Ministry for Primary Industries
Manatū Ahu Matua

Proposed Requirements for the Export of Infant Formula, Follow-on Formula, and Formulated Supplementary Foods for Young Children

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Growing and Protecting New Zealand

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1 Submissions

The Ministry for Primary Industries (MPI) invites comment from interested parties on proposed requirements for the export of dairy-based retail-ready infant formula products and formulated supplementary foods for young children. MPI will analyse submissions and respond to any outstanding issues in due course.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section in the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Where possible, reasons and data to support comments are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- the title of the discussion document;
- your name and title (if applicable);
- your organisation's name (if applicable); and
- your address.

Please submit your response by 20 August 2014.

Your comments should be sent to:
MPI Infant Formula Programme
PO Box 2835
Wellington
Email: Infant.formula@mpi.govt.nz

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Everyone has the right to request information held by government organisations, known as "official information". Under the Official Information Act 1982 (the OIA), information is to be made available to requestors unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA.

If you are submitting on this discussion document, you may wish to indicate any grounds for withholding information contained in your submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information.

Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman. For more information please visit http://www.ombudsman.parliament.nz/resources-and-publications/guides/official-information-legislation-guides

2 Executive Summary

This paper seeks submissions from interested parties on proposed requirements related to the export of dairy-based[1] infant formula products[2] and formulated supplementary foods for young children.

Summary of MPI's proposals		
	Proposal	**Who would experience a change?**
1	Reinforce existing requirements that retail-ready infant formula products and formulated supplementary foods for young children for export are processed and handled at all times by businesses with a registered risk management programme (RMP operators), or transporters operating under a regulated control scheme (RCS), in order to be eligible for export.	N/A
2	Require RMP operators to notify MPI of all product movements of retail-ready infant formula products and formulated supplementary foods for young children intended for export via MPI's electronic certification system (E-cert), regardless of the intended export market.	All RMP operators handling retail-ready infant formula products and formulated supplementary foods for young children intended for export to any market that does not already require a record of market eligibility (ROME).
3	Require declarations be made to MPI for all export consignments of retail-ready infant formula products and formulated supplementary foods for young children via E-cert, regardless of the intended export market.	Those exporting retail-ready infant formula products and formulated supplementary foods for young children to markets that do not require official assurances for those products (e.g. Hong Kong).
4	Require use of harmonised system (HS) codes as listed in the New Zealand Tariff in E-cert for retail-ready infant formula products and formulated supplementary foods for young children. The codes will change under proposal #8. This proposal was also consulted on, in relation to all exported dairy products, in MPI discussion paper 2014/26 *Amendments to the dairy official assurances specifications* (June 2014).	All exporters of retail-ready infant formula products and formulated supplementary foods for young children.
5	Require exporters of retail-ready infant formula and formulated supplementary foods for young children to nominate and hold details of a party in the overseas market responsible for product recalls.	All exporters of retail-ready infant formula products and formulated supplementary foods for young children.
6	Require records of all exported retail-ready infant formula products and formulated supplementary foods for young children consignments to be kept for a minimum of four years.	Those exporting retail-ready infant formula products and formulated supplementary foods for young children to markets that do not require official assurances for those products.
7	Require ongoing verification of RMP operators and exporters of infant formula products and formulated supplementary foods for young children for compliance with the above requirements.	All exporters of retail-ready infant formula products and formulated supplementary foods for young children.
8	Create specific HS codes in the New Zealand Tariff for exports of retail-ready and bulk finished infant formula products, and formulated supplementary foods for young children.	All exporters and importers of retail-ready and bulk finished infant formula products and formulated supplementary foods for young children.

[1] Dairy based in the context of this paper means principally dairy: the formula contains, as its predominant protein constituent, protein derived or processed from milk that is extracted from a milking animal such as a cow, goat, or sheep.

[2] Infant formula products in the context of this paper refers to products nutritionally adequate to serve as the principal liquid source of nourishment for infants, and includes infant formula and follow-on formula.

3 Introduction

Infant formula is used where an infant is unable to breastfeed, or where breastfeeding is not appropriate. Infant formula can be the sole source of nutrition for infants. Therefore, expectations for the safety of infant formula products are higher than for most other food products.

The Government Inquiry into the Whey Protein Concentrate incident recommended strengthening requirements on infant formula exporters. Four areas for improvement have been identified for exports of dairy-based retail-ready infant formula products and formulated supplementary foods for young children:

- monitoring of exports to a small number of markets that do not require official assurances (e.g. Hong Kong)
- verification of exporter compliance
- recall efficiency for exports
- data collection for the purposes of official statistics.

This paper sets out proposals to address these areas.

The term *infant formula products and formulated supplementary foods for young children* in this paper refers to dairy-based retail-ready infant formula, follow-on formula, and formulated supplementary food for young children (sometimes termed "toddler formula", or "growing up milk powder") intended for infants and young children from 0 to 36 months of age. In the context of this paper, the term retail-ready does not include trade samples.

4 Background

4.1 INFANT FORMULA PRODUCTS

The World Health Organization (WHO) recommends that infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development, and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues up to two years of age or beyond. In instances where an infant is unable to be breastfed or where breastfeeding is not appropriate, a suitable breast-milk substitute should be used. Infant formula products are the only suitable breast-milk substitutes.

Infant formula can be the sole source of nutrition for a vulnerable population group. Stronger food safety monitoring and oversight is appropriate for infant formula products than for dairy products for adult consumers. Infants have special nutritional needs and lower immunity than adults. Market expectations for safety and traceability are also particularly high for infant formula products and formulated supplementary foods for young children.

4.2 THE WHEY PROTEIN CONCENTRATE CONTAMINATION INCIDENT

In August 2013, there was a food safety incident concerning whey protein concentrate. There was a suspicion that the harmful bacteria *Clostridium botulinum* could be present in some exported infant formula and possibly other products due to the use of whey protein concentrate in these products. While the incident turned out to be a false alarm, it damaged New Zealand's reputation, caused global market disruption, and problems for market access to a number of important markets. The whey protein contamination incident highlighted the importance of effective traceability for infant formula.

Following the whey protein concentrate incident, the Government established an inquiry panel to investigate the causes and management of the incident. The Inquiry Panel's report, the *Government Inquiry Report on New Zealand's Dairy Food Safety Regulatory System*, recommended that:

> 'The Ministry should strengthen requirements for exporters of infant formula to ensure traceability.'

The Inquiry Report also noted, in the context of infant formula exports, that:

> 'Any extra regulatory burden would be justified, in the Inquiry's view, to protect New Zealand's reputation. It is important the ministry is aware of specific exports in the event of a recall.'

On 11 December 2013 the Government announced that it intended to implement all the recommendations from the Inquiry Report.

4.3 CURRENT MONITORING OF INFANT FORMULA EXPORTS

4.3.1 Official Assurances

Many markets require official assurances from the New Zealand Government. An official assurance commonly states that exported dairy products are fit for their intended purpose, have been produced under New Zealand law, and meet requirements specified by the New Zealand Government as necessary for export to other countries. MPI issues official assurances for eligible export products such as meat, seafood, and dairy.

Under the current export framework provided by the Animal Products Act 1999 all products exported must be:

- manufactured and handled only at premises operating under a registered risk management programme (RMP), and by transporters operating under a regulated control scheme (RCS);
- manufactured according to relevant specifications; and
- where products are exported to markets that require official assurances, they are associated with information on product movements, and on the markets to which they are eligible for export.

Compliance is monitored by third-party verifiers and MPI.

