

10 October 2001
05/02

FINAL ASSESSMENT REPORT
(Inquiry - s.17)

APPLICATION A411

**PASTEURISATION OF ORANGE JUICE & LABELLING OF
UNPASTEURISED JUICE**

EXECUTIVE SUMMARY

- In early 1999, a food poisoning outbreak occurred in South Australia that affected over 500 people. The implicated food was unpasteurised orange juice, which had been contaminated with *Salmonella typhimurium* phage type 135a.
- 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. ANZFSC supported a proposal by the South Australian Department of Human Services to make an application to ANZFA to amend Standard O7 - Orange Juice and Related Products of the *Food Standards Code*.
- In March 2000, ANZFA received an Application from the South Australian Department of Human Services to require all orange juice, other than freshly squeezed orange juice for immediate consumption, to be pasteurised or labelled to ensure consumers are informed of the risks associated with the consumption of unpasteurised orange juice.
- In response to the Application, eleven submissions were received at full assessment and nine at inquiry. Submissions generally supported processing requirements for all juices, not just orange juice, and some form of labelling to enable unpasteurised juices to be identified.

- The objective of the Full Assessment Report was to assess the public health risks associated with orange juice and other juices and if a risk was identified, to propose an appropriate management strategy to address that risk.
- The risk assessment in the Full Assessment Report concluded that all juice (fruit and vegetable) has the potential to be contaminated with microbiological hazards and that juice that has not undergone any form of treatment is more likely to be contaminated with pathogens than treated juice. It also concluded that while there is a low probability of untreated juice being contaminated with dangerous pathogens, if it is, the consequences can be severe for at-risk groups and in extreme cases death could occur.
- Five options were considered for managing the risks associated with untreated juices at full assessment, ranging from having no management strategy to requiring all juice to be processed in accordance with a Hazard Analysis Critical Control Point (HACCP) system that includes a 5-log reduction process for the destruction of pathogens that may be present in the juice. A sixth option has been considered in this report within Attachment 4 *Revised Regulatory Impact Analysis*.
- The preferred option in the Full Assessment Report was option 4 as it was considered to be the most cost effective way of managing the potential risks associated with untreated juice and was in line with ANZFA's section 10 objectives. However, as a result of submissions received on the Full Assessment Report and further consideration by ANZFA, the preferred option at inquiry is option 6. This option is similar to option 4 with the following exceptions:
 - it further clarifies the labelling statement by requiring untreated juices to be labelled with a statement to the effect that 'the product has not been pasteurised or treated to achieve the equivalent result'. The previous recommendation to label the products only as 'unpasteurised' could be considered misleading, as it does not recognise that juices can be pasteurised *or* subjected to an alternative equivalent treatment;
 - it permits citrus fruits to include surface treatments as contributing to the 5-log reduction process. While it was intended that this be permitted, this had not been reflected in the drafting;
 - it restricts the 5-log reduction process to being undertaken within a single facility. This has been proposed to ensure that the 5-log reduction process, if it is to be conducted in stages, is effective. If the log reduction process is conducted at different facilities, there is more opportunity for further contamination to occur; and
 - it no longer includes mandatory microbiological criteria for not detected levels of *Escherichia coli* and *Salmonella* in untreated juice. The main reason for this recommendation is that the majority of untreated juice will be consumed before test results are available and therefore this requirement was likely to only have a minimal impact on public health.

- The revised regulatory analysis in Attachment 4 also concludes that option 6 is the most cost effective risk management option for addressing the public health risks associated with untreated juices.
- Option 6 is a combination of regulatory and non-regulatory measures. These measures are outlined below.

Regulatory measures

- labelling of packaged juice with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’, if the juice has not undergone a process capable of achieving at least a 5-log reduction of the most resistant pathogen of public health significance likely to occur in the juice;
- the 5-log reduction process would need to be conducted on the juice itself with the exception of citrus fruits. Surface treatments could be applied to citrus fruits after the fruit is cleaned (i.e. washed) and culled (i.e. damaged or dropped fruit is removed);
- all 5-log reduction processes would need to be conducted within a single facility.

Non-regulatory measures

- a voluntary code of practice for producers of untreated juices outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice; and
- consumer education to increase awareness of the potential risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace.
- It is recommended that the regulatory measures not commence until six months after the gazettal of the requirements to provide producers of juice sufficient time to become familiar with the requirements and if necessary, make labelling changes and change any of their processing practices.
- This matter has already been advised to the WTO as a Technical Barrier to Trade Notification because imported product will come under the scope of the proposed requirements and there are no similar requirements specified by Codex.

Previous Authority consideration

Full assessment was undertaken at ANZFA68 in May 2001 and the Application was advertised for comment on 30 May 2001. The comment period closed on 11 July 2001.

Summary of new submissions received at Inquiry

Nine submissions were received in response to the Full Assessment Report. Of these submissions, three were from government, three from the fruit juice industry and one from a consumer group. Submissions were also received from the Food Technology Association of Victoria and InforMed Systems.

Of the submissions received, six supported or supported with some reservation the preferred option, one did not support the preferred option and one offered neither support or non-support for the preferred option.

A full summary of the issues raised in the submissions is included at Attachment 3. The main issues raised in the submissions were:

- whether the microbiological standards should be mandatory;
- concern that untreated juices which are made and packaged from the premises where they are sold will not be required to be labelled as ‘unpasteurised’;
- concern that consumers will consider any juice that is not ‘pasteurised’ as unsafe even if it has undergone an equivalent process. This was perceived to severely disadvantage producers of these juices due to loss of sales and the need for these producers to embark on a costly re-education and re-labelling program to advise consumers of the safety of these juices;
- concern about the lack of detail on the proposed consumer education strategy, particularly who will manage it and who will pay for it – producers of untreated juice could turn the ‘unpasteurised’ label into a positive by claiming it enables a better flavour compared with pasteurised juice;
- whether all fruit and vegetable juices should be covered by the requirements;
- whether ‘freshly squeezed juice’ should be defined and only refer to juice that is squeezed in front of the purchaser and for consumption on the same premises;
- an argument that, as the education strategy is not intending to promote the health benefits of unpasteurised juices, an education strategy of equal strength would be needed to inform consumers of the positive nutritional benefit of unpasteurised juices and the negatives of pasteurised product;
- whether an exemption should be provided for producers that have 3rd party HACCP certification;
- concern that safety requirements, in addition to the Food Safety Standards are considered necessary;
- a proposal that the voluntary code of practice should be mandatory; and
- an argument that option 5, which requires HACCP based food safety programs, should be mandated as it offers the best option for minimising the risks associated with juices.

ASSESSMENT OF ISSUES RAISED IN PUBLIC SUBMISSIONS AT INQUIRY

Following is an assessment of the issues raised in submissions received in response to the full assessment report.

Issues raised in response to option 1 – ‘do nothing’ i.e. maintain the status quo

No submitters supported option 1. However, the National Council of Women of Australia was concerned that the new Food Safety Standards will not provide the level of safety consumers have been led to believe they would and that it is considered necessary and appropriate to specify additional requirements to these Standards. Specifically, the Council is concerned that the Food Safety Standards rely on the manufacturer making a decision as to whether there is a reasonable likelihood or not of food-borne pathogens being present in the juice and as this decision remains subjective, it is not a good determinate for ensuring food safety.

It is agreed that the success of the processing requirement in the new Food Safety Standards in relation to juice relies on the manufacturer determining whether there is a reasonable likelihood of food-borne pathogens being present in the juice and if there are, whether these pathogens need to be destroyed. If the answer to this is yes, the juice must be processed in a way that will achieve the microbiological safety of the food. To answer no to this question, the producer would need to have a high level of assurance that fruit being juiced is not contaminated with pathogens of concern.

The code of practice is intended to complement the above legal requirement within the new Food Safety Standards as well as the general obligation under the New Zealand Food Act for food to be sold that is safe. The code of practice will explain how a producer of untreated juice could obtain a high level of assurance that fruit being juiced is not contaminated and ways to minimise contamination during and after juicing.

Issues raised in response to option 4

Option 4 was ANZFA's preferred option at Full Assessment. The majority of submitters also preferred it. Option 4 consisted of the following regulatory and non-regulatory measures:

Regulatory measures

- labelling of packaged juices as 'unpasteurised' if they have not undergone a process capable of achieving at least a 5-log reduction in the most resistant pathogen of public health significance likely to occur in the juice; and
- mandatory microbiological criteria for untreated juice requiring not detectable levels of *E. coli* and *Salmonella spp.*;

Non-regulatory measures

- a voluntary code of practice for the producers of untreated juices outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice; and
- consumer education to increase awareness of the potential risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace.

The issues raised in response to this option are addressed separately below.

Labelling

- The New Zealand Juice Association is concerned that juices which are made and packaged and sold on the same premises will not be required to carry an 'unpasteurised' statement. This concern is further highlighted by the vagueness of the requirements for a consumer education program.
- The Food Technology Association of Victoria stated that if juice is freshly squeezed but packed for the purchaser with the intention of being taken away from the premises, it should be labelled as 'unpasteurised'.
- The Australian Fruit Juice Association supports the mandatory labelling provision providing there is no exemption for businesses which make and package juice on the same premises from which it is sold.

