MPI Guidance for filling out the Certification and Accreditation Administration of the People's Republic of China (CNCA) "Imported Milk-based Infant and Follow on Formula (Formula Milk Powder and Liquid) Overseas Production Enterprise Registration Application Form"

Introduction

This guidance has been developed to aid filling out the CNCA application form for infant formula manufacturers. This form is available in English from the CNCA website at: http://www.cnca.gov.cn/rjwzcjgb/xgxz/jkspgwscqyzcxgxz/jkrpjwscqyzcxgwj/index.shtml.

MPI has sought clarification from CNCA for some aspects, and so we expect there will be future updates to this guidance.

It is important that the forms are filled out correctly and consistently. Consistency within and across forms is important to avoid processing delays by Chinese authorities.

Who should fill out the form?

This form should be filled out by all final manufacturers of finished infant and toddler formula products for export to China. An application form should be completed for each manufacturing premises, even if these are owned and operated by the same company.

If a manufacturing premises is only packing finished infant formula, then both the packing premises and the premises that produced and supply the finished bulk product should fill in separate application forms.

Premises that only manufacture ingredients or 'infant formula base powder' for further processing in New Zealand (i.e. mixing with other ingredients) or for export to China as an ingredient for further processing (i.e. mixing with other ingredients) do not need to fill in the form. These premises will be required to be listed under the general dairy listing process. MPI advice on the general dairy listing process will be released in the very near future.

Premises that expect to be manufacturing finished infant formula products for export to China, but have not yet begun production, should also fill out and submit the form, noting when production is expected to commence. Any information about prospective brands to be manufactured should also be included in the form in the appropriate section.

If your company is currently undertaking capital developments, such as new equipment installation or plant expansion, we recommend indicating this in the form, including the date on which you expect production using the new equipment/premises to commence.

CNCA has advised that only those brands listed by manufacturers in the application form will be permitted to be imported into China. Brand owners and exporters that do not manufacture infant

formula do not need to fill in the form. However, MPI strongly recommends that exporters and brand owners work with their manufacturers to ensure their brand information is included and accurate in the application form.

Process for submitting forms

Forms should be filled out by operators and provided to Recognised Agencies for verification. If satisfied, Recognised Agencies will endorse the form by way of separate letter and provide the completed form and endorsement letter directly to MPI (cc'd to the operator). MPI will check the form, and if satisfied, will provide the form to CNCA.

Enquiries

Enquiries and clarification in relation to this guidance should be provided to market.access@mpi.govt.nz.

Disclaimer: The guidance provided in this document is the best available to MPI at the date of this version. The guidance will be updated when new information or clarification becomes available. It does not represent official guidance from the Chinese Government. If there is doubt about any of the provisions in the CNCA application form, the Chinese language version is the authoritative version.

Part I: General Information About the Enterprise

Part A. General Information

1. **Production Enterprise**

Registration name: This should be the name of the premises manufacturing the finished products, as used on export certificates and on the RMP.

Registered address: This should be the street address of the manufacturing premises as per Unique Location Identifier (ULI).

Note: Be aware that China may require this address to be used on labels in the future. The draft amendments to the China Food Safety Law require the manufacturers address to be on the label. If passed, this would likely apply to all imported infant formula.

Registration number: This should be the ULI. Companies with multiple ULIs at a single manufacturing site should only fill in one form for that manufacturing site, but should list all relevant ULIs.

2. **Contact person**: this should be the name and details of the person designated as the RMP operator for the premises, as registered with MPI under the Animal Products and related RMP specifications.

3**. Registration (approval) authority**: This is the "Ministry for Primary Industries"

4. Where the address of the premises is different to the registered company address of the business, this should be clearly set out and the reason for the difference outlined. Contact details for the person(s) with legal responsibility for compliance with New Zealand food safety laws within the business should be identified (for example, this may be the same person described in question 2 but they may be located at a different site).

(Note: information provided here needs to be consistent with any information provided in Part II of the application form).

5. **Date plant established**: This should be the date of registration of the ULI with MPI.

6. **Total area:** provide details as set out in the RMP.

7. **Total building area**: provide details as set out in the RMP.

8. **Layout**: provide details as set out in the RMP. Drawings of the layout of the buildings, the division of high care areas, storage areas, people flow and logistics should be provided as attachments.

9. **Name of products to be exported to China**

Note: CNCA has advised MPI that brands must be listed by manufacturers in order to be imported into China. It is critical that manufacturers work with exporters and brand owners to ensure that brand information is accurately described in the application form. Infant formula brands in development should

also be included. However, operators should note public announcements by Chinese authorities of their intention to limit the number of infant formula brands on the Chinese markets. Businesses planning the introduction of new brands need to take the evolving Chinese regulatory environment into account. There will be the ability to request amendments to registration after the 1 May 2014 deadline (e.g. to add new brand names to a manufacturer's list). However, we do not have information yet on whether amendments to registration will require audit by Chinese authorities. In light of this uncertainty, businesses should plan for significant time delays in listing new brands for export to China.