MPI operates an electronic certification system (E-cert) that collects product data to facilitate the issuing of official assurances.[3] E-cert allows businesses (operators), verifiers, and MPI to check products' export market eligibility and inter-premises movements. Where products meet all requirements, exporters are issued with official assurances in the form of export certificates.

Record of Market Eligibility (ROME) Markets

Some official assurance markets have additional requirements. Markets such as the European Union and the Eurasian Economic Community Customs Union (Russia, Belarus and Kazakhstan) require a record of market eligibility (ROME) in addition to export certification.[4] This means that whenever dairy products are transferred from one premises to another a record is added in E-cert.[5]

4.3.2 Monitoring of Infant Formula Exports

Most exports of infant formula products and formulated supplementary foods for young children are already closely monitored through MPI's official assurance programme. In 2013 an estimated $450 million of retail-ready infant formula and foods for infants[6] were exported from New Zealand to around 38 different markets. Around 35-36 of those markets require official assurances for infant formula.[7] Table 1 below shows the eight markets that represent around 95 per cent of exports by value.

All exporters are required to hold information about the products they export. However, information on infant formula exported to markets that do not require official assurance (e.g. American Samoa), or that exempt infant formula from official assurances (e.g. Hong Kong) may not be collected in E-cert.

[3] MPI and the dairy industry are in the process of transitioning the export certification of all dairy products to an enhanced version of E-cert called Animal Products E-cert (AP E-cert). AP E-cert is used by other non-dairy animal product industries. AP E-cert offers advanced traceability, security, data-exchange and certificate generation capability and is expected to deliver cost savings for the dairy industry. Proposals to support the transition were consulted on in MPI discussion paper 2014/26 *Amendments to the dairy official assurances specifications* (June 2014). MPI anticipates that the transition will be completed by 1 September 2014.

[4] For further information on records of market eligibility see clause 7 of the Animal Products (Official Assurances Specifications – Dairy Products) Notice 2011.

[5] I.e. an Eligibility Declaration (automatically approved) or an Eligibility Document (approved by a verifier) must be raised.

[6] HS Code 190110

[7] Global Trade Atlas

Table 1: Retail-ready Infant Formula Markets in 2013			
Market	**Estimated proportion of New Zealand exports (by value, year ended Dec 2013)**	**Requires official assurance for dairy products?**	**Currently has an exemption for infant formula?**
China	38.5%	Yes	No
Australia	19.2%	Yes	No
Hong Kong	12.3%	Yes	Yes
Taiwan	12.0%	Yes	MPI suggests that exporters use certificates.
Malaysia	4.3%	Yes	No
South Korea	3.4%	Yes	No
Russia	2.7%	Yes (also requires ROME)	No
Thailand	2.1%	Yes	No
Sum	94.6%		

Note: HS code 190110 – infant formula and other food preparations for infants for retail sale.

4.4 CURRENT MONITORING OF EXPORTER COMPLIANCE

4.4.1 Duties and Obligations on Dairy Exporters

The Animal Products Act 1999 sets out a range of duties and obligations on all dairy exporters. In general, all dairy exporters (including exporters to non official assurance markets) must:

- be registered with MPI;
- comply with all relevant requirements of the Animal Products Act framework; and
- notify MPI in the event that exported animal product is refused entry by a foreign government or, once exported, is no longer compliant with the Animal Products Act framework.

4.4.2 Monitoring Exporter Registration: MPI and Customs

The New Zealand Customs Service (Customs) assists MPI to monitor exporter compliance by requiring dairy exporters to declare their registration number (or Animal Products number, APD number) prior to gaining export clearance. Customs does this by checking exports with certain harmonised system (HS)[8] code descriptions.

4.4.3 Other Duties and Obligations

There are also other duties and obligations on all dairy exporters set out in the Animal Products Act 1999 and the Animal Products (Dairy) Regulations 2005. To find out more go to: http://www.foodsafety.govt.nz/industry/sectors/dairy/exporting/.

[8]The Harmonised System (HS) is an internationally standardized system of numbers for classifying traded products, developed by the World Customs Organization. The first six digits of HS codes are universal across countries, but Customs can define and set the last four digits of HS codes for New Zealand's exports and imports.

5 Problem Definition

5.1 REQUIREMENTS FOR THE EXPORT OF INFANT FORMULA

The whey protein concentrate contamination incident demonstrated there is a need to strengthen monitoring and recall requirements for retail-ready infant formula product exports. The Report of the Government Inquiry into the Whey Protein Contamination Incident specifically recommended that the MPI strengthen requirements for exporters of infant formula to ensure traceability.

As described above, MPI does not directly monitor exports of infant formula products and formulated supplementary food for young children to markets that do not require official assurances. Exporters are required to hold records of their export activities. If there is a problem with infant formula exported to these markets, in order to identify the importer in the overseas country MPI must contact the RMP operator to identify and contact the exporter. This reduces the speed with which the RMP operator and/or MPI can locate affected product and have it withdrawn at the distribution level. The process is much faster for infant formula exported with an official assurance because MPI holds details of each consignment, such as product descriptions and details of the exporter and the importer.

Any delays in locating and withdrawing exported infant formula products and formulated supplementary food for young children may lead to the need for wider consumer recall than would otherwise be required to ensure public safety. This can have harmful commercial impacts for companies and on New Zealand's reputation. International experience shows that ineffective traceability in the food supply chain can also jeopardise the functioning of global food and ingredients markets, and can create unnecessary wider market disruption.

5.2 MONITORING EXPORTER COMPLIANCE

It is possible that some new and small-scale exporters may not be fully aware of their duties and obligations.

Some RMP operators export their own products, and undergo regular checks as part of their regular RMP verification. Exporters that do not operate an RMP are required to access product for export from an RMP operator, and to maintain records, however, they are not subject to regular verification. For exporters that do not operate an RMP (generally small-scale exporters) MPI carries out targeted compliance activities. MPI considers that regular audits, on an ongoing basis, would greatly improve the level of awareness among small-scale infant formula exporters.

The current HS codes used for infant formula also make it difficult for Customs to monitor exporter registration for some consignments of these products as they capture non-dairy infant products.[9] It is not possible for Customs to carry out the exporter registration check under these HS Codes because there is currently no way of determining if the consignment is a dairy-based product. However, in many cases it appears that exporters submit their exporter registration information as part of their Customs declaration.

[9] Exports of retail-ready and bulk-finished infant formula products under the HS codes 1901.10.09.00C and 1901.90.09.28B are not consistently checked for exporter registration.

5.3 COLLECTING STATISTICS FOR RETAIL-READY AND BULK FINISHED INFANT FORMULA PRODUCTS

It is currently difficult to provide accurate and detailed statistics for exports of infant formula products and formulated supplementary foods for young children due to the set of HS codes used. Accurate and detailed statistics are important for businesses and Government to inform commercial and regulatory decisions.

Under the current HS code descriptions it is not possible to accurately:

- report on exports of infant formula products and formulated supplementary foods for young children separately to other food products and to each other; and
- ascertain whether exporters of infant formula products and supplementary foods for young children are using the correct HS codes for their products.[10]

5.3.1 Retail-ready exports

MPI is focussing on retail-ready products because it was these products exported to markets that do not require official assurances that were some of the most difficult to track during the whey protein concentrate contamination incident. There are more exporters involved in the trade of retail-ready products than bulk finished and ingredient products. Generally, exporters of bulk finished products and ingredients also carry out manufacturing and hold RMPs that are regularly verified.

