4th June 2013

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA

Subject: Application for the inclusion of Sodium hydrosulphite to the Food Standards Code, Standard 1.3.1, Schedule 1, Section 9.4.

Attention: Standards Management Officer

To Whom It May Concern:

Please find attached our application to vary the Food Standards Code, Standard 1.3.1, Schedule 1, section 9.4, for the inclusion of sodium hydrosulphite (sodium dithionite) as a permitted food additive to be used in canned abalone.

This application is being submitted by:
Seafood New Zealand Limited
Private Bag 24 901
Wellington
New Zealand

Contact: Cathy Webb
[redacted]

Regards

Cathy Webb

Seafood Standards Manager
Seafood New Zealand Limited

Executive Summary

This application is made on behalf of the New Zealand abalone industry, to include sodium hydrosulphite (also known as sodium dithionite) as a permitted food additive for use in canned abalone (paua) as set out in the Australia New Zealand Food Standards Code, standard 1.3.1, Schedule 1 section 9.4.

Sodium hydrosulphite is used during the processing of New Zealand canned abalone in solution with water to bleach the abalone. During processing (of canned abalone) sodium hydrosulphite undergoes exothermic chemical decomposition (reduction) and both sodium bisulphite and sodium thiosulphate are formed during this process. Each of these compounds undergoes further decomposition to form sulphur dioxide in the final canned product.

Work has been commissioned to determine the fate of sodium hydrosulphite during the processing (bleaching) of New Zealand abalone. This research, carried out by Massey University in New Zealand, confirmed that the sodium hydrosulphite is fully utilised in the preparation of abalone prior to canning and that there is no evidence of residual sodium hydrosulphite in the canned product.

Sulphur dioxide performs as an antioxidant in the final product and hence acting as a food additive. Sulphur dioxide is approved for use as stipulated in the Australia New Zealand Food Standards Code, standard 1.3.1, section 5 (2).

The inclusion of sodium hydrosulphite as a permitted additive will not increase the residual level of sulphur dioxide in canned abalone as this will remain within the permitted level of 1000 ppm. There is no request to amend the maximum permitted level of Sulphur dioxide.

Canned abalone is a delicacy consumed in relatively small amounts, predominantly by Asian customers around the world. These customers pay a premium price for this delicacy with exports from New Zealand representing approximately $50 million in sales per annum.

In the international market, New Zealand competes with other abalone species (i.e. from other countries) that are naturally golden blonde to nutmeg in colour, this colour is the benchmark for abalone products. New Zealand abalone is the only species in the world where its natural colour is black. Therefore it is necessary to bleach the abalone with sulphites to provide a product of acceptable appearance (i.e. golden blonde to nutmeg colour).

Sodium hydrosulphite is the most efficient compound available to produce a finished product which has acceptable organoleptic properties. It is used as a food additive in other countries such as Canada, Japan and Korea.

This application has been developed in discussion with the Ministry for Primary Industries, who have been supplied a copy of the application, and it has been written in accordance with the Food Standards Australia New Zealand Application Handbook, 1 August 2011. Each section of the Application is headed up with the corresponding Handbook reference.

Application Handbook – 3.1 General Requirements

3.1.1 Form of Application

This application has been written in accordance with the requirements as outlined in the Food Standards Australia New Zealand Application Handbook, dated 1 August 2011.

It is in English, contains an Executive Summary and identifies the relevant section of the Handbook that is being addressed, as each section of the Application is headed up with the corresponding Handbook reference.

Two hard copies (paper) and one electronic copy (flash drive stick) are provided.

3.1.2 Applicant Details

This application has been prepared and is being submitted by:

Seafood New Zealand Limited
74 Cambridge Terrace
Private Bag 24 901
Wellington
New Zealand

Contact: Cathy Webb
Position: Seafood Standards Manager, Seafood New Zealand Limited and Secretariat of the New Zealand Seafood Standards Council
[redacted]

Seafood New Zealand Limited acts on behalf of the New Zealand seafood industry. The main focus is shaping policies and the regulatory framework, ensuring access to fisheries resources, fisheries and environmental management and improving market access.

