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

12/03
8 October 2003

FINAL ASSESSMENT REPORT

APPLICATION A476

Acidified Sodium Chlorite as a Processing aid

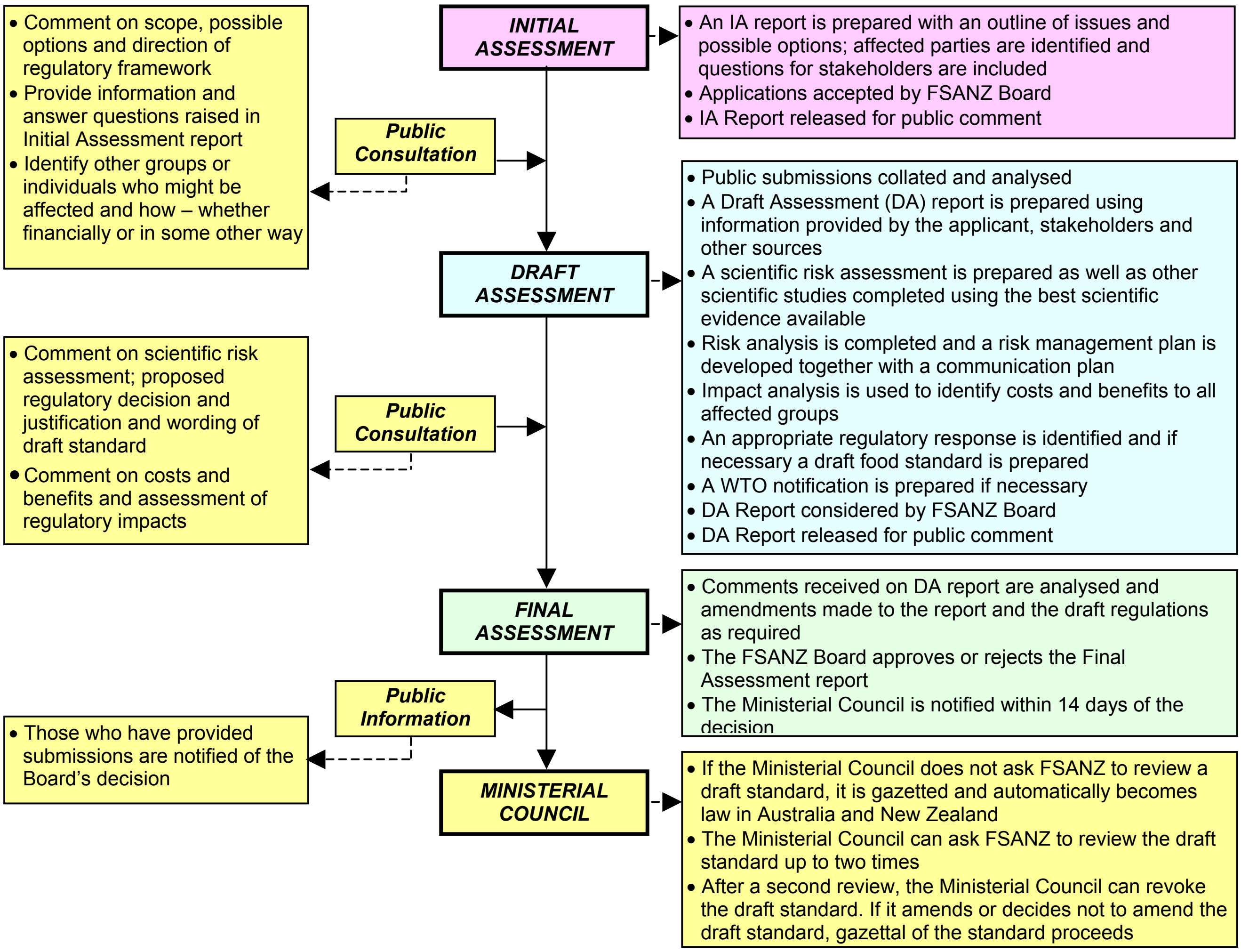
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final assessment

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

FSANZ received an application from Alcide Corporation on 10 September 2002 to amend the *Australia New Zealand Food Standards Code* (Code) to provide permission for acidified sodium chlorite as a processing aid for use on poultry meats, meat and formed meat products, fruit and vegetables, and fish. This application may require amendments to Standard 1.3.3 – Processing Aids.

A mix of sodium chlorite and citric acid (or another food grade acid such as phosphoric acid, hydrochloric acid, malic acid or sodium acid sulfate) forms acidified sodium chlorite which is applied onto food surfaces to reduce the numbers of microorganisms. The mix is applied by spraying or dipping. The time between mixing and application is less than 5 minutes. No post treatment water rinse is used for poultry, meat and meat products. A post treatment water rinse is applied to fruit and vegetables with a withholding time for processed (cut up) fruit and vegetables. Generally, chlorine dioxide levels which form in the reaction process do not exceed 3 ppm.

Sodium chlorite is currently permitted in the Code under Standard 1.3.3 as a processing aid for use in bleaching, washing and peeling. The food grade acids listed in the application added to form acidified sodium chlorite are all generally permitted as processing aids. The applicant is seeking clarification of the regulatory status of acidified sodium chlorite and the maximum permitted residual level of sodium chlorite (currently provided in units of available chlorine). The safety assessment report concluded that if acidified sodium chlorite (ASC) is used under the conditions of use provided by the Applicant (considered to be Good Manufacturing Practice (GMP)) that no residues would be detected in the raw foods following treatment and prior to sale and therefore there would be no toxicological concerns. Therefore, if Good Manufacturing Practice (GMP) were adhered to, there would be no resulting toxicological concerns for humans following the use of ASC in the proposed foods.