Questions for submitters:
1: Do you have any comments on the problems identified above? Are the additional issues you think should be identified?

[10]For instance, retail-ready infant formula and some follow-on formula and formulated supplementary food for young children are currently exported under the code 1901.10.09.00C. In addition, some retail-ready formulated supplementary food for young children and bulk finished infant formula products and formulated supplementary food for young children are being exported under the same HS code, 1901.90.09.28B, along with adult nutritional powders.

6 Proposals

6.1 STRENGTHENING REQUIREMENTS FOR THE EXPORT OF INFANT FORMULA

MPI proposes to make a general requirement for export (GREX) Notice under section 60 of the Animal Products Act 1999. The Notice would apply to:

- retail-ready infant formula products and formulated supplementary foods for young children intended for export, regardless of whether or not official assurances are required; and
- any person who manufactures or processes, transports, packs, labels, preserves, or stores retail-ready infant formula products and formulated supplementary foods for young children intended for export, regardless of whether or not an official assurance is required.

MPI intends to provide for exemptions under certain circumstances. These circumstances are yet to be determined, but could include for example, products carried as personal luggage on an aeroplane.

A summary of the proposals is set out below, and a draft Notice is attached at Appendix 2.

6.1.1 Fit with the Purposes of the Animal Products Act 1999

The proposals fit within the purposes of the Animal Products Act 1999. The proposals would protect consumers in the event of a recall, by managing risk to human health arising from the processing of animal products that are exported and later found to be unfit for their intended purpose. In addition, the proposals would support confidence in New Zealand's food systems and hence the integrity of official assurances.

The Notice would be made under section 60(1) (c): 'necessary or desirable to safeguard assurances provided by New Zealand', on the basis that supply chain traceability of all New Zealand exports underpins New Zealand's official assurances to all markets. In addition, products initially exported to markets that do not require official assurances may be re-exported to markets that do require official assurances and it may be the expectation of those markets that New Zealand can provide information about the provenance of products if required.

Table 2 Proposals					
	Proposals	**Impact on RMP operators**		**Impact on exporters that do not operate an RMP**	
		Exports to Official Assurance Markets	**Exports to Non-Official Assurance Markets**	**Exports to Official Assurance Markets**	**Exports to Non-Official Assurance Markets**
1	*Processing and handling within the risk management programme (RMP) chain* To be eligible for export, MPI requires all retail-ready infant formula products and formulated supplementary foods for young children to be manufactured or processed, packed, handled, transported, preserved, and stored within the control and scope of a registered RMP or RCS. (This will restate an existing requirement)	No change – reinforces existing requirement	No change – reinforces existing requirement	No change – reinforces existing requirement	No change – reinforces existing requirement
2	*Enhanced traceability* When transferring retail-ready infant formula products or formulated supplementary foods for young children from one premises to another, MPI would require RMP operators to raise an eligibility declaration (automatically approved) or an eligibility document (approved by verifier) in E-cert. This would be accessible by the operator of the receiving premises within a specified timeframe (yet to be confirmed). Where RMP operators failed to meet the specified timeframe it would not result in export ineligibility (as it would for markets that require a record of market eligibility (ROME)). Instead, a non-conformance/non-compliance would be recorded in the RMP operator's verification report.	**ROME markets:** no change **Other markets:** New requirement	New requirement	No change	No change
3	*Export authorisation for all markets* MPI would require exporters to make an export declaration for every consignment. The information to be included in the declaration is the exporter's full name, physical address, identifier as they appear in the exporter register, and details of the export consignment. The export declaration could be made by either raising a new export declaration form or an application for export certification. The export declaration form would be based on an eligibility declaration or eligibility document provided by the final manufacturing premises. The export declaration form would need to be cleared, prior to the product's departure, by an authorised person in the same way as an application for export certification.	No change – reinforces existing requirements	New requirement	No change – reinforces existing requirements	New requirement

Table 2 Proposals					
	Proposals	**Impact on RMP operators**		**Impact on exporters that do not operate an RMP**	
		Exports to Official Assurance Markets	**Exports to Non-Official Assurance Markets**	**Exports to Official Assurance Markets**	**Exports to Non-Official Assurance Markets**
4	*More detailed product descriptions* MPI would require exporters to specify the relevant HS code via a 'drop down box' in the application for export certification or the proposed export declaration form. As of March 2014, MPI has required that HS codes be entered as a 'free text field' for dairy products exported to markets that require official assurances. MPI also consulted on a proposal to require exporters to specify relevant HS codes for all exported dairy products in discussion paper 2014/26 *Amendments to the dairy official assurances specifications* (June 2014).	'Free text field' to 'drop down box'. New HS codes: see proposal #8	New requirement	'Free text field' to 'drop down box'. New HS codes: see proposal #8	New requirement
5	*Accountable party responsible for product recall in the export market* MPI would require exporters to nominate a party in the importing country with responsibility for product recalls and to hold records of their details.	New requirement	New requirement	New requirement	New requirement
6	*Auditing of exporters* There would be an initial audit of compliance with the proposed Notice and regular ongoing audits for infant formula exporters. MPI proposes an initial audit visit for those exporters not already routinely verified. Subsequent audits would be carried out at a frequency determined by the Director General of MPI. MPI intends to make use of existing routine verification of RMP operators where possible to avoid unnecessary duplication in the cost of verification activities.	New requirement, to be carried out as part of routine verification	New requirement, to be carried out as part of routine verification	New requirement, to be carried out by MPI[11]	New requirement, to be carried out by MPI
7	*Enhanced record-keeping* MPI would require exporters to maintain records in relation to all exported consignments of retail-ready infant formula products and formulated supplementary foods for young children for a minimum of 4 years. Records would include, at a minimum: date of export, country of destination, a full description of the product being exported (including brand name), quantity of product exported and the name of the third party client if exporting on behalf of a person or business who is not a registered exporter.	No change – reinforces existing requirement	New requirement	No change – reinforces existing requirement	New requirement

[11] There is currently no provision in the Animal Products Act 1999 to directly recover costs of routine audits of exporters that do not hold an RMP.

Questions for submitters
3: Would there be any practical problems for industry arising from any of the proposals outlined above?
4: Are there any elements missing from the proposals that should be considered?
5: What impact, if any, would these requirements have on a product intended for the domestic market?
6. How much time should be provided for transition to the new requirements?

6.2 MONITORING EXPORTER COMPLIANCE

MPI proposes to work with Customs to change the New Zealand HS codes for infant formula products and formulated supplementary foods for young children at the 9 to 10-digit level.

Table 3 Proposals continued

	Proposal	**Impact on RMP operators**	**Impact on exporters that do not operate an RMP**	**Impact on importer**
8	*Create specific HS codes for infant formula products and formulated supplementary foods for young children* Change the HS codes to create specific codes for dairy-based retail-ready and bulk finished infant formula, and for dairy-based retail-ready and bulk finished follow-on formula and formulated supplementary foods for young children.	New HS codes	New HS codes	New HS codes

Creating specific HS codes for infant formula products and formulated supplementary foods for young children would support Customs to check that exporters of these products have a valid MPI exporter registration number. MPI would also be able to more readily indentify exporters of different infant formula products and formulated supplementary foods for young children.

In addition to supporting our regulatory assurance system, the specific HS codes would improve the accuracy and detail of the statistics available to businesses and Government for these exports. Through the collection of these HS codes in E-cert, MPI's data could also be used to help identify export practices that require targeted compliance activity, verify the official export statistics, and provide confidence that the correct HS codes are being used for infant formula exports.

