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

8-04
20 October 2004

DRAFT ASSESSMENT REPORT

APPLICATION A513

OCTANOIC ACID AS A PROCESSING AID

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

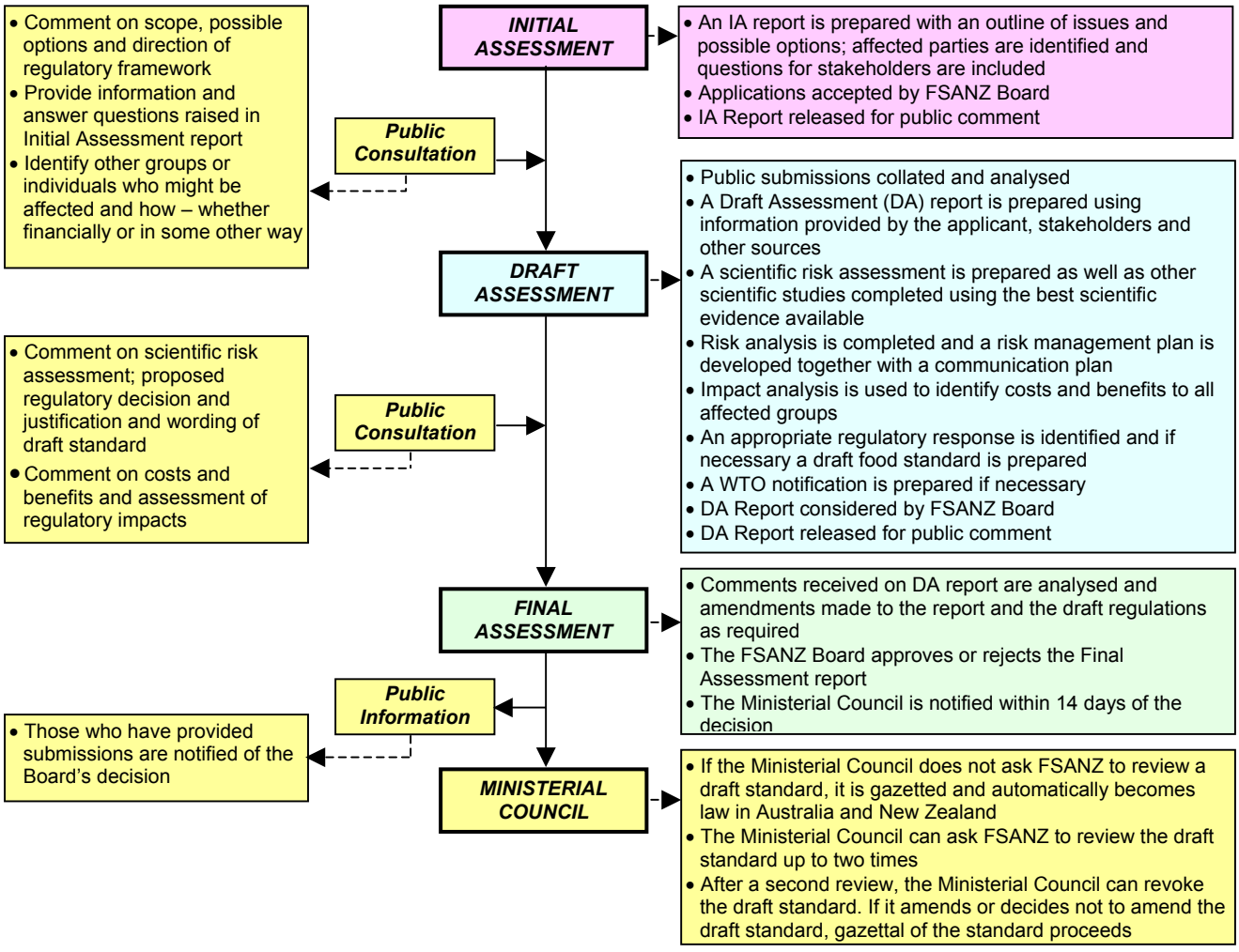
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 a Draft Assessment Report of Application A513; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code 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 1 December 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 Management 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 and Statement of Reasons

Ecolab Pty Ltd submitted an Application to FSANZ on 7 October 2003 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 in water in various formulations to be used as an antimicrobial treatment on red meat and poultry carcasses and fresh fruits and vegetables.

These formulations, namely, KX 6110 (Inspexx 100), KX 6145 (Inspexx 200) and KX 6111 (Tsunami 200) consist of a mixture of hydrogen peroxide (HP), acetic acid, octanoic acid, peroxyacetic acid (POAA), peroxyoctanoic acid (POOA) and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

Under Standard 1.3.3 of the Code, processing aids (other than already permitted processing aids) are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. There is currently no approval for the use of octanoic acid in Standard 1.3.3 – Processing Aids. HEDP is currently permitted in Table to clause 11 of Standard 1.3.3 as a permitted processing aid used in packaged water and in water used as an ingredient in other foods at good manufacturing practice levels (GMP). However, HEDP is not currently approved for use in antimicrobial formulations as a chelating agent, which is the proposed use in the above formulations. Other components of the formulations are currently regulated in the Code.

Efficacy and technological need for octanoic acid and HEDP

Following an assessment of data from the Applicant on the efficacy of octanoic acid containing formulations to reduce bacterial contamination, FSANZ concluded that each of the three formulations is effective in reducing the number of microorganisms on the surfaces of red meat, poultry, and fruits and vegetables as intended.

The use of octanoic acid as a processing aid in the formulations described in the Application is technologically justified and these formulations represent possible alternative treatments that may be used in decontamination systems. The use of HEDP as a chelating agent within the sanitizing formulations is also technologically justified.

Risk Assessment

The available data on residues of specific components of the three formulations support the safety of these components at the proposed uses envisaged by the Applicant.

The conclusions from the hazard assessment and dietary exposure analysis is as follows:

- No toxicological concerns have been identified for POAA, POOA and HP residues in the various formulations.

- For the population groups assessed, the estimated mean and 95th percentile consumer dietary exposures to octanoic acid do not change significantly between natural baseline levels in foods and when the requested permissions for octanoic acid as a processing aid in the proposed commodities are considered in conjunction with the naturally occurring levels.

High consumers (95th percentile) would have an additional increase of 3.5 mg/day. It is concluded that there would be no toxicological concerns if permission were granted for approval of octanoic acid as a processing aid in the Code.

- The exposure to HEDP residues for the mean and highest consumer was well below the level of toxicity observed in animals or the level at which therapeutic doses of HEDP is used to treat clinical conditions in humans.

Risk Management

No specific risk management strategies are proposed, as it is considered that there are no public health and safety issues and processing aids are not required to be labelled.

Issues raised in public submissions

Submissions raised issues in relation to the safety of octanoic acid containing formulations and the individual components, the technological need and effectiveness of octanoic acid against specific pathogens, the technological need of HEDP in the formulations and regulation of octanoic acid in other countries.

Impact analysis of regulatory options

The options identified were to permit or not permit the use of octanoic acid and HEDP as processing aids. The impact analysis shows that the second option (to permit) satisfies the objectives based on the outcome of the scientific risk assessment and the Regulatory Impact Statement (RIS), taking into account matters raised following the public consultation period.

These matters included the following:

- an assurance of the safety of octanoic acid containing formulations;
- a recognised technological need and efficacy of octanoic acid, HEDP and other constituents of the formulations; and
- the provision of benefits to industry and governments, in terms of enhanced market opportunities and trade.

Statement of reasons

FSANZ recommends the approval of octanoic acid and HEDP as processing aids for the following reasons:

- based on the hazard assessment and dietary exposure analysis, there are no public health and safety concerns associated with consumption of residues of octanoic acid, HEDP or other constituents of the formulations;

- based on the efficacy studies on octanoic acid and the food technology report conclusions, there is a recognised technological need and the formulations are efficacious in reducing levels of specific pathogens on meat, poultry and fruit and vegetables;

- the Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of octanoic acid and HEDP as processing aids, the benefits of the proposed amendment outweigh the costs;

- there are no alternatives that are more cost-effective than a food regulatory measure, that can address what this Application seeks, given the requirement for pre-approval of processing aids under Standard 1.3.3;

- matters raised in submissions are addressed by the reasons above; and

- accordingly, approval of octanoic acid and HEDP as processing aids would be consistent with the Section 10 objectives of the FSANZ Act because:

    - it will not adversely affect public health and safety;
    - it is based on risk analysis, using the best available scientific evidence;
    - it will promote an efficient and internationally competitive food industry; and
    - the other section 10 matters will not be prejudiced by this approval.

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.

2. Regulatory Problem

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. HEDP is currently permitted in Table to Clause 11 of Standard 1.3.3 as a permitted processing aid used in packaged water and in water used as an ingredient in other foods at GMP levels. However, HEDP is not currently approved for use in antimicrobial formulations as a chelating agent, which is the proposed use in the formulations (refer to background). Other components of the formulations are currently regulated in the Code.

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 and HEDP as processing aids for use in antimicrobial formulations on beef, poultry and fruit and vegetables.

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 (HP), acetic acid, octanoic acid, peroxyacetic acid (POAA), peroxyoctanoic acid (POOA) and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

KX 6110 (Inspexx 100) is to be used in water to spray on poultry carcasses at 180-220 ppm total peroxyacids; KX 6145 (Inspexx 200) to be used in water to spray on beef carcasses at 180-220 ppm peroxyacids; and KX 6111 is to be used in water for washing fruits and vegetables at 40 ppm total peroxyacids.

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$\leftrightarrow$Peroxyacetic acid +H_20;
- Octanoic Acid+ Hydrogen Peroxide$\leftrightarrow$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;

- HEDP is permitted in Table to Clause 11 of Standard 1.3.3 as a permitted processing aid used in packaged water and in water used as an ingredient in other foods at GMP.

HEDP is a component of the antimicrobial formulation, however HEDP has no antimicrobial efficacy. HEDP is used in the formulation to increase long-term storage stability by preventing certain metal ions from catalysing the degradation of peroxyoctanoic acid and hydrogen peroxide.

4.2 Request for additional information

The Applicant supplied data on likely residues of the individual components of the three formulations, in poultry, beef and fruit and vegetables and toxicological studies on HEDP and octanoic acid.

The Applicant presented data to support their statements that minimal residues of acetic acid, octanoic acid and HEDP will remain on treated food and that the other ingredients rapidly degrade and residues are not detectable.

During the assessment period, FSANZ requested the Applicant on 24 November 2003 and 24 February 2004 to provide further data and information on the safety and likely residues of various components of the three formulations to support the Application. The Applicant supplied this information on 24 December 2003, 24 March and 23 April 2004. FSANZ re-commenced assessment of the Application on 30 April 2004.

5. Relevant Issues

A number of issues in relation to formulations containing octanoic acid were assessed in accordance with FSANZ's section 10 objectives and also as part of addressing issues raised from the public submissions.

These consist of the following issues:

- efficacy of octanoic acid in reducing microbial contamination, in particular, human pathogens;
- the technological need of key constituents in the formulations;
- the potential for public health and safety concerns from consumption of beef, poultry or fruit and vegetables with residues of individual chemical components of the above formulations; and
- regulation in other countries in order that Australian and New Zealand industries can remain competitive in the national and international beef, poultry and fruit and vegetable markets.

5.1 Efficacy and technological need

5.1.1 Efficacy

The experimental design and data analysis in the reports provided were found to be appropriate for determining the effect of the octanoic acid formulations on reducing microbial loads when used as recommended. Specific pathogen studies for KX6110 and KX6145 were performed to verify product effectiveness against *Salmonella typhimurium*, *Listeria monocytogenes* and *Escherichia coli* O157 strains recovered from food poisoning outbreaks.

The data showed that KX6110 and KX6145 are statistically significantly better than water in reducing microbial numbers on red meat and poultry, respectively. KX6110 was shown to be at least as effective as lactic acid treatment. In addition, specific pathogen studies showed KX6110 and KX6145 were statistically significantly more effective than water in reducing the levels of *Salmonella typhimurium*, *L. monocytogenes*, and *E. coli* on red meat and poultry surfaces, respectively. KX6111 was shown to be more effective in reducing microbial numbers on the surface of fruits and vegetables than relevant alternative treatments (chlorine and Tsunami 110) when compared directly to them.

In summary, the study results show that each of the three formulations is effective in reducing the number of microorganisms on the surfaces of red meat, poultry, and fruits and vegetables as intended. A full report on the efficacy of the three formulations is provided in **Attachment 2**.

5.1.2 Technological need

Beef carcasses, which are initially sterile, become contaminated upon slaughter with bacterial pathogens via transmission of organisms from the exterior of the live animal, and/or from the environment to the product surface. Poultry carcasses and vegetable produce can carry pathogenic organisms from the gut or soil or can be contaminated during processing. Successful control of food borne human pathogens requires a paddock to plate approach involving risk management interventions applied including slaughterhouses and processors. One way of minimizing this is the use of chemical sanitisers. Other chemicals that are used on freshly slaughtered animals are acetic acid and sodium chlorite.

The peracetic and peroctanoic components of the proposed formulations are produced by the reaction of acetic acid and octanoic acid with hydrogen peroxide. The primary mode of action is oxidation. The peroxy acids disinfect by oxidation of the outer cell membrane of vegetative bacterial cells, endospores, yeast and mould spores. The mechanism of oxidation is the transfer of electrons, therefore the stronger the oxidizer, the faster the electrons are transferred to the microorganism and the faster the microorganism is inactivated or killed. This action disrupts cell membrane permeability and will penetrate bacterial cell walls to disrupt protein synthesis. The secondary effect is the acidification of the carcass surface thereby decreasing the biological activity as a result of pH changes in the cell's environment and consequent disruption to cell metabolism.

The addition of the octanoic acid is synergistic with peracetic acid in microbial reduction by reducing the surface tension of carcass application. For example, a solution of peracetic acid and octanoic acid at 63 ppm reduces *Listeria monocytogenes* on meat surfaces by more than 5 logs in 30 seconds while POAA alone at 116 ppm requires 2 minutes to achieve the same reduction.

HEDP is a phosphonic molecule. It has excellent thermal and hydrolytic properties. It can slow the rate of oxidation or decomposition because of its metal chelating activity. Metal ion sequestering agents such as HEDP are added to products containing peroxy acids in order to eliminate undesirable decomposition reactions including those involving metals which catalyse the reduction of hydrogen peroxide, peroxyacetic acid and peroxyoctanoic acid. It is a very stable chemical and does not decompose readily on contact with the meat surface.

In conclusion, the use of octanoic acid as a processing aid in the formulations described in the Application is technologically justified. These formulations represent possible alternative treatments that may be used in decontamination systems. The use of HEDP as a processing aid (chelating agent) within the sanitizing formulations is also technologically justified. A full report on the technological need of the three formulations is provided in **Attachment 3**.

5.2 Hazard assessment

FSANZ reviewed the data supplied by the Applicant on the individual components of the formulations and in addition, reviewed additional information from the scientific literature to evaluate the safety of these components (**Attachment 4**).

Due to present permissions in the Code for hydrogen peroxide, acetic acid and peroxyacetic acid (by virtue of permissions for peracetic acid in Standard 1.3.3) FSANZ did not undertake a detailed safety assessment on those components of the formulations.

However, FSANZ did examine data on POAA, POOA and HP residues submitted by the Applicant to ensure that they could meet any regulatory limits prescribed in the Code, as this data was included in the residue data submitted by the Applicant.

The conclusions from the FSANZ were as follows:

- Residues of POAA (which incorporates a combined residue analysis of peroxyacetic acid and peroxyoctanoic acid) and HP in **poultry** were very low (<1 ppm) at 2-minutes post-treatment and would be expected to be below the limit of detection (LOD) following further degradation during storage and cooking etc. Data on **beef** demonstrate that the residues were below the LOD 10-minutes post-treatment.

- When HP, POAA and POOA further degrade the resulting products are water, oxygen, acetic acid and octanoic acid.

- It is concluded that due to the low residues of the above components in the formulations applied to poultry and beef, and the rapid decomposition to acetic acid, oxygen and water applied at a concentration of 200 ppm, there are no toxicological concerns.

For **fruit and vegetables**, although there was limited data on likely residues post-application supplied by the Applicant, FSANZ does not envisage a public health and safety risk from use on fruits and vegetables for the following reasons:

- the rapid decomposition of these compounds post-treatment;
- data on a related product which suggested that limited residues would be present 10-12 h post-treatment;
- the USEPA ruling in 1988 that indicated that there were no toxicological concerns from peroxyacetic acid compounds when applied to food as an antimicrobial agent; and that
- the residues would need to meet the existing permissions for peracetic acid and HP in the Code.

Furthermore, a recent evaluation by the Joint Expert Committee on Food Additives (June 2004) concluded that peroxide compounds (HP, POAA and POOA) in octanoic acid containing antimicrobial solutions break down to acetic and octanoic acid. Consistent with what is known about the chemistry of peroxides, no residues of HP, POAA or POOA are expected on foods that are treated with these mixtures. Therefore, these components would not pose a safety concern (WHO, 2004).

FSANZ evaluated residues of the other components namely, octanoic acid and HEDP in the formulations to determine whether there were any public health and safety concerns, following use on poultry, beef and fruit and vegetables.

The conclusions were as follows:

- The Joint Expert Committee on Food Additives (JECFA) evaluated octanoic acid as a flavouring agent in 1999[1] and concluded that it raised no toxicological concerns when used as a flavouring agent. The available studies in animals reviewed by FSANZ showed that octanoic acid was not genotoxic and in subchronic studies in rats a no-observed-effect-level (NOEL) of 15,000 mg/kg bw/day was established. The latest JECFA evaluation also confirmed that octanoic acid posed no toxicological concerns[2].

