

29 September 2000

Dear Stakeholder

**ANALYSIS OF SUBMISSIONS ON FIRST DRAFT OF RISK MANAGEMENT
PROGRAMME MANUAL – ISSUED JANUARY 2000**

The Animal Products Act 1999 commenced, in the main, on 1 November 1999. Part 2 of the Act, which covers risk management programmes, is expected to commence in mid-November 2000.

To facilitate this, a draft Risk Management Programme Manual was developed and issued for public consultation in January 2000. Submissions closed on 3 March 2000. The attached document “*Analysis of submissions on draft risk management programme manual*” analyses the feedback that was received and as appropriate states the MAF Food Assurance Authority’s position.

This analysis was done by July 2000 but was not issued because associated regulations and specifications were still under development. As a result, MAF’s response has been continuously evolving since that time. It has now been decided to issue the analysis document as previously written, with this covering letter explaining the changes that have occurred since that time.

It is important that the analysis is read in conjunction with the current draft RMP Manual and the changes listed below.

Changes since the analysis was written:

- 1. Draft operational specifications and animal product specifications have just been released and are available on the MAF web site for public consultation. These specifications clarify requirements for:**
 - Poultry growing operations to have a “whole flock health scheme” as mentioned in the response to feedback on clause 1.6.1.1; and**
 - current minimum requirements for product outcomes as explained in the response to the third submission on clause 3.5.**
- 2. In the response to clause 1.6.1.3, MAF has indicated that there would be specifications for transportation and storage. These will not be developed at this stage and further consideration is being given to the requirements needed in this area.**
- 3. In the response to clause 1.6.1.3, MAF refers to a defined start and end point for an egg producer’s risk management programme. MAF’s position on this has now changed to be consistent with how other primary processing has been defined, i.e.**

by naming key processes to be included. The definition in the Animal Products Act means that harvesting of eggs is automatically included, and a Gazette Notice will be developed to require candling or equivalent processes to be included in the definition of primary processing. Egg producers will then have to individually define where their risk management programme actually starts and stops. This will depend on the inputs, outputs and management practises affecting these processes, and the effectiveness of the separation from other processes. This approach provides operators the flexibility to set realistic start and end points for their risk management programme depending on their particular circumstances.

4. In the response to clause 3.3, MAF has indicated that training requirements will be clarified in industry codes of practice. Some guidance has now also been added into the Risk Management Programme Manual on what might be appropriate training for people with specific responsibilities.
5. In the response to clause 3.5, MAF has indicated that details about “rollover” of some current systems will be added to the manual. This has now been included in a new clause 3.1.1 of the manual and is now referred to as “transitional recognition of selected current systems”. This will be revised further before the manual is finalised.
6. In addition to the response given to the third submission on clause 3.5.1, MAF and the Ministry of Health have published a document that explains how Food Safety Objectives will ultimately be used to quantify the level of consumer protection based on a formal risk assessment. This document was published in June 2000 and is titled *“Food Administration in New Zealand, A risk management framework for food safety”*.
7. MAF has added further clarification on requirements for electronic documents into the risk management programme manual.
8. The response to the first submission on clause 3.14 has been clarified further. By-products from home-kill or recreational catch service providers (including Dual Operator Butchers) cannot be sold to renderers but may be given to renderers as a disposal mechanism. Refer to the latest Homekill Guide on the MAF web site for further information.
9. A new draft of the Risk Management Programme Manual has been put onto the MAF web site. This draft reflects the changes described in the analysis document and also the changes included in this correspondence.

If you have any concerns or suggestions relating to the new draft RMP Manual (dated 11-7-00, located on the MAF web site), please make submissions by 5.00pm, Friday 13 October 2000.

Submissions should be addressed to:

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Yours sincerely

(Signed)

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Analysis of submissions on draft risk management programme manual

The Animal Products Act commenced on 1 November 1999. Part 2 of the Act relating to risk management programmes comes into effect at a later stage. The Ministry of Agriculture and Forestry released a draft risk management programme manual in January 2000 for public comment. Submissions closed on 3 March 2000.

A total of twenty five submissions were received, each with multiple recommendations. Suggestions for minor wording changes are acknowledged and will be addressed within the revision process. A summary of all other submissions and MAF Food Assurance Authority's response is given below. Where a comment was registered under more than one clause it is only listed under the first one.

SECTION 1: INTRODUCTION

- 1.3 One submitter suggested the addition of the words “periodically revising and upgrading their risk...” to show that it is a living document and subject to continuous evaluation and upgrading.

Response

MAF agrees with the concept however this is included in “operating” the programme and is adequately covered by section 7 of the manual so no change will be made.

- 1.4 One submitter wanted to clarify whether any secondary processors were required to have a RMP and seriously questioned why the scope of the Act does not apply to all sectors handling export product under New Zealand legal jurisdiction. They also highlighted problems among the international carriers.

Response

MAF agrees that for transport and cool storage the requirements are not clear.

For export products, operators will need to meet operational specifications (up until the time that the product leaves New Zealand). They may choose to have a risk management programme to demonstrate this.

For products that are intended for the New Zealand market the operator's risk management programme only has to go to the end of primary processing. For processes after this, options are available either under the Animal Products Act, Food Act regime or under other legislation, e.g. ACVM Act, depending on the nature of the animal product business and whether official assurances are required. Further clarification with the Ministry of Health is also required, with respect to the interface with the Food Act Regime.

This section will also be rewritten in line with the analysis of submissions for discussion document 16.

- 1.6.1.1 One submitter stated that poultry growing operations need to be included in the requirement to have a risk management programme (as poultry are more prone to pathogenic contamination, most likely originating from the growing operations).

Response

MAF proposes that this clause remains unchanged so long as poultry operators have implemented a whole flock health scheme in line with the provisions of the Poultry Industry Processing Standard (PIPS5) as a pre-requisite programme. This will ensure that the growing operations are appropriately controlled without the complexity of a full risk management programme. This proposal has been accepted at cabinet level.

- 1.6.1.1 One submitter wanted the legislation or regulation that takes over from the end of risk management programmes to the consumption of the product to be clarified, given the intention of risk management is the certification of fit for intended purpose to the ultimate client, the consumer. Care should be taken not to leave gaps between different pieces of legislation governed by different Ministries. The last two bulleted points are therefore vague and need better description.

Response

MAF's intention is not certification. The prime consideration is "fitness for intended purpose" for the next user (with due consideration to the end consumer - where known). The last two bullets will be reviewed based on the results of Discussion Document 16. There is a harmonisation project under way to ensure that the Ministry of Health and MAF's requirements become aligned.

- 1.6.1.2 One submitter wanted to replace the words "animal material" and "animal product" with deer velvet to make it clearer.

Response

MAF agrees and has updated the manual in line with the suggestion.

- 1.6.1.3 One submitter wanted to clarify whether transportation of shell eggs, and eggs sold via dairies and other markets had to be included in the scope of a risk management programme. They also wanted the start and end point of the risk management programme to be clearer.