Serial number: CNCA advises that this is a sequential number to be used to identify each trade-marked brand that a manufacturer produces (e.g. 1, 2, 3…).

Product type: Use one of the two terms provided: "infant formula milk powder", or "infant formula liquid milk".

Applicable age bracket: provide age range using months, e.g. 0-6 months.

Packaging form: where possible use the suggested wording, and provide additional details about the inner and outer packaging forms (e.g. tins, sachets).

Registered trademark – This refers to the 'trade mark' brand name. Where there are multiple product types under this brand, each product type should be listed (e.g. where there are products for different age ranges under the same brand name). Provide reference to trademark registration with the relevant competent authority.

10. Product quantity: MPI recommends that product quantities should be provided in ton/year for the years 1 December 2011-30 November 2012 and 1 December 2012-30 November 2013. This will enable comparison across producers.

Part B Production Information

1. **Production process**: As noted above, this application form is for final manufacturing premises of finished infant formula. Premises that only pack finished infant formula must also complete the form.

Those premises that only pack finished infant formula and do not undertake any form of blending, should indicate this in this section by including a separate box for 'packaging finished infant formula products produced by another New Zealand infant formula manufacturer'.[1]

Premises that undertake contract packing for other manufacturers, and also blend their own product, should only indicate here which form of blending they undertake (i.e. do not add the separate box referred to above). However, all of the trade-marked products packed at the premises (including those blended and packed, and those packed only) should be identified in Part I(A)(9). Those branded products

[1] If your premises packs finished infant formula imported into New Zealand, please contact MPI for further guidance: market.access@mpi.govt.nz.

that are only packed at the premises should be identified as such in the table in Part I(A)(9) above, and the premises from which the finished product is sourced should be identified in Part I(C)(2) below.

Premises providing finished product for packing at another premises should also list the relevant brand in Part I(A)(9) in their application form, indicating however that this brand is packed by another premises (identified by the relevant ULI).

2. **Production capacity and equipment**: MPI recommends operators provide high level descriptions of their equipment for pasteurization, drying, blending and any other significant processes (e.g. Niro Drier 10MT/hour).

3. **Hygiene and quality management system:** provide the HACCP as per the RMP for the premises.

4. **Isolation and washing (or cleaning) measures**: provide details of these measures.

5. **Environmental monitoring plan and air purity testing plan for cleaning work**: provide pathogen monitoring plan, and attach the two most recent testing reports.

6. **Are there any automatic valve arrays in enterprise's processing workshop?** Read 'workshop' as 'work area'.

When completing the table under this question in relation to CIP: for chemical name, provide both the product trade name and active ingredient.

Under the table include the following text:

> "Please refer to MPI register of Dairy Maintenance Compounds available at http://www.foodsafety.govt.nz/registers-lists/'

We understand that "cleaning effect validation way" refers to the methods or measures used to determine whether the cleaning is effective in meeting relevant outcomes, standards or requirements.

8. Water/ice/steam supply

(1) – (3) Water source**:** if indicating 'water for public use', it may be beneficial to provide local council test reports for reticulated supply, as well as any monitoring conducted by the premises.

Part C. Raw Material Information

1. Please specify the **raw materials** for infant formula dairy products used by the enterprise:

(1) Raw milk: Only use this option if raw milk is processed into infant formula at the premises.

Specify the milk source:

- if you source your milk via the DIRA or similar arrangement from another registered processor select "other milk source" and state:
    - "MPI registered dairy processor" and specify the relationship, length of contract and
    - "managed according to the relevant regulations of New Zealand under a risk management programme registered with MPI
- All forms should include the following text: "Please note: this statement of milk source is accurate for the date this application form was signed. However, for a range of supply and commercial reasons, milk source is subject to change. Any changes must comply with New Zealand law and are recorded in the enterprises risk management programmes for regulatory audit purposes."

(2) Dairy products (whole milk (powder), skimmed milk (powder), whey (powder) etc): use this option if you manufacture infant formula using dairy ingredients, including infant formula 'base' powder, sourced from other processors.

This is for dairy ingredients in their purchased form. Do not break down the description into individual components (e.g. refer to 'nutritional base powder', rather than 'whey protein contained in the nutritional base powder').

In addition, under "Source of raw material", the following qualifying note should be used:

> "Please note: this statement of source of raw material is accurate for the date this application form is signed. However, for a range of supply and commercial reasons ingredient source is subject to change. Under New Zealand law, any changes must be fit for purpose, and comply with the required legislation governing food safety, which also applies to imported raw materials".

Operators that pack infant formula but do not undertake blending of that infant formula on the same premises should indicate here the premises (including ULI) from which the finished bulk infant formula is sourced. This includes finished formula packed on behalf of other manufacturers. See guidance to Part I(B)(1) above.

(2)(1) **Standards for acceptance**: Describe standards of acceptance from inwards good receipt onwards.

(2)(2) **Source of raw material**: Describe the Vendor/Supplier approval system.

