Animal Products Notice: Manufacture of Dairy Based Infant Formula and Formulated Supplementary Foods for Young Children
Summary of submissions - Draft for Consultation January 9th 2017

Section	Text	Comment	MPI Response
	Title	We recommend the following change: *Manufacture of Dairy Based Infant Formula **Products** and Formulated Supplementary Foods for Young Children.* This makes it clear that follow-on products are covered. Please also note our comments above recommending greater consistency between title, definitions and terminology used in the text of the notice.	Agree
		The notice title include product groups "Dairy Based Infant Formula and Formulated Supplementary Foods for Young children"; this would indicate that Follow on formula was not included. As this notice was developed alongside two now published notices1 that are include Infant Formula Products and Formulated Supplementary Foods for Young Children. Suggest that the notice title is amended to *Animal Products Notice: Manufacturing of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children*.	See above
		We submit that the title should be changed to: Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children. This amendment to the title would provide clarity that Follow-on products are also covered. It would also align with the title of the other MPI Notices which address these products.	See above

	Commencement	The commencement details on page 1 need to be aligned with commencement and transitional details specified in 1.3 (1). Commencement or in force data for existing programmes to be 1 march 2018 to allow for planned capex and implementation of updated processes. *Allow commencement date for existing programmes to be 1 March 2018.* Commencement of the notice for existing programmes has not been specified, however in the transitional provisions section it has been stated that the notice applies on 1 September 2017. Ask that the commencement for existing programmes be 12 months from publication as per previously consulted draft, dated 4 November 2016.	Commencement date has been amended See above Six months seen to be sufficient. Longer transition period has been provided for capital works.
	Purpose	We suggest that the Animal Products (Risk Management Programme Specifications) Notice 2008 is included under (2). Please see comments made below in relation to 2.11 covering personnel. 2(e) The correct title is the "Australia New Zealand Food Standards Code". We submit that the Animal Products (Risk Management Programme Specifications) Notice 2008 should be included in Purpose (2) as a relevant requirement applying to dairy processors. (1)c) Why is there a threshold of 0.5% for dairy-based ingredients? Is this percentage based on a specific regulation?	Agree Agree Agree This clause is to exclude trace dairy ingredients from the Notice. Industry have not provided any alternative to 0.5% for this purpose.
	Background	(2) Reference is made in this clause to the WHO recommendations for infant feeding. Reference should also be made to the New Zealand Ministry of Health recommendations. (4) This clause describes the coverage of the Notice and, in the last line states: "…tracing, and audit and evaluation of manufacturing processes." This clause, as occurs in several other areas that will be identified in the balance of this submission, does not recognise that there is a significant functional difference	Amended Amended

		between 'audit' and 'verification' such that verifiers perform verifications and the regulator performs audits. This distinction is fundamental to the structure of Animal Products Act 1999 and to the MPI regulatory model. The Animal Products Act 1999 refers to 'audit' only in relation to the Food Act and in relation to the regulator functions of 'compliance and audit' e.g. see section 73(2) which reads "to facilitate the compliance, audit and other functions of the Ministry as the agency with regulatory functions under this Act." **Recommend** that clause (4) be amended such that the last line reads: "… tracing, and verification ~~audit~~ and evaluation of manufacturing processes."	
1.1		Delete bracket from end of a) 1.1(2)a) There is a typo at the end of the paragraph ")" 1.1(2)d) It is noted that consideration could be given to making a distinction between ingredients added to processes prior to heat treatment, rather than applying to all ingredients at more than 0.5%. *Include "that will not be subjected to an MPI approved heat treatment step"*	Done See above This was considered. Trace dairy ingredients only are excluded from the notice, heat treatment dealt with in 2.1 and 4.7
1.2	Definitions	We request that the definitions for infant formula, follow-on formula and infant formula product are as per definitions in FSANZ 2.9.1 shown below: ***follow-on formula*** means an infant formula product that: (a) is represented as either a breast-milk substitute or replacement for infant formula; and (b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months. ***infant formula*** means an infant formula product that: (a) is represented as a breast-milk substitute for infants; and (b) satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months. ***infant formula product*** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.	Agree

		For example the infant formula definition currently stated in the standard does not include the words 'by itself' which are very important. We also request that the definition for 'Formulated Supplementary Food' is replaced by a definition of 'Formulated Supplementary Food for Young Children.' This is consistent with our comments above recommending greater consistency between title, definitions and terminology used in the text of the notice. We consider that amending text in this definition as shown below also provides improved clarity because formulated supplementary food has a different definition in FSANZ 2.9.3 than is currently stated in the draft notice: Formulated supplementary food **for young children** means food intended for children aged between 12 and 36 months, that is specifically designed as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet the child's requirements. Alternatively definitions could be included for both 'formulated Supplementary food,' and 'formulated supplementary food for young children,' as per the APN's covering, "Labelling of retail-ready dairy-based infant formula products and formulated supplementary foods for young children intended for export," and, "Export requirements for infant formula products and formulated supplementary foods for young children. " as follows: ***formulated supplementary food*** *means a food specifically designed as a supplement to a normal diet to address situations where intake of energy and nutrients may not be adequate to meet an individual's requirements.* ***formulated supplementary food for young children*** *means a formulated supplementary food for children aged between 12 months to 36 months.* Please note that while the FSANZ definition for, 'Formulated supplementary food for young children,' refers to children from 1-3 years, we consider that it is more appropriate to apply age range of 12-36 months for consistency with the definition used in the APNs referenced above. This approach is also consistent	

		with the definition of, 'young children,' in the Codex Follow-up formula standard (STAN 156-1987, amended 2011) where the upper age limit is specified as up to 3 years (36 months) in clause 2.1.3. *2.1.3 The term young children means a person from the age of more than 12 months up to the age of three years (36 months).* The definition of "infant formula" and "formulated supplementary food" are definitions that do not align well with either Codex or the Food Standards Code. The draft Notice also does not include a definition of 'infant formula product' which is the umbrella term for infant formula and follow-on formula in the Food Standards Code. In the draft Notice, the definition of infant formula includes the term 'infant formula product' which is NOT currently defined and should be. It is vital that the distinction between infant formula and follow-on formula is made in the definitions, infant formula being the **sole source of nutrition** of infants aged under 4 to 6 months. The definition of 'formulated supplementary food' in the draft Notice has blended the definitions for 'formulated supplementary food' for the general population and the definition of 'formulated supplementary food for young children' from the Food Standards Code. Confusingly, however, the more general descriptor 'formulated supplementary food' is used throughout the draft Notice when this should be 'formulated supplementary food for young children'. The only area where we do not support alignment is in relation to the description of the applicable age for formulated supplementary food for young children which should remain 12 and 36 months. **Recommend** that the definitions in the Notice, for consistency and clarity, better align with those in the Food Standards Code and include 'infant formula products' to cover follow-on product and use of the term 'formulated supplementary food for young children'. The definitions would then read:	See above

		"**infant formula** means an infant formula product represented as a breast milk substitute for infants and which satisfies, by itself, the nutritional requirements of infants under the age of ~~aged up to~~ 4 ~~to months~~ to 6 months" "**infant formula product** means a product based on milk or other edible food constituents of animal ~~milk~~ origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, ~~depending on the age of the infant."~~ "**formulated supplementary food for young children** means a food, intended for children aged between 12 and 36 months, that is specifically formulated as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet ~~the~~ a child's requirements. The definition of "dry area" would be enhanced and the draft Notice future proofed by recognising that heat treatment may not be the only microbiocidal treatment in the future. **Recommend** that the definition in the Notice for "dry area" should read: "**dry area** means any area where dry ingredients or dry relevant products a) are or may be exposed; and b) will not subsequently be subject to heat treatment or equivalent microbiocidal treatment". Align the definitions provided for "follow-on formula", "infant formula", "infant formula product" with definitions in ANZ Food Standards Code 2.9.1 Removing interpretation ambiguity *Add definitions for:* - *Product conformance* - *Wholesomeness* - *Standard of identity*	Noted. This has been considered but for clarity at this stage we are not aware of any equivalent process that would meet this threshold See above The definition of wholesomeness is in the Animal Products Act. Product conformance is covered sufficiently in the Animal Products (Dairy Processing Specifications) Notice. Standard of identity defined in Animal Products (Export Requirements – Dairy Products) Notice.

