7 October 2014
[20–14]

Approval Report – Application A1088

Sodium Hydrosulphite as a Food Additive

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Seafood New Zealand Limited to include sodium hydrosulphite (sodium dithionite) as a food additive (antioxidant) to be used for canned abalone.

On 16 May 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 18 September 2014. The Australia and New Zealand Ministerial Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 3 October 2014.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at
http://www.foodstandards.gov.au/code/applications/Pages/A1088.aspx

SD1 Risk and Technical Assessment Report

Executive summary

Seafood New Zealand Limited, which acts on behalf of the New Zealand seafood industry, submitted an Application seeking sodium hydrosulphite (also called sodium dithionite) to be a permitted food additive to treat canned New Zealand abalone (paua). There are currently a number of sulphites permitted by the *Australia New Zealand Food Standards Code* (the Code) as food additives to treat canned abalone. The Application contends that these are unsuitable to bleach the black colour of the native New Zealand abalone to a commercially acceptable golden blonde to nutmeg colour, especially for export markets where the majority of New Zealand canned abalone is sold.

New Zealand canned abalone producers have been permitted to treat native New Zealand abalone with sodium hydrosulphite due to a permission provided in 1990 by the former New Zealand regulator, the Ministry for Agriculture and Forestry (MAF), now the Ministry for Primary Industries (MPI). However, this permission was not transferred to the current Code. This Application seeks to ensure the Code rectifies this.

Food additives are regulated by Standard 1.3.1 – Food Additives. Food additives cannot be added to food unless they are permitted in the Standard. Schedule 1 of Standard 1.3.1 contains food additive permissions for food categories. Food category 9.4 (fully preserved fish including canned fish products) contains a subcategory called 'canned abalone (paua)' which has permission for sulphur dioxide and a number of sulphites, but not sodium hydrosulphite. The permissions for sulphites to treat canned abalone have a maximum permitted level (MPL) of 1000 mg/kg, calculated as sulphur dioxide, which was requested for sodium hydrosulphite.

A key consideration in assessing this Application was whether the permission should be granted as a food additive or a processing aid. The food technology assessment concluded that sodium hydrosulphite fulfils the stated technological function as a food additive antioxidant having bleaching properties (at the proposed maximum permitted level of 1000 mg/kg). Sodium hydrosulphite bleaches the black colour of paua to a golden blonde to nutmeg colour which is more acceptable to consumers and it prevents subsequent oxidation and discolouration during shelf life. The Application indicated that sodium hydrosulphite is the most effective compound available to produce a canned abalone product with acceptable organoleptic properties.

During the processing of canned abalone, sodium hydrosulphite undergoes chemical decomposition to produce the same chemical species that result from use of the other approved sulphites. No residual hydrosulphite is detectable in the final canned product. Therefore, the use of sodium hydrosulphite in the production of canned abalone will not result in dietary exposure to a new food additive or additional dietary exposure to sulphites.

FSANZ concluded that the use of sodium hydrosulphite as a food additive in canned abalone is technologically justified and presents no identifiable public health and safety issues above those of the currently permitted sulphites in canned abalone.

Therefore, FSANZ approved draft variations to permit the use of sodium hydrosulphite as a food additive to treat canned abalone in Schedule 1 of Standard 1.3.1, along with consequential additions to Schedule 2 of Standard 1.2.4 – Labelling of Ingredients.

1 Introduction

1.1 The Applicant

The Applicant is Seafood New Zealand Limited, which acts on behalf of the New Zealand seafood industry. The Applicant's main focus is shaping policies and the regulatory framework, to ensure access to fisheries resources, fisheries and environmental management and improved market access. The Application was prepared with New Zealand abalone canning companies.

1.2 The Application

The purpose of the Application was to seek permission for sodium hydrosulphite (also called sodium dithionite[2]) to be used as a food additive to be added to canned abalone. It would be an alternative to other food additive sulphites currently permitted to be added to canned abalone. The justification for the Application was that the other sulphites are not as suitable as sodium hydrosulphite to bleach the natural black colour of the native New Zealand abalone (paua) to a more consumer-acceptable colour and maintain this bleached colour during shelf life.