MPI and Customs intend to provide sufficient notification and time for industry to prepare for the changes to the HS codes and the requirement to provide them in E-cert. MPI will also provide guidance material. If desirable, a trial of any new HS code arrangements in E-cert could be carried out to check compatibility with importing country requirements.

The detail of the new HS codes and descriptions MPI is proposing is set out in Appendix 1.

Questions for submitters:
7: Would there be any practical problems for industry arising from the proposal to change the HS codes for infant formula?
8: How much lead time should be provided for the change?

7 Options

The options discussed in this paper are either to maintain the status quo or proceed with the proposals outlined above.

7.1 OPTION 1: STATUS QUO

This option would retain the current settings for the monitoring of infant formula exports as described in the background section above. The costs and risks of the current settings have been outlined in the background and problem definition sections above.

7.2 OPTION 2: IMPLEMENT THE PROPOSALS

7.2.1 Advantages

Improved protection of consumers of infant formula and formulated supplementary foods for young children

MPI expects that, in the event of a recall, the proposals would result in greater recall efficiency. The proposals may help recall potentially affected product before it gets to retail level in the overseas market and, where it does, support the timely release of information to consumers. Overseas consumer and regulator confidence in New Zealand's system is particularly important to support market access for New Zealand's food industries.

Protect and enhance the reputation of all New Zealand food exporters

Exporters of infant formula rely on New Zealand's reputation of taking food safety issues seriously, as do exporters of other dairy products. Reputation is an important determinant of demand (and price) for infant formula. MPI expects that the proposals would protect and enhance New Zealand's reputation for food safety, particularly for infant formula, by enabling infant formula exporters and, if necessary, regulators to take action quickly if there is a food safety concern.

Greater compliance monitoring and improved export statistics

Under the proposal, there would be regular audits of all infant formula exporters. Currently, exporters that do not have an RMP are not subject to regular verification, but are subject to targeted compliance activities.

Specific HS codes for infant formula products and formulated supplementary foods for young children would enable Customs to assist MPI to check that all exports of these products are from registered exporters.

As an additional benefit, the proposals would enable the collection of more detailed information through AP E-cert and through official export statistics. The collection of HS codes in E-cert would enable MPI to verify official export statistics and to verify that exporters are using the correct HS codes. The collection of HS code data in E-cert would also enable the New Zealand Government to undertake more detailed analysis of exports of infant formula products and formulated supplementary foods for young children than under official export statistics, such as identifying the exporters of the different types of infant formula products. More accurate official export data would enable more accurate analysis by businesses and Government, including, for example, tracking how export markets respond to changes in regulations and policies.

7.2.2 Disadvantages

Additional costs for RMP operators and exporters

There would be costs to RMP operators that export to markets that do not already require a record of market eligibility. These RMP operators would need additional documentation to move all infant formula between premises regardless of intended export market.

There would be additional time and administration costs to exporters exporting infant formula to markets that do not require official assurances, arising from the requirement to use E-cert for infant formula exports to all markets. There would be a charge associated with making export declarations. This would be similar to the charge to apply for export certification.

Transition costs for exporters and importers

There would be some administration costs to exporters and importers from changes to the HS codes for infant formula products and formulated supplementary foods for young children. There may be some confusion about which HS codes to use for a time.

Costs to the Government

The Animal Products Act 1999 limits MPI's ability to cost recover for audits of exporters that do not have an RMP. Therefore, audits of those exporters would be undertaken as part of MPI's targeted compliance and audit activities. There would be costs to MPI for audit of these exporters. MPI intends to make use of existing routine verification of RMP operators where possible to avoid unnecessary duplication in the cost of verification activities. There would be some costs to MPI of providing guidance to industry to promote compliance with the requirements.

Break in statistical data

The statistical data for infant formula products and formulated supplementary foods for young children under the new HS codes would not be exactly comparable against the data under the current HS codes. As such, there would be a break in the time series data. MPI considers this can be adequately managed, and the total figures for infant formula products and formulated supplementary foods for young children should still be roughly comparable (as most of the data under the current codes is for infant formula products, rather than other products such as adult nutritional powders).

Questions for submitters
9: Are there any other advantages or disadvantages not mentioned?
10: Please provide any indication of the scale of any costs or benefits arising from the proposed requirements.

Appendix 1: Proposed New Harmonised System (HS) Codes

CURRENT HS CODES USED

MPI has identified that the following two HS codes are used for retail-ready and bulk finished infant formula products and formulated supplementary foods for young children exported from New Zealand.

HS code	**Description**	**Product exported the code**	**Total exports, 2013 calendar year (NZ$ million)**
1901.10.09.00C	Malt extract; food preparations of flour, groats, meal, starch or malt extract, not containing cocoa or containing less than 40 % by weight of cocoa calculated on a totally defatted basis, not elsewhere specified or included; food preparations of goods of headings 04.01 to 04.04, not containing cocoa or containing less than 5 % by weight of cocoa calculated on a totally defatted basis, not elsewhere specified or included: Preparations for infant use, put up for retail sale: Other	Retail infant formula, follow-on and formulated supplementary foods for young children.	$446
1901.90.09.28B	Malt extract; food preparations of flour, groats, meal, starch or malt extract, not containing cocoa or containing less than 40 % by weight of cocoa calculated on a totally defatted basis, not elsewhere specified or included; food preparations of goods of headings 04.01 to 04.04, not containing cocoa or containing less than 5 % by weight of cocoa calculated on a totally defatted basis, not elsewhere specified or included: Other:	Bulk infant formula, some formulated supplementary foods for young children (retail and bulk), adult nutritional powders	$272

PROPOSAL TO CHANGE THE HS CODES

MPI would work with Customs to change the New Zealand HS codes for exports and imports of infant formula products and formulated supplementary foods for young children. MPI would seek specific HS codes to cover:

- dairy-based infant formula for retail use (containing cocoa or not);
- dairy-based follow-on formula and formulated supplementary foods for young children for retail use (containing cocoa or not);
- dairy-based infant formula not for retail sale (containing cocoa or not); and
- dairy-based follow-on formula and formulated supplementary foods for young children not for retail sale (containing cocoa or not).

We have proposed new HS codes and descriptions to achieve this in the sections below, with input from Customs. Customs will provide the final appropriate coding and will make the final decision on appropriate wording.

The descriptions provided are indicative only, but capture the intent of the proposal to change the HS codes. MPI and Customs aim to define the descriptions for the proposed new HS codes so that, as far as practicable, only the correct products will meet them.

Implementing the proposal

It is difficult to collect separate export data on infant formula, follow-on formula and formulated supplementary foods for young children as there are differences in international standards and countries' national standards for these products. For instance, the Codex Standards (harmonised international food standards) have two categories: infant formula (0 - 12 months) and follow-up formula (6 - 36 months), while the Australia New Zealand Food Standards Code has three categories: infant formula (0 - 6 months), follow-on formula (6 – 12 months) and formulated supplementary foods for young children (one to three years). The age ranges for different companies' infant formula products and formulated supplementary foods for young children can also vary, particularly for young children.

Therefore, we propose to use two categories for the purpose of defining new HS codes: infant formula in one category, and follow-on formula and formulated supplementary foods for young children in another category. This is to be achieved by defining the minimum age the product is suitable for. The use of minimum ages takes into account that vulnerability decreases with age, so most emphasis should be placed on separating out infant formula, which can be the sole source of nutrition, from the other products. The use of two age categories is also broadly consistent with the relevant Codex Standards.