The New Zealand Seafood Standards Council is an official committee of the Seafood New Zealand Limited. The primary role is to work with regulatory agencies to ensure appropriate standards are set to ensure safe and suitable seafood.

This application has been prepared on behalf of the NZ Seafood Industry, and has been specifically developed in conjunction with the NZ abalone canning companies:

Prepared Foods Processing Limited
PO Box 942
Palmerston North

Pacific Canneries Limited
PO Box 19936
Woolston
Christchurch

3.1.3 Purpose of Application

The purpose of this application is to include a new substance in the list of permitted food additives, which is a variance to Standard 1.3.1, Schedule 1 section 9.4.

Standard 1.3.1, Schedule 1 section 9.4 allows for sulphur dioxide and various sodium and potassium sulphite compounds to be used as food additives in canned fish products (and canned abalone).

This application is to request that sodium hydrosulphite (otherwise known as sodium dithionite) be included as a permitted food additive to be used in canned abalone under Standard 1.3.1, Schedule 1 section 9.4.

3.1.4 Justification for the Application

Need and Advantages

Sodium hydrosulphite (sodium dithionite), $Na_2O_4S_2$ (along with other already approved[1] sulphites) is to be used in the bleaching of canned abalone (paua). New Zealand has a long history of producing canned abalone utilising sulphites (forming sulphur dioxide in the final product) as an effective bleaching agent since 1969.

The Australia New Zealand Food Standards Code, Standard 1.3.1, Schedule 1 section 9.4 allows for sulphur dioxide and various sodium and potassium sulphite compounds to be used as food additives in canned fish products (and canned abalone), with a maximum permitted level of 1000 mg/kg.

The New Zealand Ministry of Agriculture and Fisheries[11] approved sodium dithionite (Blankit IN – market/trade name at the time) for use as an additive in food processes, in 1990. However this approval was not transferred over when legislative change was made to the implement the Food Standards Code.

New Zealand abalone is a high value delicacy which is normally only consumed in relatively small amounts, infrequently, on special occasions. Considering this, the contribution of sulphur dioxide from canned abalone (assuming a residual SO_2 level of 1000 ppm) to the overall daily intake of sulphur dioxide will be very low.

In addition the inclusion of sodium hydrosulphite as a permitted additive will not increase the residual level of sulphur dioxide in canned abalone as this will remain within the permitted level of 1000 ppm. The sodium hydrosulphite itself is fully utilized prior to canning and there is no remaining sodium hydrosulphite residue in the final product[17].

Reason for Use

The accepted colour of canned abalone is golden blonde to nutmeg. The natural colour of New Zealand abalone is black and attempts to market black abalone have been unsuccessful. Therefore it is necessary to bleach New Zealand abalone to achieve the colour demanded by the international market.

During the processing of canned abalone, sodium hydrosulphite undergoes exothermic chemical decomposition (reduction) and both sodium bisulphite and sodium thiosulphate are formed during this process. Each of these compounds undergoes further decomposition to

form sulphur dioxide in the final canned product. The Sulphur dioxide performs as an antioxidant in the final product and hence acting as a food additive.

There is no residual sodium hydrosulphite in the final canned product[17].

Alternative Compounds
Research has been conducted by Massey University[2] in New Zealand on the use of alternative compounds for bleaching New Zealand abalone (paua). This has found that sodium hydrosulphite (sodium dithionite), is the most effective additive when compared with the use of other substances such as enzymes, surfactants, ammonium carbonate, and hydrogen peroxide. The research found that no other agent would give the same quality of product, in terms of colour, texture and flavour.

There are no other applications being made by this applicant in any other countries with regards to the use of sodium hydrosulphite.

Cost Benefit
The export of canned abalone from New Zealand represents approximately $50 million in sales per annum. As has previously been said, New Zealand competes with other abalone species (i.e. from other countries) that are naturally golden blonde to nutmeg in colour - this colour is the benchmark for abalone products.

The majority of New Zealand's wild caught abalone fishery is produced into canned product form, for the international market. Given that alternative compounds do not produce a market acceptable product, if sodium hydrosulphite is not approved it would have a significant economic impact to the New Zealand abalone (paua) industry.