Response

There will be specifications that will set out the minimum requirements for transportation and storage of exempt animal products – up until the time that they come under the Food Act regime or are exported. It is also recommended that where possible, operators include transportation in their risk management programmes to manage any risks specific to their operations. (This is not always possible as transportation is managed in a variety of different ways – sometimes by the operator themselves, sometimes by contractual arrangements, sometimes under the auspices of the buyer and sometimes independently.)

Operators that supply eggs to dairies and other markets will need to have a risk management programme for their egg production and packing operations.

MAF's proposal for the scope of risk management programmes for eggs is summarised below:

- Includes avian eggs derived from ‘layer’ hens (*Gallus domesticus*) and all other avian species, e.g., quails, geese, ducks and ostriches.
- Primary processing in the egg production/processing industry:
 - *Starts when the day old chicks or pullets or layers are grown or received at the laying facility where the eggs will be laid and collected; and*
 - *Ends where eggs in the shell have been preserved and assessed as fit for intended purpose as described in section 5 of the Animal Products Act.*
- The defined starting point provides for a barrier as a basis for checking that incoming birds have a known animal health and public health status.
- Management and maintenance of the laying flock would therefore come within primary processing as would all operations that occur soon after laying such as collection, chilling, packaging, and candling. Also inputs into the layer system, such as animal remedies and feeds, would be covered. In terms of Hazard Analysis and Critical Control Point (HACCP), this allows the known or potential biological, chemical and physical hazards to be controlled.

1.6.1.4 One submitter was concerned that the definition of primary processing would require bee product producers to have a risk management programme, and explained that this was not necessary as honey is antibacterial, and therefore is low risk.

Response

MAF’s view is that there is no scientific or economic benefit in the application of a risk management programmes to bee keeping, so MAF has recommended that bee industry primary processors should be exempt from the requirement to have a risk management programme. Standards and specifications will be used to ensure the necessary risk management controls are in place including product presentation and procurement specifications to cover beekeeper record keeping in relation to animal remedies used, environmental contaminants, disease status of the hive, and toxic honey risks. It is possible that the contaminants monitoring and surveillance regulated control scheme which is currently being developed could have some application to the bee industry where appropriate. Honey house operators that are secondary processors (by definition in accordance with the Animal Products Act) would be able to continue subject to the Food Act. These proposals are currently being reviewed at cabinet level.

1.6.1.5 One submitter proposed that the accepted method of stunning should be included as a regulated practice in order to comply with animal welfare regulations.

Response

MAF disagrees with this proposal as animal welfare is outside of the scope of the Animal Products Act and is covered by other legislation.

1.7 Two industry associations commented on the relationship between risk management programmes and Food Safety Programs (FSP) and expressed a desire to provide their members with a model that complies with both export and domestic regimes.

Response

MAF supports this stance and recommends that the industry associations develop a Code of Practice or review their current code of practice with input from MAF Food Assurance Authority and the Ministry of Health to ensure that all requirements are met.

- 1.7 One submitter asked for the following change to be made to paragraph 4, line 1: Change to “Verification and validation of...”

Response

MAF disagrees with this suggestion as validation is a separate activity that is done by the operator – not by other agencies.

- 1.8 Two industry associations were concerned about the requirements for amendments to the risk management programme to be registered and the associated fees. They felt this would be cumbersome when the programme was integrated with the rest of a quality system and was a disincentive for operators to improve their programmes. One was concerned about how much of the documentation would be audited when the risk management programme was integrated with a quality system.

Response

It is not MAF’s intention to make operators send in every change. Only those changes that impact on the appropriateness of the programme or the fitness for intended purpose of the product will need to be formally amended. Section 7.4 explains this further (and will be expanded to give more guidance). Section 7.5 explains that minor changes will be captured by the update process.

MAF has allowed for operators to include parts of their quality system in their risk management programme by cross-reference. Operators can use their normal quality control systems for updates if the reference is updated in the document that outlines their risk management programme (See sections 3.13.3 and 3.13.4). The full change would need to be evaluated but only the outline of the risk management programme needs to be submitted for registration.

Only the parts of the quality system that are included in the risk management programme (as defined by the operator in the scope and the cross references from the outline of the risk management programme) will be evaluated and verified under the Animal Products Act 1999.

- 1.8 One submitter noted that the verification agency does not have to be contracted until registration is achieved - therefore it should be the first step in operation, not registration.

Response

MAF agrees and has updated the manual to reflect this.

SECTION 2:

- 2.2 One submitter felt that “Good manufacturing Practice” (GMP’s) should be included here.

Response

MAF disagrees as this is already included in the Operational Specifications and Codes of Practices. Refer to section 2.5 which clarifies the relationship as it is used in the manual.

- 2.2 One query received was whether the Animal Product Regulations would be put on the web site as other regulations are not?

Response

Yes. All regulations relating to the Animal Products Act are, or will be, on the website.

- 2.3 One submitter suggested that there should be a link to other relevant specifications.

Response

MAF agrees that this is desirable but it may not be the best place for it. It may be explained better at the web site where the links to other documents under the Animal Products Act can easily be shown. This will be considered further at a later stage.

- 2.3 One submitter recommended that standards & specifications should be:

- outcome oriented , with
- an indication of what would constitute acceptable evidence of outcome, and
- guidance notes on the regulatory bodies view of how the outcome could be achieved.

Response

First bullet: MAF agrees – already included in 2.2. but could repeat in 2.3 to clarify.

Second bullet: this would be quite specific to the product involved so could not be described here. Refer to fitness for intended purpose and validation sections for generic information.

Third bullet: In future this should be covered in codes of practice for specific food industries. It is not possible to put these details in a generic manual.

- 2.4 One submitter queried what an operator did if there was no industry working group.

Response

An explanation that they can still use other templates etc. as a starting point has been included in the manual.

- 2.4 One submitter suggested a wording change to show that all programmes will need to be validated as there is no guarantee that a management programme based on a template will deliver the required results when it is implemented in a specific industry / processing plant.

Response

MAF agrees that all risk management programmes must be validated and this is covered in S4. The level of validation required may be less for those operators who follow a generic risk management programme or industry code of practice as some of it has been done for them. This will be particularly relevant to smaller operators with few technical resources, in assisting them to have a valid plan without excessive cost.

- 2.5 Two industry associations wanted to have a direct industry forum including MAF to enable appropriate input to Industry Agreed Standards. One was concerned that government agencies may promote a “zero risk” stance which could entail infinite cost to industry.

Response

One association already has representation on the appropriate council that issues the standards. If they desire any changes they should go through the normal channels to request them. If an industry wishes to revise their code of practice so that it can be included in the list of documents then they should contact the Director, Animal Products, MAF Food Assurance Authority and request this formally.

- 2.5 One submitter suggested that even the best code of practice can only address risk factors that are manageable in the hands of the operator. Another submitter suggested that the programme should address all currently known risk factors to make provision for emerging issues e.g. new product, processing practices, or organically grown or GM foods might need other requirements to be rendered fit for purpose.

Response

MAF agrees that the risk management programme should only address currently known hazards and other risk factors that can be reasonably expected to occur, or be controlled by each operator.