		(Batch): Will there be an allowance for batches that exceed 24 hours, as part of one continuous process? Will this be accepted after validation, in RMPs? *As per our understanding, FSANZ does not mandate a batch to be 24hrs. We understand that 24hrs batch size is a general guideline; however it may exceed if continuous homogeneous process.*	This is the standard definition of batch for New Zealand dairy production.
		(Dry Area): Heat treatment is not the only treatment that will give a bactericidal reduction. *b) will not be subsequently be subject to heat treatment or equivalent microbiocidal treatment.*	See above
		(Relevant Products): For "relevant product" c) formulated supplementary food- complete the title as per FSC 2.9.3 *c) formulated supplementary food for young children*	See above
		Formulated Supplementary Food for Young Children (FSF YC) is un-defined, however *Formulated Supplementary Food* (FSF) is. Suggest that the definition for FSFYC replace that of FSF and that this align with the Australia New Zealand Food Standards code.	See above
		Manufacturing Area – this is not aligned to the definition in the *Animal Products (Dairy Processing Specifications) Notice 2011* and therefore includes Warehousing facilities. We understood that the definition was to be amended to be clear that Warehousing was to be excluded from the definition.	Warehousing is only included if raw materials are exposed.
		For existing Infant formula plants there needs to be uniformity and consistency between various MPI documents when this Notice is issued. Concern that introducing new terminology or altering the definition of terminology commonly used in the Industry for many years could lead to a range of differing interpretations.	The terminology is necessary to be clear what is required with respect to this notice. We have modified the terms used based on feedback.

		Eg Buffer Zone, Non-hygiene area & Manufacturing areas do not line up with commonly used definitions such as Critical Hygiene and Standard hygiene areas, Level 1, 2 & 3 areas. Where does a Standard hygiene area fit into this. Is it regarded as a Manufacturing area or non-hygienic area. *Use MPI Operational Guide: Design and Construction of Dairy Premises and Equipment as a 'basis' for use of terminology and interpretation.* 1.2(1) Add "to the environment" in the definition of dry area and manufacturing area to make it clear what they are exposed to. …exposed to the environment… Expand the definition of heat treated to include UHT products Heat treated means being subject to a validated heat treatment at least equivalent to pasteurisation, or UHT for products making this claim. We submit that a definition for Formulated Supplementary Food for Young Children should be included within Section 1.2 and that this term is used within the Notice as referring to foods for young children. We make this suggestion as the term 'formulated supplementary food' has a wider definition in the FSANZ Food Standard Code than just formulated supplementary foods for young children. Suggested Amendment to the definition of Dry Area: dry area means any area where dry ingredients or dry relevant products: a) are or may be exposed; and b) will not subsequently be subject to heat treatment or equivalent micro biocidal treatment	The hygiene area terms used in the design and construction guideline don't align particularly well to infant formula manufacture or Codex. The general interpretation of "exposed" is "exposed to the processing environment". Amended to include "at least equivalent to pasteurisation" in definition of heat treatment. See above

		Formulated Supplementary Food This term should be replaced with 'Formulated Supplementary Food for Young Children' This would prevent confusion as the term Formulated Supplementary Food has a different definition in this Notice to that given in the FSANZ Joint Food Standards Code. Suggested Amendments to the definitions of Infant formula, Infant Formula Product and Follow-on formula We submit that these definitions should be exactly the same as the definitions of these terms given in the in the FSANZ Joint Food Standards Code Standard 2.9.1.	
		Definition of high hygiene, dry, wet and manufacturing areas are not completely aligned with the industry terminology and expectations. As many of these terms later define the requirements (especially in high hygiene zones), we request more clarity in regards to the exact definitions for these areas. For the definition of "manufacturing area" being any area where raw materials (packaged or unpackaged) are exposed, these needs to be clarity around what "exposed" means. Does this refer to when the raw materials are unpackaged opposed to packaged?	See above
		Dry Area: is this intended to encompass the dryers or packing areas? There are a number of processing areas that could be construed as a "dry area".	MPI considers that the dry area will typically start at packing, unless dried material is exposed post drying.
		High Hygiene Zone: - Does the definition of "high hygiene zone" include pop-tops? If so, what degree of physical separation is required between wet & dry high hygiene areas as per section 2.9 "specifications for dry areas"? - How does MPI understand companies will deal with ingredients such as liquid lecithin that may transit though non-high hygiene zones prior to pasteurisation (albeit briefly)?	Unsure what risk this poses

1.3	Transition Provisions	DGC reiterates that the date of application for existing programmes should be at least 6 months post date of issuance of notice, so the date proposed on 1 Sep 2017 is acceptable provided the date of issue for the notice does not slip beyond 1 March 2017. Clauses 1.3(1) and 1.3(2) do not work together. In essence, those holding RMPs at the date of Notice is issued (currently proposed as 1 March 2017) have a 6 month transition period (with some exemptions) meaning the Notice comes into force for existing RMP holders on 1 September 2017 as reflected in the chapeau to clause 1.3(1) and in clause 1.3(1) a) and clause 1.3(2). After the date the Notice is issued, new RMP holders must meet all the requirements irrespective of the date the RMP is registered, that is no transition period applies and clause 1.3(2) does not have any application. The confusion occurs because of the sequence of the clauses with clause 1.3(1)(b) preceding clause 1.3(2) which has no application. **Recommend** clauses 1.3(1) and 1.3(2) be redrafted along the following lines: "(1) For manufacturers whose RMP for relevant product is registered before the date on which this Notice is issued, 1 March 2017, this Notice applies on 1 September 2017. (2) For manufacturers whose RMP for relevant product is registered on or after the date this Notice is issued, 1 March 2017, this Notice applies on the date the RMP is registered." ---- (3) The exemption from application of requirements in clauses 2.3 and 2.5-2.7 which need not apply until 1 September 2020 requires a 'force majeure' clause in light of the unexpected earthquakes that have occurred in the past 3-4 years. Such an event, beyond the control of the manufacturer, could well delay works subject to an improvement plan. **Recommend** the inclusion of 'force majeure' clause in the transitional provisions contained in clause 1.3(3).	Amended Amended Such circumstances would be dealt with at the time of an event.

		Clauses 1.3.1(1) and 1.3.1(2)- confusion in interpreting these clauses and so should be split and re-worded. *(1) For manufacturers whose RMP for relevant product is registered before the date on which this Notice is issued, 1 March 2017, this Notice applies on 1 September 2017.* *(2) For manufacturers whose RMP for relevant products is registered on or after the date this Notice is issued, 1 March 2017, this Notice applies on the date the RMP is registered.* 1.3(3)b Will all premise Improvement Plans agreed by verifiers by 1 September need to be submitted to MPI or maintained between company and verifier. Are any changes to agreed plans able to be made between 1 September 2017 and 1 September 2020? *Amend Commencement date to 1 March 2018.* Sub clause (1) states that the transitional provisions only apply to RMPs registered prior to the commencement of the notice and then goes to provide sub points a) and b) which breaks the applicable RMPs to those which are registered prior to both issue and commencement dates and those which are registered between issue and commencement date. It is unclear why this distinction has been made as there appear to be no differences in the transitional provisions for either of these groups of applicable RMPs. Therefore we recommend that points a) and b) are Removed. Sub clause (2) appears to duplicate the commencement date that will be listed in the "Commencement" section on page 1 of the notice. Therefore this sub-clause should be removed.	See above See above

		There is inconsistency of transition dates both within, and between versions of, the document. As an example: Previous industry group document: 1.3 Transitional provisions (1) The requirements of this Notice apply to manufacturers as follows: a) For manufacturers who's RMP for relevant product is registered before the date on which this Notice is issued, 1 September 2017, subject to clause 1.3(2): b) For manufacturers whose RMP for relevant product is registered on or after the date this Notice is issued, or on the date the RMP is registered. Current version (MPI consultation document): 1.3 Transitional provisions (1) This clause applies to manufacturers whose RMP for premises where relevant product is manufactured is registered before the date on which this Notice comes into force. a) For manufacturers ho's RMP for relevant product is registered before the date on which this Notice is issued, 1 March 2017: b) For manufacturers whose RMP for relevant product is registered on or after the date this Notice is issued, or on the date the RMP is registered. (2) This Notice applies on 1 September 2017. We submit that within the current draft Notice; a) There is ambiguity in the wording and intent of Section 1.3 b) There is ambiguity between this section and the text on Page 1 c) There needs to be a thorough review of all transition arrangements and dates within this document to ensure a realistic and consistent time frame d) That transition arrangements should include a force majeure clause to provide contingency for earthquakes type events. With respect to the transition time period, we submit that the commencement date should be one year from the issuance of the Notice (1st March 2018), except for the provisions (Section 1.3 (3) which permit operation for a further	See above