- The available data suggests that HEDP is of low acute toxicity and is not genotoxic. The sub-chronic studies suggest that specific organs may be affected at high doses, namely the testes in dogs and liver in rats; however, a clear NOEL was established. There have been no long-term studies conducted on HEDP. Effects on some reproduction parameters were observed; however, there was no gross teratogenic potential identified and a NOEL can be established from the rat and rabbit studies.

- The lowest-observed-effect-level (LOEL) from the available studies were 75 mg/kg bw/day in dogs, 1500 mg/kg bw/day in rats and 5 mg/kg bw/day in humans (therapeutic uses).

5.3 Dietary exposure assessment

For HP, POAA and POOA, the available residue data demonstrated that no residues would be likely following use on meat, poultry and fruit and vegetables, and therefore, no dietary exposure assessment was considered necessary on these components.

However, a dietary exposure assessment was undertaken for octanoic acid and HEDP based on the submitted residue data from the Applicant, to determine the potential exposure for Australian and New Zealand consumers of these components in the formulations.

5.3.1 Octanoic acid

Three scenarios were modelled: (i) current exposure to naturally occurring octanoic acid in the diet; (ii) use of octanoic acid as a processing aid only, on the proposed food commodities (beef, poultry, fruit and vegetables) and; (iii) a combination of both scenario's –naturally occurring exposure and use as a processing aid.

For consumers of naturally occurring octanoic acid (Scenario 1), estimated mean dietary exposures to octanoic acid were the lowest for Australian children aged 2-6 years at 331 mg/day and were highest for New Zealanders aged 15 years and above at 399 mg/day. Estimated 95th percentile dietary exposures to octanoic acid were the lowest for Australian children aged 2-6 years at 696 mg/day and highest for New Zealanders aged 15 years and above at 992 mg/day.

[1] WHO (1999) Evaluation of certain food additives and contaminants (Forty-ninth report of the Joint FA0/WHO Expert Committee on Food Additives. WHO Technical Report series, No. 884.

[2] WHO (2004) Safety evaluation of peroxyacid antimicrobial mixtures. 63rd Joint FAO/WHO Expert Committee on Food Additives. 8-17 June 2004.

When exposure to octanoic acid from its use as a processing aid only was considered (Scenario 2), estimated mean dietary exposures for consumers of octanoic acid were the lowest for Australian children aged 2-6 years at 1.1 mg/day and highest for New Zealanders aged 15 years and above at 1.6 mg/day. Estimated 95th percentile dietary exposures for consumers of octanoic acid were the lowest for Australian children aged 2-6 years at 2.5 mg/day and highest for both New Zealanders aged 15 years and above and Australians aged 2 years and above at 3.5 mg/day.

Based on the proposed uses of octanoic acid as a processing aid as well as naturally occurring levels (Scenario 3), estimated mean dietary exposures for consumers of octanoic acid were the lowest for Australian children aged 2-6 years at 331 mg/day and highest for New Zealanders aged 15 years and above at 399 mg/day. Estimated 95th percentile dietary exposures for consumers were the lowest for Australian children aged 2-6 years at 696 mg/day and highest for all New Zealanders aged 15 years and above at 993 mg/day.

In conclusion, for the population groups assessed, the estimated mean and 95th percentile consumer dietary exposures to octanoic acid did not change significantly between baseline (natural occurring levels in foods) and when the requested permissions for octanoic acid as a processing aid were added.

5.3.2 HEDP

Estimated mean dietary exposures for consumers of HEDP were 0.15 mg/day for Australians aged 2 years and above and New Zealanders aged 15 years and above, and 0.11 mg/day for Australian children aged 2-6 years. Estimated 95th percentile dietary exposures for consumers of HEPD were 0.35 mg/day for Australians aged 2 years and above, 0.33 mg/day for New Zealanders aged 15 years and above, and 0.28 mg/day for Australian children aged 2-6 years.

A full dietary exposure report is provided in **Attachment 5**.

5.4 Risk assessment

The available data on residues of specific components of the three formulations support the safety of these components at the proposed uses envisaged by the Applicant.

The conclusions from the hazard assessment and dietary exposure analysis is as follows:

- No toxicological concerns have been identified for POAA, POOA and HP residues in the various formulations.

- For the population groups assessed, the estimated mean and 95th percentile consumer dietary exposures to octanoic acid do not change significantly between baseline and when the requested permissions for octanoic acid as a processing aid are considered in conjunction with the naturally occurring levels. 95th percentile consumers would only have an additional increase of 3.5 mg/day. It is concluded that there would be no toxicological concerns if permission were granted for approval of octanoic acid as a processing aid in the Code.

- The exposure to HEDP residues for the mean and highest consumer was well below the level of toxicity observed in animals and the level at which therapeutic doses of HEDP is used in humans. Even in the absolute worst-case scenario, the margin of exposure for the highest consumers of HEDP (2-6 year olds) and the level of HEDP used therapeutically was 331. Significantly higher margins of exposure occur when the dietary exposure is compared to levels of adverse effects in animals for mean and high-level consumers.

5.5 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.

The United States Food and Drug Administration (USFDA) has approved the use of Inspexx 100 (poultry) and Inspexx 200 (meat) as antimicrobial agents (containing mixtures of hydrogen peroxide, acetic acid, octanoic acid, POAA, POOA and HEDP) provided that the concentration of peroxyacetic acid (POAA) does not exceed 220 mg/kg as peroxyacetic acid, and that maximum concentrations of hydrogen peroxide of 75 mg/kg (beef) and 110 ppm (poultry) and HEDP (13 mg/kg) are not exceeded (21 CFR 173.370).

The USFDA also approves the use of the following maximum concentrations of chemicals when used in washing or to assist in the peeling of fruit and vegetables:

- HP-not to exceed 59 ppm in the wash water (21 CFR 173.315);
- POAA-not to exceed 80 ppm POAA in the wash water (21 CFR 173.315);
- HEDP-not to exceed 4.8 ppm in the wash water (21 CFR 173.315).

No limits have been established for octanoic acid or acetic acid when used as secondary food additives (21 CFR 173.370).

5.6 Specifications for octanoic acid and HEDP

Standard 1.3.4 – Identity and Purity lists the Food Chemical Codex (FCC) as a primary source and the US Code of Federal Regulations (CFR) as a secondary source of specifications. As octanoic acid is included in the FCC and HEDP is listed within the CFR, there are already suitable references to specifications within the Code.

JECFA recently proposed new specifications for HEDP and octanoic acid and refer to Food and Nutrition Paper 52 Addendum 12 (2004). The JECFA Compendium of Food Additive Specifications is also a primary source of specifications within Standard 1.3.4. A consequential amendment to Standard 1.3.4 will therefore be required at Final Assessment to include Addenda 1 to 12 of the JECFA specifications, thereby providing the updated reference to the latest revision of specifications.

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. Do not approve the use of octanoic acid and HEDP as processing aids.

Option 2. Approve the use of octanoic acid and HEDP as processing aids.

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.

7.2 Data Collection

The Applicant supplied marketing data to support the approval and need for the use of octanoic acid formulations in the meat, fruit and vegetable and poultry industry.

7.2.1 Meat

The Applicant detailed that the most immediate need for approval was in relation to an intervention step for *E. coli* O157:H7 on meat as an Overseas Market Access Requirement (OMAR) for Bobby Calf meat to the USA. The Applicant claimed that the New Zealand Food Safety Authority (NZFSA) as the agency responsible for all meat, fish and game export facilities has enforced this market access requirement. This is a substantial market for NZ with >1.4 million calves processed for exports/annum giving returns of >$70 million p.a. to the NZ meat industry.

In the event of the USA expanding its requirements for all NZ beef exports, for the North American market there may be a flow on effect to the Australian export beef market (currently valued at $1.6 million).

Therefore, there would be substantial advantages in maintaining or increasing these export opportunities for Australia and New Zealand.

7.2.2 Fresh fruit and vegetable processing

The Applicant has highlighted a specific need for effective control of food pathogens being present on fruit and vegetables marketed to consumers and in order to reduce losses during cold storage and transport from microbial rots and spoilage.

The Applicant supplied data, which estimated losses incurred for fruit and vegetables (via rotting, and molds) for New Zealand (2002) and Australia (2001) at 10% for export crops. It was estimated that an effective intervention treatment could reduce losses by at least 40%, the value of which would be worth in excess of NZ $45 million/annum and AUS $25/annum to the respective horticultural industries.

7.2.3 Poultry

The Applicant did not supply any specific quantitative data as above, but instead indicated that effective water treatment is absolutely critical to minimise or eliminate cross contamination between carcasses from pathogenic bacteria such as *E. coli*, *L. monocytogenes*, *Salmonella typhimurium* and *Campylobacter Jejuni*. The formulation applied to poultry would also ensure that odour, slime and biofilms are controlled and shelf life of the treated poultry is maximised.

Benefits to the consumer

The Applicant has suggested that approval of octanoic acid will provide the following benefits:

- More effective control of incidental pathogens on fresh fruit and vegetables leading to safer food;
- More reliable process control compared to other alternative treatments (e.g. chlorine);
- Specific control of the human pathogen, E. coli O157:H7 on beef; and
- Control of spoilage fungi on chilled fruit and vegetables.

7.3 Impact Analysis

7.3.1 Option 1 – Do not approve the use of octanoic acid and HEDP as processing aids.

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefits	Although there is no perceived cost for the government, failure to approve octanoic acid formulations 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 octanoic acid as a processing aid to function as an antimicrobial treatment on poultry, meat, and fruit and vegetables.
Consumers	No perceived benefits	Consumers may not have foods that could be treated with the processing aid to improve shelf-life and safety.

7.3.2 Option 2 – Approve the use of octanoic and HEDP as processing aids

AFFECTED PARTY	BENEFITS	COSTS
Government	No perceived benefit.	No perceived cost other than the cost of amending the Code.
Industry	Permitting the use of octanoic acid as an antimicrobial agent would provide food manufacturers with a processing aid that can function on meat, poultry, and fruits and vegetables. It may also facilitate export markets for Australian and New Zealand companies	No perceived costs. Industry has the choice of whether to use the processing aid in the production of food.
Consumers	Permitting the use of octanoic acid may be of benefit to consumers who will 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 permission to use octanoic acid and HEDP as processing aids 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 octanoic acid and HEDP as processing aids 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.

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

8. Consultation

FSANZ conducted an Initial Assessment on A513 and public comments on the application were called for from the period 17 December 2003 to 16 February 2004. The Initial Assessment Report sought submissions from the general community on a range of issues concerning the safety, efficacy and regulation of octanoic acid formulations

FSANZ sought public comment to assist with assessment of the application on the following:

- scientific aspects of the application, in particular, any information relevant to the safety assessment;
- parties that might be affected by having this application approved or rejected; and
- potential costs and benefits to consumers, industry and government.

A total of 5 submissions were received and are summarised in **Attachment 6.** These submissions have been addressed under the issues identified as most important in the Draft Assessment Report. Overall there was general support for approval of octanoic acid subject to a safety assessment and determination of a specific technological need by FSANZ.

All individuals, groups or organisations who made a submission in relation to this application were included on a mailing list to receive further FSANZ documents pertaining to this Application.

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.

There are not any relevant international standards, namely a Codex standard for octanoic acid, although the USFDA regulate octanoic acid containing formulations. Amending the Code to allow octanoic acid may have a liberalising effect on international trade via removal of the prohibition on the sale of food following use of octanoic acid formulations. However, at this stage of the assessment this does not appear to warrant notification to the WTO as either a TBT or SPS issue.

9. Conclusion and Recommendation

The conclusions from the Draft Assessment are as follows:

- Based on the hazard assessment and dietary exposure analysis, there are no public health and safety concerns associated with consumption of residues of octanoic acid, HEDP or other constituents of the formulations.

- Based on the efficacy studies on octanoic acid and the food technology report conclusions, there is a recognised technological need and the formulations are efficacious in reducing levels of specific pathogens on meat, poultry and fruit and vegetables.

- The Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of octanoic acid and HEDP as processing aids, the benefits of the proposed amendment outweigh the costs.

- There are no alternatives that are more cost-effective than a food regulatory measure, that can address what this Application seeks, given the requirement for pre-approval of processing aids under Standard 1.3.3.

- Matters raised in submissions are addressed by the reasons above.

- Accordingly, approval of octanoic acid and HEDP as processing aids would be consistent with the section 10 objectives of the FSANZ Act because:

    - it will not adversely affect public health and safety;

- it is based on risk analysis, using the best available scientific evidence;
- it will promote an efficient and internationally competitive food industry; and
- the other Section 10 matters will not be prejudiced by this approval.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Efficacy studies on octanoic acid formulations
3. Food Technology Report
4. Safety Assessment report
5. Dietary Exposure Assessment report
6. Summary of Public Submissions

Attachment 1

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

To commence: on gazettal

Standard 1.3.3 *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 14 –

1-Hydroxyethylidene-1,1-diphosphonic acid	Metal sequestrant for poultry, beef, fruit and vegetables	GMP
Octanoic acid	Anti-microbial agent for poultry, beef, fruit and vegetables	GMP

[2] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by omitting subclause 3(i), substituting –*

Code of Federal Regulations of the United States of America, 1 April, 2004; or

Attachment 2

Assessment of Efficacy Studies on KX6110, KX6145 and KX6111 - Microbiology Report

Introduction

The purpose of this assessment was to determine if the study reports supplied by the Applicant provide convincing evidence that the products (i.e. the three formulations using octanoic acid – KX6110 (INSPEXX 200), KX6145 (INSPEXX 100) and KX6111 (TSUNAMI 200) reduce microbial numbers on the surface of freshly killed carcasses and fresh fruits and vegetables as claimed.

Efficacy studies designed to detect a reduction of microbial loads on the intended surface, including, the ability to reduce specific meat and poultry pathogens were provided for 1) KX6110 used on red meat carcasses, 2) KX6145 used on poultry carcasses, and 3) KX6111 used on fruits and vegetables. They were evaluated for appropriateness of experimental design and data analysis, including, but not limited to, materials and methods (standardised), controls, statistical methods used to analyse data and raw data sufficient for an independent evaluation.

Overview of Efficacy Studies

All studies were conducted following the Principles of Good Laboratory Practice and utilised standardised methods or, if a standardised method was not available, a method developed by Ecolab, Inc. Chemical characterisation was performed on test substances to determine hydrogen peroxide and peracid content. Log transformation of microbial cell counts (cfu/ml) was used to calculate the log reduction response. Sufficient raw data was included to permit independent analysis of the study results. [However, independent analysis was not performed.] The isolates of *Salmonella typhimurium*, *Escherichia coli* 0157:H7, and *Listeria monocytogenes* used in the pathogen studies were chosen because of their association with food borne illness. Fourteen key reference articles representative of the literature review on carcass decontamination were provided.

Efficacy of KX6110 on red meat carcasses: in-plant trial and pathogen study

The objective of the in-plant trial (conducted at an Excel Corporation facility in Nebraska) was to determine the efficacy of KX6110 as an antimicrobial spray treatment in reducing bacterial contamination on red meat surfaces. Three separate tests were conducted in which 10, 30, and 128 carcasses were sampled for microbial analysis at three carcass sites referred to as before, after and final samples (that is, immediately before the pre-evisceration spray cabinet, following the pre-evisceration spray cabinet (immediate effect) and immediately after final inspection (extended effect)). Microbial evaluation included total aerobic bacteria, coliform bacteria and *Escherichia coli* counts using serial dilution. For comparison, historical data on the application of lactic acid was included. The data showed that total plate count values for KX6110 were reduced by an average of 0.43 $\log_{10}$.

For all 4 sets of data (Before, After, Final and Historical Lactic acid) a significant improvement ($p<0.05$, t-test) in the total aerobic log reduction count was detected in the After and Final sample sets. *Escherichia coli* contamination was reduced by a statistically significant ($p\sim0.058$, one-sided sign test) amount after the application of KX6110.

The objective of the pathogen study was to demonstrate that KX6110 is an effective antimicrobial red meat surface spray treatment against *Salmonella typhimurium* ATCC 13311, *Listeria monocytogenes* ATCC 19115 and *Escherichia coli* O157:H7 EO139 isolated from venison jerky. Samples were serially diluted and plated in quadruplicate on media designed to facilitate recovery of injured cells. To demonstrate that the spray application was not just washing the bacteria off the meat, a water control was compared to KX6110. The results showed a 1.22 $\log_{10}$ reduction for *Salmonella,* a 1.62 $\log_{10}$ reduction for *Listeria monocytogenes* and a 1.48 $\log_{10}$ reduction for *Escherichia coli*. KX6110 showed greater log reductions than those achieved using distilled water for each of the bacteria, namely, 0.32, 0.40, and 0.70, respectively.

Efficacy of KX6145 on poultry carcasses: bacteria reduction study conducted under processing plant conditions, pathogen study, and pathogen cross-contamination study

The objective of the bacteria reduction study was to determine if adding KX6145 to water use for spraying or immersing poultry carcasses provided an improved reduction of total aerobic bacteria, coliform bacteria and *Escherichia coli* on poultry carcasses. Improvement was assessed by statistical comparison to a tap water treatment control. Data was collected for two test sets for each of 4 treatments for KX6145 and water: sprayed and submersion chilled, submersion chilled, sprayed, and no treatment. The log reduction values for each group are listed in **Table 1**. A statistical analysis commensurate with a split-plot design was carried out on the summary data. Significant differences were detected between KX6145 and water for the total aerobic and *Escherichia coli* counts with KX6145 yielding a significantly larger reduction than water. No significant difference between the coliform counts for KX6145 and water was detected.