Statement of Reasons

The draft variation to Standard 1.3.3 – Processing Aids, of the Code*,* thereby clarifying approval for the use of sodium chlorite as a processing aid is agreed for the following reasons:

- The use of sodium chlorite is technologically justified since it has a function in food as an antimicrobial agent.
- There are no significant public health and safety concerns associated with the use of the antimicrobial agent.
- The safety evaluation of acidified sodium chlorite concluded that if ASC was used under the conditions of use provided by the Applicant that there would be no toxicological concerns.
- An approval will give food manufacturers access to a broader range of antimicrobial agents, so encouraging an efficient and internationally competitive industry. Approval also promotes consistency with international food standards.
- The proposed draft variation to the Code is consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991.*
- The Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of sodium chlorite as a processing aid with the function of an antimicrobial agent, the benefits of the proposed amendment outweigh the costs. The benefits of using sodium chlorite for food manufacturers outweigh any costs associated with its use.

1. Introduction

FSANZ received an application from Alcide Corporation on 10 September 2002 to amend the *Code* to provide permission for acidified sodium chlorite as a processing aid for use on poultry meats, meat and formed meat products, fruit and vegetables, and fish. This application may require amendments to Standard 1.3.3 – Processing Aids. This application is at the draft assessment stage.

1.1 Nature of Application

The application received from Alcide Corporation is to:

- amend if necessary Standard 1.3.3 – Processing Aids of the Code in order to permit acidified sodium chlorite as a processing aid on poultry meats, meat and formed meat products, fruit and vegetables; and fish; and
- confirm the regulatory status of acidified sodium chlorite and the maximum permitted level of sodium chlorite (currently provided in units of available chlorine).

2. Regulatory Problem

Alcide Corporation developed a food treatment process where a mix of sodium chlorite and citric acid (or another food grade acid such as phosphoric acid, hydrochloric acid, malic acid or sodium acid sulfate) forms acidified sodium chlorite which is applied onto food surfaces to reduce numbers of microorganisms. The mix is applied by spraying or dipping. The time between mixing and application is less than 5 minutes. No post treatment water rinse is used for poultry, meat and meat products. A post treatment water rinse is applied to fruit and vegetables with a withholding time for processed (cut) fruit and vegetables. Generally, chlorine dioxide levels which form in the reaction process do not exceed 3 ppm.

The Applicant has limited their application to:

a) 50 to 150 ppm acidified sodium chlorite for whole carcass of poultry; and
b) 500 to 1200 ppm acidified sodium chlorite for carcass parts of poultry; meats and formed meats (such as sausages, luncheon meats, and pressed hams);
c) 500 to 1200 ppm acidified sodium chlorite for fruit and vegetables (intact and cut-up); freshwater fish and seafood.

Sodium chlorite is currently permitted in Standard 1.3.3 – Processing Aids as a processing aid for bleaching, washing and peeling. The food grade acids listed in the application to form acidified sodium chlorite are permitted as processing aids except for sodium acid sulfate. The applicant is seeking clarification of the regulatory status of acidified sodium chlorite and the maximum permitted residual level of sodium chlorite or other reaction products (currently provided in units of available chlorine).

2.1 Current Regulations

Standard 1.3.3 – Processing Aids defines **processing aid** as a substance listed in clause 3 to 18, where -

(a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and
(b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.

Sodium chlorite is listed in the Code in Standard 1.3.3 - Processing Aids, Table to clause 12. This table lists permitted bleaching agents, washing and peeling agents.

Substance	**Food**	**Maximum permitted level (mg/kg)**
Sodium chlorite	All foods	1.0 (available chlorine)

Citric acid, hydrochloric acid, and malic acid are listed in Schedule 2 of Standard 1.3.1 - Food Additives as generally permitted food additives and are therefore generally permitted to be used as processing aids as stated in Clause 3 (b). Phosphoric acid is listed in Schedule 1 of Standard 1.3.1 – Food Additives. Sodium acid sulphate is not a permitted food additive or processing aid.

2.2 Overseas Regulatory status

United States

Code of Federal Regulations Volume 21, 173.325 approves a range of acidified sodium chlorite solutions of 500 to 1200 ppm at a pH of 2.3 to 2.9 for poultry meats, red meats, and processed, comminuted or formed meat products, intact fruits and vegetables, processed fruit and vegetables. Seafood is permitted to be treated at 50 ppm of acidified sodium chlorite.

Code of Federal Regulations Volume 21, 186 – Indirect Food Substances Affirmed as Generally Recognized as Safe (GRAS) lists 186.1750 - Sodium chlorite (CAS Reg. No. 7758-19-2).

Canada

Meat Hygiene Directive 2001-27, May 24, 2001 approves the use of acidified sodium chlorite at levels of 500 to 1200 ppm at a pH of 2.5 to 2.9 for use on poultry.

3. Objective

In developing or varying a food standard, FSANZ is required to meet three primary objectives which are set out in section 10 of the *Food Standards Australia New Zealand Act 1991*. 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.

This application is to amend the Code to provide permission for acidified sodium chlorite as a processing aid for use on poultry meats, meat and formed meat products, fruit and vegetables, and fish.

4. Background

4.1 Historical Background

A preliminary scoping of this application placed it in work plan group 3, category of assessment 3 (see FSANZ website for further information about the work plan and the different groups and categories).

As sodium chlorite is already permitted in the Code, FSANZ staff held a meeting with the applicant on 16 October 2002 to clarify the scope of the application. The regulatory status of acidified sodium chlorite is unclear as the maximum permitted level for sodium chlorite is currently provided in units of available chlorine (See Section 6.3).

5. Relevant Issues

5.1 Technological Justification

The use of acidified sodium chlorite is intended as an antimicrobial intervention on a variety of raw food types to reduce the microbial contamination arising from the presence of pathogenic and spoilage species of microorganisms. The applicant has supplied technical data with the application supporting the technological justification.

<u>Evaluation</u>

The Food Technology Report (Attachment 3) concludes that the use of acidified sodium chlorite as an antimicrobial agent on a variety of raw food types to reduce the microbial contaminations arising from the presence of pathogenic and spoilage species of microorganisms is technologically justified.

