

09/03
21 May 2003

INITIAL ASSESSMENT REPORT

APPLICATION A493

IODINE AS A PROCESSING AID

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
2 July 2003

(See 'Invitation for Public Submissions' for details)

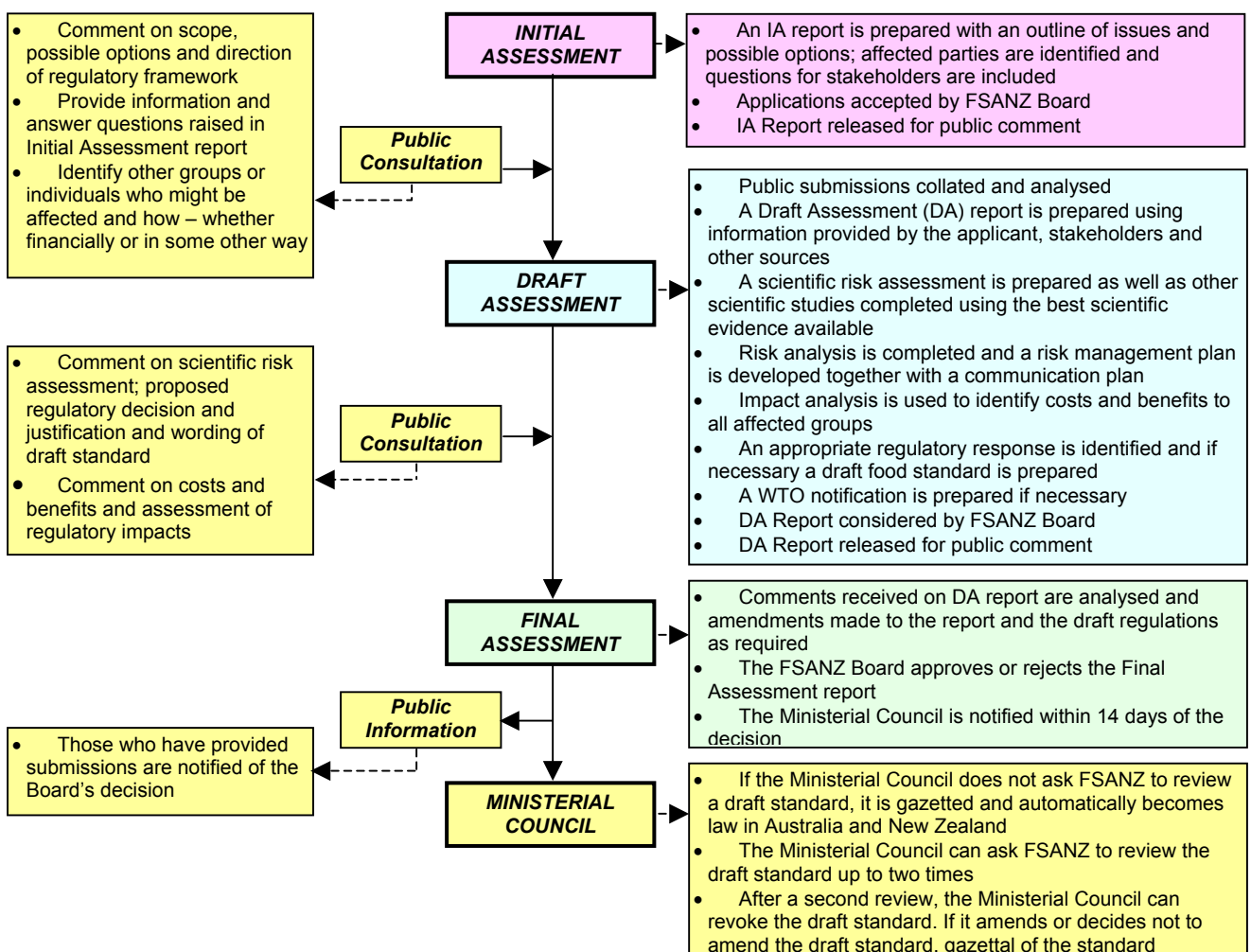
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 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.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial Assessment Report of Application A493, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Australia New Zealand 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 Draft Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand 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. Section 39 of 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: **2 July 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards 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.

Further Information

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

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

Food Standards Australia New Zealand received an application on 21 February 2003 from Iodine Technologies Australia Pty Ltd to approve the use of iodine as a processing aid under Standard 1.3.3 Processing Aids of the *Australia New Zealand Food Standards Code* (the Food Standards Code).

