## Summary of submissions – Proposed Labelling Requirements for Export Infant Formula, Follow-on Formula, and Formulated Supplementary Foods for Young Children (MPI Discussion Paper No: 2014/31)

Submitter Comment	MPI Response
Overall Comments	
Generally supportive of the objectives and agrees with intent, with caveats:  New Zealand infant formula exporters should not be placed at a commercial disadvantage Improvement to NZ origin claims are needed as they are too prescriptive Further consideration of health claims and express permissions are needed Labelling requirements are already appropriately controlled by importing countries and these should be the prevailing requirements.	Noted. MPI considers specific minimum requirements are justified, as per the reasons outlined in the discussion document. The Notice specifies that if the Notice and importing country requirements are in conflict, then the importing country requirements, as expressly detailed in their laws, take precedence. 'Absence' of a specific requirement is not considered a conflict. If there are no requirements in place in an importing country, or the importing country is silent on matters, then the Notice applies.
<ul> <li>Important to be mindful of the International Code of Marketing of Breastmilk Substitutes</li> <li>Document is biased towards industry and there are no considerations about the health risks of undermining breastfeeding</li> </ul>	The proposals have been developed with reference to NZ's WHO Code obligations.
<ul> <li>Important we do not allow the interests of NZ's most important export industry to impact on the long-term health of children and adults in other countries; nor should we allow a lower standard than what is acceptable in NZ. NZ has a particular responsibility not to undermine the health of people in developing countries.</li> <li>Recommend that the Ministry notes the potential for the</li> </ul>	Imposing minimum labelling requirements, including criteria around health, nutrition and origin claims, is a clear indication that MPI considers that stronger food safety monitoring and oversight is appropriate for these products and for the protection of overseas consumers.
development and marketing of nutritional dairy products for mothers rather than vulnerable babies and children.	MPI notes that many companies have developed powders for mothers. Ultimately this is a commercial decision for companies to make.
1. Do you agree with problem definition?	
Generally agrees and considers that clarity will be helpful to	Noted. The aim of the proposals is to help consumers identify authentic NZ products, and ensure

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new players in the industry, as well as for protecting the reputation of foods manufactured in NZ by ensuring no false or misleading claims are made. NZ Government should have appropriate regulatory oversight of nutrition and health claims, but claims must be able to conform to the regulations that apply in the importing country.	claims made on these products do not damage New Zealand's reputation.
<ul> <li>Variation in labelling may have been overstated when you consider the full range of countries NZ exports to, and it is not clear that variation in labelling actually impacts on perceptions of the standard of these products</li> </ul>	MPI considers that the lack of minimum standards and clear guidelines for industry and verifiers is contributing to variation and labelling non-compliance.
Needs to be recognised that different markets take different approaches to the classification and regulation of products	MPI considers suitability statements for both categories are required as there is potential for consumer confusion between product types.
designed for 12-36 months. Some markets follow Codex and so they fall under follow-on requirements (6-36 months); other markets the 12-36 month age range are categorised as general purpose foods.	The importing country requirements take precedence. If product for 12-36 months is regulated as a follow-on product in the market (i.e. 6-36 months, and is suitable from six months) then the statement will most probably be required. The Notice has no requirement for a statement regarding the importance of breastfeeding for the 12-36 month category, so if a country categorises these products differently from follow-on, then the warning statement would not be required.
MPI should be demanding official confirmation that labels are approved by relevant authorities in the importing country, prior to generating an Export Certificate.	Evidence of product label acceptance is already the case for all retail ready exports to China (OMAR 13/14), but MPI does not consider it appropriate to ask for official confirmation that labels are approved for all markets, but if an exporter was to obtain this, it could be used as evidence for verification purposes that the label meets importing country requirements. However please note label acceptance by an importing country would not be sufficient to comply with the Notice in full.
The number of brands exported from NZ is in considerable decline and will inevitably have a consolidation effect on the label claims even without this Notice.	The impact of the new China regulations has seen a reduction in the number of brands being sent from NZ to that market. It does not necessarily mean it will lead to improvement labelling compliance for exports to all markets.
2. Proposed introduction of minimum labelling requirements	
Generally supportive of proposed introduction of minimum labelling requirements, as a way to ensure integrity of NZ exports, if they are genuinely minimum standards. Supports retention of the generic exemption for labelling for all dairy	Noted.

