Submission to Food Standards Australia New Zealand in response to the Consultation Paper – Proposal P1028 - Infant Formula released 23 February 2016.

Enzymotec Ltd.

This submission is made by Enzymotec Ltd, on behalf of Advanced Lipids AB (a Joint Venture of AAK and Enzymotec). Advanced Lipids sells and markets InFat™, an ingredient in baby formula products. InFat™ is an edible fat rich in beta-palmitate, derived from edible oils of vegetable origin, namely high palmitic acid oil (typically palm stearin) and a source for oleic acid (typically a high oleic oil such as sunflower oils). InFat^{TM} is produced through enzymatic transesterification of high-palmitic acid oil , where the palmitic in the beta position is maintained, and a source for oleic acid, which contributes with a surplus of oleic fatty acids, to achieve the InFat™ product. The enzymatic process is followed by standard oil purification procedures. The final product is a triglyceride composition in which palmitic acid is predominantly esterified in the *sn*-2 position in order to imitate breast milk fat composition. Beta palmitate vegetable oil has a long history of safe use in several countries overseas and has been the subject of several safety evaluations. The Food Standards Australia New Zealand (FSANZ) Advisory Committee on Novel Foods (ACNF) has reviewed "Beta palmitin vegetable oil" and concluded that it is a non-traditional food but is not a novel food. The reasons given for this decision are: *"Use in infant formula products in overseas markets with no safety concerns identified based on this use. No concerns regarding composition"*.

Enzymotec Ltd, would like to thank Food Standards Australia New Zealand for the opportunity to make a submission on this important review. This submission expressly responds to the questions posed by FSANZ in the consultation documents, in their original order.

Summary of questions to submitters

Supporting Document 1: Definitions and Nutrient Composition

Q1.1 For all views presented in this SD, do you agree with FSANZ's preliminary view?

If so, indicate this in your submission and provide your reasons where appropriate.

If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

Enzymotec Ltd agrees with the general approach outlined by FSANZ, in particular that it is appropriate to align the compositional provisions for infant formula of Standard 2.9.1 – Infant Formula Products (and Schedule 29 in the revised Code) with those in the Codex *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex STAN 72-1981).

The use of the nutrient content measured in breast milk as the primary criterion for the revised Standard is also supported.

Q1.5 What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale

Currently there is no definition of the sources or types of fat that may be used in infant formula. Control is achieved through (i) limits placed on the fatty acid composition of the formula and (ii) the pre-assessment requirements for Novel Foods and Novel food ingredients, to ensure that the product is safe and suitable for infants. This creates uncertainty for manufacturers regarding the use of edible fats, such as InFat^{TM}, which is not a Novel Food and can be used in combination with other vegetable oils to achieve the desired fatty acid profile. The standard would benefit from greater clarity regarding the use of macro-nutrients that may be used in infant formula in order to distinguish them from those ingredients currently "used as a nutritive substance".

Supporting Document 2: Safety and Food Technology

Q2.1 For all views presented in this SD, do you agree with FSANZ's preliminary view?

Enzymotec Ltd agree with the proposition that, in principle, substances that present a potential risk to public health and safety should undergo premarket assessment before their inclusion in infant formula products. However, as outlined below, we suggest that further work is required to identify and classify those substances to which this requirement should apply and the appropriate assessment processes.

We also suggest that consideration be given to alternative assessment procedure, other than an application process leading to amendment of the Standard, such as formalised self-assessment protocols and assessment by overseas government and non-government authoritative bodies, consistent with those outlined in proposal P1024 – Novel Foods and Nutritive Substances.

Q2.14 Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

Document SD2 6.1 states "*Prior to use in infant formula, nutritive substances and novel foods need to be established as safe and be demonstrated that they provide a nutritive or health benefit for formula-fed infants. This approach means infant formula companies or other applicants seeking permission to add a new substance to infant formula must make a pre-market application to FSANZ*."