- 2.6 One submitter commented that the existence of a HACCP plan or a risk management plan does not prevent the occurrence of food poisoning outbreaks. Implementation, usage and upgrading is required and needs to be monitored to achieve the set objectives of this whole initiative.

Response

MAF has added a new sentence, i.e. “If so, they must be maintained in accordance with all risk management programme requirements.”

- 2.8 There was one query about the basis for considering technical publications to be acceptable.

Response

MAF agrees this should be clarified and should be consistent with section 4.2.2.2 without being too restrictive. The main issue is to ensure that scientifically sound information is used.

- 2.9 One submitter asked for an explanation of “trials and experimentation protocol”.

Response

MAF agrees this should be clarified and will add in a cross reference to an appropriate guide or appendix, as it becomes available.

SECTION 3:

- 3.2 Table 3 A: One submitter recommended that "honey extraction" be deleted from processes as it is not primary processing.

Response

MAF disagrees as honey extraction from the hive has been deemed as primary processing under the Animal Products Act 1999. Processes at the honey house are considered to be secondary processing (but must be under the Animal Products Act for export products).

- 3.2 One submitter wanted the risk management programme to adequately describe the **physical boundaries** of its application, in the scope so that there is no confusion as to what parts are included in the risk management programme.

Response

MAF agrees and will elaborate on this in the manual.

- 3.2 Table 3 A: One submitter was concerned about MAF extending its role into labelling and wholesomeness. They felt that other legislation adequately covered labelling for the Australasian market but agreed that there may be a need for MAF to oversee labelling of export product. They also wanted clarification on how wholesomeness could be controlled within their industry sector, and wanted input into any standard operating procedures that would apply to them.

Response

The Animal Products Act 1999 covers both New Zealand and export requirements so it is necessary to address wholesomeness and truth of labelling issues on behalf of both customers. Risk management programmes target New Zealand's requirements which MAF agrees are, to a great extent, covered by other legislation. It may be that other regulators will enforce this as well as MAF. Alternatively, the external verifiers of the risk management programmes may be able to verify that the requirements of all regulatory bodies are met, to minimise the amount of verification that an operator is subject to. It is agreed that further clarity is needed on MAF's expectations for labelling and wholesomeness, and this will be included in the manual. Further clarification on wholesomeness and labelling specific to a particular industry is expected to be covered by an industry code of practice. There are already standard operating procedures in place for product destined for the United States market for these two issues.

- 3.2 One submitter questioned the inclusion of "Water" in the location of a premises or place in Table 3A.

Response

Water is included in definition of place given in section 4 of the Animal Products Act 1999. This refers to where animal material may be produced or may be present. e.g. Pacific Ocean, a particular lake.

- 3.2 Table 3 A: One submitter was concerned that the word "manage" in *Risk Management Plan* significantly broadens the classic HACCP definition, giving more weight to *Standard Operating Procedures* (SOP's) and *Good Manufacturing Practices* (GMP's).

Response

The Codex Alimentarius Food Hygiene Basic Text includes a section on the “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application”. Under the guidelines it states: “Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation.” The General Principles of Food Hygiene document covers aspects of a business operation that are often called prerequisite programmes, Standard Operating Procedures or Good Manufacturing Practice. Therefore MAF’s approach is consistent with Codex Alimentarius guidelines.

- 3.2 One submitter queried why Table 3A states that the scope needs to include only those risk factors that are relevant to the programme.

Response

MAF agrees that the operator is to indicate the applicability or non-applicability of all four risk factors and has updated this section of the manual accordingly.

- 3.2 One submitter questioned how a risk management programme could apply to multiple locations when it is a well documented fact that it is not possible to compare individual slaughter days, premises, seasons etc. as far as microbiological contamination is concerned. This submitter recommended that individual programmes for each site and management group are needed.

Response

MAF agrees with the comment in principle but there is nothing to stop an operator having individual outcomes for individual premises within one risk management programme. The manual will be updated to clarify this point.

- 3.3 One submitter suggested that this section is confusing and suggested splitting it into 3.3.1 (dealing with the listed references to the APA); and 3.3.2 explaining the meaning of "operational authorities and responsibilities.

Response

MAF agrees and has updated the manual accordingly.

- 3.3 One submitter suggested adding sampling to monitoring in table 3C.

Response

MAF disagrees as sampling is intrinsic in monitoring.

- 3.3 One submitter wanted it clarified that there are no specific qualifications required for persons identified under Authorities and Responsibilities.

Response

The operator is required to train people appropriately by section 16c of the Animal Products Act 1999. An industry code of practice may clarify the industry sector’s preferences for training. Otherwise it is the responsibility of the operator.

- 3.3 One submitter identified a conflict with requirements as stated in Section 3.13.4 relating to the requirement to have name, position or designation of the person responsible for the day to day operation of the RMP.

Response

MAF agrees and has changed section 3.13.4 of the manual.

- 3.3 One submitter suggested that larger premises may not be able to name a specific person or position or designation on any one day for each of the operational responsibilities and authorities. They felt that it is likely that the person with overall responsibility will delegate responsibility on a day to day, shift to shift basis, according to who is available with the required level of competency.

Response

MAF agrees and has added in clarification to the manual that delegation is acceptable so long as the mechanism or procedure for making the delegation is documented.

- 3.4 One submitter queried whether partially finished product being transferred elsewhere, e.g. green casings, had to be included in the product descriptions.

Response

MAF specifies that all animal material or animal product that is leaving the risk management programme to be used for human or animal consumption must be covered by the product descriptions. The table has been amended to allow for animal materials to also be described.

- 3.4 Three submitters said that the table was daunting and confusing. It is not clear which details are mandatory and which are optional. It is not clear how intended purpose relates to intended use and intended consumer. It is not clear why the information is needed and a suggestion was made that it is to help the operator with risk analysis.

Response

MAF agrees and has simplified the table in the updated manual. MAF has avoided the use of the term risk analysis at this stage because proper quantitative risk analysis is not currently achievable.

- 3.4 One submitter suggested adding use-by-date to labelling instructions.

Response

MAF agrees and has added this to the table.

- 3.5 After discussions with MAF Food one industry believes that the current GHP (prerequisite programmes) will provide adequate management of wholesomeness as defined by the Act.

Response

MAF has agreed to rollover (accept) some of the current systems until the time that the updates are due. The actual criteria for rollover is still being finalised and will be added into the manual when it is ready.

- 3.5 Two submitters queried where the regulator's interests would start and stop for wholesomeness and truth of labelling and whether it would include commercial elements of a company's business. They also questioned whether these risk factors should be covered at all within the RMP. Another industry strongly opposed any move by MAF to have influence over areas relating to product quality and commercial arrangements between producer and buyer. They also felt that the requirements were unclear for labelling especially what verification would be required of the outcomes relating to labelling.

Response

MAF is required to cover wholesomeness and truth of labelling by section 17 (2) of the Animal Products Act 1999. The definition of risk factors is given under section 4 of the Act. MAF is not concerned with any other "commercial" issues. MAF agrees that further clarification on wholesomeness and truth of labelling would be useful. Operator will however be able to define the scope themselves so long as they are able to justify what has been included and excluded. This is industry and product specific so guidelines should be added into industry codes of practice. The question about verification really relates to operator validation and may simply involve checks that the labels consistently conform to requirements. Verification will be done by independent accredited verification agencies and will review all documented aspects in the RMP as written.

