Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

8 February 2017

Infant Formula Dairy Submission
Ministry for Primary Industries
PO Box 2526
Wellington 6140
NEW ZEALAND

Email: animal.products@mpi.govt.nz

Dear Sir/Madam

Thank you for the opportunity to comment on the ***Draft Animal Products Notice – Manufacture of Dairy Based Infant Formula and Formulated Supplementary Foods for Young Children***. INC members have been pleased to have been involved in the developmental work associated with this Notice and we are especially pleased to see many of our concerns addressed in the Notice.

Comments on this 9 January 2017 consultation draft are in the attached. We would be happy to discuss any of these points with you or answer questions about the issues that our comments may raise.

Yours sincerely

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Chief Executive

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SUBMISSION ON DRAFT ANIMAL PRODUCTS NOTICE – MANUFACTURE OF DAIRY BASED INFANT FORMULA AND FORMULATED SUPPLEMENTARY FOODS FOR YOUNG CHILDREN

BY AUSTRALIA NEW ZEALAND INFANT NUTRITION COUNCIL

Executive Summary

1. INC welcomes this penultimate draft of the Animal Products Notice – Manufacture of dairy-based infant formula and formulated supplementary foods for young children. We congratulate the Ministry for Primary Industries (MPI) on a fulsome consultation process that has resulted in the publication of this draft Notice and make the following few comments.

2. INC considers the Notice should be clear about New Zealand's recommendations for infant feeding, published by the Ministry of Health, which draw on the recommendations of the World Health Organisation (WHO). Reference to these is important in a Notice that is relevant for both domestic and export product.

3. In several areas in the Notice, there is significant confusion about audits and verifications and auditors and verifiers. The distinction of these concepts is fundamental to the structure of Animal Products Act 1999 and to the roles ascribed to players described in the MPI regulatory model. There is a very clear functional difference between 'audit' and 'verification', and between the role of verifiers who perform verifications and the role of the regulator in performing audits. It is important that this confusion in the Notice is addressed and INC has made several recommendations in relation to a number of clauses for this purpose.

4. There is a significant inter-relationship between the application of the Animal Products Act 1999 and the Australia New Zealand Food Standards Code (Food Standards Code). Manufacturers generally have to comply with both. It is therefore vital that relevant definitions in this Notice align with the definitions that have been included in the Food Standards Code for the past couple of decades. This is particularly important for definitions of 'infant formula', 'infant formula products' and 'formulated supplementary food for young children'. INC makes several recommendations to ensure this alignment.

5. INC appreciates that the 6 month transition period for operators of registered risk management plans (RMPs) between the issue of the notice and the Notice coming into force (with some exceptions) is not applicable to operators who register an RMP after the Notice has been issued. INC makes recommendations to clarify this distinction.

6. INC also appreciates that where substantial reconstruction of existing premises is required, the transition period extends to 2020. INC recommends that a force majeure clause be included for this latter transition period since an occurrence of earthquakes as has been recently experienced in New Zealand, could seriously impact efforts to achieve this deadline.

7. Intentional adulteration is a risk in any food manufacturing facility. Recent events in New Zealand and overseas have highlighted this and manufacturers have a much-heightened awareness of the risks and measures to address them. However, for reasons of practicality and coordination of all amendments required by this Notice, INC recommends a coherent and comprehensive plan that brings together all measures to prevent intentional adulteration should be in place 90 days after the Notice comes into force, not the 30 days proposed.

8. The roles and responsibilities of raw material manufacturers, the suppliers of those raw materials and the manufacturers of final products are all important for the integrity of the supply chain. Recommendations are made to maintain the clarity of these roles and responsibilities and the integrity of the supply chain.

9. While the shelf life of ingredients is important for the manufacturer of product, the shelf life of the final product is the key focus. INC strongly contends that the validation of the shelf life of the final product will address any over-ride of an ingredient's shelf life that occurs as a result of the manufacturing process. INC recommends addressing this point in a couple of key areas as noted below.

10. Finally, INC notes that the Animal Products Act 1999 reserves the term 'register' to mean 'public registers'. It is therefore incorrect and misleading to refer to records of product formulations as registers. They are records held by the manufacturer and are not in the public arena.

Detailed comments

Purpose
Clause 2(e)

11. The correct title is the "Australia New Zealand Food Standards Code".

Background
Clause (1)

12. Reference is made in this clause to the WHO recommendations for infant feeding. Reference should also be made to the New Zealand Ministry of Health recommendations.

