Analysis of Submissions on MPI Discussion Paper 2014/26: Amendments to the Animal Products (Official Assurances Specifications - Dairy Products) Notice 2011

Summary

1. Consultation on the proposed amendments to the Animal Products (Official Assurances Specifications – Dairy Products) Notice 2011 commenced on 05 June 2014 and closed on 30 June 2014.

2. MPI received 7 external submissions from the dairy industry, one submission from a third party verifier and two internal submissions. One company requested an extension of the consultation timeframe to 04 July 2014 as the company's regulatory representative was away overseas. The company representative informed MPI on 04 July 2014 that the company would not be making a submission as they have seen the submissions prepared by certain other industry members and agreed with them.

3. MPI has made various amendments to the original draft notice to take into account issues raised during consultation.

4. The Animal Products (Official Assurances Specifications – Dairy Products) Notice 2011, with the exception of clause 7 of that notice, is now revoked and replaced by the Animal Products Notice: Official Assurances Specifications – Dairy Material and Dairy Products. Clause 7 of the Animal Products (Official Assurances Specifications – Dairy Products) Notice 2011 is subject to the transitional provisions of clause 4.9 of the new notice.

Response to submissions

5. All issues raised during consultation were considered by a panel of MPI experts set up for that purpose on 18 July 2014. For information in respect of the issues raised during consultation and MPI's response to those issues, refer to the table in the attached Schedule.

Amendments made to the notice due to consultation

The E-cert Help Files document is not incorporated by reference

6. MPI has decided not to incorporate the E-cert Help Files into the notice by reference at this stage due to submissions from 4 companies. If the E-cert Help Files document is to be incorporated by reference in the future, MPI will ensure that the dairy industry is given a reasonable opportunity to be heard.

7. Regardless of the non-incorporation of the E-cert Help Files by reference, guidance statements have been included in the notice to remind authorised users that they should, at all times, follow the instructions in that document . Most of the instructions in the E-cert Help Files are necessitated by the functionality of the E-cert system so a failure to follow them may likely cause submission problems.

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Transitional period for clause 7 expires on 30 April 2015

8. The transitional period for mandating the use of eligibility declarations and eligibility documents for traceability purposes has been extended from the proposed date of 31 December 2014 to 30 April 2015 after consideration of submissions received about this subject.

9. This means that operators may choose to operate under clause 7 of the current notice instead of Part 4 of the new notice until 30 April 2015. However, MPI strongly recommends that dairy exporters and operators start operating under Part 4 of the new notice as soon as practicable. Clause 4.9 of the notice sets out the relevant transitional provisions.

Inclusion of provisions relating to business continuity plan

10. MPI has incorporated into the notice a new Part 12 and a new Part 13, which relate to business continuity plan. These parts mandate the existing requirement for exporters and operators to have a business continuity plan, and set out the existing rules relating to how exporters, operators and MPI may approach dairy export certification in situations where access to E-cert is interrupted or not available.

Inclusion of provisions relating to the availability of a compliance database

11. MPI has included, under clause 3.7, new provisions relating to the availability of a compliance database, as a result of an internal submission. The provisions are adapted from clause 6.8 of the Official Assurance Programme and require the recognised agency providing official assurance service to provide official assurance verifiers with access to a compliance database. The database will be used by verifiers to record product restrictions and other information relevant to the issuing of official assurances.

Application provision of Part 4 has been clarified

12. MPI has clarified the application provision for Part 4 due to submissions received from 3 companies seeking clarification about the criteria for determining which countries are subject to full traceability.

13. The qualifying criteria remain the same, meaning that a country must require premises listing as part of its OMARs before it can be considered for Part 4. MPI will then assess the nature and sensitivity of the country and make a decision on whether or not Part 4 would apply to that country. If a decision is made to include a country under Part 4, MPI will notify exporters and operators of the decision. Exporters and operators will be given a reasonable opportunity to make appropriate adjustments to their business processes and systems.

Clarification on who may certify copies of Foreign Ingredient Certificates (FICs) as true copies of the originals

14. An additional sub clause has been added to clause 3.2 to clarify the categories of officials who may certify copies of FICs as true copies of the originals, due to submissions received from 4 companies. Sub clause 3.2(4) now provides that the following categories of officials may certify copies of FICs as true copies of the originals:

    (a) Animal Products Officers;

    (b) Biosecurity Officers;

    (c) Customs officials; and'

    (d) Official Assurance verifiers with current firsthand knowledge of the premises that first receives the imported dairy material or product.