Aside from the direct loss of sales of approximately $50 million per annum, the loss of the New Zealand abalone canning industry would have a direct impact on employment opportunities for abalone divers, processors and canneries. It would also have an indirect impact on associated industries such as, transport and logistics operations. These two in combination would have a significant impact on the New Zealand abalone industry and those industries that rely on it.

Impact on International Trade
It is not anticipated that this proposed change will impact on foods imported into Australia or New Zealand.

3.1.5 Information to Support the Application

We believe that sufficient supporting information and data is supplied with this application, this includes the information contained in Section 3.3 and the references provided. A full reference section is provided in Appendix 1. The source, author(s) and year the data was produced is provided in this reference section.

All data referenced is publically available, with the exception of 4 reports, these are:

- Massey University, Dr Marl Downy (2007)[2]. Investigation of alternative bleaching agents.

- New Zealand Laboratory Services Ltd, Hernandez, N, Prasad, R (2006)[6]. Report Number: 396893
- Facsimile from Ministry of Agriculture, Neil Armitage, 1990[11], Approval of Blankit IN
- Massey University, David RK Harding (2011)[17]. Tracking the fate of sodium dithionite during the bleaching of New Zealand black abalone – paua.

Information in this application is not considered confidential, with the exception of the following report:

- Massey University, David RK Harding (2011)[17]. Tracking the fate of sodium dithionite during the bleaching of New Zealand black abalone – paua.

This report was specifically commissioned by one of the commercial paua processing entities and for commercial reasons, they have requested that the information disclosed in the report (identified above) all intellectual property (or part thereof) arising there from ("the information") is and shall at all times be confidential to the property of (Prepared Foods entity who is submitting this report). The Information therefore can only be used and disclosed to representatives of New Zealand Seafood Industry Council Ltd, New Zealand Food Safety Authority or Food Standards Australia New Zealand, to the extent necessary to undertake the proper purpose of assessing this document and for no other use or disclosure.

Application Support

This application has been prepared on behalf of the New Zealand Seafood Industry, and has been specifically developed in conjunction with the abalone canning companies operating in New Zealand:

Prepared Foods Processing Limited
PO Box 942
Palmerston North

Pacific Canneries Limited
PO Box 19936
Woolston
Christchurch

3.1.6 Assessment Procedure

We estimate that this application will be assessed as a General Procedure – Level 1.

3.1.7 Confidential Commercial Information

Information in this application is not considered confidential, with the exception of the following report:

- Massey University, David RK Harding (2011)[17]. Tracking the fate of sodium dithionite during the bleaching of New Zealand black abalone – paua.

This report was specifically commissioned by one of the commercial paua processing entities and for commercial reasons, they have requested that the information disclosed in the report (identified above) all intellectual property (or part thereof) arising there from ("the information")

is and shall at all times be confidential to the property of (Prepared Foods entity who is submitting this report). The Information therefore can only be used and disclosed to representatives of New Zealand Seafood Industry Council Ltd, New Zealand Food Safety Authority or Food Standards Australia New Zealand, to the extent necessary to undertake the proper purpose of assessing this document and for no other use or disclosure.

This report is reference number 17 and is provided separately in both electronic and hard copy form.

3.1.8 Exclusive Capturable Commercial Benefit

The applicant does not expect to receive an Exclusive Capturable Commercial Benefit as a result of this application, as there are a number of companies manufacturing canned abalone, an no one manufacturer would receive the exclusive benefit.

3.1.9 International and Other National Standards

A. International Standards

Sodium hydrosulfite (sodium dithionite)
While the primary use of sodium hydrosulfite (sodium dithionite) has been as a bleaching agent in textile industries, it is approved for the following uses in food or food related materials:

The Canadian Food Inspection Agency[12] has approved sodium dithionite for use in prepared crustaceans at 150 mg/kg.

The Food and Drug Administration, of the United States of America[16] has identified Sodium hydrosulfite as being Generally Regarded as Safe (GRAS) for use in packaging that is in contact with food for human consumption.