It is proposed to use iodine as a washing agent to reduce the levels of pathogenic bacteria and natural microflora on the surface of food, particularly fresh produce. The sanitising system that has been developed delivers iodine in treatment water at a controlled concentration, which can be set within the range of 3 to 30 ppm. The iodine concentration used depends on the contact time and the microbial load on the product to be treated.

This Initial Assessment report is not an assessment of the merits of the application but rather is an assessment of whether the application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the Act). It has been concluded that, having regard to the criteria specified in section 13 of the Act, the application be accepted for further assessment.

The purpose of this report is to provide relevant information supplied by the applicant, to assist in identifying the affected parties and to outline the relevant issues necessary to complete assessment of the application, now that it has been accepted. The information needed to complete the assessment will include information received from public submissions.

If this application is successful, FSANZ will amend the Food Standards Code and insert permission for the use of iodine as a washing agent in the Table to clause 12 of Standard 1.3.3.

Public submissions are now invited on this Initial Assessment report. Comments are specifically requested on the scientific aspects of this application, in particular, information relevant to the safety of iodine as a washing agent for food and the technological justification for its use.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an application on 21 February 2003 from Iodine Technologies Australia Pty Ltd to approve the use of iodine as a processing aid under Standard 1.3.3 Processing Aids of the *Australia New Zealand Food Standards Code* (the Food Standards Code). It is proposed to use iodine as a washing/sanitising agent for foods.

An Initial Assessment of the application has been completed and public comment is now being sought to assist in the Draft Assessment of the application.

2. Regulatory Problem

Under Standard 1.3.3, processing aids, unless expressly permitted, must not be added to food. A processing aid is defined as:

processing aid means a substance listed in clauses 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.

There is currently no approval for the use of iodine as a processing aid in the Food Standards Code. The Applicant has applied to have iodine listed as a washing agent in the Table to clause 12 of Standard 1.3.3. The substances listed in that Table may be used as bleaching agents, washing and peeling agents in the course of manufacture of the corresponding foods specified in the Table provided the final food contains no more than the corresponding maximum permitted level specified in the Table. The Applicant has requested that permission for iodine as a washing agent apply to all foods at good manufacturing practice (GMP)¹ levels.

3. Objective

The objective of this application is to determine whether it is appropriate to amend Standard 1.3.3 of the Food Standards Code to permit the use of iodine as a processing aid. 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.

¹ Under GMP, the amount of iodine used should be the minimum amount necessary to have the intended effect (i.e. sanitisation).

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

Chlorine has been used extensively by the food industry as a primary sanitising agent at all levels of growing, processing, manufacturing and distribution to reduce to acceptable levels pathogens such as *Escherichia coli*, Listeria, Salmonella and Hepatitis A on the surfaces of foods. The Applicant reports, however, that there is a growing international trend away from the use of chlorination because it can lead to the formation of potentially hazardous by-products such as trihalomethanes and chlorofuranones, and also because of concerns related to the discharge of chlorine into the workplace and broader environment.

Elemental iodine, which has been used as a water disinfectant for many years, and also as a sanitising compound by the dairy industry, is now being promoted as a viable alternative to chlorine for the sanitation of food.

The Applicant reports they have developed a fully automated post harvest sanitising system, using elemental iodine as the active ingredient, to reduce the levels of bacteria and fungi on the surface of food, particularly fresh produce. The sanitising system delivers iodine in treatment water at a controlled concentration, which can be set within the range of 3 to 30 ppm. The iodine concentration used depends on the contact time and the microbial load on the product to be treated.

4.2 Work Plan Classification

This application had been provisionally rated as complexity Category 3 and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment amends the previous complexity rating, which has now been increased to Category 4 to reflect that the application raises more complex issues than first realised. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Safety Considerations

Iodine is a well-known chemical element and an extensive amount of literature is available on its toxicology. Iodine is also an essential micronutrient that is necessary for the synthesis of the thyroid hormones, thyroxine and triiodothyronine. A certain amount of iodine is

therefore required in the diet.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) last evaluated iodine in 1988 and set a provisional maximum tolerable daily intake (PMTDI) from all sources of 0.017 mg iodine/kg body weight (approximately 1 mg iodine/day for adults). The Committee noted however that while this level is considered safe for the majority of the population, it may not be fully protective for people with thyroid disorders or people who are particularly sensitive to iodine.