Whilst this statement is correct for new substances that are either novel foods or are "used as a nutritive substance", pre-market assessment would not apply currently to a new ingredient in infant formula that was neither a novel food nor "used as a nutritive substance". The situation further is confused by the lack of clarity in the definition of "used as a nutritive substance".

We suggest that not all substances used in infant formula are currently or should be subject to formal pre-assessment by a regulatory authority. This should be limited to substances that are new to the food supply and raise potential issues of public health and safety significance whereas substances derived from established animal or plant commodities (e.g. cow milk or vegetable oils) should be exempt. For example, beta-palmitate is naturally present in human breast milk. Beta-palmitate rich edible fats, such as InFat™, that are derived from safe and suitable edible vegetable fats are used in infant formula to provide a fatty acid positioning that more closely resembles breast milk. The FSANZ Advisory Committee on Novel Foods has previously provided an opinion that such fats are non-traditional but not novel, meaning that they do not require a further assessment of public health and safety, when used in infant formula. A requirement for an additional pre-market assessment and listing of such substances in the infant formula standard would impose an additional regulatory burden that would inhibit innovation and could not be justified on public health and safety grounds.

In relation to the current definitions of novel foods and nutritive substances, the discussion paper identifies a potential for category overlap, however, this conclusion depends on a particular interpretation in relation to the definition applied to "used as a nutritive substance" that does not align well with existing precedents within the Code, and in particular Standard 2.9.1, and, thus, highlights the confusion in complying with the current standard. A number of categories of ingredients in food are subject to premarket approval in the Food Standards Code, including novel foods, nutritive substances, food additives and processing aids. There is a clear delineation between novel foods and food additives or processing aids, since the scope of the latter two categories is defined and based on their performing an identified technological purpose.

Precedents within the Code, particularly Standard 2.9.1, also provide guidance as to when an ingredient should be considered to be "used as a nutritive substance". Standard 1.1.1 defines, infant formula product as *a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.* Standard 2.9.1 does not list the safe and suitable edible food constituents of infant formula that may be used to achieve nutritional adequacy, despite many of them being concentrated or refined (e.g. milk powders or plant fraction rich in protein, fat or carbohydrate), or even synthesised, and added for a nutritional purpose.

Instead, Divisions 3 and 4 of the Standard establish acceptable ranges for energy, protein and fatty acids for infant formula and follow-on formula. Effectively therefore, those ingredients derived from established animal or plant commodities that provide "nutritional adequacy" in terms of the macronutrient profile of the formula are treated as intrinsic components of the food rather than as added nutritive substances, irrespective of their degree of refinement, and are not subject to pre-market assessment unless they are Novel Foods.

In contrast, the substances listed as permitted to be "used as a nutritive substance", in Standard 2.9.1 and elsewhere in the Code, are substances that may be derived from other sources and do not contain significant quantities of protein, fat or carbohydrate but provide "nutritional properties" beyond these macro-nutrients.

We suggest that the separation between substances added as macronutrients to achieve "nutritional adequacy" and those added in small quantities for supplementary nutritional purposes should be maintained in a revised standard, although, a clear distinction between these categories of ingredients would be beneficial. A classification similar to that proposed for "eligible" foods in Proposal P1024, which acknowledges the fact that foods produced from animal and plant commodities are generally considered safe, would also be appropriate for infant formula. "Eligible food components" such as those derived from established animal or plant commodities (e.g. milk or vegetable oils) and containing predominantly macromolecules, could then be expressly exempted from a requirement for a formal pre-market authorisation or listing in the Code.

Q2.15 What would be the cost and trade implications of your preferred position?

The introduction of clear guidelines and the acceptance of overseas expert assessment and standards would significantly decrease the regulatory costs for government and industry in Australia & New Zealand and facilitate trade in infant formula products to overseas markets.

Q2.16 If only certain substances for use in infant formula should require pre-market assessment, where should the 'line' be drawn for the substances that do require pre-market assessment and those that do not? What is your rationale?

