FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

8-06
13 December 2006

INITIAL ASSESSMENT REPORT

APPLICATION A570

FERRIC SODIUM EDETATE AS A PERMITTED FORM OF IRON

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 7 February 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Azko Nobel Pty Ltd (the Applicant) on 11 August 2005 seeking to amend Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions of the *Australia New Zealand Food Standards Code* (the Code), to approve ferric sodium EDTA as a permitted form of the mineral iron.

Where permissions are given in the Code to add iron to foods, then the Code also requires that the added iron be in one of the 16 forms listed in the Schedule to Standard 1.1.1 (except for infant formula and foods for infants, which have their own special provisions). Ferric sodium EDTA is not listed in Standard 1.1.1, and therefore an amendment to this Standard is required before ferric sodium EDTA would be permitted for use in the general food supply.

The specific objective of this assessment is therefore to determine whether or not a permission in the Code to use ferric sodium EDTA will be safe and efficacious.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the listing of ferric sodium EDTA as a permitted form of iron in the Code. Such an approval, if accepted, would warrant a variation to Standard 1.1.1.

- There are currently no permissions that allow for the use of ferric sodium EDTA as a source of iron in the Code.

- The Application is not so similar to any previous application that it ought not be accepted.

- There are no other measures that would be more cost-effective than a variation to Standard 1.1.1 that could achieve the same end.

- At this stage no other relevant matters are apparent.

FSANZ has also identified two options that are available for Application A570:

Option 1. **Not approve** ferric sodium EDTA as a permitted form of iron in Standard 1.1.1 of the Code.

Option 2. **Approve** ferric sodium EDTA as a permitted form of iron in Standard 1.1.1 of the Code.

FSANZ will undertake a full impact analysis at Draft Assessment, however a preliminary consideration of the impacts from these two options has been included under Section 9 of this Initial Assessment Report.

Consultation

A number of questions have been posed in this Initial Assessment Report to facilitate consideration of Application A532. Public comment is invited on these questions, the proposed regulatory options, and the report as a whole.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles and the draft variation/s to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 7 February 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received an Application from Azko Nobel Pty Ltd (the Applicant) on 11 August 2005 seeking to amend Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions of the Code, to approve ferric sodium EDTA as a permitted form of the mineral iron.

This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comments (particularly in relation to the expected regulatory impact) from stakeholders to assist FSANZ in making an assessment of this Application.

1. Nature of the Application

The Applicant has requested that the Schedule to Standard 1.1.1 be amended to include ferric sodium EDTA as a permitted form of iron.

Fortification of food with iron is only permitted in the Code if the iron is in one of the 16 forms listed in the Schedule to Standard 1.1.1. There is currently no listing of ferric sodium EDTA in Standard 1.1.1, and therefore an amendment to this Standard is required before ferric sodium EDTA would be permitted for use in the general food supply.

Excluded from consideration in this Application is the addition of iron to infant formula and to foods for infants. These foods are regulated by Standards 2.9.1 and 2.9.2 respectively, which contain their own separate lists of iron forms permitted for addition.

2. Background

2.1 The chemistry and food technology applications of ferric sodium EDTA

Ferric sodium EDTA is one of the common names for sodium iron (III) ethylene-diamine-tetraacetate trihydrate, also known as ferric sodium edetate and sodium feredetate. It has the molecular formula:

$$C_{10}H_{12}N_2O_8FeNa{\cdot}3H_2O \text{ (trihydrate)}$$

It differs from other permitted forms of iron in that the iron in ferric sodium EDTA is a chelate. As a chelate, the iron remains bound to the ethylene-diamine-tetra-acetic acid (EDTA) molecule in the acidic environment of the stomach and is not released until it is exposed to the alkaline conditions of the small intestine.

The Applicant has mentioned that because the iron is bound very tightly in to the EDTA molecule, ferric sodium EDTA can overcome many of the common food technology problems associated with the forms of iron currently listed in Standard 1.1.1. These problems involve rancidity and off colours, and undesirable reactions with other nutrients (such as ascorbic acid) that can degrade important food components. When added to foods, ferric sodium EDTA produces very little free iron to react with other nutrients or food components.