The former New Zealand Ministry of Agriculture and Fisheries approved sodium hydrosulphite (called sodium dithionite in the notice) for use like other sulphites as a food additive in 1990. This permission was not transferred into the current joint *Australia New Zealand Food Standards Code* (the Code) when it became the sole food Code for both countries in 2002. This Application seeks to rectify this situation and so ensure the current industry practice of treating canned New Zealand abalone with sodium hydrosulphite is consistent with the Code. In New Zealand, the Ministry for Primary Industries (MPI) is able to permit the export of food that is not compliant with the Code, though some product is also sold in New Zealand.

1.3 The current Standard

Food additives are regulated by Standard 1.3.1. Food additives cannot be added to food unless they are permitted in the Standard. This Standard includes the permissions and any qualifications for adding food additives to processed food.

There is currently no permission for adding sodium hydrosulphite to canned abalone or any processed food in the Standard. Schedule 1 of Standard 1.3.1 contains food additive permissions for food categories. Food category 9.4 (fully preserved fish including canned fish products) contains a subcategory called 'canned abalone (paua)' which has permission for sulphur dioxide and a number of sulphites, but not sodium hydrosulphite. The currently permitted sulphites are 220 (sulphur dioxide), 221 (sodium sulphite), 222 (sodium bisulphite), 223 (sodium metabisulphite), 224 (potassium metabisulphite), 225 (potassium sulphite) and 228 (potassium bisulphite).

Bleaching agents permitted as processing aids are listed in clause 12 (permitted bleaching agents, washing and peeling agents) of Standard 1.3.3 – Processing Aids. It is noted that some substances can be classified as either a processing aid or a food additive, depending on the technological function they perform.

[2] This report uses the term sodium hydrosulphite throughout, unless the international regulations use the term sodium dithionite, in which case that name is used. When international regulations use the alternative spelling of 'hydrosulfite' this is also used in the report.

Schedule 2 food additives are also generally permitted processing aids due to subclause 3(b) of Standard 1.3.3 but this does not apply for sulphites. An assessment of whether sodium hydrosulphite performs its technological function for the stated purpose of this Application as a food additive or processing aid formed part of the assessment. This is addressed in section 2.3.1 in the report.

1.3.1 International Standards

The international and national permissions for use of sodium hydrosulphite as a food additive relevant to this Application are summarised below.

1.3.1.1 Codex Alimentarius

Sodium hydrosulphite is not currently a permitted food additive in Codex's General Standard for Food Additives (GSFA). Therefore, the substance is not listed nor does it have a Codex food additive number (International Numbering System, INS) in the Codex Standard CAC/GL 36-1989 (Class Names and the International Numbering System for Food Additives).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not made an assessment of sodium hydrosulphite. Food additives are usually assessed by JECFA before they are considered for addition to the GSFA. Because there are only a small number of countries that have a technological need for the use of sodium hydrosulphite as a food additive, it is possible that no request has been made for either a JECFA assessment or Codex permission.

1.3.1.2 Canada

The Canadian Food and Drug Regulations (C.R.C., c. 870) permit sodium dithionite as a class II preservative food additive to be added to a variety of foods as detailed in section B.16.100, Table XI, Part II. Sodium dithionite is listed in this Table as item S.8, where the permissions and maximum levels of use are for the same foods and the same levels as listed for sulphurous acid (item S.10). Food category 11 in S.10 is crustaceans, where the maximum level of use is listed as in accordance with 'Good Manufacturing Practice. Residues in the edible portion of the uncooked product not to exceed 100 ppm (mg/kg), calculated as sulphur dioxide'.

There is also a specific regulation in the Food and Drug Regulations dealing with the food additive permissions for crustaceans (B.21.006.(o)) that allows crustaceans to contain sodium dithionite or other sulphites: potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium metabisulphite, sodium sulphite or sulphurous acid. Regulation B.01.010 allows that the permitted sulphites may be listed in the ingredients list by the common names 'sulphites, sulphiting agents, sulphites or sulphiting agents'. This food additives list is the same as that listed above in regulation B.21.006.(o).

The Canadian Food Inspection Agency references this same regulation (B.21.006.(o)) in the list of permitted additives in fish and fish products which includes sodium dithionite.

1.3.1.3 Japan

Japan's Specification and Standards for Food Additives (7th Edition, 2000) permits sodium hydrosulfite, along with a number of other sulphites, as food additives to be added to a wide variety of foods with specific maximum limits determined as sulphur dioxide. The technological function is as a bleaching agent. Among the treated foods are frozen raw shelled crab and shelled prawn, both with a maximum limit of 0.1 g/kg (residue limit of SO_2) (equivalent to 100 mg/kg (ppm)).