5.2 Public Health and Safety Issues

Acidified sodium chlorite is applied onto the surfaces of the food at low levels. The oxychlorine species that are stable, and found in acidified sodium chlorite treatment solutions both after mixing and after contact with food surfaces are chlorite, chlorate and chlorine dioxide. Chlorine dioxide that forms is either lost by evaporation or reduction and is not present as a residue.

Toxicological Evaluation

A safety assessment (Attachment 2) concluded that if ASC was used under the conditions of use provided by the Applicant (considered to be GMP) that no residues would be detected in the raw foods following treatment and prior to sale. Therefore, if GMP were adhered to, there would be no toxicological concerns for humans following the use of ASC in the proposed foods.

5.3 Determining available chlorine as a measure of sodium chlorite

The Table to clause 12 of Standard 1.3.3 – Processing Aids, lists a maximum permitted level of 1.0 mg/kg (available chlorine) for sodium chlorite when used as a bleaching, washing or peeling agent. When acidified sodium chlorite is applied to food as an antimicrobial agent, using a measure of available chlorine as a limit on sodium chlorite may not be appropriate.

Evaluation

Determination of available chlorine as a measure of the residual level of sodium chlorite is appropriate when sodium chlorite is used as a water treatment agent since the available chlorine level can be measured.

The determination of available chlorine as a measure of the permitted level of sodium chlorite when used as an antimicrobial agent applied to food is not appropriate since available chlorine is not a residue on food from the use of sodium chlorite. The safety assessment (Attachment 2) concluded that if acidified sodium chlorite is used according to GMP that there would be no residues of chlorite, chlorate or chlorine dioxide in the raw foods following treatment and prior to sale. Determining available chlorine levels would not be an appropriate regulatory measure since it cannot be currently performed.

The New Zealand Food Safety Authority (NZFSA) suggested that rather than permitted levels of chlorate, chlorite and or chlorine dioxide their preference would be for process parameters such as the level of acidified sodium chlorite and pH to be specified which are known to result in acceptable levels of chlorate, chlorine and chlorine dioxide.
To prescribe the processing parameters for acidified sodium chlorite is not necessary, as its use could be more effectively managed by requiring a maximum permitted level to the limit of detection for chlorite, chlorate, chlorous acid and chlorine dioxide. This information might be based on laboratory analysis using HPLC or other methods.

5.4 Issues raised at Draft assessment

Editorial note

It was raised by the New Zealand Food Safety Authority (NZFSA) that the editorial note contains the phrase “a specified laboratory method and/or item of laboratory equipment”. The NZFSA considers that this means any validated, reputable method, but food processors may consider that a particular method is specified, when it is not. The NZFSA commented that it is their interpretation that the responsibility for compliance with the limits for chlorite, chlorate, chlorous acid and chlorine dioxide lie with the food processor. For example the food processor may have a risk management programme and /or food safety programme in place that demonstrates that the levels of the four components are at or below the limit of detection, because at the level of ASC used (i.e. GMP), the residues are documented to be below the limit of detection. This information might be based on information from the supplier of the sodium chlorite/acid system or based on laboratory analysis using HPLC or other methods. In other words, the food processor is not required to conduct frequent laboratory analyses to determine residue levels for chlorite, chlorate, chlorous acid and chlorine dioxide. They might conduct random checks to demonstrate due diligence and compliance, or might refer to the GMP level of ASC used, and the expected residue limits based on the known data.

The Department of Agriculture, Fisheries and Forestry commented that making the maximum permitted level for sodium chlorite in a food equivalent to the limits of determination for chlorite, chlorate, chlorous acid and chlorine dioxide would lead to a subjective interpretation of this Standard because the limit of determination for an analyte varies according to method of analysis employed. The editorial note contains the definition for a ‘limit of determination’ that would not be enforceable.

Evaluation

The interpretation by the NZFSA is valid although there is no information to support that food processors would interpret the editorial note differently. The editorial note has been amended to remove the word “specified” to clarify the meaning of “limit of determination”. It is considered that there is no need to include further detail in the editorial note.

The ‘limit of determination’ is part of in the drafting for the Table to clause 14 of Standard 1.3.3 and will be the legally enforceable maximum permitted level of the specified chemicals upon Gazettal. An explanation of the meaning of “limit of determination” is placed in the editorial note for assistance in interpretation. The “limit of determination” is dependent on the method of analysis employed. However, this is not peculiar to limits of determination. The levels of substances detected will more generally be dependent on the method of analysis employed and the method of analysis for the maximum permitted limits of processing aids are generally not specified in Food Standards. Analytical laboratories have the best knowledge of detection methodologies and it is expected that the laboratories will use the most appropriate methodology.

6. Regulatory Options

Options available are:

Option 1. Reject the application as permission for the components of acidified sodium chlorite is already provided in Standard 1.3.3 - Processing aids. There are existing permissions of sodium chlorite and food grade acids.

Option 2. Amend the Table to clause 14, Permitted processing aids with miscellaneous functions, of Standard 1.3.3 – Processing Aids to specifically list sodium chlorite permitted an antimicrobial agent with a maximum permitted level to the limit of detection for chlorite, chlorate, chlorous acid and chlorine dioxide.

Option 3. Amend the Table to clause 12 - Bleaching, peeling and washing agents, of Standard 1.3.3,– entry for sodium chlorite, permitted to GMP use.

7. Impact Analysis

Parties affected by the options outlined above include:

1. Those sectors of the food industry wishing to use acidified sodium chlorite on food. Specifically the applicant and other similar companies with knowledge and experience in the technologies outlined in the application.

2. Consumers who may benefit by having some treated food products with improved safety and a longer shelf life. There may be a slight price increase to cover the use of the new technology.

3. Government agencies enforcing the food regulations.

7.1 Option 1

Reject the application as permission for the components of acidified sodium chlorite is already provided in Standard 1.3.3 Processing aids. There are existing permissions of sodium chlorite and food grade acids.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefits	No perceived costs. Although there is no perceived cost for the government, failure to clarify approval in Australia or New Zealand may be construed as a non-tariff barrier to trade.
Industry	No perceived benefits	Cost to industry in not having a clear permission to use acidified sodium chlorite as a processing aid to function as an antimicrobial treatment on fish, poultry, meat, and fruit and vegetables.
Consumers	No perceived benefits	Consumers may not have foods that could be treated with the processing aid - acidified sodium chlorite to improve shelf-life and safety.