It is recommended that juices, which are made and packaged on the premises from where they are sold, not be specifically labelled with a statement to the effect that 'the product has not been pasteurised or treated to achieve the equivalent result', for the following reasons:

- in relation to mandatory advisory statements the new joint Food Standards Code requires all food which is made and packaged on the premises from which it is sold to be displayed on or in connection with the food or provided to the purchaser upon request and therefore requiring these juices to be specifically labelled would conflict with the new Code; and
- one of the aims of the consumer education strategy is to inform consumers that freshly squeezed juices are not pasteurised or otherwise treated and if in doubt to ask the seller of the juice.

It is accepted that the education strategy will need to be effective in increasing consumer awareness of the fact that freshly squeezed juices are not pasteurised or otherwise treated. ANZFA is prepared to work with the juice industry on the education strategy.

- Grove Fruit Juice was concerned that ‘unpasteurised’ would refer to any product that has not been subjected to thermal treatment, regardless of any other alternative means of pathogen minimisation.
- Grove Fruit Juices stated that the labelling statement ‘unpasteurised’ does not fully recognise alternative treatments to pasteurisation and infers that pasteurisation is the only means of treatment.

It is agreed that the recommendation at Full Assessment to label untreated juices as ‘unpasteurised’ is potentially misleading as it implies that there are only two groups of products, those that are ‘pasteurised’ and those that are ‘unpasteurised’. This is incorrect. The two groups of products are in fact those that have been ‘pasteurised or treated to achieve the equivalent result’ and those that ‘have not been pasteurised or otherwise treated to achieve the equivalent result’. It is therefore proposed to change the labelling statement proposed at Full Assessment for ‘untreated juices’ to more accurately reflect this group of juices. This is achieved by requiring ‘untreated juices’ to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. The regulatory impact of this new recommendation is discussed under option 6 within the revised regulatory impact analysis at Attachment 4.

- Grove Fruit Juice was concerned that the proposed labelling terminology will result in consumer confusion, with the result that they may believe that any product not pasteurised is unsafe and purchase only products marked as ‘pasteurised’.

As indicated above, it is agreed that the recommendation at Full Assessment to label untreated juices as ‘unpasteurised’ could have been potentially misleading and it is therefore proposed to change this labelling statement to require these juices to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. This should assist consumer understanding that the at-risk groups can safely consume pasteurised products *and* those that have been subjected to an equivalent treatment. It will also be important for the consumer education strategy to explain this.

An editorial note has also been included with the drafting to clarify that producers of juice, which has undergone an equivalent process, can include information on the label to this effect. This will assist consumers identify these products in the marketplace.

- Grove Fruit Juice raised several concerns with the use of the terms ‘unpasteurised’, ‘pasteurised’ and ‘treated’ and ‘untreated’. The definition of treated and untreated is unclear and confusing as the Application refers to unpasteurised juice as being untreated but also to products that have achieved a 5-log reduction as being treated, yet in other contexts as being untreated. ‘Pasteurisation’ is not specifically defined but associated with 5-log reduction. This conflicts with the reference to pasteurisation in Standard 1.6.2 Processing Requirements, which refers to thermal treatments only. The terminology ‘pasteurised’ and ‘unpasteurised’ does not necessarily refer to 5-log reduction.

It is agreed that the decision at Full Assessment to require untreated juices to be labelled as ‘unpasteurised’ was confusing. As stated above, this decision did not fully recognise that juices can be pasteurised or otherwise treated to achieve an equivalent result. The two categories of juices are more correctly categorised as ‘treated’ and ‘untreated’. ‘Treated juices’ are those that have been subjected to the 5-log reduction process whether by pasteurisation or another process. ‘Untreated juices’ are those that have not been subjected to this 5-log reduction process. To assist consumer understanding of the two different categories, it has been proposed above that the labelling statement be changed to require ‘untreated juices’ to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’.

- The Food Technology Association of Victoria stated that ‘unpasteurised juice’ should be adequately labelled with a ‘use by’ date.

The new date marking requirements in Standard 1.2.5 of the Joint Code specifies that only food that needs to be consumed within a certain date because of health or safety reasons is to be date marked with a ‘use by’ date. All other foods requiring date marking must be date marked with a ‘best before’ date. It is the manufacturers responsibility to determine whether a ‘use by’ date is necessary.

However, in respect to ‘untreated juice’ a ‘best before’ date is likely to be more appropriate. Bacterial pathogens will not reproduce in typical fruit juices due to the low pH. The pathogens that have been responsible for the majority of outbreaks in untreated juice, pathogenic *E. coli* and *Salmonella*, do not grow in juice. Therefore younger juice will not be any safer than older juice.

Consumer education Program

- The New Zealand Juice Association raised concerns about the lack of detail as to how a proposed consumer education program would be funded and run. If run within the industry, there will be potential conflict between manufacturers of treated and untreated juice. Those making untreated juice could well turn the ‘unpasteurised’ label into a positive by claiming it enables a better flavour compared with pasteurised juice. There is no requirement for them to indicate to the consumer that there is any risk from being unpasteurised.

It is proposed that the consumer education strategy will be funded and run by ANZFA. ANZFA will work with both producers of treated and untreated juice on the strategy to alleviate these concerns.

- Grove Fruit Juice is concerned that the consumer education strategy will cause alarm amongst consumers and no matter how it is proposed and presented it will imply that ‘fruit juice is no longer safe’.

As per the comment above, ANZFA is prepared to work with both producers of treated and untreated juice on the strategy. ANZFA also considers that the proposed change to the labelling statement will better assist consumers to distinguish between the ‘treated’ and ‘untreated’ juices in the marketplace.

- Grove Fruit Juice stated that the education program is not intending to promote the health benefits of unpasteurised juices. Therefore, an education strategy of equal strength would be needed to inform consumers of the positive nutritional benefit of unpasteurised juices and the negatives of pasteurised product.

The proposed consumer education strategy is not intended to discuss the nutritional benefits of either unpasteurised or pasteurised juice. The strategy will aim to increase awareness of the potential risks associated with untreated juices, particularly for at-risk groups and provide advice on how to distinguish between treated and untreated juices in the marketplace. This does not prevent producers of juice from marketing their products.

- Grove Fruit Juice consider that the education strategy provides a competitive advantage to producers in the market who use pasteurisation processing methods and can market directly against those who are using alternatives but still achieving a 5-log reduction. Producers of products using alternatives to pasteurisation (but still achieving 5-log reduction) are therefore severely disadvantaged. The producers will need to embark on a costly re-education and re-labelling program to advise consumers of the safety of their products and to negate the adverse publicity engineered and financed by government.

ANZFA is proposing to change the labelling requirement for ‘untreated juices’ from ‘unpasteurised’ to a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. This should better enable consumers to understand that at-risk groups can safely consume both pasteurised products as well as those that have been subjected to an alternative treatment. An editorial note has also been included in the drafting to clarify that producers of juice who use alternative treatments to pasteurisation are permitted to include information on the label to this effect. This will assist consumers identify these products in the marketplace.

- Grove Fruit Juice considers that the education strategy imposes a major cost to government.

The costs and benefits of option 4, including the education strategy, are discussed in the regulatory analysis at Attachment 4.

Mandatory microbiological criteria

The following comments were received on the proposed requirement for mandatory microbiological criteria of nil detected levels of *E. coli* and *Salmonella* in untreated juice.

- The South Australian Department of Human Services requested more information on how the proposed microbiological criteria relates to the policy principles developed during the review of all microbiological standards in the Code. The Department also stated that the detection of *Salmonella* in any juice would render the food unsafe regardless of whether or not a standard was included in the Code.
- The New Zealand Juice Association supported the inclusion of mandatory microbiological criteria. However, the Association recommended the inclusion of a maximum coliform level as well to provide an indication of poor hygiene as it could be argued that if *Salmonella* and *E. coli* are detected it is too late to prevent consumption of the product.
- InforMed Systems queried whether 5 x 1mL samples would be sufficient to define the presence of small numbers of this organism, which could multiply during storage.
- The Food Technology Associated stated that a fully defined microbiological specification should be included in the Standard.
- Grove Fruit Juice stated that the assumption is made that treated juice has no mandatory requirements for *E. coli* and *Salmonella* but a broader term – ‘pathogens – nil’.

A general policy underpinning the review of microbiological standards was that the setting of mandatory microbiological criteria (a standard) would be based on a risk assessment which indicated that a microbiological standard would contribute to the management of the microbiological risks identified. The risk assessment for fruit and vegetable juices (Attachment 5) concludes that juice may contain microbiological hazards and that untreated juices are more likely to be the source of such a hazard than in treated juices. It also concludes that while there is a low probability of untreated juice being contaminated with dangerous pathogens, the consequences can be severe for at-risk groups and in extreme cases death could occur.

Mandatory microbiological criteria were therefore recommended for untreated juices due to the increased likelihood of pathogens being present in this juice and the increased risk this poses to at-risk groups. Pathogenic *E. coli* and *Salmonella* were identified as the pathogens responsible for the vast majority of outbreaks in untreated juice. A standard for *Salmonella* was proposed and for *E. coli* as an indicator of faecal contamination (standards for specific pathogenic *E. coli* are not generally set). By setting these criteria it was implied that producers of untreated juice would be required to take steps to minimise the risks associated with the untreated juice rather than simply labelling their products as ‘unpasteurised’ or, for those exempted for labelling, not to do anything.