		36 months after commencement provided it is subject to a verifier agreed premises improvement plan. If a one year commencement period was adopted for existing programmes, this would negate the need for the 30 day additional transition permitted under Section 3.9 (1) Protection from Adulteration and we suggest that this clause could be deleted in that instance.	
2	Premise, equipment and personnel	2.4(2), 2.4(3) and 2.9(1) state the requirements for physical separation between wet and dry areas unless there is a validated procedure in place to demonstrate cross contamination is managed successfully yet in conflict, clause 2.9(6) states that there must be a buffer zone (or redline) between wet and dry areas. Can MPI please confirm that a redline or buffer zone needs to be in place or can a manufacturer validate an alternative control measure? As per clause 1.3, transitional provisions, clauses 2.3,2.5, 2.6 and 2.7 can be met by 1st September 0202 if there is an agreed plan in place to achieve them. This extension however, does not apply to 2.9(6). This clause would require us to build redlines in our dryer towers by 1st September 2017 which is not likely to be possible within this timeframe. We request that if we must have redlines in this area that 2,9(6) is added to the list of clauses with the later deadline of 2020.	Amended to include 2.9.1 and 2.9.6 in the transition clause MPI in most cases would see the packing room as the first dry area assuming product is enclosed from the end of drying post fluid bed, given that drying continues throughout the fluid bed. However, a manufacturer may determine that the dry area starts at an earlier point.
2.2	Areas Identified in RMP	The boundaries of the “manufacturing area” are required to be identified. “Manufacturing area” requires definition or description in a guidance box. **Recommend** the inclusion of guidance following clause 2.2(1) on what is meant by ‘manufacturing area’.	The definition of manufacture has been amended. Guidance will be provided as necessary.
2.3	Design and Construction of Manufacturing Areas	This whole section seems to be a simplification of what is in the MPI Operational Guide. Simplification, generalisation and relying on ‘Validation’ Procedures to address issues that could have been avoided at the design and construction phase of a building is contrary to the overall aim of ‘preventing’ potential food safety hazards. *Use the relevant sections of the MPI Operational guide for building design and construction aspects. It contains more encompassing then section 2.3.*	This notice is in places more prescriptive, however where possible flexibility is being provided. The MPI guidance still applies.

		2.3(1) This clause will be difficult to apply in practice as it is subjective. It is noted that the current wording of "final product" encompasses all products covered by the notice including ingredients for canned IF products. *Clarify the wording if this is not what was intended.* 2.3(2)b) It would be beneficial to add a reference to minimising ledges *…crevices and open joints, and minimise ledges; …* 2.3(3) This should be expanded to include being coved and crevice free and resistant to mechanical wear and damage. Reference could also be made to the selection of colour. *a) be made of impervious material, which will withstand mechanical wear and damage; and* *b) be coved, crevice free and sealed and (in wet areas) sloped so that they are easily cleaned; and* *c) be free-draining or dry readily; and* *d) be of a colour to allow visual confirmation of cleanliness.* 2.3(4) Which gap that needs to be sealed should be defined. *…the gap between the wall and penetrating service must be sealed…* 2.3 There is no reference to ensuring that there is sufficient lighting to perform inspection tasks *Add requirements for lighting.* We would like to acknowledge and commend the approach taken by MPI which, in many cases, has avoided an overly prescriptive style in this section of the Notice. The alternative 'validation approach' approach which has been incorporated in many instances, achieves food safety outcomes whilst recognising differences in design and construction of manufacturing areas.	Noted Yes, this is intended Amended Amended to use a-c d more suited to guidance The additional clarification not considered necessary at this time MPI consider 2.3(6) covers inspection tasks adequately Noted

		Overall we feel this section contains standard and reasonable clauses however we would like to point out the following issues: (3)c) The cost to comply with this clause could be high and the real benefit of this is limited if it is considered a dry zone. (6) Depending on the interpretation, some of the plant items (e.g. pipework) could only be reached with significant scaffolding or cost.	This is not a new expectation
2.5	Air pressure in high hygiene areas	2.5(1) There is no minimum positive air pressure requirement. Need to specify a value otherwise it will be open to interpretation creating non-uniformity in the Industry. There is no clarification of air pressure differences between hygienic/manufacturing and non-hygienic areas. Air pressure differential of at least 10 Pa between high hygiene area and the non-high hygiene areas. For positive air pressure requirement refer to MPI Operational Guide: Design and Construction of Dairy Premises and Equipment. 2.5(2) This subclause states the air flowing into high hygiene areas must be filtered and purified. Does it mean the use of air purifier or air cleaners? More clarification required for the definition of "purified air flowing". Air purification to remove 'odours' implies air filtration beyond the use of HEPA filters. It would be beneficial to have the minimum pressures, filtration requirements and moisture contents clarified in the Notice.	Tolerances will be documented in the RMP under 2.5(4). MPI acknowledge there may be variability between operators and facility designs. 2.5 (1) protects high hygiene areas. Other critical hygiene areas are covered under other requirements Specified air pressure removed following earlier industry submissions. The required outcome is suitable air quality. This clause is intended to provide some flexibility in achieving the outcome. See above

		(1) Does the definition of High Hygiene Zone cover concentrate (i.e. post pasteurisation) from the dryer and beyond? Is the intention to cover these major plants areas under the High Hygiene Zone designation? (2) Which areas of the plant does this clause specifically apply to? We would question the need for dehumidification in the Canterbury climate or other similar non-humid regions and this clause would have the potential to cause high costs in the future without any significant benefit. Dehumidification of high hygiene zones is not generally required expect for the specific areas of the plant or in specific climates.	Current definition identifies exposed products as a determining factor. For many drying situations this will be the point of packing final product. Have inserted "as required" to make it clear that there is some flexibility in meeting the outcome.
2.7	People entering hygiene areas	This section should include the requirements to have adequate storage for clothing and footwear worn in the area and also the clothing and footwear that is being removed. 2.7(1)b) There should be a requirement to sanitise hands in addition to washing and drying. *...washed dried <u>and sanitised</u> his…or washes, dries <u>and sanitises</u> them…* We submit that changing some items of clothing (e.g. hair nets) between hygiene areas can introduce a foreign matter risk through hair. We suggest that the amendment of this section as below would enable resolution of this issue: (1) A person may enter a high hygiene area only if he or she: a) is wearing clean protective outer clothing and footwear that: i) is worn only in the high hygiene area or adjacent buffer zone unless the changing of outer clothing increases the risk of foreign matter and an alternative system has been developed by the manufacturer and approved by the manufacturers verifier' (1)Does pulling and cleaning the concentrate filters result in "product exposure" mean that the concentrate rooms would be considered a high hygiene zone? If so, this would require significant building modifications to comply, and so would at least require a transition lead time.	This can be covered in guidance if required. MPI consider 2.7(2) addresses this sufficiently. Agree. MPI consider the benefit outweigh the risk. Consider this would be done when no product is going through the plant. Is product exposed?

