Analysis of Submissions: Proposed amendments to the:

Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product

Date: 6 December 2016

MPI received 5 submissions on the proposed document. These submissions have been analysed in the following table. As a result of the consultation process, and where appropriate based on the analysis below, amendments have been made to the Notice. MPI would like to thank those parties who have taken the opportunity to comment on the proposal.

General Comments:

Submitter Ref	Submission comment(s)	MPI Response
Sub 4	In future it would really helpful if MPI are able to highlight the exact changes between the two documents as it was quite difficult to work out what the changes were. We also do not want to miss any important new clauses.	Noted.
Sub 4	Is there a minimum quantity of product to be disposed of that triggers a notification to the RA?	No, any non-conforming product requires notification as per the Animal Products (Dairy Processing Specifications) Notice 2011 Part 2 5(2).
Sub 3	We support the more effective management of dispositions and minimisation of decision making delays through clarity and through the increased scope of recognised agency approvals	Noted.
Sub 3	As the schedule extends the scope events that the Recognised Agency may manage we support the amendments and any further extensions of the scope. Similar to our general comment we believe that this will lead to the more time efficient management of disposition product.	Noted.
Sub 1	Schedule - the change to heat treatment to include those which are not CCPs is a good change.	Noted.

Submission Analysis:

Submitter ref	Submission clause	Submission comment(s)	Submitter proposed amendment(s)	MPI response
PART 1				
Sub 3	1.1	Clause 1.1 Incorporation by reference a. The list of incorporated references does not include two documents that we consider should be included; These are: i. Guideline for managing dairy material or product potentially exposed to chemical residues – Part A: Raw milk and raw material issued July 2008, and ii. Guideline on managing dairy material or product potentially exposed to chemical residues - Part B: Dairy material and product issued March 2009 MPI has published these guidance documents for managing material or product potentially exposed to chemical residues; however in discussions with the Recognised Agency we have experienced direction from the Recognised Agency in contradiction to these.	We ask that these are formally incorporated to provide clarity to all parties that these guidelines are endorsed by MPI.	These documents are guidelines to assist in determining if the raw milk, dairy material or product is non-conforming. MPI does not believe it is necessary or appropriate to incorporate them into this Notice.
Sub 1	1.2	The Notice makes a number of reference to "ACVM Regs" which is not defined	Include a definition of ACVM Regs.	Amended. Included in clause 1.2.
Sub 3	1.2	Sub clause (1) does not include the definition of "Regulations" however sub clause (2) refers to regulations without specificity, previously it was defined to be the Animal Products (Dairy) Regulations 2005. Inclusion of the definition or specific reference to particular regulations would provide clarity.		Defined in Purpose (1) a.

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PART 2				
Sub 2	2.2 (1)	With reference to 2.2(1), please clarify if operators are no longer able to manage non conforming product that does not require exception reporting as an operator managed event where by immediate reporting to the recognised agency is not required. Rather consultation and proof of disposal is discussed during PBV audits – this would be the preferred option for such scenarios.		An operator managed event in section 9 of the previous notice relates to operator managed product disposal (PD) in clause 2.2 of this notice. The clause heading has been updated to reflect the activity.
Sub 4	2.2 (1)	All non-conforming dairy material or dairy product must be reported to the applicable recognised agency responsible for verification of the RMP by the operator of the programme without delay, except as provided for under subclause (2). The term 'without delay' is ambiguous.	We would prefer a stipulated timeframe to report non-conforming dairy product to our RA so we clearly understand our reporting obligations.	Refer to section 7 Reporting Requirements in DPC 1: Animal Products (Dairy): Approved Criteria for General Dairy Processing
Sub 4	2.2 (2)	A RMP operator may notify non-conforming liquid dairy material to the applicable recognised agency at an agreed frequency provided that the liquid dairy material is delivered directly to: a) a primary producer for the purpose of animal consumption; or b) the place of disposal. Why would the 'agreed frequency' differ across different dairy companies?	Suggest there should be one stipulated timeframe for all dairy operators for consistency purposes.	This is an RMP defined frequency as an alternative option to the reporting requirements timeframe in DPC 1.
Sub 1	2.2 (3)	This change is supported		Noted.
Sub 2	2.2 (3)	The schedule and 2.2(3) refer to the requirement to notify the next premises undertaking any further processing of the non-conforming product as to the nature of the non-conformance and any		Amended to remove general application.

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		applicable conditions. As this is a new addition to the notice, please provide an explanation as to why this has since been included. Although the product may have been deemed as non-conforming, there are situations where the recognised agency will allow for the unrestricted use (with or without further processing) of the non-conforming product. When these situations arise and RA approval has been given, in the interest of being financially competitive for proven quality product, it would be commercially unwise to inform the customer of a non compliance when the product has proven to be and has been authorized for use as fit for purpose. The prior notice stated that it was the recognised agency that approved the PD that must notify the receiving premises' recognised agency of any applicable conditions to the product disposal ruling rather than the RMP operator to customer. Insight into the transfer of responsibility would be appreciated.		
PART 3				
Sub 3	3.2 (2)	Sub clause (2) b) does not allow that, should liquid dairy material be found to be non-conforming after delivery to a manufacturing site, that it be segregated then transported to or collected by a primary producer. This scenario would still satisfy the intent of the requirement in that the material is processed by a primary producer but allows greater flexibility in the transportation options.	To allow this the clause could be amended to something similar to the following: "*the liquid dairy material is delivered directly to the primary producer, or is segregated from manufacturing infrastructure for later transportation".*	As per clause 1.2, liquid dairy material means raw milk or partially processed unpackaged dairy material in a liquid state. This definition allows for non-conformance at the manufacturing site.