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products.	
Recommends consideration is given to provide more guidance and less prescription for the 12-36 month category, given the greater variety of regulatory approaches in place internationally.	Noted, this is essentially the approach of the proposal. The requirements listed for this age group (in 2.5 (1)) are all basic requirements and are likely to be expected by all markets. The only prohibition is to restate the existing prohibition on using any emblem or logo of a NZ Government agency used without permission. Health and nutrition claims are allowed as long as they fulfil the criteria (i.e. are accepted by the market).
With the issuing of this standard, there will be more rigorous requirements for exported products than for domestic, which may set a double standard and create inequity between exported and domestic products.	MPI is currently undertaking a survey of Nutrition Content Claims and Health Claims made on infant formula products on the domestic market. This work is being undertaken to determine the current use of and range of claims on these products in the market. This information will be used create a guide for infant formula product producers selling product in New Zealand and Australia. The need to develop this guide has been based on feedback from the industry on several parts of the Food Standards Code they believe to be unclear. The information will also be shared with FSANZ for its upcoming review of Standard 2.9.1 of the Australia New Zealand Food Standards Code.  Once the guide is published, active compliance action would be progress with those producers and importers that are not following the legislative requirements.
Proposed mandatory requirements are based on the Codex, the Food Standards Code and the WHO Code of Marketing. NZ expression of the WHO Code is contained in the INC Code of Practice; surprised this is not referenced. However this has been in operation for several years without needing a legislative base.	The labelling requirements in the Food Standards Code are the means by which New Zealand incorporates the labelling expectations set out in the WHO Code into domestic legislation. The INC Code of Practice is a domestic/New Zealand focused code. The Notice focuses on exports only.
Neither the WHO Code nor the INC Code of Practice apply to follow-on formula; both are specifically applicable to infant formula for infants from 0-6 months where the formula is the sole source of nutrition and the most suitable substitute for infant formula.	It is noted that countries interpret the WHO Code differently – e.g. in Australia, the WHO Code applies to products for infants aged up to 12 months. This Notice (and discussion document) references the WHO Code as it is an international agreement to help ensure the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution. New Zealand, as a signatory, is also expected to incorporate the requirements of the WHO Code into legislation as appropriate (e.g. labelling).
Packaging requirements do not need to mention the premises registration	The Notice requires lot identification and the ULI. Date marking may be used for lot identification purposes unless other requirements apply in an importing country. This can be on the label artwork or elsewhere visible on packaging. The infant formula manufacturing standard currently under development by MPI will also require the batch ID and ULI of the manufacturer for all retail-ready packages.

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•	Do not believe the requirements should match the FSANZ standards which have complete prohibition on Health Claims (1.2.7) clause 3, and complete prohibition in advertising or other media (1.1.1 clause 13). Believe the standard should be around the minimum requirement, including warning and advisory statements.	The health/nutrition claims permissions in the Notice are based on Codex standards (which holds that "national standards apply" in this area). The permissions proposed in this Notice are different to what is allowed for under FSANZ Standards in recognition of different importing country requirements.  Advertising is outside the scope of this Notice. MPI is not able to regulate advertising in other countries. However, the guidance document will remind exporters that they need to comply with any advertising requirements of the importing country, and should be mindful of their ethical obligations under the WHO Code to not promote formula as an equivalent or better alternative to breastmilk.
•	Minimum age statement should not be allowed on any complementary foods used in New Zealand or for export. A replacement for this should be one that alerts parents to the risks of introduction of complementary foods before six months of age.	The phrase 'should not be used for infants aged under six months, and infants over the age of six months should be offered foods in addition to formula' is used. This is in line with Codex requirements.  Wording on foods for infants (as regulated under Standard 2.9.2 of the Food Standards Code) is outside the scope of this Notice.
•	Follow-on should be considered under the same Code restrictions as Stage One milks.	Noted. The approach of this Notice is aligned with Codex provisions, which distinguish follow-up formula from infant formula.
•	Ideally there would be no follow-on or toddler formula, or further use of the 'stages' strategy e.g. for 3-5 years.	The wider issue of the availability of stages for 3-5 years is outside the scope of this Notice.
	If you do not agree, are there other ways to achieve the jectives?	
•	Export labels are more appropriately controlled by the importing country, and assume that evidence of compliance with the importing country requirements will be sufficient to satisfy this Notice.	Evidence of compliance with importing country requirements can be used for verification purposes, but it will not be sufficient to comply with the Notice in full.
•	Requirements need to be supplemented with guidance material	A guidance document will also be issued for industry and verifiers.
4.	Comments on proposed mandatory requirements	
•	Generally agree with proposed mandatory requirements, but there could be situations where importing country	The Notice states that where the requirements of the Notice and the importing country are in conflict, then the importing country requirements prevail.

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	requirements may preclude requirements being met.	
•	Unclear if 'supplier' listed in point j) name and business address of supplier is intended to be as defined by 'supplier' in the definition section	If a term is used in the Notice and defined in the Interpretation, then the meaning in the definition should be taken to apply to use of the term throughout the Notice.
•	Interpretation of supplier will be variable and should be consistent with that of importing country	The Notice provides flexibility in this respect. Supplier is intended to be as defined in the definitions section: 'means the packer, manufacturer, vendor or importer'. The definition in the Notice allows the use of more than one party, and the guidance document notes that it should be the business or entity that can be contacted by the regulator for recall and product tracing purposes.
•	'Net weight of product' should be amended to 'net contents of product' to allow for declarations by weight or volume.	Agree, and it has been amended in the Notice, but noting that the required metric is the one 'required by importing country'.
•	Disagree with the requirement to have the supplier address. A consumer needs a method to contact the brand (web or phone), not necessarily the supplier address.	The physical location of an entity with responsibility for a product in market is a basic traceability and recall provision. The Notice intends to put in place the minimum requirement necessary, which is deemed to be the supplier address. An importing country may require more, or a company could put on the website address and contact numbers as a point of difference for its consumers.
•	Disagree that the "label" needs to contain the lot number. This should be clarified that somewhere on the outer packaging of the smallest unit the lot number is attached or printed.	The guidance document clarifies that a lot number can be on the bottom of a tin (as well as the ULI), and does not need to be on the face of the label.
•	A prescribed format for nutrition information labelling for each territory would reduce the risk of non-compliance.	The approach in the Notice is to specify what information must be included, but to not prescribe the formatting. Prescribing format would create difficulties for exporters where different markets require different formats. It is up to the exporter to determine the format for nutrition labelling for the market.
•	Where Goat Milk formula includes any cow's milk ingredient, it should be declared. Otherwise the label can be misleading and imply a 100% goat milk product.	This will be addressed in the guidance document – manufacturers will be reminded to avoid false or misleading statements, e.g.to imply or state a '100% goat milk product' when bovine lactose has been used would be misleading.
•	[non-industry] Supports the proposed labelling requirements and the permissions needed for claims and country of origin	Noted.

