

08/03
19 March 2003

INITIAL ASSESSMENT REPORT

APPLICATION A476

ACIDIFIED SODIUM CHLORITE
AS A PROCESSING AID

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
30 April 2003

(See “Invitation for Public Submissions” for details)

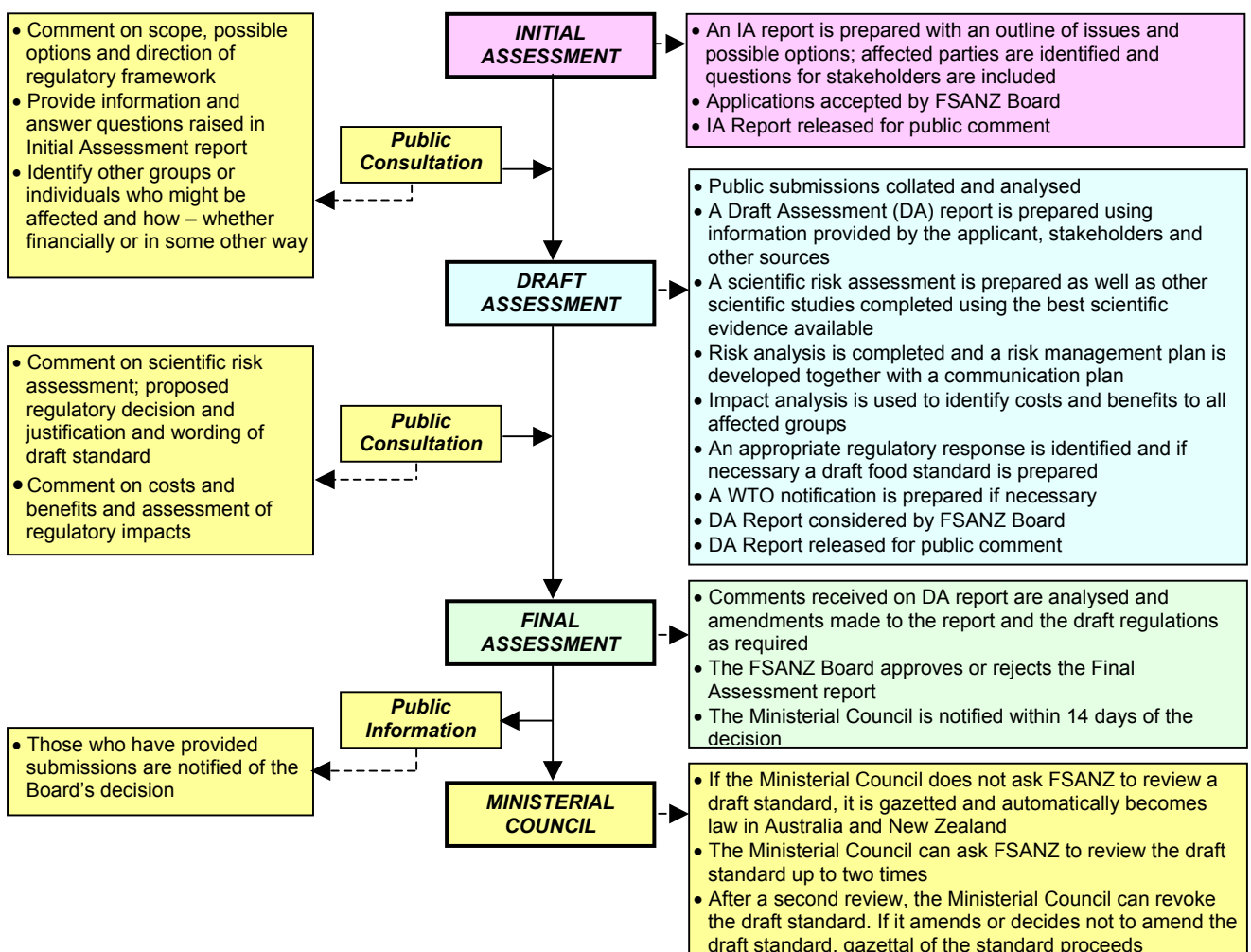
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 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 *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.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial Assessment Report of Application A476, which includes the identification and discussion of the key issues; and has prepared a draft variation to Volume 2 of the *Food Standards Code*.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

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

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

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

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

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

Submissions should be received by the Authority **by 30 April 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

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

CONTENTS

EXECUTIVE SUMMARY	5
1. INTRODUCTION.....	6
2. REGULATORY PROBLEM.....	6
2.1 CURRENT REGULATIONS.....	6
2.2 OVERSEAS REGULATORY STATUS	7
3. OBJECTIVE	7
4. BACKGROUND	8
4.1 HISTORICAL BACKGROUND	8
5. RELEVANT ISSUES	8
5.1 TECHNOLOGICAL JUSTIFICATION	8
5.2 PUBLIC HEALTH AND SAFETY ISSUES	8
6. REGULATORY OPTIONS.....	8
7. IMPACT ANALYSIS	9
8. CONSULTATION	9
8.1 PUBLIC CONSULTATION.....	9
8.2 WORLD TRADE ORGANIZATION (WTO) NOTIFICATION	9
9. CONCLUSION AND RECOMMENDATION	10

APPLICATION A476

USE OF ACIDIFIED SODIUM CHLORITE AS A PROCESSING AID

Executive Summary

This is an initial assessment report only and based on available information provided by the applicant. Public submissions are invited on this initial assessment report and will be used as part of the draft assessment stage.