The HS codes and descriptions for infant formula, follow-on formula and formulated supplementary foods for young children must also fit within The Working Tariff Document of New Zealand, in line with New Zealand's obligations under the International Convention on the Harmonized Commodity Description and Coding System. The Harmonised Systems Committee of the World Customs Organisation has defined infants as covering the ages 0 to 36 months of age. Therefore, in the HS codes descriptions only infants are referred to, but for the purposes of Tariff classification, this covers products suitable for use up to 36 months of age (i.e. follow-on formula and formulated supplementary food for young children).

As a result, the HS code descriptions are different to the definitions for infant formula, follow-on formula and formulated supplementary foods for young children used in the proposed export (GREX) Notice outlined in this paper. There is no single set of consistent definitions for infant formula, follow-on formula and formulated supplementary foods for

young children used internationally. It should be noted that the HS codes are used to collect data and do not define products to be covered by regulation.

Dairy-based infant formula, follow-on formula and formulated supplementary foods for young children for retail use

We propose that the current retail codes, 1901.10.01.00B (containing cocoa) and 1901.10.09.00C (not containing cocoa), are each split into four new codes: one for retail-ready infant formula, one for retail-ready follow-on formula and formulated supplementary foods for young children, and two for remaining products.

New suggested codes and descriptions	**Details**
New subheading: "Of goods of headings 04.01 to 04.04:"	
1901.10.01.10 (containing cocoa) 1901.10.09.10 (not containing cocoa) "Infant formula, suitable for use from birth."	These codes are designed to capture dairy-based infant formula for retail sale. They include liquid infant formula.
1901.10.01.15 (containing cocoa) 1901.10.09.15 (not containing cocoa) "Follow-on formula and other formulated supplementary foods, suitable for infants aged 6 months or older."	These codes are designed to capture dairy-based follow-on formula and formulated supplementary foods for young children for retail sale. They include liquid follow-on formula and other supplementary foods for young children.
1901.10.01.19 (containing cocoa) 1901.10.09.19 (not containing cocoa) "Other".	These codes are designed to capture other dairy foods for infants and young children for retail sale i.e. non-supplementary dairy foods for infants.
1901.10.01.29 (containing cocoa) 1901.10.09.29 (not containing cocoa) "Other"	These codes are designed to capture non-dairy foods for infants and young children for retail sale, such as infant cereal.

Dairy-based infant formula, follow-on formula and formulated supplementary foods for young children, not for retail sale

We propose that the not for retail sale codes, 1901.90.01.00A and 1901.90.09.28B, are each replaced by five new codes: one for infant formula not for retail sale, one for follow-on formula and formulated supplementary foods for young children not for retail sale, and three for the remaining products.

New suggested code and descriptions	**Details**
New subheading: "Preparations for infant use, of goods of headings 04.01 to 04.04:"	
1901.90.01.10 (containing cocoa)	These codes are designed to capture dairy-

1901.90.09.21 (not containing cocoa) "Infant formula, suitable for use from birth."	based infant formula not for retail sale (i.e. bulk finished, fully formulated infant formula).
1901.90.01.15 (containing cocoa) 1901.90.09.25 (not containing cocoa) "Follow-on formula and other formulated supplementary foods for infants aged 6 months or older."	These codes are designed to capture dairy-based follow-on formula and formulated supplementary foods for young children not for retail sale (i.e. bulk finished formula).
1901.90.01.19 (containing cocoa) 1901.90.09.29 (not containing cocoa) "Other".	These codes are to cover other dairy products for infants and young children not for retail sale i.e. non-supplementary dairy foods for infants.
New subheading: "Other"	
1901.90.01.21 (containing cocoa) 1901.90.09.31 (not containing cocoa) "Food preparations of goods of headings 04.01 to 04.04"	These codes are to cover dairy products not for infants (whether or not for retail sale).
1901.90.01.29 (containing cocoa) 1901.90.09.39 (not containing cocoa) "Other"	These codes are designed to cover non-dairy products not for infants (whether or not for retail sale).

Questions for submitters:
11: Do the above HS code descriptions adequately separate out infant formula, from follow-on formula and formulated supplementary foods for young children in a practical way?

The table below outlines the proposed changes to the HS codes using the basic layout for the New Zealand Tariff document.

Number	Code	Unit	Goods
			Malt extract; food preparations of flour, groats, meal, starch or malt extract, not containing cocoa or containing less than 40 % by weight of cocoa, calculated on a totally defatted basis, not elsewhere specified or included; food preparations of goods of headings 04.01 to 04.04, not containing cocoa or containing less than 5 % by weight of cocoa calculated on a totally defatted
19.01			**basis, not elsewhere specified or included:**
			- Preparations for infant use, put up for
1901.10			**retail sale:**

1901.10.01			- - Containing cocoa
			. . . Of goods of headings 04.01 to 04.04:
			. . . . Infant formula, suitable for use from
	10	kg	birth
			. . . . Follow-on formula and other formulated supplementary foods, suitable for
	15	kg	infants aged 6 months or older
	19	kg	. . . . Other
	29	kg	. . . Other.
1901.10.09			- - Other
			. . . Of goods of headings 04.01 to 04.04:
			. . . . Infant formula, suitable for use from
	10	kg	birth
			. . . . Follow-on formula and other formulated supplementary foods, suitable for
	15	kg	infants aged 6 months or older
	19	kg	. . . . Other
	29	kg	. . . Other
1901.20			No change to this area
1901.90			- Other:
1901.90.01			- - Containing cocoa
			. . . Preparations for infant use, of goods of headings 04.01 to 04.04:
			. . . . Infant formula, suitable for use from
	10	kg	birth
			. . . . Follow-on formula and other formulated supplementary foods, suitable for
	15	kg	infants aged 6 months or older
	19	kg	. . . . Other
			. . . Other:
			. . . . Food preparations of goods of headings 04.01 to
	21	kg	04.04
	29	kg	. . . . Other
1901.90.09			- - Other
			. . . Malt extract:
			. . . . For use in home brewing:
	03G	kg	. . . . . In retail packs
	05C	kg	. . . . . In other packs
	12F	kg	. . . . For use in commercial brewing
	18E	kg	. . . . Other
			. . . Preparations for infant use, of goods of headings 04.01 to 04.04:
	21	kg	. . . . Infant formula, suitable for use from

		birth
		. . . . Follow-on formula and other formulated supplementary foods, suitable for
25	kg	infants aged 6 months or older
29	kg	. . . . Other
		. . . Other:
		. . . . Food preparations of goods of headings 04.01 to
31	kg	04.04
39	kg	. . . . Other

Animal Products Notice

Animal Products Notice: Export Requirements - Infant Formula Products and Formulated Supplementary Foods for Young Children

.

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TITLE

Animal Products Notice: Export Requirements - Infant Formula Products and Formulated Supplementary Foods for Young Children

COMMENCEMENT

This Animal Products Notice comes into force on ..

ISSUING AUTHORITY

This Animal Products Notice is issued under sections 60 and 167(1)(ja) of the Animal Products Act 1999, being satisfied of the matters in section 60(1)(a) and (c) of that Act.

Dated at Wellington this ... day of 2014

Paul Dansted
Manager, Food Assurance
Ministry for Primary Industries
(acting under delegated authority of the Director General)
A copy of the instrument of delegation may be inspected at the Director General's office.