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•	'Breast is best' statement serves no purpose in its current form. A statement that recognised the risks of not breastfeeding should be required.	The term 'breast is best' is not mandated, but a statement 'breast milk is the best food for your baby' under the heading 'Important Notice' or equivalent, is line with Codex and the WHO Code.
•	Amend 2.3 (1) I) 'Important Notice' to require the statement 'Breast is best' to be on the front of the product and require a statement to the effect should only be used on the advice of a health professional.	The statement 'breast milk is best for babies' must appear somewhere on the label under the heading 'Important Notice' or equivalent. International standards and most importing countries do not mandate this statement to appear on the front of the label. The Notice imposes a requirement to have a statement that the product should only be used on the advice of an independent health worker.
•	Tins of powdered formula need to be labelled with 'this is not a sterile product'. As there is Chinese concern about the safety of NZ products being exported to China, it would seem wise to reconsider the preparation instructions given.	A statement 'this is not a sterile product' is not required under Codex or FSANZ standards. The Notice imposes a requirement for a statement on safe preparation and storage once made up, as well as instructions for use. If such a statement is required by an importing country (e.g. China), then the statement should be included on the label.
•	Formula for age range 0-6 months should be labelled as 'breast milk substitute' and not as infant formula. This will give more effect to the WHO recommendations on infant feeding.	Infant formula is the usual name used internationally for products 0-6 months. Consideration of renaming it 'breast milk substitute' is outside the scope of this consultation.
•	Amend 2.3(1) to 'the product may be used from birth to six months'.	Amending the suitability statement to add 'to six months' would not align with Codex or the Food Standards Code. Infant formula formulated for use from birth can be used for babies older than six months.
5.	Comments on proposed prohibitions	
•	Statement concerning idealisation of infant formula should have 'in relation to breastfeeding' added.	Codex and the WHO Code do not require such a statement. The Notice is made with reference to international standards, and so will not include the additional text suggested.
•	Supports the principle of prohibiting health claims on 0-6 months, unless expressly permitted, but requirement for 'express permission as detailed in importing country laws' is too narrow in practice, as importing country requirements are notified in a variety of ways in addition to laws, e.g.	The Notice will be amended to state: 'in the importing country or market/s laws or executive directives'. In MPI's view 'official documents' is too wide. The intent of the provision is to capture positive laws and regulations (e.g. standards), rather than administrative decisions (e.g. product registration).

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documents or directives issued by the Competent Authority. Recommends the statement 'or other official documents' is added.	
Some countries may allow for certain health claims, without 'express' permission. If NZ only allows for express permissions, then NZ exporters will be at a disadvantage.	MPI considers that prohibiting health claims on products for infants aged 0-6 months (unless 'expressly permitted') strikes the right balance between allowing for innovation while ensuring that New Zealand's obligations under the World Health Organization Code of Marketing are considered. Exporters will be able to make health claims on infant formula if permitted by the importing country in that country's standards.
Propose: "this notice prohibits health claims on infant products for infants intended for infants aged 0-6 months unless the claim is made on other products in the market of the importing country, and the claims have scientific verified development". Of particular concern are claims allowed in developed countries around DHA, ARA, GOS and FOS but are not allowed under FSANZ. If regulations restrict the consumers need to be aware of these ingredients, infants will miss out on receiving these products. If not on the label, why would consumers purchase a product at a higher price with these additional ingredients, and why would companies invest further development if they were unable to make reference at point of sale.	This Notice allows companies to put health claims (including nutrient function claims) on labels, of products intended for infants and young children from 6 months where the importing country accepts these, and they do not imply the product is nutritionally equivalent or superior to breastmilk. Companies should be aware of their ethical obligations under the WHO Code to not promote formula as a better alternative to breast milk. It is not intended to be specific in the Notice as to what specific claims are allowed.  In MPI's view reference to common market practices (rather than regulation) is not a justification for permitting label claims. In addition, substantiation of health benefit claims for infant formula is very challenging, and so in reality most health claims are unlikely to be supported by robust substantiation (e.g. see EFSA's assessment of lutein).
Suggest prohibitions extend to infants up to 12 months to keep it consistent.	MPI considers that prohibiting health claims on products for infants aged 0-6 months (unless 'expressly permitted') strikes the right balance between allowing for innovation while ensuring that New Zealand's obligations under the World Health Organization Code of Marketing are considered.
Health and nutrition claims should not be permitted on any formula products – this includes follow-on and all toddler ranges. Misleading claims undermine breastfeeding and risks to infant, young child and maternal health, both short and long-term. Recommend the 'express permission' restriction is extended from six months to two years.	Noted. MPI considers the approach strikes the right balance between allowing for innovation while ensuring that New Zealand's obligations under the World Health Organization Code of Marketing are considered. Any claims made must not be misleading and must not imply the product is equivalent or superior to human milk.
6. Comments on proposed approach to nutrition and health claims	