Clause (4)

13. This clause describes the coverage of the Notice and, in the last line states: "… tracing, and audit and evaluation of manufacturing processes." This clause, as occurs in several other areas that will be identified in the balance of this submission, does not recognise that there is a significant functional difference between 'audit' and 'verification' such that verifiers perform verifications and the regulator performs audits. This distinction is fundamental to the structure of Animal Products Act 1999 and to the MPI regulatory model.

14. The Animal Products Act 1999 refers to 'audit' only in relation to the Food Act and in relation to the regulator functions of 'compliance and audit' eg see section 73(2) which reads "to facilitate the compliance, audit and other functions of the Ministry as the agency with regulatory functions under this Act."

15. **INC recommends** that clause (4) be amended such that the last line reads:

    "… tracing, and verification ~~audit~~ and evaluation of manufacturing processes."

Part 1: Requirements
Clause 1.2 Definitions
Clause 1.2(1)

16. The definition of "infant formula" and "formulated supplementary food" are definitions that do not align well with either Codex or the Food Standards Code. The draft Notice also does not include a definition of 'infant formula product' which is the umbrella term for infant formula and follow-on formula in the Food Standards Code. In the draft Notice, the definition of infant formula includes the term 'infant formula product' which is NOT currently defined and should be.

17. It is vital that the distinction between infant formula and follow-on formula is made in the definitions, infant formula being the **sole source of nutrition** of infants aged under 4 to 6 months.

18. The definition of 'formulated supplementary food' in the draft Notice has blended the definitions for 'formulated supplementary food' for the general population and the definition of 'formulated supplementary food for young children' from the Food Standards Code. Confusingly, however, the more general descriptor 'formulated supplementary food' is used throughout the draft Notice when this should be 'formulated supplementary food for young children'. The only area where we do not support alignment is in relation to the description of the applicable age for formulated supplementary food for young children which should remain 12 and 36 months.

19. **INC recommends** that the definitions in the Notice, for consistency and clarity, better align with those in the Food Standards Code and include 'infant formula products' to cover follow-on product and use of the term 'formulated supplementary food for young children'. The definitions would then read:

    "**infant formula** means an infant formula product represented as a breast milk substitute for infants and which satisfies, by itself, the nutritional requirements of infants under the age of ~~aged up to~~ 4 ~~to months~~ to 6 months"

    "**infant formula product** means a product based on milk or other edible food constituents of animal ~~milk~~ origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants~~, depending on the age of the infant~~.

    ***"*formulated supplementary food for young children** means a food, intended for children aged between 12 and 36 months, that is specifically formulated as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet ~~the~~ a child's requirements.

20. The definition of "dry area" would be enhanced and the draft Notice future proofed by recognising that heat treatment may not be the only microbiocidal treatment in the future.

21. **INC recommends** that the definition in the Notice for "dry area" should read:

    "**dry area** means any area where dry ingredients or dry relevant products
    a) are or may be exposed; and
    b) will not subsequently be subject to heat treatment or equivalent microbiocidal treatment".

Clause 1.3 Transitional provisions
Clauses 1.3(1) and 1.3(2)

22. Clauses 1.3(1) and 1.3(2) do not work together. In essence, those holding RMPs at the date of Notice is issued (currently proposed as 1 March 2017) have a 6 month transition period (with some exemptions) meaning the Notice comes into force for existing RMP holders on 1 September 2017 as reflected in the chapeau to clause 1.3(1) and in clause 1.3(1) a) and clause 1.3(2). After the date the Notice is issued, new RMP holders must meet all the requirements irrespective of the date the RMP is registered, that is no transition period applies and clause 1.3(2) does not have any application. The confusion occurs because of the sequence of the clauses with clause 1.3(1)(b) preceding clause 1.3(2) which has no application.

23. **INC recommends** clauses 1.3(1) and 1.3(2) be redrafted along the following lines:

    "(1) For manufacturers whose RMP for relevant product is registered before the date on which this Notice is issued, 1 March 2017, this Notice applies on 1 September 2017.
    (2) For manufacturers whose RMP for relevant product is registered on or after the date this Notice is issued, 1 March 2017, this Notice applies on the date the RMP is registered."