Japan's Specification and Standards for Food Additives (7th Edition, 2000) also contains a specific specification for sodium hydrosulfite.

The same permissions for sodium hydrosulfite from Japan's Specification and Standards for Food Additives (7th Edition) are also listed in the later document 'Specifications and Standards for Foods, Food Additives, etc Under the Food Sanitation Act (Abstract) 2010' (produced by the Japan External Trade Organization, JETRO).

1.3.1.4 Korea

The Korean Food and Drug Administration regulates food additives via the Korean Food Additives Code. The Korean Food Additives Code contains permissions for addition of sodium hydrosulfite to different types of foods as well as a specification for the substance. There is permission to use sodium hydrosulfite as a food additive for shrimp flesh to a permitted level of 0.1 g/kg (100 mg/kg).

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that might be developed as a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

The issues raised in submissions have been reviewed and addressed by FSANZ in Table 1. The report and SD1 has been amended following these submissions.

The main issues raised in submissions are summarised as:

- The cultural significance of New Zealand abalone (paua) to Māori and New Zealanders has not been recognised. Changing the colour of paua by bleaching changes its identity and its prestige.

- What is the cost of not allowing sodium hydrosulphite to bleach canned abalone? Are there any other alternative treatments?

- Is the technological function of sodium hydrosulphite when it is used to bleach canned abalone more appropriate to be considered a processing aid rather than a food additive? Standard 1.3.3 – Processing Aids contains bleaching agent as a current processing aid function while there is no food additive function, class or sub-class in Standard 1.3.1 or Standard 1.2.4 for bleaching agent.

- Will sodium hydrosulphite treated exported canned abalone be accepted in other countries?

Table 1: Summary of issues

Issue	Raised by	FSANZ response
There has been a failure to highlight (and assess) the cost of not allowing sodium hydrosulphite to be added to treat canned abalone.	Two New Zealand individuals	The Application, and FSANZ's cost benefit analysis (section 2.5.11 of the Call for Submissions) notes that the canned New Zealand abalone (paua) export market is quite valuable to New Zealand exporters; worth about NZ$50 million in sales per annum. The vast majority (approximately 95-98%) of the canned abalone market is exported; mainly to Asian markets. These Asian markets have a strong consumer preference for a bleached colour, rather than the natural very dark colour of the native New Zealand abalone. As noted in section 2.2 of SD1, the New Zealand canned abalone industry commissioned research to investigate alternatives to sodium hydrosulphite but they were unable to identify any suitable alternative bleaching agent. Only canned abalone is treated with sulphites, not other forms of New Zealand abalone sold for consumption such as live, chilled or frozen abalone.
No consideration of alternative solutions	Two New Zealand individuals	As noted in the Application and discussed in section 2.2 of SD1, research was commissioned by the New Zealand canned abalone industry investigating alternative treatments to bleach New Zealand canned abalone for the export market. No alternative treatments were identified.
There has been no consideration of the cultural significance of New Zealand abalone (paua) to Maori, and New Zealanders. **To change its colour is to change its identity and its significance. Will canned bleached paua also be sold to the domestic New Zealand market?**	Two New Zealand individuals	FSANZ acknowledges the cultural significance of paua to Māori. We also understand that the view that modern processing should not be applied to fish and shellfish is not held by all Māori, as evidenced by their involvement in a broad range of fish commercialization operations. Māori are well represented on the New Zealand Seafood Council, the Applicants for this Application. Māori commercial enterprises relating to paua harvesting, processing or export make up a large portion of the paua industry. The company which is responsible for 70% of the NZ total commercial paua quota is Māori owned and many iwi (Māori tribe) are represented. The company responsible for the bleaching of paua is wholly owned by this major Māori fisheries company. Therefore, it may be concluded that the Application has broad support from Māori. It is also noted that canned paua has been bleached using sodium hydrosulphite for many years; essentially for the export markets where there is a consumer expectation of a lighter, more acceptable golden blonde to nutmeg colour. Most of the canned bleached paua is produced and sold for the export Asian market, however some is sold domestically, mainly to cater for the Asian food market. It is important to note that only canned New Zealand abalone are bleached via treatment with sulphites. Other forms of paua sold or consumed in New Zealand, such as live, chilled or frozen, will not be bleached, since the permission is only for canned product.