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Generally agree with proposed approach that allows NZ exporters to meet importing country requirements while ensuring that NZ obligations under the WHO Code are considered. Some concerns around 'express permissions' (see above).	Noted.
Important that in countries that permit health and nutrition claims, NZ exporters must be able to make claims in order to compete on a level playing field.	Noted. Exporters will be able to make health claims on infant formula if permitted by the importing country, and health and nutrition claims on other products if accepted by the importing country and do not imply the product is nutritionally equivalent or superior to breastmilk.
Guidance documentation should be developed to help align understanding across industry and verifiers, and ensure consistency and fairness is achieved.	A guidance document will also be issued for industry and verifiers.
<ul> <li>Health and nutrition claims should not be permitted on any formula products marketed for infants under one year. Use of claims on products contributes to decreasing or ceasing breastfeeding; and persuades parents to purchase unneeded expensive products.</li> </ul>	Noted. MPI considers the approach strikes the right balance between allowing for innovation while ensuring that New Zealand's obligations under the World Health Organization Code of Marketing are considered.
Was not aware that NZ legislation did not permit nutrition and health claims for products for infants aged 0-12 months, as the INC Code of Practice is industry written and self regulated.	The restriction is stated in FSANZ Standard 1.2.7 'Nutrition, Health and Related Claims.' In addition Clause 20 of Standard 2.9.1 limits infant formula manufacturers from referring to nutrition information anywhere on the label other than in the nutrition information statement and the statement of ingredients. Together these clauses are intended to prohibit nutrition content and health claims on infant formula products.
7. If your company was currently using claims, could you continue to do so?	
Claims are compliant with importing country requirements.	Noted
8: Comments on the proposed criteria for NZ origin label claims 9: How easy or difficult would it be for your company to	Responses to these questions are provided together in the section below.
make a claim under the criteria?	
General comments	

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•	Agree in principle for need to protect image and reputation of New Zealand based on integrity of export products.	Noted.
•	Chinese characters can have a range of meanings. How will MPI know that a label in Chinese is meeting the criteria for NZ origin claims, when the claim in Chinese could imply different things?	Certified translations of labels are required to demonstrate compliance with the Notice during verification. The Notice applies to claims in English and translations. There are challenges in picking up shades of meaning in other languages. The Notice clarifies what is likely to be misleading. For instance, any claim on a product that was dry blended only using imported ingredients would need to clearly state this. Any other form of unqualified claim in translation about the NZ origin of the product would be misleading.
•	Notes there are already prohibitions on false or misleading claims in relation to origin in the Animal Products (Dairy) Regulations 2005 and the Animal Products (Export Requirements – Dairy) Notice 2005.	In MPI's view, these existing provisions effectively prohibit "product of NZ" claims on infant formula, and create doubt as to whether a "made in NZ" claim can be for these products.
•	Do not agree with the proposals on the grounds they are:              Likely to be misleading to the consumer             Not consistent with other origin statements from other countries             Not promoting NZ industry, and will act as a disincentive to grow the economy.	The proposals have been developed to clarify provisions so that MPI can better enforce the general requirements of export legislation that origin labelling claims are not false and misleading. The way New Zealand regulates 'product of NZ' and 'made in NZ' is broadly consistent with other comparable English speaking countries (e.g. Australia and Canada). There are some specific differences as a result of whether or not a country mandates country of origin labelling.  MPI is responsible for regulating products and ensuring that misleading claims are not made. A robust regulatory system is the basis for export trade in food products.
•	Know how, IP, quality of end product, and safety systems are more important to the meaning of NZ origin claims that simply where the ingredients come from.	Noted. Consumer research in China, for example, shows that safety and trust in the production system is an important aspect of product origin. For that reason, providing clarity about when a made in NZ claim can be made is important. 'Product of NZ' is a higher claim, which refers to the origin of ingredients (i.e. where they are 'grown').
•	A broad food industry discussion should take place before specific origin claims criteria are applied to a specific sector.	See response below in relation to the precedent setting effect of the proposed infant formula origin claim criteria.
•	Proposed claims criteria make no reference to the safety focused NZ regulatory framework.	This is implied in the criteria for substantial manufacturing (wet blend/combined process) and packing in NZ. All such activities in relation to infant formula in NZ must be carried out within the MPI regulated supply chain.
•	Support for all packaging to take place in New Zealand in order to make a "product of NZ" or "made in NZ" claim.	Noted. Standard would apply to retail ready export products only.