- 3.5 One submitter queried whether there were any existing standards or specifications for animal products, and if not asked what outcomes should be based on. Another submitter felt that the requirement for documentation of expected outcomes and the requirement for outcomes to consist of measurable parameters are both open to broad interpretation.

Response

Yes, there are standards and specifications currently included in technical directives, industry agreed standards and other documents. These will be collated into the operational specifications so that operators are clear on which requirements are mandatory. If there is no specification or standard the operator will be expected to set outcomes for each risk factor based on their process capability, industry codes of practice or scientific literature etc. The evaluators and verifiers will review all documented outcomes in the risk management programme in the light of any standards or specifications and the operator's validation information. The manual has been updated to make these points clearer.

- 3.5 One submitter asked whether premises that managed hazards to human health primarily through the use of prerequisite programmes would need measurable outcomes to be defined for all prerequisite programmes. If so, the submitter strongly opposed this requirement.

Response

MAF requires operators to define **product outcomes** (not outcomes for each control system) for all currently known hazards and risk factors that are reasonably likely to occur. For each of these hazards or risk factors this is likely to be "one" outcome for each product or group of products that the operator has described in their risk management programme. The mechanism used to achieve this is up to the operator. It may be that several prerequisite programmes contribute to each outcome.

- 3.5.1 One submitter asked how "where appropriate" was defined.

Response

MAF agrees that this is confusing and has deleted these words from this and following sections. A paragraph has been added to section 3.5 to explain that all four risk factors must be considered when establishing product outcomes.

- 3.5.1 Two submitters believed that current food safety objectives in HACCP plans would meet the requirements for product outcomes for hazards to human health. One queried whether food safety programmes met the requirements. Another submitter queried whether those who had food safety objectives would need to double check them to ensure that they met any regulatory standards or specifications.

Response

MAF agrees that current food safety objectives from HACCP plans can be used as product outcomes for hazards to human health so as long as the complete specification given in section 3.5 is met (all 3 bullets). The last sentence will be reworded to clarify this and also to reinforce that food safety programmes that don't yet have food safety objectives and are to be incorporated or converted into a risk management programme will also need to be revised to meet this specification.

- 3.5.1 One submitter suggested that the issue of outcomes for human health needs serious evaluation between MAF, Ministry of Health, industry and consumer representatives to develop acceptable outcomes for different classes of foods. Another said that neither the Ministry of Health nor MAF have ever stated this in objective terms, so wondered how an operator could be expected to do so. They also queried why operators should have to grapple with the debate between prevention and treatment when no western government has been willing to do so.

Response

Some outcomes will be specified by MAF where there is sufficient data to support this stance. MAF supports qualitative or quantitative association with risk to human health. MAF has included Food Safety Objectives in the generic HACCP plans that it has developed. See also MAF's risk assessment model for *T. saginata*.

- 3.5.1.1 Two submitters recommended that a different example be used as the achievement of zero tolerance for *Listeria monocytogenes* in ready-to-eat foods is in question and is in the process of reevaluation. It could also be put differently to emphasise that the absence of *Listeria* is the ultimate target.

Response

MAF has used this as an example because it is still a current specification. The example will be amended if the specification is changed.

- 3.5.1.1 One submitter stated that the setting of microbiological Food Safety Objectives is inappropriate for processes where there is no effective lethal step (or series of steps) constituting a true CCP under the control of the primary processor. They also queried whether the phrase "tolerable in relation to an appropriate level of human protection", is appropriate for raw product. This submitter suggested that where there are no CCPs, the GMP could be validated against system outcomes based on their process capability.

Response

A CCP does not have to be a lethal step but may be one that reduces or minimises a hazard to an acceptable level. MAF believes that microbiological Food Safety Objectives for primary processing which **indicate** a level of control of microbial contamination is the best control option available currently. It has a qualitative linkage to human health.

Risk management programmes only have to achieve product outcomes. The operator may use process capability as one means of validating these product outcomes so long as the link between the two can be established.

- 3.5.2. One submitter stated that MAF must provide objective criteria for all factors that impact on wholesomeness to overcome concerns about differing interpretations of “wholesomeness”, and also what is “offensive”. They gave an example of a product that would be offensive to people of certain religious persuasions. Another submitter queried which of the following issues would fall into the “wholesomeness” area for meat products: tenderness, colour, drip, fat/lean ratios, marbling, smell, or any other aesthetic that the customers decide on. A third submitter also expressed concern about interpretation of wholesomeness between operators, evaluators and verifiers.

Response

MAF agrees that some products would be offensive to certain consumers and recommends that product labels clearly describe the product ingredients so those consumers can choose not to buy products that will offend them. Companies should determine what they believe are the relevant wholesomeness issues as a starting point and use their historical data from customer and consumer complaints to support their decisions. Any objective criteria for wholesomeness would vary from product to product. At some future time the main risks to the main products should be clarified in industry codes of practice. If this part of the Act is shown to be unworkable, or that it has unexpected adverse effects it may be possible to amend the Act – but it has to be tried first.

Verifiers should not be disputing the definition of wholesomeness or the contents of a registered RMP. The verifiers role is to check that the “operator” is implementing what has been documented, validated, evaluated and registered, i.e. the registered RMP. If however they are concerned that the risk management programme is **seriously** deficient this should be reported back to MAF Food for resolution.

- 3.5.2 One submitter stated that the major factor in wholesomeness of food is decomposition i.e. the population density, species and metabolic by-products of contaminating bacteria. They were concerned that higher numbers of bacteria in aged products (compared with fresh products) would be “expected” by one consumer and totally unacceptable to another.

Response

The Animal Products Act requires product to be fit for intended purpose (as stated or could reasonably be presumed to be intended having regard to its nature, packaging and identification). This means that wholesomeness outcomes have to be considered in the light of individual animal products and the processes and storage conditions applied to it. Products that are “aged” may have different wholesomeness outcomes from those that are not. If consumers find this unacceptable the operator may need to alter their outcomes or educate the consumer about the product in some manner so that they “expect” what they get.

- 3.5.3 One submitter suggested that where a risk could be classified either as a hazard to human health or as a risk to wholesomeness then it should be listed as a health hazard to reinforce its importance.

Response

MAF agrees and will update the manual to reflect this.

- 3.5.3 One submitter wanted to clarify whether wholesomeness would include moulds and rots in eggs.

Response

Yes.

- 3.5.4 One submitter queried what happens if different pieces of legislation conflict with respect to truth of Labelling requirements, i.e. which takes precedence?

Response

Acts have precedence over any regulations. Any regulations containing specific statements take precedence over those that are general. The proposed Joint Food Standards Code will have equivalent status to a regulation. MAF will not set standards that disagree with other Acts. A note has been added to the manual that labelling requirements of other legislation, e.g. Food Regulations, must still be met. The reason that labelling has been added into the Animal Products Act is to get operators to identify and control risks associated with labelling within the process as well as in the normal manner. If there are conflicting requirements at the same hierarchical level then this should be made known to the appropriate regulatory bodies so that the issue can be resolved. If there is a true conflict then the operator could be prosecuted under the Act that they were not meeting.