Issue	Raised by	FSANZ response
Concern about the technological function that sodium hydrosulphite is performing when it is used to bleach the abalone when it is canned. **Bleaching is not listed as an appropriate classification, class or sub-class, for technological function of a food additive (schedule 5 of Standard 1.3.1) or for labelling of food additives (Schedule 1 of Standard 1.2.4). However there is a processing aid category, being the Table to clause 12 of Standard 1.3.3 which is titled 'bleaching, washing and peeling agents'.**	Victorian Department of Environment & Primary Industries Victorian Department of Health	This issue has been more fully addressed in section 2.3.1 of this Report and section 2.2 of SD1. The reports have been altered and the issue more fully addressed as a result of this submission. The issue was also discussed at FSANZ's Jurisdictional Forum and a subsequent targeted consultation with three jurisdictions.
A minority of members of the Technical Sub Committee supported accepting the Application but had some concerns and issues, especially: • **Lacking of toxicological information** • **Only supported use in one country i.e. Japan** • **Will exported product be permitted in other countries?** • **Not clear that the substance will only be permitted for canned abalone (paua) under food category 9.4 in Schedule 1 of Standard 1.3.1. Expect to see the changes to the Code following gazettal in the Application.** •	Food Technology Association of Australia	The safety assessment (being the hazard assessment and risk characterisation) for sodium hydrosulphite in SD1 was quite brief since the active species are no different to other sulphite chemicals which are currently permitted and have been fully assessed. Sodium hydrosulphite is not currently a permitted Codex food additive but it is permitted for use by Canadian, Japanese and Korean food regulations. It is the responsibility of the exporters to determine regulatory compliance in the country of designation and this is not a consideration in the approval of the Application. Canned New Zealand abalone treated with sodium hydrosulphite has been successfully exported for many years; mainly to Asian countries, without regulatory issues. The approved variation (which is unchanged from the proposed drafting at Attachment A in the Call for Submissions) only permits the use of the substance in relation to canned abalone (paua) under food category 9.4 in Schedule 1 of Standard 1.3.1. The Application did not contain a version of what the amended drafting to the Code would look like if it was successful but the purpose statement in the Application was clear as to what was requested.

2.2 Risk assessment

FSANZ's Risk and Technical Assessment Report is provided as SD1 (Attachment 2), with the conclusions summarised here. The food technology assessment concluded that sodium hydrosulphite fulfils the stated technological function as a food additive antioxidant with bleaching properties and at the proposed level of use. Sodium hydrosulphite bleaches the black colour of paua to a golden blonde or nutmeg colour which is more acceptable to the consumer and prevents subsequent oxidation and discolouration during shelf life, especially for the international market. The Application provided research in the Application conducted by Massey University that indicated that sodium hydrosulphite is the most effective compound available to produce a canned abalone product with acceptable organoleptic properties.

During the processing of canned abalone, the hydrosulphite anion ($S_2O_4^{2-}$) undergoes chemical decomposition to produce the same chemical species that result from use of the other approved sulphites, with the sulphite anion (SO_3^{2-}) as the predominant form and a minor proportion as the bisulphite anion (HSO_3^-). No residual hydrosulphite anion is detectable in the final canned product. Therefore, the use of sodium hydrosulphite in the production of canned abalone will not result in dietary exposure to a new food additive or additional dietary exposure to sulphites.

FSANZ is currently conducting a risk assessment of sulphites in the Australian and New Zealand food supply as part of Proposal P298 - Benzoate and Sulphite Permissions in Food. The sulphite permissions for canned abalone are not under review in that Proposal because consumption of canned abalone is very low compared to foods that are the major contributors to total dietary exposure to sulphites.

Some individuals are sensitive to sulphites (e.g. some asthmatics) and this will also be the case for sodium hydrosulphite.

It is concluded that the use of sodium hydrosulphite as a food additive in canned abalone is technologically justified and presents no identifiable public health and safety issues above those of the sulphite food additives currently permitted in canned abalone.

2.3 Risk management

2.3.1 Technological function, food additive or processing aid?

The risk assessment conclusion is that sodium hydrosulphite is technologically justified and is safe to be used to treat canned abalone.