		(2)This could be challenging depending on the final definition of "high hygiene zone". We understand this would require clothing exchange separating the medium hygiene zones and high hygiene zones. Can MPI please confirm this?	
2.8	Things entering high hygiene areas	We recommend the following amendment to sub-clause (6). In our view, the conditions of use specified under a) to e) should apply irrespective of whether heat treatment has been applied or not: **(**6) Wood ~~that is not intended to be subject to a validated heat treatment~~ must not be used or introduced into high hygiene areas unless: 2.8(6) Delete wording "that is not intended to be subject to a validated heat treatment" *Re-word- "Wood must not be used in or introduced.."* "Things" entering high hygiene areas. The use of the word "things" is not appropriate in this type of document? *"Items" entering high hygiene areas* There are requirements for items entering high hygiene areas, but not for items leaving high hygiene areas, to cover items such as sealing of exit conveyors and which areas they can exit into or buffer zones etc. *Add a section for "Things exiting High Hygiene Areas"* 2.8(5) It should be clearer that gases include compressed air. ***Gases*** *(including steam <u>and compressed air</u>) …* 2.8(6) It is not clear what is intended by wood that could be subjected to a validated heat treatment would be. We are concerned with the practicality of validated heat treatment of wood and submit that the wording of this section should be amended as below: *(6) Wood ~~that is not intended to be subject to a validated heat treatment~~ must not be used in or introduced into high hygiene areas unless:….*	Amended Amended Amended Amended Amended Amended Amended

		(4) This clause is very broad, restrictive and is not necessarily practical to implement in all high hygiene zones under the current definition.	Noted
2.9	Specifications for dry areas	2.9.3(1)a) Define maximum relative humidity in relation to temperature for operation in the dry room. *a) 65% <u>rH</u> that then allows for a specific time temperature relation to be determined by the manufacturer.* The implications of this section is dependent on the zoning definitions. 2.9.1(1) The definition of "physical separation" is needed as this could potentially have a significant impact. 2.9.5 (1) Thus clause requires the area to be off production, which would affect downtimes significantly. We also suggests that paragraph (a) should include the words "of any wet areas" added after the word "drying".	MPI consider existing wording preferable See 2.4 for example of physical separation meaning Disagree.
2.10	Construction of CIP systems	Add in requirements regarding design. It is not clear if this section should be here or would be better captured in 3.2. *Every CIP system must be <u>designed and</u> constructed …* (1) Can MPI please clarify the intention of this statement in comparison to the existing requirements? Can MPI also please elaborate on what is meant by "cannot inter-mix"?	Included as 2.10, being a premesis design consideration. Amended for clarity. Intermix = cross contamination. Clairifies that dry cleaning CIP is included.
2.11	Personnel	This section overlaps to some degree with requirements detailed in clause 15 of the Animal Products (Risk Management Programme Specifications) Notice 2008. We recommend that it is reviewed to ensure there is full alignment of requirements. It should be clear in this Notice what additional requirements apply to manufacture of relevant product.	2.11(3) removed. Others are additional requirements.

		2.11(1) Please define "necessary qualifications and practical experience". Who would determine if a staff member had the necessary qualifications and/or practical experience and who will arbitrate in case of disagreement. "Necessary qualifications" will not "ensure…do not compromise…" *Recommend re-drafting of clause for clarity* *Or* *Refer to Clause 15 in RMP to avoid duplication and definition/ interpretation issues.* We submit that this Section of the Notice should be reviewed against the requirements of the Animal Products (Risk Management Programme Specifications) Notice 2008 ; Clause 15 to ensure alignment of requirements and to ensure that only those requirements specific to the manufacture of dairy based infant formula and formulated supplementary foods for young children are included in this Notice.	The operator has primary responsibility and verifier will confirm. This clause is as much about coverage as it is about qualifications. We see this as additional requirements. See above
2.12	Equipment	This section is far too general and vague. It should not be viewed as an alternative to the MPI Operational Guide which has been in use for many years. The 'hygienic' design and fabrication of product contact equipment is a key factor in the 'prevention' and 'lowering the risks' of product contamination. This document lacks specific details and does not highlight the importance of product contact equipment in terms of design and fabrication. It is one area that requires special attention. The last several years has seen an influx of Asian powder blending and packing equipment which does not meet the design and fabrication criteria laid out in the MPI Operational Guide: Design and Construction of Dairy Premises and Equipment. Equipment has been found to use design features similar to what would have been used many years ago in the New Zealand Food Industry. Examples are equipment containing sources of potential metal contamination, use of non-food grade materials, corrosion risks, crevices, cleanability challenges, gross welding defects etc.	This section isn't an alternative but applies mandatory measures. 2.12 (4) addresses this. This clause is intended to strike a balance between prescription and outcome focus. Further clarifications may be more appropriately placed in the operational guide for premises.

		The absence of specific references and requirements for the hygienic design and fabrication of product contact equipment in this document, together with reliance placed on 'Validation' procedures to overcome design and fabrication hazards, will lead to a lowering of the standard of equipment used in the this sector of the Dairy Industry. This is contrary to the overall intent of this document.	Unsuitable equipment should be identified at the validation/evaluation stage and not be present in an operational premesis.
		Highlight the importance of the hygienic design and fabrication of product contact related equipment. Rather than attempting to generalise and simplify which opens up to interpretation, make direct reference the MPI Operational Guide: Design and Construction of Dairy Premises and Equipment for specific details on design, fabrication and installation requirements.	Not appropriate to reference guidance from a Notice.
		2.12(2) This excludes a number of technical grade products (such as some pharmaceutical products), which whilst they are not intended for human consumption, would exceed the requirements for human consumption product and would not be a source of contamination. *Equipment used to manufacture something that is not intended for human consumption must not be used in the manufacture of relevant product <u>unless all ingredients are suitable for human consumption and the finished products meet the standards for human consumption.</u>*	Amended
		2.12(4) There should be clear that there are requirements for the external surfaces of equipment to allow for cleaning and sanitising. *All equipment (<u>including the external surfaces</u>) in the manufacturing area …* (2) We propose that if there is a requirement for dedicated Infant Formula product lines, this would create significant product constraints. Could this rule be applied with the option for shared lines within the definition? (3) This clause would have a huge impact on the production schedule and create the need to have a dedicated infant plant, as it would not be	Amended

		feasible to perform full Cleaning in Place (CIP) between every commodity and Infant Formula product run. If commodity production runs are managed to the same standard as an Infant Formula product run then that should negate any risk. We propose that a clause be added to the Notice regarding that the manufacturing conditions are the main risk factor for cleaning and sanitation, not the product type. We believe there is a good reason to run a product such as Whole Milk Powder after a wash and before the production of Infant Formula products as it helps reduce subsequent fouling. It also helps to flush out the lines in case of any post wash issues.	
3.1	Cleaning programme set out in RMP	3.1(2) There is a typo at the end of the clause "`````````` " There could be a significant burden to comply with parts of this section. That said, we agree that overall, section (3) is the correct approach to be taken.	Corrected Noted
3.2(1)		This section should reinforce the requirements of 2.10 for separation of CIP and other streams.	New (3) refer reader back to 2.10
3.4(3)		There is a typo and this section should start at "(1)" rather than "(3)"	Corrected
3.5	Environmental monitoring programme	(4) We are concerned that stipulation of 'all surfaces' under (b) is too broad as there are some areas in the plant which are best not opened for monitoring purposes. We suggest the word 'all' is deleted. (4) The environmental monitoring programme must provide for the monitoring of: a) Air quality (by using, for instance, exposure plates for relevant hygiene indicators); and b) **~~All s~~Surfaces** (by, for instance, taking swabs, dust samples and.. We submit that this clause should be amended to recognize that it is not possible to monitor all surfaces at all times. This would be consistent with the latter part of this clause. Recommend deleting the word "all"	Amended Amended though the clause itself clarified the intent
3.6	Maintenance compounds and other chemicals	In order to improve clarity we recommend inserting the word 'adversely' in (1) b) ii) as shown below:	Amended

		(1) b) ii) not going to **adversely** affect of contaminate the relevant product; and (1)b) There may be a situation where maintenance compounds or other chemicals have a neutral affect on the relevant product. To address this situation the affect needs to be qualified as an 'adverse effect'. Recommend clause 3.6(1)b) be amended to read: ii) not going to **adversely** affect or contaminate the relevant product; and Notes Maintenance Compounds Approved by MPI – Does this still recognised MAF, AQ or not for dairy approved chemicals? We submit the addition of the word 'adversely', as below, assists in the clarity of the clause's intent: *ii) not going to adversely affect or contaminate the relevant product; and*	See above If in doubt, the approved list is on the MPI website irrespective of what is on the product label. See above
3.9	Protection from intentional adulteration	3.9 (1) This clause proposes that every RMP includes a plan for the protection of relevant product from intentional adulteration within 30 days of the Notice coming into force. This timing is impractical for identification and articulation of a plan, validation and evaluation and approval by MPI within 30 days. Companies already have a range of steps in place that contribute to protecting product from intentional adulteration but collecting these together into a coherent and comprehensive plan takes time. This Notice has also been more than 2 years in development without the demands for explicit and standalone adulteration plans to be in place. Additional time to meet this requirement will also mean that all amendments required by the Notice to the RMP, including this one, might be coordinated so that the amendments can be dealt with as a package for the approval process. For all these reasons, but primarily impracticality, additional time to meet this requirement is necessary.	Amended due to change in commencement criteria