However, as raised by the New Zealand Juice Association, microbiological testing of untreated juice usually occurs after most of the product has been consumed as the vast majority of untreated juice will be sold freshly squeezed for immediate consumption. Therefore, mandatory microbiological criteria are unlikely to be very effective in improving the safety of untreated juice.

ANZFA also considered submissions from InforMed Systems and the New Zealand Juice Association in relation to the difficulty of detecting small number of pathogens in juice and that testing for indicator organisms in juice may be more effective. Microbiological testing, particularly for pathogens that may only be present in very small numbers in the entire batch, cannot provide a guarantee that the batch is not contaminated. The use of coliform testing is not appropriate for fruit and vegetable juices, unless faecal coliforms are specified. The criteria proposed at full assessment for *E. coli* is as an indicator of faecal contamination.

The SA Department of Health and Grove Fruit Juice are also correct in stating that juice, whether untreated or treated should not be contaminated with pathogens. If pathogens such as enterohaemorrhagic *E. coli* and *Salmonella* were detected in juice, the juice would be considered unsafe and could not be sold regardless of whether a microbiological standard existed or not.

The Food Technology Association has requested that a full microbiological standard for juice be included in the Code and the New Zealand Fruit Juice Association has recommended maximum coliform levels be prescribed for untreated juice. Due to the fact that the majority of untreated juice will be consumed before test results are available, resulting in this having a minimal impact on the safety of the juice, and the limitation of testing for small numbers of pathogens in food, it is recommended that mandatory microbiological criteria for *E. coli* and *Salmonella* not be included. The regulatory impact of this recommendation is discussed under option 6 within the revised regulatory impact analysis at Attachment 4.

In lieu of the mandatory microbiological criteria, it is recommended that guideline microbiological criteria be included in the code of practice. These criteria could include pathogens and indicator organisms. Producers of treated and untreated juice will still be obligated to produce safe food and therefore if pathogens such as *Salmonella* were detected in juice, the juice would be considered unsafe and could not be sold.

Code of practice

- The New Zealand Juice Association indicated that both it and the Australian Fruit Juice Association are preparing generic food safety programs for the fruit juice industry and that these could satisfy the proposed non-regulatory measures for a voluntary code of practice for the producers of untreated juice. It queried whether ANZFA proposed having an input.

ANZFA would develop the code of practice in consultation with the New Zealand and Australian Juice Associations and could use any work that has already been completed on ways to minimise the risks associated with untreated juice.

- The National Council of Women does not support a voluntary code of practice since there is no guarantee that all manufacturers would adhere to it and it is not enforceable. There should be no additional cost of compliance to industry between a voluntary code of practice and a mandatory one and consumers could at least be reassured in the knowledge that all manufacturers would comply.

Codes of practice are not intended to be mandatory. In the context of the Joint Food Standards system, codes of practice are non-binding measures, which may be useful to influence activities regarding food production, manufacturing, retail and hospitality.

While compliance is voluntary, it is expected and if a high degree of compliance is not achieved, other regulatory options can be considered. The recommended code of practice is intended to provide assistance to producers of untreated juice to meet their legal obligations under the Food Safety Standards for Australian producers and the New Zealand Food Act, for New Zealand producers. If these manufacturers do not comply with the code of practice, legal action could be taken under this legislation.

It does not adequately address all risks

- Grove Fruit Juice stated that this option fails to adequately address all the risks associated with juice. It does not address physical and chemical hazards in juice as outlined in the risk assessment document nor does it address the risk of post pasteurisation as occurred in the 'Norwalk-like' virus outbreak identified in Australia in 1991.

The regulatory aspect of this application does not seek to specifically address the hazards associated with juice. The recommended requirement is for untreated juice to be labelled. This labelling requirement will enable packaged untreated juices to be identified. However, the non-regulatory recommendation for a code of practice will seek to address all hazards associated with juice, physical, chemical and microbiological. It will also address the issue of post process contamination. All juice producers are required to sell safe food. The code of practice will provide guidance to producers of untreated juice on how to achieve this.

No recognition of existing HACCP programs

- Grove Fruit Juice considers that this option fails to recognise the benefit of HACCP with 3rd party certification. Many growers and producers including Grove Fruit Juice have already implemented a voluntary code of practice. These codes of practice take the form of food safety programs and good manufacturing practice based on Codex based HACCP principles. Many of these growers and producers have already incurred expenses to have HACCP and SQF programs 3rd party certified and are already generally recognised as producing 'safe food'. Grove Fruit Juice suggests an exemption be provided for producers based on 3rd party HACCP certification and historical performance.

An exemption from the only regulatory requirement being recommended i.e. labelling, is already provided for producers of juice that subject the juice to a process capable of achieving a 5-log pathogen reduction. This recognises those producers who pasteurise juice as well as those using alternative but equivalent processes. If a producer of untreated juice has a HACCP system in place that is capable of achieving the 5-log reduction process, labelling is not required.

- Grove Fruit Juice stated that under the Food Safety Standards all producers are required to produce safe food and in principle to do so, will require the implementation of a HACCP program. Producers of untreated juice will have the expense of developing a HACCP program without any commercial benefit and probably a reduction in sales due to consumer education program.

The Food Safety Standards that are mandatory do not obligate any food business to develop a HACCP program. These Standards require businesses to produce safe food but the systems they have in place to achieve this do not need to be set out in a Program. Producers of untreated juice that have in place equivalent processes to pasteurisation are not required to label their products. The education strategy will seek to inform at-risk consumers that not only are pasteurised juices safe but also those that have undergone an equivalent process.

Liability issues for ANZFA

- Grove Fruit Juice considers that a trade restriction liability issue exists for ANZFA if Grove experiences loss of sales and damage to brand if it still complies with a 5-log requirement but is not using pasteurisation due to the unclear definition of 'pasteurisation'.

Producers of untreated juice that have in place equivalent processes to pasteurisation are not required to label their products. The education strategy will seek to inform at-risk consumers that not only are pasteurised juices safe but also those that have undergone an equivalent process.

- Grove Fruit Juice consider that as option 5 is acknowledged as the most effective in controlling food safety risks associated with untreated juice, in the event of a major outbreak from juice and this option has not been adopted, ANZFA may be liable to answer questions of due diligence.

All food businesses are legally obligated to produce safe food, regardless of whether HACCP programs are mandatory.

Research and development of alternative methods would become stifled

- Grove Fruit Juice considers that research and development of alternative methods would become stifled as no commercial advantage could be realised.

This option recognises alternative methods, as it does not require labelling of juices that have undergone an equivalent process to pasteurisation.

Health impact of pasteurised juice

- Grove Fruit Juice considers that the impact of pasteurised juice has not been fully explored. While it offers a food safety benefit, it can also have a negative outcome on our health by resulting in a lower number of health-promoting organisms inside our gut (Hourigan Eat Healthy No. 2, Nutrition Australia).

Pasteurisation is a relatively mild heat treatment process commonly utilised in food processing. The pasteurisation of juices does not cause significant changes in dietary intakes when consideration is given to the total diet and the nutritional qualities that a balanced diet provides. In addition, this referenced article was primarily written on the health impact of pasteurised milk and not juice.

Use of the terms ‘fresh’ and ‘freshly squeezed’

- The Food Technology Association of Victoria considers that the terms ‘fresh’ and ‘freshly squeezed’ should be defined and that ‘freshly squeezed’ should only refer to juice that is squeezed in front of the purchaser and for consumption on the same premises.

As indicated in the Full Assessment Report, the review of the juice standards determined that these terms would be regulated by general offences in State/Territory Food Acts and fair trading legislation, which prohibit false, misleading and deceptive claims in labels.

Issues raised in response to option 5 – mandatory HACCP programs

Grove Fruit Juice supported option 5 for the following reasons:

- it provides the best protection for consumers and processors;
- it will not impose prohibitive costs to industry;
- it addresses all areas of food safety risk;
- the health/safety liability issue for ANZFA is properly addressed;
- it provides a level playing field for industry and avoids unnecessary cost to government and concern to consumers;
- smaller processors would be required to comply. It is unacceptable and a major risk to industry and consumers alike that retail outlets should be exempted. Organically grown fruit and vegetables present a major risk because of contamination from the use of untreated animal fertilisers contaminating the external surface of the fruit or vegetable; and
- compliance costs to government will be low if current 3rd party certification to a recognised food safety standard was provided to local government with annual application for licensing of their food business premises.

As indicated in the Full Assessment Report, option 5 does address the potential risks associated with untreated juice by requiring all juice to be produced under a HACCP system that includes a 5-log reduction process. While this option provides the greatest food safety benefit to consumers by ensuring untreated juices are not sold, it is likely to deny consumers the choice to purchase these juices. Small producers and retail outlets sell the majority of untreated juice and are likely to find a mandatory HACCP program too expensive to justify continuing to sell this product. This makes this option the most expensive for the juice industry due to the high compliance costs and the loss of market in the sale of untreated juices. This option may also be costly to government if industry and consumers are not supportive of this strict approach. It is therefore still considered that the cost of this option currently outweighs the benefits.