Japan - Sodium hydrosulphite is approved under the Specifications and Standards for Foods, Food Additives[14], under The Food Sanitation Law for use in a variety of food, measured as residue limit of SO_2, including frozen raw crab at 100 mg/kg residual SO_2, prawn at 100 mg/kg residual SO_2 and dried fruits at 200 mg/kg residual SO_2.

Korea – sodium dithionite/hydrosulphite is permitted for food use[17] in a variety of foods and levels.

Sulphur dioxide
Given that sodium hydrosulfite (sodium dithionite) undergoes chemical decomposition (reduction) to form sodium bisulphite and sodium thiosulphate, which are further reduced to form sulphur dioxide in the final canned product, it is also important to consider approvals of sulphur dioxide and sulphite compounds in general.

Codex alimentarius (GFSA on-line)[15] identify Sulfites (provisions are defined at additive group level and thus apply to the total content of the additives participating in this group), are approved for use in a variety of food, including:

Number	Food Category	Max Level	Note
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans and echinoderms	150 mg/kg residual SO_2	140 This note states: Except for use in Canned Abalone (PAUA) which allows 1000 mg/kg residual SO_2.

The Food and Drug Administration, of the United States of America has identified sulphur dioxide as being Generally Regarded as Safe (GRAS)[13, 16] for use in food when used in accordance with good manufacturing practice, except that it should not be used in meats; in food recognized as a source of vitamin B1, on fruits or vegetables intended to be served raw to consumers or to be presented to consumers as fresh.

B. National Standards

The New Zealand Ministry of Agriculture and Fisheries[11] approved sodium dithionite (Blankit IN – market/trade name at the time) for use as an additive in food processes, in 1990.

3.1.10 Statutory Declaration

See attached Statutory Declaration.

3.1.11 Checklist

See attached Checklist.

Section 3.3 Standards Related to Substances Added to Food

3.3.1 Food Additives

A. Technical Information on the Food Additive

1. Nature and Technological Function of the Additive

As previously described in Section 3.1.4, Justification for the Application, the natural colour of New Zealand abalone is black. To produce an acceptable product for to meet international market demand (primarily Asian countries) New Zealand abalone is required to be processed (bleached) to achieve the desired colour (i.e. golden blonde to nutmeg).

During processing, the following reactions occur:

The abalone are placed in a solution of Sodium hydrosulphite and water, where the following occurs:
Sodium hydrosulphite (sodium dithionite) undergoes exothermic chemical decomposition[4,5] (reduction) forming sodium bisulphite and sodium thiosulphate.

Sodium hydrosulphite ($Na_2S_2O_4$) $\longrightarrow$ *Sodium Bisulphite ($NaHSO_3$) + Sodium Thiosulphate ($Na_2S_2O_3$)*

These compounds undergo further decomposition during the canning process to form compounds which are measured as sulphur dioxide in the final canned product.[4, 5]

Sodium Bisulphite ($NaHSO_3$) + Sodium Thiosulphate ($Na_2S_2O_3$) $\longrightarrow$ *Sulphur dioxide (SO_2)*

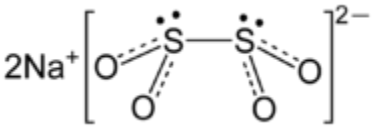
Through this reduction process the black colour of the abalone is changed to a golden blonde to nutmeg colour. The residual Sulphur dioxide performs as an antioxidant reagent in the final product (canned abalone) and hence acting as a food additive, as per Schedule 5 of Standard 1.3.1 – Food Additives.

Note:
Sodium hydrosulphite is fully utilized during processing and no residual sodium hydrosulphite remains in the final canned product[17].