		Recommend the time within which an explicit and standalone adulteration plan be included in an RMP be extended from 30 days to 90 days of the Notice coming into force. Clause 3.9(1) would then read: "(1) Every manufacturer must ensure that, within 90 days after this Notice comes into force, the RMP includes a plan for the protection of relevant product from intentional adulteration."	See above
		3.9(1) if the commencement date is changed to 1 March 2018, this clause should be changed to indicate that the plan for protection of product from intentional adulteration would need to be changed prior to 1 March 2018.	See above
		It is noted that it would be beneficial to have guidance on the expectations of a plan for the protection of intentional adulteration.	Guidance is being drafted currently
		(1) We request further information in regards to the breadth of this requirement. Does this include more of a focus on milk movements (and intercompany milk movements)? Would this clause include the tagging and locking of milk tankers?	This will be covered separately in guidance.
3.10		2 c) States that "any test pieces used must be located at the point where they will be most difficult to locate." Wording is not clear. *Test pieces must be placed on (or in) product at the point where detection is most difficult.*	Amended
		3.10(3) There is a word missing from the sentence. *… and the frequency <u>of</u> product testing …*	Corrected

3.11	Calibration	In alignment with our general comments with regard to reporting to verifiers we recommend the following amendment: 3.11 (5) b) report the findings to the verifier **within 48 hours.**	Changed to raise an exception report
		3.11(5) b) This clause and clauses 3.12(2) and 4.2(3) all make reference to reporting to the verifier. Clause 3.11(5)(b) has no time frame, clause 3.12(2) requires reporting 'immediately' and clause 4.2(3) requires reporting 'within 48 hours'. Standardisation of the time for reporting would greatly enhance both consistency and usability of the Notice. INC supports this timeframe being 'within 48 hours'.	See above
		Recommend that reporting to verifiers on issues detected be consistently set at 'within 48 hours'. As a result, clause 3.11(5) b) would read: "b) report the findings to the verifier <u>within 48 hours</u>."	See above
3.12	Responses for failure	3.12 (2) Any failure to apply effective cleaning that results in, or may result in, relevant product being adversely affected must be reported ~~**immediately**~~ **within 48 hours** to the verifier….	amended
		3.12 (2) As noted above, consistency in the timeframe for reporting matters to the verifier is supported by INC. **Recommend** that the reporting to verifiers be set at 'within 48 hours'. As a result, clause 3.12(5) would read: "(2) … affected must be reported ~~immediately~~ to the verifier <u>within 48 hours</u>, …."	amended
		3.12(2),(3) It is unclear by what is meant by "adversely affected". For example, pathogens, excess cleaning chemicals etc. can be considered adverse, but	"Adversely affected" is used in other animal products legislation eg Dairy Processing Specification

		minor carryover of some ingredients that have no adverse effect would not be considered "adverse". *Recommend to provide a guidance box to assist manufacturers in determining if a relevant product has been "adversely affected" by a cleaning failure.*	
		3.12(4) Under an RMP, a risk assessment is conducted on non-conforming product. Only food safety/regulatory breaches are notified to RA. This is part of an RMP that has been verified by the RA. *Recommend re-wording this Clause to include (CCP) immediately after "critical measurements". This would be incorporated into an RMP (if not already these) that is verified by RA. The procedure is then clear. Definitions of non-conformity already exit in DPC1 and should be aligned with this AP Notice.*	This clause is intended to add clarity regarding product status. MPI consider that reporting of CCP failures is adequately addressed.
		(2) Requirement to report failure of effective cleaning that results in product being adversely affected must be reported immediately to the verifier. Does this mean Exception Reporting? If so, reporting is within 24 hours? Needs clarification regarding level of reporting. (4) Likewise the failure to comply with critical measurements – is this reported and then reviewed by the verifier to determine if an Exception Report is required?	Agree Expectation is that this will be reported as an exception identifying where the product is or isn't affected, and will be reviewed by the verifier. Related clauses to be amended for consistency.
4.1	Procurement of raw materials	(6) On review of this section we think that 'manufacturer' should be replaced by 'supplier' in a) and that both a) and b) should apply where the supplier is not the manufacturer of the raw material. With these changes it would read as follows: (6) If a supplier is not the manufacturer of the raw material, the manufacturer must be satisfied that **the supplier:** a) ~~**The manufacturer**~~ knows who the original manufacturer of the material is; ~~**or**~~ **and**	MPI consider the current wording appropriate.

		b) ~~**The supplier**~~ has reliable and robust systems in place to ensure raw material The supplier integrity. If it is intended that the manufacturer must know who the original manufacturer of all raw materials are we suggest re-wording to make this clear.	
		4.1(2) and 4.1(6) The first problem with these clauses is that the term 'manufacturer' has two meanings in the clause: the manufacturer of the raw material and the manufacturer of the relevant product. The Notice contains one definition of 'manufacturer' in Clause 1.2 which states that the manufacturer is the manufacturer of the relevant product.	Correct
		The second problem is that the supply chain is either broken or unnecessarily duplicated by the requirement for the manufacturer of relevant product to hold records of the manufacturer of the raw materials. Both issues can be addressed by qualifying which 'manufacturer' is being referred to in the clause. **Recommend** that 'manufacturer' of raw materials is qualified throughout the clause and responsibility for supply chain integrity is maintained by requiring suppliers of raw materials to hold the details of manufacturers of raw materials. This does not preclude manufacturers of relevant products also holding information on manufacturers of raw materials but it does not mandate manufacturers of relevant products to do so. Clauses 4.1(1) and 4.1(6) should be amended to read:	See above
		"(2) Manufacturers must review any reports from accredited laboratories, certificates of analysis, and ~~manufacturer's~~ declarations <u>from manufacturers of raw materials</u> to assess the suitability of those raw materials. (6) If a supplier is not the manufacturer of the raw material, the ~~manufacturer~~ <u>supplier</u> must be satisfied that: a) the manufacturer knows who the original manufacturer of the raw material is; ~~or~~ and	Amended This appears to tighten the requirement and may not be possible in all situations.

		b) the supplier has reliable and robust systems in place to ensure raw material integrity. “ 4.1(6)a) Re-word start of a) *“a) they can identify the original manufacturer..”* 4.1(6) If it is intended that the manufacturer must know who the original manufacturer of all raw materials are, we suggest that the following amendment to wording clarifies the responsibilities of ensuring traceability: *If a supplier is not the manufacturer of the raw material, the manufacturer of the final product must be satisfied that:* *a) ~~The manufacturer~~ They know~~s~~ who the original manufacturer of the raw material is; or* *b) The supplier of the raw material has reliable and robust systems in place to ensure raw material integrity*	Original wording is drafting preference See above
4.2	Raw material acceptance	(2) Dairy material and product intended for inclusion in relevant product must be conforming dairy material or product, or material for which consent has been obtained from the Director-General under Regulation 5 of the Regulations. Regulation 5 of the regulations (the Animal Product [Dairy] Regulations 2005) state: *(1) A risk management programme operator or any person specified in specifications for the purpose of this subclause must follow any prescribed procedures specified by the Director-General or obtain the consent in writing from the Director-General before disposing of any diary material or dairy product that is non-conforming.* *(2) For the purpose of subclause (1). Specifications may specify criteria for what is considered to be non-conforming dairy material or dairy products, and specify management requirements for non-conforming material or products.*	