FSANZ did carefully consider the question of what is the appropriate technological function for sodium hydrosulphite when used to bleach the colour of paua. It is not always clear what is the predominant or appropriate technological function that a chemical substance performs when it is added to food.

There is no listing of a 'bleaching agent' function in Schedule 5 of Standard 1.3.1 (which lists the technological functions which may be performed by food additives). However, 'antioxidant' and 'preservative' are listed functions in Schedule 5. Bleaching agent is a permitted form of processing aid (listed in the Table to clause 12 of Standard 1.3.3 – Processing Aids).

All sulphites, including hydrosulphite, are antioxidants and also are reducing agent bleaches. Sodium hydrosulphite is a stronger reducing agent than other sulphites so it is a strong antioxidant with bleaching properties.

Sulphites, including sodium hydrosulphite, are added to abalone prior to canning to have an antioxidant effect to prevent the oxidation of blood pigment (haemocyanin). That is, after the dark colour of the paua has been bleached using hydrosulphite, the lighter colour is maintained by preventing oxidation and discolouration of the treated paua flesh during storage and shelf life of the canned product. Therefore, sodium hydrosulphite performs an ongoing technological function as an antioxidant, after it initially bleaches the original dark colour of paua, by preventing discolouration of the treated lighter coloured flesh.

As noted, there are seven sulphites already permitted as food additives to be added to canned abalone in Schedule 1 of Standard 1.3.1. To regulate sodium hydrosulphite differently to the other seven already permitted sulphite food additives to treat canned abalone was considered inappropriate and inconsistent.

FSANZ considered the option of permitting the substance solely as a processing aid (bleaching agent) but concluded that since it does have an ongoing technological function as an antioxidant food additive that was inappropriate. Adding a new food additive functional class of 'bleaching agent' to Schedule 5 of Standard 1.3.1 was not considered appropriate as an outcome of this Application as it could have broader ramifications.

FSANZ noted the concern raised by a jurisdiction in their submission on this issue and it held further consultation with some specific jurisdictions to further explore all the available options noted above. It was concluded that the broader issue of possible inconsistencies in assignment of substances between Standard 1.3.1 and 1.3.3 were beyond the scope of this Application but need to be addressed in a broader review of these two Standards at a later stage.

Therefore, FSANZ decided to add sodium hydrosulphite to the list of permitted food additives for the food category 'canned abalone (paua)' under category 9.4 (Fully preserved fish including canned fish products) in Schedule 1 of Standard 1.3.1.

2.3.2 Other risk management matters

The Application requested that the same maximum permitted level (MPL) for the current sulphite permissions (1000 mg/kg calculated as sulphur dioxide) for canned abalone be permitted for sodium hydrosulphite. It was noted that this level is higher than the residues for comparable products (i.e. shrimp, prawns etc) regulated in other countries but these countries do not specifically list permissions for sodium hydrosulphite in canned abalone. This MPL is viewed as appropriate since the risk assessment concludes that the same active species formed from treatment with sodium hydrosulphite exist as those formed by treatment with the other permitted sulphites.

To address the issue of consumers who are sensitive to sulphites (e.g. some asthmatics), sulphites must be declared on the label in the ingredients list when added to food in concentrations of 10 mg/kg or more (clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations). This labelling requirement provides sulphite-sensitive consumers with the information required to avoid these foods. This requirement would also apply to sodium hydrosulphite used for canned abalone.

Sodium hydrosulphite does not have a Codex Alimentarius INS number so a dash ('-') in the column for INS numbers is used in the Code.

The food additive name to be added to the Code, for both permissions (Schedule 1 of Standard 1.3.1) and for ingredient labelling purposes (Schedule 2 of Standard 1.2.4) was proposed to be the name used in the Application and in this report, being 'sodium hydrosulphite'.

A specification is not required to be written for the food additive in the Schedule for Standard 1.3.4 (Identity and Purity) since there is a specification in the Japanese Specifications and Standards for Food Additives, 7th edition (2000) which is a secondary source of specifications in clause 3 of the Standard.

2.4 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal.

The approved draft variation is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on the Application was considered and reviewed by FSANZ staff, who examined the issues identified and prepared a response (see Table 1). All comments are valued and contribute to the rigour of our assessment.

FSANZ called for public comment between 16 May 2014 and 27 June 2014 following assessment of the Application. Six submissions were received from two jurisdictions, one food industry association, one food technology association and two individuals. The two individual submissions opposed the progression of the Application, two submissions supported it, while two submissions had general support, but raised a number of questions and issues which they asked to be addressed (see Table 1).