2. Identification of the Additive

Common Name:	Sodium hydrosulphite (sodium dithionite)
CAS Registry Number:	7775-14-6
IUPAC Name:	Dithionous acid, disodium salt (8CI, 9CI)
Molecular Formula:	$Na_2O_4S_2$
Molecular Weight:	174.114 g/mol

Molecular Structure:



Synonyms:

Disodium hydrosulphite
Dithionous acid, disodium salt (8CI, 9CI)
Sodium dithionite
Sodium hydrosulphite
Sodium hyposulphite
Sodium sulfoxilate

Information Source: OECD SIDS Initial Assessment Report[5]

3. Chemical and Physical Properties of the Additive

The Physico-Chemical properties[5] of Sodium hydrosulphite (sodium dithionite) are:

Property	**Value**	**Reference/Comments**
Physical State	Solid	white powder
Melting Point	Decomposition >90°C	Ullmann, 2000
Boiling Point	Not applicable	
Relative Density	2.38 (20°C)	Ullmann, 1994
Vapour Pressure	Not applicable	Non-volatile inorganic salt
Water Solubility	Approx 182 g/l (20°C)	Patel and Rao, 1952
Partition coefficient n-octanol/water (log value)	<-4.7	BASF AG, 1988a
Henry's law constant	Not applicable	Due to ionic solution in water, very high water solubility and decomposition in water

Sodium hydrosulphite is not stable under physiological conditions. It has strongly reducing properties and decomposes rapidly in moisture, with the rate of decomposition increasing with increasing acidity.

Metabolic Fate
Upon contact with moisture, it is oxidized to hydrogen sulphite (HSO_3), sulphite (SO_3) and hydrogen sulphate (HSO_4), with Sulphur dioxide (SO_2) then forming. Under anaerobic conditions (such as in the lower gastrointestinal tract), hydrogen sulphite (HSO_3), and thiosulphate (S_2O_3) may be formed. Hydrogen sulphite (HSO_3) can be absorbed after ingestion. It if efficiently metabolized and the major part rapidly excreted as sulphate into the urine.

Particle size is not important to achieving the technological function as the compound completely dissolves.

Reference: OECD SIDS Initial Assessment Report[5]

4. Impurity Profile

The following profile is taken from the OECD SIDS Initial Assessment Report[5]

Purity	>88 % w/w
Impurities	Disodium disulfite (1 - 5% w/w)
	Sodium sulfite (1 – 5% w/w)
	Sodium thiosulfate (0 – 2 % w/w)

Remarks:
Data refer to product Hydrosulphite P Conc. BASF (BASF AG, 2004a)

According to McKenna et al. (1991) products from commercial suppliers in the USA had a purity <84% w/w. No additional data are available from these production sites.

Samples of Sodium hydrosulphite (sodium dithionite) have been tested in New Zealand by New Zealand Laboratory Services Ltd for impurities and the following results obtained – see attached laboratory report[6].

Impurity	**Result (unit: mg/kg)**	**Limit**	**Reference**
Arsenic	0.8	None (except if indicated by manufacturing method or source)	FAO/WHO Proposed General Limit[7]
Lead	<0.5	2 mg/kg Not more than 5 mg/kg	FAO/WHO Proposed General Limit[7] Compendium Addendum 6/FNP 52 Add.6/159. R; FAO JECFA Monographs 1 vol. 3/465[9]
Mercury	<0.01	1 mg/kg	FAO/WHO Proposed General Limit[7]
Selenium	<1.0	Not more than 20 mg/kg	Compendium Addendum 6/FNP 52 Add.6/159. R; FAO JECFA Monographs 1 vol. 3/465[9]
Copper	<0.2	Not specified	
Iron	4.6	Not specified	

5. Manufacturing Process

Sodium hydrosulphite (sodium dithionite) is relatively unstable and therefore is usually stablised with Sodium Carbonate (INS 500) and Sodium Sulphite (INS 221) (approximately 20%).

Preparations are based on sodium hydrosulphite (sodium dithionite) alkalis, complexing agents and stabilizers.

6. Specification for Identity and Purity

Sodium hydrosulphite (sodium dithionite) undergoes exothermic chemical decomposition[4,5] during preparation and processing of abalone and forms residual Sulphur Dioxide (SO_2, INS no 220) in the final canned product. The sodium hydrosulphite is fully utilized during processing and there is no residual sodium hydrosulphite remaining in the final canned product[17].