		We have concerns about this clause because we are not sure how to interpret it. Our initial interpretation was that all dairy materials and product intended for inclusion in relevant product must conform to all the requirements specified in this Notice. This would effectively preclude the use of dairy material or product produced outside of New Zealand, for example lactose. This in turn would result in inability to continue manufacture of some existing products and restrict alternative sources of supply as needed to ensure continuity of end product supply. We seek clarification that it does not preclude the use of foreign dairy materials which cannot be verified against the requirements of this Notice. It is our view that a risk management approach needs to be taken when developing requirements set out for each individual raw material (including dairy-derived materials and products) which take into account factors such as whether or not ingredient will undergo further heat treatment and addition rate to finished products. An alternative interpretation of 4.2 (2) is that dairy material or products which do not conform to the specifications set internally, or acceptance criteria if out-sourced, can only be used if consent has been obtained by the Director General. If this interpretation is correct we suggest re-wording as follows to increase clarity: (2) Dairy material and product intended for inclusion in relevant product must ~~**be conforming dairy material or product**~~ **conform to the relevant specifications or acceptance criteria. If it is non-conforming it may only be used in the manufacture of relevant product if ~~for which~~** consent in writing has been obtained from the Director-General under Regulation 5 of the Regulations. Alternatively, we suggest consideration is given to deleting this sub-clause. (3) If raw material is received from a supplier in a state that, were the raw material use in the final product the product would be non-conforming,	All dairy raw material must be conforming dairy material. There is no obvious reason why imported dairy material wouldn't be conforming material. Amended for clarity This clause provides protection for the wider industry and has been applied by manufacturers on a voluntary basis in the past.

		the problem with the raw material must be reported to the verifier within 48 hours of being detected. Please refer to our general comments above regarding increasing the consistency in relation to verifier reporting. We do not see any benefit to MPI to maintain this clause as it is and recommend that it is amended as follow: 4.2(3) ~~**If raw material is received from a supplier in a state that, were the raw material used in final product, the product would be non-confirming, the problem with the raw material**~~ **Any failure to apply raw material acceptance criteria leading to use of a raw material that results in, or may result in, relevant product being non-conforming** must be reported to the verifier within 48 hours of being detected. This improves alignment with clauses 3.11 (5) and 3.12 (2). The receipt and management of lots of raw materials which do not meet acceptance criteria should be covered by non-conformance systems which can be reviewed by verifiers during verification audits. Clause 4.2(3) is not clear and difficult to follow. We understand that what is intended is that if a particular raw material was so unacceptable that its use in final product would result in that final product being non-conforming, then the unacceptability of the raw material must be reported. The supplier role is in relation to having supplied raw material that has not met acceptability criteria. The issue is not meeting acceptability criteria. Supplier details might form part of the report to the verifier. Recommend redrafting clause 4.2(3) to better reflect intent along the following lines: "(3) If raw material <u>is supplied to a manufacture that has not met acceptance criteria and if that</u> raw material <u>was to be</u> used in final product, <u>that may then result in that</u> product ~~would be~~ <u>being</u> non-conforming, the problem with the raw material, <u>together with details of the supplier of the raw material</u>, must be reported to the verifier within 48 hours of being detected."	This is not the intent of this clause. The clause as written provides a warning that raw materials are not suitable. Amended and guidance box added.

		4.2(3) If a non-compliance raw material is not used in manufacture then this should not be reported to the verifier. The manufacturer, through contracts, can deal with this type of issue direct with the supplier, without reporting to verifier, as no non-conforming product will be produced. *Delete this clause*	See above
		(3) Problems with raw materials must be reported to the verifier within 48 hrs of being detected? Is this to be on an Exception Report or is it more of a notification? How is this to be managed by the Verifier/RA?	Text to be amended as this isn't a true exception report
		4.2(3) The wording of this section would require reporting of damages that have occurred during transit (or storage). These should be excluded from reporting requirements. *If raw material is received from a supplier in a state that, were the raw material used in final product, the product would be non-conforming, the problem raw material must be reported to the verifier within 48 hours of being detected. <u>This requirement does not apply to product that has obviously been damaged through the transportation processes.</u>*	Amended
		Notification to verifier even if the non-complying ingredient has not been used in product. We submit that non-compliant ingredients become a food safety risk only if, through a failure of acceptance criteria, they are incorporated into the product and suggest the following rewording: *4.2(3) ~~If raw material is received from a supplier in a state that, were the raw material used in final product, the product would be non-confirming, the problem with the raw material~~* ***Any failure to apply raw material acceptance criteria leading to use of a raw material that results in, or may result in, relevant product being non-conforming*** *must be reported to the verifier within 48 hours of being detected.*	As above, this is not the purpose of this clause

		(3) We believe this should be a matter adequately managed by the operator in accordance with their raw material acceptance procedures. Any product deemed to be non-conforming would not be used in the production of Infant Formula products.	As above
4.3	Milk and other liquid dairy material	Please correct wording of the guidance: Process hygiene testing will typically include aerobic plate count (30 °C/~~every~~ **72 hours**) with a maximum 300,000 cfu/ml at the start of manufacture. The guidance refers to APC "(30oC every 72 hours)". It is not clear if this means that the test is every 3 days or that the sample should be incubated for 72 hours. *Clarify the use of "every"* (1) We suggest definition of heat treatment is further defined. Does this include thermalization as well as pasteurisation (4) Can MPI please be clear on the exact time period? When does the clock start- is it on farm or upon arrival at the factory? **Guidance Section:** 300,000 cfu/ml for the limit on aerobic plate count seems quite strict and we would like to understand how this limit was determined.	Corrected As above Refer to heat treatment definition. 4.3(1) addresses raw milk while 4.3(4) requires the RMP to ensure all other liquid dairy material is managed appropriately. This needs to consider all sources. 300,000 is a historic figure from the EU and is entirely appropriate given that the action limit at collection from the farm dairy is 100,000 and the national averate at the point of collection is below 10,000.
4.4	Monitoring of raw materials at the premises	We recommend that the Guidance section is re-worded to include outcomes of historical testing by the supplier as well as by the manufacturer. We propose the following wording: **Guidance** The intensity of raw material testing will vary depending on the intended intensity of final product testing, the outcome from historic testing of material from **the supplier and by** the manufacturer, hazard analysis, and the intended use of the raw material.	Amended

		Historical testing of raw materials should feature in the monitoring programme of raw materials. **Recommend** that the guidance be reworded to include reference to historic testing. The Guidance would then read: Guidance "The intensity of raw material testing will vary depending on the intended intensity of final product testing, the outcome from historic testing of material from the supplier and by the manufacturer, ~~and~~ hazard analysis, and the intended use of the raw material."	See above. Note the guidance recognizes the historic testing as a component
		MPI indicated that this would be amended from the Microbial requirements to pathogen requirements; the amendment has not been made. The clause does allow the RMP to specify a different limit for a microbe, this would allow the testing to be done over different volumes between the raw materials versus the final product, however, this could be clarified through the guidance to the clause. Suggest that the guidance is amended to include something similar to the following: *Where the final product testing requires a specified volume of product to be tested, the testing of the raw material could be over a reduced volume, provided that reduced volume is determined with consideration to the addition rate of that raw material.* (1)b) Can MPI please define "critical macro and macro nutrients". Product homogeneity also seems to already be covered by section 6: Validation.	Microbiological has been retained as not all limits are for pathogens. This is out of scope for this notice. Covered by DPC1 and Australia New Zealand Food Standards Code Amended to remove reference to macro and micro. In relation to homogeneity, section 6 refers to validation of the manufacturers' processes.

4.5	Storage and unpacking of raw materials	4.5(1)e) This clause sets out conditions for the use of raw materials and in clause 4.5(1)e) states that raw materials must be "spaced so as to permit inspection". It is not clear what 'spaced' is referring to. We note that in section 8 of the "Operational Guideline: Design and Construction of Dairy Premises and Equipment" regarding the layout of manufacturing equipment the wording is a lot clearer. To ensure verifier and regulator consistency of interpretation, either rewording or reference to the "Operational Guideline" would assist. **Recommend** the inclusion of a Guidance box following clause 4.5(1) e) that explains what "spaced so as to permit inspection" actually means in relation to raw materials stored by the manufacturer.	Amended
4.6	Ingredient Shelf-life	In alignment with our general comments on end product versus ingredient shelf-life we request that clauses (1) c and (2) are deleted. Clause 4.6(2) requires justification for the shelf life of a raw material being overridden by a longer shelf life of a final product. This is unnecessary since the processes and other impacts in the manufacture of the final product clearly affects each raw material's shelf life. The focus should be validating the shelf life of the product. **Recommend** deleting clause 4.6(2) as unnecessary. 4.6(1)c) not relevant for shelf life studies once incorporated into final product. Shelf life studies are conducted on final product. *Delete c)* 4.6(2) Retain initial comment from first feedback document- would like a valid reason why this is necessary? Ingredients usually do not have a longer expiry date than the finished good it is used in. Shelf life studies should be sufficient to justify the use of an ingredient beyond its individual shelf life.	(1) c deleted The age of ingredients is likely to have an impact on shelf life beyond that established during initial shelf life determination. See above See above. MPI has provided flexibility – on condition that this can be justified.