Table 1. Summary data of KX6145 and water treatment on chicken carcasses

Test	*Average Log Reduction** Aerobic Plate Count		*Average Log Reduction** Escherichia coli *Count*		*Average Log Reduction** *Coliform Count*	
	Water	**KX6145**	**Water**	**KX6145**	**Water**	**KX6145**
Spray	0.38	0.62	0.46	0.84	0.33	0.64
Submersion chilled	0.53	1.21	0.56	1.37	0.60	1.27
Spray and submersion chilled	0.84	1.33	0.85	1.44	0.78	1.31

*Log reduction was calculated by subtracting average log cfu/ml of treated carcasses from untreated carcasses of the same test set.

The objective of the pathogen study was to determine if a spray application of KX6145 provides a statistically significant reduction in levels of *Salmonella typhimurium* ATCC 13311, *Listeria monocytogenes* (Petit Scott A) ATCC 49594 and *Escherichia coli* O157:H7 ATCC 43895 on poultry carcasses or carcass parts. Chicken skin squares were inoculated then sprayed with either a KX6145 solution or water. After treatment bacterial counts were performed on the skin squares. A one-sided, two-sample t-test on the log transformed data of 5 replicates detected a statistically significant ($p< 0.50$) reduction in each of the bacteria over the application of tap water.

The objective of the pathogen cross-contamination study was to determine if a submersion application of KX6145 provides a significant reduction in cross-contamination of *Salmonella typhimurium* ATCC 13311, *Listeria monocytogenes* (Petit Scott A) ATCC 49594 and *Escherichia coli* O157:H7 ATCC 43895 on poultry carcasses, carcass parts and organs. Inoculated and uninoculated test surfaces (chicken wings or livers) were placed in either a KX6145 or water only solution. After a 60-minute exposure bacterial counts were performed on the uninoculated test surfaces. A one-sided, two-sample t-test on the log transformed data of 5 replicates detected a statistically significant ($p< 0.05$) reduction for each of the bacterial strains in the KX6145 submersion treatment over the tap water treatment.

Efficacy of KX6111 on fruits and vegetables: 3 field studies

Field Test Vegetables

The antimicrobial efficacy of KX6111 (Tsunami 200) on vegetables was compared to that of Tsunami 100 (a formulation without octanoic acid). The points of comparison were microbial counts on unwashed vegetables (celery, potatoes, cabbage), on wash water and on vegetables after exposure to the treatment. Total aerobic bacteria, coliform bacteria, and yeast and mould plate counts were obtained. The results show that KX6111 reduced a greater number of organisms on the surface of cut celery, potatoes and cabbage than Tsunami 100. The most significant differences were observed in yeast and mould counts, primarily in the wash water. It was noted that the principle reason for using antimicrobial agents in vegetable processing water is to prevent water from becoming a vector of cross-contamination.

Field Test Blueberries

The objectives of this field test were to determine how effectively three concentrations of KX6111 reduced microorganisms in blueberry wash water and on blueberries and to compare KX6111 results to results obtained from an existing chlorine rinse. The points of comparison were microbial counts on unwashed blueberries, in wash water and on blueberries after exposure to the treatment. Total aerobic bacteria, coliform bacteria, and yeast and mould plate counts were obtained. The results showed that KX6111 reduced microorganisms in blueberry wash water and on blueberries and in all instances performed better than the chlorine rinse. The log increase in performance ranged from 1.1 to > 2 in the wash water and from 0.25 to >2 on the blueberry surface.

Field Test Strawberries

This field test was designed to determine how effectively a spray rinse of KX6111 reduced microorganisms on strawberries and to compare KX6111 results to those obtained by using Tsunami 100 and sodium hypochlorite spray rinses. The points of comparison were microbial counts on unwashed strawberries and on strawberries after exposure to the treatment. Total aerobic bacteria, coliform bacteria, and yeast and mould plate counts were obtained. All the treatments reduced the number of microorganisms on strawberries. Rinsing with KX6111 provided the largest reduction (in excess of 1 log).

Conclusion

The experimental design and data analysis in the reports provided were found to be appropriate for determining the effect of the octanoic acid formulations on reducing microbial loads when used as recommended. Specific pathogen studies for KX6110 and KX6145 were performed to verify product effectiveness against *Salmonella typhimurium*, *Listeria monocytogenes* and *Escherichia coli* O157 strains recovered from food poisoning outbreaks.

The data show that KX6110 and KX6145 are statistically significantly better than water in reducing microbial numbers on red meat and poultry, respectively. KX6110 was shown to be at least as effective as lactic acid treatment. In addition, specific pathogen studies showed KX6110 and KX6145 were statistically significantly more effective than water in reducing the levels of *Salmonella typhimurium*, *Listeria monocytogenes*, and *Escherichia coli* on red meat and poultry surfaces, respectively. KX6111 was shown to be more effective in reducing microbial numbers on the surface of fruits and vegetables than relevant alternative treatments (chlorine and Tsunami 110) when compared directly to them.

In summary, the study results show that each of the three formulations is effective in reducing the number of microorganisms on the surfaces of red meat, poultry, and fruits and vegetables as intended.

Attachment 3

Food Technology Report

Introduction

Ecolab Pty Ltd (Australia & New Zealand) submitted an application on 13 October 2003 to Food Standards Australia New Zealand (FSANZ) to amend Standard 1.3.3 – Processing Aids, of the Code to include octanoic acid as a processing aid.

The Applicant proposed that a mixture that includes octanoic acid in three different products (formulations) will be added to processed water used during the washing of red meat carcasses, poultry carcasses and fruit and vegetables produce in order to significantly decrease human pathogens including *Salmonella typhimurium, Listeria monocytogenes and Escherichia coli* 0157:H7.

The formulations, namely, KX 6110 (Inspexx 100), KX 6145 (Inspexx 200) and KX 6111 (Tsunami 200) consist of mixtures of hydrogen peroxide, acetic acid, octanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP). Peroxyacetic acid (POAA) and peroxyoctanoic acid (POOA) are formed by combination of hydrogen peroxide with acetic acid and octanoic acid respectively.

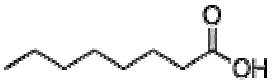
The Code currently permits:

- hydrogen peroxide, in the table to 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, 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); and
- peracetic acid, in the table to clause 12 of Standard 1.3.3 as a permitted bleaching, washing and peeling agent for all foods at levels determined by GMP.

There is currently no approval for the use as processing aids of octanoic acid or 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) in the Code.

Octanoic Acid

Octanoic acid (or caprylic acid) occurs naturally in many foods. Octanoic acid is a short chain fatty acid, with eight carbon atoms as indicated in the diagram below.



Chemical Structure of Octanoic Acid

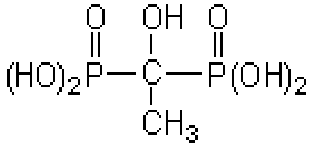
(Source: **Flavornet** by Terry Acree & Heinrich Arn, http://www.flavornet.org)

OCTANOIC ACID (Caprylic Acid)	
ISN Number	184.1025
Synonyms	Caprylic acid, n-Octanoic acid, (Merck)
Structure	$CH_3 (CH_2)_6 COOH$ (Merck)
Formula Weight	144.21 (Merck)
Description	A colourless oily liquid having a slight unpleasant rancid taste (Merck)
Boiling Point	239.7 ° C (Merck)
Specific Gravity g/cm^3	0.910 (Merck)
Acid Value	366-396 (Merck)
Stability	Normally stable (Cheminfo)
Hazardous Polymerization	Does not occur (Cheminfo)
Preparation	Commercially prepared by oxidation of n-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil or palm kernel oil (GrokFood)
Other uses	Flavouring and Defoaming agent

* The Food Chemicals Codex (FCC), 4th Edition contains a specification for octanoic acid.

1-Hydroxyethylidene-1,1-Diphosphonic Acid (HEDP)

HEDP is used in the Applicant's formulations as a chelating agent to prevent any metal ions present from catalyzing unwanted reactions. HEDP has a chemical structure as indicated in the diagram below:



Chemical Structure of HEDP
(www.kelien.com/products/HEDP_2809-21-4.htm)

1-Hydroxyethylidene-1, 1-Diphosphonic Acid (HEDP)	
CAS Reg No.	2809-21-4
Other Names	Etidronic Acid (Kelien)
Appearance	Clear, colourless up to yellowish solution (Kelien)
Molecular Weight	206 (Kelien)
Specific Gravity g/cm^3	1.44 (Kelien)
Major Functions	Sequestriant, dispersive, hydrolytic stabiliser, corrosion control, chlorine stabiliser
pH 1% Solids Solution	< 2 (Monsanto)
Iron	< 35 ppm (Monsanto)

Sequestration or chelation is the process of forming coordination complexes of an ion in solution. Sequestration often involves the formation of chelate complexes and is used to prevent the chemical effect of an ion without removing it from solution (Oxford Dictionary of Chemistry, 4th edition).

HEDP is a phosphonic molecule. It has excellent thermal and hydrolytic properties. It can slow the rate of oxidation or decomposition because of its metal chelating activity. Metal ion sequestering agents such as HEDP are added to products containing peroxy acids in order to eliminate undesirable decomposition reactions including those involving metals which catalyse the reduction of hydrogen peroxide, peroxyacetic acid and peroxyoctanoic acid. It is a very stable chemical and does not decompose readily on contact with meat surfaces.

Specifications

Standard 1.3.4 – Identity and Purity lists the Food Chemical Codex (FCC) as a primary source and the US Code of Federal Regulations (CFR) as a secondary source of specifications. As octanoic acid is included in the FCC and HEDP is listed within the CFR, there are already suitable references to specifications within the Food Standards Code.

The joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) recently proposed new specifications for HEDP and octanoic acid and refer to Food and Nutrition Paper 52 Addendum 12 (2004). The JECFA Compendium of Food Additive Specifications is also a primary source of specifications within Standard 1.3.4. A consequential amendment to Standard 1.3.4 will therefore be required to include addenda 1 to 12 of the JECFA specifications, thereby providing the updated reference to the latest revision of specifications.

FDA Approval for Octanoic Acid and HEDP

The USFDA has given approval in the FDA Code of Federal Regulations Title 21 CFR section 173.370 (Revised as of April 1, 2003) – Peroxyacids, in response to a petition from Ecolab as follows:

Peroxyacids may be safely used in accordance with the following prescribed conditions:

a) The additive is a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid.

b) (1) The additive is used as an antimicrobial agent on red meat carcasses, parts, trim, and organs in accordance with current industry practice where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, and the maximum concentration of hydrogen peroxide is 75 ppm.
(2) The additive is used as an antimicrobial agent on poultry carcasses, poultry parts, and organs in accordance with current industry standards of good manufacturing practice (unless precluded by the U.S. Department of Agriculture's standards of identity in 9 CFR part 381, subpart P) where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, the maximum concentration of hydrogen peroxide is 110 ppm, and the maximum concentration of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is 13 ppm.

Also under 21 CFR section 173.315(5)(a) Chemicals used in washing or to assist in the peeling of fruits and vegetables, HEDP may be used with peroxyacetic acid at a level not to exceed 4.8 ppm in the washing water.

Technological Purpose for Addition of Octanoic Acid

Extensive contamination, or abusive conditions that allow bacteria to reproduce, increase risk for presence of pathogenic bacteria and formation of toxins in food (Sofos et al., 1999). Beef tissue, which is initially sterile, becomes contaminated upon slaughter with bacterial pathogens via transmission of organisms from the exterior of the live animal, and/or from the processing environment to the carcass surface. Similarly, poultry carcasses and vegetable produce can carry pathogenic organisms from the gut or soil or can be contaminated during processing. One way of minimizing this is the use of chemical sanitisers on freshly slaughtered animals or produce e.g., acetic acid and sodium chlorite.

The peracetic and peroctanoic components of the formulation are produced by the reaction of acetic acid and octanoic acid with hydrogen peroxide. The primary mode of action is oxidation. The peroxy acids disinfect by oxidation of the outer cell membrane of vegetative bacterial cells, endospores, yeast and mould spores. The mechanism of oxidation is the transfer of electrons, therefore the stronger the oxidizer, the faster the electrons are transferred to the microorganism and the faster the microorganism is inactivated or killed. This action disrupts cell membrane permeability and will penetrate bacterial cell walls to disrupt protein synthesis. A secondary effect is the acidification of the carcass surface which further inhibits bacteria.

The addition of the octanoic acid is synergistic with peracetic acid in microbial reduction by reducing the surface tension of carcass application. For example, a solution of peracetic acid and octanoic acid at 63 ppm reduces *Listeria monocytogenes* on meat surfaces by more than 5 logs in 30 seconds while POAA alone at 116 ppm requires 2 minutes to achieve the same reduction (Morris, 1999).

Cords (1993) described an improved peroxidated acid sanitiser containing octanoic acid. The octanoic acid equilibrated with its peroxidated form, results in increased effectiveness. Its enhanced effectiveness is thought to be due to the membrane altering capability of the peroctanoic acid associated with its hydrophobic character.

Processing Applications

Microbial decontamination technologies include animal cleaning, chemical dehairing at slaughter, spot cleaning of carcasses by knife trimming or steam, and rinsing carcasses with water, chemical solutions and/or steam.

Most commercial meat packing plants apply chemical sanitisers via spray rinsing cabinets through which carcasses pass. The Applicant proposes that the relevant formula will be sprayed onto meat and produce as a processing step.

Intended Applications–

The following information is taken from product labels used and approved in the USA.

KX 6110 or Inspexx 100 –For Poultry Carcasses - Mix with water to achieve no more than 200 ppm of peroxy acid (as peroxyacetic acid) or 1.49 ml per 1 litre of water. Application can be by spray, wash, dip or use in other poultry processing water.

KX 6145 or Inspexx 200 – Red Meat Carcasses. Dilute product 1.3-5.2 L/1000L of water to give 50-200 ppm of peroxyacetic acid. Application can be sprayed under pressure and or using preheated water up to 50°C.

KX 6111 or Tsunami on Processed Fruit & Vegetables surfaces. Mix with water to achieve no more than 40 ppm residual peroxy acetic acid in solution of 31.1 ml Tsunami 200 to 100 litres of water. A contact time of 60 seconds is recommend, for use on fruit and vegetables that have been processed by peeling, cutting, chopped, milled, frozen or cooked, etc.

Formula Comparison of the Inspexx Products

Component	**% KX-6145**	**% KX-6110**
Hydrogen Peroxide	6.2	4.5
Acetic Acid	40.6	48.0
Peroxyacetic Acid	12	14
Octanoic Acid	3.2	8.8
Peroxyoctanoic Acid	.8	1.4
HEDP	.6	.6
Water	36.6	22.7

NB. No data for the formula of KX 6111 (Tsunami 200) was provided in the Application.

Possible Environmental Issues

The Applicant claims that in comparison to other sanitizers used in the food industry, this formula may be more compatible than the use of halogen based sanitizers and disinfectants such as chlorine, iodine–phosphorous and quaternary ammonium products. Chlorination can cause serious damage to marine life and form chlorinated hydrocarbons with carcinogenic properties (Arturo-Schaan et al., 1996). Quaternary ammonium products have the longest residual activity of all chemical sanitizers (Block, 1991).

Future chemical interventions include sanitizing solutions such as peroxyacetic acid and octanoic acid, both effective over a broad pH range and less affected by organic matter than other sanitizers. Unlike chlorine, which leaves residual by-products in the water, peroxyacetic acid (POAA) decomposes to water, oxygen and acetic acid (Morris, 1999).
A report by the US Food Safety and Inspection Service (FSIS) found that sanitizers that have proven most effective against *Listeria monocytogenes* are quaternary ammonia compounds, chlorine solutions and newer products containing peracetic acid. Rotating sanitizers periodically is generally a good practice as it will provide more effectiveness against bacteria. Alternating between alkaline-based detergents and acid-based detergents daily also helps to avoid hard-water buildups and biofilms. Alternating detergents also helps change the pH regularly to prevent adaptation of bacteria to a particular environment. Care must be taken not to use chlorine and acid-based detergents simultaneously due to potential occupational health and safety hazards to employees (USDA FSIS, 2001).

Conclusion

The use of octanoic acid as a processing aid in the formulations described in the Application, is technologically justified. These formulations represent possible alternative treatments that may be used in decontamination systems. The use of HEDP as a processing aid (chelating agent) within sanitizing formulations is technologically justified.

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Attachment 4

Safety Assessment Report

Octanoic acid is the key active component in three chemical product formulations applied to raw foods (beef, poultry and fruit and vegetables) to reduce microbiological contamination. The three formulations: KX 6110 (Inspexx 100), KX 6145 (Inspexx 200) and KX 6111 (Tsunami 200) consist of varying concentrations of hydrogen peroxide (HP), acetic acid, octanoic acid, peroxyacetic acid (POAA), peroxyoctanoic acid (POOA) and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

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$\leftrightarrow$Peroxyacetic acid +H_20;

- Octanoic Acid+ Hydrogen Peroxide$\leftrightarrow$Peroxyoctanoic acid +H_20

KX 6110 (Inspexx 100) is to be used in water to spray on poultry carcasses at 180-220 ppm total peroxyacids; KX 6145 (Inspexx 200) to be used on processed water to spray on beef carcasses at 180-220 ppm peroxyacids; and KX 6111 is used in water for washing fruits and vegetables at 40 ppm total peroxyacids.

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.

The USFDA has approved the use of Inspexx 100 (poultry) and Inspexx 200 (meat) as antimicrobial agents (containing mixtures of hydrogen peroxide, acetic acid, octanoic acid, POAA, POOA and HEDP) provided that the concentration of peroxyacetic acid (POAA) does not exceed 220 mg/kg as peroxyacetic acid, and that maximum concentrations of hydrogen peroxide of 75 mg/kg (beef) and 110 ppm (poultry) and HEDP (13 mg/kg) are not exceeded (21 CFR 173.370).

