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Infant Formula does not meet New Zealand Standards

Questions and Answers

DIRECTOR GENERAL STATEMENT

16 July 2007

NZFSA has been notified that Karicare Nutriprem Gold Plus Ready-to-Feed Pre-term Formula; Karicare Gold Plus Ready-to-Feed Infant Formula; Karicare Gold Plus Infant Formula; and Karicare Gold Plus Follow-On formulas are non-compliant under the joint Australia New Zealand Food Standards Code.

The Acting Chief Executive, Director-General of the New Zealand Food Safety Authority (NZFSA) for purpose of section 37 of the Food Act 1981, is advising parents and caregivers that Nutricia Karicare Gold Plus Infant Formula and Follow-On Formula both contain added substances called fructo-oligosaccharides, (FOS). FOS has not been subject to the required risk-based safety assessment for the purposes of permitting their addition to infant formula products for sale in New Zealand. In the absence of such a safety assessment, NZFSA is taking a cautionary approach to this situation, particularly, for New Zealand infants who may consume them as their total dietary intake.

FOS does occur naturally in a range of plants but can also be synthetically produced. Prebiotics may assist infants in achieving softer, looser and more frequent bowel motions.

Until there has been an opportunity to fully assess all safety implications associated with the inclusion of FOS in infant formula products under New Zealand conditions, NZFSA recommends that parents and caregivers with infants consuming either Nutricia Karicare Gold Plus Infant Formula or Follow-On Formula gradually change to an alternative product.

It is important that infant diets are not changed suddenly as this can cause digestive upsets. The packaging of Karicare Gold Plus Infant and Follow-On Formula does not contain instructions for transitioning off these products, however NZFSA recommends that parents and caregivers choosing to make a change to an alternative product do so in a gradual manner. This could mean replacing one to two feeds a day over three to four days.

The advice of an appropriate health professional should be sought if parents and caregivers are concerned about any symptoms associated with the use of Karicare Gold Plus Infant Formula and Follow-On Formula or with the transition to an alternative product. Alternatively, parents and caregivers can call Healthline on 0800 611 116 for advice, or NZFSA's consumer helpline for more information on 0800 693 721.

Nutricia Karicare Gold Plus Infant and Follow-On Formula are sold through retail outlets such as supermarkets mainly in 900g tins. NZFSA has discussed these issues with the manufacturer.

Ends

This statement is made under section 37 of the Food Act 1981 by the Acting Chief Executive, NZFSA under delegated authority. It is protected by qualified privilege.

Signed by

Andrew McKenzie Date: 16 July 2007

Acting Chief Executive of the New Zealand Food Safety Authority

Acting under delegated authority

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Questions and Answers

What is the issue with it in Nutricia Karicare Gold Plus Infant formula and Follow-On formula?

These products contain an added substance called FOS. FOS and other substrates with similar functions are called prebiotics.

FOS has not undergone a safety assessment for addition to infant or follow-on formulas in New Zealand and Australia. Manufacturers must only use substances that have had a safety assessment and been approved by Food Standards Australia New Zealand.

FOS that has been extracted and added to infant formula products has not been through this safety assessment process. Lack of a safety assessment is of particular concern because infant formula may be the sole source of nutrition for some babies, and follow-on formula is likely to provide a significant proportion of a baby's nutritional requirements.

Prebiotics have been associated with an increase in stool frequency as well as softer stools. This may increase faecal water losses and put some infants at risk of dehydration. Without a safety assessment, it is unknown if this is an issue for New Zealand babies and infants.

What is FOS?

FOS is short for fructo-oligosaccharides, which consist of chains of sugar units, mostly the sugar fructose, but with some glucose as well. FOS is the collective term used to describe molecules that consist of between two and ten units of sugar.

FOS for the most part is indigestible and therefore acts as a non-digestible fibre in the diet. This is because people do not have the enzymes to break down the FOS as it travels down the digestive tract.

Is FOS found naturally in food?

Yes. FOS is a natural component of many foods such as fruits and vegetables (including bananas, onions, chicory root, garlic, asparagus, barley, wheat and tomatoes). The Jerusalem artichoke and its relative, yacón have been found to have the highest concentrations of FOS in cultured plants. FOS is not found in breast milk.

What does FOS do?

FOS is believed to serve as a substrate for many bacterial species in the large intestine. This can encourage overall gastrointestinal tract health if the bacteria are beneficial ones. FOS and other substrates with similar functions are called prebiotics.

Prebiotics are resistant to digestion and alter the bacteria in the intestine towards a healthy balance of bacteria. A bifidus-dominated gut flora (such as is common in breast-fed infants) is considered protective because it may activate the immune system and inhibit invading pathogens.

Has FOS been approved for addition to infant formula in other countries?

Yes, FOS is approved in the European Union for addition in restricted amounts to infant formula (for babies up to six months) and follow-on formula (for babies between six and 12 months). Infant and follow-on formula products containing FOS have been sold in the EU for seven years.

A safety assessment for the addition of FOS to infant and follow-on formula has not been undertaken in New Zealand and Australia.

Is FOS in other infant and follow-on formulas?

NZFSA is not aware of any others. FOS is only in these two Nutricia infant and follow-on formula products.

Should I change formulas immediately?

No. There is no cause for alarm. This information is being provided to help parents and caregivers make informed decisions about the care of their baby. For parents who wish to change formulas, NZFSA suggests that an alternative product be identified and a gradual change made. This could mean replacing one to two feeds a day over three to four days. It is important that infant diets are not changed suddenly as this can cause digestive upsets. If you have any concerns about the Karicare Gold Plus Infant and Follow-on formulas, or require assistance choosing a suitable alternative, you should contact your doctor or appropriate health professional.

Is this a safety issue or a regulatory issue?

Both. When an application is made to FSANZ for permission to add a substance into a specified food, FSANZ undertakes a full assessment. This includes an analysis of the nature, source, function and risk of the substance. In the absence of such an assessment, the level of risk and therefore the safety issues cannot be adequately determined. One of the key functions of regulation, especially in products such as infant formula, is to assess the safety concerns before the product is released for general consumption.

Nutricia has said in Australia that this is not a safety issue, but 'an administrative bungle'. Is this true?

NZFSA cannot comment on the situation in Australia. The New Zealand position is clear. FOS is not approved under the Joint Food Standards Code for addition to infant or follow-on formulas. Therefore, the two Nutricia products are non-compliant in the New Zealand market.

Where can I get more information?

You can call NZFSA on 0800 693 721.

If you are concerned about any symptoms associated with the use of Karicare Gold Plus Infant and Follow-On formulas or with the transition to an alternative product, you should seek the advice of an appropriate health professional. Alternatively, parents and caregivers can call Healthline on 0800 611 116 for advice.

All information on this website is subject to a disclaimer.

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