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INFORMATION SUMMARY

APPLICATION A411

PASTEURISATION OF ORANGE JUICE OR LABELLING OF UNPASTEURISED ORANGE JUICE

The Australia New Zealand Food Authority has received an application to amend the Australian *Food Standards Code* on the above matter. The Authority's Preliminary Assessment Report is provided below and provides further detail. The Authority now invites public submissions on any issue raised in the Report for the purposes of making a full assessment.

PRELIMINARY ASSESSMENT REPORT

Applicant: South Australian Department of Human Services

Date received: 23 March 2000

BACKGROUND:

The South Australian Department of Human Services has made an application to vary Standard O7, Orange Juice and Related Products, in the Australian Food Standards Code (AFSC). The applicant proposes a provision in Standard O7 requiring all orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises, to either:

- (i) undergo a pasteurisation process that would kill pathogenic bacteria; or
- (ii) be labelled to ensure consumers are informed of the risks associated with the consumption of unpasteurised orange juice.

Acidic foods such as orange juice have not been routinely regarded as likely sources of enteric infections such as salmonellosis. Recent salmonella outbreaks in South Australia and in the United States have been associated with the consumption of unpasteurised orange juice. In early 1999, over 500 cases of *Salmonella* Typhimurium phage type 135a were reported to the South Australian Department of Human Services. A case control study implicated a brand of commercially available unpasteurised orange juice. In 1996, in the United States there were outbreaks of *Escherichia coli* 0157:H7 infections and cryptosporidiosis associated with unpasteurised apple cider and apple juice.

In August 1999, the Australia New Zealand Food Standards Council (ANZFSC) discussed the management of public health risks associated with the consumption of unpasteurised orange juice in response to the South Australian incident. ANZFSC supported the proposal by the

South Australian Department of Human Services to make an application to ANZFA to amend Standard O7 of the AFSC.

Currently, the AFSC does not require either the pasteurisation of any juice (including orange juice) or the labelling of any unpasteurised juice as 'unpasteurised'. However, currently the majority of orange juice and other juice products are pasteurised. The New Zealand Food Regulations 1984 require that fruit juices be prepared in accordance with Good Manufacturing Practice. (Reg 184)

OBJECTIVE:

The applicant proposes to vary Standard O7, Orange Juice and Related Products in the AFSC by requiring that all orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises, either:

- (i) undergo a pasteurisation process that kills pathogenic bacteria; or
- (ii) be labelled to ensure consumers are informed that the product is unpasteurised and are made aware of the risks associated with its consumption.

The applicant does not intend that the proposed requirement would apply to freshly squeezed orange juice or to juice which was expressed for immediate consumption by the consumer.

The applicant proposes that the following process may be considered an effective pasteurisation step, although acknowledges it would require further assessment:

- (i) heating the juice to not less than 72°C for 15 seconds; or
- (ii) heating the juice to any other time and temperature that can be demonstrated to produce a 5-log reduction in the most resistant microorganism of public health significance likely to occur in the product.

The applicant contends that the proposed provision provides increased protection of public health and safety and enables consumers to make more informed choices regarding the purchase of unpasteurised orange juice.

DIETARY IMPLICATONS

All fruit juice, including orange juice is a good source of Vitamin C. Currently, Standard O7 in the AFSC, requires orange juice and reconstituted orange juice to contain no less than 400mg/L of vitamin C (ascorbic acid).

Vitamin C is a heat labile vitamin. Pasteurisation and other heat treatments will reduce the level of vitamin C in orange juice and other juices processed in this way. However, Standard A9 in the AFSC permits the addition of Vitamin C to orange juice and other juices.

POSSIBLE OPTIONS

OPTION 1

Maintain the status quo and do not require orange juice or any other juice to be either pasteurised or labelled as unpasteurised.

OPTION 2

Amend the AFSC as requested and include a requirement for orange juice other than freshly squeezed orange juice for immediate consumption on the same premises, to either:

- (i) undergo a pasteurisation process that would kill pathogenic bacteria or another process which provides an equivalent safety outcome; or
- (ii) be labelled to ensure consumers are informed that the product is unpasteurised and are made aware of the risks associated with its consumption.

Option 3

Amend the AFSC and include a requirement for all fruit and vegetable juices including cider, other than freshly squeezed juices for immediate consumption on the same premises, to either:

- (i) undergo a pasteurisation process that would kill pathogenic bacteria or another process which provides an equivalent safety outcome; or
- (ii) be labelled to ensure consumers are informed that the product is unpasteurised.

IDENTIFICATION OF AFFECTED PARTIES

Parties affected by the options listed above include:

- Manufacturers and importers of orange juice, orange juice products, juice and juice products.
- Government agencies regulating the food industry in Australia and New Zealand.
- Consumers of orange juice, orange juice products, juice and juice products.

