

Assessment Material

Explain development and implementation of risk management programmes in relation to the Animal Products Act 1999

Assessors must be aware of the assessor criteria and moderation requirements for this unit standard.

Evidence may be provided by the candidate in writing and/or orally. Oral evidence is preferred. Written evidence must be supported by a face-to-face or telephone interview. If part of an actual RMP is submitted as written evidence, then the candidate must obtain written permission from the operator.

For the entire unit standard, copying from the MAF RMP Manual or other literature is not acceptable evidence. While this is an open book exercise where documents may be referred to, the assessor may ask the candidate to amplify on any given answer and provide examples to demonstrate true understanding.

Elements and Performance Criteria		Assessment Notes	Evidence
1	Discuss the Animal Products Act 1999 (the Act) and other NZ legislation relevant to RMPs.		
1.1	<p>The Act is discussed in relation to the objects of the Act, the controls of the risk management system and how they interrelate.</p> <p>Range: controls include RMPs, Regulated Control Schemes, Official Assurances, duties.</p>	<p>The candidate must give an accurate description of the Objects of the Act (Section 2).</p> <p>The candidate must identify three controls of the Act and how they interrelate – RMPs, RCSs, and Official Assurance.</p> <p>The candidate must give two examples of where an RCS may be applied.</p> <p>The candidate must discuss the “duties” covered by the Act – various duties are included within the Act (in particular, Sections 16, 51, 106, 107) and are mentioned in the RMP Manual.</p> <p>Range – MAF’s responsibilities, Operator, exporters, recognised agencies, accredited persons.</p> <p>The candidate must give two examples of duties for</p>	

		each of group within the above range.	
1.2	The discussion includes reference to specific parts of the Act and its subordinate legislation that relate to RMPs.	<p>The candidate must briefly discuss all eleven parts of the principal Act and provides detailed discussion on:</p> <ul style="list-style-type: none"> • parts 2-6 of the Act and their relevance to RMPs; • purpose of transitional Act and effect on operators and RMPs; • the transition period (and what happens when it is over); • Schedule 1 (A&T Regs 2000) in that it exists and its relationship to RMPs; • Regulations for both Acts (purpose and linkage of standards with specs); • Orders (must mention Exemptions and Inclusions Order); • Notices (must mention Definition of Primary Processor Notice and RMP Notice, plus one other Notice relevant to RMP development and implementation). <p>Candidate must demonstrate good familiarity with current legislation as at the date of assessment.</p> <p>Candidate must explain who is required to have an RMP and the various legal instruments that support their answer (which must cover primary and secondary processing). Candidate does not need to give details of contents of the legal instruments.</p> <p>Candidate must explain the factors that determine when a new and an existing operator must have an</p>	

		RMP.	
1.3	The discussion outlines the way that other NZ legislation may impact on or interface with RMPs and the Act.	<p>The candidate must explain the current interface between RMPs and the APA, and</p> <ul style="list-style-type: none"> • the Meat Act 1981; • the Food Act Amendment 1996 and FSPs (cover options under APA); • relevant aspects of the Dairy Industry Act 1952 and current status of PSPs; • Agricultural Compounds and Veterinary Medicines Act 1997, and • the Medicines Act 1981. 	
1.4	The discussion outlines the goals and objectives of the food administration harmonisation project in relation to RMPs, FSPs and PSPs.	The candidate must discuss the risk management approach, seamless administration, current roles of regulators administering food legislation and the Regulatory Model.	
2	Discuss the process for developing a RMP.		
2.1	The role of resources in the development of a RMP is discussed.	<p>The candidate must discuss at least one mandatory and four optional resources (must include industry codes of practice) considering the relative use and suitability of each for RMP development.</p> <p>Where the candidate has developed a RMP, evidence of resources used can be provided.</p>	
2.2	The discussion includes the components of a RMP consistent with the <i>MAF Food Assurance Authority</i>	The candidate must discuss all components of a RMP in sufficient detail to provide evidence of clear understanding. Where possible, use a specific	