Part D: Product Traceability and Recall

1. **Logos, symbols or number** and other items **for traceability** printed on product packages: Specify any traceability information included on consumer packages, including ULI or RMP identification, batch/lot identification, manufacturing or Julian date and unit/sequence identification (as applicable), any other traceability label information including commercial traceability systems (e.g. QR codes).

2. **Product recall system**: detail recall system, as well as any recall simulation activities that are regularly undertaken.

Part E: Product testing

1. **Identify laboratories**: Use the following definitions of laboratories:

- "official testing laboratory" – MPI operated laboratory. This is not likely to apply to any operators.
- "third party testing laboratory" – independent external MPI-recognised and IANZ accredited dairy laboratory (this is the category we would expect most operators will use). If ticking this option please add the text "this laboratory is recognised by MPI and accredited to IANZ for the purposes of dairy product testing".
- "laboratory owned by enterprise" – company laboratory

Following the laboratory name, include the MPI recognition identifier (i.e. L123) and the nature of testing undertaken (eg. Microbiological, Chemical, Functional, or Sensory) and note "refer to MPI register of recognised dairy laboratories" as registered here: http://www.foodsafety.govt.nz/registers-lists/recognised-lab/

Note: MPI will provide an overview of the laboratory testing system used by the New Zealand dairy system in our response to CNCA.

2. **Disposal procedures for non-conforming product**: Identify the system used for disposal and, in the case of dairy material and product deemed non conforming, state "Disposed In accordance with, Animal Products (Disposal of non conforming dairy material or dairy product) Notice 2013".

Part F: Enterprise Location and Plant Environment

1. **Premises location**: as a general guide, use the following definitions:

- "far away" = greater that 1km radius
- "surrounding" = less than or equal to 1km radius

In responding to this question, please also note that environmental hazards are managed under RMPs.

Note: MPI will include a description of New Zealand's environmental protection and resource management regime in our response to CNCA

2. **Pest control**: provide evidence of pest control activity and monitoring.

Part G: Enterprise Statement

1. **Compliance with relevant Chinese laws**, regulations and food safety standards: (Note: this includes existing Chinese standards for labelling).

The "legal representative" is the person in the company who is legally responsible for the production premises, which is the RMP operator or legal delegate as defined under the Animal Products Act and related RMP specifications.

Part H: Confirmation by Competent Authority

The Ministry for Primary Industries is the 'competent authority'. MPI will confirm completed forms that have been verified by Recognised Agencies. Recognised Agencies will provide a letter to MPI setting out endorsement of the information contained in the application form.

Part II: Overview of Enterprise's Export to China

Note: MPI suggests that manufacturers completing this form provide a separate "Part II" section for each exporter and importer they work with. Manufacturers will need to work with brand owners and exporters to ensure the importer information is correct for product manufactured for that brand owner or exporter.

Supply chain accountability for infant formula is a top priority for China. It is important that supply chain information, including the identity of supply chain participants is accurate and verifiable.

Part A: Supply chain relationships

Provide details of arrangements between the parties listed in the question, including long-term arrangements, and any indication of company integration/joint venture etc.

Note: in the case of the New Zealand system, 'the responsible party that exports the products to China' refers to the registered exporter. However, it is important to emphasise that any food safety incidents are the responsibility of the manufacturer and that New Zealand's regulatory system provides the traceability arrangements to enforce this responsibility.

Part B: Import information

1. Importer information: If there is more than one importer of the same export product(s), then details of all relevant importers should be provided.

2. list of trademarks of products to be exported to China.

This refers to the trade-marked 'brand name' of infant formula products, and expands on the information provided at Part I(A)(9). Please ensure the information provided here is consistent.

3. Formulation: provide a list of ingoing ingredients according to the amount of ingredient added for each product as listed above.

Note: we are clarifying with CNCA whether this also includes conformance with regulatory composition standards (e.g. nutrition information panels)

4. Provide information about any **traceability** information (e.g. ULI, RMP number or commercial system) used on the product label for each trade-marked brand. Ensure information is consistent with Part I(D).

5. Provide information about **customer support platform** for product in China.

Note: in China's draft domestic standard for infant formula, enterprises are required to establish a customer complaints/inquiry/support service. It is likely that Chinese authorities will expect similar services to be provided for imported infant formula products

6. Provide details of a **person or legal entity** in China liable and **responsible for undertaking recall** of imported products.

Note: in public statements, Chinese authorities have expressed an expectation that infant formula businesses have the ability to conduct full product recalls and, if necessary provide compensation to affected consumers. China's draft infant formula manufacturing standard includes a requirement that enterprises take out insurance to fund any such incidences. This has not been specified for imported products, but New Zealand operators and exporters should be aware of the context for these questions.

Part B: Export Information

1. **Exporter information**: The details of all exporters that export trade-marked brands produced by the manufacturer should be included in this section. The person with legal responsibility as registered exporter should be identified.

The **exporter name** should be identical to that registered with MPI (see: http://www.foodsafety.govt.nz/registers-lists/exporters-dairy/index.htm)

The **exporter address** should be identical to the physical address registered with MPI.

2. **Product information**

The trade-marked brand information should be consistent with Part I(A)(9) and Part II(B)(2) Import information.