14-03
17 December 2003

INITIAL ASSESSMENT REPORT

APPLICATION 513

OCTANOIC ACID AS A PROCESSING AID

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
11 February 2004
(See 'Invitation for Public Submissions' for details)

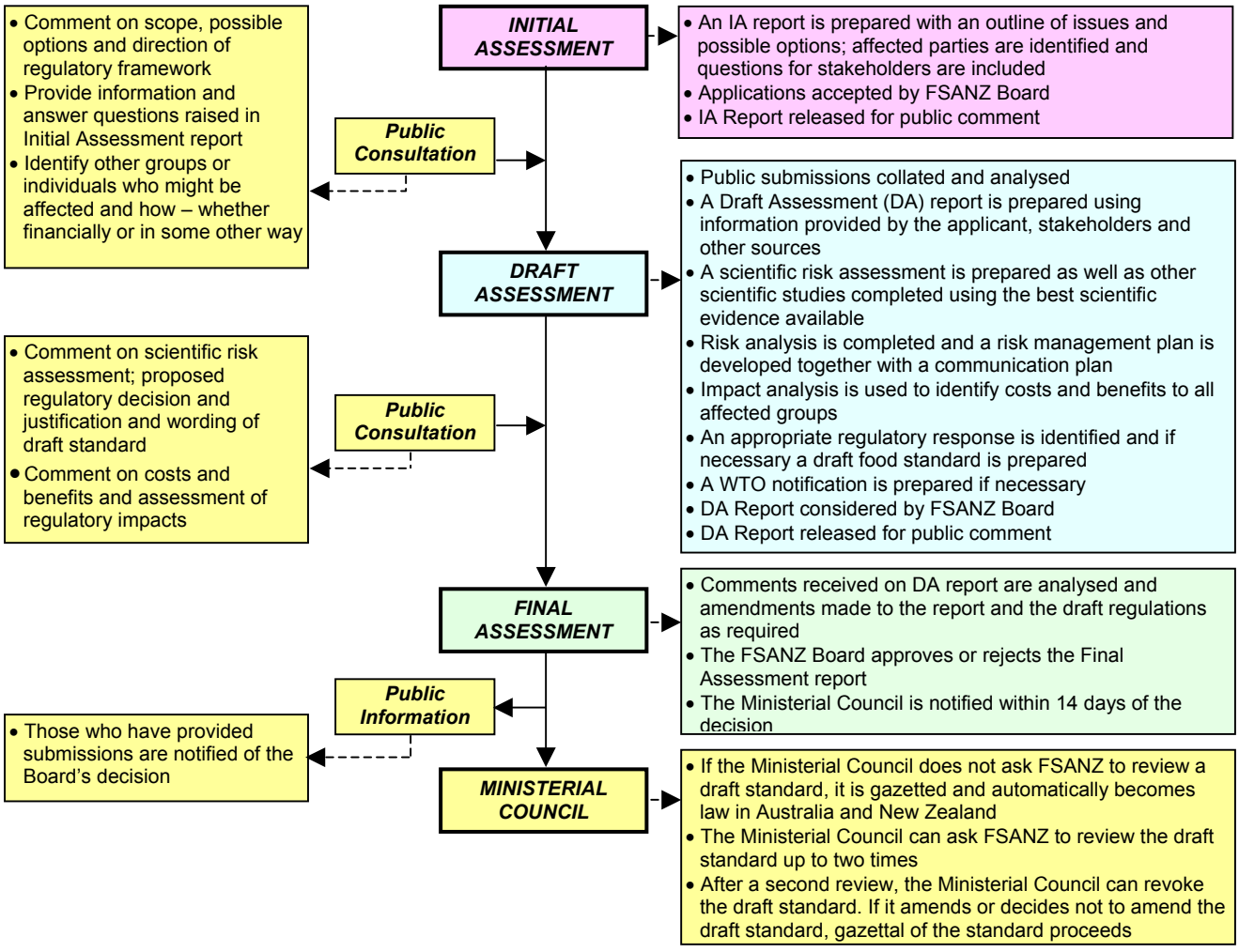
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

FSANZ has prepared an Initial Assessment Report of Application A513, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the 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 FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ 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 FSANZ **by 11 February 2004**.

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. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

FSANZ received an application on 7 October 2003 from Ecolab Pty Ltd to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of octanoic acid as a processing aid. Work commenced on this cost recovered application on 13 October 2003.

Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. The objective of this assessment is to determine whether the Code should be amended to permit the use of octanoic acid as a processing aid in Standard 1.3.3.

The Applicant states that octanoic acid 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 species of microorganisms. The Applicant has supplied some technical data with the application supporting the technological need and safety of octanoic acid. This will be assessed at Draft Assessment.

This Initial Assessment Report is not a detailed assessment of Application A513 but rather an assessment of whether the application should undergo further consideration. The Report is based mainly on information provided by the Applicant and has been written to assist in identifying the affected parties and to outline expected relevant issues to complete the assessment. The information needed to complete the assessment will include information received from public submissions.

This Application has been assessed against the requirements of section 13 of the FSANZ Act and FSANZ accepts this Application following initial assessment for the following reasons:

- The Application seeks approval of the use of octanoic acid as a processing aid as an antimicrobial intervention on a variety of raw food types to reduce the microbial contamination.
- Under Standard 1.3.3-Processing Aids, there is no permission for octanoic acid. Therefore, the Application relates to a matter that warrants a variation to Standard 1.3.3, if further assessment supports such a variation.
- This Application is not so similar to any previous application that it ought not be accepted.
- There is no basis for considering at this stage of the assessment, that the costs that would arise from a variation to Standard 1.3.3 to permit octanoic acid as a processing aid would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- There are no measures other than a variation to the Code available to permit this processing aid for use on raw foods as an antimicrobial agent.

Accordingly, it is recommended that this Application be accepted and progressed to Draft Assessment subject to the payment of fees assessed pursuant to section 66 of the Act and the *Food Standards Australia New Zealand Regulations 1994* (the Regulations). Submissions are invited to assist in assessing this Application, the proposed Regulatory options and the Report as a whole.

1. Introduction

FSANZ received an Application on 7 October 2003 from Ecolab Pty Ltd to amend Standard 1.3.3 – Processing Aids of the Code to approve the use of octanoic acid as a processing aid in water in various formulations to be used as an antimicrobial treatment on red meat and poultry carcasses and parts and fresh fruits and vegetables. On 13 October 2003, fees were paid to FSANZ and work commenced on this cost-recovered Application.

2. Regulatory Problem

2.1 Current Standard

Under Standard 1.3.3 of the Code, processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. A processing aid is a substance 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.

There is currently no approval for the use of octanoic acid in Standard 1.3.3 – Processing Aids.

3. Objective

The objective of this Application is to determine whether it is appropriate to change the Code to approve the use of octanoic acid 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 FSANZ Act. 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 Background

The Applicant has proposed that octanoic acid in three different products (formulations) will be added to processed water used during the washing of carcasses or produce in order to significantly decrease human pathogens (e.g. *Salmonella typhimurium*). These formulations, namely, KX 6110 (Inspexx 100), KX 6145 (Inspexx 200) and KX 6111 (Tsunami 200) consist of a mixture of hydrogen peroxide, acetic acid, octanoic acid, peroxyacetic acid (POAA), peroxyoctanoic acid (POOA) and hydroxyethylidene-1,1-diphosphoric acid (HEDP).

The formulation is sprayed onto poultry and red meat carcasses at concentrations of 180-220 ppm total peroxyacids post-slaughter. It is also envisaged that octanoic acid formulations added to water would be applied to fruit and vegetables to decrease spoilage micro-organisms, although the Applicant has not provided the specific use levels for fruit and vegetables. FSANZ is currently seeking data from the Applicant on the proposed levels in fruit and vegetables, which will be detailed at Draft Assessment.

The peroxyacetic and peroxyoctanoic acid are formed by the reaction of acetic acid with hydrogen peroxide and octanoic acid with hydrogen peroxide, respectively:

- Acetic acid+Hydrogen Peroxide↔Peroxyacetic acid +H_20;
- Octanoic Acid+ Hydrogen Peroxide↔Peroxyoctanoic acid +H_20.

In the Code permission is granted for the following processing aids and/or food additives:

- Hydrogen peroxide is permitted in Clause 12 of Standard 1.3.3 as a permitted bleaching, washing and peeling agent in all foods up to a maximum level of 5 mg/kg;
- Acetic acid is permitted in Schedule 2 of Standard 1.3.1-Food Additives in accordance with good manufacturing practice (GMP) in processed foods and therefore in Standard 1.3.3 as a generally permitted processing aid by virtue of Clause 3(b).
- Peracetic acid is permitted in Clause 12 of Standard 1.3.3 as a permitted bleaching, washing and peeling agent in all foods at GMP.