As per the Food Standards Code, Sulphur dioxide, sulphites including bisulphites and metabisulphites shall be calculated as sulphur dioxide. Reference Standard 1.3.1, section 5 (2)[1]:

JECFA Evaluations of Sulphur dioxide has been carried out. The Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives[8] for Sulphur dioxide refer to:
Monograph: FAS 42-JECFA 51/95.
Specification: Compendium Addendum 6/FNP 52 Add.6/159. R; FAO JECFA Monographs 1 vol. 3/465[9]

Summary of Purity Specification

Impurity	Limit	Reference
Arsenic	None (except if indicated by manufacturing method or source)	FAO/WHO Proposed General Limit[7]
Lead	2 mg/kg Not more than 5 mg/kg	FAO/WHO Proposed General Limit[7] Compendium Addendum 6/FNP 52 Add.6/159. R; FAO JECFA Monographs 1 vol. 3/465[9]
Mercury	1 mg/kg	FAO/WHO Proposed General Limit[7]
Selenium	Not more than 20 mg/kg	Compendium Addendum 6/FNP 52 Add.6/159. R; FAO JECFA Monographs 1 vol. 3/465[9]

7. Information for Food Labelling

All products are labeled in accordance with the Food Standards Code, Part 1.2 Labelling and Other Information Requirements[10]. Specifically, in accordance with Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations, this requires the mandatory declaration that the product contains sulphites.

The potential for allergic reactions (sulphites) should be assumed in sensitive individuals following oral or inhalation exposure, and therefore all canned Abalone is labelled to declare that the product contains sulphites.

8. Analytical Method for Detection

This application seeks approval for Sodium hydrosulphite (sodium dithionite) as a food additive to compliment an array of other already approved sulphite compounds. Sodium hydrosulphite (sodium dithionite) undergoes exothermic chemical decomposition to form residual Sulphur dioxide in the final product.

Sulphur dioxide is the primary compound of concern and is analysed using the Monier-Williams test.

As per the Food Standards Code, Sulphur dioxide, sulphites including bisulphites and metabisulphites shall be calculated as sulphur dioxide. Reference Standard 1.3.1, section 5 (2):

The maximum permitted level of Sulphur dioxide (SO_2) for canned Abalone is 1000 mg/kg.

9. Potential additional functions of the food additive when added to food

N/A

B. Safety of the Food Additive

Additive Safety
As is explained further in this application, during processing of canned abalone, sodium hydrosulphite (sodium dithionite) undergoes chemical decomposition (reduction) to form sodium bisulphite and sodium thiosulphate. These are further reduced to form sulphur dioxide in the final canned product.

The Australia New Zealand Food Standards Code, Standard 1.3.1, Schedule 1 section 9.4 allows for sulphur dioxide and various sodium and potassium sulphite compounds to be used as food additives in canned fish products (and canned abalone), with a maximum permitted level of 1000 mg/kg.

Research has been carried out to determine the effects of sulphur dioxide by the World Health Organisation. The Joint FAO/WHO Expert Committee of Food Additives (JECFA) has carried out studies[3] of Sulphur dioxide in rats and humans. It was noted that local irritation of the stomach occurred with a NOEL of 0.25% sodium metabisulphite in the diet equivalent to 70 mg/kg Body Weight (BW) per day of Sulphur dioxide equivalents.

Eating a whole piece of abalone from the can, gives 2 mg SO_2 per kg BW which is lower than the findings reported to cause stomach irritations.

New Zealand Abalone is a high value delicacy which is normally only consumed in relatively small amounts, infrequently, on special occasions. Considering this, the contribution of sulphur dioxide from canned abalone (assuming a residual SO_2 level of 1000 ppm) to the overall daily intake of sulphur dioxide will be very low.

In addition the inclusion of sodium hydrosulphite as a permitted additive will not increase the residual level of sulphur dioxide in canned abalone as this will remain within the permitted level of 1000 ppm.

The potential for allergic reactions (sulphites) should be assumed in sensitive individuals following oral or inhalation exposure.

Samples of Sodium hydrosulphite (sodium dithionite) have been tested in New Zealand by New Zealand Laboratory Services Ltd[6] for impurities. Refer to section 4 above.

