12 December 2001
06/02

INITIAL ASSESSMENT REPORT
(PRELIMINARY ASSESSMENT S.13)

APPLICATION A429

USE OF HYDROGEN PEROXIDE, PERACETIC ACID AND CARBONIC ACID AS MICROBIOLOGICAL CONTROL AGENTS

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter: **6 FEBRUARY 2002** (See 'Invitation for Public Submissions' for details)

SUMMARY

An application was received from Vaporex Pty Ltd on 11 January 2001 to amend Volume Two of the *Food Standards Code* to broaden the permission for using hydrogen peroxide, peracetic acid and carbonic acid as processing aids for use as microorganism control agents on food. This would require amending Standard 1.3.3 – Processing Aids.

The process uses a moist gaseous stream of hydrogen peroxide and/or acetic acid (producing peracetic acid) in carbon dioxide as a carrier gas, which is directed onto food surfaces to reduce microbiological spoilage organism numbers. The gases are applied just prior to packaging to extend the shelf life of the food.

The residual concentrations of the applied chemicals on the treated packaged foods are stated to be very low, and in most cases below detection limits after one to two days storage time, due to the reactive and volatile nature of the chemicals used.

This application fulfils the requirements for Initial Assessment (Preliminary Assessment) as prescribed in section 13 (2) of the *Australia New Zealand Food Authority Act, 1991*. The application relates to a variation of a food regulatory measure (the best measure to address the application), and is not similar to any previous application. The direct and indirect benefits and costs to the community from the application will be further addressed at draft assessment.

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

1. PROBLEM

The current permissions in the *Food Standards Code* for use of hydrogen peroxide, peracetic acid and carbonic acid as food processing aids are limited to a small number of specific uses. An amendment to the *Food Standards Code* is required to provide broader permissions for the use of these chemicals as microbiological agents.

2. ISSUES

Process Details

Vaporex developed a food treatment process where a blend of hydrogen peroxide and acetic acid (to form peracetic acid) as moist vapours in various ratios, or either chemical alone, in a carbon dioxide carrier gas is used to treat food as a microbiological control agent. Vaporex has Australian and international patents for their process. Gaseous carbon dioxide is bubbled through separate aqueous solutions of hydrogen peroxide and acetic acid so producing a vapourous stream of moist hydrogen peroxide and acetic acid (or one individual chemical) in carbon dioxide carrier gas. The applicant also believes carbonic acid (produced by bubbling carbon dioxide through aqueous solutions or from the reaction of carbon dioxide with moisture on food) is important for their process so permission is requested for its use. This treatment is used to reduce microbiological contamination on the surface of the food, just prior to packaging, and to extend the shelf life of the food.

Foods Proposed to be Treated

The applicant has not limited their application to specific foods, although they have mentioned a few food examples, which they have tested and they supplied data as part of their application. Examples of such foods are sliced sandwich ham, sliced chicken, sliced cheese, crumpet-splits, sliced bread, frankfurt sausages and packaged peaches. The applicant also mentions general food categories, meat and chicken, smallgoods, cheese, frozen meals, baked goods, "fresh" pasta, wholegrain cereals, herbs, spices "fresh" fruit and dried fruit, which they think could be treated by their technology. The applicant requests that the permission for use of these chemicals as processing aids in the *Food Standards Code* be applicable to all foods.

Technological Justification

The efficacy and technical justification of the application will be assessed in detail during the Draft Assessment.

The applicant is currently working with a number of food manufacturers. Some technical data has been supplied with the application supporting the technical justification. Three letters of support, from Primo Smallgoods, George Weston Foods and Food Science Australia have been supplied giving technical support for the applicant's process.

Public Health and Safety Issues

The applicant submits that the chemicals are applied to the surfaces of the food at low levels. The levels of residual chemicals are likely to be low as they are reactive and many of the reaction products are volatile. The applicant claims that the residual amount of these compounds, expressed for the total mass of food treated will be lower than current permissions for some of the proposed applications (i.e. 5 mg/kg (ppm) for hydrogen peroxide as a processing aid). Data has been supplied supporting this claim, which will need to be fully assessed. A safety assessment of any chemical residues on food will be performed as part of the draft assessment.