2.2 Sources of iron

Two broad categories of dietary iron are present in food: haem- and non-haem iron. Haem iron is found in haemoglobin and myoglobin proteins of animal meat and fish. Non-haem iron is derived from various sources (e.g. vegetable foods, dairy products and dietary iron fortificants).

The human body's small intestine absorbs ingested haem iron and non-haem iron by different mechanisms. Haem iron is more readily absorbed than non-haem iron and is less influenced by the body's iron status and the constituents of a diet (MacPhail, 2002).

2.3 Iron nutrition

Iron is a component of a number of proteins used in the body including haemoglobin, myoglobin, cytochromes and enzymes involved in redox reactions. Almost two thirds of the body's iron is found in circulating red blood cells as haemoglobin, which is the protein responsible for carrying circulating oxygen around the body for delivery to body tissue. A quarter of the body's iron is also found in readily metabolised storage chemicals such as ferritin or haemosiderin, which are located in the liver and reticulo-endothelial system.

The body's remaining iron is distributed in the myoglobin of muscle and a variety of enzymes necessary for oxidative metabolism and other cell functions (MacPhail, 2002; NHMRC, 2006).

2.3.1 Iron Reference Values for Australia and New Zealand

The Australian and New Zealand governments recently endorsed a set of Nutrient Reference Values for use as nutritional benchmarks. FSANZ intends to use the relevant iron values where appropriate in the scientific assessments that take place at Draft Assessment.

2.3.2 Low iron status and anaemia

A reduction in iron status, often referred to as 'iron deficiency' can be categorised into three stages:

- iron depletion – iron stores are depleted but there is enough circulating iron to ensure red blood cell production is not compromised;

- iron deficient erythropoiesis – iron stores are empty and lower circulating levels of iron begin to compromise red blood cell production;

- iron deficiency anaemia – the amount of circulating iron is very low and red cell production is dramatically reduced. Severe anaemia is associated with fatigue, weakness and potentially heart failure (MacPhail, 2002).

Data from one New Zealand (Ferguson *et al*., 2001) and two Australian studies (Salder and Blight, 1996; Rangan *et al*., 1997) show that the prevalence of iron deficiency amongst Australian and New Zealand women is approximately 7-14%. These figures are slightly better than other developed countries, where adult female rates are 20-30% for iron depletion/iron deficient erythropoiesis and 2-8% for iron deficiency anaemia (WHO and FAO, 2004).

FSANZ has been unable to obtain further data on iron deficiency rates for other sectors of the population.

2.3.3 Iron overload and haemochromatosis

Although the body has the ability to modulate iron absorption according to its needs, excessive amounts of iron may accumulate in the body and result in organ damage.

Individuals with hereditary haemochromatosis are more susceptible to iron overload than the remainder of the population, even at normal dietary iron intakes. As such, those with haemochromatosis are advised to avoid iron supplements and iron fortified foods (NHMRC, 2006).

Haemochromatosis as an overt clinical condition occurs when an individual inherits a copy of the haemochromatosis gene from both parents (homozygous). If an individual inherits only one copy (heterozygous), then they become a carrier of the condition and rarely express any adverse clinical symptoms. It is estimated that 0.5% of Caucasians are homozygous for the condition. However, actual rates in Australia and New Zealand are unknown, as homozygous individuals are usually identified only when enough iron has accumulated in their system to produce adverse effects (United States Institute of Medicine, 2001; NHMRC, 2006).