Clause 1.3(3)

24. The exemption from application of requirements in clauses 2.3 and 2.5-2.7 which need not apply until 1 September 2020 requires a 'force majeure' clause in light of the unexpected earthquakes that have occurred in the past 3-4 years. Such an event, beyond the control of the manufacturer, could well delay works subject to an improvement plan.

25. **INC recommends** the inclusion of 'force majeure' clause in the transitional provisions contained in clause 1.3(3).

Part 2: Premises, equipment and personnel
Clause 2.2 Areas identified in RMP
Clause 2.2(1)

26. The boundaries of the "manufacturing area" are required to be identified. "Manufacturing area" requires definition or description in a guidance box.

27. **INC recommends** the inclusion of guidance following clause 2.2(1) on what is meant by 'manufacturing area'.

Part 3: Cleaning and maintenance
Clause 3.6 Maintenance compounds and other chemicals
Clause 3.6(1) b)

28. There may be a situation where maintenance compounds or other chemicals have a neutral affect on the relevant product. To address this situation the affect needs to be qualified as an 'adverse affect'.

29. INC recommends clause 3.6(1)b) be amended to read:

    "b) have been assessed by the manufacturer as:
        i) suitable for its intended purpose; and
        ii) not going to <u>adversely</u> affect or contaminate the relevant product; and
        iii) not going to accelerate the deterioration of the processing equipment or components."

Clause 3.9 Protection from intentional adulteration
Clause 3.9(1)

30. This clause proposes that every RMP includes a plan for the protection of relevant product from intentional adulteration within 30 days of the Notice coming into force. This timing is impractical for identification and articulation of a plan, validation and evaluation and approval by MPI within 30 days. Companies already have a range of steps in place that contribute to protecting product from intentional adulteration but collecting these together into a coherent and comprehensive plan takes time. This Notice has also been more than 2 years in development without the demands for explicit and standalone adulteration plans to be in place. Additional time to meet this requirement will also mean that all amendments required by the Notice to the RMP, including this one, might be coordinated so that the amendments can be dealt with as a package for the approval process. For all these reasons, but primarily impracticality, additional time to meet this requirement is necessary.

31. **INC recommends** the time within which an explicit and standalone adulteration plan be included in an RMP be extended from 30 days to 90 days of the Notice coming into force. Clause 3.9(1) would then read:

    "(1) Every manufacturer must ensure that, within 90 days after this Notice comes into force, the RMP includes a plan for the protection of relevant product from intentional adulteration."

Clause 3.11 Calibration
Clause 3.11(5) b)

32. This clause and clauses 3.12(2) and 4.2(3) all make reference to reporting to the verifier. Clause 3.11(5)(b) has no time frame, clause 3.12(2) requires reporting 'immediately' and clause 4.2(3) requires reporting 'within 48 hours'. Standardisation of the time for reporting would greatly enhance both consistency and usability of the Notice. INC supports this timeframe being 'within 48 hours'.

33. **INC recommends** that reporting to verifiers on issues detected be consistently set at 'within 48 hours'. As a result, clause 3.11(5) b) would read:

    "b) report the findings to the verifier <u>within 48 hours.</u>"

Clause 3.12 Response to failures
Clause 3.12(2)

34. As noted above, consistency in the timeframe for reporting matters to the verifier is supported by INC.

35. **INC recommends** that the reporting to verifiers be set at 'within 48 hours'. As a result, clause 3.12(5) would read:

    "(2) … affected must be reported ~~immediately~~ to the verifier <u>within 48 hours</u>, …."

Part 4: Raw materials and formulation
Clause 4.1 Procurement of raw materials
Clauses 4.1(2) and 4.1(6)

36. The first problem with these clauses is that the term 'manufacturer' has two meanings in the clause: the manufacturer of the raw material and the manufacturer of the relevant product. The Notice contains one definition of 'manufacturer' in Clause 1.2 which states that the manufacturer is the manufacturer of the relevant product.

37. The second problem is that the supply chain is either broken or unnecessarily duplicated by the requirement for the manufacturer of relevant product to hold

records of the manufacturer of the raw materials. Both issues can be addressed by qualifying which 'manufacturer' is being referred to in the clause.