All producers of juice will still be obligated to sell safe juice and fruit contaminated with pathogens such as enterohaemorrhagic *E. coli* and *Salmonella*, whether organic or not, would not be suitable for untreated juice.

- The National Council of Women is concerned that Standard 3.2.1 – *Food Safety Programs* is a model Standard and has not been adopted. While the Council accepts business, especially small business has been severely affected by the cost of implementing the GST and there is a desire to protect industry from further costs, until food safety programs are introduced, food safety may still be compromised.

The Commonwealth and States and Territories is considering the issue of whether food safety programs should be mandated at a national level. The Department of Health and Ageing is coordinating further studies into the costs and efficacy of food safety programs. The results of this study are expected to be available in the first half of next year. In the interim, all food businesses are still obligated to sell safe food and comply with other food safety legislation.

Issues raised in response to risk assessment

- The SA Department of Human Services queried the inclusion of all fruit and vegetable juices and considers that closer consideration of the characteristics and risk associated with these juices should be undertaken. The Department stated that it is not aware of any unpasteurised juices, other than orange juice, being on sale. It also stated that given the higher pH of some fruit (e.g. melon) and all vegetable juices, which allows the growth of pathogens, the concern is that including a standard, which allows for the sale of these juices as unpasteurised packaged products is counter productive as it may imply safety.

The risk assessment report (Attachment 5) indicates that there is the potential for any fruit or vegetable juice to be contaminated with pathogens. Food-borne illness has occurred from orange, apple, watermelon, tomato and carrot juice. It also states that while juices are acidic, certain species of pathogens including an *E. coli* O157:H7 strain can survive exposure to extremely acidic (pH <3) environments. Most juices, including apple (pH = 3.4-4.0), orange (pH=3.6-4.3), grapefruit (pH = 3), prune (pH = 3.7), tomato (pH = 4.1 – 4.2), and pineapple (pH = 3.5), are not acidic enough to guarantee pathogen inactivation. A study by Parish (see risk assessment) has also shown that salmonellae could survive in detectable numbers in orange juice up to 27 days at pH 3.5, 46 days at pH 3.8, 60 days at pH 4.1 and 73 days at pH 4.4.

It is agreed that there may be no other packaged untreated juice, apart from orange juice available for sale. However, this does not mean that other packaged untreated juices may not be sold and if they are, they need to be labelled. It is also important for the code of practice to include all fruit and vegetable juices as there are a whole variety of fruits and vegetables sold ‘freshly squeezed’ from retail outlets. Regardless of what type of untreated juice is sold, it will still be required to be safe.

- InforMed Systems stated that it is important that recognition be given to unpasteurised fruit juice as a vehicle for verotoxigenic *E. coli* transmission. This occurred on the West coast of the USA relatively recently. It is therefore not really true to say that the risk of ‘untreated juice being contaminated is of low probability’. In contrast, Grove Fruit Juice stated that untreated juice is not a ‘high risk’ food as there is a low probability of untreated juice being contaminated with dangerous pathogens.

To date, there are only two documented outbreaks of juice-related food-borne illness in Australia and none in New Zealand. Of the two outbreaks in Australia, one was caused by unpasteurised juice made from contaminated fruit and the other was caused by contaminated water being used to reconstitute juice. While other illness may have occurred as a result of contaminated juice in Australia and New Zealand, it has not been documented. Given the amount of untreated juice that is consumed in Australia and New Zealand and the apparent small number of illness occurring, it is not unreasonable to conclude that there is a low probability of untreated juice being contaminated with dangerous pathogens.

However, the concern with untreated juice is that if it is contaminated, it can have severe or even life threatening consequences for at-risk consumers. These consumers should therefore avoid drinking untreated juice and in order to do this, need to be able to identify it in the marketplace.

- Grove Fruit Juice stated that the risk assessment fails to identify and differentiate between the frequency of human pathogens in fruit or vegetable juice that may or may not be present naturally and those that are caused by processing failures. GMP and HACCP addresses these issues, pasteurisation does not guarantee food safety. One of the largest food-borne outbreaks was related to the consumption of pasteurised milk in the US in 1985, with 16,284 confirmed cases of salmonellosis.

The risk assessment lists all outbreaks that have been attributed to juice, whether pasteurised or unpasteurised, and recognises that juice can become contaminated after pasteurisation. However, of the 29 outbreaks listed in the risk assessment report, 22 or 76% were attributed to unpasteurised juices. It therefore concludes that untreated juices are more likely to be a source of a microbiological hazard than treated juices. All producers of juice are obligated to produce safe food and this will include ensuring that pasteurised juice is not contaminated after the pasteurisation step.

CHANGES TO FULL ASSESSMENT/RIS RESULTING FROM INQUIRY

Four changes are proposed as a result of the submissions received on the Full Assessment Report and further consideration by ANZFA. These four changes are discussed below.

These recommended changes impact on the regulatory impact analysis. The revised regulatory impact analysis at Attachment 4 discusses the impact of these changes under Option 6 and concludes that this option is the most cost effective way of managing the public health and safety risks associated with untreated juices.

1. Labelling

At Full Assessment, it was proposed to require ‘untreated juice’ to be labelled as ‘unpasteurised’. It is now proposed to require these juices to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. This change has been proposed in recognition that labelling these untreated juices as ‘unpasteurised’ was potentially misleading as it implied that the only other category of products was pasteurised juices. This is not correct as ‘treated juices’ include those juices that have undergone equivalent treatments to pasteurisation. It is considered that this labelling change will assist consumers understand that both pasteurised juice and juice that has undergone an equivalent process are safe for at-risk consumers to drink. This will benefit producers of juice that has been subjected to alternative treatments, as consumers will also identify these juices as safe to consume.

2. Surface treatments on citrus fruits

At Full Assessment the definition of ‘untreated fruit juice or vegetable juice’ was defined to mean ‘*juice* which has not undergone a process capable of producing a minimum of a 5-log reduction in the most treatment resistant organism of public health significance that is likely to occur in the juice’. Therefore, treated juice is considered to be *juice* that has been pasteurised or subjected to another treatment that is capable of producing the 5-log reduction.

This approach was based on the US Food and Drug Administration (FDA) requirements for labelling. The FDA labelling requirement was finalised on 8 July, 1998 and required a warning statement on juice that had not been processed in a manner that would produce, at a minimum, a 5-log reduction in the most resistant micro-organism of public health significance that is likely to occur in the juice.

In relation to the 5-log reduction process, the FDA indicated that for most fruits and vegetables, the pathogen reduction treatment must be applied to the juice after extraction due to the possibility of pathogen internalisation. However, in relation to citrus fruit, the structure of citrus fruits is likely to prevent the internalisation of microorganisms, and thus, for citrus fruits, pathogenic microorganisms are likely to be restricted to the surface of the fruit.

The US labelling requirement was put in place largely as an interim step towards the preparation of a HACCP regulation for juice processors. On 19 January 2001, the FDA finalised requirements for the application of HACCP principles to the processing of fruit and vegetable juices. As part of finalising these requirements, the US National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has outlined five basic consensus decisions in relation to the application and measurement of the 5-log reduction standard to citrus juices:

1. The 5-log reduction need not start with the extracted juice but may begin with the exterior decontamination of citrus fruit. However, processors should not start a cumulative 5-log reduction until after the fruit is cleaned (i.e. washed) and culled (i.e. damaged or dropped fruit is removed so that the remaining fruit is USDA choice level or higher quality);
2. Laboratory studies indicate that microbial infiltration of fruit occurred when warm fruit was washed or submerged into cold water;

3. The entire 5-log process must occur under one firm's control and in one processing facility;
4. Packing of the juice from bulk containers may occur at another facility in certain circumstances; and
5. As part of a HACCP verification program, firms should conduct microbial testing on the final product if the 5-log reduction process relies in part on fruit surface treatment.

As a result of these further recommendations from the NACMCF, in the FDA HACCP regulations, juice processors must meet the 5-log reduction through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning and the reduction is accomplished within a single production facility.

It is therefore considered appropriate to allow surface treatments to contribute to the 5-log reduction process for citrus fruits, provided the fruit is cleaned and culled first. It was never intended to restrict producers of citrus fruits from using surface treatments as part of their 5-log reduction processes. However, this issue was overlooked at Full Assessment and consequently the drafting does not recognise the use of surface treatments. This change will benefit producers of juice made from citrus fruit that wish to utilise alternative treatments to pasteurisation.

At this stage, only citrus fruits have been demonstrated to be adequately impervious to internal contamination and therefore the use of surface treatments has been restricted to these fruits. However, ANZFA will review this restriction if additional scientific data becomes available for other fruits and vegetables.

3. 5- log production process to be conducted within a single facility

It is proposed to specifically require the 5-log reduction process to be conducted within a single facility. While pasteurisation treatments do occur within a single facility, some alternative treatments could potentially be split between more than one facility. For example, in respect to citrus fruits, the surface treatments could occur within one facility and then the fruit could be transported to another facility for processing. If the 5-log reduction process is split over more than one facility, there is greater potential for additional contamination to occur. The process may then not be able to remove this contamination. The US FDA specifically requires the 5-log reduction process for citrus fruit to be conducted within a single facility. This change potentially benefits consumers, as it provides a greater level of assurance in the safety of treated juices.