- 3.5.4 One company queried how to handle truth of labelling requirements when they use different ingredients (depending on availability) to make some products. Despite this the end compositional and nutritional product specifications are still met.

Response

An operator would need to label their products in a manner that allowed them flexibility e.g. using “may contain” statements.

- 3.5.4 One industry queried what truth of labelling issues there would be for their industry. Another suggested that this should be limited to those labelling issues that are mandated by the importing country and not other labelling requirements. They suggested that some labelling issues are market issues not regulatory issues.

Response

As for wholesomeness it is not possible for MAF to list all possible issues. The “ins” and “outs” or labelling are still being debated by MAF and industry working groups. In the future, refer to industry codes of practices for clarification.

- 3.5.4 One submitter queried who would determine the adequacy of the operator’s justification for self-set targets.

Response

Where possible, specifications and standards should be used to quantify parameter targets. Where there is no available specification or standard the evaluator would determine whether

the justification was adequate. MAF will take this into account when developing competencies and boundaries for evaluators.

- 3.6 Page 3-10, paragraph 3: One submitter queried whether inputs that enter and exit the process should also be considered, rather than just those inputs that form part of the end product.

Response

MAF agrees - other inputs can be considered - but the minimum to be covered in the risk management programme is as written, i.e. those that will form part of product.

- 3.6 One submitter suggested adding a reference to Section 4 (Validation) to the final paragraph as the checking of the description of the process against reality is a validation process.

Response

MAF agrees and has updated the manual to reflect this suggestion.

- 3.7 One submission noted that MAF has made a “new” presentation of HACCP principles 1 and 2 and that the process of CCP determination has been combined with the hazard identification and analysis. They felt that this and other changes to the HACCP approach proposed by MAF in this document is unacceptable.

Response

MAF disagrees. Principles 1 & 2 have not been altered with respect to CCP determination. Principle 1 is to conduct a hazard analysis and Principle 2 is to determine the critical control points. Both of these principles are still covered in risk management programmes.

- 3.7.1 One submitter suggested adding a note for the operator to align the risk management programme with other requirements for incoming raw materials, e.g. previous operation's RMP, RCS, procurement/presentation specifications etc. They also recommended that the operator should confirm that these requirements are being met in some manner, e.g. supplier declarations, inspection and testing.

Response

MAF agrees and has updated the manual accordingly.

- 3.7.2. One submitter queried what they should do if they did not have an industry council to go to.

Response

The manual has been altered to recommend that the operator does the work themselves or hires outside expertise to assist them.

- 3.7.2 Figure 3c, decision diamond 1: One submitter recommended that consideration should be given to the effectiveness of the supporting programmes here rather than (or as well as) in Figure 3d.

Response

MAF agrees and has updated the manual accordingly.

- 3.7.3 Figure 3d: One submitter felt that this decision tree does not work too well for supporting programmes and recommended a different option.

Response

MAF agrees that the decision tree can be improved and has updated the manual accordingly.

- 3.7.3 Figure 3d: One submitter said that control points including CCPs can only apply up to the CCP not beyond and queried how a cook stage can protect from subsequent recontamination. They felt this appears technically unsound.

Response

MAF did not understand the point being made and will contact the submitter to clarify this.

- 3.7.3 Figure 3d: One submitter queried if it mattered if operators have too many critical control points (as per verifier's opinion) if outcomes are still being met. (Currently there are some issues where supporting systems have been improved so CCPs are no longer necessary but the programme hasn't been amended).

Response

No. This would be considered to be an update and is not urgent. It would be in the operator's interest to update (and therefore simplify) their risk management programme as soon as possible, but if it is still achieving the outcomes there is nothing technically wrong with it so long as the operator is following the written programme.

- 3.7.3 Figure 3d and 3.8.1: Two submitters felt that the use of the term critical control point for non-food safety hazards and risks may be confusing to industries already used to HACCP.

Response

MAF feels that the jargon used should be consistent throughout the risk management programme so that extra terms don't have to be introduced. MAF has now suggested in the manual that operators may wish to use subscripts, superscripts, colour-coding or other suitable means to clarify which CCPs relate to hazards to human health and which ones relate to other risk factors. The manual has been updated to explain this further.

- 3.8 One submitter recommended explaining how both the simplest and most complex systems could work.

Response

MAF disagrees as this would be too difficult to make relevant for all industries but we have added in further clarification to this section of the manual to make it simpler.

- 3.8 One submitter was concerned about the use of new terminology "confirmation procedures" to replace verification as one of the HACCP steps, and recommended that the terms internal and external verification are used instead.

Response

Confirmation was used to align with terminology from section 17 of the Animal Products Act and to differentiate from verification which is an external activity under section 4 of the Act. Internal and external verification is not an option under current definitions in APA.

MAF does however agree that this is confusing and would like to keep this consistent with Codex international HACCP jargon. The fact that MAF Verification Agency are called “verifiers” created the problem as it was felt that it would confuse operators if they were also expected to do “verification”. A name change for MAF VA was not considered to be an option at the time that the Act was written. Currently MAF’s hands are tied on this matter. MAF now intends that when the Act is next reviewed it will recommend that “confirmation” becomes “verification” and “verification” becomes assessment in line with international norms. This may or may not be accepted at the cabinet level.

- 3.8 One submitter considered the details necessary for monitoring, corrective action and verification (confirmation) in Table 3E to be excessive and felt this could be explained in industry HACCP Guidelines.

Response

MAF agrees but has put the detail into Table 3E to assist those industries that do not have HACCP guidelines.

- 3.8.1 One submitter recommended that a glossary of HACCP terminology be added to the manual to explain such terms as critical control point, critical limits, parameters etc.

Response

MAF agrees and has added this into the manual.

- 3.8.2 Page 3-17: One submitter suggested we clarify the expectations for the control of hazards within the supporting programmes i.e. limits, monitoring, corrective actions, confirmation still apply as per 3.8.1. They also wanted clarification on what would be required for those systems already recognised as valid by MAF Verification Agency.

Response

MAF agrees and has added both points into the manual.

- 3.9 One industry did not agree with the examples used in Table 3F and suggested some alternative examples. Another submitter said that although some of the examples were undesirable, whether they were offensive or not may well depend on the acuity of the examiner’s eyesight. Another submitter said that some of the examples were related to “quality” rather than “wholesomeness”.

Response

MAF agrees with the alternative examples but still believes that the original examples are valid – although in some cases it would be relate to the degree of the problem. The acceptable limits would need to be defined by the operator. This would also overcome the “eyesight” issue mentioned above. The manual has been updated to clarify these points.

- 3.9 One submitter queried if the minimum acceptable system for control of wholesomeness would be a complaints system with follow-up and corrective action for each incident.

Response

MAF agrees that this would be a practical approach and has added this option into the manual.

- 3.9.2 One submitter recommended adding a prompt to consider allergies or religious factors.

Response

MAF agrees. The manual has been updated to clarify these points.