The USFDA also approves the use of the following maximum concentrations of chemicals when used in washing or to assist in the lye peeling of fruit and vegetables:

- HP-not to exceed 59 ppm in the wash water (21 CFR 173.315);
- POAA-not to exceed 80 ppm POAA in the wash water (21 CFR 173.315);
- HEDP-not to exceed 4.8 ppm in the wash water (21 CFR 173.315).

No limits have been established by the USFDA for octanoic acid or acetic acid when used as secondary food additives (21 CFR 173.370).

Information and data supplied by the Applicant

The Applicant supplied data on likely residues of the individual components of the three formulations, in poultry, beef and fruit and vegetables. The Applicant has presented some data to support their statements that minimal residues of acetic acid, octanoic acid and HEDP will remain on treated food and that the other ingredients rapidly degrade and residues are not detectable.

Acetic acid was previously evaluated by the Joint Expert Committee on Food Additives (JECFA) and was found to present no safety concerns as a flavouring agent (WHO, 1999).

Octanoic acid (a naturally occurring medium chain fatty acid in food) was also reviewed as a flavouring agent by JECFA (WHO, 1999). JECFA did not specify an ADI as octanoic acid was considered to raise no toxicological concerns as a flavouring agent at dietary intakes levels of 650μg/day for the US and 3, 800μg/day for Europe. JECFA also commented that octanoic acid could be predicted to undergo complete metabolism to endogenous products via the fatty acid tricarboxylic pathways in humans.

The Applicant supplied dietary intake data on the following:

- estimates of octanoic acid levels that occur naturally in foods (milk, meat, fats and oils);
- estimates of octanoic acid levels from use as a flavouring;
- estimates of use from the use of octanoic acid as an antimicrobial treatment.

The Applicant concluded from this data that the intended use of octanoic acid as an antimicrobial agent would result in a negligible increase in octanoic acid consumption as compared to naturally occurring sources.

HEDP was evaluated by the USFDA and the Applicant has provided FSANZ with data on likely residues and key toxicological studies.

HP, POAA, POOA were described as ingredients that break down immediately upon application to ordinary and naturally occurring substances such as acetic acid, octanoic acid, water and oxygen. The Applicant supplied data on likely residues in poultry, meat and fruit and vegetables and concluded that due to no residues of these components likely in the final foods, a formal toxicological assessment was not undertaken.

Joint Expert Committee's recent review of peroxyacid antimicrobial mixtures

JECFA at its 63rd meeting in June 2004 considered the safety of antimicrobial solutions that were prepared from acetic acid and octanoic acid, singly or in combination together with hydrogen peroxide and HEDP as a stabilizer. The safety of these solutions was assessed on a component-by-component basis, considering the potential residue of each component or its breakdown products in food as consumed.

The Committee concluded that the peroxide compounds in these solutions (HP, POAA and POOA) would break down to acetic and octanoic acid and that consistent with what is known about the chemistry of peroxides, no residues of HP, POAA or POOA are expected on foods that are treated with these mixtures. Therefore, these components would not pose a safety concern.

Therefore, the Committee focused its evaluation on the residues of HEDP that were expected to remain on foods. The Committee compared the highest dietary exposure to HEDP (0.004 mg/kg bw/day) to the starting oral dose used to treat Paget's disease[3] (5 mg/kg bw/day) in humans and noted that the margin of exposure was >1000. Based on this margin of exposure, the conservative nature of the dietary exposure to HEDP, and the available toxicity data, JECFA concluded that HEDP did not pose a safety concern.

FSANZ assessment

FSANZ also approached the safety assessment of octanoic acid containing formulations on a component-by-component basis.

Due to present permissions in the Code for hydrogen peroxide, acetic acid and peroxyacetic acid (by virtue of permissions for peracetic acid in Standard 1.3.3) FSANZ did not need to undertake a safety assessment on those components of the formulations. However, in light of residue data on POAA, POOA and HP being submitted by the Applicant, FSANZ examined this data to ensure that they would meet the maximum limits prescribed in the Code.

FSANZ also evaluated residues of the other components namely, octanoic acid and HEDP in the formulations to determine whether there were any public health and safety concerns, following use on poultry, beef and fruit and vegetables.

1. Resulting residues of POAA, POOA and HP in poultry and beef and their toxicological significance

Hilgren J. Concentrations of total peroxyacid (as peroxyacetic acid) and hydrogen peroxide on poultry carcasses after treatment with KX-6145. Ecolab Research Centre, USA, November 20, 2000.

Richardson Ed. Residual of peracetic acid, peroxyoctanoic acid and hydrogen peroxide associated with KX-6110 on beef samples. Ecolab Research Centre, USA, April 13, 2000.

The Applicant provided residue data on POAA and POOA (combined residue analysis) and HP in two formulations, KX 6145 (poultry) and KX6110 (beef). The Applicant indicated that current analytical techniques couldn't differentiate the residue for POAA and POOA, therefore a combined residue was reported. HP can be measured separately (**Table 1**).

[3] HEDP is used at oral starting doses of 5 mg/kg bw/day for not longer than 6 months to treat patients with Paget's disease

Results

Table 1

Commodity	HP (ppm)	POAA (ppm)
Poultry	<1 (2 minutes post-treatment)	<1 (2 minutes post-treatment)
Beef	<0.003 (10 minutes post-treatment)	<0.05 (10 minutes post-treatment)

KX-6145 solutions were prepared by diluting KX-6145 with tap water to achieve 200 ppm total peroxyacid (measured as POAA) and then applied to **poultry** as a 15 second spray at ambient temperature followed by a 60-minute submersion chill at $<4^0$C. The total POAA[4] and HP[5] were <1 ppm at 2 minutes post-treatment. The residues in poultry would be expected to be well below the limit of detection of both POAA and HP before consumption, as the above results are prior to further processing (e.g. storage or cooking) of the food.

KX -6110 solutions were applied at 200 ppm on treated **beef** under conditions simulating use in a meat processing plant. At the applied concentration of 200 ppm, POAA residues were <0.05 ppm and HP <0.003 ppm at 10 minutes post-treatment.

Conclusion

Residues of POAA (which incorporates a combined residue analysis of peroxyacetic acid and peroxyoctanoic acid) and HP in **poultry** were very low (<1 ppm) at 2-minutes post-treatment and would be expected to be below the LOD following further degradation during storage and cooking etc. Data on **beef** demonstrate that the residues were below the LOD 10-minutes post-treatment.

When HP, POAA and POOA further degrade the resulting products are water, oxygen, acetic acid and octanoic acid. It is concluded that due to the low residues of the above components in the formulations applied to poultry and beef, and the rapid decomposition to acetic acid, oxygen and water applied at a concentration of 200 ppm that there are no toxicological concerns. Residue data on octanoic acid is presented in Section 3 below.

2. Resulting residues of POAA, POOA and HP in fruit and vegetables and their toxicological significance

POAA, POOA and HP are very reactive and short-lived compounds by virtue of the instability of the peroxide bond and half-lives can be as short as a few minutes. The USEPA (1988) issued a final rule (40 CFR Part 180) that indicated that there were no toxicological concerns from peroxyacetic acid compounds when applied to food as an antimicrobial agent (e.g., fruits, tree nuts, cereal grains, herbs and spices) based on the rapid decomposition of these components into compounds that are also of no toxicological concern and that an exemption from a specific tolerance levels was provided up to 100 ppm on raw agricultural commodities. The USFDA considers that the toxicity of POOA is similar to that of POAA (USFDA 2001; Federal Register 65/228, 70660-70661).

[4] The Limit of Detection for POAA was cited in residue studies as 0.25 ppm.
[5] The Limit of Detection for HP was cited in residue studies as 0.003 ppm.

FSANZ asked the Applicant to supply specific data on the residue levels of POAA, POOA and HP in fruit and vegetables, in particular, that that residues of POAA, POOA) and HP are at or below the limit of detection (LOD) post further processing (e.g. following storage or cooking) for fruit and vegetables

The Applicant could not supply specific data that supported that residues were at or below the LOD post further processing. However, the Applicant supplied data submitted to the USFDA for registration on a similar product, OXY-151 (Tsunami 100) which is similar to Tsunami 200 with the exception that is contains no octanoic acid (data on octanoic acid is considered in Section 3 below).

Data on studies conducted on OXY-15 suggested that a significant decrease in both POAA and HP occurred over a 4-6 h period post-treatment when OXY-15 was used at a concentration of 200 ppm in water used to rinse tomatoes and green peas (**Table 2**). The authors of the study suggested that at 10-12 h post-treatment that no residues of POAA or HP would be present, although no specific data supported this assertion.

Residue data post-treatment was as follows:

Table 2

Commodity	**HP (ppm)**	**POAA (ppm)**
Ground peas	3.28 (6 h)	3.71
Tomatoes	9.18[6] (4 h)	2.49 (4 h)

Conclusion

For **fruit and vegetables**, although there was limited data on likely residues post-application supplied by the Applicant, FSANZ does not envisage a public health and safety risk from use on fruits and vegetables for the following reasons:

- the rapid decomposition of these compounds post-treatment;
- data on a related product which suggested that limited residues would be present 10-12 h post-treatment;
- the USEPA ruling in 1988 that indicated that there were no toxicological concerns from peroxyacetic acid compounds when applied to food as an antimicrobial agent;
- the conclusions from a recent evaluation by JECFA, indicated no safety concerns (WHO, 2004); and that
- the residues would also need to meet the current permissions for peracetic acid and HP in the Code.

3. Toxicological significance of residues of HEDP and octanoic acid in poultry, beef and fruit and vegetables following use of the above formulations

In order to ascertain whether resulting residues of HEDP and octanoic acid were of any toxicological significance following use on the proposed commodities, a toxicological report on both substances was prepared (**Appendix 1**).

[6] The maximum level in the Code permitted is 5 ppm

In addition, a dietary exposure assessment (**Attachment 5)** incorporating residue data supplied by the Applicant was prepared in order to calculate the potential exposure of Australian and New Zealand consumers to HEDP and octanoic acid following use of the formulations.

HEDP

The available data suggests that HEDP is of low acute toxicity and is not genotoxic. There have been no long-term studies conducted on HEDP, although there is no evidence from the overall toxicological database available that HEDP would be carcinogenic. The sub-chronic studies suggest that specific organs may be affected at high doses, namely the testes in dogs and liver in rats; however, a clear No-Observed-Effect-Level (NOEL) was established. Effects on some reproduction parameters were observed at high-doses; however, there was no gross teratogenic potential identified and a NOEL can be established from the rat and rabbit studies.

An overall summary (**Table 3 below**) has been prepared, where the dietary exposures for mean and 95th percentile consumers for Australian and New Zealand consumers (**Attachment 5**) were compared to the Lowest-Observed-Effect-Level (LOEL) at which an effect is produced in sub-chronic studies performed in dogs (250 mg/kg bw/day), rats (1500 mg/kg bw/day) or the therapeutic dose of HEDP used for treating Paget's disease in humans (5 mg/kg bw/day).

Table 3 Australian and NZ consumers (third row in italics)

Compared to LOEL of 250 mg/kg bw/day in dogs

Mean dietary exposure (mg/day)(mg/kg bw/day)	**Margin of exposure (Mean consumer)**	**95th percentile consumers (mg/day)(mg/kg bw/day)**	**Margin of exposure (95th percentile consumer)**
0.15 (2 years+) (0.0026 mg/kg bw/day)	96,000	0.35 (2 years +) (0.0067 mg/kg bw/day)	37,000
0.11 (2-6 years) (0.0063 mg/kg bw/day	40,000	0.28 (2-6 years) (0.0151 mg/kg bw/day)	16,000
0.15 (15 years+) (0.0021 mg/kg bw/day)	*96,000*	*0.33 (15 years+) (0.0045 mg/kg bw/day)*	*55,500*

Compared to LOEL of 1500 mg/kg bw/day in rats

Mean dietary exposure (mg/day)(mg/kg bw/day)	**Margin of exposure (Mean consumer)**	**95th percentile consumers (mg/day)(mg/kg bw/day)**	**Margin of exposure (95th percentile consumer)**
0.15 (2 years+) (0.0026 mg/kg bw/day)	577,000	0.35 (2 years +) (0.0067 mg/kg bw/day)	224,000
0.11 (2-6 years) (0.0063 mg/kg bw/day	238,000	0.28 (2-6 years) (0.0151 mg/kg bw/day)	99,000
0.15 (15 years+) (0.0021 mg/kg bw/day)	*714,000*	*0.33 (15 years+) (0.0045 mg/kg bw/day)*	*333,300*

Compared to therapeutic doses of HEDP in humans (5 mg/kg bw/day)

Mean dietary exposure (mg/day)(mg/kg bw/day)	**Margin of exposure (Mean consumer)**	**95th percentile consumers (mg/day)(mg/kg bw/day)**	**Margin of exposure (95th percentile consumer)**
0.15 (2 years+) (0.0026 mg/kg bw/day)	1923	0.35 (2 years +) (0.0067 mg/kg bw/day)	746
0.11 (2-6 years) (0.0063 mg/kg bw/day	793	0.28 (2-6 years) (0.0151 mg/kg bw/day)	331
0.15 (15 years+) (0.0021 mg/kg bw/day)	*2380*	*0.33 (15 years+) (0.0045 mg/kg bw/day)*	*1111*

When the dietary exposure for the highest consumers (2-6 year olds)[7] of food commodities, which may contain residues of HEDP, was compared to the lowest dose shown to cause adverse effects in animals and humans, the calculated margin of exposures were 16, 000; 99,000; or 331 fold compared to the LOEL in dogs, rats and humans respectively.

However, the mean consumption figure is more realistic for long-term exposure. If mean exposures for 2-6 years olds is compared to the LOEL, the calculated margin of exposures were 40, 000; 238,000; or 793 fold compared to the LOEL in dogs, rats and humans respectively.

[7] This is considered the worst-case scenario

In conclusion, the exposure to HEDP residues for the mean and highest consumer was well below the level of adverse effects observed in animals or the level at which therapeutic doses of HEDP is used to treat clinical conditions in humans. It is concluded that there would be no toxicological concerns if permission were granted for approval of HEDP as a processing aid in the Code.

Octanoic acid

The Joint Expert Committee on Food Additives (JECFA) previously evaluated octanoic acid as a flavouring agent (WHO, 1999) and concluded that there were no safety concerns when used in this way.

The available studies in animals reviewed by FSANZ, show that octanoic acid was not genotoxic and in a subchronic study in rats, the NOEL was 15,000 mg/kg bw/day, i.e., the highest dose tested.

For the population groups assessed, the estimated mean and 95th percentile consumer dietary exposures to octanoic acid do not change significantly between baseline (natural levels) and when the requested permissions for octanoic acid (and resulting residues) as a processing aid are considered together with naturally occurring levels. 95th percentile consumers would only have an additional increase of only 3.5 mg/day. It is concluded that there would be no toxicological concerns if permission were granted for approval of octanoic acid as a processing aid in the Code. The dietary exposure intake if permission were approved for use in formulations on beef, poultry and fruit and vegetables is insignificant in relation consumption of foods containing octanoic acid naturally (**Attachment 5**).

This conclusion is consistent with the recent JECFA (2004) evaluation on octanoic acid-containing formulations (WHO, 2004) in which they concluded that the estimated exposure to octanoic acid from use in antimicrobial solutions posed no safety concerns.

References

WHO (1999) Evaluation of certain food additives and contaminants. Forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, No. 884, p 30.

WHO (2004) Safety evaluation of peroxyacid antimicrobial mixtures. 63rd Joint FAO/WHO Expert Committee on Food Additives. 8-17 June 2004.

APPENDIX 1

Toxicological profile of HEDP

Summary

Several toxicological studies were conducted in rodents, dogs and rabbits and were independently reviewed by FSANZ. These studies appear to have been conducted in accordance with accepted protocols and standards for toxicological testing, although no specific reference to OECD guidelines or GLP was made.

Metabolism studies

Studies were performed in rats, rabbits, dogs and monkeys to determine the absorption, distribution, metabolism and excretion of disodium etidronate (HEDP). There was limited absorption following single or repeated oral doses of 50 mg/kg (<10% of total dose) in the rat, rabbit and monkey, with dogs absorbing the compound to the greatest extent (17-21%). There was no accumulation in any major organs, the carcass or soft tissues with the skeleton the target site for distribution of disodium etidronate (3-9% of total dose), which was reflected in the half-life of 12 days calculated in the skeleton of rats. An analysis of the urine from rats and urine, faeces, serum and bone from dogs did not reveal any metabolites. The major route of excretion was the faeces (>80%).

Acute studies

Acute toxicological testing in rats suggested that HEDP administered via the oral route was of low toxicity with LD_{50} values ranging between 1340 to 3130 mg/kg.

Sub-chronic studies

In a 13-week study conducted in dogs there was evidence of toxicity (decreased food consumption and testicular effects) at doses of 250 mg/kg bw/day. In a separate 13-week study in rats, decreased bodyweights, reduced haemoglobin and haematocrit values and increased liver weights were observed at doses of 1,500 mg/kg bw/day. The NOEL for dogs was 75 mg/kg bw/day and 500 mg/kg bw/day for rats.

Genotoxicity studies

HEDP was found to be negative in *in vitro* genotoxicity tests conducted in bacterial and mammalian cells.

Developmental and reproductive studies

There was some evidence of reproductive effects (reduced number of live pups and average number of implantations and corpora lutea formation) in rats at doses of 250 mg/kg bw/day with a NOEL of 50 mg/kg bw/day. No developmental effects were noted in rabbits up to the highest dose of 100 mg/kg bw/day.

Conclusions

The available data suggests that HEDP is of low acute toxicity and is not genotoxic. There have been no long-term studies conducted on HEDP, although there is no evidence from the overall toxicological database available that HEDP would be carcinogenic.