Contact for further information
Ministry for Primary Industries (MPI)
Standards Branch
Food Assurance
PO Box 2526,
Wellington 6140

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Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

Purpose

This Notice is issued for the purposes of facilitating access to overseas markets and for safeguarding assurances provided by New Zealand in respect of the export of dairy based Infant Formula Products and Formulated Supplementary Foods for Young Children. To achieve these purposes, this Notice specifies requirements for ensuring that-

(a) Infant Formula Products and Formulated Supplementary Foods for Young Children are eligible for export;

(b) the movement of Infant Formula Products and Formulated Supplementary Foods for Young Children between premises prior to export is fully traceable;

(c) Infant Formula Products and Formulated Supplementary Foods for Young Children can be effectively recalled if necessary; and

(d) dairy operators and exporters have appropriate systems in place to cover product eligibility, traceability, and recall.

Background

(1) Infant Formula Products, Formulated Supplementary Foods for Young Children, as well as those dairy ingredients specifically used to manufacture them, are regarded internationally as particularly sensitive commodities.

(2) There is an expectation that New Zealand would implement enhanced traceability and assurance controls irrespective of any additional consignment-specific official assurances provided. Such controls need to ensure that all parties in the manufacture and distribution chain-

  (a) are held accountable for both the fitness for purpose and compliance of all products intended for export; and

  (b) play an appropriate role should any problems be detected.

(3) This Notice sets out such controls.

Who should read this Animal Products Notice?

This notice should be read by-

(a) all operators who process Infant Formula Products and Formulated Supplementary Foods for Young Children intended for export; and

(b) all exporters who intend to export Infant Formula Products and Formulated Supplementary Foods for Young Children.

Why is this important?

(1) Operating other than in accordance with this notice will result in a product not being eligible for export.

(2) For the purposes of section 135(1)(c) of the Animal Products Act 1999, a failure to comply with this Notice, without reasonable excuse, is an offence.

Contacts

(1) For all matters relating to the operation of this Notice, please dial MPI's general enquiry line 0800 00 83 33 (local) and request to be put through to the Food Assurance Team.

(2) Alternatively, you can write to us on the address provided at the bottom of page 1 of this Notice.

Other information

This Notice does not contain an exhaustive list of prerequisite requirements for the export eligibility of Infant Formula Products and Formulated Supplementary Foods for Young Children. It is the responsibility of dairy operators and exporters to ensure familiarity with the Animal Products Act 1999 and regulations and notices issued under it that are of relevance to the subject matter.

Part 1: General provisions

1.1 Application

(1) Subject to sub clauses 3, 5, and 6, this notice applies to-

(a) Infant Formula Products and Formulated Supplementary Foods for Young Children intended for export for the purpose of sale, regardless of whether or not official assurances are required;

(b) any person who processes Infant Formula Products or Formulated Supplementary Foods for Young Children intended for export for the purpose of sale, regardless of whether or not an official assurance is required; and

(c) any person who intends to export Infant Formula Products or Formulated Supplementary Foods for Young Children for the purpose of sale, regardless of whether or not an official assurance is required.

(2) All references to Infant Formula Products and Formulated Supplementary Foods for Young Children in this Notice only apply to the retail ready dairy based versions of those products.

(3) This Notice does not apply to any Infant Formula Products or Supplementary Foods for Young Children that are exported for the purpose of personal consumption.

(4) The exportation of Infant Formula Products or Formulated Supplementary Foods for Young Children in a quantity that is more than that which a reasonable person would consider to be reasonably required for the purpose of personal consumption must, unless the contrary is proved, be treated as an exportation of the Infant Formula Products or Formulated Supplementary Foods for Young Children for the purpose of sale.

(5) Part 3 of this Notice does not apply to Infant Formula Products and Formulated Supplementary Foods for Young Children requiring official assurances, which are subject to Part 4 of the Animal Products (Official Assurances Specifications – Dairy Products) Notice 2014.

(6) Part 4 of this Notice does not apply to Infant Formula Products and Formulated Supplementary Foods for Young Children requiring official assurances.

1.2 Incorporation of material by reference

The E-cert Help File is incorporated into this Notice by reference for the completion of eligibility documentation and export certificate requests electronically generated in E-cert.

1.3 Definitions

(1) In this Notice, unless the context otherwise requires,-

Act means the Animal Products Act 1999, unless otherwise stated;

authorised person means a person designated by the Director-General under section 65 of the Act as an authorised person for the purposes of issuing official assurances for dairy product;

authorised user means a person that has been given authority by the Director-General to access E-cert;

consignment means the goods identified in one bill of lading;

dairy based means that an Infant Formula Product or Formulated Supplementary Food for Young Children contains, as its predominant protein constituent, protein derived or processed from milk extracted from a milking animal such as a cow, goat or sheep;

E-cert means the electronic programme provided by the Director-General for the processing of eligibility declarations, eligibility documents, and export certificates, and includes the E-cert Help File in that programme;

E-cert Help File means the document prepared by MPI, which sets out guidance and requirements to authorised users for the raising and issuing of eligibility declarations, eligibility documents, and export certificates;

Eligibility Declaration (EDec) means a document raised by an operator and automatically approved by E-cert, which confirms the eligibility for export of any Infant Formula Products or Formulated Supplementary Foods for Young Children;

Eligibility Document (ED) means a document raised by an operator and approved by an official assurance verifier, which confirms the eligibility for export of any Infant Formula Products or Formulated Supplementary Foods for Young Children;

Export certificate means the form of an official assurance for dairy product determined by the Director-General pursuant to section 62 of the Act;

Export Declaration Form means the form associated with a consignment of Infant Formula Products or Formulated Supplementary Foods for Young Children that is to be submitted by an exporter and approved by an authorised person before the consignment can be exported;

Formulated Supplementary Food means a food specifically designed as a supplement to a normal diet to address situations where intakes 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;

Infant Formula Product means a product based on milk or other edible food constituents of milk origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants, and includes infant formula, follow-on formula, lactose-free formula and low lactose formula, and pre-term formula;

> infant formula means 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;
>
> 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;
>
> lactose-free formula and low lactose formula means infant formula products which satisfy the needs of lactose intolerant infants;
>
> pre-term formula means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight;

issued in relation to the issuing of an export declaration form, means signed by an authorised person; or in the case of E-cert documents means, approved by an authorised person; and issue has a corresponding meaning;

MPI means the Ministry for Primary Industries;

mobile operation means a land based premises that is able to be transported to another physical location;

official assurance verifier means a person recognised under section 103 of the Act to undertake official assurance verification and includes an MPI Animal Product Officer; and verifier has a corresponding meaning;

overseas market access requirement (OMAR) means an export requirement specific to an identified

overseas market or markets issued by notice under section 60 of the Act;

process includes extract, manufacture, pack, preserve, transport, and store;

raise means to complete and submit an eligibility declaration, eligibility document or an export declaration form in E-cert in accordance with the E-cert Help File;

records means any record that exists in written form, and can be either paper based or electronic;

RMP means risk management programme; and

specifications means any specification issued by notice by the Director-General under the Act, including export requirements.

(2) Unless the context otherwise requires, any term or expression that is defined in the Animal Products Act 1999, or regulations made under that Act and used, but not defined, in this Notice has the same meaning as in that Act or regulations.

Part 2: Requirements on operators and exporters

2.1 Object of this Part

The object of this part is to set out the obligations of-

(a) operators of RMP premises where Infant Formula Products and Formulated Supplementary Foods for Young Children intended for export are processed; and

(b) exporters of Infant Formula Products and Formulated Supplementary Foods for Young Children.