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions were notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

The FSANZ Board considered the draft variation taking into account public comments received from the call for submissions.

The Applicant, individuals and organisations that made submissions on this Application are notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

The FSANZ Board's decision has been notified to the the Australia and New Zealand Ministerial Forum on Food Regulation[3] (Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Cost benefit analysis

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to food additives as they are machinery in nature and the permission, if granted, is voluntary.

However, FSANZ performed a summary cost benefit analysis. FSANZ concluded that permitting sodium hydrosulphite as a food additive antioxidant to treat canned abalone provides an overall benefit. There are no added costs to consumers or government agencies. There are economic benefits to the New Zealand canned abalone industry for export markets, from being able to produce a coloured product that is acceptable to consumers and which cannot be produced using other sulphites.

2.6.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.6.1.3 Any relevant New Zealand standards

There are no relevant New Zealand standards.

2.6.1.4 Any other relevant matters

There are no other relevant matters.

2.6.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) of sodium hydrosulphite and concluded that there are no specific public health and safety concerns with this particular form of sulphite compared to those already currently permitted to treat canned abalone. Sodium hydrosulphite addition is covered by the same mandatory declarations for sulphites as noted in section 2.3, which provides labelling information to consumers who have sulphite sensitivities to make informed purchasing choices.

[3] convening as the Australia and New Zealand Food Regulation Ministerial Council

2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The existing labelling requirements in Standard 1.2.4 – Labelling of Ingredients for declaring food additives will apply. These requirements are considered to be appropriate for canned abalone (see section 2.3).

2.6.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

This Application was assessed using the best available scientific evidence. The Applicant submitted a dossier of scientific studies in support of the Application. Other resource material including published scientific literature and general technical information was also used in assessing this Application.

- **the promotion of consistency between domestic and international food standards**

The variations are consistent with some international food standards which permit the use of sodium hydrosulphite to treat crustaceans.

- **the desirability of an efficient and internationally competitive food industry**

The variations are expected to have a positive effect on the competitiveness of the New Zealand canned abalone industry, allowing it to export product that has been treated with a new, effective food additive that is permitted in the Code.

- **the promotion of fair trading in food**

The variations will assist the New Zealand canned abalone industries compete with other international competitors, by ensuring a product acceptable to consumers can be produced.

- **any written policy guidelines formulated by the Ministerial Council[4].**

The Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals' includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function

[4] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting sodium hydrosulphite as a food additive to treat canned abalone is consistent with the specific order policy principles for 'Technological Function'.

3 Transitional arrangements

3.1 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website[5]. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has proposed changes to the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code. The amendment to the new Code resulting from Application A1088 is provided at Attachment C.

4 References

Codex Alimentarius Codex STAN 192-1995 General Standard for Food Additives (GSFA), updated 2013
http://www.codexalimentarius.net/gsfaonline/docs/CXS_192e.pdf

Codex Alimentarius CAC/GL 36-1989 Class Names and the International Numbering System for Food Additives, updated 2013
http://www.codexalimentarius.org/download/standards/13341/CXG_036e.pdf

Health Canada, Food and Drug Regulations (C.R.C., c. 870) latest amendment 8 November 2013
http://laws-lois.justice.gc.ca/PDF/C.R.C., _c._870.pdf

Japan's Specifications and Standards for Food Additives (7th Edition, 2000) published by the Ministry of Health and Welfare,
http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa

Specifications and Standards for Foods, Food Additives, etc. Under the Food Sanitation Act (Abstract) 2010, April 2011, Japan External Trade Organization (JETRO)
http://www.jetro.go.jp/en/reports/regulations/pdf/foodext2010e.pdf

Korean Food Additives Code, Ministry of Food and Drug Safety, Food Safety Bureau, updated April 2013
http://www.mfds.go.kr/files/upload/eng/Food_Additive_code.zip

Attachments

A. Approved draft variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

[5] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

Attachment A – Approved draft variations to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1088 – Sodium Hydrosulphite as a Food Additive) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1088 – Sodium Hydrosulphite as a Food Additive) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] Standard 1.2.4 is varied by

[1.1] inserting in Schedule 2, Part 1 in alphabetical order

"

Sodium hydrosulphite	–

"

[1.2] inserting in Schedule 2, Part 2 above "Curcumin or turmeric"

"

Sodium hydrosulphite	–

"

[2] Standard 1.3.1 is varied by

[2.1] omitting from subclause 5(2) "**sulphur dioxide**, sulphites including bisulphites and metabisulphites shall be calculated as sulphur dioxide." and substituting

"**sulphur dioxide** and sulphites including hydrosulphites, bisulphites and metabisulphites shall be calculated as sulphur dioxide."