POTENTIAL REGULATORY IMPACTS

Option 1

- May result in a risk to public health and safety given the recent food poisoning outbreaks associated with unpasteurised orange juice and similar products.
- In the event of an outbreak of food borne illness, there are significant costs to the community in providing health care and undertaking enforcement activities. There are also productivity losses due to absences from work for those affected by such an outbreak.
- Industry would be advantaged by this approach as they would not incur any additional processing or labelling costs.

Option 2

- Option 2 would impose additional labelling costs on manufacturers with respect to warning statements on unpasteurised orange juice.
- Manufacturers may incur additional processing costs in complying with specified pasteurisation requirements.
- Retailers and restaurants preparing freshly squeezed orange juice for immediate consumption would be exempt from these requirements and subsequent costs.
- Consumers may be advantaged by the ability to clearly identify pasteurised and unpasteurised orange juice.
- Consumers may be disadvantaged if unable to distinguish between other pasteurised and unpasteurised juices, hence the potential for consumers to be exposed to a health risk remains.
- Option 2 is not equitable for identified affected parties, particularly for processors of orange juice.

- Option 2 may result in additional enforcement costs.

Option 3

- Option 3 would impose additional costs for manufacturers processing and packaging for sale any pasteurised and unpasteurised juice or juice product.
- Retailers and restaurants preparing freshly squeezed juice for immediate consumption would be exempt from these requirements and subsequent costs.
- Consumers would be advantaged by the provision of specific information about pasteurised and unpasteurised juice and juice products and could therefore make more informed purchase decisions.
- Any potential health and safety risk for all juices would be addressed by specified processing requirements or by proposed labelling requirements.
- Option 3 may result in additional enforcement costs.

CONSIDERATION OF ISSUES UNDER SECTION 13

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, and is not so similar to a previous application that it ought not be accepted.

Costs and benefits arising for any food regulatory measure or other measures developed or varied as a result of this application, will be further considered at Full Assessment.

OTHER RELEVANT MATTERS

AUSTRALIAN FOOD SAFETY STANDARDS

Clause 5 of draft Standard 3.2.2 proposed for inclusion in the joint Australia New Zealand Food Standards Code, intends that food businesses must, where a process step is needed to reduce to safe levels any pathogens which may be present in food, use a process step that is reasonably known to achieve the microbiological safety of the food. When adopted, the Food Safety Standards will address the processing requirements for orange juice and similar products. These standards will not apply in New Zealand.

The proposed Food Safety Standards do not propose specific labelling requirements with respect to processing.

CODEX REGULATIONS

There is currently no requirement in any of the Volume 6 Codex Standards for fruit juices and related products for the pasteurisation of juice or the labelling of unpasteurised juice. It is recommended that products covered by individual standards within Volume Six are prepared in accordance with the General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev 2 – 1985).

UNITED STATES

From September 1998, the US Food and Drug Administration require that fruit juice products carry warning statements unless they have been pasteurised or treated in another way capable of achieving a 5-log reduction in pertinent microorganisms. The warning statement required is:

Warning: *This product has not been pasteurised and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.*

CONCLUSIONS

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, as provided for in section 13 of the *ANZFA Act 1991*. Costs arising from any food regulatory measure so developed will be assessed at Full Assessment.

Accordingly ANZFA has decided to accept the application and will now make a full assessment of it.

If subsequently recommended by ANZFA and agreed to by the Australia New Zealand Food Standards Council, an amendment to the Code, as suggested by the applicant, would require all orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises, to either:

- (i) undergo a pasteurisation process that would kill pathogenic bacteria or another process which provides an equivalent safety outcome; or
- (ii) be labelled to ensure consumers are informed that the product is unpasteurised and are made aware of the risks associated with its consumption.

Such an amendment, if successful, would also be necessary in draft Standard 1.2.3 Mandatory Warning and Advisory Statements in the joint Australia New Zealand Food Standards Code.

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. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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 the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia other than from New Zealand** must comply solely with the *Australian Food Standards Code*.
- **Food imported into New Zealand from Australia** must comply with either the *Australian Food Standards Code* or the *New Zealand Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the *Australian Food Standards Code*. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may be imported into Australia from New Zealand if it complies with the *New Zealand Food Regulations 1984* or *Dietary Supplements Regulations 1985*.

- **Food manufactured in Australia and sold in Australia** must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

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*.

INVITATION FOR PUBLIC SUBMISSIONS

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

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for public inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. 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 inquiry which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A411** at one of the following addresses:

Australia New Zealand Food Authority	Australia New Zealand Food Authority
PO Box 7186	PO Box 10559
Canberra Mail Centre ACT 2610The Terrace	WELLINGTON 6036
AUSTRALIA	NEW ZEALAND
Tel (02) 6271 2222 Fax (02) 6271 2278	Tel (04) 473 9942 Fax (04) 473 9855

The Authority should receive submissions by **5 July 2000**.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general

information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.