Overseas Approvals

The applicant has stated that they are not aware of any similar application made to other international regulatory agencies to use hydrogen peroxide and peracetic acid for microorganism control purposes on food.

The USA Food and Drug Administration (FDA) has recently (19th September 2001) amended the Code of Federal Regulations to allow the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and 1-hydroxyethylidene-1, 1-diphosphonic acid as an antimicrobial agent on poultry carcasses, poultry parts, and organs (21 CFR section 173.370 Peroxyacids).

Relevant Provisions in Code

Currently there are permissions in both Volume One and Two of the *Food Standards Code* for use of hydrogen peroxide, peracetic acid, acetic acid and carbonic acid as processing aids.

Hydrogen Peroxide

Volume One of the *Food Standards Code*

The following extracts from tables are the current approvals for hydrogen peroxide in Volume One of the *Food Standards Code*. All the approvals have a maximum permitted residue of 5 mg/kg.

Standard A16, Table II Group II "Bleaching agents, washing and peeling agents".

Column 1 **Substance**	**Column 2** **Maximum permitted residue (mg/kg)**
Hydrogen peroxide	5

Standard A16, Table III "Processing aids with miscellaneous functions".

Column 1 **Substance**	**Column 2** **Function**	**Column 3** **Maximum permitted residue (mg/kg)**
Hydrogen peroxide	Micro-organism control agent for dried vine fruits, fruit and vegetable juices, sugar, vinegar and yeast autolysate	5
	Removal of glucose from egg products	5
	Removal of sulphur dioxide	5

Standard A16, Table VI "Processing aids used in packaged water and in water used as an ingredient in other foods".

Column 1 **Substance**	**Column 2** **Maximum permitted residue (mg/kg)**
Hydrogen peroxide	5

Volume Two of the *Food Standards Code*

The approvals in Volume One have been included in Volume Two.

The permission in Volume One, Standard A16, Table II, Group II is included in Volume Two, Standard 1.3.3, the Table to clause 12.

The permission in Volume One, Standard A16, Table III is included in Volume Two, Standard 1.3.3, the Table to clause 14.

The permission in Volume One, Standard A16, Table VI is included in Volume Two, Standard 1.3.3, the Table to clause 11.

Peracetic Acid

Volume One of the *Food Standards Code*

The following extracts from tables are the current approvals for peracetic acid in Volume One of the *Food Standards Code*.

Standard A16, Table II Group II "Bleaching agents, washing and peeling agents".

Column 1 **Substance**	**Column 2** **Maximum permitted residue (mg/kg)**
Peracetic acid	NS

Standard A16, Table II Group III "Catalysts".

Column 1 **Substance**	**Column 2** **Maximum permitted residue (mg/kg)**
Peracetic acid	0.7

Volume Two of the *Food Standards Code*

Again the permissions listed for peracetic acid in Volume One are included in Volume Two.

The approval for Volume One, Standard A16, Table II, Group II is included in Volume Two, Standard 1.3.3, the Table to clause 12, for all foods at levels determined by GMP (Good Manufacturing Practice).

The approval for Volume One, Standard A16, Table II, Group III is included in Volume Two, Standard 1.3.3, the Table to clause 5.

Acetic Acid

Acetic acid has general permission as a processing aid in Volume One, Standard A16, Table I and in Schedule 2 of Standard 1.3.1 as a miscellaneous food additive. Clause 3 of Standard 1.3.3 states that food additives listed in Schedule 2 of Standard 1.3.1 have permissions as generally permitted processing aids.

Carbonic Acid

The applicant states that carbonic acid is required for their process to be effective. Carbonic acid currently only has permission as a bleached tripe washing agent at levels determined by GMP.

Volume One of the *Food Standards Code*

Standard A16, Table III "Processing aids with miscellaneous functions".