1. Toxicokinetics and Metabolism of the Food Additive and its Degradation Products

The OECD SIDS Initial Assessment Report[5] included an assessment on Human Health Hazards. As part of this assessment, Sodium hydrosulphite (sodium dithionite), was not tested in toxicokinetics or metabolism studies. The report (section 3.1.1) concludes:

Sodium hydrosulphite (sodium dithionite) is not stable under physiological conditions, with the rate of decomposition increasing with acidity. Upon contact with moisture it oxidizes to hydrogen sulphite and hydrogen sulphate, and under strongly acidic conditions, may liberate sulphur dioxide. Under anaerobic conditions, hydrogen sulphite and thiosulphate may also be formed. Hydrogen sulphite can be absorbed after ingestion. It is efficiently metabolized and the major part rapidly excreted as sulphate into the urine

The full report is submitted with this application.

2. Toxicity of the Food Additive and its Degradation Products

The OECD SIDS Initial Assessment Report[5] included an assessment on Human Health Hazards.

The report on hazards to human health covered the following aspects:

- Toxicokinetics, Metabolism and Distribution
- Acute Toxicity
- Irritation
- Sensitization
- Repeated Dose Toxicity
- Mutagenicity
- Carcinogenicity
- Toxicity for Reproduction

The full report is submitted with this application.

3. Safety Assessment Reports

A Safety Evaluation of Certain Food Additives, WHO Food Additives Series 42, Prepared by the Fifty-first meeting of the joint FAO/WHO Expert Committee on Food Additives (JECFA)[3] was carried out for Sulphur dioxide and sulphites.

The report covered sulphur dioxide and sulphur dioxide equivalents arising from sodium and potassium metabisulphite, sodium sulphite and sodium hydrogen sulphite. The outcome of this report is that the committee retained the ADI of 0-0.7 mg/kg BW allocated to this group of compounds.

The ADI was based on long-term studies in rats, including a three-generation study of reproductive toxicity, with a NOEL of 0.25% sodium metabisulphite in the diet (supplemented with thiamine, as treatment of foods with sulphites reduces their thiamine content), equivalent to 70 mg/kg bw per day of sulphur dioxide equivalents. At higher doses (≥ 1%), local irritation of the stomach was observed with inflammatory changes and hyperplasia, and occult blood was detected in the faeces at even higher doses. The histopathological changes were limited to the stomach; the incidence of neoplasms was not increased at any site or any does. A safety factor of 100 was used.

The committee also reviewed case studies and challenge tests for idiosyncratic sensitivity to sulphiting agents and noted the life-threatening nature of the adverse effects in some cases. The committee reiterated the view that appropriate labeling is the only feasible means of protecting individuals who cannot tolerate certain food additives.

This report covered the following areas:

- Biological data
  - Biochemical aspects
    - Biotransformation
    - Effects on enzymes and other biochemical parameters
  - Toxicological studies
    - Short-term studies of toxicity
    - Genotoxicity
    - Developmental toxicity
    - Special studies
      - Nephrotoxicity
      - Promotion of carcinogenesis
  - Observations in humans
    - Case studies
    - Food challenges
    - Prevalence studies
      - Adults
      - Children

The full report[3] is submitted with this application.

C. Information related to Dietary Exposure to the Food Additive

1. Food Groups or Food Proposed to Contain the Additive

The only food group this is being proposed to be used in is canned abalone (paua). The relevant section of the Australia New Zealand Food Standards Code is standard 1.3.1, Schedule 1 section 9.4[1].

The average serving size of canned abalone is approximately 38g, this will give an approximate intake of 0.69 mg/kg of SO_2, to a person weighing 55 kg. However, New Zealand Canned Abalone is a high value delicacy which is only consumed infrequently, on special occasions. Considering this, the contribution of sulphur dioxide from canned Abalone (assuming a residual SO_2 level of 1000 ppm) to the overall daily intake of sulphur dioxide will be very low.