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•	Support for exemption from the criteria, where necessary to meet rules of origin labelling requirements of imported country.	Noted.
•	Does not support specifying placement of country of origin for rules of origin purpose.	Noted. However, without specifying location on the label, such claims could be used as marketing claims thereby undermining the intent of the standard.
•	Thought should be given to harmonise with Australia.	Australia introduced mandatory country of origin labelling for most food products. New Zealand opted out of this decision in 2005.
•	Labelling should promote the NZ economy, and preserve the reputation for New Zealand for clean, green, high quality foodstuffs and products.	The proposed criteria are intended to enable made in NZ origin claims on infant formula. In MPI's view, the existing provisions under the Animal Products Act cast doubt on whether "Made in NZ" claims can be made on a typical infant formula manufactured here. Any criteria must be justifiable to overseas Governments to protect New Zealand and MPI's reputation as a trusted regulator.
•	The product can be said to be made in NZ if it is manufactured to our strict production standards.	The revised criteria recognise substantial manufacturing as the key criteria to a 'made in NZ' claim.
•	100% NZ should be prohibited. Provide the skim milk solids are wet dried in NZ, and the ethos of the product is created in NZ, MPI should allow:  Origin: NZ Product of NZ Made in NZ.	We consider that different origin claims imply different product characteristics. It is therefore necessary to develop criteria to reflect the meanings of different claims.
•	Origin claims can be a source of trade restriction for safe and suitable New Zealand origin ingredients. The adoption of voluntary origin claims criteria should not put New Zealand exporters at a disadvantage compared to overseas competitors.	Noted. See response below in relation to the precedent setting effect of the proposed infant formula origin claim criteria.
•	If food additives are not of NZ origin, then this should be stated. All content of the product should be described on the label.	In most markets, ingredient labelling provisions require food additives to be identified, but not the origin of the individual additives.
•	NZ's clean green image is used a proxy health claim, and marketing that draws on this reputation should be prohibited on infant formula as it could influence people's infant	Noted. For many countries the origin of an infant formula is used as a proxy for the safety of the product. A claim implying safety is not the same as a health claim implying benefit. Those purchasing infant formula from New Zealand should be able to have complete trust in the safety of

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	feeding decisions.	the product. Health claims are regulated separately by the Notice.
•	Insufficient evidence was presented in the discussion paper to indicate there is a problem with consumers and regulators ability to identify authentic NZ products in overseas markets.	Noted.
"10	00% NZ" claim	
•	A 100% New Zealand claim means that every aspect of the product must come from NZ (Commerce Commission)	Noted. Reference to 100% New Zealand has been removed from the draft standard. The Guidance document clarifies that a product that claims to be 100% NZ must be exactly that, and that this is an existing requirement under the general false and misleading claims provisions of the Animal Products regulations.
•	There is a different between "100% NZ" and "Product of NZ": this needs to be clear in the paper.	Agree. As above, reference to 100% New Zealand has been removed from the draft standard.
•	The "100% NZ" is similar to the Government's "100% Pure NZ" marketing campaign and should be treated in the same way, as a simple marketing line.	There is an element of puffery in the claim the 100% Pure NZ tourism marketing campaign. It also refers to the tourism experience of people visiting NZ. As NZ does not have contiguous borders with any other country, any visit to NZ is a visit only to NZ (excepting transit and onward journeys). Food is different. A 100% origin claim on a food is very likely to be taken by the consumer as referring to the substance of the product and where its constituents were grown. Therefore, if a 100% New Zealand claim is made on a food, 100% of the constituents would need to come from New Zealand. A 100% New Zealand claim on an infant formula would not be puffery because other food products can legitimately carry such a claim (e.g. New Zealand kiwifruit).
•	Does not support 100% NZ being included on labels of infant formula (but does not oppose its use in advertising).	Noted. MPI cannot regulate advertising of infant formula in other jurisdictions. We note that advertisements in New Zealand must comply with the Fair Trading Act. The INC Code of Marketing of Infant formula and the Advertising Standards Authority guidelines are also very good references to assist businesses to comply with New Zealand laws and regulations.
"P	roduct of NZ" criteria	
•	Setting "product of NZ" claims criteria for infant formula at the proposed level could create an unwanted precedent for other dairy export products – this would place NZ at a significant disadvantage (for example, in submitters views cheese and butter would be unable to make "Product of NZ" claim)	Under the existing provisions of the Fair Trading Act, and the relevant Animal Products Act regulations, the tests for origin claims can be generally stated as:  • Where is the essential character of the product created?  • Where is substantial transformation/manufacturing undertaken?  If the "essential character" of the product is created in New Zealand, then a "product of NZ" claim

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		may be able to be made. This will generally be when the product is grown in New Zealand.
		In the case of infant formula, a product is only an infant formula if it contains all the nutrients necessary to be the sole source of nutrition for infants (a breastmilk substitute). These nutritional requirements are set out in regulation. Therefore, the essential character of an infant formula can be seen as all the ingredients used to meet the nutritional requirements as set out in regulation. This is, in practice, "all or virtually all" the ingredients used in these products.
		It should be noted that this is effectively an existing requirement. The proposed notice essentially restates the existing requirement as it applies to infant formula.
		However, each food product needs to be considered on its own merits. For instance, the minor imported ingredients in NZ butter or cheese may not affect the essential character of these products as "products of NZ". Any instances of "product of NZ" claims on these products will still need to meet the general requirements in the Fair Trading Act and Animal Products Act regulations (for export product).
		The operation of the existing general provisions is clarified in the guidance associated with the standard.
		The new provisions introduced by the proposed standard are in relation to "made in NZ" claims. Please see comments below.
•	No company could meet this criteria now, but there could be a time in the future when it is possible.	Noted.
•	The definition of "essential constituents" is not provided.	The discussion paper includes a definition of essential constituents in Appendix 1 on page 11.
•	Other countries don't impose such domestic requirements on their exports. The "Product of NZ" criteria is unrealistic in this respect and places NZ exporters at a severe disadvantage.	Canada and Australia both have requirements in place for certain origin claims on export products. As noted above, the criteria for "Product of NZ" claims on export infant formula essentially restate the existing requirements under Fair Trading Act and Animal Products Act regulations as they would relate to infant formula. These general requirements are consistent with those of comparable food exporting countries like Canada and Australia.
•	Some international companies have indicated these requirements would make them reconsider New Zealand as a manufacturing location for their brands.	Noted. However, the intent and anticipated effect of the Notice is to strengthen the value behind the 'made in NZ' claim.
•	<ul> <li>"Product of NZ" claim criteria should be:</li> <li>The product must be manufactured using all NZ origin constituents; and</li> </ul>	Noted. This would be similar to the criteria as proposed in the discussion paper, and also essentially restates the existing general provisions under Fair Trading Act and Animal Products Act regulations as they would apply to infant formula.