- 3.9.2 One submitter recommended that the first sentence could end after “..intended consumer (animal or human)”, and that there is no need for the additional text and 3 bullets.

Response

MAF disagrees as industry working groups have asked for further elaboration on the requirements, not less.

- 3.10 One submitter opposed the requirement for excessive details for the control systems for wholesomeness and truth of labelling which included the following:
- Specific points in the process where the risk factors can be controlled;
 - Criteria at each of these points that must be met for each risk factor;
 - Monitoring for each point;
 - Corrective actions;
 - Verification activities to confirm effectiveness.

Response

The HACCP principles do underpin the requirements of section 17 of the Animal Products Act for all risk factors. This is not out of line with Codex as any government may elect to apply HACCP principles wider than the Codex guideline. MAF however agrees with the concerns and believes that supporting programmes such as a consumer complaint system for wholesomeness and a product development system covering truth of labelling may be adequate, rather than the full HACCP approach (which may suit some situations). The manual has been updated to add in these options.

- 3.10 One submitter queried what the requirements would be for new premises in relation to this requirement?

Response

MAF believes that a new operator can use literature searches, own previous experience and industry codes of practice to set up initial controls for wholesomeness and truth of labelling and may adapt these once they have sufficient data to establish their own control mechanisms. The manual will be updated to clarify this point.

- 3.11 One industry stated that they believed that their current recall procedures would meet the stated requirements.

Response

MAF agrees that where current systems meet the requirements no change will be required. MAF will be clarifying how existing systems that have been recognised as valid be MAF Verification Agency can be “rolled over” into the system without the need for re-evaluation.

- 3.11 One submitter recommended that we add a reference to the Ministry of Health’s recall document for guidance especially on media statements.

Response

MAF agrees and has updated the manual on this.

- 3.11 One submitter queried if there would be a policy on when the operator must do a recall.

Response

MAF believes this point needs further consideration and has yet to make a decision on it.

- 3.12 4th and 5th bullets: Five submitters questioned whether the verifier should have the authority to intervene and direct alteration or cessation of processing. They recommended that this was a decision that must be taken by MAF Food. One felt that there should be a disputes process. One said that this third person approach was even more necessary if agencies other than MAF VA become involved in verification activities. Two of these submitters also queried whether the verifier should be able to detain product.

Response

MAF has altered the specifications so that the verifier can only interrupt processing or temporarily detain product. In all other cases the verifier must notify MAF Food of the issues. Verification activities may be done by agencies other than MAF VA except where Overseas Market Access Requirements dictate government involvement. MAF is considering whether a disputes process is necessary.

- 3.12 Two submitters felt that the last bullet point should also be highlighted as it is a specification and suggested inserting “RMP of the” into the sentence, i.e. “...and any other specific provisions relevant to the **RMP of the** business or operation.”

Response

MAF agrees and has updated the specifications and the manual.

- 3.12 Page 3-22, paragraph 2, line 5: One submitter recommended changing this to “...Authority or its authorised agent of...” to all for if MAF Food decides to use third party organisations such as CRI’s TLA’s or RA’s.

Response

MAF disagrees. These organisations may become recognised agencies but the disclosure should only be made upwards to MAF Food.

- 3.12 One submitter recommended that the verifier should give the operator notice that they are coming and should arrive at a reasonable hour.

Response

This is reasonable for routine verification, but not for verification that could result from poor performance. MAF will consider adding some recommendations into the manual.

- 3.12 One submitter was concerned that their customers for whom they contract manufacture may not be happy for their documentation to be made available to a verifier for confidentiality reasons. There are also privacy issues for staff training records etc. They recommended that MAF Food add confidentiality requirements into the specifications for accredited evaluators and verifiers.

Response

There is a confidentiality requirement under section 107 (d) of the Act. MAF already has a confidentiality clause in relevant specifications. The operator could also add confidentiality into their contract with the recognised verification agency.

- 3.13 One submitter suggested that reference should be made to regular programme review and documentation.

Response

MAF disagrees as Section 7.2.3, 7.4 and 7.5 of the manual covers it adequately.

- 3.13 One submitter questioned whether so much of this section needs to be in the specification, and suggested that the specifications for this section are reviewed and only the completely essential elements are maintained as specifications. They also queried the level of detail required for records. As an example they stated that the time of observation is not relevant in some cases, particularly for verification activities. What does it matter is someone reviews the monitoring records at 9.00 am or 3.30 PM? Often, monitoring is done during the day but is not written up until the end of the day.

Response

MAF disagrees with the reduction in specification. The only way that operators can prove to an evaluator or verifier that their programme is valid is by using their documentation and records. It is paramount that records are kept for this reason. MAF also disagrees with the reduction in detail in records. It is relevant what time people do their monitoring – especially if a problem is found which could indicate that there is non-conforming product. Recording times would greatly reduce the amount of product that would be subject to rework, rejection, recall etc. Times are also important for identification of problems that are time or shift related. MAF also queries whether it is an acceptable practice to write up all documentation at the end of a day. It is not likely that a person can keep accurate, detailed information in their heads for the whole day. Timely record-keeping is essential.

- 3.13.2.1 Two submitters said they would like to see further clarification about the legal status of electronic documents and records (for risk management programmes and E-cert), audit trails, document security etc.

Response

MAF has noted this suggestion and will consider it in due course.

- 3.13.3 One submitter recommended that column 4 of Table 3G should include an abbreviated record of any changes made, so that the operator maintains a record in one place of all the

amendments (both minor and major) to the RMP. This would provide an excellent reference for the company, external verifiers and evaluators.

Response

MAF agrees that this could be an option, but MAF does not want to dictate how an operator's document control system should work. A paragraph will be added into the manual asking the operators to record amendments and updates and will indicate that the above suggestion is one way of achieving this.

3.13.4 One submitter produced a "dummy" risk management programme based on this list.

Response

MAF encourages people to have a go, but it must be made clear that the minimum list is not the "whole" risk management programme as assumed by the submitter but merely an outline or summary of the programme. The manual has been updated to make this clearer.

3.13.4 One submitter said that the Act did not require operators to contract verifiers before registration so recommended adding 'which has indicated its willingness to provide the service' to the 6th bullet.

Response

MAF agrees and has updated the manual with this change.

3.13.4 One submitter suggested that this list should also be consistent with the registration requirements of section 6.2 (i.e. number of copies, evaluation report, application forms etc also required). They felt that the heading needs changing. This submitter and one other submitter wanted further clarification of the detail required for the process description.

Response

MAF agrees that the heading should be changed and further clarification is needed for some items in the list. The level of detail required should be similar to that used in HACCP plans.

3.13.4 One submitter recommended that the manual explains that if only part of any referred documents are intended to be included in the risk management programme, then the references should make it clear which parts, sections, clauses etc. are included. The rest of the document should then be excluded from the risk management programme.

Response

MAF agrees and has updated the manual to clarify this.

3.14 One submitter queried whether the first bullet meant that by-products from home-kill or recreational catch cannot be sold or given to renderers (as this could then end up in products for animal consumption). They also wanted to know how they should dispose of excess fat, trimmings etc. if this is not permitted.