4. Microbiological criteria for untreated juice

It is recommended that there no longer be mandatory criteria for untreated juice prescribed requiring nil detected levels of *E. coli* and *Salmonella*. The main reason for this recommendation is that the majority of untreated juice will be consumed before test results are available and therefore this requirement was likely to only have a minimal impact on the safety of the juice.

In lieu of the mandatory microbiological criteria, it is recommended that guideline microbiological criteria be included in the code of practice. These criteria could include pathogens and indicator organisms. Producers of treated and untreated juice will still be obligated to produce safe food and therefore if pathogens such as enterohaemorrhagic *E. coli* and *Salmonella* were detected in juice, the juice would be considered unsafe and could not be sold.

CONCLUSIONS

The following conclusion takes into account the changes made to the assessment of this matter since Full Assessment.

Juice that has not undergone any form of treatment is more likely to be contaminated with pathogens than treated juice. While there is a low probability of untreated juice being contaminated with dangerous pathogens, the consequences can be severe for at risk groups and in extreme cases death could occur.

The most cost effective way of managing the potential risks associated with untreated juice is considered to be a combination of regulatory and non-regulatory measures. These measures are outlined below.

Regulatory measures

- labelling of packaged juice with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’, if the juice has not undergone a process capable of achieving at least a 5-log reduction of the most resistant pathogen of public health significance likely to occur in the juice;
- the 5-log reduction process would need to be conducted on the juice itself with the exception of citrus fruits. Surface treatments could be applied to citrus fruits after the fruit is cleaned (i.e. washed) and culled (i.e. damaged or dropped fruit is removed); and
- all 5-log reduction processes would need to be conducted within a single facility.

Non-regulatory measures

- a voluntary code of practice for producers of untreated juices outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice; and
- consumer education to increase awareness of the potential risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace.

It is recommended that the regulatory measures not commence until six months after the gazettal of the requirements to provide producers of juice sufficient time to become familiar with the requirements and if necessary, make labelling changes and change any of their processing practices.

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 (ANZFS) 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*.

FURTHER INFORMATION

Submissions

No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia New Zealand Food Standards Council for consideration.

Further Information

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at 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

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

ATTACHMENTS

1. Proposed Draft Variation (as amended)
2. Statement of Reasons
3. Summary of Public Comment Received
4. Revised Regulatory Impact Analysis
5. Risk Assessment of fruit and vegetable juices
- 5A. Australian average daily consumption of fruit juice and fruit drinks by sex and age
- 5B. New Zealand average daily consumption of fruit juice and fruit drinks by sex and age

**DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*
APPLICATION A 411**

To commence: 6 months from gazettal

[1] **Standard 1.2.3** of Volume 2 of the Food Standards Code is varied by –

[1.1] *inserting in clause 1, immediately following the definition of royal jelly –*

untreated fruit juice or vegetable juice means juice, other than citrus juice, which, at a single facility, has not undergone a process capable of producing a minimum of a 5-log reduction in the most treatment resistant organism of public health significance that is likely to occur in the juice.

untreated citrus juice means citrus juice which, in its production, after cleaning and culling, and at a single facility, has not undergone a process capable of producing a minimum of a 5-log reduction in the most treatment resistant organism of public health significance that is likely to occur in the juice.

[1.2] *inserting in columns 1 and 2 respectively of the Table to clause 2, immediately following the entry for Food containing guarana or extracts of guarana –*

untreated fruit juice or vegetable juice	Statement to the effect that the product has not been pasteurised or treated to achieve the equivalent result
untreated citrus juice	Statement to the effect that the product has not been pasteurised or treated to achieve the equivalent result

[1.3] *inserting immediately following the Table to clause 2 -*

Editorial note:

In relation to the advisory statement for untreated fruit juice or vegetable juice and untreated citrus juice –

1. If, by treatment, a 5-log reduction in the product has occurred, the advisory statement is not required.
2. If, by an equivalent treatment to pasteurisation, a 5-log reduction in the product has been achieved, the advisory statement is not required. Additionally, nothing in this Code prohibits manufacturers from including on the label of fruit juice or vegetable juice, information about the impact on the safety of the food of the equivalent treatment used to achieve a 5-log reduction in the product.
3. If the product has not undergone any process to achieve a 5-log reduction in the product, then the advisory statement has to be made in accordance with clause 2 of this Standard.

[2] **Standard O2** of Volume 1 of the Food Standards Code is varied by –

[2.1] *inserting immediately following subclause 1(7) –*

(8) Untreated fruit juice or vegetable juice is juice which, at a single facility has not undergone a process capable of producing a minimum of a 5-log reduction in the most treatment resistant organism of public health significance that is likely to occur in the juice.

(9) Untreated citrus juice is citrus juice which, in its production, after cleaning and culling, and at a single facility, has not undergone a process capable of producing a minimum of a 5-log reduction in the most treatment resistant organism of public health significance that is likely to occur in the juice.

[2.2] *inserting immediately following clause 10 –*

Labelling of untreated fruit juice or vegetable juice

11. The label on or attached to a package of untreated fruit juice or vegetable juice must include a statement to the effect that the product has not been pasteurised or treated to achieve the equivalent result.

Labelling of untreated citrus juice

12. The label on or attached to a package of untreated citrus juice must include a statement to the effect that the product has not been pasteurised or treated to achieve the equivalent result.

[2.3] *inserting immediately following clause 12 -*

Editorial note:

In relation to the statement for untreated fruit juice or vegetable juice and untreated citrus juice –

1. If, by treatment, a 5-log reduction in the product has occurred, the statement is not required.
2. If, by an equivalent treatment to pasteurisation, a 5-log reduction in the product has been achieved, the statement is not required. Additionally, nothing in this Code prohibits manufacturers from including on the label of fruit juice or vegetable juice, information about the impact on the safety of the food of the equivalent treatment used to achieve a 5-log reduction in the product.
3. If the product has not undergone any process to achieve a 5-log reduction in the product, then the statement has to be made in accordance with clauses 11 and 12.

STATEMENT OF REASONS

APPLICATION A411 - PASTEURISATION OF ORANGE JUICE AND LABELLING OF UNPASTEURISED JUICE

The Australia New Zealand Food Authority (ANZFA) has before it an application to amend Standard O7 – Orange Juice and Related Products, to require all orange juice, other than freshly squeezed orange juice for immediate consumption, to be pasteurised or labelled to ensure consumers are informed of the risks associated with the consumption of unpasteurised orange juice.

ANZFA recommends the adoption of the draft variation, as amended, for the following reason:

- the requirement for packaged untreated juices to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’ will enable at-risk consumers to identify these juices in the marketplace.

The drafting prepared after Full Assessment is amended for the following reasons:

- the labelling statement for packaged untreated juices has been extended from ‘unpasteurised’ to a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. This change has been proposed in recognition that labelling untreated juices as ‘unpasteurised’ was potentially misleading as it implied that the only other category of products was pasteurised juices. This is not correct as ‘treated juices’ include those juices that have undergone equivalent treatments to pasteurisation;
- surface treatments of citrus fruits can now be counted towards the 5-log reduction process, provided this treatment occurs after the fruit is cleaned and culled. It has been demonstrated that citrus fruits are adequately impervious to internal contamination and therefore surface treatments are effective in reducing the numbers of pathogens potentially present on the fruit;
- the 5-log reduction process is now required to take place within a single facility. This will reduce the likelihood of further contamination occurring if the 5-log reduction process is to be achieved by applying more than one treatment; and
- mandatory microbiological criteria for nil detected levels of *E. coli* and *Salmonella* in untreated juice is no longer recommended, primarily because the majority of untreated juice will be consumed before test results are available and therefore this requirement was unlikely to be an effective risk management measure.

It is recommended that the commencement date of the amended draft variation be six months from the date of gazettal. (see Attachment 1)

REGULATION IMPACT

ANZFA has undertaken a regulation impact assessment process which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment.

Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter was notified to the WTO as a Technical Barrier to Trade (TBT) Notification because imported product will come under the scope of the proposed requirements and there are no similar requirements specified by Codex.

Summary of Public Comment Received

Following is a summary of the submissions received in response to the Full Assessment Report released for public comment on 30 May 2001. The options outlined in this Report are summarised below. Option 4 was the preferred option at Full Assessment.

Option 1

'Do nothing' i.e. maintain the status quo. There would be no specific processing requirements for juice and no requirement for untreated product to be specifically identified.

Option 2

Non-regulatory approach whereby producers of untreated juice would be encouraged to comply with a code of practice and to label their product as 'unpasteurised'. The voluntary labelling would also be supported by an education strategy to raise awareness about the potential risks associated with untreated juices.

Option 3

All fruit and vegetables juices would need to either be subjected to a 5-log pathogen reduction process or be labelled with a mandatory advisory statement

Option 4

This option consists of the following regulatory and non-regulatory measures:

Regulatory measures

- labelling of packaged juices as 'unpasteurised' if they have not undergone a process capable of achieving at least a 5-log reduction in the most resistant pathogen of public health significance likely to occur in the juice; and
- mandatory microbiological criteria for untreated juice requiring not detectable levels of *Escherichia coli* and *Salmonella* spp.