		Remove this clause as part 4.11 clause 2 states shelf life monitoring is sufficient reason to use an ingredient which has a shorter shelf life than a packaged final product.	
		MPI indicated that sub clause (1) c) would be removed; the amendment has not been made. This point requires individual components to have their shelf life assessed when incorporated into the relevant product. We do not understand why, when the stability of the complete product is required to have a validated shelf life, the 40 or more ingredients are also individually validated for stability once incorporated into the relevant product. The checking of individual components seems superfluous given the complete product shelf life requirements in 4.11 (2).	Previously indicated that 4.6 had been amended rather than 1 (c) specifically
		We submit that both of the following clauses should be deleted, as once the ingredient becomes part of the product it can be impacted by processes and other components of the product mix. The focus should be on the validation of the product shelf life. *(1) For each ingredient, the manufacturer must know and record: {…….}* *c) how long it remains stable once incorporated into relevant product.*	See above
		(2) If a final product has a shelf life that takes it beyond the shelf life of an ingredient (as at the time it is incorporated), the manufacturer must document the justification for the shelf life applied to the product	See above
		(2) This would be rather difficult to manage from a logistics point of view without significantly reducing the current validated shelf-life of "relevant product". Is there any allowance for significant reprocessing as part of shelf-life determination? This clause does not seem to be current industry practice for shelf-life management. Stability in the finished product is managed by validation of finished product shelf life, irrelevant of the age of the ingredients. Also in many cases, base-powder shelf-life is limited	MPI consider that additional safeguards are warranted to ensure that shelf life studies accurately reflect ongoing production methods, especially regarding age of ingredients.

		specifically to ensure compliance of the final product at the end of the final products (consumer ready) shelf-life. Can MPI please clarify the intention of this new clause and the process expected for "document justification"?	
4.9	Formulation	We recommend that clause (3) c) is amended such that information on use of internal staff versus external parties is captured. We suggest the following wording: (3)c) **in-house staff and/or external parties** who provide… 4.9(3)c) it is considered unnecessary for "in-house" staff of global companies to keep records of internal, expert advice as asked in c). This should only apply for when companies use external advice/ experts that they have contracted. *Amend to take into account where external experts/advice is contracted.* 4.9(3) We submit that the requirements of this clause should differentiate between the manufacturing company's employees and external parties (e.g. consultants). We suggest rewording of this clause as below: *c) **training and experience of formulation staff employed by the manufacturing company*** *~~c~~d) **names of external parties** who provided advice or opinion, and their qualifications, skills and experience, to the manufacturer when the manufacturer was doing the things referred to in clause 4.9(1); and* *~~d~~e) how product suitability and stability is confirmed.* (1)c) Can MPI please elaborate on what is deemed to be a "suitably qualified" person? (3)b) Can MPI please advise if this is in reference to the product specification limits and what "routine monitoring" refers to?	Existing clause covers internal or external individuals. Disagree See above Consider addressing this in guidance if necessary. Refers to the limits that test results will be compared to.
4.10	Register of formulation of final product	This section is much improved from the previous version. We recommend that the title is now amended to better align with the wording in this section as revised. We suggest:	Amended

		4.10 ~~**Register**~~ **Records** of formulations of final product. In the Animal Products Act 1999, the term 'register' generally refers to publicly accessible registers: registers of RMPs, register of exporters, registers of recognised agencies and persons, registers of users of the Joint Border Management System and registers of secondary processors. Clause 4.10 is not referring to a public register and does not use the term 'register' in the body of the clause. The distinction between 'register' and 'records' is vital to avoid confusion and any expectation that records of formulations are not public. In relation to the title of Clause 4.10, we are of the view that, as stated in clause 4.10(2), the required information can be held in multiple locations (systems/places) provided that the manufacturer can collate the information on request, that is, there is no requirement to maintain such information in the form of a single repository or register. **Recommend** the term 'register' in the title of clause 4.10 'records'. The title of clause 4.10 would then read: **Clause 4.10 ~~Register~~ <u>Records</u> of formulations of final product** Products are not required to be "registered". The title could be seen as confusing. *Amend title to read "Records of formulations of final product"* *We submit that the title of this section should be amended to:* *~~Register~~* ***Records*** *of formulations of final product.* *Such an amendment would better reflect the content of the section.*	See above See above See above
4.11	Shelf life of final product	We recommend that clause (3) c) is deleted. We consider that verifier approval should not be necessary for shelf-life extensions for retail-ready infant formula given the requirements stipulated for shelf-life and shelf-life extension detailed within the other sub-clauses under 4.11.	Amended and guidance box added.

		It is not clear under which circumstances a verifier would approve extending shelf life for retail ready infant formulas. These products would already have this date printed onto the packaging. (2)a)&b) These two clauses need to reference a study conducted by the manufacture of the product as well as the manufacturer of the ingredients (as both parties can conduct such studies). (3) Can MPI please clarify what the definition of "final product" includes? We assume that this refers to a product for sale in the consumer ready form i.e. a can of Infant Formula or a finished bag of base powder (as opposed to a product for internal use). Please advise.	MPI considers that the current wording covers this See definition of final product. This refers to product in the form that it will leave the premises.
5.2	Wet processing	(1)Clarification is needed regarding the filtration on systems such as the vitamin tanks. Although these are not technically defined as the main "filter controlling pasteurisation particle size", they are managed very similarly to a Critical Control Point (CCP).	If the intent of the filter is to ensure correct particle sizes immediately prior to pasteurisation, then the filters are expected to form part of the CCP.
5.5		5.5(3)c) Does the Clause provide scope for an alternative method to be used that has been validated against the MPI specified test method and is either included in the local laboratory ISO 17025 scope or is conducted by an overseas laboratory, even where there is a laboratory available in NZ? Some international companies have testing systems that have products tested in overseas laboratories even though there are labs available In NZ. *Expand Clause to allow use of validate alternative methods to be used and use overseas labs even where there is a NZ lab available.* We suggest rewording of 5.5(1) as below to assist in clarity of text: 5.5 (1) Analysis of dairy material, dairy product, and environmental samples for any of the following purposes~~; must be undertaken in a laboratory in accordance with this clause:~~ a) food safety: b) product conformance: c) wholesomeness: d) standard of identity:	The principal is that where MPI has specified a method or methods, these must be used. A laboratory can request for a method to be added to the MPI CLT. Drafting preference

		e) RMP compliance, including with the environmental monitoring programme. **must be undertaken in a laboratory in accordance with this clause**	
5.6		It is not clear if the purpose of this clause is to require the manufacturers to take additional retentions to be available in addition to their own retention samples. For instance, would they need approval form the verifier to release these retentions for any testing?	Yes
5.7	Non-conforming batches	As stated under our general comments: this section specifies what is meant by non-conforming batches, but no requirements or guidance on their management and reporting is included in the notice other than where sub-clauses 3.11 (5), 3.12 (2) and/or 4.2 (3) apply. The range of non-conformances detailed in 5.7 is very broad. We recommend that this section is reviewed and amended to include details on management and reporting which differentiate urgent/critical non-conformances that must be reported to the verifier within 48 hours from other non-conformances that should be managed by appropriate internal management systems which record findings and actions which can be reviewed by verifiers during verification audits. 5.7(1)c) Typo- “retail-reading” should read “retail-ready” 5.7(1)c)i) Previous comments not addressed, although comments note issued by MPI from November 2016 consultation says it has been amended. c)i) it is an expectation to report whenever a leak check/seamer issue is found? c)iv) What is the quantitative level or definition of “unacceptable foreign matter” and “objectionable material” d) what is the definition of “not permitted”- is it not permitted as per the Food Standards Code?	This notice is additional to the Animal Products (Dairy Processing Specifications) Notice, which sets out the requirements for non-conforming dairy material and product. Corrected Apologies. MPI was still considering alternative at the time the draft was released for consultation. Now amended. See above Defined by operator in RMP. Refer to DPC1 Dairy Product Safety, and Animal Products (Dairy Processing Specifications) Notice, for definition of foreign matter. Not permitted according to the requirements that apply to the product.

