Analysis of Submissions: Proposed amendments to the

Risk Management Programme Manual for Animal Product Processing

Date: 5 September 2018

MPI received 6 submissions on the proposal document(s). These submissions have been analysed in the following table into themes. As a result of the consultation process, and where appropriate based on the analysis below, amendments have been made to the document. MPI would like to thank those parties who have taken the opportunity to comment on the proposal(s).

Submission Analysis

Theme number	Submission theme	MPI response
1	Some methodology in the RMP manual is different from industry practice. Specific examples: 1. The dairy industry has adopted a probability x consequence approach to hazard analysis. 2. RMP scope is too narrow to capture customer quality management system requirements. 3. The RMP document list is not appropriate near the beginning of the document as the list is extensive and better managed as an appendix. Inclusion of date and version numbers means the document list needs to be updated every time a change is made to the document list. 4. How to justify operator-defined limits that are based on customer requirements.	The RMP manual is a guide for all animal sectors, and is one way the operator can show they are meeting the regulatory requirements. Businesses can use alternative procedures, as long as the regulatory requirements are met and the method is validated. For any sector specific guidance, refer to Operational Codes or other guidance documents. Response to the particular examples: 1. Industries are able to use alternative procedures, provided the regulatory requirements are met and the alternate procedures are validated. 2. The Animal Products Act requires businesses to document the components of a RMP. Businesses can have their own quality management systems e.g. FSSC22000. They can incorporate by reference the relevant sections required in an RMP from their quality management system, as long as they do not contradict the regulatory requirements. 3. The RMP document list is suggested to be at the start of the RMP to act as a contents list for easy reference, as long as the RMP components can be easier located by the operator and the verifier when needed. The RMP is required to have document control for the versions or dates of the listed

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		documents. 4. Customer requirement has been added as a justification for operator-defined limits.
2	Suggested changes on grammatical errors, spelling mistakes, abbreviations, formatting and flow of document.	Noted and amended. Regulatory requirements have not changed as part of the RMP manual update. Excerpts from the Animal Products Regulations and Notices have been removed from the RMP manual. Instead, references to these requirements are noted at the end of sentences that paraphrase these requirements in square brackets. This has been done to condense the RMP manual. The major changes are discussed below: • section on 'how to interpret the RMP manual' has been added to explain the difference between regulatory requirements and guidance in the RMP manual. • Table 1A in the 2009 version of the RMP manual was moved to section 4 to better reflect the tasks involved in developing the RMP, so all the information is grouped under one heading. • The components of the RMP (Figure 3A in the 2009 version, Table 2 in the Nov 2017 draft for consultation version) was updated in line with recent updates to various Codes of Practices and upcoming RMP template reviews. Corrective actions, recall procedures, document control and record keeping have been grouped under the heading 'supporting systems'. • Guidance in some RMP components (e.g. recall procedures) have been updated to better reflect other guidance documents issued by MPI.
3	Query if regulatory requirements have changed as part of the changes in the RMP manual from its previous version.	It is important to further emphasise that regulatory requirements have not changed as part of the RMP manual update. The RMP manual provides food businesses information and guidance on how to write their RMP, the requirements that must be meet are prescribed in the Animal Products Act 1999 and any relevant subordinate legislation.
4	Request for more examples (for specific animal products sectors such as dairy) to be included in the	Noted. Examples have been added where requested. However, conscious of the length of

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	RMP manual. A better example of an RMP site plan.	the manual, likely scenarios are covered. Food businesses should refer to the relevant Codes of Practice for more sector specific examples and guides. The RMP site plan in Appendix I is the minimum requirements for an RMP site plan. There are suggestions on what you can also include on the RMP site plan to make it easier for the verifier and the operator during verification visits. The RMP Operator Resource Toolkit is referenced in the RMP manual, which includes example forms and procedures.
5	It is often difficult to find the relevant information on the MPI website. The search function does not work well.	Comments have been passed onto the MPI Web Services team to action.
6	Request further explanation and clarification in the RMP manual. Specific examples include: 1. Different between requirements and guidance. 2. Intended purpose for products not intended for human and animal consumption (e.g. industrial use, experimental samples). 3. RMP templates should not be modified. To do so makes them a custom RMP. 4. Process validation for specific animal products (e.g. infant formula). 5. Revalidation when a change has been made that may affect the control of hazards. 6. Explanation on RCS templates. 7. Legibility of amendments e.g. use of twink™.	Noted and added. In some cases, the requested information was already in the draft for consultation version of the RMP manual. MPI is conscious of the length of the RMP manual, thus further clarifications were not added in some cases. However, references were made to the relevant Codes of Practice and guidance documents for specific animal product sectors for further information. For sectors where additional guidance may be useful, this has been passed on to the relevant teams. RMP manual is intended to cover the principles of validation only, the relevant codes of practice or guidance documents that have been developed (or to be developed) will contain the specific guidance for the animal product sectors. MPI has also published a guidance document: What is Validation?
7	Industry disagrees with statement "it is your choice to include export requirements…". Indications from MPI have been that export requirements should be referenced within the RMP (procedures etc), particularly for listed markets.	Guidance on the incorporating OMARs and export requirements into the RMP are included in the RMP manual.

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8	MPI often asks for more information at the time of RMP registration, often more questions than the evaluator. What is the objective of registration? If the evaluation is not adequate then the operator should be told as the evaluation process is often costly.	MPI asks for more information during the registration process to make sure that the RMP meets all relevant regulatory requirements. If MPI feels that if the information supplied does not provide enough evidence, MPI will request for more information from the business or the evaluator. MPI keeps a register of issues raised from the registration process and will notify the evaluator as required
9	The RMP manual listed a lot of competency standards that have expired or will be expiring soon. Can you provide further clarification around these standards?	The list of competency standards have been removed from the RMP manual as some of these standards have expired and many of them will be expiring soon. Also, many new competency standards have been developed since the list thus difficult to have an exhaustive list of competency standards. Further clarification has been provided on where you can obtain courses relevant to the animal product sectors. The RMP manual also provides an explanation for expired standards and skills maintenance required.