4.2 Work Plan Classification

This application had been provisionally rated as Category of Assessment 3 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. 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 Efficacy and technological need

The Applicant states that octanoic acid 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 species of microorganisms. The Applicant has supplied technical data with the Application supporting the technological need.

The technological need for octanoic acid as a processing aid will be assessed by FSANZ in a Food Technology Report at Draft Assessment. In addition, a Microbiology Report which will be included as part of the Draft Assessment Report to address the issue of efficacy of octanoic acid formulations applied to raw foods.

5.2 Safety assessment

The Applicant has stated that acetic acid and octanoic acid (caprylic acid) are generally recognised as safe (GRAS) in the USA, are normal constituents of the human diet found in living cells and that a safety evaluation of these components is not necessary.

The Applicant also suggested that as hydrogen peroxide, peroxyacetic and peroxyoctanoic acid are all peroxides that are likely to have a common mechanism of toxicity and consequently submitted residue data on all three peroxides grouped together. A separate risk assessment was submitted by the Applicant on HEDP, which is used in the formulations to chelate metals and hence preserve the mixture and function in the final food.

FSANZ will evaluate octanoic acid, POAA, POOA and HEDP in the formulations to determine whether there are any public health and safety concerns, following use on poultry, beef and fruit and vegetables. In order to undertake this safety assessment it is necessary to establish whether there are any residues of the individual components from the use of the formulations on the proposed foods. Therefore, a safety assessment of these components and an examination of any resulting chemical residues on food will be performed as part of the Draft Assessment.

5.3 Other international regulatory standards

The Applicant states that octanoic acid is approved for use in various formulations (products) in the US, Canada and Mexico for use on red meat and poultry carcasses.

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 Code will be analysed using regulatory impact principles.

The following two regulatory options are available for this application:

Option 1. Not approve the use of octanoic acid as a food processing aid.

Option 2. Approve the use of octanoic as a food processing aid.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include those listed below:

1. Those sectors of the food industry wishing to use octanoic acid based formulations as a processing aid to reduce microbial contamination of raw foods and produce;

2. Consumers who may benefit by having some treated food products with improved food safety via reductions in microorganisms and safer food; and

3. Commonwealth, State, Territory and New Zealand Government enforcement agencies that enforce food regulations.

The impact of the proposed change to the regulation will be determined at the Draft Assessment.

8. Consultation

FSANZ is seeking public comment in order to assist in assessing this Application. There will also be a further round of public comment after the Draft Assessment Report is completed.

Such comments could cover:

- Scientific aspects of the Application, in particular, any information relevant to the safety assessment;
- Technological need and efficacy of octanoic based formulations;
- Parties that might be affected by having this application approved or rejected;
- Potential costs and benefits to consumers, industry and government.

8.1 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.

There are not any relevant international standards and amending the Code to approve octanoic acid 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's 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

Section 13 of the FSANZ Act prescribes those matters that must be taken into account by FSANZ in making an Initial Assessment. FSANZ accepts this Application following Initial Assessment for the following reasons:

- The Application seeks approval of the use of octanoic acid as a processing aid as an antimicrobial intervention on a variety of raw food types to reduce the microbial contamination.
- Under Standard 1.3.3-Processing Aids, there is no permission for octanoic acid. Therefore, the Application relates to a matter that warrants a variation to Standard 1.3.3, if further assessment supports such a variation.
- This Application is not so similar to any previous Application that it ought not be accepted.
- There is no basis for considering at this stage of the assessment, that the costs that would arise from a variation to Standard 1.3.3 to permit octanoic acid as a processing aid would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the variation.
- There are no measures other than a variation to the Code available to permit this processing aid for use on raw foods as an antimicrobial agent.

Accordingly, FSANZ now seeks public comment in order to proceed to the Draft Assessment Report. If subsequently approved by FSANZ and agreed by the Ministerial Council, Standard 1.3.1 would allow the use of octanoic acid as an antimicrobial intervention on a variety of raw food types to reduce the microbial contamination arising from the presence of pathogenic species of microorganisms.