[2.2] inserting in item 9.4 of Schedule 1 under the heading "canned abalone (paua)"

"

–	Sodium hydrosulphite	1000	mg/kg	

"

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1088 which seeks to include sodium hydrosulphite (sodium dithionite) as a food additive (antioxidant) to be used in canned abalone. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[6], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved the use of sodium hydrosulphite as a food additive to be added to canned abalone.

Other sulphite food additives currently permitted to treat canned New Zealand abalone (paua) are less effective in bleaching the natural black colour to a commercially acceptable colour for consumers, especially for export markets. Sodium hydrosulphite bleaches New Zealand abalone to the usual honey blonde colour favoured by consumers and importers.

The variation will add sodium hydrosulphite to the list of food additives permitted for use on canned abalone (paua) under food category 9.4 in Schedule 1 of Standard 1.3.1. The maximum permitted level for sodium hydrosulphite is the same as the levels permitted for the other currently permitted sulphite food additives in relation to canned abalone (paua) at the time of this variation.

In addition, hydrosulphites, including sodium hydrosulphite, will be added to the list of other sulphites that are calculated as sodium dioxide in relation to maximum permitted levels under subclause 5(2) of the Standard.

The variation will also amend Schedule 2 of Standard 1.2.4 to provide the prescribed name of the food additive for labelling purposes.

[6] convening as the Australia and New Zealand Food Regulation Ministerial Council

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1088 included one round of public consultation following an assessment and the preparation of draft variations and associated reports. Submissions were called for on 16 May 2014 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.2.4 and 1.3.1 is a broadening of food regulations to permit an alternative food additive and is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Schedule 2 of Standard 1.2.4 to include a reference to Sodium hydrosulphite in Parts 1 and 2 of that Schedule. There is no food additive number for that substance.

Item [2] amends Standard 1.3.1.

Item [2.1] amends the statement in subclause 5(2) of Standard 1.3.1 for calculation of sulphur dioxide and sulphites. A reference to hydrosulphites is included in the statement. The statement's meaning is also clarified by the addition of the word 'and'.

Item [2.2] amends Schedule 1 of Standard 1.3.1 to insert a permission to use sodium hydrosulphite as a food additive to treat canned abalone and to set a maximum permitted level in relation to that use. The maximum permitted level is the same as that currently permitted for the other currently permitted sulphite food additives in relation to canned abalone (paua).

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

Background

FSANZ is reviewing the Australian New Zealand Food Standards Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, such as the variations proposed by A1088. This is the rationale for the draft variation below. It is provided for background only. Its content and structure may change as P1025 progresses.

Draft instrument

Food Standards Code—Variation

Made under the *Food Standards Australia New Zealand Act 1991*

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 2).*

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Standard 1.3.1

Schedule 1 varies the Australia New Zealand Food Standards Code – Standard 1.3.1 – Food Additives.

4 Variation of Schedule 8

Schedule 2 varies the Australia New Zealand Food Standards Code – Schedule 8 – Food additive names and code numbers (for statement of ingredients).

5 Variation of Schedule 15

Schedule 3 varies the Australia New Zealand Food Standards Code – Schedule 15 – Substances that may be used as food additives.

Schedule 1 Variation of Standard 1.3.1

(section 4)

[1] Omit paragraph 1.3.1—4(6)(j) and substitute

(j) sulphur dioxide and sulphites including hydrosulphites, bisulphites and metabisulphites, are calculated as sulphur dioxide.

Schedule 2 Variation of Schedule 8

(section 2)

[1] Insert into the table to section S8—2 Food additive names—alphabetical listing, in alphabetical order

Sodium hydrosulphite	-

Schedule 3 Variation of Schedule 15

(section 5)

[1] Insert into the table to section 15—5, under the heading 9.4.1 Canned abalone (paua)

-	Sodium hydrosulphite	1 000