An application was received from Alcide Corporation on 10 September 2002 to amend Volume 2 of the *Food Standards Code* to provide permission for acidified sodium chlorite as a processing aid for use on poultry meats, meat and formed meat products, and fruit and vegetables. This may require amendments to Standard 1.3.3 – Processing Aids.

A mix of sodium chlorite and citric acid (or other 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 *Food Standards Code* 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 (defined in units of available chlorine).

1. Introduction

An application received from Alcide Corporation to:

- amend if necessary Standard 1.3.3 – Processing Aids of the *Food Standards Code* (Volume 2) in order to permit acidified sodium chlorite as a processing aid on poultry meats, meat and formed meat products, and fruit and vegetables; and
- confirm the regulatory status of acidified sodium chlorite and the maximum permitted level of sodium chlorite (defined in units of available chlorine).

This application is at the initial assessment stage under section 14 of the *Food Standards Australia New Zealand Act 1991*.

2. Regulatory Problem

Alcide Corporation developed a food treatment process where a mix of sodium chlorite and citric acid (or other 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 up) 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).

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. The applicant is seeking clarification of the regulatory status of acidified sodium chlorite and the maximum permitted residual level of sodium chlorite (defined in units of available chlorine).

2.1 Current Regulations

The definition of a processing aid contained in Standard 1.3.3 – Processing Aids is **processing aid** means 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 Volume 2 of the Food Standards Code in Standard 1.3.3 - Processing Aids, Table to clause 12.

Permitted bleaching agents, washing and peeling agents.

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

Citric acid, phosphoric acid, hydrochloric acid, malic acid and sodium acid sulfate (by specification) are listed in Standard 1.3.1 Food Additives Schedule 2 as generally permitted food additives and are therefore generally permitted to be used as processing aids as stated in Clause 3 (b).

2.2 Overseas Regulatory status

United States

Code of Federal Regulations Volume 21, 173.325 approves the range for use 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 Recognised 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 by its legislation 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.

4. Background

4.1 Historical Background

A preliminary scoping of this application placed it in work plan group 3, category 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 Food Standards Code, FSANZ staff held a meeting with the applicant on 16 October 2002 to clarify with the applicant that there is a concern about the regulatory status of acidified sodium chlorite and that sodium chlorite is defined in units of available chlorine for the maximum permitted level.

5. Relevant Issues

5.1 Technological Justification

The applicant states that the acidified sodium chlorite is intended for use 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.

5.2 Public Health and Safety Issues

The applicant submits that the acidified sodium chlorite is applied onto the surfaces of the food at low levels. The oxychlorine species that are stable, and that are actually able to be found in acidified sodium chlorite treatment solutions both after mixing and after contact with food surfaces are restricted to chlorite, chlorate and chlorine dioxide. Any chlorine dioxide that forms is either lost by evaporation or reduction. The Table to Clause 12 of Standard 1.3.3 – Processing Aids, states a maximum permitted level of 1.0 mg/kg (available chlorine) for sodium chlorite. Clarification of the appropriateness of determining available chlorine as a measure of sodium chlorite will be considered as part of the Draft Assessment.

A safety assessment of the process and any resulting chemical residues on food will also be performed as part of the Draft Assessment.

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 citric or other food grade acid such as phosphoric acid, hydrochloric acid, malic acid or sodium acid sulfate).
- Option 2. 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.

Option 3. Accept the application and prepare a draft assessment report to consider amending Standard 1.3.3 Table to clause 12 – entry for sodium chlorite.

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.

8. Consultation

8.1 Public consultation

This Initial Assessment Report will be made available for public submissions. This allows interested parties (food industry groups, food companies, consumers and consumer groups and government agencies) to make submissions including any technical matters that may be relevant. There is no plan to consult wider than this.

Areas that FSANZ is seeking public comment on in order to assess this application include:

- Technological justification and efficacy of the application;
- Public health and safety of acidified sodium chlorite and the maximum permitted level of any resulting residues in foods.
- The appropriateness of specifying the maximum level of acidified sodium chlorite in terms of residual chlorine.

8.2 World Trade Organization (WTO) Notification

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

Amending the Code to approve the addition of acidified sodium chlorite to foodstuff is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (formerly Full Assessment) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Conclusion and Recommendation

The above application fulfils the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991*.

In making an initial assessment of the application, the Authority must have regard to the following matters:

- (a) whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure, as the case requires;
- (b) whether the application is so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted;
- (c) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation;
- (d) whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
- (e) any other relevant matters.

The Application relates to a matter that may warrant a variation of a food regulatory measure. As sodium chlorite is already permitted in the Food Standards Code, FSANZ staff held a meeting with the applicant on 16 October 2002 to clarify with the applicant that there is a concern about the regulatory status of acidified sodium chlorite and that the maximum permitted level of sodium chlorite is defined in units of available chlorine. Accordingly the Authority has decided to accept the application and will now proceed to the Draft Assessment Report - section 15.

If subsequently agreed by the Authority and supported by the Australia and New Zealand Food Regulation Ministerial Council, an amendment to the *Food Standards Code*, as suggested by the applicant, would permit the use of acidified sodium chlorite as a processing aid and clarify the maximum permitted level of sodium chlorite in food.