	<i>Risk Management Programme Manual.</i>	product / process / RMP to demonstrate understanding. Refer to Figure 3a from the RMP Manual (including the Dual Op Butcher component).	
2.3	The discussion includes the application of the Animal Products (Ancillary and Transitional Provisions) Regulations 2000, when developing a RMP.	In particular, reference to Regulation 11. The candidate must discuss any potential differences in RMP requirements for a new operation and one that has been in existence under another legislative regime. The candidate must be clear about what additional components need to be included / documented over and above those covered by the transitional arrangements. See RMP Manual.	
2.4	The discussion includes the application of HACCP principles within a RMP consistent with the <i>MAF Food Assurance Authority Risk Management Programme Manual.</i>	A candidate without competency against unit standard 19514, must explain how HACCP principles can be applied to “other sources”. Each candidate must explain how HACCP principles could be applied to risk factors other than hazards to human health (in the context of a RMP).	
2.5	The discussion includes details of the risk factors that must be considered when developing a RMP. Range: risk factors include hazards to human health and animal health, risks to wholesomeness, risks from false or misleading labelling.	The candidate must discuss all four risk factors with at least one example of each risk factor using animal material or animal product familiar to the candidate.	

2.6	Product outcomes in relation to animal material and animal product are discussed in relation to risk factor control and examples provided for all risk factors.	<p>The candidate must demonstrate a clear understanding of when a product outcome is required, and give at least two examples of when it is not required (including for uncontrolled risk factors).</p> <p>The candidate must demonstrate a clear understanding of what is acceptable as an animal material or animal product outcome for a RMP.</p> <p>Discuss RMP Spec 7.</p> <p>The candidate must provide eight examples (could be from more than one product):</p> <ul style="list-style-type: none"> • three for hazards to human health, including one for biological, one for chemical, one for physical; • three for hazards to animal health including one for biological, one for chemical, one for physical; and • one each for wholesomeness and truth of labelling. 	
2.7	Options for overseas market access requirements are discussed in relation to a RMP.	<p>The candidate must discuss the pros and cons of putting OMARs into an RMP.</p> <p>The candidate must provide at least one example of an OMAR that could realistically be included and one that should not.</p>	
3	Discuss validation of a RMP.		
3.1	The components of RMP validation are discussed.	The candidate must demonstrate a clear understanding of all aspects of validation. (Discuss	

	<p>Range: components include responsibility, confirmation that documentation is complete, that it meets legislative requirements, premises is ready to operate, that the RMP accurately reflects the operation, that the RMP is capable of achieving stated product outcomes, that the RMP has been implemented effectively, confirmation that the product outcomes are consistently achieved.</p>	<p>RMP spec 18).</p> <p>The candidate may provide evidence where they have carried out their own RMP validation –this may include a validation protocol, validation report, collation of data, etc.</p>	
3.2	<p>The discussion includes the evidence and resources that can be used to validate a RMP.</p> <p>Range: evidence and resources must include but are not limited to data, historical records, literature, company trials, reference books, industry codes of practice, technical/expert reports.</p>	<p>The candidate must discuss the range of evidence and resources and their relative use and suitability for RMP validation. This must include reference to industry codes of practice and situations where either codes of practice are not available or the operator chooses to use own systems.</p>	
3.3	<p>The discussion includes validation of supporting systems.</p>	<p>The candidate must provide examples of supporting systems that need to be validated and how this could be done.</p>	
3.4	<p>The discussion includes the procedures to be followed when validation of a RMP is incomplete and the responsibilities associated with those procedures.</p> <p>Range: procedures include development and documentation of validation protocol, evaluation, registration, operation/completion of</p>	<p>The candidate must provide at least one example of a situation where a RMP validation is incomplete, and describes what action should be taken.</p> <p>The candidate must explain the development of a validation protocol including the data collection procedures and proposed product disposition.</p> <p>The candidate must explain the impact of incomplete validation on evaluation and registration (including conditions). An accurate</p>	