The sub-chronic studies suggest that specific organs may be affected at high doses, namely the testes in dogs and liver in rats; however, a clear NOEL was established. Effects on some reproduction parameters were observed; however, there was no gross teratogenic potential identified and a NOEL can be established from the rat and rabbit studies.

Absorption, distribution, metabolism and excretion studies

Michael WR, King WR and Wakim JM (1972) Metabolism of disodium ethane-1-hydroxy-1,1-diphosphonate (disodium etidronate) in the rat, rabbit, dog and monkey. *Toxicology and Applied Pharmacology*, **21**, 503-515.

Rats

Male Sprague-Dawley rats (3 weanling and 4 young adults) were administered radiolabeled disodium etidronate-^{14}C (radioactivity 4.5 mCi/g; purity >99%) by gavage at single doses of 50 mg/kg. Urine and faeces was collected for a period of 72 h post-dosing, and in addition, respiratory CO_2 was collected over the same period from the 4 adults. The excreta, carcass and various organs were assayed for radioactivity. In addition, 10 mg/day of disodium etidronate-^{14}C was administered by gavage to rats (exact number of rats used was not stated in the methods) for 5 days. 2 rats were sacrificed at 1, 3, 5, 7, 14, 21 and 28 days post-dose to determine the length of retention in the carcass and bone. A final study was performed where at least 3 adult rats were administered the compound at single doses between 0.5 to 1000 mg/kg.

Results

At 72h following single doses of compound, approximately 96% was recovered in the faeces and gastrointestinal contents of adults, and 88% in weanling rats suggesting a 4% absorption rate in adults and 12% in weanling rats. Repeat dose studies found that most of most of the radioactivity was detected in the faeces and gastrointestinal contents with the carcass retaining 1.2%, urine <1%, and organs <0.02% of the total dose administered. These values remained constant until the end of the study period (day 28 post-dose). Residual radioactivity remaining in the carcass at 72h post-dose and in the skeleton with the half-life in the skeleton of disodium etidronate-^{14}C calculated as 12 days. At the highest dose tested of 1000 mg/kg the carcass contained 5% and the urine 11% of the total dose, indicating increased absorption at very high doses of disodium etidronate.

No metabolites of disodium etidronate were detected and there was no enterohepatic circulation in the rat.

Rabbits

Three male NZ rabbits were administered single doses of disodium etidronate-^{14} C by gavage at 50 mg/kg. No other details were available in the methods.

At 72h post-dose total absorption was not appreciably different compared to the rat (approximately 4%) with limited distribution to the carcass (0.5%) or organs (<0.03%).

Dogs

Three purebred female beagles were administered single doses of disodium etidronate-^{14}C by gavage at 50 mg/kg. Radiolabelled ^{32}P was administered to 8 young dogs (4-6 months) and 4 older dogs (5-8 years) at single doses of 20 mg/kg to ascertain any differences in absorption rates between young and old dogs.

At 48 hours post-dose, all animals were killed and a gross autopsy performed. The gastrointestinal tract and its contents and selected organs (brain, heart, lungs, spleen, kidneys and liver), blood, urine, faeces, saliva, femur) were sampled to determine radioactivity.

Results

At 72 h post-dose approximately 83% of ^{14}C was recovered in the faeces of dogs, and gastro-intestinal contents suggesting an absorption rate of 17%. This absorption rate was similar in the ^{32}P studies in older dogs; however, for younger dogs the rate increased to 21%. Distribution of both Radiolabelled compounds was virtually identical, with the radioactivity found in the carcass (12% for ^{14}C ; <1% for ^{32}P) and skeleton (3-9%) post-dosing with limited distribution to any internal organs (<2%).

Monkeys

Two rhesus monkeys (1 male and 1 female) were administered single doses of disodium etidronate-^{14}C and Radiolabelled ^{32}P by gavage at 20 mg/kg. Blood was collected at 30 min, 1, 2, 4, 8, 24 and 48h post-dose, urine and faeces at 24 and 48h. One other male was administered single doses of disodium etidronate-^{14}C by gavage at 50 mg/kg and urine and faeces collected for 72h.

Absorption of disodium etidronate averaged approximately 6% with limited distribution to any organs (<0.5%), carcass (<1.7%) or skeleton (3.6%).

Acute toxicity

Rats

Younger FM (1965) Toxicological investigation of DEQUEST 2010. Monsanto Project Number Y-65-74. Younger Laboratories. 7 September 1065.

Groups of 3 male and female Sprague-Dawley rats received single doses (2,000 to 3980 mg/kg) of HEDP administered orally by gavage. No controls were used and the vehicle was not stated in the methods. The oral LD_{50} for males and females was 3130 mg/kg. Clinical signs consisted of weakness and dyspnoea. Gross examinations revealed inflammation of the gastric mucosa and haemorrhagic areas in the lungs.

*Nixon GA, Buehler EV and Newman EA (1972) Preliminary safety assessment of disodium etidronate as an additive to experimental oral hygiene products. Toxicology and Applied Pharmacology, **22**, 661-671.*

Groups of 10 male and female Charles River CD rats received single doses of disodium etidronate (disodium salt of ethane-1-hydroxy-1,1-diphosphonic acid) administered orally by gavage using a constant progression of doses (exact doses and vehicle not stated in methods).

The oral LD_{50} for males and females was 1340 mg/kg. No clinical signs were reported in this study. Gross examination revealed pale light grey kidneys with dilated tubules and mucosal irritation of the stomachs.

Acute toxicity of HEDP in rats

Species	**Route of exposure**	**Dose (mg/kg)**	**No. animals**	**LD_{50} mg/kg**
Rats (Sprague-Dawley)	Oral 4 dosage groups	2000, 2510, 3160 or 3980	3/sex/dose	♂ 3130; ♀ 3130
Rats (Charles River CD)	Oral	Exact dose levels not stated	10/sex/dose	1340

Subchronic toxicity

Levandoski M (1975) 90-day subacute oral toxicity study with Dequest 2010 in Beagle dogs. Industrial Bio-Test Laboratories. May 27, 1975.

Test material:	HEDP (Dequest 2010)-purity not stated
Control material	Purina dog chow
Test Species:	Beagles 4 animals/sex/per test dose; administration into a stock diet.
Dose:	0, 1000, 3000 or 10,000 ppm (equivalent to 0, 25, 75 or 250 mg/kg bw/day) for 90-days.
GLP/guidelines:	Not stated

Study conduct

Four groups of purebred beagle dogs (4/sex/group) were treated with HEDP in the diet at 0, 1,000, 3,000 or 10,000 ppm (equivalent to 0, 25, 75 or 250 mg/kg bw/day) for 90-days.

Bodyweight and food consumption were recorded daily; urinalysis, haematology and blood chemistry was conducted before treatment and at day 42 and 84 post-treatment. At the end of the study, animals were sacrificed and a complete necroscopy performed (gross examination, organ weights and histo-pathology on selected organs).

There was no statistical analysis undertaken.

Results

No deaths were observed. There was a trend of slight reductions in mean bodyweight gains in females in the treated groups, however, this appears confined to only 1 animal/dose group. A dose related reduction in mean food consumption was observed in females at doses of 25 (-10%), 75 (-18%) or 250 mg/kg bw/day (-28%). However, without any statistical analyses it is difficult to determine the significance of these findings.

A dose-related increase in erythrocyte counts were observed in males (23 to 26%) and females (24 to 28 %) at doses of 250 mg/kg bw/day at day 42 and 84 post-treatment and in blood glucose at day 84 (males and females 24%). Increased numbers of leucocytes were observed in the urine at all treatment doses with the highest numbers (10-50) observed at day 84 in the high dose group compared to 0-10 in the control group. Other urinalysis, haematology and blood chemistry parameters showed no treatment related changes other than isolated sporadic changes without any dose-response relationship.

A reduction in testicular weight (10%) and an increase in thyroid weight were observed at doses of 250 mg/kg bw/day. Mild to moderate bilateral focal degeneration of the germinal epithelium of the testes and focal interstitial infiltrations of the epididymides were observed at doses of 250 mg/kg bw/day.

The NOEL for his study was 75 mg/kg bw/day based on adverse effects observed (decreased food consumption, increased erythrocyte counts and testicular effects) at the next highest dose.

Marias Aj (1976) 90-day subacute oral toxicity study with Dequest 2010 in Albino rats. Industrial Bio-Test Laboratories. December 23, 1976.

Test material:	HEDP (Dequest 2010)-purity not stated
Control material	Standard rat diet (Purina rat chow)
Test Species:	15 animals/sex/per test dose
Dose:	0, 3000, 10,000 or 30,000 ppm (equivalent to 0, 150, 500 or 1,500 mg/kg bw/day) administered in rat chow for 90-days.
GLP/guidelines:	Not stated

Four groups of Charles River rats (15/sex/group) were treated with HEDP in the diet at 0, 3,000, 10,000 ppm or 30, 000 ppm (equivalent to 0, 150, 500 or 1500 mg/kg bw/day) for 90-days.

Clinical signs and any deaths were recorded daily. Bodyweight and food consumption were recorded weekly; urinalysis, haematology and blood chemistry was conducted before treatment and at day 42 and 84 post-treatment. At the end of the study, animals were sacrificed and a complete necroscopy performed (gross examination, organ weights and histo-pathology on selected organs). A Statistical analysis was conducted on the results of the study.

Results

There was 1 death in both control and the 150 mg/kg bw/day group, no deaths at 500 mg/kg bw/day and 11 deaths at the highest dose level used (attributed to trauma at the time of blood collection). There were no specific clinical signs reported in this study that would indicate a toxicological reason for the deaths in the high-dose group.

Statistically significant ($p<0.05$) reductions in mean bodyweight gains were observed in males (16%) and females (8%) at day 90 post-treatment at doses of 1500 mg/kg bw/day. Mean food consumption was also reduced in male and females; however, this was not significant.

A statistically significant increase (8%) in erythrocyte counts in males at day 45 and day 84, reductions in haemoglobin (range 7-12%) and haematocrit (range 8-17%) in both males and females at day 45 and 84 and a reduced total leukocyte count (31% at day 84 only) were observed at doses of 1500 mg/kg bw/day. Other haematology, blood chemistry and urinalysis parameters showed no treatment related changes.

Statistically significant reductions in absolute liver weights (25%) and organ to body (15%) and organ to brain weights (22%) were observed at doses of 1500 mg/kg bw/day; however, there were no accompanying adverse histo-pathogical changes observed in the liver.

The NOEL for his study was 500 mg/kg bw/day based on adverse effects observed (decreased body weights, reduced haemoglobin and haematocrit, and increased liver weights) at the next highest dose.

Sub-chronic toxicity

Species	Route of exposure	Dose (mg/kg/bw/day)	No. Animals	NOAEL
Dogs	Oral	0, 25, 75 or 250	4/sex/dose	75 mg/kg bw/day
Rats	Oral	0, 150, 500 or 1500	15/sex/dose	500 mg/kg bw/day

Genotoxicity studies

The Applicant upon request from FSANZ could not supply original studies on the genotoxicity of HEDP. However, it is noted that the European Commission's (2003) assessment and the most recent JECFA (2004) evaluation concluded that HEDP was not mutagenic in five *Salmonella typhimurium* tester strains and in L5178Y TK Mouse lymphoma cells [+-] metabolic activation.

Reproduction/developmental toxicity

Nolen GA and Buehler EV (1971) The effects of disodium etidronate on the reproductive functions and embryogeny of albino rats and New Zealand rabbits. **Toxicology and Applied Pharmacology**, *18*, 548-561.

Rats (Combined two-generation/developmental study)

Test material:	Disodium etidronate (disodium salt of ethane-1-hydroxy-1,1-diphosphonic acid) -purity not stated
Control material	Administered in the diet
Test Species:	22 animals/sex/per test dose
Dose:	0, 0.1% or 0.5% in the diet (equivalent to 0, 50 or 250 mg/kg bw/day) administered in the diet
GLP/guidelines:	Not stated

Study conduct

Five groups of Charles-River rats (22 males and 22 females) were orally administered disodium etidronate in the diet in a combined two-generation reproduction/developmental study at doses of 0, 50 or 250 mg/kg bw/day continuously for 8 weeks following mating or only during day 6 to 15 of gestation in females. This was repeated for the first generation (F1). Fo females were allowed to deliver the first 2 litters and then they were evaluated for growth, food consumption, bodyweights, number of resorptions, corpora lutea and implantations, with the third litter used for a detailed teratogenic evaluation. 25 rats of each sex from each treated group were selected, paired and mated to form the second generation (F2). Similarly, the first two litters of the F2 generation were evaluated and the third litter used for a teratogenic evaluation.

Results

No significant differences were observed in growth, food consumption or bodyweights from weaning to maturity in either the first or second generations. A significant reduction in number of live pups born (F1 generation) was observed when dams were dosed during day 6 to 15 at 250 mg/kg bw/day with no effect on other parameters. No significant differences were observed in corpora lutea or implantations in females (Fo) sacrificed on day 21 post mating.

Significant reductions were observed in the average number of implantations and corpora lutea at day 21 in F1 dams receiving doses of 250 mg/kg bw/day. Out of 1028 foetuses examined for teratogenic effects in either the F1 or F2 generation, only 1.2% showed any abnormalities following treatment. Controls had higher incidences than the dose-groups and generally incidences of defects were randomly spread throughout dose groups.

Based on the reductions in numbers of live pups, average number of implantations and corpora lutea formation at the highest dose, the NOAEL for reproductive/developmental effects was 50 mg/kg bw/day.

Rabbits (Developmental studies)

Test material:	Disodium etidronate (disodium salt of ethane-1-hydroxy-1,1-diphosphonic acid) -purity not stated
Control material	Administered in the diet and by gavage
Test Species:	20 NZ rabbits/sex/per test dose
Dose:	0, 25, 50 or 100 mg/kg bw/day) administered in the diet
GLP/guidelines:	Not stated

Study conduct

Groups of 20-mated female rabbits were orally administered disodium etidronate either in the fed at doses of 0, 25, 50 or 100 mg/kg bw/day or by gavage (in a H_20 vehicle) at a dose of 100 mg/kg bw/day from day 2 to 16 of gestation. The dams were examined throughout the study for clinical signs of toxicity. At day 29 of gestation caesarean sections were performed and their offspring examined for external, visceral and skeletal abnormalities.

Results

There were no significant differences in the numbers of corpora lutea, resorptions or live foetuses. There was a significant reduction in foetal weights in the group gavaged at a dose of 100 mg/kg bw/day. Of the 868 foetuses examined <2% demonstrated any developmental abnormalities and treated groups were not significantly different from controls.

In conclusion, under the conditions of the study, disodium etidronate was not teratogenic in rabbits up to doses of 100 mg/kg bw/day either by administration in the diet or by gavage. The NOAEL was the highest dose tested.

Reproduction studies

Species	**Route of exposure**	**Dose (mg/kgbw/day)**	**No. animals**	**NOAEL**
Rats	Oral	0, 50 or 250	22/sex/dose	50 mg/kg bw/day
Rabbits	Oral in diet or gavage	0, 25, 50 or 100	20/sex/dose	100 mg/kg bw/day

Studies in humans

HEDP is used clinically to treat Paget's disease in humans at an oral starting dose of 5 mg/kg bw/day for not longer than 6 months (WHO, 2004).

Toxicological profile of Octanoic acid

Octanoic acid (caprylic acid; C8) is a medium chain fatty acid that occurs naturally in foods, including milk products, meats, fats and oils (particularly coconut oil). When absorbed from the digestive tract it is hydrolysed and the fatty acids are catabolised to C2 fragments, which may be further either to $C0_2$ or to form long-chain fatty acids[8].

The Joint Expert Committee on Food Additives (JECFA) evaluated octanoic acid as a flavouring agent in 1999 and concluded that it raised no toxicological concerns when used as a flavouring agent at low levels (650µg/day for the US and 3, 800µg/day for Europe). JECFA also commented that octanoic acid could be predicted to undergo complete metabolism to endogenous products via the fatty acid tricarboxylic pathways in humans.

JECFA recently reconfirmed that octanoic acid in antimicrobial solutions posed no toxicological concerns (WHO, 2004).

FSANZ evaluated the following studies on octanoic acid found from searching the general scientific literature:

Genotoxicity studies

Zeiger E, Anderson B, Haworth S (1988) Salmonella mutagenicity tests: IV. Results from the testing of 300 chemicals. **Environmental and Molecular Mutagenesis**, Volume II, Supplement 12: 1-158.

Test	Test material	Concentration	Test object	Result
Reverse mutation (in vitro)	Octanoic acid	0, 3333 µg/plate	S. typhimurium TA 98, 97, 1001535, 1537.	-ve

These studies were designed with appropriate negative and positive controls and where S9 mix was used as a metabolic activating system, the S9 preparation was listed.

Subchronic studies

Webb DR, Wood FE, Bertram TA and Fortier (1993) A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, *31*, 935-946.

Test material:	Caprenin[9]-purity not stated
Control material	Corn oil in standard rat chow
Test Species:	25 Sprague-Dawley rats/sex/per test dose
Dose:	0, 5, 10 or 15% w/w (equivalent to 0, 5000, 10,000 or 15,000 mg/kg bw/day) administered in rat chow for 90-days.

[8] Final Report of the safety assessment for caprylic/capric triglyceride. Journal Env. Path. Tox., 4, 105-20.
[9] Caprenin is a triglyceride composed of caprylic (C8:0), capric (C10:0) and behenic acids (C22:0).

GLP/guidelines: Not stated

Four groups of Sprague-Dawley rats (25/sex/group) were treated with caprenin in the diet at 0, 5, 10 or 15% for 90-days.