		Lack of alignment with DPC1 definition "any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements." The overall risk for businesses is more reporting to MPI, product release delay or write-off due to extra requirements that are not related to food safety or regulatory breaches. *Require explanation of c)i), c)iv), d) for clarity* (c) States "retail-reading" Amend to "retail-ready" The requirements for non-conforming product only specifically relate to food safety foreign matter in relation to retail ready products. This is inconsistent with standard reporting expectations. This section reads as if there is one can at fault within a "batch"; this would deem the entire batch to be non-conforming. This is a critical area, which needs further review from a manufacturing perspective. Also how does this impact cut-off testing- would this be permitted? These clauses could result in a large amount of wasted product, which is disposed of unnecessarily.	See above. Amended to clarify these are additional measures. 5.7 is related to food safety and/or regulatory conformance. These examples have been provided for clarity Amended Yes, interpretation is correct. MPI already has guidelines for sub-lotting.
5.8	Packaging for retail-ready product	5.8(2)d) This provision reads "not easily break or tear under expected handing conditions". **Recommend** clause 5.8(2) d) read: "d) not easily break or tear under expected <u>handling</u> conditions". 5.8(4) The last phrase of this clause reads "if it is incorporated while is a non-high hygiene area". **Recommend** the last phrase of clause 5.8(4) read: "if it is incorporated while in a non-high hygiene area".	Corrected Corrected
5.13 & 5.15		5.13(5) and 5.15(3) As discussed at the outset, there is a significant functional difference between 'audit' and 'verification' such that verifiers perform	Will be amending to refer to on-site verification noting that verification functions extend beyond on-site "audit".

		verifications and the regulator performs audits. This distinction is fundamental to the structure of Animal Products Act 1999 and to the MPI regulatory model. The term 'verification audit' totally confuses functions and roles and must be corrected. Similarly, there must be a very clear distinction between reporting to the regulator (the auditor) and the verifier. Only in extreme food safety situations would an issue be reported to the regulator/auditor and this would likely only occur when the verifier also received a report. **Recommend** deletion of 'audit' when used in conjunction with 'verification'. Clause 5.13(5) c) would read: "c) inform the verifier at the next verification ~~audit~~ of the actual time the tracing exercise took." **Recommend** that internal investigations by manufacturers that identifies compliance failures within the manufacture's area of responsibility be reported to the verifier. Clause 5.15(3) would then read: "(3) If an investigation identifies a failure by the manufacturer to comply with the RMP or any regulatory requirements, the failure must be notified to the verifier ~~or auditor~~ in an exception report.	Corrected
5.15	Complaints to manufacturer	We suggest that the wording of sub-clause (3) is amended to delete 'and auditor', so that it reads as follows: (3) If an investigation identifies a failure by the manufacturer to comply with the RMP or any regulatory requirements, the failure must be notified to the verifier ~~**or auditor**~~ in an exception report. This is consistent with other text dealing with notifications to the verifier. 5.15(3) It is unclear why there is a reference to the Auditor for supplying exception reports as an alternative to the Verifier.	Corrected (see above) See above
6.2	Validation to be undertaken	We request the following change to sub-clause (g): (g) the shelf-life of ingredients before ~~**and after**~~ incorporation into relevant product **and the shelf-life of the finished product.**	Amended

		As per our introductory general comments, we request that all references to raw material shelf-life post use in manufacture of products are deleted and replaced with references to product shelf-life.	Amended
		6.2(2)g) As noted previously in relation to clause 4.6(2), the validation of the shelf life of the final product should be the focus and would address on over-riding of the shelf life of a raw material used in the final product. **Recommend** clause 6.2(2) g) be amended to remove reference to "g) the shelf life of ingredients before ~~and after~~ incorporation into relevant product".	See above
		6.2(2)g) Delete some words for clarity, the words "and after " are not relevant.	See above
		g) the shelf life of ingredients before incorporation into relevant product. As a consequential amendment from our earlier comment regarding Section 4.6, we submit that all references to raw material shelf-life post use in manufacture of products should be deleted and replaced with references to product shelf-life. Suggested rewording is: *the shelf-life of ingredients before ~~and after~~ incorporation into relevant product* ***and the shelf-life of the finished product.***	See above
		(2)g) We would like to understand if there could be an exception around wet reprocessing and incorporation in comparison to dry blending (i.e. significant reprocessing). (2)h) Can MPI please elaborate on what "packing processes" encompass? Would simple systems such as the tuner be included?	"packing" is defined, and validation of the packing process includes consideration of packaging, packing equipment and the atmosphere within the final packaged product.

6.3		(1) "whether the thing achieves the intended outcomes" Use of the word "thing" not appropriate 2b) "the outcomes intended to be achieved by that thing" 2c) "how the manufacturer intends to validate whether the thing achieves the required outcomes;" *(1) "whether the intended outcomes are achieved"* *(2b) "the outcomes intended to be achieved; and"* *(2c) "how the manufacturer intends to validates whether the required outcomes are met; "* 6.3(2) The validation protocol should also include details of what is going to happen to any product produced as part of the validation protocol. *e) the disposition of product manufactured during the validation activities.*	This is the preferred drafting Amended
6.4		(1c) "the outcomes required from the thing that was validated" **Proposed Amendment** "the outcomes required from the item validated" or "the outcomes required from the validation process"	See above
7.1		7.1(2) Assessment of the Premises and equipment needs to be carried out by a technical expert. An RMP Verifier needs to ensure that this is carried out by an MPI recognised Premises Evaluator. *Ensure that a formal Premises Evaluation is carried out by a Recognised Agency.* It is not clear the extent of technical expertise that needs to be available to verifiers and how this can be identified if it relates to an area where limited expertise exists. Can this be by reference to MPI?	Deleted

7.2,7.3,7.4		As discussed at the outset, and again in relation to clauses 5.13(5) c) and 5.15(3), there is a significant functional difference between 'audit' and 'verification' such that verifiers perform verifications and the regulator performs audits. This distinction is fundamental to the structure of Animal Products Act 1999 and to the MPI regulatory model. The term 'verification audit' totally confuses functions and roles and must be corrected. **Recommend** that the terms 'verification audit', 'verification audits' and 'audit' be deleted from the titles and body of clauses 7.2, 7.3 and 7.4, including deletion from the guidance note, and replaced with 'verification' or 'verifications' as the case may be, to maintain consistency with the structure of the Animal Products Act 1999 and remove confusion in relation verifier and regulator roles and functions. The clauses would then read as follows: **"7.2 Unannounced <u>verifications</u> ~~verification audits~~** (1) Premises that manufacture infant formula products must receive at least one unannounced <u>verification</u> ~~verification audit~~ each dairy season. (2) Notice may be given to the manufacturer not more than 24 hours before an unannounced <u>verification</u> ~~verification audit~~, in order to ensure access to the premises and that key personnel can be present. (3) An unannounced <u>verification</u> ~~verification audit~~ may be inspection based if key personnel are not available. **7.3 Increased verification ~~verification audit~~ intensity** (1) This clause applies if, during a verification ~~an audit~~: a) Required information proves difficult to obtain; or…. (2) If this clause applies, verifiers must: a) Extend the onsite <u>verification</u> ~~audit~~; or…..	Refer to comments on 5.13 and 5.15

		Guidance Manufacturers should expect more intense verification ~~verification audit~~ scrutiny than other dairy processors. This is best achieved by more intense verifications ~~verification audits~~ rather than more frequent verifications ~~verification audits.~~ During verifications ~~verification audits~~, information is expected to be made available immediately or, for archived information, within 2 working days. **7.4 Verification ~~Verification audit~~ frequency** (1) This clause applies to any manufacturer who is not covered by the Animal Products Notice: Export Verification Requirements, and is for the purpose of ensuring that those manufacturers are subject to the same frequency of verification ~~verification audit~~ as manufacturers who are covered by that Notice.	
7.4		What is an example of premises that is not compliant to the Export Verification Requirements? Is this an infant plant supplying local market only?	The Animal Products (Export Verification Requirements) Notice only covers exporters exporting with an official assurance