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Sub 3	3.2 (3)	Sub clause (3) allows operator managed disposal to land or waste systems which was previously a recognised agency managed event. If we were to utilise this sub clause, point vi) requires notification to the recognised agency of the place and method of disposal which would require a more rigorous traceability than is currently in place for all discharge of liquid dairy material to land or waste systems regardless of if it was non-conforming product. We support the intent of this for when there is knowledge that the liquid waste is non-conforming prior to disposal, however, in the event that the non-conformance is not known prior to disposal, there are limitations on the level of detail for the reporting. The current system would only allow trace backwards to the 48 hour period that the liquid was disposed in and the total volume of land that the liquid from that period was disposed onto.		The notice applies to suspected or known non-conforming liquid dairy material. It does not apply to liquid dairy material that is disposed of for reasons other than non-conformance.
Sub 4	3.3	Recognised agency managed product disposal. The wording states 'may submit'. This implies the clause is optional but suspect its mandatory?	'May' and 'must' are used interchangeably throughout the document. Where 'may' is used we understand the clause is guidance only and where 'must' is used it is in reference to a mandatory requirement.	'May' has been used throughout the document to provide an alternative to the requirement to obtain written consent for disposal from the Director-General (DG).
Sub 1	3.3 (4)	This as an area where inconsistencies could occur. It would be beneficial to discuss this at a Verifiers workshop or have some other guidance on what MPI would expect in different situations.		Noted.

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Sub 2	3.3 (4)	With regard to the labeling requirements for product disposal applications in the manner of further processing at other premises 3.3(4), please clarify if this is required for all situations. For example, transfers between RMP's for further processing within the same company vs transfer to a customer RMP for further processing. Transfers between RMPs within the same company should have internal systems that allow for the management and traceability of the further processing requirements of non conforming product rather than adding an additional labeling requirement.		Amended. If the applicable recognised agency applies a labelling requirement to the approval of a product disposal application, the RMP operator must comply.
Sub 3	3.3 (4)	Sub clause (4) includes additional requirement of relabeling of disposal product that is intended for further processing. It is not clear how that relabeling be done, we consider that electronic control through an effective inventory management system should be sufficient to satisfy this clause. We could only support physical labelling for limited situations, i.e. where the product leaves the ownership of an RMP operator. This would exclude where the product is moved to another RMP under common ownership or a contract processing operation where ownership is not transferred to the processor. For product moving within RMPs under common ownership we would not support this where there are systems that can demonstrate clear control and prevention of		See above.

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		product destined for rework or stock food from being sold to customers.		
Sub 3	3.5 (1)	Sub clause (1) details record keeping requirements. This is a duplication of the requirements in the Animal Products (Risk Management Programme Specifications) Notice 2008 clause 20 (Requirements for records), therefore we ask that the duplication be removed.		Inclusion of record retention requirements is part of MPI's requirements and guidance process (RGP) review.
SCHEDULE – Circumstances for recognised agency managed product disposal				
Sub 1	Schedule	It is noted that there is reference to notifying of conditions prior to release in a number of sections; is this needed if it is a general notice requirement?		Amended.
Sub 1	Schedule	During review we received internal comments regarding rendering options; it is considered that this is covered under the Technical grade applications. Can you please confirm that this is the only rendering option contained?		Depending on the non-conformance, the option to render is covered under further processing and technical grade disposal options. Restrictions where rendering is not for human or animal consumption are documented in the notice, where applicable.
Sub 1	Schedule	It is noted that relabelling of product has been considered further processing (in accordance with the definition of processing), this has been used for truth of labelling failures. If this is not the intent of the Notice it would be good to have this option specifically included. Examples of where this is used maybe when product is being downgraded to stockfood, or "fortified" can be added to the labelling.		Amended clause 2.5.