Response

At present it is permitted to sell or give by-products to renderers. Under the Animal Products Act it cannot be done. It may be possible to introduce a regulation or amend the Act to allow them to sell by-products if there is no acceptable alternative disposal option.

- 3.14 One submitter recommended that the manual is altered to make it clear that the risk management programme must manage risks to the regulated animal product, meet special homekill requirements (eg inventory control) and also the requirements given in the 2 bullets at the bottom of the page.

Response

MAF agrees and has changed the manual to agree with this suggestion.

SECTION 4:

- 4 One submitter commented that they did not want to see higher expectations from MAF with respect to validation – especially of prerequisite programmes. They strongly oppose any suggestion that prerequisites be validated in any other way than through the standard checks and reviews undertaken through a company’s internal compliance programme. Another submitter suggested that internal audits of compliance would be sufficient to validate prerequisite programmes.

Response

MAF reinforces that validation is to do with product outcomes, which will reflect the effectiveness of supporting systems, e.g. prerequisite programmes. This effectiveness can be assessed by audits of compliance with the documented programme.

- 4.1 Page 4-1, second to last paragraph: One submitter suggested that it is made clear that the validation is done by the operator. Another submitter proposed rewording the paragraph as shown: “Operators with animal products covered by HACCP plans or hazard identification and analyses that have already been validated **by the operator** and recognised **as valid** by MAF Verification Agency, do not need to repeat the validation of this part of their risk management programme, i.e. in relation to food safety outcomes. However, these operators will need to consider other risk management programme requirements, i.e. animal health hazards, risk factors associated with wholesomeness and risk factors associated with false or misleading labelling.” They also recommended that this section be consistent with section 5.1, and to add a prompt that the supporting programmes still need to be validated.

Response

MAF agrees with all comments except that supporting programmes are not validated (as explained above). MAF will add in a paragraph explaining how current systems can be “rolled over”.

- 4.1 Page 4-1, paragraph 2, line 3: One submitter proposed that the wording be changed to “...when changes or failures occur...” to ensure that the whole plan is revised and revalidated.

Response

MAF believes failures will be addressed by the 2nd bullet. Where failure results in a change that is significant enough to result in an amendment then this would lead to revalidation.

4.2.2 One submitter queried what an operator should do if they don't have any evidence.

Response

MAF would require them to collect some evidence. If they don't know how to do this they may need to get some expert assistance.

4.2.2 One submitter suggested the manual should explain that after validation the final product testing frequency could be reduced if defined parameters are met on an ongoing basis within the process. They also felt there should be a clearer link between validation and other confirmation activities.

Response

MAF agrees with these suggestions and will reword this section of the manual.

4.4.2.5 One submitter recommended that the following clauses be added about predictive modelling:

“In order to get provisional validation as per section 4.4.2, operators can present for evaluation, a certificate of performance or present predictive modelling data to support design of process parameters.

A certificate of performance from a competent person can be used for provisional validation of an RMP in respect of refrigeration or thermal processing performance.

Predictive models will include, but are not restricted to, thermal performance, water activity and microbiological outcomes.

Where any process parameters are designed according to a predicted process outcome, the outcome in real terms shall be validated using methods that generate quantitative data appropriate to the modelled parameters.

To expand on this we then include the provision for predictive methods as a means of getting provisional validation in section 4.4.2 second bullet point of second group of bullet points.”

Another submitter also suggested that predictive modelling should be covered.

Response

MAF agrees that this is what we want to achieve, but will reword it a little to make it simpler to understand.

4.2.2.1 Page 4-3, paragraph 1, line 5: One submitter proposed a wording change to “...are based on accepted and accredited standardised methods...” as methods which are not necessarily providing accurate results, might also be standardised.

Response

MAF feels this is a valid point but queries the use of the words “accepted” and “accredited” as these may not be correct. This will be investigated further.

- 4.2.2.2 One submitter commented that this avenue was great if you have the capacity – but little guys don’t.

Response

MAF agrees and that is why it will recommend that some of this information is provided in industry codes of practice in the future.

- 4.2.2.2 Page 4-3, paragraph 1, line 1: One submitter suggested rewording to “...from peer reviewed literature published in citation indexed journals”.

Response

MAF agrees that a change is needed but queries if people will understand what citation indexed journals are. Consideration will be given to alternative wording.

- 4.2.2.4 Page 4-3, paragraph 1, line 4: One submitter proposed a wording change to “...a protocol with in some cases, the assistance of a recognised science provider i.e. ESR or others.”

Response

The Act does not make any provision for recognised science providers. It is however a valid point that the operator may wish to gain expert assistance where required and a comment to this effect will be added into the manual.

- 4.3.1 One submitter queried whether an operator who has only “hard yacker experience” will find this sufficient to validate their programme.

Response

MAF feels that data is necessary to validate a programme and anecdotal evidence is not sufficient. An operator may however use a signed statement about their relevant experience, e.g. no consumer complaints received in last 6 months, as part of their validation information.

- 4.4 One submitter recommended that appendices on Trials and Experiments and Statistical Process control be added to the manual.

Response

MAF agrees that this would be useful. Appendices will be developed as time permits.

- 4.4.1 Page 4-5, last bullet point: One submitter felt that the words “that the programme is implemented...” contradict those in the last paragraph “...before commencing operations” and recommended adding a comment that full validation is only likely to apply to animal product businesses switching from operation under the Meat Act 1981 to operation under the Animal Products Act 1999 with no significant changes to their operation. They also suggested adding “under the RMP” to the last paragraph of 4.4.1.

Response

MAF agrees that this is confusing and will reword to make it clearer.

- 4.4.2 Three submitters suggested that operators also have an adequate programme for developing, collecting or completing validation data as part of their evidence for provisional validation. One recommended that this be reviewed by the evaluator.

Response

MAF agrees and has added this into the manual.

SECTION 5:

- 5 One submitter suggested adding details of the information required in an evaluation report.

Response

This information is in the Evaluation specifications and guide. MAF will either repeat this information in the manual or put in a cross reference to other relevant documents.

- 5 One submitter queried what would happen if an evaluator didn't get their evaluation right and a verifier picks it up. Another submitter queried what happens in disputes between validators and verifiers. They said that the competency requirements for Validators and Verifiers are very similar, but that for a given RMP the Validator may have far more knowledge and expertise than the Verifier - yet some element of the RMP validated by the Validator may be rejected by the Verifier. This submitter was of the view that MAF does have a monopoly on the knowledge and skills associated with food safety or risk management, and they may not be right. They felt that there must be a balanced expert government/industry arbitration panel to deal with these types of conflicts – and that the findings of the arbitration panel must be binding on all parties.

Response

Validation is done by the operator – and there are no specified competency requirements for this person. The evaluation of a risk management programme's validity is done by an evaluator (who may or may not be a MAF person, but will have specified competencies). It is likely that if there are any disagreements it will be between these two parties – not the verifier who audits the programme after registration and implementation. If the operator believes that the evaluator has got it wrong they can submit the evaluator's report and also their own data to MAF when they apply for registration. If MAF does not have in-house expertise on this matter it then it consults with relevant industry and academic professionals. If the registration is declined, there is a right of review when delegated authority is involved and ultimately it could go to court if the operator was still unhappy. The suggested panel is not allowed for under the Act. If a verifier believes that a registered risk management programme is inadequate and the operator disagrees, this should, where possible, be resolved with the verification agency. Otherwise, MAF should be notified.