2.2 Requirements on operators

An RMP operator intending to process Infant Formula Products or Formulated Supplementary Foods for Young Children for export must-

(a) ensure that the Infant Formula Products or Formulated Supplementary Foods for Young Children are eligible for export according to Part 3 of this Notice; and

(b) incorporate procedures as part of their RMP to ensure compliance with the requirements of this Notice; and

(c) record in inventory records information relating to the usage and inward and outward movement of Infant Formula Products and Formulated Supplementary Foods for Young Children to ensure traceability; and maintain this information for a minimum of 4 years.

2.3 Requirements on exporters

(1) An exporter intending to export Infant Formula Products or Formulated Supplementary Foods for Young Children must ensure that-

(a) only Infant Formula Products or Formulated Supplementary Foods for Young Children that comply with Part 3 of this Notice are presented for export; and

(b) any specific requirements from the importing country notified under section 60 of the Act regarding imported Infant Formula Products or Formulated Supplementary Foods for Young Children and its certification are be complied with; and

(c) Eligibility Declarations and Eligibility Documents are not sent to foreign governments, overseas agents or importers except where authorised by the Director-General; and

(d) records of commercial transactions in relation to all consignments of Infant Formula Products or Formulated Supplementary Foods for Young Children they export are maintained for a minimum of 4 years.

(2) For the purpose of sub clause (1)(d) any such records must, at a minimum, include the-

(a) date of export; and

(b) country of destination; and

(c) full description of the product being exported (including brand name); and

(d) quantity of product exported; and

(e) name of third party client if exporting on behalf of a person or business who is not a registered exporter.

(3) Every exporter must ensure that for every exported consignment of Infant Formula Products or Formulated Supplementary Foods for Young Children, there is a person at the importing country who can be responsible in the event of a product recall.

(4) For the purpose of sub clause (3), exporters must maintain records containing the name and contact details of such person and must be able to provide this information to the Director-General when required.

Part 3: Export eligibility

3.1 Object of this Part

(1) The object of this Part is to specify requirements that must be met in relation to all Infant Formula Products and Formulated Supplementary Foods for Young Children in order for them to be eligible for export.

(2) Unless expressly stated in this notice, nothing under this part affects any other eligibility requirements issued by notice by the Director-General under section 60 of the Act.

3.2 Eligibility requirements

(1) To be eligible for export, Infant Formula Products and Formulated Supplementary Foods for Young Children must at all times-

(a) be processed under the control and within the scope of a registered RMP;

(b) be processed according to specifications; and

(c) be accompanied by an Eligibility Declaration or Eligibility Document when transferred from one premises to another as specified under Part 4 of this Notice.

(2) In the case of transport between premises, Infant Formula Products and Formulated Supplementary Foods for Young Children may be transported under a registered transport operating under a Regulated Control Scheme.

(3) Infant Formula Products and Formulated Supplementary Foods for Young Children are not eligible for export if-

(a) the Infant Formula Products and Formulated Supplementary Foods for Young Children are processed outside the control and scope of a registered RMP; or

(b) the Infant Formula Products and Formulated Supplementary Foods for Young Children are transferred from one premises to another without an Eligibility Declaration or Eligibility Document being made available in accordance with Part 4 of this Notice; or

(c) the Infant Formula Products or Formulated Supplementary Foods for Young Children are processed at a receiving premises without the Eligibility Declaration or Eligibility Document being available to the operator or official assurance verifier of the receiving premises, as required by sub clause 4.5(1); or

(d) the export declarations associated with those Infant Formula Products and Formulated Supplementary Foods for Young Children have not been approved by an authorised person.

Part 4: Traceability Requirements

4.1 Object of this Part

The object of this part is to demonstrate, through traceability documentation generated within E-cert, that-

(a) all Infant Formula Products or Formulated Supplementary Foods for Young Children intended for export are processed only within premises operating under a registered RMP; and

(b) the traceability of all Infant Formula Products or Formulated Supplementary Foods for Young Children intended for export is established at all stages of production, processing, and distribution.

4.2 Traceability documentation – Eligibility Declarations and Eligibility Documents

(1) RMP operators must ensure that all Infant Formula Products or Formulated Supplementary Foods for Young Children intended for export are associated with an Eligibility Declaration or Eligibility Document electronically raised in E-cert in accordance with sub clause (4) whenever those products are -

(a) transferred between premises; or

(b) transferred to the exporter, or between exporters; or

(c) sent directly to a port or airport facility for export.

(2) Despite sub clause (1), Eligibility Declarations and Eligibility Documents are not required for the transfer of Infant Formula Products or Formulated Supplementary Foods for Young Children –

(a) to or from vehicle docking facilities (VDFs); or

(b) between premises with multiple RMPs, owned or occupied by the same operator and situated within the same boundary fence with an inventory control system in place that provides for adequate traceability equivalent (in the view of the official assurance verifier) to that provided for in an Eligibility Declaration or Eligibility Document, and if the transfer is under the direct control of the operator; or

(c) between RMP operators that are directly adjoining and managed by a common managerial structure; with an inventory control system in place that provides for adequate traceability equivalent (in the view of the official assurance verifier) to that provided for by an Eligibility Declaration or Eligibility Document, and if the transfer is under the direct control of the operator.

(3) The exemption in sub clause (2)(c) does not apply to mobile operators.

(4) Eligibility Declarations or Eligibility Documents must be-

(a) raised by the operator of the consigning premises; and

(b) accessible in E-cert to the operator of the receiving premises within 3 working days of the products' departure from the consigning premises.

(5) Where an Eligibility Declaration or Eligibility Document is not accessible in E-cert within 3 working days, the operator must promptly notify the official assurance verifier and explain the reason for the delay.

4.3 Preparation of Eligibility Declarations and Eligibility Documents

(1) Eligibility Declarations and Eligibility Documents must only be raised by operators who have been granted access to E-cert in accordance with Part 6 of this notice.

(2) Eligibility Declarations and Eligibility Documents must be raised in accordance with the E-cert Help File.

(3) Where an operator is granted access in accordance with sub clause 6.2(2) to raise Eligibility Declarations, that operator may raise Eligibility Documents in place of Eligibility Declarations at any time.

(4) Eligibility Documents raised by an operator may only be issued by a recognised agency verifier who has current first-hand knowledge of the operator's business so as to confirm that the details provided in the Eligibility Documents are complete and accurate.

4.4 Management of Eligibility Declarations and Eligibility Documents

The operator must have a system to show any movement of Infant Formula Products or Formulated Supplementary Foods for Young Children from the incoming Eligibility Declaration or Eligibility Document to the outgoing Eligibility Declaration or Eligibility Document.

4.5 Receipt of Eligibility Declarations and Eligibility Documents

(1) The Eligibility Declaration or Eligibility Document must be in approved state before the Infant Formula Products or Formulated Supplementary Foods for Young Children concerned are:

(a) processed at the receiving premises; or

(b) despatched from the receiving premises, but not processed at that premises.

(2) For the purposes of sub clause (1) the word "processed" does not include refrigeration or other means of preservation and storage necessary to ensure that the Infant Formula Products or Formulated Supplementary Foods for Young Children can be held without deterioration.

(3) An operator that receives a consignment of Infant Formula Products or Formulated Supplementary Foods for Young Children without an Eligibility Declaration or Eligibility Document must identify and segregate that consignment from all other Infant Formula Products or Formulated Supplementary Foods for Young Children at the premises.

4.6 Amendment of Eligibility Declarations and Eligibility Documents

Any amendment of Eligibility Declarations or Eligibility Documents must be carried out in accordance with the procedure set out in the E-cert Help File.