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<ul> <li>All or virtually all of the processes involved in the products manufacture must take place in NZ; and</li> <li>All packaging must be carried out in NZ.</li> </ul>	
Criteria should be amended to be less stringent, particularly the requirement for vitamins and minerals to be of NZ origin.	Noted. As above, the criteria reflect existing requirements. Less stringent criteria could possibly be considered for "product of NZ" claims, particularly around the minor ingredient content. However, infant formula manufactured in NZ is still unlikely to have sufficient NZ content to make a "product of NZ" claim.
A NZ content threshold, for example at 80% might be useful, and might one day enable an infant formula to make	Noted. However, proportional thresholds are very difficult to verify, and are almost always arbitrary.
a "Product of NZ" claim.	Given the typical composition of infant formula and the ingredient products produced in New Zealand, it is unlikely that an infant formula would ever have 80% NZ ingredients.
"Made in NZ claims" criteria	
Supports the criteria, including dairy protein content.	Noted
Further consideration should be given to appropriateness of including an NZ content requirement	Noted. Following feedback from the majority of submitters, MPI is proposing to remove the protein content element from the criteria for 'made in NZ' claims on infant formula.
Dairy protein content requirement should be removed as most infant formula will not qualify (as all IF base producers currently use imported protein ingredients).	Noted. This has been removed from the notice.
There is inequity between "made in NZ" and "made in NZ from local and imported ingredients" as products with NZ dairy protein would still have imported oils. This could be misleading for the consumer.	Noted. In light of the changes to the criteria for 'Made in NZ' claims outlined below, the 'Made in NZ from local and imported ingredients' category has been removed from the standard. This claim can still be made on infant formula products as long as it is truthful and not misleading.
Should be "majority of dairy ingredients".	Noted. However, this would be difficult to enforce. One of the objectives of the proposed standard is to provide clarity on requirements for industry and verifiers.
We should adapt criteria from other countries include Australia and the EU. These do not focus on the origin of constituent components. For example in these tests could	Noted. However, these are criteria at the principle level, rather than the product level. Criteria at the principle level do not assist industry or verifiers to determine if a particular claim on a NZ infant formula is acceptable.
<ul> <li>be used:</li> <li>Where the product underwent their last and substantial, economically justified process or working (EU)</li> </ul>	The proposal in the draft standard is to create clear product level criteria for infant formula in a regulatory standard that enables a "made in NZ" claim to be made.

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<ul> <li>For products whose main features were produced in Germany or step from Germany's production (Germany)</li> <li>Where the core design and manufacturing occurs in Britain (UK)</li> <li>Where the product is substantially transformed and at least 50% of the cost of production has been incurred in Australia (Australia).</li> </ul>	
• It is not clear whether "protein constituent" refers to protein ingredient or protein content. Protein ingredients have significant variation in the amount of protein in them, and in general this is balanced by lactose. Because the protein and lactose content always has to be balanced there is potential for the "protein constituent" approach to be misleading in terms of overall dairy ingredient origin.	Noted. This technical detail is very helpful. The intention was to capture New Zealand dairy content. We anticipated that the origin of protein ingredients could be a surrogate for that, but feedback from consultation indicates this may not always (or even usually) be the case. As noted above, the dairy protein component of the "Made in NZ" claim criteria has been removed from the notice.
<ul> <li>In any formulation the skim milk solids would contribute around 5-6% of the protein and around 7% of the carbohydrate. The remainder of the protein and lactose comes from protein ingredients (such as WPC or demineralised whey) and lactose. For example, a product using NZ WPC 80 and imported lactose at around 45% of the product could make a "made in NZ claim", while a product with imported WPC 80 and New Zealand lactose could not, even though the NZ component of the product would be significantly higher.</li> </ul>	
There is no evidence cited in the discussion document to show that consumers have concerns about the source of protein in IF products.	As noted above, the dairy protein component of the "Made in NZ' claim criteria has been removed from the notice.
Focus should be on NZ manufacturing system, and so criteria should focus on the system under which the product is made.	Agree. The use of criteria for substantial manufacturing requires that this is undertaken under the NZ food safety regulatory system.
If consumers are interested in the origin of particular ingredients then this could be additional criteria.	Noted. The standard provides for other claims to be made as long as those claims are not misleading. This is further clarified in the guidance that will accompany the standard.