- 5.1 Three submitters queried why the same person could not be both the evaluator and the verifier (to help keep costs down by using available resources effectively).

Response

MAF will update the manual in line with the analysis of the submissions on discussion document 18. This question will be considered during the harmonisation project with Ministry Of Health.

SECTION 6:

- 6 One submitter suggested that the registration process be written to include “provisionally validated” risk management programmes.

Response

MAF agrees in principle but has decided to avoid the use of the word “Provisional” as this is just more jargon. Instead the manual has been updated to explain what happens when validation is incomplete.

- 6.2 Two submitters queried how authorisations and signatures could be authenticated on electronic copies.

Response

This is a problem and initially MAF will ask for all copies to be sent in as hard copies until this issue can be resolved.

- 6.2 One submitter felt it should be made clear that there is also a fee for assessing the documentation.

Response

MAF agrees and has added this requirement into the manual.

- 6.3 Two submitters wanted a maximum time frame for MAF to process registration applications.

Response

MAF agrees that this is desirable and will develop a policy in the future. It is likely that the first registrations will take longer than normal while everyone learns the process. The actual time taken may also depend on the number of applications received at any one time. It will also depend on whether or not the evaluation process is working effectively.

- 6.3 One submitter queried whether an operator’s unique risk management programme identifier would have to be shown on animal product packaging.

Response

MAF feels that this is optional so long as the information on the packaging allows for traceability of product to the premises or place that produced it.

- 6.5.1 One submitter queried whether a change in verifying agency would constitute a change in registration.

Response

Section 16 (2) of the Animal Products Act requires the operator to notify such a change to MAF Food in writing. The query has prompted consideration of other possible changes, e.g. operator name, person responsible for day to day management, any of other information on the register. These situations will be clarified in the manual.

- 6.6 One submitter queried whether the time limits are in working days or calendar days. Another suggested that this should have a time limit of 30 days to be consistent.

Response

Time limits are in calendar days. MAF disagrees with having a standard time frame for operator submissions as this will vary on a case by case basis depending on the complexity of the issue.

- 6.6 One submitter wanted a right of review if the Director-General made the decision.

Response

This right is not currently allowed for in the Animal Products Act but section 162 (8) does provide for appeals to a court of law. MAF has added a cross reference to this into the manual.

SECTION 7:

- 7.2 One submitter suggested expanding section 7.2 to cover training.

Response

MAF agrees that further information on training should be added to the manual as it becomes available.

- 7.2.3 One submitter queried if a minimum confirmation frequency should be specified.

Response

MAF believes that the frequencies will vary according to the product, the hazards and other risk factors identified, the performance history, the part of RMP being confirmed etc. For this reason flexibility must be left with the operator to determine their own frequencies based on their superior knowledge of their own operation.

- 7.3.1 Page 7-4, 4th bullet: One submitter questioned where the evaluator fits within this loop. They felt that if, in the verifier's opinion the documented system is not effective then the first communication should be back to the evaluator.

Response

MAF disagrees. The reason that the verifier believes that the plan is not effective could relate to several things - including operator additions that the evaluator will not be familiar with. Evaluation is a one off exercise and the same evaluator may not be available.

- 7.3.1 One submitter felt that the last bullet point needs some clarification, i.e. does "operating outside the risk management programme" mean:
- Not complying with the risk management programme in some way (i.e. non-conformance

- and how serious does it have to be before notification is necessary)? or
- Operating outside the scope of the RMP (eg processing a product not covered by the RMP)?

Response

MAF only requires notification when the operator is operating outside the scope of the programme. The manual will be reworded to make this clearer. A separate bullet will also be added to cover the situation where the operator is not meeting the conditions imposed by the Director-General. Non-conforming product should be handled by the corrective action system.

- 7.3.2 One submitter wanted to have a right of review if the verifier is being overly picky to try to justify increasing the frequency of the verification visits. Two submitters queried what the verification frequency would be for their industry, and asked to have input to this.

Response

MAF will set a performance based verification frequency and switching rules for each industry. The frequency should be related to the risk associated with the products made. The right of review of a verifier's decision has not yet been discussed.

- 7.4 Two submitters felt that the terms "amendment" and "updates" can be confusing to some as the word "amendment" is used in the industry when talking about any sort of system amendment – not just those for risk management programmes. They also felt that there may be some problems getting people to understand which amendments need to be registered.

Response

MAF agrees but believes that this is a training issue that cannot be fixed by changing the manual.

- 7.4 Three submitters recommended that further guidelines be added on what constitutes an amendment – especially for "major" alterations to processing facilities for their industries.

Response

MAF agrees and will add more information into the manual, or into generic templates, or industry codes of practice as they are updated.

- 7.4 Three submitters queried how long a product has to be out of production before processing is deemed to have permanently ceased. Some companies may have all sorts of products on the books that they only process every couple of years

Response

MAF believes that this is the operator's call.

- 7.4 One submitter queried whether it would be necessary to amend the risk management programme if the change constitutes an improvement.

Response

Yes. This is necessary so that a true understanding of industry capability is maintained and improvements can be captured in codes of practice when relevant.

- 7.5 Two submitters felt that the second sentence of the first paragraph is not clear in the way that it refers to section 7.4. They also queried if it should be the operator’s responsibility instead of (or as well as) the verifier’s responsibility.

Response

MAF agrees and has updated the manual accordingly.

- 7.5 One submitter suggested that this should be reworded to make operator responsible for updates.

Response

MAF agrees and has updated the manual accordingly.

- 7.5 Two submitters queried the need to re-evaluate and re-register a risk management programme every three years.

Response

The Director, Animal Products has asked for this requirement but has said that this may be reviewed in the future.

SECTION 8:

- 8.3 One submitter felt that it was not clear enough that suspension may apply to only parts of a risk management programme whereas deregistration would apply to the whole programme.

Response

MAF agrees and has amended the first sentence to make it clearer.

- 8.3 and 8.4 One submitter wanted MAF to be required to give some warning that this was going to happen. They believe that if they are going to appeal the decision they should be able to operate while the review is carried out.

Response

MAF disagrees. This action would only be taken if there were serious issues with respect to human or animal health, or fitness for intended purpose of the product. It is likely that the operator would already be aware that there were problems.

SECTION 9:

- 9.3 One submitter felt that an explanation of what is meant by “intermittent basis” is needed.

Response

MAF agrees and will put an explanation in the manual.

GLOSSARY:

One submitter stated that the definition of confirmation should not refer to monitoring.

Response

MAF agrees but this is how it is currently defined in the Animal Products Act. MAF will recommend that it is amended when the next amendment is made to the Act.

GENERAL COMMENTS:

A number of general submissions were received – many of them quite detailed. These submissions will not be summarised here as they are relevant to the particular industry that submitted them. Where necessary MAF will follow-up individually with submitters on the matters raised.