Clinical signs and any deaths were recorded daily. Bodyweight and food consumption were recorded weekly; urinalysis, haematology and blood chemistry was conducted at day 90 post-treatment. An ophthalmoscope examination was performed before treatment and at day 90 post-treatment. At the end of the study, animals were sacrificed and a complete necroscopy performed (gross examination, organ weights and histo-pathology on selected organs). A Statistical analysis was conducted on the results of the study.

Results

There were no treatment-related deaths and any clinical signs observed following demonstration of caprenin in the diet were not considered related to treatment. No differences were observed in weight gain or food consumption between controls and treated groups.

A significant increase in absolute colon weights at mid and high dose (15%; $p<0.05$) in males was observed; however, as there was no dose-response relationship and this observation was confined to males only, it appears of no toxicological significance.

Sporadic isolated changes were observed in some haematological and blood chemistry parameters; however, these lacked a dose-response relationship and there was not accompanying histopathological changes that suggested they were toxicologically significant.

The NOEL for his study was 15,000 mg/kg bw/day, the highest dose tested.

References

EC Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health- The evaluation of antimicrobial treatments for poultry carcasses. Adopted on 14-15 April 2003.

WHO (1999) Evaluation of certain food additives and contaminants (Forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report series, No. 884.

WHO (2004) Safety evaluation of peroxyacid antimicrobial mixtures. 63rd Joint FAO/WHO Expert Committee on Food Additives. 8-17 June 2004.

Attachment 5

Dietary Exposure Assessment Report

Summary

A dietary exposure assessment was undertaken to determine the potential impact of allowing octanoic acid use as a processing aid on the Australian and New Zealand populations. The Applicant proposes to use octanoic acid as an antimicrobial agent on red meat and poultry meat carcasses and parts and also in the processing of fresh fruits and vegetables. Octanoic acid is a component of a mixture of chemicals, all of which have current permissions in the Code, except hydroxyethylidene diphosphonic acid (HEDP), octanoic acid and peroxyoctanoic acid. Therefore, for the purpose of this dietary exposure assessment, octanoic acid and HEPD were considered.

A dietary exposure assessment was conducted for the Australian population 2 years and above and for the New Zealand population 15 years and above. A dietary exposure assessment was also carried out for children 2-6 years (Australia only). Since no reference health standards exist for octanoic acid or HEDP, the results are simply expressed in milligrams per day (mg/day).

Three scenarios were modelled; assuming exposure to naturally occurring octanoic acid, octanoic acid as a processing aid only, and a combination of these. For consumers of naturally occurring octanoic acid (Scenario 1), estimated mean dietary exposures to octanoic acid were the lowest for Australian children aged 2-6 years at 331 mg/day and were highest for New Zealanders aged 15 years and above at 399 mg/day. Based on the proposed uses of octanoic acid as a processing aid as well as naturally occurring levels (Scenario 3), estimated mean consumer dietary exposures to octanoic acid were the lowest for Australian children aged 2-6 years at 331 mg/day and highest for New Zealanders aged 15 years and above at 399 mg/day.

Estimated 95th percentile dietary exposure to naturally occurring octanoic acid were the lowest for Australian children aged 2-6 years at 696 mg/day and highest for New Zealanders aged 15 years and above at 992 mg/day. Based on the proposed uses of octanoic acid as a processing aid as well as naturally occurring levels, estimated 95th percentile dietary exposures were the lowest for Australian children aged 2-6 years at 696 mg/day and highest for all New Zealanders aged 15 years and above at 993 mg/day.

For the population groups assessed, the estimated mean and 95th percentile consumer dietary exposures to octanoic acid do not change greatly between baseline and when the requested permissions for octanoic acid as a processing aid are considered in conjunction with the naturally occurring levels.

The major contributors to dietary exposure to octanoic acid at baseline and for Scenario 3 were milk (82%-91%) and coconut (7%-13%) for all population groups assessed.

There were no naturally occurring levels of HEDP, therefore dietary exposures to HEDP were calculated based on its use as a processing aid only. The estimated dietary exposures for HEDP are shown in Figure 3 (full results in Table A1.4 in Appendix 1).

Estimated mean exposures for consumers of HEDP are 0.15 mg/day for Australians aged 2 years and above and New Zealanders aged 15 years and above, and 0.11 mg/day for Australian children aged 2-6 years. Estimated 95th percentile exposures for HEPD are 0.35 mg/day for Australians aged 2 years and above, 0.33 mg/day for New Zealanders aged 15 years and above, and 0.28 mg/day for Australian children aged 2-6 years.

For all population groups assessed, the major contributors (>5%) to HEDP dietary exposure were citrus fruits, mammalian meat, root and tuber vegetables, other fruiting vegetables, pome fruits, and tropical fruits – inedible peel. For the population groups of Australians aged 2 years and above and New Zealanders aged 15 years and above, berries and other small fruits were also major contributors to HEDP dietary exposure.

The dietary exposures to octanoic acid as a processing aid would make minimal difference to predicted dietary exposures to octanoic acid from natural sources. The dietary exposures to octanoic acid would result in residues of HEDP of less than 1 mg/day for any population group assessed.

Background

The aim of this application is to gain approval to use octanoic acid as a processing aid to reduce microbial contamination. Octanoic acid, also known as caprylic acid, is a medium chain saturated fatty acid (C8:0) that occurs naturally in foods and is also used commercially as a flavouring agent and adjuvant[10]. Sources of naturally occurring octanoic acid include milk, eggs and coconut.

Octanoic acid, as a processing aid, is a component of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and HEDP. The formulation is intended to be used as an antimicrobial agent on red meat and poultry carcasses, parts and organs and in water contacting fruits and vegetables for processing (i.e. cut, chopped, sliced, peeled, ground, milled, frozen, cooked or homogenised). When octanoic acid is applied to meat and poultry carcasses, some residual product remains on the surface of the product but much is lost due to drainage, washing, trimming and evaporation. Of the above listed components of the formulation of octanoic acid, hydrogen peroxide, acetic acid and peracetic acid are already listed in the Code. 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; 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; and 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).

HEDP is a component of the antimicrobial formulation, however HEDP has no antimicrobial efficacy. HEDP is used in the formulation to increase long-term storage stability by preventing certain metal ions from catalysing the degradation of peroxyoctanoic acid and hydrogen peroxide.

[10] An adjuvant is "an ingredient…that modifies the action of the principal ingredient" (Merriam-Webster 2004)

The residues of octanoic acid and HEDP expected in foods due to the use of the octanoic acid processing aid formulation, as provided by the Applicant, are listed in Tables 1 and 2, respectively.

Table 1: Estimated residues of octanoic acid in foods, as provided by the Applicant

Food Name	Concentration Level (ppb)
Poultry carcasses, parts and organs	1 325
Meat carcasses	1 437
Meat, parts and organs	4 005
Combined carcase and meat trim use	1 689
Further processed fruits and vegetables: tomatoes	103
Further processed fruits and vegetables: broccoli	1 658

Table 2: Estimated residues of HEDP in foods, as provided by the Applicant

Food Name	Concentration Level (ppb)
Poultry carcasses, parts and organs	198
Meat carcasses	58
Meat, parts and organs	161
Post-harvest and fresh-cut fruits and vegetables: tomatoes	4.2 x 2
Post-harvest and fresh-cut fruits and vegetables: broccoli	67.5 x 2
Further processed fruits and vegetables: tomatoes	4.2
Further processed fruits and vegetables: broccoli	67.5

For the residues of HEDP on fruits and vegetables, the Applicant indicated that formulations containing HEDP could be used as a part of post-harvest treatment and twice during processing i.e. in a worst case scenario, the concentration of HEDP could be equal to 202.5 ppb (= 67.5 ppb x 3).

Dietary exposure assessment

The Applicant provided exposure assessment data that may be expected to result from the use of octanoic acid as a processing aid and HEDP. Daily exposure estimates of octanoic acid and HEDP were derived using data collected by the USDA in the nutrient Database for Standard Reference (USDA, 2003) combined with food consumption information from the USDA's Continuing Survey of Food Intakes by Individuals, 1994-1996, 1998. Daily exposure estimates for octanoic acid, based on these data, for the average and 90th percentile exposures in the US were 0.201 grams per day (g/day) and 0.412 g/day, respectively. The Applicant stated that more than 50% of total exposures were from naturally occurring octanoic acid from milk and milk products. Daily exposure estimates for HEDP, based on the USDA data, at the 90th percentile for poultry intake were approximately 0.021 mg/day and 0.007 mg/day at the 90th percentile intake for beef intake.

The dietary exposure assessment provided in the Application was not considered detailed enough to allow FSANZ to determine a conclusion for the Australian and New Zealand populations. This is due to the use of US consumption data, and limited dietary exposure data provided for HEDP. Therefore FSANZ conducted a dietary exposure assessment.

Dietary modelling by FSANZ

The dietary exposure assessment was conducted by FSANZ using dietary modelling techniques that combine food consumption data with food chemical concentration data to estimate the exposure to the food chemical from the diet. The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary exposure = food chemical concentration x food consumption

The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with naturally occurring and proposed levels of use of octanoic acid and HEDP in foods.

Dietary survey data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

Additional food consumption data or other relevant data

No further information was required or identified for the purpose of refining the dietary exposure estimates for this Application.

Population groups assessed

The dietary exposure assessment was conducted for both Australian and New Zealand populations. An assessment was conducted for the whole population, as well as for children 2-6 years (Australia only). A dietary exposure assessment was conducted for children because children generally have higher exposures due to their smaller body weight, and they consume more food per kilogram of body weight compared to adults. It is important to note that, while children aged 2-6 years (Australia only) have been assessed as a separate group, this group has also been assessed in the whole population's dietary exposure assessment.

Octanoic acid and HEDP concentration levels

The levels of octanoic acid and HEDP in foods that were used in the dietary exposure assessment were derived from naturally occurring levels present in foods and the data supplied in the Application. The foods and levels used in the dietary exposure assessment are shown below in **Table 3** for naturally occurring octanoic acid, and in **Table 4** for octanoic acid and **Table 5** for HEDP from data supplied by the Applicant.

Concentrations of octanoic acid and HEDP were assigned to food groups using food classification codes. These codes are based on the Australian New Zealand raw commodity classification codes adapted from the Codex raw commodity classification system. The foods proposed by the Applicant to contain octanoic acid and HEDP (as shown in **Table 1 and 2**) were matched to the most appropriate raw commodity code(s) for dietary modelling purposes.

Where the Applicant provided a range of possible concentrations, the highest level in the range was used for calculating the estimated exposures in order to assume a worst-case scenario. The Applicant provided concentrations of octanoic acid and HEDP in foods as parts per billion (ppb). These were converted to mg/kg concentrations for use in the DIAMOND program.

The naturally occurring concentrations of octanoic acid in foods were derived from Supplement to NUTTAB95 (ANZFA 1999) and New Zealand fatty acid data (Crop and Food Research 2000).

Scenarios for dietary modelling

For the purpose of the octanoic acid dietary exposure assessment, three scenarios were modelled:

- Scenario One was based on naturally occurring levels of octanoic acid in foods ('naturally occurring' scenario);
- Scenario Two was based on the levels of octanoic acid that may be present from its use as a processing aid ('A513 octanoic acid' scenario); and
- Scenario Three was based on a combination of naturally occurring levels and those that may be present due to its use as a processing aid ('naturally occurring plus A513 octanoic acid' scenario).

There are no naturally occurring levels of HEDP in foods therefore only one scenario was conducted, based on the levels provided in the application ('A513 HEDP' scenario).

Table 3: Naturally occurring levels of octanoic acid in foods for Australia and New Zealand

DIAMOND Food Code	Food	Octanoic Acid Concentration Level used in modelling (mg/kg)		Source of Data	
		Australia	New Zealand	Australia	New Zealand
ML	Milk	500	490	1	2
ML0184	Goat milk	700	960	1	2
OR0665	Coconut oil, refined	75 300	36 800	1	2
PE	Poultry eggs	500	500	1	1
TN0665	Coconut	20 900	20 900	1	1
VA	Bulb vegetables	200	200	1	1
VA0381	Garlic	200	200	1	1

(1) Supplement to NUTTAB95 (ANZFA 1999); (2) New Zealand fatty acid data (Crop and Food Research 2000)

Table 4: Proposed use of octanoic acid in foods and levels used in the dietary exposure assessment

DIAMOND Food Code	Food Name	Concentration Level (mg/kg)
DM0305	Olives, processed	1.658
FB	Berries and other small fruits	1.658
FC	Citrus fruits	1.658
FI	Tropical fruit – inedible peel	1.658
FP	Pome fruits	1.658

DIAMOND Food Code	Food Name	Concentration Level (mg/kg)
FS	Stone fruits	1.658
FT	Tropical fruits – edible peel	1.658
MF	Fat, mammalian	4.005
MM	Meat, mammalian	4.005
MO	Offal, mammalian	4.005
PF	Poultry fat	1.325
PM	Poultry meat	1.325
PO	Poultry offal	1.325
VA	Bulb vegetables	1.658
VB	Brassica vegetables	1.658
VC	Cucurbits	1.658
VD	Pulses	1.658
VL	Leafy vegetables	1.658
VO	Other fruiting vegetables	1.658
VP	Legume vegetables	1.658
VR	Root and tuber vegetables	1.658
VS	Stalk and stem vegetables	1.658

Table 5: Proposed use of HEDP in foods and levels used in the dietary exposure assessment

DIAMOND Food Code	Food Name	Concentration Level (mg/kg)
DM0305	Olives, processed	0.2025
FB	Berries and other small fruits	0.2025
FC	Citrus fruits	0.2025
FI	Tropical fruit – inedible peel	0.2025
FP	Pome fruits	0.2025
FS	Stone fruits	0.2025
FT	Tropical fruits – edible peel	0.2025
MF	Fat, mammalian	0.161
MM	Meat, mammalian	0.161
MO	Offal, mammalian	0.161
PF	Poultry fat	0.198
PM	Poultry meat	0.198
PO	Poultry offal	0.198
VA	Bulb vegetables	0.2025
VB	Brassica vegetables	0.2025
VC	Cucurbits	0.2025
VD	Pulses	0.2025
VL	Leafy vegetables	0.2025
VO	Other fruiting vegetables	0.2025
VP	Legume vegetables	0.2025
VR	Root and tuber vegetables	0.2025
VS	Stalk and stem vegetables	0.2025

How were the estimated dietary exposures calculated?

The DIAMOND program allows octanoic acid and HEDP concentrations to be assigned to food groups. Each individual's exposure to octanoic acid and HEDP was calculated using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of octanoic acid and HEDP by the amount of food that an individual consumed from that group in order to estimate the exposure to octanoic acid and HEDP from each food.

Once this has been completed for all of the foods specified to contain octanoic acid and HEDP, the total amount of octanoic acid and HEDP consumed from all foods is summed for each individual. Population statistics (mean and 95th percentile exposures) are then derived from the individuals' ranked exposures.

Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, apples (pome fruit) eaten as raw apple, canned apple, and apple in a pie, are all included in the consumption of apples. Where a higher-level food classification code (e.g. ML - Milk) is given an octanoic acid concentration, as well as a sub-category (e.g. ML0184 – Goats milk), the consumption of the foods in the sub-classification is not included in the higher level classification code.

In DIAMOND, all mixed foods have a recipe. Recipes are used to break down mixed foods into their raw commodity components (e.g. bread will be broken down to wheat flour, yeast, water etc). The data for consumption of the raw commodities are then used in models that assign octanoic acid or HEDP permissions to raw commodity classifications.

When a food is classified in two food groups (for example, mixed fruit juice may be entered in the apple and pear groups), and these food groups are assigned different octanoic acid or HEDP permissions, DIAMOND will assume that the food is in the food group with the highest assigned octanoic acid or HEDP level to assume a worst-case scenario. If the food groups have the same permitted octanoic acid or HEDP level, DIAMOND will assume the food is in the food group that appears first, based alpha-numerically on the DIAMOND food code.

Assumptions in the dietary modelling

The aim of the dietary exposure assessment was to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary exposure assessment did not underestimate exposure.

Assumptions made in the dietary modelling include:

- where a permission is given to a food classification, all foods in that group contain octanoic acid or HEDP;
- all the foods within the group contain octanoic acid or HEDP at the levels specified in Tables 3, 4 and 5. Unless otherwise specified, the maximum concentration of octanoic acid and HEDP in each food category has been used;
- consumers always consume the products containing octanoic acid or HEDP;
- the processing aid formulation containing octanoic acid and HEDP will not be used on dried fruits and vegetables;
- consumption of foods as recorded in the NNS represent current food consumption patterns;
- all octanoic acid and HEDP present in food is absorbed by the body;
- where there were no Australian or New Zealand data on naturally occurring octanoic acid concentrations of food groups, it was assumed that overseas data were representative of these food groups;

- where no concentration data was available, the concentration was assumed to be zero and those foods or food groups were not included in the exposure assessment;
- where a food has a specified octanoic acid or HEDP concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. apples in apple pie;
- fruits and vegetables are not washed with water prior to preparation and consumption in the home;
- there are no reductions in octanoic acid or HEDP concentrations from food preparation or due to cooking; and
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. milk).

These assumptions are likely to lead to a conservative estimate for octanoic acid and HEDP dietary exposure.

Limitations of the dietary modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

Daily food consumption amounts for occasionally consumed foods based on 24 hour food consumption data would be higher than daily food consumption amounts for those foods based on a longer period of time. This specifically affects the food groups in this assessment such as tropical fruits and pulses.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This is so that actual food consumption amounts do not become distorted and unrealistic which would make exposure estimates unrealistic. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand National Nutrition Survey so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards this population group in the dietary exposure assessment because population weights were not used.