2.4 Relevant Australian and New Zealand regulations

The Schedule to Standard 1.1.1 provides details on the chemical forms of vitamins and minerals that can be added to food if permission is given for their addition to food within the Code. Unless another standard in the Code provides a list of further chemical forms that can be added to food, then the forms listed in Standard 1.1.1 are the only forms that can be used. In the case of iron, the chemical forms in Standard 1.1.1 affect the permissions to add this nutrient within the following standards:

2.4.1 Standard 1.3.2 – Vitamins and Minerals

Currently, Standard 1.3.2 permits the addition of iron to the following foods:

- cereal products: biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugars, bread, breakfast cereals, cereal flours and pasta (labels can only claim up to a maximum of 25% RDI per reference quantity);
- extracts of meat (labels can only claim up to a maximum of 15% RDI per 5 g);
- analogues of meat derived from legumes, where no less than 12% of the energy value of the food is derived from protein, and the food contains 5 g protein per serve of the food (labels can only claim up to a maximum of 30% RDI per 100 g); and
- formulated beverages (labels can only claim up to a maximum of 25% RDI per 600 mL).

2.4.2 Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods

Standard 2.9.3 permits the addition of iron to:

- formulated meal replacements – labels can only claim up to a maximum of 40% RDI per one meal serving;

- formulated supplementary foods – labels can only claim up to a maximum of 50% RDI per one meal serving; and
- formulated supplementary foods for young children – labels can only claim up to a maximum of 50% RDI per one meal serving.

2.4.3 Standard 2.9.4 – Formulated Supplementary Sports Foods

Standard 2.9.4 permits the addition of iron to formulated supplementary sports foods - labels can only claim up to 12 mg per one day quantity.

The Applicant has requested that ferric sodium EDTA be listed as a permitted form in the Schedule of Standard 1.1.1 so that it can be added to foods regulated by Standard 1.3.2, Standard 2.9.3, and Standard 2.9.4.

2.5 Overseas and international regulations

2.5.1 Joint FAO/WHO Expert Committee on Food Additives

In 1992, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) provisionally approved the use of ferric sodium EDTA in supervised food fortification programs. However, at this meeting there was a concern about the potential for over fortification of food from the enhanced bioavailability of ferric sodium EDTA. Therefore, a condition of this approval was that additional studies be conducted, to assess the site of deposition of iron administered as ferric sodium EDTA and the metabolic fate of ferric sodium EDTA (JECFA, 2000).

JECFA re-evaluated ferric sodium EDTA in 1999, at which time it removed the provisional conditions of approval and stated that the use of ferric sodium EDTA could be considered safe when used in supervised food fortification programs, which were intended to respond to an urgent need for iron supplementation of the diet (as determined by national public health officials). Such programs would provide iron intakes of approximately 0.2 mg/kg body weight/day from fortified foods (JECFA 2000). The committee considered the safety of ferric sodium EDTA for use in supervised fortification programs only; concerns were raised over its increased bioavailability and use as a fortificant in the general food supply, although the committee did not explicitly recommend against the use of ferric sodium EDTA outside of supervised fortification programs.

2.5.2 United States of America

In December 2004, ferric sodium EDTA, as manufactured according to the procedure described by Kraft Foods Global, was considered to be Generally Recognized as Safe (GRAS) for use as a source of dietary iron in powdered meal replacements, flavoured milk, and fruit- flavoured beverages designed for fortification programs in areas of the world with high prevalence of iron deficiency (US FDA, 2002). More recently, ferric sodium EDTA was determined to be GRAS for use in the iron fortification of soy, fish, teriyaki, and hoisin sauces at a level of 0.024% iron by weight, and in sweet and sour sauce at a level of 0.012% iron by weight (US FDA, 2006).

2.5.3 European Union

An application was submitted to the European Food Safety Authority (EFSA) by the Applicant in July 2006 for approval of ferric sodium EDTA as a novel food ingredient under novel food regulations (Azko Nobel Functional Chemicals, 2006). The Applicant is proposing to market ferric sodium EDTA as a direct replacement for current forms of iron permitted within the European Union for use in foods for particular nutritional uses and food supplements.

Currently, the use of ferric sodium EDTA is not permitted in the European Union as a source of iron in foods and food supplements.