Non-regulatory measures

- a voluntary code of practice for producers of untreated juices outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice; and
- consumer education to increase awareness of the potential risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace.

Option 5

This would require all juice manufacturers to implement a HACCP system that includes a 5-log pathogen reduction process. Labelling would not be required as there would not be a need to distinguish between juices in the marketplace as all juices would have been subject to the same process requirements.

1. New Zealand Juice Association

Supports preferred option recommended in report (Option 4) with the following reservations:

- juices which are made and packaged and sold on the same premises will not be required to carry an ‘unpasteurised’ statement. This concern is further highlighted by the vagueness of the requirements for a consumer education program;
- the NZJA is very concerned as to the lack of detail as to how a proposed consumer education program would be funded and run. If run within the industry, there will be potential conflict between manufacturers of treated and untreated juice. Those making untreated juice could well turn the ‘unpasteurised’ label into a positive by claiming it enables a better flavour compared with pasteurised juice. There is no requirement for them to indicate to the consumer that there is any risk from being unpasteurised; and
- agrees with mandatory microbiological criteria for untreated juices requiring not detected levels of E. coli and Salmonella spp. However, as it could be argued that if these are detected it is too late to prevent consumption of the product, it could be worth including a maximum coliform level as well to provide an indication of poor hygiene before there is necessarily a food safety issue.

Both the Australian and New Zealand Juice Industry Associations are currently preparing generic food safety programs for the fruit juice industry. These could satisfy the proposed non-regulatory measures for a voluntary code of practice for the producers of untreated juice. The New Zealand food safety program will be approved by the New Zealand Ministry of Health. Do ANZFA propose having an input?

2. InforMed Systems

Supports the Application.

It is important that recognition be given to unpasteurised fruit juice as a vehicle for verotoxigenic E. coli transmission. This occurred on the West coast of the USA relatively recently. One would hope that 5 x 1mL samples would be sufficient to define the presence of small numbers of this organism, which could multiply during storage. This event also shows that it is not really true to say that the risk of ‘untreated juice being contaminated is of low probability’.

3. Grove Fruit Juice Pty Ltd

Supports option 5. Does not prefer Options 1-3 as insufficient control measures to ensure food safety. Also does not support proposed option (Option 4).

Supports option 5 for the following reasons:

- provides the best protection for consumers and processors;
- it will not impose prohibitive costs to industry;
- addresses all areas of food safety risk;

- health/safety liability for ANZFA properly addressed;
- provides a level playing field for industry and avoids unnecessary cost to government and concern to consumers;
- smaller processors would be required to comply. It is unacceptable and a major risk to industry and consumers alike that the outlets should be exempted. Organically grown fruit and vegetables present a major risk because of contamination from the use of untreated animal fertilisers contaminating the external surface of the fruit or vegetable; and
- compliance cost to government low if current 3rd party certification to a recognised food safety standard was provided to local government with annual application for licensing of their food business premises.

Reasons provided for not supporting option 4

Untreated juice not a 'high risk' food

- low probability of untreated juice being contaminated with dangerous pathogens.

It does not adequately address all risks

- fails to address physical and chemical hazards in juice as outlined in the risk assessment document;
- fails to address 'Norwalk-like' virus outbreak identified in Australia in 1991 where water was identified as a source;
- this option does not address the risk of post pasteurisation, which still presents a major risk; and
- risk assessment fails to identify and differentiate between the frequency of human pathogens in fruit or vegetable juice that may or may not be present naturally and those that are caused by processing failures. GMP and HACCP addresses these issues, pasteurisation does not guarantee food safety. One of the largest food-borne outbreaks related to the consumption of pasteurised milk in the US in 1985 with 16,284 confirmed cases of salmonellosis.

Requirement to label juice as 'unpasteurised'

- unpasteurised would refer to any product that has not been subjected to thermal treatment, regardless of any other alternative means of pathogen minimisation;
- 'pasteurisation' not specifically defined but associated with 5-log reduction. Pasteurisation refers to thermal treatments only as outlined in processing standard 1.6.2 Dairy Standard;
- terminology 'pasteurised' and 'unpasteurised' does not necessarily refer to 5-log reduction;

- definition of treated and untreated is unclear and confusing as application refers to unpasteurised juice as being untreated but also to products that have achieved a 5-log reduction as being treated, yet in other contexts as being untreated;
- confusing terminology will result in consumer confusion, with the result that they may become panicked into believing that any product not pasteurised is unsafe and purchase only products marked as ‘pasteurised’; and
- labelling ‘unpasteurised’ does not fully recognise alternative treatments to pasteurisation and infers that pasteurisation is the only means of treatment.

Mandatory microbiological criteria for untreated juice

- assumption is made that treated juice has no mandatory requirements for E. coli and Salmonella but a broader term – ‘pathogens – nil’.

No recognition of existing HACCP programs

- many growers and producer including Grove Fruit Juice have already implemented a voluntary code of practice. These codes of practice take the form of food safety programs and good manufacturing practice based on Codex based HACCP principles. Many of these growers and producers have already incurred expenses to have HACCP and SQF programs 3rd party certified and are already generally recognised as producing ‘safe food’;
- under Standard 3.2.1, all producer are obligated to produce safe and in principal to do so this will require the implementation of a HACCP program. These producer will have the expense of developing a HACCP program without any commercial benefit and probably a reduction in sales due to consumer education program;
- fails to recognise HACCP with 3rd party certification;
- SA Government permits the sale of unpasteurised milk by 8 producers – 4 cow’s milk and 4 goats milk and monitors these under a strict code of practice; and
- suggests an exemption be provided for producers based on 3rd party HACCP certification and historical performance.

Negative effect of consumer education strategy

- will cause alarm amongst consumers no matter how proposed and presented will imply that ‘fruit juice is no longer safe’;
- education program is not intending to promote the health benefits of unpasteurised juices. Therefore, an education strategy of equal strength would be needed to inform consumers of the positive nutritional benefit of unpasteurised juices and the negatives of pasteurised product;

- competitive advantage given to players in market who use pasteurisation processing methods and can market directly against players who are using alternatives but still achieving 5-log reduction;
- producers of products using alternatives to pasteurisation (but still achieving 5-log reduction) are severely disadvantaged. They would need to embark on a costly re-education and re-labelling program to advise consumers of the safety of their products and to negate the adverse publicity engineered and financed by government; and
- imposes major cost to government in implementing an education program

Liability issues for ANZFA

- a trade restriction liability issue for ANZFA if Grove experiences loss of sales and damage to brand if still complies with 5-log requirement but not pasteurising due to unclear definition of ‘pasteurisation’; and
- as option 5 is acknowledged as the most effective in controlling food safety risks associated with untreated juice, in the event of a major outbreak from juice and this option has not been adopted, ANZFA may be liable to answer questions of due diligence.

Research and development of alternative methods would become stifled

- research and development of alternative methods would become stifled as no commercial advantage could be realised.

Health impact of pasteurised juice

- the impact of pasteurised juice has not been fully explored. While it offers a food safety benefit, it can also have a negative outcome on our health by resulting in a lower number of health-promoting organisms inside our gut (Hourigan Eat Healthy No. 2, Nutrition Australia).

4. Health Department of Western Australia – Western Australian Food Advisory Committee

Supports option 4 as it offers consumer protection through industry best practice and improved awareness of the potential risks and handling requirements of unpasteurised orange juice.

Option 1 is the least preferred as it would not offer any extra protection to at risk consumers. It also has an implied costs to government in the investigation of manufacturers allegedly associated with food poisoning and the treatment of people affected by enteric illness.

Options 2 and 3 are not supported as these are both dependent on public education about the risks of unpasteurised juice and imply that it is the consumer’s responsibility to identify pasteurised juice. In the absence of a code of practice, labelling and a public education program, these option are unlikely to afford a significant increase in the protection of public health and safety.

Option 5 provides the best protection from product contamination and is not dependent on labelling or consumer education to achieve a public health outcome. However, implementation is dependent on other health legislation reforms and the implementation of the Standard 3.2.1 – Food Safety Programs.

5. New Zealand Ministry of Health

The New Zealand Ministry of Health had no comment on this Application.

6. Food Technology Association of Victoria Inc

Accepts option 4 with the addition of the following comments:

- the term ‘freshly squeezed’ should be defined and only refer to juice that is squeezed in front of the purchaser and for consumption on the same premises;
- if it is freshly squeezed but packed for the purchaser with the intention of being taken away from the premises, it should be labelled as ‘unpasteurised’;
- ‘unpasteurised juice’ should be adequately labelled with a ‘use by’ date;
- the term ‘fresh’ also needs to be defined; and
- a fully defined microbiological specification should be included in the Standard.

7. National Council of Women of Australia

Strongly supports the introduction of processing requirements for all juices and some form of labelling to enable unpasteurised juices to be identified and is therefore pleased that ANZFA has also recognised this problem and moved to address it.

Supports option 4 but with a mandatory code of practice.