7.2 Option 2

Amend the Table to clause 14, Permitted processing aids with miscellaneous functions, of Standard 1.3.3 – Processing Aids to specifically list sodium chlorite permitted an antimicrobial agent with a maximum permitted level to the limit of detection for chlorite, chlorate, chlorous acid and chlorine dioxide.

AFFECTED PARTY	BENEFITS	COSTS (Testing Methodology)
Government	No perceived benefit.	No perceived cost other than the cost of amending the Food Standards Code.
Industry	Permitting the use of sodium chlorite as an antimicrobial agent would provide food manufacturers with a processing aid that can function on meat, poultry, fish and fruits and vegetables.	No perceived costs. Industry has the choice of whether to use the processing aid in the production of food.
Consumers	Permitting the use of sodium chlorite would provide food manufacturers with a processing aid that can function as an antimicrobial agent on meat, poultry, fish and fruits and vegetables. This may be of benefit to consumers who will have food available that has an additional food safety control measure and longer shelf-life. An appropriate maximum permitted level of chlorate, chlorite and or chlorine dioxide will protect public health and safety.	No perceived costs.

7.3 Option 3

Amend the Table to clause 12 - Bleaching, peeling and washing agents, of Standard 1.3.3 – Processing aids, entry for sodium chlorite, permitted to GMP use.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefits	No perceived cost other than the cost of amending the Code.
Industry	No perceived benefits.	Permitting the use of sodium chlorite as a bleaching, washing and peeling agent would not clearly provide food manufacturers with a permission for processing aid that can function as an antimicrobial on meat, poultry, fish and fruits and vegetables.
Consumers	Consumers may have food available that has an additional food safety control measure and longer shelf-life.	No perceived costs.

7.4 Evaluation

Maintaining the *status quo* (Option 1) appears to provide no benefit to the government, industry and consumers. Option 1 denies industry clear permission to use sodium chlorite as a processing aid to function as an antimicrobial agent, which has been demonstrated to be safe and achieve a number of beneficial functions in food.

Option 2, which proposes to amend the Code to permit the use of sodium chlorite as a processing aid to function as an antimicrobial agent appears to impose no significant costs on government, industry or consumers and may be of benefit to industry and consumers. An appropriate maximum permitted level of chlorate, chlorite and or chlorine dioxide will protect public health and safety.

Option 3 still allows industry permission to use sodium chlorite as a processing aid but does not clarify its function as an antimicrobial agent, which has been demonstrated to be safe and achieve a benefit in food.

Assessment of the costs and benefits of Options 1, 2 and 3 indicates that there would be a net benefit in permitting the use of sodium chlorite as a processing aid with the function of an antimicrobial agent. Therefore, Option 2 is the preferred option.

8. Consultation

Five submissions were received in response to the section 13A notice required under the FSANZ Act. Submissions were received from Food Technology Association of Victoria Inc., Queensland Public Health Services, Australian Food and Grocery Council, and The New Zealand Food Safety Authority and Australian Quarantine and Inspection Service (AQIS). All submissions supported option 2 (except AQIS who will defer comment until after draft assessment), to accept the application and prepare a draft assessment report to consider amending Standard 1.3.3 to specifically list acidified sodium chlorite with an appropriate maximum permitted level of chlorate, chlorite and or chlorine dioxide.

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.

There are not any relevant international standards for sodium chlorite as a processing aid and amending the Code to provide clarification for permission for sodium chlorite as a processing aid is unlikely to have a significant effect on international trade as it is a matter of minor significance. No notification to the WTO was made.

9. Conclusion and Recommendation

The Final Assessment Report concludes that approval of the use of sodium chlorite as a food processing aid for antimicrobial use is technologically justified and raises no to public health and safety concerns.

The draft variation of the Code to Standard 1.3.3 – Processing Aids, thereby giving approval for the use of sodium chlorite as a processing aid for antimicrobial use, is agreed for the following reasons.

- The use of sodium chlorite is technologically justified since it has a function in food as an antimicrobial agent.
- There are no significant public health and safety concerns associated with the use of the antimicrobial agent.
- The safety evaluation of acidified sodium chlorite concluded that if ASC was used under the conditions of use provided by the Applicant that no residues would be detected in the raw foods following treatment and prior to sale and therefore there would be no toxicological concerns.
- An approval will give food manufacturers access to a broader range of antimicrobial agents, so encouraging an efficient and internationally competitive industry. Approval also promotes consistency with international food standards.
- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act.
- The Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of sodium chlorite as a processing aid with the function of an antimicrobial agent, the benefits of the proposed amendment outweigh the costs. The benefits of using sodium chlorite for food manufacturers outweigh any costs associated with its use.

ATTACHMENTS

Attachments to the Final Assessment Report could include:

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety Assessment report
3. Food Technology report
4. Summary of issues raised in public submissions

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

To commence: on gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by* –

[1.1] *inserting in the* Table to clause 14 –

Sodium chlorite	Anti-microbial agent for meat, fish, fruit and vegetables	Limit of determination of chlorite, chlorate, chlorous acid and chlorine dioxide

[1.2] *inserting after the* Table to clause 14 -

Editorial note:

The limit of determination is the lowest concentration of a chemical that can be qualitatively detected using a laboratory method and/or item of laboratory equipment (that is, its presence can be detected but not quantified).

Attachment 2

Safety Assessment Report - Acidified Sodium Chlorite

Acidified sodium chlorite (ASC) is a clear colourless liquid with a mild chlorine-like odour, which is produced by adding a weak acid to a solution of sodium chlorite ($NaClO_2$). The active ingredient (at pH 2.3 to 3.2) consists mainly of chlorous acid ($HClO_2$) in equilibrium with chorite ion (ClO_2^-) and H+. ASC in solution consists mainly of chlorite ions (65-95% at pH 2.3 to 3.2, respectively), H+ ions and chlorous acid (35-5% at pH 2.3 to 3.2, respectively). At a pH>7 chlorine dioxide is the primary species present slowly decomposes to chlorate and chloride (EC, 2003).