3. The Regulatory Issue

Standards 1.3.2, 2.9.3 and 2.9.4 of the Code permit the addition of iron to certain foods only if the added iron is in one of the forms listed in Standard 1.1.1. There is currently no listing of ferric sodium EDTA in Standard 1.1.1, and therefore an amendment to this standard is required before ferric sodium EDTA can be permitted for use in the general food supply.

Permitting the addition of ferric sodium EDTA as a form of iron is dependent on demonstrations of its safety and efficacy.

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The objective of this assessment is to determine whether or not a permission in the Code to use ferric sodium EDTA will be safe and efficacious.

5. Key Risk Assessment Questions

The key risk assessment questions at Initial Assessment are:

- Does ferric sodium EDTA administration result in increased absorption / bioavailability relative to the forms of iron currently permitted in the Code?
- What are the risks associated with increased iron absorption / bioavailability in the general population?
- Are certain population groups more vulnerable to an increased (high) absorption of iron?
- What is the potential impact of increased iron bioavailability and absorption on other nutrients in the diet?
- Are there any risks arising from the addition of ferric sodium EDTA to special purpose foods (e.g. Formulated Meal Replacements, Formulated Supplementary Foods, or Formulated Supplementary Sports Foods)? Are these risks different from the risks associated with the addition of ferric sodium EDTA to general purpose foods?

RISK ASSESSMENT

6. Risk Assessment Issues

FSANZ has undertaken a preliminary evaluation of the scientific issues that underpin the questions listed in Section 5. This preliminary evaluation is intended to identify the key areas of assessment that will be investigated in detail at Draft Assessment, and the type of information that will be needed for these assessments.

For the purposes of this assessment an iron deficient population is considered to represent those with a serum ferritin level of <16 μg/L (this level has a 98% specificity and a 75% sensitivity (Australia Iron Status Advisory Panel, 2006a)).

6.1 Bioavailability

There are two different pathways of absorption for orally consumed iron, depending on whether it is haem or non-haem iron. Haem iron is highly bioavailable and is relatively unaffected by dietary factors. In contrast, non-haem iron absorption is greatly affected by the presence of binding agents in food, which either enhance (e.g. ascorbic acid) or inhibit (e.g. phytate) absorption. The iron from ferric sodium EDTA is in the non-haem iron form.

The Applicant has provided studies showing that iron from ferric sodium EDTA is absorbed at much higher levels than other synthetic non-haem iron sources (iron sulphate, iron sulphite, iron chloride, ferrous fumarate and ferrus biglycinate), especially when dietary inhibitors are present in a meal. A number of studies have also been provided that assess the effectiveness of fortifying foods with ferric sodium EDTA as a means of addressing a low or deficient iron status.

This information would seem to indicate that ferric sodium EDTA may have a significantly high bioavailability than the forms of iron currently permitted in the Code. However, FSANZ notes that this research was conducted on iron deficient populations. Given that the severity and prevalence of this condition is relatively low by international standards in Australia and New Zealand (WHO and FAO, 2004; Australia Iron Status Advisory Panel, 2006b), ferric sodium EDTA may not be as effective in the domestic environment as this literature suggests.

On the basis of the material submitted by the Applicant, FSANZ has therefore identified the following issues as requiring detailed investigation at Draft Assessment:

- The bioavailability of ferric sodium EDTA in the context of a mostly iron replete population; and

- The effectiveness of ferric sodium EDTA in delivering iron to the human body compared to other forms of iron permitted in the Code.

6.2 Potential risks associated with the use of ferric sodium EDTA as a source of iron

The Applicant has supplied evidence on the safety and toxicology of ferric sodium EDTA in support of this Application. These data include but are not limited to:

- a JECFA safety evaluation of ferric sodium EDTA and a United States Food and Drug Administration GRAS notice for use of ferric sodium EDTA as an iron form in areas of world where iron deficiency is highly prevalent;

- toxicological studies of ferric sodium EDTA, including acute, sub-chronic, chronic, developmental, reproductive, mutagenicity, genotoxicity and carcinogenicity studies; and

- studies investigating the effects of ferric sodium EDTA on the absorption and metabolism of other nutrients, including zinc, copper and calcium.