Results

Estimated dietary exposures to octanoic acid and HEDP

Octanoic Acid

The estimated dietary exposures for consumers of octanoic acid for each scenario are shown in **Figures 1 and 2** (full results in **Table A1.1, A1.2 and A1.3 in Appendix 1**).

For consumers of naturally occurring octanoic acid (Scenario 1), estimated mean dietary exposures to octanoic acid were the lowest for Australian children aged 2-6 years at 331 mg/day and were highest for New Zealanders aged 15 years and above at 399 mg/day. Estimated 95th percentile dietary exposures to octanoic acid were the lowest for Australian children aged 2-6 years at 696 mg/day and highest for New Zealanders aged 15 years and above at 992 mg/day.

When exposure to octanoic acid from its use as a processing aid only was considered (Scenario 2), estimated mean dietary exposures for consumers of octanoic acid were the lowest for Australian children aged 2-6 years at 1.1 mg/day and highest for New Zealanders aged 15 years and above at 1.6 mg/day. Estimated 95th percentile dietary exposures for consumers of octanoic acid were the lowest for Australian children aged 2-6 years at 2.5 mg/day and highest for both New Zealanders aged 15 years and above and Australians aged 2 years and above at 3.5 mg/day.

Based on the proposed uses of octanoic acid as a processing aid as well as naturally occurring levels (Scenario 3), estimated mean dietary exposures for consumers of octanoic acid were the lowest for Australian children aged 2-6 years at 331 mg/day and highest for New Zealanders aged 15 years and above at 399 mg/day. Estimated 95th percentile dietary exposures for consumers were the lowest for Australian children aged 2-6 years at 696 mg/day and highest for all New Zealanders aged 15 years and above at 993 mg/day.

For the population groups assessed, the estimated mean and 95th percentile consumer dietary exposures to octanoic acid did not change greatly between baseline and when the requested permissions for octanoic acid as a processing aid were added.

HEDP

The estimated dietary exposures for HEDP are shown in Figure 3 (full results in Table A1.4 in Appendix 1). Estimated mean dietary exposures for consumers of HEDP were 0.15 mg/day for Australians aged 2 years and above and New Zealanders aged 15 years and above, and 0.11 mg/day for Australian children aged 2-6 years. Estimated 95th percentile dietary exposures for consumers of HEPD were 0.35 mg/day for Australians aged 2 years and above, 0.33 mg/day for New Zealanders aged 15 years and above, and 0.28 mg/day for Australian children aged 2-6 years.

Figure 1: Estimated mean dietary exposures to octanoic acid for different scenarios and different population groups for Australia and New Zealand

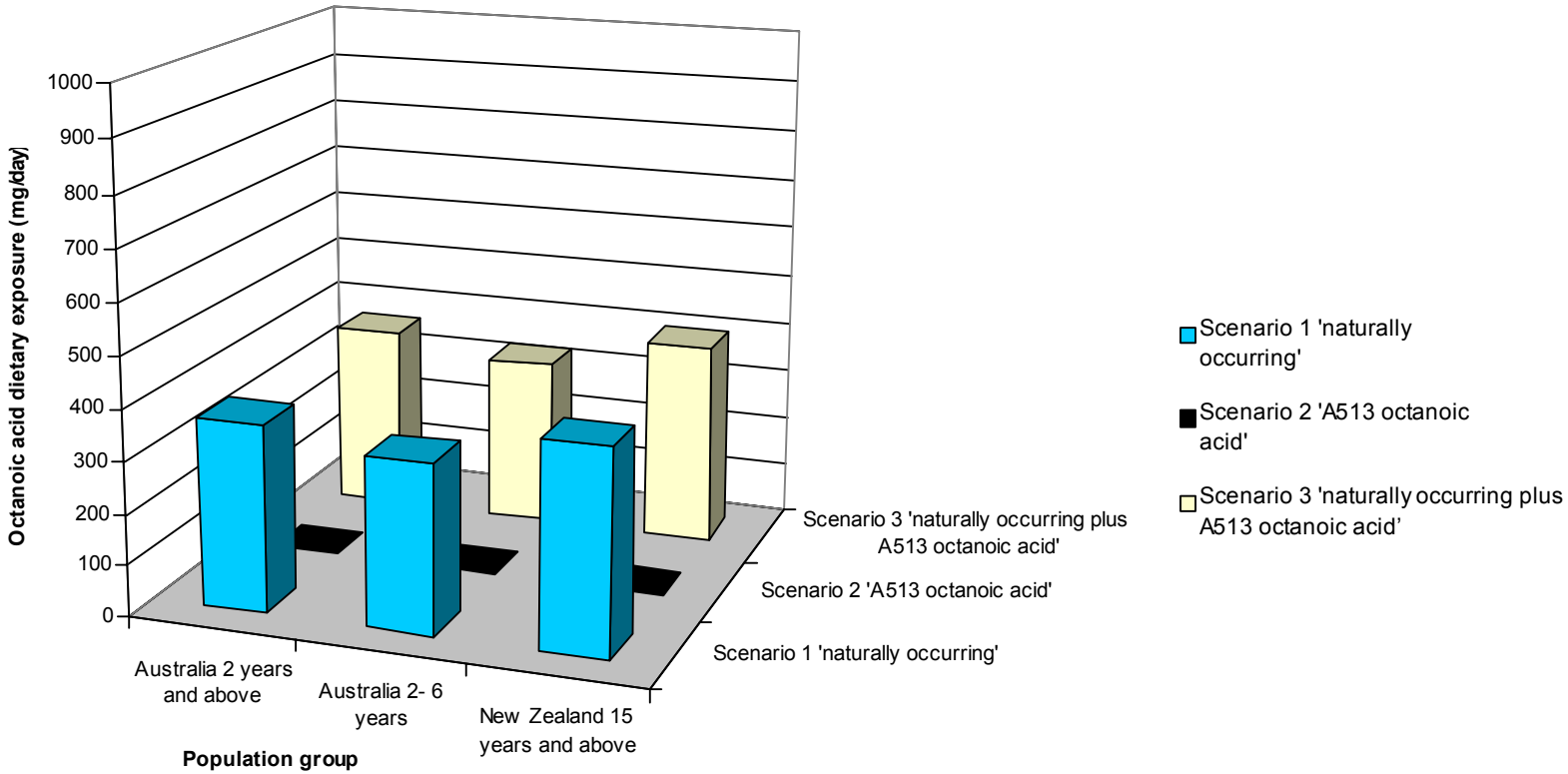


Figure 2: Estimated 95th percentile dietary exposures to octanoic acid for different scenarios and different population groups for Australia and New Zealand

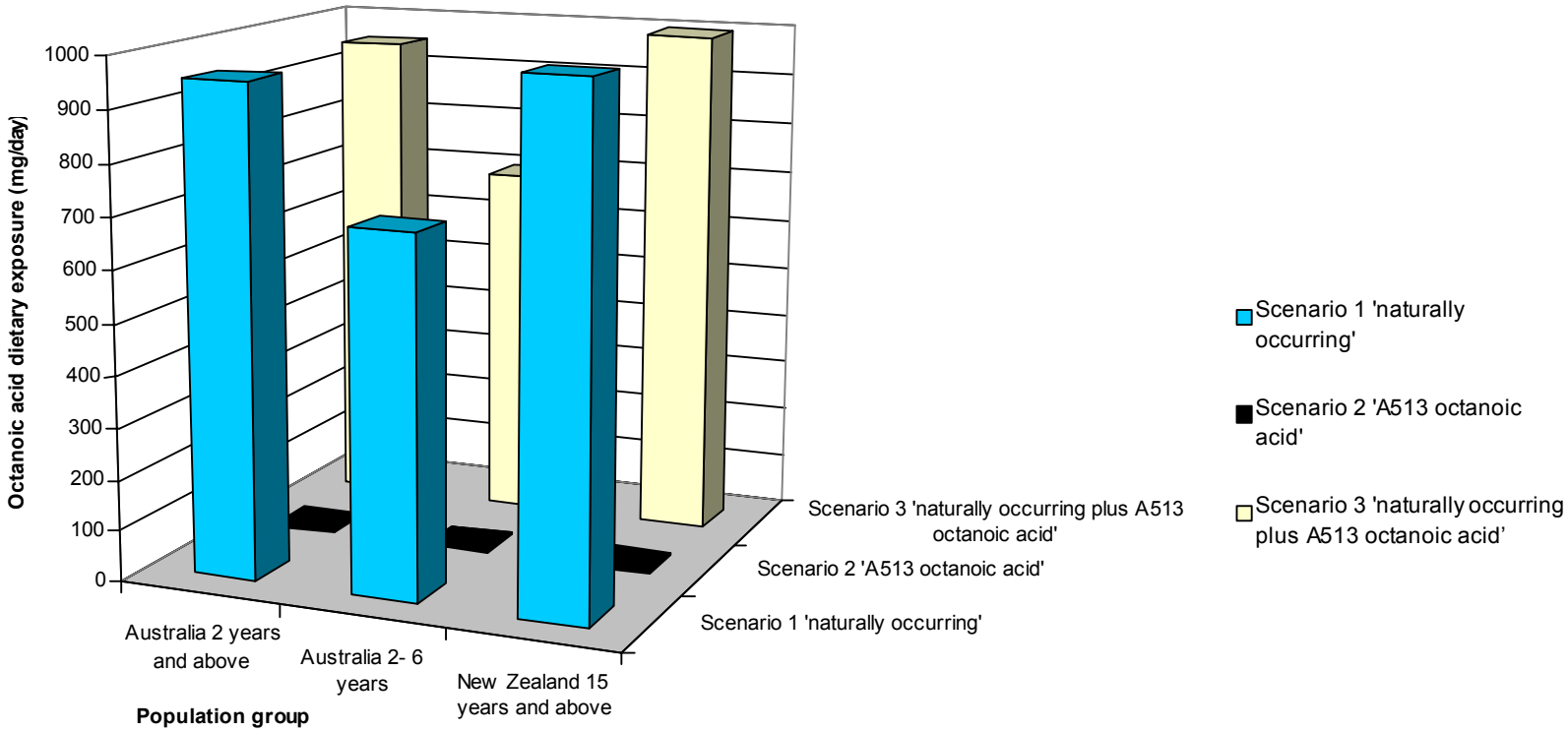
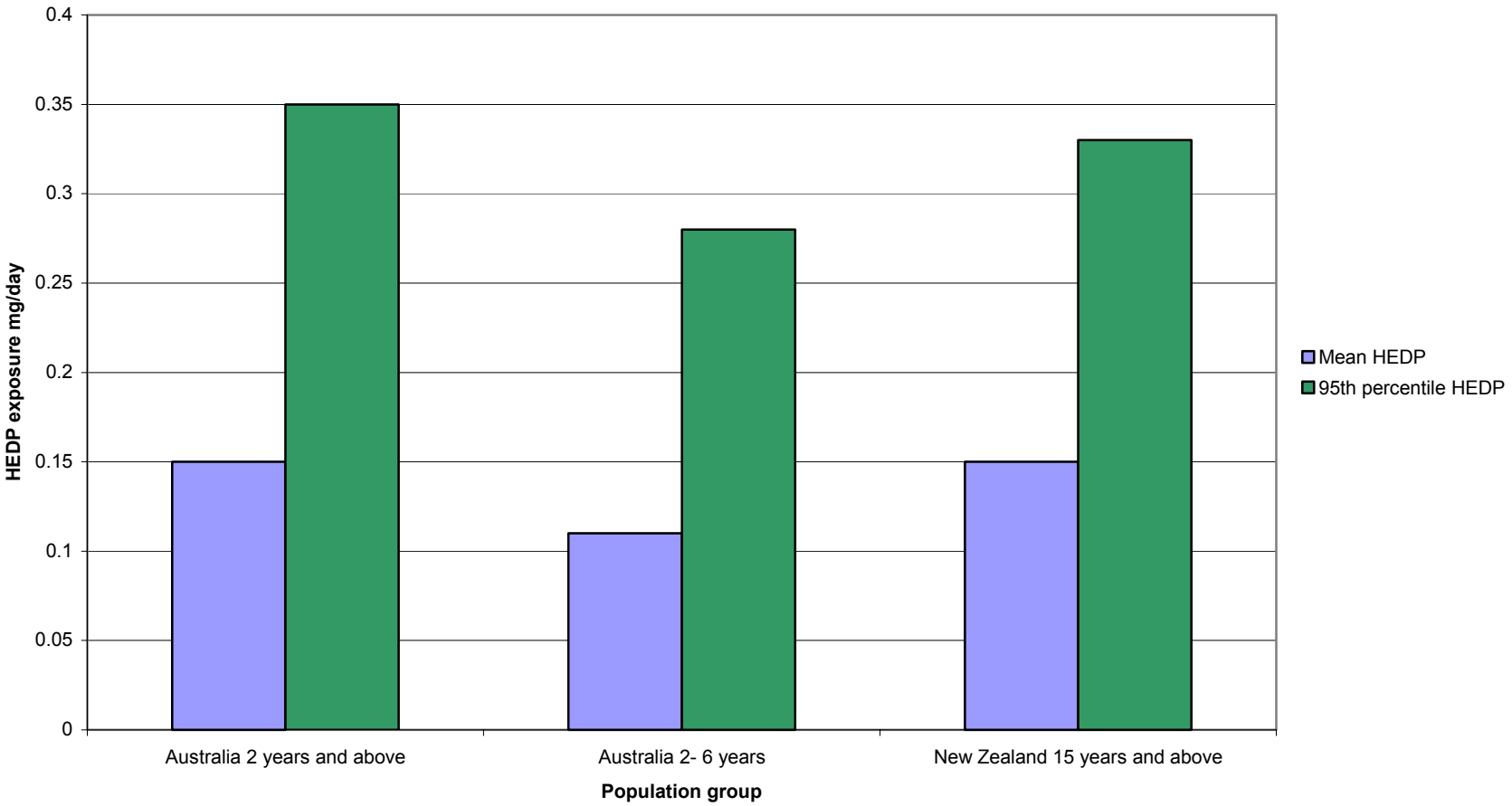


Figure 3: Estimated mean and 95th percentile dietary exposures to HEDP for different population groups for Australia and New Zealand



Major contributing foods to total estimated dietary exposures

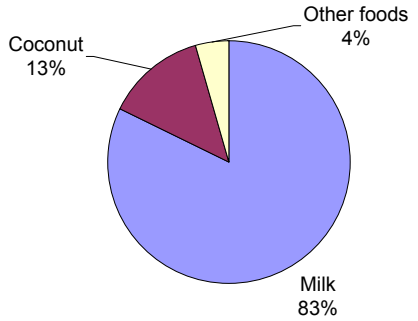
The major contributors (>5%) to total octanoic acid dietary exposures are shown in Figure 4 (Scenario 1), Figure 5 (Scenario 2) and Figure 6 (Scenario 3) for Australia and New Zealand. These are displayed for the total population assessments as well as for children 2-6 years (Australia only). The major contributors to octanoic acid dietary exposures at baseline and for Scenario 3 were milk (82%-91%) and coconut (7%-13%) for all population groups assessed for Australia and New Zealand. A full list of all the food groups and their contributions can be found in Table A1.5, A1.6 and A1.7 in Appendix 1.

The major contributors to total HEDP dietary exposures are shown in Figure 7 (Australians aged 2 years and above), Figure 8 (2-6 years Australia) and Figure 9 (New Zealanders aged 15 years and above). The major three contributors to HEDP dietary exposure for Australians aged 2 years and above were citrus fruits (19%), mammalian meat (12%) and root and tuber vegetables (12%). The major three contributors to HEDP dietary exposure for New Zealanders aged 15 years and above were root and tuber vegetables (21%), mammalian meat (15%) and citrus fruits (9%). The three major contributors to HEDP dietary exposure for Australian children aged 2-6 years were citrus fruits (28%), pome fruits (23%) and tropical fruit with inedible peel (10%). A full list of all the food groups and their contributions can be found in Table A1.8 in Appendix 1.

Conclusion

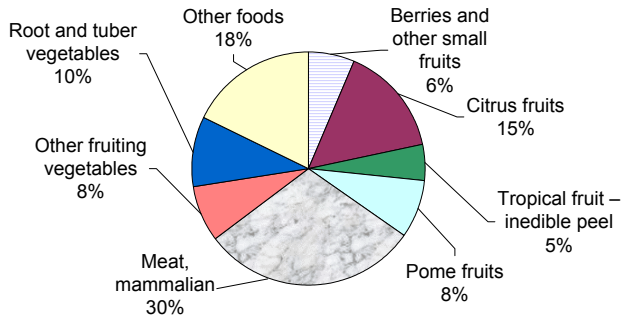
The approval of A513 for octanoic acid as a processing aid would make minimal difference to predicted dietary exposures to octanoic acid from natural sources and result in residues of HEDP that were less than 1 mg/day for any population group assessed.