The Applicant has submitted that the use of iodine as a washing agent for foods would result in an approximate doubling of the iodine levels associated with the food but that this should be considered in light of the fact that background iodine levels can vary by up to 500% between growing regions and that fruits and vegetables only contribute about 5% of the iodine in an average diet.

The safety of iodine for use as a washing agent for foods will be more fully considered at Draft Assessment.

5.2 Technological Justification

The Applicant claims that iodine is effective as a sanitiser for fruits, vegetables and other food products and if used properly has the potential to overcome the problems caused by the use of chlorine in wash water. The Applicant also reports that iodine is more active than chlorine against a number of microorganisms in water.

In support of these claims, the Applicant has provided several studies conducted with their sanitising system by the Sydney Post Harvest Laboratory in collaboration with Food Science Australia. These studies examined the effectiveness of iodine to:

- inactivate pathogenic *Salmonella spp.* and *Listeria monocytogenes* on food surfaces;
- inactivate *Salmonella* in free solution; and
- reduce the levels of natural microflora (bacteria and fungi) on the surfaces of fresh produce.

These and other data provided by the Applicant will be used at Draft Assessment to examine the technological justification for the use of iodine as a processing aid.

5.3 Nutritional Implications

The Applicant reports that the doubling in iodine levels associated with fruits and vegetables treated with their sanitising system will result in a slight increase in iodine intake for the population. The Applicant argues that while fruits and vegetables only contribute about 5% of the average iodine intake, a slight increase in iodine intake from treated fruits and vegetables is likely to be beneficial as the typical Australian diet is deficient in iodine.

The nutritional implications arising from the use of iodine as a washing agent for foods will be more fully considered during Draft Assessment.

5.4 Other Relevant Issues

5.4.1 Other National Regulations

The Applicant obtained a permit from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) (now known as the Australian Pesticides and Veterinary Medicines Authority; APVMA) for the period 1 February 2001 to 1 August 2001 for the purpose of evaluating the efficacy of iodine (application rate of 3.5 to 35 mg/L) against bacteria and other microorganisms on fruit and vegetables. Iodine, under the product name of Biomaxa Iodine Granules Post harvest Sanitiser, was subsequently registered on 6 November 2002. The registration ends on 30 June 2003.

5.4.2 Overseas Regulatory Status

Overseas legislation for the use of iodine as a sanitising agent for foods primarily relates to its use on food contact surfaces. The relevant regulations are:

- United States Code of Federal Regulations Title 21, 178.1010 – Sanitising Solutions (food contact surfaces and utensils only).
- United Kingdom Statutory Instrument 1999 No 919, Schedule 2 – Approved Disinfectants (sanitisation of dairies).

A range of provisions also exists for the short-term use of iodine to treat water supplies in emergency situations.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Food Standards Code will be analysed using regulatory impact principles.

The following two regulatory options are available for this application:

- Option 1.** Maintain the status quo and not approve the use of iodine as a food processing aid.
- Option 2.** Amend the Food Standards Code and approve the use of iodine as a food processing aid.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this application include those listed below:

- consumers;

- those sectors of the food industry wishing to produce and market food products produced using iodine as a processing aid; and
- Australian Commonwealth, State, Territory and New Zealand government enforcement agencies.

7.2 Impact of Regulatory Options

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

The regulatory impact of the proposed change to the Food Standards Code will be determined at Draft Assessment. To assist in developing the impact analysis of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

8. Consultation

The Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the application.

All stakeholders that make a submission in relation to the application will be included on a mailing list to receive further FSANZ documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this application, they should bring this to their attention. Other interested parties as they come to the attention of FANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this application. Comments that would be useful could cover:

- the technological justification and efficacy of iodine as a washing agent for foods;
- the safety of elemental iodine as a washing agent for foods;
- parties that might be affected by having this application approved or rejected;

- arguments in support or opposition to permitting iodine as a processing aid; and
- potential costs and benefits to consumers, industry and government.

8.2 World Trade Organization (WTO)

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

Amending the Food Standards Code to allow the use of iodine as a processing aid is unlikely to have a significant effect on international trade. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

Having regard to the criteria specified in section 13 of the Act, it is concluded that the application be accepted for further assessment.

Accordingly, FSANZ will now undertake a Draft Assessment and prepare a Draft Assessment Report.

10. Implementation and review

This information will be provided once the Draft Assessment has been completed.