6.2.1 Excess iron absorption

As discussed above, the bioavailability of ferric sodium EDTA may be enhanced compared to other forms of iron, especially when dietary iron inhibitors are present. If ferric sodium EDTA is added to foods at the same level as other forms of iron, it could potentially result in greater levels of dietary iron contributing to the body's iron stores and thus lead to an increased risk of iron overload within the population.

6.2.2 Safety of increased EDTA consumption

JECFA has set an acceptable daily intake for EDTA of 2.5 mg/kg body weight (JECFA, 1974). As ferric sodium EDTA is broken down into iron and EDTA in the small intestine, the contribution of ferric sodium EDTA to total dietary intake of EDTA also needs to be evaluated as part of this Application.

EDTA is already present in the food supply through permission in the Code for the use of calcium disodium EDTA as a preservative and antioxidant of:

- fully preserved fish including canned fish products;
- sauces and toppings (including mayonnaises and salad dressings); and
- fruit drinks and water based flavoured drinks.

The Applicant has not provided any data on current EDTA intake or the contribution to EDTA intake anticipated from fortification with ferric sodium EDTA.

6.2.3 The impact of ferric sodium EDTA on other nutrients

The nutritional safety and the impact of ferric sodium EDTA on the absorption of minerals (such as calcium, zinc, copper, manganese, and magnesium) has been investigated in both animal and human studies. The Applicant has indicated that these studies show no adverse effects.

Studies provided by the Applicant in support of this position include one animal study (Hurrell *et al*., 1994) and four human studies (Solomons *et al*., 1979; Davidsson *et al*., 1994; Davidsson *et al*., 1998; Davidsson *et al*., 2005). The animal study and some of the human data provided by the Applicant shows that the fortification of foods with ferric sodium EDTA has no effect on the absorption or biochemical markers of zinc, calcium, copper, manganese or magnesium. However, one human study (Solomons *et al.,* 1979) shows that at low levels in a meal, ferric sodium EDTA had no effect on plasma zinc levels compared to the control meal, but that higher levels produced a significant decrease in plasma zinc levels.

As there is some uncertainty on how ferric sodium EDTA affects non-iron nutrients, FSANZ will investigate this issue further at Draft Assessment.

6.2.4 Additional data required on the risks associated with ferric sodium EDTA

FSANZ considers that the following data will be needed for a rigorous analysis of the risks associated with ferric sodium EDTA:

- the iron status of Australian and New Zealand populations;
- predicted dietary intake of EDTA; and
- increased iron absorption and EDTA intake due to the use of ferric sodium EDTA as a permitted form of iron.

These data are currently not available to FSANZ and will need to supplied or generated during Draft Assessment.

6.3 Risk assessment summary

This preliminary risk assessment has identified the following issues as potential health risks and benefits associated with the use of ferric sodium EDTA as a source of iron:

- a potentially different bioavailability of the iron available from ferric sodium EDTA compared to iron available from other forms permitted in the Code;

- the ability for ferric sodium EDTA to contribute to the iron status of consumers when it is used as a fortificant in food;

- potential risks associated with excessive iron absorption and/or EDTA intake; and

- the impact on non-iron nutrients that may occur with the consumption of ferric sodium EDTA.

These issues will be explored more fully at Draft Assessment as a means of answering the questions posed in Section 5. To assist in this process, FSANZ invites submitters to comment on Sections 6.1-6.3, and has provided a number of questions below as guidance for such comments.

Questions (Risk Assessment):

1. **How bioavailable is iron sourced from ferric sodium EDTA compared to other sources of iron?**

- Are you aware of studies on the bioavailability of iron from ferric sodium EDTA in addition to those provided by the Applicant?
- The information provided by the Applicant on bioavailability consists predominantly of studies on iron-deficient populations. How relevant then is this data for iron-replete populations, given that ferric sodium EDTA permissions could allow its use in foods that are consumed by the whole population, both iron-deficient and iron replete?