Therefore, the use of ASC (depending on the pH) may result in the production of the following four primary chlorine compounds and chloride (Cl^-) when a food grade acid (eg citric acid) is mixed with sodium chlorite (CanTox Inc., 1998):

- Chlorite (ClO_2^-), chlorate (ClO_3^-), chlorous acid ($HClO_2$) and chlorine dioxide (ClO_2).

Residue data on chlorite and chlorate

The Applicant supplied data on the resulting residues following the use of ASC in a range of foods. FSANZ examined Section 6.4 of the application (Summary of safety of acidified sodium chlorite in foods) where there was a summary table of foods (poultry, red meat, produce and processed comminuted formed meats) in which the residues for both chlorite and chlorate were listed as below the Limit of Detection (Range <0.1 to 0.54 ppm for chlorite and <0.1 to <0.3 ppm for chlorate) covering the above foods. Residue data in seafood and freshwater fish[1] was also examined and it was concluded that no chlorate residues were detectable at any time point and at 24 hours post-treatment with ASC that no chlorite residues were detected.

The residue levels for both chlorate and chlorite were based on using Good Manufacturing Practice (assuming application and post-treatment recommendations are followed) and suggested that residues of chlorate and chlorite were below measurability. However, the data did not appear to cover the other oxychlorine compounds: chlorous acid, chlorine dioxide and chloride.

Consequently, FSANZ asked the Applicant to supply further information on the other oxychlorine compounds and whether residues of these compounds were likely to be present and/or were also below the LOD. This was to determine whether these compounds were of toxicological concern and would consequently need a safety assessment performed by FSANZ.

Residue data on chlorous acid, chlorine and chlorine dioxide

Chlorous acid is the semi-stable intermediate that forms when sodium chlorite is acidified i.e. essentially the chlorite ion and hydrogen ions (originating from the citric acid) in equilibrium. Thus post-ASC treatment residue analysis by High Pressure Liquid Chromatography (HPLC) for chlorite effectively encompasses and quantifies any sodium chlorite and/or chlorite ion (chlorous acid) that are still present on the treated surfaces.

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[1] Additional information on residues in treated seafood and fresh water products to be included into Section 6.3 – Safety submitted by the Applicant in December 2002.

Chlorine dioxide is a relatively soluble compound with any that is generated in a fresh solution of ASC (generally <3.0 ppm) tending to remain in solution. However, if the ASC solution is being sprayed, any chlorine dioxide in the solution is usually immediately off-gassed - with greater off-gassing as spray particle size decreases (i.e. the surface area to volume ratio increases).

Where the ASC treatment is applied by immersion, any chlorine dioxide that is present is conceivably available for contact with the treated surfaces and consequent antimicrobial effect. In this scenario, chlorine dioxide through reaction with microbial organisms would be reduced to chlorite and the typical degradation pathways for chlorite would then follow with oxidation to form a small amount of chlorate and reduction to form the major residue component - chloride.

Chlorine dioxide is also reduced very rapidly in organic load burdened solutions or waste streams (with iron, manganese, reduced sulfur species, microbial populations etc. that are present) again principally through reduction to form chlorite. The latter then undergoes the same degradation pathways as above to form chlorate and chloride.

Therefore, the toxicological end point for any chlorine dioxide in an ASC solution is the potential formation of additional chlorite, chlorate or chloride but the additive impact of any of these ions derived from chlorine dioxide cannot be measured with current techniques.

While the major residue component that is formed from an ASC solution is chloride ions, the added impact of these treatment-derived chloride ions on the typical background levels of sodium chloride found in all foods is not measurable or detectable with current test sensitivities. Since toxicologically these chloride ions are not of concern at the typical levels found in the foods, there is not an impact from any "added" chloride deriving from ASC treatment.

Conclusion

From the data and information available, it is concluded that by virtue of the chemistry of ASC the available residue data for chlorate and chlorite covers all four oxychlorine compounds, other than chloride. This is following the use of ASC on the range of foods proposed to be treated.

The residue levels for both chlorate and chlorite are based on the conditions of use specified in this application, which according to the applicant represent Good Manufacturing Practice. Under these conditions, the residues of chlorate and chlorite are below the level of determination and therefore do not raise any toxicological concerns.

Chlorine dioxide appears extremely volatile and would be expected to evaporate from the food surface quickly. Chloride ion is present in the ASC solution and appears toxicologically inert, as it is a normal endogenous constituent of body water in humans. The toxicological impact of any chlorine dioxide generated in an ASC solution is minimal to the overall effects and/or final measurable concentrations of chlorite, chlorate or chloride.

References

EC (2003) Draft Opinion on the evaluation of antimicrobial treatments for poultry carcasses. 14-15 April, 2003.

CanTox Inc (1998) Safety assessment of acidified sodium chlorite for use as an antimicrobial intervention during the processing of foods. 27 August, 1998.

Attachment 3

Food Technology Report

Sodium chlorite is already an approved processing aid that is listed in Standard 1.3.3 - Processing Aids, Table to clause 12 – Permitted bleaching agents, washing and peeling agents. The application is for sodium chlorite for use as a processing aid with the function of antimicrobial agent.

A processing aid is defined as a substance that is used in the processing or raw materials, foods or ingredients, to fulfil a technological purpose, but does not perform a technological function in the final food. Sodium chlorite is acidified with approved food acids to acidified sodium chlorite. Acidified chlorite is intended to be applied during processing of raw food materials to act as an antimicrobial agent. In the final food, the applicant claims that there are no detectable residues and that it does not perform a technological function.

Acidified sodium chlorite precursors:-

- sodium chlorite ($NaClO_{2}$), (CAS Reg. No.: 7758-19-2); and
- any approved food acid such as citric acid, phosphoric acid, hydrochloric acid, and malic acid.