38. **INC recommends** that 'manufacturer' of raw materials is qualified throughout the clause and responsibility for supply chain integrity is maintained by requiring suppliers of raw materials to hold the details of manufacturers of raw materials. This does not preclude manufacturers of relevant products also holding information on manufacturers of raw materials but it does not mandate manufacturers of relevant products to do so. Clauses 4.1(1) and 4.1(6) should be amended to read:

    "(2) Manufacturers must review any reports from accredited laboratories, certificates of analysis, and ~~manufacturer's~~ declarations from manufacturers of raw materials to assess the suitability of those raw materials.
    (6) If a supplier is not the manufacturer of the raw material, the ~~manufacturer~~ supplier must be satisfied that:
        a) the manufacturer knows who the original manufacturer of the raw material is; ~~or~~ and
        b) the supplier has reliable and robust systems in place to ensure raw material integrity. "

Clause 4.2 Raw material acceptance
Clause 4.2(3)

39. Clause 4.2(3) is not clear and difficult to follow. We understand that what is intended is that if a particular raw material was so unacceptable that its use in final product would result in that final product being non-conforming, then the unacceptability of the raw material must be reported. The supplier role is in relation to having supplied raw material that has not met acceptability criteria. The issue is not meeting acceptability criteria. Supplier details might form part of the report to the verifier.

40. INC recommends redrafting clause 4.2(3) to better reflect intent along the following lines:

    "(3) If raw material is supplied to a manufacture that has not met acceptance criteria and if that raw material was to be used in final product~~,~~ that may then result in that product ~~would be~~ being non-conforming, the problem with the raw material, together with details of the supplier of the raw material, must be reported to the verifier within 48 hours of being detected."

Clause 4.4 Monitoring raw materials at the premises
Guidance to clause 4.4

41. Historical testing of raw materials should feature in the monitoring programme of raw materials.

42. **INC recommends** that the guidance be reworded to include reference to historic testing. The Guidance would then read:

    "Guidance
    The intensity of raw material testing will vary depending on the intended intensity of final product testing, the outcome from historic testing of material from the supplier and by the manufacturer, ~~and~~ hazard analysis, and the intended use of the raw material."

Clause 4.6 Ingredient shelf life
Clause 4.6(2)

43. Clause 4.6(2) requires justification for the shelf life of a raw material being over-ridden by a longer shelf life of a final product. This is unnecessary since the processes and other impacts in the manufacture of the final product clearly affects each raw material's shelf life. The focus should be validating the shelf life of the product.

44. **INC recommends** deleting clause 4.6(2) as unnecessary.

Clause 4.5 Storage and unpacking of raw materials
Clause 4.5(1) e)

45. This clause sets out conditions for the use of raw materials and in clause 4.5(1) e) states that raw materials must be "spaced so as to permit inspection". It is not clear what 'spaced' is referring to. We note that in section 8 of the "Operational Guideline: Design and Construction of Dairy Premises and Equipment" regarding the layout of manufacturing equipment the wording is a lot clearer. To ensure verifier and regulator consistency of interpretation, either rewording or reference to the "Operational Guideline" would assist.

46. **INC recommends** the inclusion of a Guidance box following clause 4.5(1) e) that explains what "spaced so as to permit inspection" actually means in relation to raw materials stored by the manufacturer.

Clause 4.10 Register of formulations of final product

47. In the Animal Products Act 1999, the term 'register' generally refers to publicly accessible registers: registers of RMPs, register of exporters, registers of recognised agencies and persons, registers of users of the Joint Border Management System and registers of secondary processors. Clause 4.10 is not referring to a public register and does not use the term 'register' in the body of the clause. The distinction between 'register' and 'records' is vital to avoid confusion and any expectation that records of formulations are not public.

48. In relation to the title of Clause 4.10, we are of the view that, as stated in clause 4.10(2), the required information can be held in multiple locations (systems/places) provided that the manufacturer can collate the information on request, that is, there is no requirement to maintain such information in the form of a single repository or register.

49. **INC recommends** the term 'register' in the title of clause 4.10 'records'. The title of clause 4.10 would then read:

    Clause 4.10 ~~Register~~ <u>Records</u> of formulations of final product

Part 5: Manufacture
Clause 5.8 Packaging for retail-ready product
Clause 5.8(2) d)

50. This provision reads "not easily break or tear under expected handing conditions".

51. **INC recommends** clause 5.8(2) d) read:

    "d) not easily break or tear under expected <u>handling</u> conditions".