Column 1	**Column 2**	**Column 3**

Substance	Function	Maximum permitted residue (mg/kg)
Carbonic acid	Bleached tripe washing agent	NS

Volume Two of the *Food Standards Code*

The permission in Volume One, Standard A16, Table III is included in Volume Two, Standard 1.3.3, the Table to clause 14, at levels determined by GMP.

Carbon dioxide is listed in Schedule 2 of Standard 1.3.1 and is a generally permitted processing aid. The applicant states that carbon dioxide contains a small amount of carbonic acid, due to the small amount of water found in commercial carbon dioxide gas cylinders. They argue that separate approval for carbonic acid as an approved processing aid is not required. A separate permission for carbonic acid as a processing aid maybe required for consistency with the current permission for carbonic acid as a bleached tripe washing agent.

3. OBJECTIVE

The objective of this application is to determine whether treating food with gaseous hydrogen peroxide and acetic acid in carbon dioxide to control micro-organisms is safe for consumers and technically justified.

4. OPTIONS

Options available are:

Option 1. Not to allow a broadening of the permissions for the use of hydrogen peroxide, peracetic acid and carbonic acid as processing aids and thus restrict their use to control microorganisms on food.

Option 2. Allow a broadening of the permissions for the use of hydrogen peroxide, peracetic acid and carbonic acid as processing aids in order that they may be used to control microorganisms on a broader range of foods.

5. IMPACT ANALYSIS

Parties affected by the options outlined above include:

1. Those sectors of the food industry wishing to use hydrogen peroxide, peracetic acid and carbonic acid as microorganism control agents on food. Specifically the applicant and other similar companies with knowledge and experience in the technologies outlined in the application.

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

3. Government agencies enforcing the food regulations.

6. CONSULTATION

This Initial Assessment Report will be made available for public submissions. This allows interested parties (food industry groups, food companies, consumers and consumer groups and government agencies) to make submissions including any technical matters that may be relevant.

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

- Technical justification and efficacy of the application;
- Safety of the residues on food;
- Potential costs and benefits to consumers, industry and government.

7. OTHER RELEVANT MATTERS

Workplan Classification

The scoping of this application placed it in Workplan group 2, category 3 (see ANZFA website for further information about the Workplan and the different groups and categories).

Commercial-in-confidence

There are no commercial-in-confidence claims with this application.

WTO Implications

As a member of the World Trade Organisation (WTO) Australia must 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.

The *Food Standards Code* contains mandatory standards applying to both domestic and imported food. Suppliers of food products are not required to take up permissions granted through amendments to the Code, however, food products not complying with the Code cannot legally be supplied in Australia and New Zealand.

Amending the Code to broaden the permissions for hydrogen peroxide, peracetic acid and carbonic acid as processing aids to act as microorganism control agents is unlikely to significantly affect trade. This issue will be fully considered in the context of the Regulatory Impact Statement at draft assessment and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

8. CONCLUSIONS

This application warrants a variation of a food regulatory measure, as provided for in section 13 (2) of the *Australia New Zealand Food Authority Act 1991*. The identification of costs and benefits arising from any food regulatory measure so

developed will be further assessed at draft assessment and will take into account public submissions.

Accordingly, the Authority has decided to accept Application A429 and is seeking public comment before moving to undertake a more detailed draft assessment (that is, full assessment under section 15 of the *Australia New Zealand Food Authority Act 1991*). Following the completion of the draft assessment, the Authority may prepare a draft amendment to the *Food Standards Code* or reject the application. If the Authority prepares a draft amendment, a further round of public consultation will be held before a final assessment is made (that is, before an inquiry is held under section 18 of the *Australia New Zealand Food Authority Act 1991*).

The Authority may then recommend to the Ministerial Council that it adopt the draft variation to the *Food Standards Code,* with or without amendment, or that it reject it.

9. FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code,* as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code,* but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974,* and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

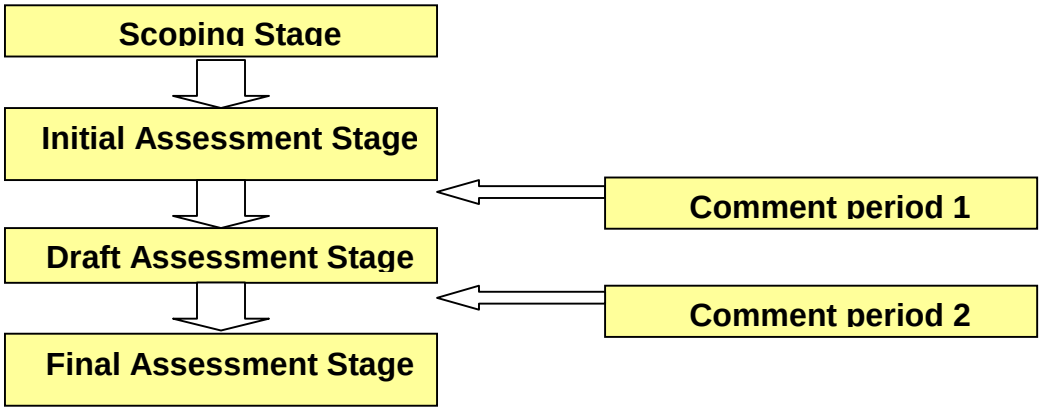
10. INVITATION FOR PUBLIC SUBMISSIONS

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the ANZFA Act 1991. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code.

Any individual or organization may make an 'application' to the Australia New Zealand Food Authority (the Authority) seeking to change the Code. The Authority itself, may also seek to change the Code by raising a 'proposal'. In the case of both applications and proposals there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. This process varies for matters that are urgent or minor in nature.

Following the initial assessment of an application or proposal the Authority may decide to accept the matter and seek the views of interested parties. If accepted, the Authority may then undertake a draft assessment including preparing a draft standard or draft variation to a standard (and supporting draft regulatory impact statement). If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the final assessment, which the Authority will hold to consider the draft standard or draft variation to a standard.

Comment opportunities in the usual assessment process
to change the Australia New Zealand Food Standards Code
(Note: this process may vary for matters that are urgent or minor)



Content of Submissions
Written submissions containing technical or other relevant information which will assist ANZFA in undertaking an assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organizations. 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 presented should be in sufficient detail to allow independent scientific assessment.

Submissions may provide more general comment and opinion on the issue although those framing their submissions should bear in mind ANZFA's regulatory role specifically relates to food supplied for human consumption in Australia and New Zealand. The ANZFA Act 1991 sets out the objectives of the Authority in developing food regulatory measures and variations of food regulatory measures as:

(a) the protection of public health and safety; and
(b) the provision of adequate information relating to food to enable consumers to informed choices; and
(c) the prevention of misleading or deceptive conduct.

In developing food regulatory measures and variations of food regulatory measures The Authority must also have regard to the following:

(a) the need for standards to be based on risk analysis using the best available scientific evidence;
(b) the promotion consistency between domestic and international food standards;
(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food.

Submissions addressing the issues in the context of the objectives of the Authority as set out in the *ANZFA Act 1991* will be more effective in supporting their case.

Transparency
The processes of ANZFA are open to public scrutiny, and any submissions will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA 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 reasonable be expected to be destroyed or diminished by disclosure.

Contact details for submitters are recorded so that the Authority can continue to keep them informed about progress of the application or proposal.

Deadlines
The deadlines for submissions are clearly indicated in the advertisements calling for comment and in the relevant Assessment Reports. While the Authority often provides comment periods of around 6 weeks, the periods allowed for comment may vary and may be limited to ensure critical deadlines for projects can be met. Unless the Project Manager has given specific consent for an extension, the Authority cannot guarantee that submissions received after the published closing date will be considered.

Delivery of Submissions
Submissions must be made in writing and should be clearly marked with the word **'Submission'** and **quote the correct project number and title**. Submissions may be sent by mail, fax or email to one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
Fax (02) 6271 2278
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
Fax (04) 473 9855
email: anzfa.nz@anzfa.gov.au

Submissions should be received by the Authority by: 6 FEBRUARY 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

Further Information
Further information on the application and submission process should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the above addresses.

Assessment reports are available for viewing and downloading from the ANZFA website or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.