2. **How effective will the use of ferric sodium EDTA be in addressing a reduced iron status compared to other forms of iron permitted in the Code?**

- How does this efficacy relate to Australian and New Zealand populations, given that Australia and New Zealand have a lower prevalence of iron deficiency than most other countries, and that the Applicant's efficacy data is from developing nations?

3. **Are you aware of any evidence on iron overload associated with the use of ferric sodium EDTA as a permitted source of iron?**

4. **Has the use of ferric sodium EDTA as a source of iron in overseas countries increased the intake of EDTA to excessive levels, and if so what were the associated health effects on the population?**

5. **Do submitters consider that ferric sodium EDTA has an effect on non-iron nutrients?**

If yes, then is this impact likely to increase or decrease the bioavailability of non-iron nutrients?

- Are you aware of any scientific evidence detailing the impact of ferric sodium EDTA on non-iron nutrients in addition to that provided by the Applicant?

RISK MANAGEMENT

7. Increased bioavailability and a maximum permitted level

At Initial Assessment, studies indicate that the bioavailability of ferric sodium EDTA may be greater than other synthetic forms of iron currently permitted. If ferric sodium EDTA is added to foods at the same permitted level as other forms of iron, this could potentially result in greater absorption of iron leading to excessive iron levels in the population.

The potential for iron overload requires an investigation of the need to set a maximum permitted level should ferric sodium EDTA be included in the Code as a permitted form of iron. This will be further investigated at Draft Assessment.

8. Options

There are no options other than a variation to the Code for this Application. Therefore the two regulatory options available for this Application are:

Option 1. **Do not approve** ferric sodium EDTA as a permitted form of iron in Standard 1.1.1 of the Code.

Option 2. **Approve** ferric sodium EDTA as a permitted form of iron in Standard 1.1.1 of the Code.

9. Impact Analysis

9.1 Affected Parties

The parties likely to be affected by the Application are: **consumers** of general purpose foods and special purpose foods; manufacturers and / or marketers of specialty ingredients for application in foods and manufacturers or importers of foods with added iron **(industry)**; and the **government enforcement agencies** of Australian States/territories and New Zealand.

9.2 Benefit Cost Analysis

This analysis provides a preliminary assessment of the potential impacts of the regulatory options on the affected parties. A more comprehensive assessment will be undertaken at Draft Assessment.

9.2.1 Consumers

It is likely that maintaining the *status quo* would not have a significant impact on consumers as the iron fortification of general purpose foods and special purpose foods will continue as permitted in Standards 1.1.1, 1.3.2, 2.9.3 and 2.9.4.

Option 2 would provide consumers with a form of iron considered to be more bioavailable than other forms of iron, especially in consumers with low iron status. Those consumers with low iron status, or who have special dietary needs e.g. vegetarian may also potentially benefit from the increased bioavailability of ferric sodium EDTA.

Ferric sodium EDTA is reported to have improved taste and odour which could be considered an advantage to consumers.

The use of ferric sodium EDTA as a permitted form of iron may result in additional costs to industry which would likely be passed on to consumers.

9.2.2 Industry

Maintaining the *status quo* is unlikely to have a significant effect on industry, as manufacturers could continue to add iron to foods in the permitted forms listed in Standard 1.1.1.

Option 2 would provide an additional option for food manufacturers when adding iron to foods. The Applicant indicates that ferric sodium EDTA has excellent stability during processing and storage, with reduced rancidity, off flavours, off colours, metallic taste and unpleasant odours when compared to current permitted forms of iron.

Currently ferric sodium EDTA is permitted as a source of dietary iron in a specific range of foods in the United States of America (USA). Option 2 could provide some consistency with the USA permissions and may potentially provide a trade advantage for the food industry.

9.2.3 Government

There is no particular benefit to Government of either maintaining the *status quo* or Option 2.