Chemical and Physical Properties

Colour	White Crystalline Solid (80% Technical Grade) Solutions: Colourless to light green
Density/Specific Gravity	2.468 Crystal 1.176 Bulk, Packed, 80% Technical Grade 1.21 (25% aqueous solution)
Dissociation Constants	pK_a of chlorous acid ($HClO_2$) = 1.72 @ 25°C
Hydrolysis	Sodium chlorite reacts with hydrogen ions to form chlorous acid. pK_a of chlorous acid ($HClO_2$) = 1.72 @ 25°C
Melting or Crystallization Points (liquids)	-8°C (25% Solution)
Melting Point or Range (solids)	180—200°C, Decomposes
Molecular Weight	91.45
Odour	Slight chlorinous odour
Oxidation Stability (air)	Stable to air oxidation
Photolysis	80% Technical Grade is stable to photolysis. Photolysis sodium chlorite solutions produces chlorine dioxide.
Physical State	White Crystalline Solid, slightly hygroscopic (80% Technical)
Solubility in Organic Solvents	Not soluble in nonpolar solvents. Sparingly soluble in polar solvents.
Solubility in Water	43.6% @ 25°C
Thermal Stability	Decomposes at 180—200°C
Vapour Pressure	21.085 mm Hg (25% solution @ 25°C)
Viscosity (liquids)	1.851 cps @25°C (25% solution)

Sodium chlorite is provided an appropriate specification for identity and purity from a secondary source -The Merck Index, 12th Edition (1996) in accordance with Standard 1.3.4 – Identity and Purity.

Intended use

The applicant proposes that the acidified sodium chlorite (ASC solutions) will be applied to raw foods as either a spray or a dip. The treatment of larger quantities of raw foods will be facilitated by spray application, in an enclosed or semi-enclosed, environmentally controlled spray compartment. Smaller-scale treatments may be more compatible with a quick dip application, also inside a semi-enclosed, environmentally controlled application compartment. Low volume dispensing of the ASC solutions may also be accomplished via hand-held, two-chamber spray dispensers, which are currently commercially available.

Poultry Meats

- Spray or dip of pre-chill whole poultry carcass or carcass parts - no post-treatment water rinse;
- Immersion chilling of whole poultry carcass or carcass parts - no post-treatment water rinse; and
- Spray or dip of post-chill whole poultry carcass, carcass parts, trim or organs - no post-treatment water rinse.

Red Meats (beef, swine, sheep, deer, others as similarly defined)

- Spray or dip of pre-chill whole red meat carcasses or carcass parts (beef, swine, sheep, deer) - no post-treatment water rinse; and
- Spray or dip of post-chill whole red meat carcass, carcass parts, trim or organs - no post-treatment water rinse.

Processed, Comminuted or Formed Meat Products

- Spray or dip of uncooked products in casings, such as fresh sausages and uncooked smoked sausages - no post-treatment water rinse; and
- Spray or dip of cooked products, with or without casings, such as cooked smoked sausages, other cooked sausages, luncheon meats, pressed hams, deli meats - no post-treatment water rinse.

Fruits and vegetables

- Spray or dip of immediate post-harvest up to pre-process, intact (skin-on) fruits and vegetables – post-treatment water rinse; and
- Spray or dip of processed (cut up) fruits and vegetables – post-treatment water rinse and 24 hour withholding time.
-

Freshwater fish and seafood

- Spray or dip.

Levels of use on foods

- 50 to 150 ppm acidified sodium chlorite for whole carcass of poultry; and
- 500 to 1200 ppm acidified sodium chlorite for carcass parts of poultry; meats and formed meats (such as sausages, luncheon meats, and pressed hams); fruit and vegetables (intact and cut-up); and freshwater fish and seafood.

The applicant provided data supporting the efficacy for the levels of use of acidified sodium chlorite on these foods.

General Description of the Process

The germicidal activity of the acidified sodium chlorite (ASC) antimicrobial system derives from the degradation of chlorous acid, which forms as a calculable fraction of the chlorite (ClO_2^-) ion in solution. The level of chlorous acid, which forms in aqueous solution, depends on the hydrogen ion concentration (*i.e.* pH) of the mixed solution of chlorite and acid. Chlorous acid is an unstable material, its stability being proportionate to its concentration, i.e. the lower the concentration the slower its rate of degradation. From the pKa[1] of chlorous acid (1.1×10^{-2} at 20°C) one can calculate its relative molar level with respect to chlorite. For the petitioned pH range of 2.3 to 2.9 covering a sodium chlorite concentration of 500 to 1200 ppm the rate of dissociation is circa 31% at pH 2.3 reducing to circa 10.0% at pH 2.9. Sustained antimicrobial activity deriving from chlorous acid is based on reservoirs of chlorite and hydrogen ions in the solution. As chlorous acid is oxidatively consumed, through interaction with microorganisms and other organic matter, re-equilibration from reservoir ions produces additional chlorous acid.

The hydrogen ion source for an acidified sodium chlorite solution can be any approved food acid, although fully ionized strong mineral acids typically lack the reservoir capacity to provide additional $[H]^+$ ions once the initial chlorous acid is consumed. The quantity of food acid required to achieve the appropriate pH (and level of chlorous acid) will depend upon the strength of the acid, the buffering capacity of the solution itself and, to a lesser extent, the alkalinity of the water used in the formulation. Weaker acids are needed in the approximate 0.20% to 1.2% concentration, while a stronger acid, such as phosphoric is needed at ~0.04% to 0.10% concentration. An even stronger acid, such as sulfuric acid must be used at lower levels i.e. <~50 ppm, not including any allowance for makeup water alkalinity.

Acidified Sodium Chlorite Chemistry

ASC chemistry is principally the chemistry of chlorous acid ($HClO_2$), a metastable oxychlorine species which decomposes to form chlorate ion, chlorine dioxide, and chloride ion. To better understand chlorous acid chemistry, a brief overview of the chemistry of various oxychlorine species will be given.