In addition, the inclusion of sodium hydrosulphite as a permitted additive will not increase the residual level of sulphur dioxide in canned abalone as this will remain within the permitted level of 1000 ppm. There is no request to amend the maximum permitted level of sulphur dioxide. Research has shown that all of the sodium hydrosulphite is fully utilized prior to canning (during preparation and processing) and there is no residual sodium hydrosulphite remaining in the final canned product.

Extensive research has been carried out to determine the effects of sulphur dioxide by the World Health Organisation. The WHO Food Additive Series (42)[3] recommend an acceptable daily intake (ADI) for sulphur dioxide of 0 to 0.7 mg/kg BW.

2. The Maximum Proposed Level and/or Concentration

As previously described Sodium hydrosulphite (sodium dithionite) undergoes exothermic chemical decomposition to form residual sulphur dioxide in the final product.

As per the Food Standards Code, sulphur dioxide, sulphites including bisulphites and metabisulphites shall be calculated as sulphur dioxide. Reference Standard 1.3.1, section 5 (2):

The maximum permitted level of sulphur dioxide (SO_2) for canned Abalone is 1000 mg/kg.

As stated, the inclusion of sodium hydrosulphite as a permitted additive will not increase the residual level of sulphur dioxide in canned abalone as this will remain within the permitted level of 1000 ppm.

There is no request to amend the maximum permitted level of sulphur dioxide.

3. N/A

4. Percentage of the Food Group in which the Additive is Proposed to be Used

Approximately 90% of commercially harvested abalone (in New Zealand) is processed into Canned abalone for the international markets. All canned abalone requires the addition of sulphites to bleach the abalone to a suitable colour for market acceptance.

Sodium hydrosulphite is not used in live or fresh abalone.

5. Use of Food Additive in Other Countries

The OECD SIDS Initial Assessment Report[5] notes the following:
All uses of sodium dithionite are based on its reducing properties. It is predominately used as a bleaching agent, and in some countries for bleaching sugar, fruit, edible oils, edible fats and gelatin.

As described in the General Section, 3.1.9 A & B of this application, sodium hydrosulphite (sodium dithionite) is also approved for use in food and food related materials in the following countries.

The New Zealand Ministry of Fisheries[11] approved Sodium dithionite (Blankit IN – market name) for use as an additive in food processes, in 1990.

The Canadian Food Inspection Agency[12] has approved sodium dithionite for use in prepared crustaceans at 150 mg/kg.

The Food and Drug Administration, of the United States of America[13] has identified Sodium hydrosulfite as being Generally Regarded as Safe (GRAS) for use in packaging that is in contact with food for human consumption.

Japan - Sodium hydrosulphite is approved under the Specifications and Standards for Foods, Food Additives[14], under The Food Sanitation Law for use in a variety of food, measured as residue limit of SO_2, including frozen raw crab at 0.10 g/kg residual SO_2, prawn at 0.10 g/kg residual SO_2 and dried fruits at 2.0 g/kg residual SO_2.

Korea – sodium dithionite/hydrosulphite is permitted for food use[17] in a variety of foods and levels.

6. Changes in Consumption and Likely Current Food Consumption

As previously described approximately 90% of commercially harvested abalone (in New Zealand) is processed into canned abalone for the international markets, the export volumes have remained relatively stable and as such there is no evidence to suggest there has been any significant changes in consumption levels.

Appendix 1: Reference List

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9. Compendium Addendum 6/FNP 52 Add.6/159. R; FAO JECFA Monographs 1 vol. 3/465

10. Australia New Zealand Food Standards Code, Part 1.2 Labelling and Other Information Requirements. http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm

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13. Code of Federal Regulations (2009) Title 21, Part 182 Substances Generally Recognized as Safe, Subpart D Chemical Preservatives. Revised, April 1 2009: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=182

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15. Codex Alimentarius GSFA Online Food Additive Group Details for Sulfites, 32nd Session of the Codex Alimentarius Commission (2009)

    http://www.codexalimentarius.net/gsfaonline/groups/details.html?id=161

16. US Food and Drug Administration GRAS Substance (SCOGS) Database. http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASSubstancesSCOGSDatabase/ucm084104.htm

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