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"Made in NZ" claim criteria should be:     The product must be manufactured in NZ in a wet mix or combined process     The final blending and packing of the product must be carried out in NZ.	As noted above, the dairy protein component of the "Made in NZ' claim criteria has been removed from the notice.
Typcially step 1 infant formula product is made of the following ingredients:  Lactose 20%  Whey 30%  Milk (skim or whole) 15%  Oils and fats 30%  Vitamins/minerals/nutritional elements 5%  It is therefore misleading to focus on protein content, as this would only be around 45% of the total product. Typically, for many NZ companies lactose is imported as are oils and fats for all companies.	This technical detail is very helpful. As noted above, the dairy protein component of the "Made in NZ' claim criteria has been removed from the notice.
<ul> <li>"Made in NZ" claim should focus on the "made" – meaning created, transformed or developed, not the ingredients themselves, otherwise the claim is misleading.</li> <li>This claim should focus on substantial transformation.</li> </ul>	As noted above, the dairy protein component of the "Made in NZ' claim criteria has been removed from the notice.
If any dairy protein constituents are not of NZ origin, then the label should reflect this.	Noted. Country of origin labelling is not mandatory in New Zealand for the domestic market or export. However, any label claims or statements (e.g. about origin) must not be false or misleading. As noted above, the dairy protein component of the "Made in NZ' claim criteria has been removed from the notice. If dairy protein constituents used in infant formula for export are imported, this would only need to be reflected on the label if a specific claim about the New Zealand dairy content of the product was made.
"Made in NZ from local and imported ingredients"	
This is statement of fact, and so criteria is not required.	Noted.
When read next to the criteria for "made in NZ" it portrays the claim as misleading.	Noted. Criteria for this claim have been removed from the notice, and manufacturers will be reminded in the guidance document that claims such as these may be used, as long as they are

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	not false and misleading.
Technical definition of "wet blend process" and "combined process"	
There is discrepancy between the description of these processes in the discussion document and the proposed notice. The discussion document version would be overly restrictive.	Noted. The definitions in the proposed notice would apply.
The definition of "wet mix process" currently states that heat treatment "may" be required. Heat treatment should be a requirement for wet mix process.	Noted. This definitions used are those as defined in the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)
The standard does not differentiate between the mixes of infant formula, follow-on formula, and growing up milks. Oil addition is necessary for infant formula and follow-on formula, but not for growing up milks.	Noted. The definitions of combined process, dry-mix process and wet-mix process are only used in relation to the NZ origin criteria (Part 3 and schedule 1) of the Notice. This issue will be addressed in the infant formula manufacturing standard currently in development.
Definition of "combined process" should be:  "All milk protein ingredients must undergo a suitable heat treatment process and all oils must be incorporated via wet mix process with the exception of LCPUFAs added in encapsulated form. Note: formulated supplementary foods for young children manufactured from milk powders without vegetable oil addition are considered to meet the necessary criteria for combined process."	Noted. This definitions used are those as defined in the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)
10. Proposed verification requirements	
Agree the verification requirements are workable.	Noted.
Verification from in-market regulatory teams should be adequate evidence of compliance with importing country requirements.	Evidence of conflicting overseas market requirements, or an express permission in relation to health claims on products for infants aged 0-6 months needs to be held at the manufacturing site for the product for verification purposes. Overseas regulatory teams should be able to provide this information to the manufacturing site.
Industry and verifiers should receive training and guidance on the application of the Notice.	Agreed. A guidance document has been developed. Training and guidance for Recognised Agencies will be considered as part of implementation of all three Notices for infant formula

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		(Labelling; manufacturing; and exporter requirements) at verifiers summits etc.
an im discu Reco	email from a customer demonstrates compliance with importing country standard, as mentioned in the cussion document, would not be accepted by ognised Agencies as documentary evidence to meet 4 of the Standard.	Agree this would not be sufficient evidence. This will be covered off in the guidance document. The expectation for 'acceptance' of a label is a message from an overseas official in the relevant market, a product registration, or evidence of border clearance of first shipment.
	ognise the importance of clear, non-ambiguous uage, rigorously enforced.	Noted.
11. Other	r ways to meet requirements for translation	
langu	ld dual language certification (English and another uage) be satisfied by certified translations of the label ub clause (1).	The expectation is that compliance with the Notice would be demonstrated by providing certified document stating that the information in each language is consistent.
transl minim Evide shoul transl the transl	11 (17/08/2011) sets out the requirements for slations for all dairy products and should form the mum requirements to be required by this notice. ence of importing country compliance (in English) ald be sufficient without the requirement for a slation. In a situation where the verifier was checking ranslated version they are in fact verifying the slation of what was submitted to the importing countries petent authorities, which should be unnecessary.	FYIs are guidance documents only. F24-11 notes that where wording is used in English and more than one other language, then its meaning must be consistent. Operators can demonstrate compliance by obtaining translations, independent from commercial clients, of any labels. This Notice specifies that a certified translation must be available for the verifier, and if the labels are dual language, an operator must obtain a certified document stating the two versions are consistent. The guidance associated with the Notice will clarify that a 'certified translation' is a translation that is independent of the manufacturer and the customer, and for most cases, should be sourced from within New Zealand.
'certif label will be Agen applic	lance on the Notice to determine what constitutes ified' in relation to a translation of a foreign language and what constitutes 'standards' in overseas markets be important. This will need to flow on to Recognised incies to ensure consistency and fairness in the location of the Notice. Such Agencies should also live training on that application.	'Certified' will be clarified in the guidance document that it means it has been undertaken by a service in New Zealand independent of the manufacturer and/or brand owner, and is certified (or signed) by a person with responsibility for undertaking the translation.  For the purposes of the Notice, standards are regulatory instruments issued under executive authority by the governing authority of the country or market.
verific	ports the need for good quality translations and for cation of translations that is independent of ufacturers, exporters and their distributors. However,	As above, guidance will be provided that MPI considers a 'certified translation' to be an independent translation. The process for establishing the independent translation is a matter for the provider of the service.