Part 5: Export Requirements

5.1 Object of this Part

The object of this part is to ensure that exporters only export Infant Formula Products and Formulated Supplementary Foods for Young Children that comply with the eligibility and traceability requirements of this notice by-

(a) ensuring that MPI is made aware, through the submission of export declaration form, of every consignment of Infant Formula Products or Formulated Supplementary Foods for Young Children that the exporter is intending to export; and

(b) ensuring that all export declaration forms are based on an Eligibility Declaration or Eligibility Documents from the operator of the last premises to have control of the product.

5.2 Export declaration form

(1) An exporter must raise an Export Declaration Form in E-cert for every consignment of Infant Formula Products or Formulated Supplementary Foods for Young Children that the exporter is intending to export.

(2) An exporter must not export any consignment of Infant Formula Products or Formulated Supplementary Foods for Young Children until the associated Exporter Declaration Form has been approved by an authorised person.

(3) An Export Declaration Form may only be raised by an exporter who has been granted access to E-cert in accordance with Part 6 of this notice.

5.3 Preparation of Export Declaration Forms

(1) Export Declaration Forms must be raised in E-cert in accordance with the E-cert Help File.

(2) In raising an Export Declaration Form, an exporter must ensure that-

(a) the consignor is a New Zealand exporter or the New Zealand agent for a foreign exporter and their full name and physical address and identifier as appear in the exporter register are included in the form.

(b) the Export Declaration Form is raised correctly;

(c) the Export Declaration form is based on an incoming Eligibility Declaration or Eligibility Document, which must have been raised by the operator of the last premises to have control of the Infant Formula Products or Formulated Supplementary Foods for Young Children before the products were transferred to the exporter or directly to the port or airport facilities for export.

5.4 Approval of Export Declaration Forms

(1) An authorised person may only approve an Export Declaration Form if-

(a) the form is supported by the appropriate Eligibility Declaration or Eligibility Document; and

(b) where the form is supported by an Eligibility Declaration, the authorised person is also an official assurance verifier who has current firsthand knowledge of the on-site operation of the premises from which the Eligibility Declaration originated to be able to state that the information on the form is complete and accurate.

(2) An authorised person must not approve an Export Declaration Form-

(a) if the information provided by the exporter is known by the authorised person to be incomplete, inaccurate, or, otherwise not in accordance with any requirement of the Act; and

(b) if the form has been altered or modified in any way other than in accordance with this Notice or the E-cert Help File.

Part 6: Access to E-cert

6.1 Object of this part

The object of this part to specify the process by which an operator or an exporter may be granted access to E-cert for the purpose of raising Eligibility Declarations, Eligibility Documents or Export Declaration Forms as required by this Notice.

6.2 E-cert approval process

(1) An operator or exporter who wishes to access E-cert for the purpose of this notice must apply to the Director-General in the manner and form required by the Director-General.

(2) The Director-General may decide the scope of access granted to an applicant, having had regard to the nature of the applicant's business and the knowledge possessed by the applicant in relation to that business.

(3) Operators and exporters who are granted approval by the Director-General to access and use E-cert for the purpose of this notice must comply with the relevant terms and conditions of use of E-cert.

6.3 Authority to raise Eligibility Declarations

(1) An operator or exporter who wishes to obtain authorisation to raise Eligibility Declarations must ensure that he or she-

(a) has current firsthand knowledge of the operation of the premises for which they are responsible; and

(b) understands all relevant requirements issued under the Act, including specifications and export requirements.

(2) Eligibility Declarations may be subject to ongoing desktop verification by official assurance verifiers to ensure accuracy and truthfulness.

(3) An operator or exporter who does not have current firsthand knowledge of the operation of the premises for which they are responsible must only raise Eligibility Documents.

Part 7: Verification requirements

7.1 Object of this Part

(1) The object of this part is to specify the frequency and intensity of verification to which exporters and operators who deal Infant Formula Products or Formulated Supplementary Foods for Young Children may be subject.

(2) This part also sets out the applicable corrective measures that may be imposed where non-compliances are detected.

7.2 Verification of exporters

An exporter's compliance with this notice will be subject to verification by an official assurance verifier as specified by the Director-General

(a) initially at a time prior or subsequent to when the exporter exports the first consignment; and

(b) at any other times after the first verification as will be decided by the Director-General in accordance with sub clause (2).

(c) Where the exporter is also an operator then the verification may take place at the same time as the operator verification.

(1) When deciding the frequency of audits, the Director-General may have regard to-

(c) the nature of the exporter's business;

(d) intelligence gathered by MPI regarding the exporter;

(e) the exporter's compliance record; and

(f) the availability of funds for verification purposes.

(2) Exporters of Infant Formula Products or Formulated Supplementary Foods for Young Children must take all reasonable steps to accommodate any verification by animal products officers as required under this part.

(3) Any verification carried out under this part must ensure that-

(a) export declaration forms raised by exporters were raised in accordance with the requirements of Part 4 of this Notice; and

(b) exporters comply with the requirements set out under clause 2.3 of this notice.

(c) exporters are aware of and in compliance with their duties as exporters as specified in Section 51 of the Animal Products Act 1999.

7.3 Verification of operators

(1) Official assurance verifiers must verify operators' compliance with this notice as part of their routine on-site verification audits.

(2) The official assurance verifier must check-

(a) the operator's compliance with the requirements of clause 2.2; and

(b) all supporting documentation in relation to a selection of Eligibility Declarations, which have been raised by operators due to the requirements of this Notice.

(3) For the purpose of sub clause (2)(b), a verification check must ensure that supporting documentation-

(a) identifies lots; and

(b) has traceability via the inventory control system; and

(c) has traceability to incoming eligibility declarations; and

(d) includes examination of eligibility declarations to verify that there is sufficient information to support the submission of Export Declaration Forms.

(4) In addition to sub clause 3, a verifier may at any time, where there is a reasonable ground for doing so, verify documentation supporting an Export Declaration Form.

7.4 Non-compliance

(1) Where non-compliances are detected during a verification check, the official assurance verifier or animal products officer may increase the frequency of verification as he or she deems appropriate in light of the severity and frequency of the non-compliance.

(2) If the type or frequency of non compliance is of a significant nature or it has not been possible to audit the Exporter after reasonable efforts, the official assurance verifier may make a recommendation in writing to the Director-General in respect of the person's suitability to raise eligibility documentation and Export Declaration Forms in E-cert.

(3) The Director-General may, having had regard to the recommendation of the official assurance verifier,-

(a) remove the authorised user's access to raise Eligibility Declarations and require the user to raise Eligibility Documents only; or

(b) remove the authorised user's access to raise export declaration forms; or

(c) require the authorised user to undergo further training; or

(d) suspend the authorised user's access to E-cert altogether.

(4) Where the Director-General proposes to make a decision under sub clause 3, he or she may give written notice of the fact to the operator or exporter, specifying-

(a) the reason for the decision; and

(b) the period of any restriction or suspension; and

(c) the date on which or time at which the decision commences; and

(d) any conditions or requirements in relation to the decision.

(5) The Director-General may cancel a decision notice at any time if he or she is satisfied that the person is fit to regain his or her authorised user status.

(6) Notwithstanding sub clause 3, if the nature of the non-compliance is deemed significant enough, the Director General may do any or all of the following-

(a) direct the exporter to suspend any or all export operations; or

(b) suspend the registration of the exporter in accordance with Section 58 of the Act; or

(c) cancel the registration of the exporter in accordance with Section 58 of the Act.