Questions (Risk Management):

7. What is the likely impact on consumers, industry and government if the *status quo* was maintained?

8. What is the likely impact on consumers, industry and government if ferric sodium EDTA was permitted to be added as a form of iron to general purpose foods and/or special purpose foods?

9.3 Comparison of Options

At this Initial Assessment stage, no comparison of the identified options can be undertaken. Further information on the risk assessment and risk management aspects of the Application is required before such a comparison can be made. A comparison will therefore be provided at Draft Assessment.

COMMUNICATION

10. Communication and Consultation Strategy

At Initial Assessment, FSANZ does not intend to undertake specific communication and consultation work outside of the two statutory public consultation periods. FSANZ will review the nature of the feedback received from submitters to the Initial Assessment, and determine whether a communication strategy is required for Draft and Final Assessments.

11. Consultation

11.1 Public Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist it in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this Report, which are also presented at Attachment 1.

11.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the listing of ferric sodium EDTA as a permitted form of iron in the Code. Such an approval, if accepted, would warrant a variation to Standard 1.1.1.

- There are currently no permissions that allow for the use of ferric sodium EDTA as a source of iron in the Code.

- The Application is sufficiently different from previous applications to warrant its further consideration.

- There are no other measures that would be more cost-effective than a variation to Standard 1.1.1 that could achieve the same end.

- At this stage no other relevant matters are apparent.

Attachments

1. Questions for Consideration at Initial Assessment

Reference List

1. Australia Iron Status Advisory Panel (2006a) *Definitions and Laboratory Assessment of Iron Status*. http://www.ironpanel.org.au/AIS/AISdocs/labq1ab.htm. Accessed on 20 November 2006a.

2. Australia Iron Status Advisory Panel (2006b) *Iron deficiency in adults: how common is it?* http://www.ironpanel.org.au/AIS/AISdocs/adultdocs/Acommon.html. Accessed on 20 November 2006b.

3. Azko Nobel Functional Chemicals (2006) *Application for the approval of Ferrazone (R) ferric sodium EDTA as a source of iron for use in the manufacture of PARNUTS products and food supplements*. Azko Nobel Functional Chemicals, Netherlands.

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Attachment 1

Questions for Consideration at Initial Assessment

Risk Assessment

1. How bioavailable is iron sourced from ferric sodium EDTA compared to other sources of iron?

    - Are you aware of studies on the bioavailability of iron from ferric sodium EDTA in addition to those provided by the Applicant?
    - The information provided by the Applicant on bioavailability consists predominantly of studies on iron-deficient populations. How relevant then is this data for iron-replete populations, given that ferric sodium EDTA permissions could allow its use in foods that are consumed by the whole population, both iron-deficient and iron replete?

2. How effective will the use of ferric sodium EDTA be in addressing a reduced iron status compared to other forms of iron permitted in the Code?

    - How does this efficacy relate to Australian and New Zealand populations, given that Australia and New Zealand have a lower prevalence of iron deficiency than most other countries, and that the Applicant's efficacy data is from developing nations?

3. What is the potential risk of iron overload from the use of ferric sodium EDTA as a permitted source of iron?

4. What are the potential risks associated with increased EDTA intake from the use of ferric sodium EDTA as a permitted source of iron?

5. Do submitters consider that ferric sodium EDTA has an effect on non-iron nutrients?

    - If yes, then is this impact likely to increase or decrease the bioavailability of non-iron nutrients?
    - Are you aware of any scientific evidence detailing the impact of ferric sodium EDTA on non-iron nutrients in addition to that provided by the Applicant?

Risk Management

6. Is there evidence to support a need to set a maximum permitted level for the addition of ferric sodium EDTA to general purpose foods and / or to special purpose foods?

7. What is the likely impact on consumers, industry and government if the *status quo* was maintained?

8. What is the likely impact on consumers, industry and government if ferric sodium EDTA was permitted to be added as a form of iron to general purpose foods and/or special purpose foods?