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Sub 1	Schedule Foreign Matter Release to local market for animal consumption after further processing:	This requires a filtration step managed as a CCP; it is not clear if ACVM premises have CCPs. Suggest using the wording in the human consumption section.	Validated step (for examples, filters, separators or sifters) which will remove the potential foreign matter present	Amended.
Sub 1	Schedule Heat Treatment Failures Release for unrestricted use without further processing:	This section is specific to meeting the minimum time and temperature requirements from DPC3. Formerly this release required all DPC3 criteria to be met. The minimum time and temperature criteria have been previously assessed as being compliant on a different section of pipe, using different probes, or with different records, than the typical pasteurisation step. It is not clear that this would be acceptable to all markets. The current wording does not include UHT failures (as there are no minimum time and temperatures only commercially sterile outcome criteria).	Revert to current notice which requires the RA to confirm all requirements have been met for release to unrestricted markets. This allows the inclusion of UHT and also ensures that all markets would be accepting of the outcomes. Revert to current notice and include the minimum time and temperature requirements only to restricted markets.	Amended.
Sub 1	Schedule CCP Failures Release for unrestricted use after further processing	Inclusion of a new section to allow for release after further processing if all criteria have been met. Examples would be product that has not passed through a function metal detector and gets reworked (e.g. bulk products). This is not technically foreign matter contamination so	CCP failures Release for unrestricted use after further processing Further processing is carried out within New Zealand in a premises which has an RMP registered by MPI for this type of operation, and the further processing will	Amended.

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		cannot be approved under that section of the notice.	address the potential contamination addressed by the failed CCP.	
Sub 1	Schedule Foreign matter detection CCP failures	Release for local market stockfood after further processing: Inclusion of a new section, as above this is not specifically allowed for under the current notice.	Wording as per the foreign matter contamination section.	Amended.
Sub 1	Schedule Cronobacter sakazakii rework options.	It is not clear from the notice wording if the plant completing the processing is not able to use the same equipment for infant formula and contaminated product. This is because even if the further processing includes wet rework (tipping in a segregated area, including heat treatment) in the blending and packing areas the rework product will still be the same equipment where the IF would be processed. It is not evident that this is the intention. It is also not clear why there is a restriction on processing back into infant formula if this is reconstituted and pasteurised in areas physically separated from the dry processing areas. Data we have identified indicates that heat treatment conditions would not result in bacterial survival and the product should not be considered higher risk than raw milk.	Clarify the intention of the rework criteria to address the processing restrictions.	Amended.
Sub 1	Schedule B.cereus or Staph aureus failures	The notice does not include local market options after further processing through an ACVM premises.		Amended.

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		It is not clear if this is a deliberate exclusion; most product undergoes a level of further processing (blending and packing) before release.		
Sub 1	Schedule Truth of labelling failures other than infant formula products	The option provided excludes the current PD approvals which are completed after the product (each can) is labelled as stockfood. There is no option to address truth of labelling issues in infant formula (with release to stockfood applications) after the product is tipped from cans into stockfood bins. This needs to include local market options where there is no RMP (as per the exemption order).	Wording from the incorrect scoop size could be considered.	Amended to include animal consumption options.
Sub 4	Schedule Truth of labelling	Failures other than infant formula products: Why does this clause not include Infant Formula? (note other Infant Formula issues are included e.g. missing scoops).	What is then the process to deal with truth of labelling issues for Infant Formula products and subsequent rework and/or disposal? Please clarify.	PD applications for 'unrestricted use with further processing' for infant formula products labelling failures must be submitted to the DG.
Sub 1	Schedule Expired date mark	It should be clearer that this is a requirement for product exceeding a stated expiry date rather than a best before date. Product outside the best before date for stockfood manufacture is not currently considered non-conforming.		Amended refer clause 2.2 (4).
Sub 2	Schedule Expired date mark	In the 2013 notice, the schedule for circumstances for recognised agency managed product disposal did not include recognised agency management of an expired date mark. Please provide insight into this decision to include in the 2016 notice. Prior to this draft, any product with an expired date mark was managed internally as an operator managed event, allowing the operator the flexibility to manage as		Amended refer clause 2.2 (4).

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		and how the operator deem as fit for purpose. This expired date mark also makes reference to the ACVM act7 & 8, please provide context to this decision as these regulations refer to veterinary compounds rather than finished dairy product so it is not clear on whether the intent of this requirement is directed at all 'dairy product' or specifically for veterinary compounds.		
Sub 4	Schedule Expired date mark	We understand that these requirements cover the situation where non-conforming product can be sold to another RMP holder or a local business however, it does not cover the situation where we are exporting reworked product. What if we are able to determine that we can safely extend the shelf life of a product and can demonstrate we meet applicable regulations including OMARs?	Perhaps it is MPIs intention that these types of situations will need to be discussed and approved by MPI as opposed to an operator managed event with oversight from the RA? Please clarify.	Shelf-life extension applications that fall outside procedures defined under the RMP will typically need to be submitted to the DG.
Sub 5	Schedule Expired date mark	Could we include that where the manufacturer still owns the product then this is appropriately managed by them by not having to do a separate disposal application, i.e. an operator managed product disposal. However where the manufacturer no longer owns the product and has been on sold to another party that an exception is required by whoever currently holds the product under an RMP.		Amended refer 2.2 (4).
Sub 1	Schedule	Sorbic acid, antibiotics and nitrate/nitrites We would like guidance on what is an acceptable level under ACVM as we have not been able to access such information.		Due to the varied products and animal species, it is not practical to provide specific guidance.

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Sub 1	Schedule Nitrates and Nitrites	Release for consumption after further processing: The requirements include sampling and testing of the reworked product at increased frequency; not all product types have specific limits.	Add “where limits apply” to the sampling and testing requirements.	Amended.