As illustrated in Table I, chlorine can exhibit oxidation states from –1 to +7. As a consequence, its chemistry is varied and complex.

Table1. Oxidation States of Chlorine

ClO_4^-	+7	Perchlorate ion
ClO_3^-	+5	Chlorate ion
ClO_2	+4	Chlorine dioxide
ClO_2^-	+3	Chlorite ion
ClO^- or OCl^-	+1	Hypochlorite ion
Cl_2	0	Chlorine (molecular)
Cl^-	-1	Chloride ion

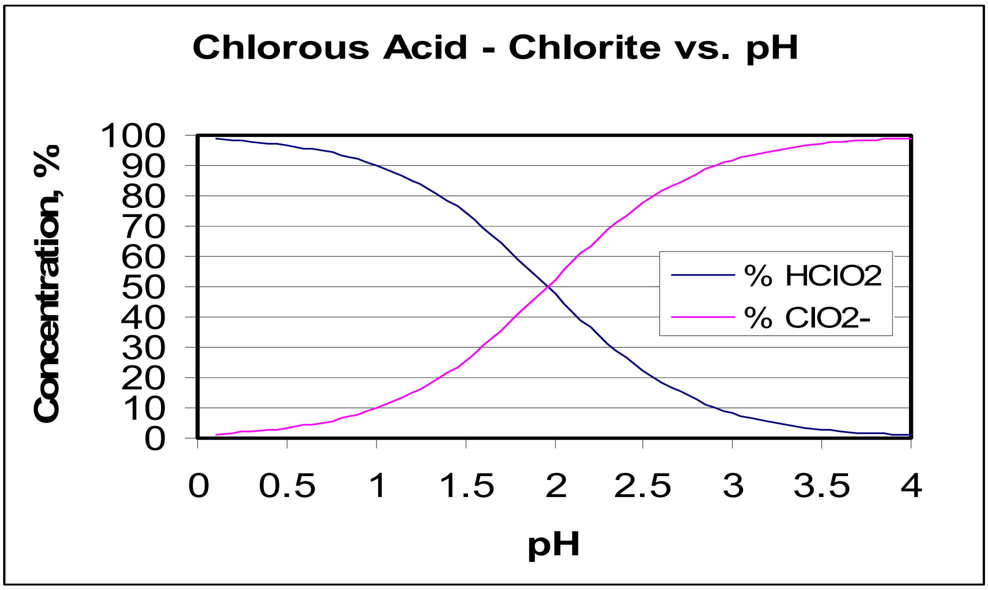
Oxychlorine species are important as oxidants in a number of applications. The strength of an oxidant is measured by its oxidation strength, or oxidation potential. The chlorous acid ($HClO_2$) reaction, with its 1.57 V oxidation strength and 4-electron oxidation capacity, ranks just below ozone and the hydroxyl-radical generation reaction of hydrogen peroxide. In aqueous solution, chlorous acid, a relatively weak acid, dissociates as follows:

$$HClO_2 \overset{K_a}{\Leftrightarrow} H^+ + ClO_2^-$$

where K_a, the acid dissociation constant, is 1.01×10^{-2} at 23°C.[10] In terms of the acid dissociation constant (ionization constant) and the hydrogen ion concentration of the solution ($=10^{-pH}$), the chlorous acid concentration can be found from the total titratable chlorite concentration as follows:

$$\%\ HClO_2 = \frac{1}{1 + (1.1 \times 10^{-2})/[H^+]} \times 100\%$$

The following is a graph of this relationship.



Purpose

ASC is intended for use as an antimicrobial agent on a variety of raw food types to reduce the microbial contaminations arising from the presence of pathogenic and spoilage species of microorganisms. The end benefits of ASC use are the creation of safer foods through the reduction of such bacterial species as *Escherichia coli, Escherichia coli* O157:H7, *Salmonella spp., Campylobacter spp., Listeria monocytogenes* and others. In addition, use of ASC can also cause an overall reduction of the total microbial populations that are present on the surface of foods as well as have direct effects against spoilage specific bacteria, yeast, mould or fungal species. A direct consequence of this action is an extension of shelf life for treated foods.

Need for the processing aid

The potential for the presence of pathogenic species of microorganisms on raw foods is a recognized problem, which arises from a number of possible sources during the growth and processing of food items. Primarily, these sources include the development and presence of background contamination levels on foods during their growth e.g. from such sources as the soil – for produce items – or the housing environment – for meat products. Secondly, there is the risk of new contaminations and/or cross contaminations of foods that may occur during their processing e.g. in the meat processing plant as a result of inadvertent faecal contamination of exposed muscle or fascia surfaces. In modern food production systems a holistic approach is generally taken in all attempts to control the presence and levels of pathogenic microorganisms on foods. This includes efforts to reduce the presence of pathogenic species in the growing environment by genetic selection of breeder stocks (poultry industry), competitive exclusion of pathogenic species (poultry and beef industries) and the implementation of special control processes over growth media to inhibit microbial growth e.g. in the production of mushrooms. Within the processing environment, Hazards Analysis and Critical Control Points (HACCP) principles have been implemented to attempt to identify key areas or points of contamination and then having identified and quantified the extent of the problem, to create specific management practices to minimize or eliminate these events.

Where they have been properly implemented, these practices – and many more – have generally been successful in reducing the overall contamination levels for pathogenic microbial species on foods and have frequently significantly reduced the subsequent risk of illness to the consuming public. What has been evident in the implementation of these practices however is that no single change in production or processing practices is ever likely to result in the creation of 100% safe foods. Instead, multiple changes to practice are required to effect maximum impacts on pathogenic microbial species i.e. the multiple hurdle approach to microbial control.

A significant component of the multiple hurdle approach in the processing plant is the use of antimicrobial interventions at specific critical control points during processing. Antimicrobial interventions have the ability – assuming adequacy of efficacy and appropriateness of application – to dramatically reduce microbial populations on foods. When applied at appropriate points in the processing chain, they can have some impact on the pathogenic contaminations that may be present.