Option 1

Does not support option 1 as it does not provide for labelling of untreated juice. In addition, the Council is concerned that the new Food Safety Standards will not provide the level of safety consumers have been led to believe they would and that it is considered necessary and appropriate to specify additional requirements to these Standards. This is because exactly what, if anything, would be done will depend upon whether the manufacturer thinks there is a reasonable likelihood or not of food-borne pathogens being present in the juice. This decision remains subjective, which is not a good determinate for ensuring food safety.

Option 2

The Council does not support any non-regulatory approach, particularly in matters involving food safety. The Canadian non-regulatory approach has not as yet been evaluated so cannot be pointed to as being a success. Also those that choose not to comply put the system at risk.

Option 3

Agree with ANZFA's comments that this option does not adequately manage the risks associated with untreated juices that are sold unpackaged. It does not provide the consumer with either information or protection.

Option 4

Supports option 4 with the exception of the voluntary code of practice. The Council cannot support a voluntary code of practice since there is no guarantee that all manufacturers would adhere to it and it is not enforceable. Council supports this option if the code of practice was mandatory. There should be no additional cost of compliance to industry between a voluntary code of practice and a mandatory one and consumers could at least be reassured in the knowledge that all manufacturers would comply.

Option 5

There is no doubt that a HACCP based system would be the best option for ensuring consumer safety, providing it applied to all manufacturers. It is of some concern that the Standard 3.2.1 – Food Safety Programs, is a model Standard and has not been adopted. While Council accepts business, especially small business has been severely affected by the cost of implementing the GST and there is a desire to protect industry from further costs, until food safety programs are introduced, food safety may still be compromised.

8. South Australian Department of Human Services

The South Australian Department of Human Service stated that the following issues should be addressed before the proposed amendment is progressed:

- the inclusion of all fruit and vegetable juices is questioned without closer consideration of the characteristics and risk associated with these juices;
- not aware of any unpasteurised juices, other than orange juice, being on sale;
- given the higher pH of some fruit (e.g. melon) and all vegetable juices, which allows the growth of pathogens, the concern is that including a standard, which allows for the sale of these juices as unpasteurised packaged products is counter productive as it may infer safety;
- requests more information on how the microbiological criteria proposed relates to the policy principles developed during the review of all microbiological standards in the Code; and
- the detection of Salmonella in any juice would render the food unsafe regardless of whether or not a standard was included in the Code.

9. Australian Fruit Juice Association

The Australian Fruit Juice Association (AFJA) supports option 3 (on the proviso that pasteurised product which contains no added concentrate, no added preservatives and a maximum shelf life of 21 days may still be labelled as “fresh”). Additionally, the AFJA also supports the regulatory and non-regulatory measures contained in option 4. However, the labelling exemption for juices sold from the premises where they were made and packaged is strongly opposed and the AFJA propose that these products should also be labelled as “unpasteurised”.

The AFJA argue that the labelling exemptions for food made and packaged on the premises from which it is sold, as specified in Standard 1.2.1 “Application of labelling and other information requirements” should not cover packaged juices and that it was not the intent of the standard to do so. Oranges used for the manufacture of packaged juices made on the premises would probably be purchased from a packing shed where, as for the 1999 Salmonella outbreak, contamination can occur.

The AFJA supports mandatory labelling for unpasteurised juice providing that all producers of packaged juices, including fruit and vegetable outlets, are required to conform.

Revised Regulatory Impact Analysis

Following is a revised regulatory impact analysis for this Application. This analysis has been revised to take into account comments received from the Office of Regulation Review. It also takes into account the regulatory changes recommended in this report. These changes are:

- the labelling statement for packaged untreated juices be extended from ‘unpasteurised’ to a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. This change has been proposed in recognition that labelling untreated juices as ‘unpasteurised’ was potentially misleading as it implied that the only other category of products was pasteurised juices. This is not correct as ‘treated juices’ include those juices that have undergone equivalent treatments to pasteurisation;
- citrus fruits be permitted to use surface treatments as part of the 5-log reduction process, provided this treatment occurs after the fruit is cleaned and culled. It has been demonstrated that citrus fruits are adequately impervious to internal contamination and therefore surface treatments are effective in reducing the numbers of pathogens potentially present on the fruit;
- the 5-log reduction process be required to take place within a single facility. This will reduce the likelihood of further contamination occurring if the 5-log reduction process is to be achieved by applying more than one treatment; and
- the removal of the mandatory microbiological criteria for nil detected levels of *E. coli* and *Salmonella* in untreated juice primarily because the majority of untreated juice will be consumed before test results are available and therefore this requirement was unlikely to be an effective risk management measure.

The regulatory impact of these changes are considered under a new option, Option 6.

PROBLEM

The problem presented in this application is whether the mandatory pasteurisation of fruit juice or the labelling of unpasteurised product are the best means of managing the public health risks associated with unpasteurised juices. What is the most cost-effective and practical risk management option?

BACKGROUND

Fruit juice is a popular drink in both Australia and New Zealand. Berri Ltd is Australia’s largest fruit juice manufacturer, with an annual turnover of approximately \$500 million. The company crushes 130,000 tonnes of fresh citrus fruit annually. Frucor Beverages is New Zealand’s leading manufacturer of juices, which sells approximately \$70 million (New Zealand) worth of fruit juices and drinks each year. Frucor estimates that approximately \$123 million (New Zealand) of fruit juice is sold in New Zealand each year.

There is a wide range of fruit juice products in the marketplace. The majority of juice sold is pasteurised and shelf stable. However, there is also a significant amount of chilled and freshly squeezed juice available. The Australian Fruit Juice Association believes that approximately 95% of juice sold has undergone some form of pasteurisation process. The NZ Juice Association estimates that approximately 10% of the juice market in New Zealand is made up of untreated chilled juice, with the majority of producers moving towards pasteurisation.

Acidic foods such as orange juice were previously considered to be safe foods. However, recent outbreaks in Australia and overseas from unpasteurised juices contaminated with pathogens such as *Salmonella* spp., *Escherichia coli* O157:H7 and *Cryptosporidium parvum* have demonstrated that unpasteurised juice can be a vehicle for food-borne illness. These and other acid-tolerant food-borne pathogens can contaminate the fruit during growing and subsequent handling and are able to survive in the juice. While the pathogens are not able to grow in the juice, they can cause illness in small numbers.

Pasteurisation can effectively destroy pathogens that may be present in the juice. However, if juices have not been pasteurised or otherwise treated, pathogens may be present.

The young, the elderly and the immunocompromised are more susceptible to food-borne illness and can also be more severely affected by food-borne illness. Infants, small children, the elderly and immunocompromised persons represent those risk populations typically affected when juice borne outbreaks occur. In one of the outbreaks of apple juice contaminated with *E. coli* O157:H7 in the USA in 1996, the majority of persons affected were young (56% were ≤ 5 year of age). This outbreak also caused serious illness with 36% of cases requiring hospitalisation, 20% developing haemolytic uraemic syndrome and 1 death.

Data from the Australian 1995 National Nutrition Survey (NNS) estimates that fruit juices and drinks are consumed in significant quantities by a large sector of the population. Approximately thirty-five percent of all respondents to the Australian 1995 NNS reported to consume fruit juices and drinks, with the mean consumption being 250ml per day. The highest consumption rates of fruit juices and drinks in the Australian population on the day of the survey were reported by 16-18 year-old males consuming 420ml, and 16-18 year-old females consuming 395ml. Alternatively, the lowest consumption rates of fruit juices and drinks were reported by 65+ year-old males consuming 190ml, and 65+ year-old females consuming 180ml. In addition it was reported that over 60% of 2-3 year-old male children consumed over 300ml of fruit juices and drinks and over 53% of 2-3 year-old female children consumed over 310ml. No specific consumption data is available for immunocompromised persons.

Approximately 20% of the consumers in the New Zealand 1997 NNS consumed fruit juices and drinks with the mean consumption being 250ml. The highest consumption rates of fruit juices and drinks in the New Zealand population on the day of the survey were reported by 15-18 year-old males consuming 545ml, and 19-24 year-old females consuming 365ml. Alternatively, the lowest consumption rates of fruit juices and drinks were reported by 65+ year-old males consuming 165ml, and 65+ year-old females consuming 150ml. Note that, 15 year-old and under children were not surveyed in the New Zealand 1997 NNS. Furthermore, no specific consumption data is available for immunocompromised persons.

While at-risk groups are not the highest consumers of juice, the consumption data indicates that children and the elderly do drink juice. The majority of this juice will be pasteurised, but approximately 5% will not. The risk assessment (Attachment 5) concludes that unpasteurised juices are more likely to be the source of a microbiological hazard than pasteurised juices. Of the 29 outbreaks from juices listed in this report, 22 were attributed to unpasteurised juices or 76%. It also concludes that while there is a low probability of unpasteurised juice being contaminated with dangerous pathogens, if it is, the consequences can be severe for at-risk groups and in extreme cases death could occur.

It is therefore important that consumers and in particular at-risk consumers of juice products are aware of the increased risks of drinking juice that has not been pasteurised or otherwise treated and are able to identify these juices in the market place. Currently, consumers are unlikely to be aware of these risks and juices that have not been pasteurised or otherwise treated may not be able to be distinguished from pasteurised juices. This is particularly the case for packaged chilled juices.