As indicated in our response to Q2.14, above, we suggest that not all substances used in infant formula need to be subject to formal pre-assessment by a regulatory authority. In making this suggestion, we note that all food suppliers already have a responsibility under food law to ensure that the foods they sell are safe and suitable. We further suggest that a series of categories or protocols, to which different levels of pre-assessment would apply, similar to those recommended in P1024 - Novel Food and Nutritive Substances, may also be appropriate to infant formula products. The classification should be based on the source of the ingredient, the extent of processing applied to it and purpose for which it is being added to the infant formula.

For example, a product like InFat™ which is produced through enzymatic transesterification of edible vegetable oils and has a triglycerides composition rich in beta-palmitic acid, may be added in order to imitate breast milk fat composition. Beta palmitate vegetable oil has a long history of safe use in infant formula in other countries and has been the subject of several safety evaluations. On this basis it would be reasonable to classify InFat™ as an "eligible" food or ingredient, that could be included in infant formula, within the context of the established fatty acid range, without the need for a formal pre-market assessment or listing in the Code and thus resolve the confusion inherent in the current Standard.

Q2.17 If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

As discussed above, the revised Standard would benefit from a clear delineation between those ingredients that contribute "nutritional adequacy" in terms of the prescribed macro-nutrient (i.e. fat protein and energy) criteria and those which are added primarily to provide supplementary nutritional properties.

New ingredients used to achieve the basic "nutritional adequacy" of infant formula products could include milk powders or milk fractions prepared from alternative mammalian milks or by new separation processes, or plant derived protein, fat or carbohydrate fractions. Where a potential risk to public health and safety risk is evident, either formal self-assessment by the supplier or by a regulatory authority may be appropriate but in many cases documentation of prior use in other foods, experience of the same components from other safe food sources, or safety evaluations conducted by appropriate overseas panels, could make such an assessment unnecessary. Relevant factors could be whether the constituents in the ingredient are already components of milk, whether the source materials have a history of safe use in the food supply or whether they, or the processes used to produce them, are new to the food supply. Ingredients derived from other safe foods but comprised of substances that are normally present in human breast milk or formulas already in the market may also be seen as comparable with "eligible foods" proposed under P1024. A requirement that a supplier maintains adequate documentation to demonstrate "eligibility" could be sufficient. In this context, we, suggest that "nutritional adequacy" should be benchmarked against human breast milk.

New substances, other than those discussed in the preceding paragraph, that are derived from non-established food commodities and are proposed to be added to infant formula products to achieve supplementary functional outcomes beyond the relevant benchmarked "nutritional adequacy", could be identified as requiring pre-market approval. Formal assessment for these substances could include an assessment of the evidence linking the physiological, biochemical and/or functional effects of the substance to specific health outcomes for the target population, may be appropriate. However, in these cases it is suggested that consideration is given to supplier self-assessment protocols and also to acceptance of assessments undertaken by overseas government and non-government authoritative bodies and recognition of equivalent standards in Codex, the EU and North America.

Conclusions

In conclusion, there is currently a high level of confusion within Standard 2.9.1 regarding the use of macromolecules derived from animal or vegetable commodities in infant formula. This confusion arises primarily from interpretation applied to the definition of “used as a nutritive substance” that appear inconsistent with the definition of Infant Formula and the structure of the Standard itself.

The situation could be clarified by revisions to the standard to:

- Introduce a classification system that distinguishes between
    - ingredients that are predominantly macro-molecules derived from established animal and plant commodities and contribute to the nutritional adequacy of the formula, benchmarked against human breast milk, and
    - highly refined ingredients, which may be from other sources and are added to provide supplementary nutritional properties,
- To clarify when premarket approval and listing in the standard is required based on the source of the ingredient and the documented history of safe consumption by infants and young children, and
- Expressly recognise that ingredients derived from established animal or plant commodities which contribute to the macronutrient profile of the formula are “eligible” for inclusion in infant formula products without express approval, unless they are Novel Foods.