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	this can be achieved in alternative ways to the single approach proposed of having certified translations of every non-English label, and a less prescribed approach is recommended. For example, certified translators are not always sufficiently knowledgeable with respect to technical terms used to deliver the most appropriate translations.	
12.	Transition period	
	An 18 month transition period is workable but 24 months is preferable to most in industry and would be comparable to changes to standards under the Food Standards Code. The following changes would need to be allowed for: reviewing origin claims; customer approval of artwork changes; any re-registration with importing countries (which can be a lengthy process); transition of existing packaged product and stocks; and lead time.	Noted. MPI considers the transition period should remain at 18 months as this will be adequate time to prepare for any changes required to labels. Manufacturers should bring their operations in line with the notice as early as possible, as verifiers will be able to issue non-conformances against the notice once the 18 month transition period finishes.
•	Clarification that the final date for implementation applies to date of packing of consumer ready packs.	The guidance document will clarify that all labels must be compliant with this Notice at the end of its transition period, from the date of production. From this date, verifiers will be able to issue non-conformances for non-compliance with the Notice.
•	Do not support a lengthy transition period. The interests of vulnerable infants need to be put ahead of the interests of industry. A shorter transition time would improve the reputation of NZ's dairy exporters.	Noted. The implementation period needs to be realistic for industry so there is time allowed for the change without excessive costs or disruption to supply.
Other comments		
	Where a term is defined and subsequently used later in the document without capitalisation it is unclear if the term is to be taken as per the definition. It is suggested that this is clarified by use of capitalisation or addition of a clause to that effect.	If a term is used in the document and defined in the Interpretation, then that meaning should be taken to apply, regardless of capitalisation.
•	Where a health certificate is required for registration and registration is evidence of label compliance, we would like to clarify that the health certificate will still be issued prior to the label registration.	An export certificate would be issued for the product's first shipment. The guidance document notes that for verification purposes, where necessary, evidence of acceptance of labels can be provided after samples or initial shipments have been sent to market for product acceptance or product registration purposes, and a verifier can follow up the verification at a later date.

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Suggests that since the definitions defer to those used in Standard 2.9.1 of the Food Standards Code, then it is misleading to refer to "Infant formula is a product formulated to be used from birth" without identifying that infant formula means, according to the definition in Standard 2.9.1 of the Food Standards Code "an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months." Therefore the definition in the Notice should read "Infant formula is a product formulated to be used from birth and represented as a breast milk substitute for infants which satisfies the nutritional requirements of infants aged up to four to six months".	Agreed. Amendment to definitions made in the Notice.
<ul> <li>Similarly, the definition for follow-on formula in Standard 2.9.1 is "follow-on formula means an infant formula product represented as either a breast-milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months." The definition in the Notice should therefore reflect this definition.</li> <li>Suggests that same approach is taken for Formulated Supplementary Foods for Young Children, to include the full definition from Standard 2.9.3 is included.</li> </ul>	Agreed. Amendments to the definitions made to the Notice, with the difference that formulated supplementary food for young children, the age range only goes up to 36 months of age.
Recommend that the Notice be clear that it reflects the outermost label of a single unit (and does not restrict information on other advertising, websites or other material).	This will be addressed in the guidance document, and in the Purpose section of the Notice – clarify it applies to retail-ready packages.  The Notice does not apply to advertising. However, exporters will need to comply with any advertising requirements of the importing country, and should be mindful of their ethical obligations under the World Health Organization Code to not promote formula as a better alternative to breastmilk.
All consultation documents concerned with infant and young child feeding should be sent to all people working in the appropriate health area to afford transparency and allow for	Noted. FSANZ is a separate agency to MPI, and undertakes its own consultation processes on changes to the Australia New Zealand Food Standards Code (e.g. P274 Minimum age labelling).

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other voices, other than industry. Consultation should also include all those who have been interested enough to make previous submission in this area. Despite submitting on numerous occasions on the topic of formula milks, complementary foods, marketing and the International Code I not get included in subsequent new consultation rounds and also never hear any of the results or outcomes of the consultation. For example still waiting to hear the results of the FSANZ Proposal P274, Minimum age labelling of foods for infants and this was a process undertaken in November 2013.	Summaries of submissions for these processes are available on the FSANZ website.  MPI's current consultation process applies only to products for export from New Zealand (except to Australia).
Agree with providing minimum requirements, but MPI should also approve labels as this would assist exporters to be sure that their labels comply.	The Notice does not require individual label approvals. Instead, it puts in place a system to verify that manufacturers have their own systems in place to meet the labelling requirements. There are consultant services available that can assist companies in meeting regulatory requirements, including in relation to labelling. While there is a cost in engaging consultants to review labels, if MPI were to require label approval, this would need to be cost recovered from users as well.
The Standard should require MPI to publish the list of New Zealand infant formula brands that can be exported.	Noted. MPI does not collect information about the infant formula brands exported to all markets. There may be market sensitivities to publishing such information and it would therefore need to be considered on a market-by-market basis. In the absence of an importing country requirement, MPI would look to the industry as whole for direction on whether publishing brand information was in the interests of NZ Inc.
Samples should be exempted from the requirements of the Notice.	The Notice does not set up an approval process for labels, and so there is no need to exempt product samples. For verification purposes, MPI would expect operators to have documented procedures for product development. Differentiating between samples and retail product would be key to those procedures. Verification of this Notice would focus on retail products.