Figure 4: Major contributors to total octanoic acid dietary exposures for Australians aged 2 years and above, for different scenarios



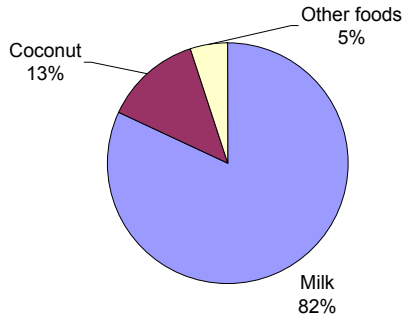
Scenario 1

(367 mg/day)



Scenario 2

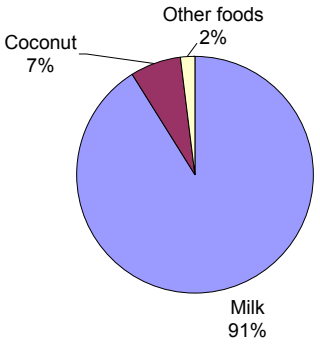
(1.5 mg/day)



Scenario 3

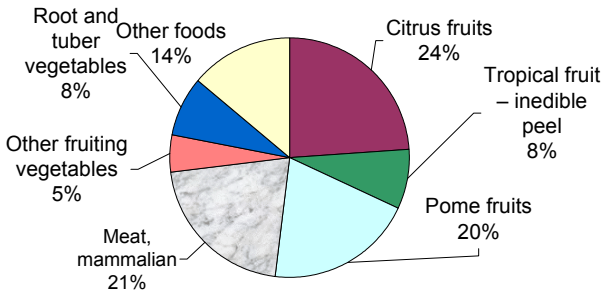
(366 mg/day)

Figure 5: Major contributors to total octanoic acid dietary exposures for Australians aged 2-6 years, for different scenarios



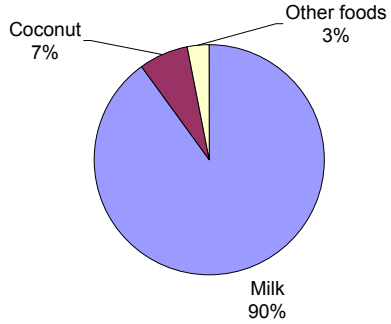
Scenario 1

(331 mg/day)



Scenario 2

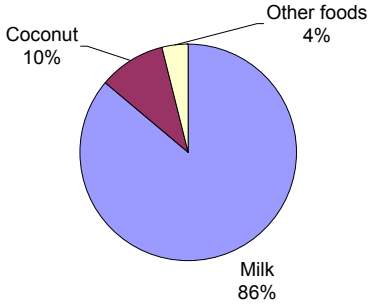
(1.1 mg/day)



Scenario 3

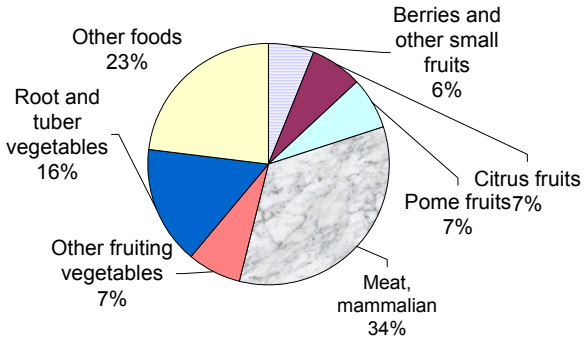
(331 mg/day)

Figure 6: Major contributors to total octanoic acid dietary exposures for New Zealanders aged 15 years and above, for different scenarios



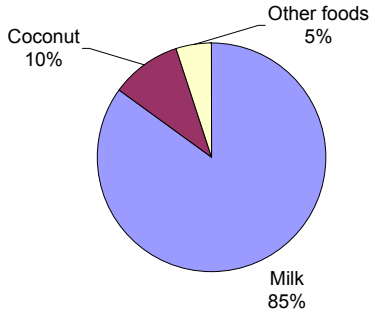
Scenario 1

(399 mg/day)



Scenario 2

(1.6 mg/day)



Scenario 3

(399 mg/day)

Figure 7: Major contributors to total HEDP dietary exposures for Australians aged 2 years and above

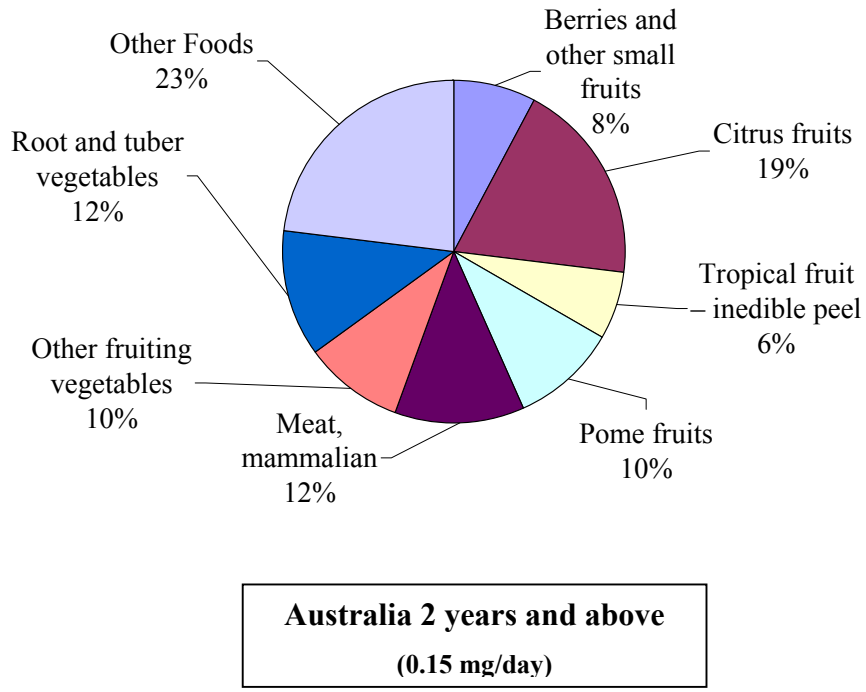


Figure 8: Major contributors to total HEDP dietary exposures for Australians aged 2-6 years

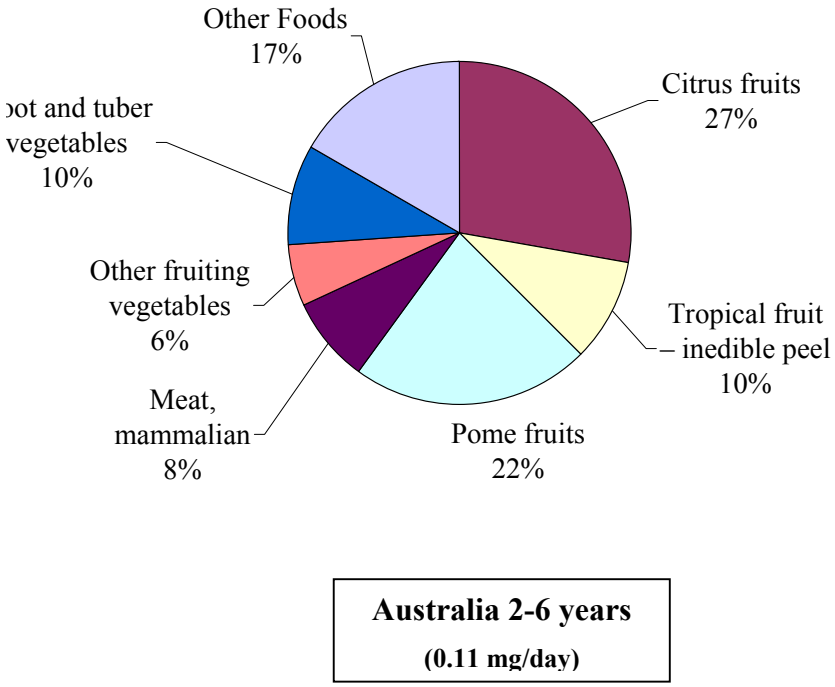
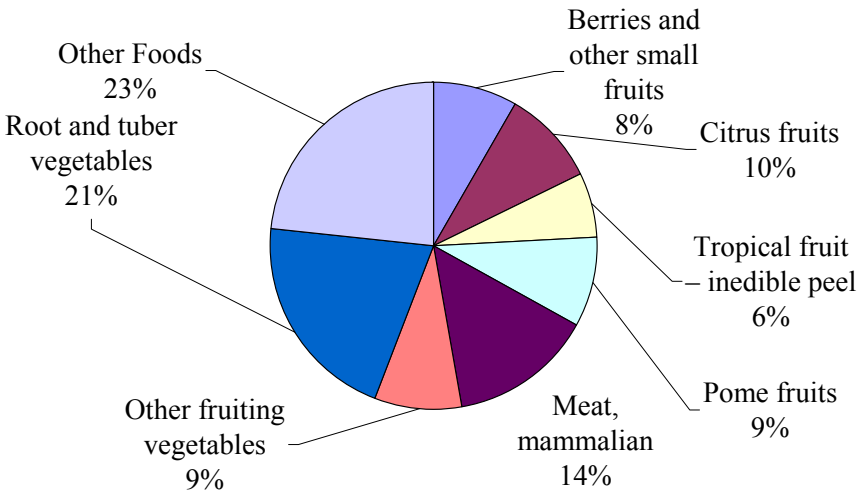


Figure 9: Major contributors to total HEDP dietary exposures for New Zealanders aged 15 years and above



Complete information on dietary exposure assessment results

Table A1.1: Scenario 1 (n **New Zealand 15 years and above (0.15 mg/day)** *ted octanoic acid dietary exposures*

Country	Population group	Number of consumers of octanoic acid	Consumers♦ as a % of total respondents#	Mean all respondents mg/day	Mean consumers mg/day	95th percentile consumers mg/day
Aust.	Whole population (2 years+)	13754	99.2	365	367	951
	2-6 years	986	99.7	330	331	696
New Zealand	Whole population (15 years+)	4613	99.5	397	399	992

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains octanoic acid.
♦ Consumers only – This only includes the people who have consumed a food that contains octanoic acid.

Table A1.2: Scenario 2 (A513 octanoic acid) estimated octanoic acid dietary exposures

Country	Population group	Number of consumers of octanoic acid	Consumers♦ as a % of total respondents#	Mean all respondents mg/day	Mean consumers mg/day	95th percentile consumers mg/day
Aust.	Whole population (2 years+)	13828	99.8	1.5	1.5	3.5
	2-6 years	989	100	1.1	1.1	2.5
New Zealand	Whole population (15 years+)	4624	99.7	1.6	1.6	3.5

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains octanoic acid.
♦ Consumers only – This only includes the people who have consumed a food that contains octanoic acid.

Table A1.3: Scenario 3 (naturally occurring plus A513 octanoic acid) estimated octanoic acid dietary exposures

Country	Population group	Number of consumers of octanoic acid	Consumers♦ as a % of total respondents#	Mean all respondents mg/day	Mean consumers mg/day	95th percentile consumers mg/day
Aust.	Whole population (2 years+)	13852	99.96	366	366	950
	2-6 years	989	100	331	331	696
New Zealand	Whole population (15 years+)	4631	99.9	399	399	993

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains octanoic acid.
♦ Consumers only – This only includes the people who have consumed a food that contains octanoic acid.

Table A1.4: Estimated HEDP dietary exposures

Country	Population group	Number of consumers of HEDP	Consumers♦ as a % of total respondents#	Mean all respondents mg/day (mg/kg bw/day)	Mean consumers mg/day (mg/kg bw/day)	95th percentile consumers mg/day (mg/kg bw /day)
Aust.	Whole population (2 years+)	13828	99.8	0.15 (0.0026)	0.15 (0.0026)	0.35 (0.0067)
	2-6 years	989	100	0.11 (0.0063)	0.11 (0.0063)	0.28 (0.0151)

New Zealand	Whole population (15 years+)	4624	99.7	0.15 (0.0021)	0.15 (0.0021)	0.33 (0.0045)

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains HEDP.
♦ Consumers only – This only includes the people who have consumed a food that contains HEDP.

Table A.1.5: Scenario 1 (naturally occurring octanoic acid) contribution of each food group to total octanoic acid dietary exposure for all population groups assessed for Australia and New Zealand

Food Name	**% Contribution to octanoic acid dietary exposure**		
	Australia 2 years and above	**Australia 2-6 years**	**New Zealand 15 years and above**
Milk	**82.7**	**90.5**	**85.8**
Goat milk	0.04	0.08	0.02
Coconut oil, refined	0.7	1.1	0.7
Poultry eggs	2.1	1.3	2.9
Coconut	**13.3**	**6.5**	**9.7**
Bulb vegetables	1.2	0.5	0.9
Garlic	0.01	0.00	0.01

Table A.1.6: Scenario 2 (A513 octanoic acid) contribution of each food group to total octanoic acid dietary exposure for all population groups assessed for Australia and New Zealand

Food Name	**% Contribution to octanoic acid dietary exposure**		
	Australia 2 years and above	**Australia 2-6 years**	**New Zealand 15 years and above**
Olives, processed	0.05	0.01	0.02
Berries and other small fruits	**6.3**	3.0	**6.4**
Citrus fruits	**15.4**	**24.1**	**7.3**
Tropical fruit – inedible peel	**5.1**	**8.4**	4.8
Pome fruits	**7.9**	**19.5**	**6.8**
Stone fruits	2.0	1.8	1.9
Tropical fruits – edible peel	0.04	0.05	0.09
Fat, mammalian	0.05	0.01	1.3
Meat, mammalian	**30.1**	**20.8**	**33.7**
Offal, mammalian	0.2	0.08	0.5
Poultry fat	-	-	-
Poultry meat	3.2	2.0	2.8
Poultry offal	0.02	0.00	0.01
Bulb vegetables	2.4	1.2	1.8
Brassica vegetables	2.4	0.9	2.7
Cucurbits	3.2	2.3	2.4
Pulses	0.7	0.7	1.0
Leafy vegetables	1.2	0.4	1.6
Other fruiting vegetables	**7.7**	**5.0**	**6.5**
Legume vegetables	2.0	1.1	1.8
Root and tuber vegetables	**9.6**	**8.3**	**16.1**
Stalk and stem vegetables	0.6	0.2	0.4

Table A.1.7: Scenario 3 (naturally occurring and A513 octanoic acid) contribution of each food group to total octanoic acid dietary exposure for all population groups assessed for Australia and New Zealand

Food Name	**% Contribution to octanoic acid dietary exposure**		
	Australia 2 years and above	**Australia 2-6 years**	**New Zealand 15 years and above**
Olives, processed	0.00	0.00	0.00
Berries and other small fruits	0.03	0.01	0.03
Citrus fruits	0.06	0.08	0.03
Tropical fruit – inedible peel	0.02	0.03	0.02
Pome fruits	0.03	0.06	0.03
Stone fruits	0.01	0.01	0.01
Tropical fruits – edible peel	0.00	0.00	0.00
Fat, mammalian	0.00	0.00	0.00
Milk	**82.3**	**90.2**	**85.4**
Goat milk	0.04	0.08	0.02
Meat, mammalian	0.1	0.07	0.1
Offal, mammalian	0.00	0.00	0.00
Coconut oil, refined	0.7	1.1	0.7
Poultry eggs	2.0	1.3	2.9
Poultry fat	-	-	-
Poultry meat	0.01	0.01	0.01
Poultry offal	0.00	0.00	0.00
Coconut	**13.3**	**6.5**	**9.7**
Bulb vegetables	1.2	0.5	0.9
Garlic	0.01	0.00	0.01
Brassica vegetables	0.01	0.00	0.01
Cucurbits	0.01	0.01	0.01
Pulses	0.00	0.00	0.00
Leafy vegetables	0.01	0.00	0.01
Other fruiting vegetables	0.03	0.02	0.03
Legume vegetables	0.01	0.00	0.01
Root and tuber vegetables	0.04	0.03	0.06
Stalk and stem vegetables	0.00	0.00	0.00

Table A.1.8: Contribution of each food group to total HEDP dietary exposure for all population groups assessed for Australia and New Zealand

Food Name	% Contribution to HEDP dietary exposure		
	Australia 2 years and above	**Australia 2-6 years**	**New Zealand 15 years and above**
Olives, processed	0.06	0.01	0.02
Berries and other small fruits	**7.8**	3.5	**8.3**
Citrus fruits	**19.2**	**27.9**	**9.5**
Tropical fruit – inedible peel	**6.3**	**9.7**	**6.3**
Pome fruits	**9.9**	**22.5**	**8.9**
Stone fruits	2.5	2.0	2.5
Tropical fruits – edible peel	0.05	0.06	0.1
Fat, mammalian	0.02	0.00	0.6
Meat, mammalian	**12.4**	**7.9**	**14.3**
Offal, mammalian	0.1	0.03	0.2
Poultry fat	-	-	-
Poultry meat	4.9	2.9	4.7
Poultry offal	0.02	0.00	0.02
Bulb vegetables	2.9	1.4	2.3
Brassica vegetables	2.9	1.0	3.6
Cucurbits	3.9	2.7	3.2
Pulses	0.8	0.8	1.3
Leafy vegetables	1.5	0.5	2.0
Other fruiting vegetables	**9.5**	**5.8**	**8.5**
Legume vegetables	2.5	1.3	2.3
Root and tuber vegetables	**11.9**	**9.6**	**21.0**
Stalk and stem vegetables	0.7	0.3	0.6

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Attachment 6

Summary of submissions

Four submissions were received on the Initial Assessment Report:

Department of Agriculture, Fisheries and Forestry (DAFF)

DAFF views the Application as a routine application with no regulatory impact under the Imported Food Control Act 1992.

Queensland Health

At this time neither accepts or rejects the Application but will review their position once a safety assessment and additional data requested from the Applicant has been reviewed by FSANZ.

New Zealand Food Safety Authority

- Agrees that FSANZ needs to seek additional data on use of octanoic acid for fruit and vegetables. The safety assessment will need to take into account that consumers may eat the skins of fruit and vegetables without washing, peeling or heating the product first.
- The Food Technology Report should consider if there is a technological need on fruit and vegetables.
- The effectiveness of octanoic acid against pathogens of concerns should be demonstrated.
- The drafting in the Code should be clear that permission is granted for the mixture and its resulting products and suggest that the USFDA approach (where individual components of the formulation are approved) be used.
- The status of HEDP needs to be clearly addressed in the Draft Assessment report.
- The safety assessment needs to consider the safety of all components and any resulting residues.

Australian Food and Grocery Council

Supports the approval of Application A513, subject to an appropriate safety assessment by FSANZ.

Food Technology Association of Victoria (FTA)

Supports the Application.