Inclusion of new Part 11, which contains provisions about "New Zealand Standard Export Certificate"

15. For the benefit of the dairy industry, a new Part 11 has been included in the notice. Part 11 contains provisions relating to "New Zealand Standard Export Certificate". This is a unique certificate, which exporters may apply for in a situation where a dairy material or dairy product is exported or intended for export to a country for which there are no known or notified OMARs. This certificate will be issued, upon application, at MPI's discretion.

Inclusion of a definition of the term "firsthand knowledge"

16. A definition for the term "firsthand knowledge" has been added in respect of the qualification of authorised users and official assurance verifiers. This was requested in one of the submissions.

Clarification on the use of control declarations

17. Provisions relating to the use of control declarations have been clarified due to a number of submissions. The relevant provisions have been separated into two clauses. Clause 4.7 now refers to the use of control declarations where a product's country eligibility is pending or unconfirmed and clause 4.8 now refers to the use of control declarations when changes to a product's country eligibility is identified after the product has left the manufacturer.

Operators may further process dairy material and dairy product before receiving the approved EDec/ED

18. Due to a number of submissions, MPI has re-considered the proposed requirement for operators not to further process product before the approved associated EDec/ED is received. MPI has decided that due to the nature and reality of dairy processing, it is reasonable to remove this requirement as requested by a number of companies. However, companies must note that the requirement which prohibits receiving operators from despatching product from their premises before the approved associated EDec/ED is received still stands.

Failing to make the EDec/ED available within 48 hours will not result in automatic loss of eligibility

19. MPI received a submission from a company that stated that the penalty of automatic loss of eligibility where a consignor operator fails to make the associated EDec/ED available in E-cert to the consignee operator within 48 hours is excessive and disproportionate to the seriousness of the failure. MPI has now removed the penalty provision and replaced it with a new provision stating that such product will be subject to existing non-conformance process.

Requirements relating to the provision of HS Codes have been amended

20. MPI received a number of submissions against the inclusion of HS Codes in all EDecs/EDs. However, there was a significant level of support for HS Codes to be included only in final EDecs/EDs supporting export certificate requests. MPI has amended the requirements so HS Codes will only be required for final EDecs/EDs supporting export certificate requests. HS Codes will also not be printed on export certificates unless required by OMARs.

21. This means that the default "zzzzzz" value for the HS Code field will be re-instated so it can be used for all EDecs/EDs other than the final ones supporting export certificate requests.

Schedule: Table of submissions

Submission	Response
The E-cert Help Files should not be incorporated into the notice by reference. The industry has not had the opportunity to review the material and the process for introducing changes into the material is not clear.	The E-cert Help Files will not be incorporated into the notice by reference at this stage. MPI is leaving the door open for future incorporation. The process for incorporating a material by reference into specifications issued under the Animal Products Act 1999, and the process for amending an incorporated material are set out under section 168 of that Act. There is no requirement for consultation; although, there are requirements for making copies of the incorporated material available for inspection and for notifying any amendments in the Gazette. Any amendments to an incorporated material do not come into effect until the date specified by the Director-General for that purpose in the Gazette. In accordance with good regulatory practice, MPI's default position would be to engage with industry on matters that are reasonably likely to have a material effect on them.
The requirement to have the product's HS Code in all EDecs or EDs should not be made compulsory. If MPI intends to mandate the inclusion, it should consider only doing so for final EDecs or EDs supporting export certification.	Operators will only be required to input the actual HS Code on the final EDec/ED supporting an export certificate request. For all other preceding EDecs/EDs, the default zzzzzz value that use to be used will be switched back on so the relevant field is automatically populated.
HS Codes should not be included in the export certificates as this could create problems at overseas markets that use a different numbering system.	The HS Codes will only be printed on an export certificate if it is required by the importing countries' OMARs.

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The rule under Part 4, which requires the consignor to make an EDec/ED available in E-cert to the consignee within 48 hours of the product's departure is too restrictive and should be extended to 72 hours.	MPI considers the current 48 hour timeframe as appropriate. It is not a good look from a traceability perspective to have no record of the whereabouts of a product more than 48 hours after it has left a premises. It could be argued that the movement is readily traceable through the company's own inventory system; but a company's inventory system is not an alternative to or replacement of the regulator's traceability system.
The rule under Part 4, which requires the consignor to make an EDec/ED available in E-cert to the consignee within 48 hours of the product's departure, is too long and MPI should consider restricting the timeframe to real time transfer, i.e. the EDec/ED is to be raised before the product departs the consignor's premises. This is important from a product identification perspective; i.e. receiving stores should already have information about a product before it arrives so they can identify it especially if immediate load out is required.	MPI considers that the 48 hour timeframe is appropriate. There is nothing to stop contractual partners from agreeing to have real time traceability or to have EDecs and EDs raised earlier than the 48 hour timeframe.
The rule under Part 4, which requires premises operators not to further process or despatch the product before the associating EDec/ED is approved, should be removed. In most cases, material that is moved by tanker needs to be processed on receipt to ensure it does not deteriorate; in some instances the documents may not be received and approved in this timeframe, especially for EDs, which require verifier approval. It is also typical for one EDec or ED to be generated covering all movements within a calendar day; this could not occur if an approved EDec or ED is needed before manufacturing could commence.	MPI has removed the requirement that prohibits operators from further processing dairy material or dairy product before the associating EDec or ED is approved, but maintained the requirement that prohibits operators from despatching such dairy material or dairy product before the associating EDec or ED is approved as per existing requirements.
The penalty of loss of eligibility where an EDec/ED is not made available to the operator of the receiving premises within 48 hours under Part 4 is excessive and should be removed.	MPI has removed this sanction and a provision has been included, which provides that in such cases, the product will be treated as non-conforming and therefore subject to existing product non-conformance process.

