a review of internal records and reports); and
- customer (e.g. processor, distributor, retailer) and consumer complaints.

Procedures for controlling any identified risk factors must be established and documented by the operator. These procedures may be documented in process control procedures or in supporting systems.

The process of identification and control of these risk factors does not require the application of HACCP principles.

5.2 Wholesomeness

A wholesome risk factor is a condition of the product that is offensive; or anything that could be contained or in contact with a product, that is offensive, or whose presence would be unexpected or unusual in product of that description. Examples of wholesomeness risk factors relevant to rendered products are:

- foreign objects that are not physical hazards; and
- oxidation of fish oil; and
- spoilage of fish meal and meat & bone meal.

Section 2.9 of the Generic RMP Model gives examples of risk factors and controls related to wholesomeness.

5.3 Labelling

Animal products intended for animal consumption that are produced for the New Zealand market must meet all relevant legislative requirements related to labelling including:

- The Animal Product Regulations 2000, regulations 8 and 19;
- Part 3 of the current Animal Products (Specifications for Products For Animal Consumption) Notice;
- Agricultural Compounds and Veterinary Medicines Regulations 2001.

A labelling risk factor is anything that could cause false or misleading labelling of a product. Examples of labelling risk factors are:

- wrong information in labels (e.g. ingredient list);
- wrong labels attached onto packs;
- wrong products packed in pre-labelled packaging; and
- printers not properly set.

When identifying risk factors, consideration should be given to the type and intended use of the product, the intended consumer, specific consumer groups and requirements for authenticating certain claims.

Those operators who export their products will also need to consider the labelling requirements of the relevant market. These requirements may be additional to those needed in the RMP.

Section 2.10 of the Generic RMP Model gives examples of risk factors and controls related to false or misleading labelling.