ASC is one such antimicrobial intervention. It is capable of being applied to a wide range of different food types and forms, of having a short term but intense effect on the microbial populations that may be present yet leaving no residual components. A lower level of use of ASC may be required on a food with a lower initial population level of bacteria present eg whole poultry carcass may require less ASC compared to poultry parts.

Inherent in the gradual degradation of all foods is the involvement of spoilage organisms either those that are naturally present on the external surfaces of products as a function of the growth/production environment e.g. the bacteria, fungi, yeasts and moulds that exist on whole (skin intact) fruits and vegetables, or from the contamination/recontamination of sterile surfaces with spoilage organisms from the processing environment. The ability of antimicrobial processes to extend product shelf life by modification of the spoilage populations that are present on foods is a well-recognized effect. ASC solutions impact on spoilage populations just as they do on pathogenic microorganisms although generally speaking the level of impact is lower. This is due to the overall greater degree of sensitivity of pathogenic populations to the oxidative effects of chlorous acid when compared with spoilage populations. None-the-less, ASC solutions can have a marked effect on spoilage organisms to the extent that the shelf life of treated products – meats or produce – may be extended by several days. Additionally, losses to the retail trade associated with "shrinkage" – loss of produce during transport and storage - can be significantly reduced as a result of ASC treatment. Once again, application of an ASC solution represents a process which has a short term but intense effect on the spoilage populations that may be present.

Manufacture of Acidified Sodium chlorite

Acidified sodium chlorite solutions are typically not constituted for application until immediately just prior to the actual time of use because of their unstable nature,. Thus a typical ASC mixing system would consist of the two components stored separately: either in bulk as concentrates as would be the case in typical commercial-type operations; or formulated as stable, typically "double strength" solutions, for combination in a 1:1 ratio at time of use as would be the case in low volume applications where unit-of-use situations apply. Where the components are stored as concentrates, some dilution process using potable water would typically be applied to the individual components, again to achieve a final "double strength" solution for ultimate mixing in a 1:1 ratio prior to application. The time taken between mixing and use for a typical ASC solution is between 1 to 2 minutes.

Conclusion

Sodium chlorite is an approved processing aid that is listed in Standard 1.3.3 - Processing Aids, Table to clause 12 – Permitted bleaching agents, washing and peeling agents. The use of acidified sodium chlorite as an antimicrobial agent on a variety of raw food types to reduce the microbial contaminations arising from the presence of pathogenic and spoilage species of microorganisms is technologically justified.

Attachment 4

Summary of submissions at Initial assessment

Submitter	Comments
1. Food Technology Association of Victoria Inc.	• Support Option 2 – accept application;
2. Queensland Public Health Services	• Support Option 2 - accept application; and • Acknowledge that there is evidence from the European Union that acidified sodium chlorite is a superior listericidal agent in chicken spin chillers.
3. Australian Food and Grocery Council	• Support option 2 – subject, if necessary, to satisfactory safety assessment by FSANZ; • FSANZ needs details of residual levels of available chlorine in the finished foods before it can make a decision on whether an amendment to Standard 1.3.3 – Processing Aids is necessary and to carry out a safety assessment if the residual level of 1.0 mg/kg (or 10 mg/kg) is exceeded.
4. New Zealand Food Safety Authority	• Support option 2 – accept application; • The levels specified in the application are in line with levels specified in the US Code of Federal Regulations, Volume 21, 173.325; • Rather than permitted levels of chlorate, chlorite and or chlorine dioxide our preference would be for process parameters such as the level of acidified sodium chlorite and pH to be specified which are known to result in acceptable levels of chlorate, chlorine and chlorine dioxide.
5. Australian Quarantine and Inspection Service	• Defers comment until after draft assessment.

Attachment 5

Summary of submissions at Draft assessment.

Submitter	Comments
1. Food Technology Association of Victoria Inc.	• Supports Option 2 to amend the Table to clause 14 – permitted processing aids with miscellaneous functions, of Standard 1.3.3 – Processing Aids to specifically permit sodium chlorite as an antimicrobial agent.
2. Food Regulation and Safety Department of Agriculture, Fisheries and Forestry.	• Supports Option 2. Making the maximum permitted level for sodium chlorite in a food equivalent to the limits of determination for chlorite, chlorate, chlorous acid and chlorine dioxide would lead to a subjective interpretation of this Standard because the limit of determination for an analyte varies according to method of analysis employed. Concerned that the editorial note contains the definition for a 'limit of determination' that would not be enforceable.
3. Environmental Health Unit of Queensland Health	• Support Option 2. Accept that the use of sodium chlorite as a food processing aid for antimicrobial use is technologically justified and raises no public health and safety concerns.
4. Australian Meat Industry Council	• Support Option 2. Sodium chlorite is already available in many major international food markets that Australia competes with, such as US and Canada. It has been proven scientifically to increase the level of food safety through the reduction of food spoilage bacteria with no significant public health and safety concerns.
5. Australian Food and Grocery Council (AFGC)	• The AFGC supports approval of A476 (Option 2) without its previous reservation expressed at initial assessment.
6. New Zealand Food Safety Authority (NZFSA)	• Support Option 2. Agree that an editorial note should be included to clarify the intention of the maximum permitted levels for chlorite, chlorate, chlorous acid and chlorine dioxide. It is not clear what is intended by the phrase "specified laboratory method and/or item of laboratory equipment." The NZFSA considers that a particular method is specified, when it is not. We therefore request that this phrase be amended to clarify the intent. It is our interpretation that the responsibility for demonstrating compliance with the limits for residues lie with the food processor. • The Executive Summary of the EU "Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on the Evaluation of Antimicrobial Treatments for Poultry Carcasses" supports the safety of acidified sodium chlorite and its residues.
7. Susan George University student	• Supports Option 2. Provided research information that supported the use of acidified sodium chlorite as an antimicrobial agent in accordance with Good Manufacturing Practice.
8. Y. Lau	• Supports Option 2. Provided research information that supported the use of acidified sodium chlorite as an antimicrobial agent in accordance with Good Manufacturing Practice.