There should be an exception to the traceability requirements under Part 4, which would apply where the product is transferred between premises with recognised operator export eligibility information tracking systems. The principles that apply to the recognition of an operator export eligibility information tracking system will be based on those principles applied to the E-cert tracking system.	MPI has ruled out this option at this stage but leave the door open for further discussions about this proposal in the future. MPI's lack of comfort in the proposed system is due to the perceived lack of regulatory oversight over the movement of products under this model. Even though it could be argued that the regulatory oversight issue is sufficiently addressed by the ability of MPI and the relevant verifiers to have unrestricted remote access to the system at all times, it does not address the issue that the system is ultimately owned and controlled by the regulated, not the regulator.
The transitional provision for Part 4 should be amended so dairy operators can choose to continue using Record of Market Eligibility (ROMEs) for traceability purposes until after the peak season for milk production i.e. June 2015.	MPI has decided to extend the transitional period to 30 April 2015. This timeframe is considered appropriate because- • the 6 month period post 01 September when MP E-cert will still be available to MPI's Dairy Certification Unit expires on 01 March 2015, the extension will allow a bit more time; • the training environment for the new system has been opened since November 2013 so operators have had enough opportunity to train their E-cert users; • dairy activity will be off peak at this time; and • it removes the burden of having to make extra arrangements during the holiday period.
The application clause for Part 4 should be clarified so the criteria or conditions that would trigger full traceability are clear and transparent.	This has been clarified. The qualifying criteria remain the same, meaning that a country must require premises listing as part of its OMARs before it can be considered for Part 4. MPI will then assess the nature and sensitivity of the country and make a decision on whether or not Part 4 would apply to that country. If a decision is made to include a country under Part 4, MPI will notify exporters and operators of the decision. Exporters and operators will be given a reasonable opportunity to make appropriate adjustments to their business processes and systems.
MPI should clarify who may certify copies of Foreign Ingredient Certificates as true copies of the original.	A new clause has been added, setting out the categories of officials who may certify copies of Foreign Ingredient Certificates as true copies of the original. These officials include: Animal Products Officers; Biosecurity Officers; Customs officials; and Official Assurance verifiers with current firsthand knowledge of the premises that first receives the imported dairy material or product.

Where an importer submits an original or certified copy as per the E-cert Help Files, there should be no requirement for manufacturers to submit the same document. Manufacturers should be able to reference the Foreign Ingredient Certificate (FIC)	MPI agrees. This will be added into the Help Files.
Is there a threshold for proportion of imported dairy material in order to be a foreign product? E.g. <5% would not be considered foreign. If there is such a threshold, this should be stated.	There is no threshold. It is OMAR driven.
Requirements around control declarations should be clarified and the term "control declaration" should be defined.	Provisions relating to control declarations have been clarified. The relevant provisions have been separated into two clauses. Clause 4.7 now refers to the use of control declarations where a product's country eligibility is pending or unconfirmed and clause 4.8 now refers to the use of control declarations when changes to a product's country eligibility is identified after the product has left the manufacturer.
Requirements under clause 6.3 of the Official Assurances Programme in respect of chilled airfreight, fish consignments transiting freight forwarders (12 hour rule) should be adapted into the notice for dairy products in the same situation.	MPI does not consider this proposal as appropriate at this stage. The provision under the Official Assurances Programme was meant for seafood that will start to deteriorate if it is delayed. MPI will consider this going forward.
Requirements under clause 22.1 of the Official Assurances Programme in respect of trade samples should be adapted into the notice, with necessary modifications, for dairy products.	MPI does not consider this proposal as appropriate. In the Official Assurances Programme, this relates to giving non-registered exporters the ability to export trade samples and samples for research and development on a case by case basis.
The term "process" should be defined so it is clear if it applies to all processing or is intended to be only manufacturing processes.	The term "process" is used in the notice as defined in the Act.
The term "unprocessed", which also means, "not subject to any primary processing", should be deleted. It is not clear why it is there given the fact that all dairy processing is primary processing as defined in the Act.	This term has been removed.