Clause 5.8(4)

52. The last phrase of this clause reads "if it is incorporated while is a non-high hygiene area".

53. **INC recommends** the last phrase of clause 5.8(4) read:

"if it is incorporated while in a non-high hygiene area".

Clause 5.13(5) c) and 5.15(3)

54. As discussed at the outset, there is a significant functional difference between 'audit' and 'verification' such that verifiers perform verifications and the regulator performs audits. This distinction is fundamental to the structure of Animal Products Act 1999 and to the MPI regulatory model. The term 'verification audit' totally confuses functions and roles and must be corrected. Similarly, there must be a very clear distinction between reporting to the regulator (the auditor) and the verifier. Only in extreme food safety situations would an issue be reported to the regulator/auditor and this would likely only occur when the verifier also received a report.

55. **INC recommends** deletion of 'audit' when used in conjunction with 'verification'. Clause 5.13(5) c) would read:

"c) inform the verifier at the next verification ~~audit~~ of the actual time the tracing exercise took."

56. **INC recommends** that internal investigations by manufacturers that identifies compliance failures within the manufacture's area of responsibility be reported to the verifier. Clause 5.15(3) would then read:

"(3) If an investigation identifies a failure by the manufacturer to comply with the RMP or any regulatory requirements, the failure must be notified to the verifier ~~or auditor~~ in an exception report.

Part 6: Validation
Clause 6.2 Validation to be undertaken
Clause 6.2(2) g)

57. As noted previously in relation to clause 4.6(2), the validation of the shelf life of the final product should be the focus and would address on over-riding of the shelf life of a raw material used in the final product

58. INC recommends clause 6.2(2) g) be amended to remove reference to

"g) the shelf life of ingredients before ~~and after~~ incorporation into relevant product:".

Part 7: Evaluation and verification
Clauses 7.2, 7.3 and 7.4

59. As discussed at the outset, and again in relation to clauses 5.13(5) c) and 5.15(3), there is a significant functional difference between 'audit' and 'verification' such that verifiers perform verifications and the regulator performs audits. This distinction is fundamental to the structure of Animal Products Act 1999 and to the MPI regulatory model. The term 'verification audit' totally confuses functions and roles and must be corrected.

60. **INC recommends** that the terms 'verification audit', 'verification audits' and 'audit' be deleted from the titles and body of clauses 7.2, 7.3 and 7.4, including deletion from the guidance note, and replaced with 'verification' or 'verifications' as the case may be, to maintain consistency with the structure of the Animal Products Act 1999 and remove confusion in relation verifier and regulator roles and functions. The clauses would then read as follows:

“7.2 Unannounced verifications ~~verification audits~~

(1) Premises that manufacture infant formula products must receive at least one unannounced verification ~~verification audit~~ each dairy season.

(2) Notice may be given to the manufacturer not more than 24 hours before an unannounced verification ~~verification audit~~, in order to ensure access to the premises and that key personnel can be present.

(3) An unannounced verification ~~verification audit~~ may be inspection based if key personnel are not available.

7.3 Increased verification ~~verification audit~~ intensity

(1) This clause applies if, during a verification ~~an audit~~: a) Required information proves difficult to obtain; or

b) Key personnel are not available to provide required information; or

c) Initial findings indicate a need for more in-depth assessment.

(2) If this clause applies, verifiers must:

a) Extend the onsite verification ~~audit~~; or

b) Unless any required information is provided within 2 working days of being requested, either:

i) Record a failure to provide the required information (if applicable); or

ii) schedule a revisit to occur within 30 days of the original audit visit.

Guidance

Manufacturers should expect more intense verification ~~verification audit~~ scrutiny than other dairy processors. This is best achieved by more intense verifications ~~verification audits~~ rather than more frequent verifications ~~verification audits~~.

During verifications ~~verification audits~~, information is expected to be made available immediately or, for archived information, within 2 working days.

7.4 Verification ~~Verification audit~~ frequency

(1) This clause applies to any manufacturer who is not covered by the Animal Products Notice: Export Verification Requirements, and is for the purpose of ensuring that those manufacturers are subject to the same frequency of verification ~~verification audit~~ as manufacturers who are covered by that Notice.

(2) Manufacturers to whom this clause applies must be verified:

a) once a month; or

b) at intervals, determined by the verifier, of no more than 3 months, but only if the manufacturer continues to achieve an acceptable verification outcome.”