	validation (in accordance with validation protocol and conditions), re-evaluation, change of conditions Responsibilities include operator, evaluator, MAF.	discussion is provided, covering the actions required for completion of validation.	
3.5	The discussion includes the option to compile an outline of the validated RMP in preparation for evaluation and registration.	The candidate must be clear about the components required to be included in an outline. The candidate must discuss the reasons for selecting the option of a RMP outline.	
4	Discuss the process for evaluation of a RMP.		
4.1	The discussion includes the procedures an operator would follow in preparation for evaluation. Range: selection of evaluator, availability of RMP documentation, arrangement of site visit	The candidate must demonstrate understanding that evaluators need to have technical expertise relevant to their process, or else have access to a technical expert. The candidate must demonstrate understanding as to the legal requirements for when to undergo evaluation. The candidate discusses both the desk top review process and site visits.	
4.2	The discussion includes the reporting and endorsement requirements that the operator expects from the evaluator.	The candidate must discuss the need to have: <ul style="list-style-type: none"> • the evaluator’s report; • the evaluator endorse the report; • the evaluator endorse the RMP or RMP outline. 	
5	Discuss the process for registration of a RMP.		
5.1	The discussion includes RMP status at the time of registration or re-	The candidate must briefly discuss each item in the range and how these may arise.	

	<p>registration.</p> <p>Range: RMP with or without conditions, RMP with incomplete validation, RMP following completion of validation, RMP amendment</p>		
5.2	<p>The likely scenarios associated with registration of a RMP are discussed.</p> <p>Range: scenarios must include initial registration, re-registration, registration of amendments, refusal to register, suspension and de-registration.</p>	<p>The candidate must demonstrate clear knowledge of the scenarios within the range (initial registration, re-registration, registration of amendments, refusal to register, suspension and de-registration) and the reasons for their occurrence.</p> <p>This includes:</p> <ul style="list-style-type: none"> • a clear understanding as to when amendments need to be evaluated and registered; • a description of three scenarios that may result in de-registration; • a reason for RMP suspension; • a reason for MAF refusing to register a RMP. 	
5.3	<p>The discussion details the information and documentation that must be submitted for registration of a RMP.</p>	<p>The candidate must demonstrate clear knowledge of the overall registration process and the details required for RMP registration. This includes the</p> <ul style="list-style-type: none"> • why different registration forms are available; • the documents submitted for registration; and • the fees involved. <p>The information provided takes into account a variety of registration situations:</p>	

		<ul style="list-style-type: none"> • initial registration, incomplete validation; • completion of validation; • registration of amendment; • re-registration. 	
6	Discuss the procedures involved in on-going operation of a RMP.		
6.1	The discussion includes reference to the duties of operators as required by the Act.	<p>Section 16 of APA.</p> <p>The candidate must demonstrate clear understanding of the operator duties. Note that this may have been covered adequately under 1.1, or the candidate may go into detail here rather than under 1.1.</p> <p>The candidate must be clear of the consequences if the operator is found not to have complied with these duties.</p>	
6.2	<p>The discussion includes operator verification activities.</p> <p>Range: activities must include but are not limited to internal audits, calibration checks, review of monitoring records, product tests, review of non-conformance and corrective action records, RMP review.</p>	<p>The candidate must give a detailed explanation of the range of verification activities that can be used.</p> <p>Where candidates are operators or involved with the day to day management of a RMP, specific examples can be provided.</p>	
6.3	The discussion includes external verification and verifiers' rights in relation to RMPs.	<p>The candidate must demonstrate clear understanding of external verification. Specific reference is given to:</p> <ul style="list-style-type: none"> • the legislative requirements for external verification (RMP spec 27); and 	

		<ul style="list-style-type: none"> • “verifiers rights” (RMP spec 15). <p>The candidate must explain the difference between external verification for</p> <ul style="list-style-type: none"> • RMPs; and • Overseas market access requirements. 	
6.4	The discussion includes changes that would give rise to an update or amendment of a RMP.	<p>The candidate must be clear about the difference between amendments that would require evaluation, and amendments that can be “held over” as updates until re-registration is required.</p> <p>Answer clearly relates to the effect of any changes on product outcomes (fitness for purpose), the documented scope, and changes to the content of the RMP.</p> <p>See also 5.2 – registration of amendment.</p>	