The following statement in respect of the duty of the operator who processes the final product to provide test reports seems to be implying that they only need to provide information to the verifier when requested by the Director-General. This should be amended to read that the operator should provide the relevant test reports to MPI, the relevant exporter, or a recognised agency verifier, or when requested by the Director-General or the authorised person.	This clause (clause 9 of the current notice) has been removed because it is no longer relevant. The subject covered by this clause is more adequately covered in other specifications.
The need for exporters to obtain eligibility documentation from the premises of final control under clause 2.2.2 needs to be reconciled with the fact that the current notice requires that for clause 6 countries, it is the premises of final manufacture that raises the EDec/ED.	Clause 2.2.2 has been amended to say that the manufacturer of the final product must raise an EDec/ED in AP E-cert when an export certificate request is submitted for that product.
In respect of clause 3.3 and 3.5, it would be beneficial to define the term "firsthand knowledge" as far as it relates to authorised users and official assurance verifiers.	A definition for the term "firsthand knowledge" has been added.
It is unclear why there is a requirement for official assurance verifiers to follow the Veterinarian Code of Conduct. It is not a requirement of the Act for official assurance verifiers to be veterinarians.	This requirement has been removed. For veterinarians, compliance with the Veterinarian Code of Conduct is inherently a part of their profession so it is binding on them regardless.
Where a product covered by Part 4 (traceability) is diverted to a premises other than it intended destination, the amended or replacement EDec/ED should be made available to the operator or verifier of the diverting premises within 48 hours of the product arriving at that premises as oppose to within 48 hour of the product departing the consignee's premises as proposed. It is a regular occurrence for transport to take more than 48 hours and a product could indeed take more than 48 hours to reach the diverting premises as well.	MPI considers that the current 48 hour timeframe is appropriate. Operators are expected to arrange the appropriate replacement/amendment as soon as they are aware that the product has been diverted so the length of the journey is therefore immaterial.

In relation to the rule under Part 4 where a product is not allowed to be further processed at or despatched from the receiving premises before the associating eligibility documentation is approved, it should be clarified in the notice that the rule does not cover liquid material that needs to be immediately processed on arrival for preservation purposes. The current provision makes reference to "other means of preservation or storage necessary to ensure that the dairy material or dairy product can be held without deterioration" but this is not clear enough.	MPI has removed the requirement that prohibits operators from further processing dairy material or dairy product before the associating EDec or ED is approved, but maintained the requirement that prohibits operators from despatching such dairy material or dairy product before the associating EDec or ED is approved as per existing requirements.
A provision should be included to require the manufacturer of a dairy material or dairy product to amend the EDec/ED where the manufacturer becomes aware of a change in the country eligibility of the material or product after sending it. This would ensure that all receiving premises and verifiers are aware of the changes in eligibility. This proposal is consistent with the Dairy Transition Guidelines section 4.3.13 which refers to making amendments if the product is identified to be non-conforming.	A new clause 4.8 has been inserted to address this issue.
Operators of consigning premises should be allowed to add or remove control declarations without verifier approval. This would remain a part of the routine onsite verification audits. If verifier approval is required, there should be clarification in terms of the circumstances that such declarations are required and the criteria for approval.	Provisions relating to control declarations under clause 4.7 have been amended and clarified to address this issue. Further operational guidelines on control declarations can be accessed in the Dairy Transition Guidelines document, which is available on the MPI food safety website.

There are multiple dairy tanker deliveries such as cream, UF permeate (lactose solutions) and UF retentates (milk proteins) that are moved between RMP operators. Under the current proposal, each load would need an EDec/ED approved prior to further processing. Each EDec/ED would need to be used as a source document for the resultant dairy materials and products. Tracing the material on the manufacturing site can be completed; however, as the dairy processes are almost exclusively continuous and milk is mixed in large silos, the list of products which may contain the milk from any singular tanker delivery can be extensive. It is proposed that the requirements could be that the RMP operator of the manufacturing premises receives the incoming EDec/ED and must know the eligibility of the material but does not need to link this as a source document on every outgoing EDec/ED. The RMP operator must still retain traceability of all dairy material and products as required under the Act and Dairy regulations. If the eligibility of any material or product was impacted, this product would need to be fully traced through the system and segregated in accordance with the relevant OMARs. This would be the same requirement that is currently in place for ROMEs.	There always has to be a source EDec/ED so the movement of product can be continuously traced through E-cert. It is important to note that an operator's inventory system is not a replacement for the regulator's E-cert system.