In summary, there are identified public health risks associated with the consumption of unpasteurised juices and the management of these risks need to be addressed.

OBJECTIVE

The objective of this assessment is to identify strategies for dealing with the public health risks associated with untreated juices and to propose the most cost-effective risk management option.

ASSESSMENT OF OPTIONS AND REGULATORY IMPACT

To address the risks associated with juice, there are two main management strategies that can be considered:

1. processing - require juices to be processed such that pathogens of concern are reduced to safe levels; and
2. labelling - require juices that have not been treated to be labelled so that consumers are able to identify these products.

This section outlines four options for controlling the microbiological hazards associated with juice. Each option discusses how it addresses or does not address the processing and labelling management strategies.

The option as outlined by the applicant has not been considered. The reasons for not including the applicant's option are discussed under Option 3, which is similar in approach.

Option 1 'Do nothing' i.e. maintain the status quo

Processing

There would be no specific processing requirement for juice.

However, food safety standard 3.2.2 - Food Safety Practices and General Requirements requires the following:

7(1) A food business must:

(b) when processing food:

(ii) where a process step is needed to reduce to safe levels any pathogens that may be present in the food – use a process step that is reasonably known to achieve the microbiological safety of the food.

This requirement will take effect as the States and Territories implement the new Food Safety Standards. All States and Territories are expected to have implemented these Standards by the end of 2002.

This requirement means that the manufacturer must first decide whether there is a reasonable likelihood of food-borne pathogens being present in the juice and if there are, whether these pathogens need to be destroyed. If the answer to this is yes, the juice must be processed in a way that will achieve the microbiological safety of the food. To answer no to this question the manufacturer would need to have a high level of assurance that fruit being juiced is not contaminated with pathogens of concern.

The above requirement will apply equally to all juice manufacturers, including retail establishments that sell 'freshly squeezed juice'.

However, this requirement will not apply in New Zealand, as the Food Safety Standards have no effect in New Zealand. In New Zealand, manufacturers would be generally obligated to ensure juice sold is safe.

Labelling

There would be no requirement for untreated product to be specifically identified.

Regulatory Impact of option

Industry

Apart from possible costs associated with complying with the processing requirement in the Food Safety Standards or the general obligation in New Zealand to ensure juice sold is safe, industry will not incur any additional costs with this option. However, if an outbreak of illness were to occur, the fruit juice industry will incur the costs of this outbreak. For the company whose product is affected this will include the cost of recalling and destroying product, loss of sales, cost to re-build the reputation of the company and an increase in insurance costs. There may also be costs to modify products such as the purchase of a pasteurising unit. For the fruit juice industry generally, juice sales could decrease if consumers are concerned about the safety of juices and insurance costs could increase.

Following the Salmonella outbreak that occurred in Australia in early 1999, the company who sold the contaminated juice closed for 3 weeks and sales decreased. The company now sells pasteurised product only and sales are better than they were before the outbreak but not as high as was projected if the outbreak had not occurred. The company estimates that the outbreak cost approximately \$2 million dollars. This includes loss of sales and reputation as well as the cost of recalling and destroying product at the time of the outbreak. It does not include the cost to compensate the persons affected, as this cost will be borne by the insurance company. However, the cost of insurance has increased by 30% for this company, despite the fact it now sells pasteurised product only. The company also spent \$110,000 installing a pasteurisation unit.

The compensation pay-out to the persons affected by the Salmonella outbreak in Australia in early 1999 is still to be finalised. However, the Australian food industry's bulletin *Foodweek* of 9 April, 2001 page 14, reported that the Federal Court in Adelaide has approved a settlement, with most of the claimants expected to receive between \$2000 and \$4000 based on the severity of their illnesses. Some of the claimants could receive up to \$100,000 after the merits of each claim have been assessed individually.

While the number of claimants is not reported, if each of the approximate 500 persons that were affected by this outbreak submitted a claim, the total cost would be between \$1,000,000 and \$4,000,000 based on an amount between \$2000 and \$4000 for each claimant.

Consumers

Consumers and in particular at-risk consumers would not be informed about the risks of untreated juices and would not be able to identify untreated juice in the marketplace. This option also does not include any specific strategies to lower contamination levels in untreated juices and therefore this juice would be no safer.

At-risk consumers could continue to unwittingly consume untreated juices that may be contaminated, as they would not be aware of the risks, and they could therefore contract a food-borne illness. While the probability of untreated juice being contaminated is low, the consequences could be severe if at-risk consumers contract a serious or even fatal case of food-borne illness. For example, if a young child was infected with enterohaemorrhagic *Escherichia coli*, the child could develop Haemolytic Uraemic Syndrome, which can cause renal failure and death.

Government

There would be no new enforcement costs for government. However, as this option has no specific strategies for reducing the potential risk of at-risk consumers becoming ill from untreated juices, another outbreak could occur. If another outbreak of illness were to occur, health care costs could be significant, especially for severe illnesses. The Australian *Salmonella* outbreak in early 1999 affected approximately 500 persons, and of these 500, 23 required hospitalisation. Salmonellosis can also lead to the condition of reactive arthritis, which would result in further health care costs for persons affected.

While there have been no documented cases of illness from enterohaemorrhagic strains of *E. coli* from juice in either Australia or New Zealand, these strains have caused numerous outbreaks in juice overseas. Enterohaemorrhagic strains of *E. coli* can lead to severe illness, including haemolytic uraemic syndrome and death. Survivors of haemolytic uraemic syndrome may require long term health treatment including dialysis and kidney transplants.

Government would also bear the cost of investigating and managing any outbreaks.

Assessment of option

This option does not impose any new costs on industry and government. However, this option has no specific strategies for reducing the potential risk of at-risk consumers becoming ill from untreated juices. The risk assessment (Attachment 5) concludes that untreated juices do pose a risk and in particular, to the young, the elderly and the immunocompromised. With this option, at-risk consumers would not be informed about the potential hazards of consuming untreated juices or how to distinguish between treated and untreated juices in the marketplace, and consequently could become ill from consuming these juices. The option also does not include any strategy to lower the contamination levels in untreated juices outside the general requirement to ensure that the food is safe.

Conclusion

This option does not ensure that at-risk consumers are informed about the potential hazards of consuming untreated juices, nor enable consumers to identify these products in the marketplace. It also does not include any strategies to lower the contamination levels in untreated juice. The costs of this option, illness or even death occurring from at-risk consumers contracting food-borne illness from untreated juices, are therefore likely to outweigh the benefits, which are no new compliance costs for industry and enforcement costs for government.

Option 2 – Non regulatory approach as per Canada

A non-regulatory approach could be introduced similar to Canada. Canada has encouraged producers of unpasteurised juice to follow a code of practice and to label their products as ‘unpasteurised’. Canada has also implemented a consumer education strategy to raise awareness about the potential risks associated with these products.

Processing

There would be no specific processing requirements for juice. Producers of untreated juice would be encouraged to comply with a code of practice.

Labelling

Manufacturers of untreated juice would be encouraged to label their product as ‘unpasteurised’. The voluntary labelling would be supported by an education strategy to raise awareness about the potential risks associated with untreated juices.

Regulatory impact of option

Industry

Producers of untreated juices that chose to comply with the code of practice and label their products would incur the associated compliance costs. The actual cost of labelling products is expected to be relatively small. One company estimated that it would cost approximately \$300 to redesign a label to include the word 'unpasteurised'. The total cost is then dependent on how many labels the company has to modify. However, the greater cost may be a reduction in sales, if consumers choose to no longer purchase the unpasteurised product. If a company perceives that labelling its products as 'unpasteurised' will result in a reduction of sales, it is unlikely to voluntarily choose to do this.

Those who chose not to comply would avoid these costs. If there were producers who did not label their products, consumers and in particular at-risk consumers would not be able to identify the untreated juices. This could result in consumers unknowingly drinking untreated juice and illness could occur.

If voluntary compliance is low and an outbreak did occur, the industry as a whole would incur the costs of lost sales if consumer confidence in the juice industry falls.

Consumers

Consumers would benefit from the education strategy, as it would raise awareness about the potential risk of untreated juices. However, this strategy can only be fully effective if there is high compliance with the voluntary labelling, as otherwise consumers will have difficulty distinguishing the untreated juice in the marketplace. Consumers would also benefit if producers of untreated juice followed a code of practice, as it would lower the risks associated with this product. If there were low compliance with the code of practice and labelling, consumers would incur similar costs to option 1, as there would be little difference from the status quo.

Government

Theoretically this option does not include any new enforcement costs for government. However, government is likely to incur the cost of encouraging producers of untreated juice to comply with the voluntary code of practice and labelling as well as monitoring the level of compliance. This could be costly if producers are reluctant to comply. If compliance is low, government will incur similar costs to option 1.

Government will also incur the cost of an education strategy. The cost of an education strategy is discussed further under option 4.

Assessment of option

A non-regulatory approach could be effective in reducing the risks associated with untreated juices if compliance was high. Government is likely to incur costs to encourage compliance and monitor level of compliance. It will also incur the cost of an education strategy. However, there may still be a percentage of producers who choose not to comply. This is particularly the case with labelling, as manufacturers of untreated juices may be reluctant to label their products as such due to the risk of a reduction in sales. If compliance is low, the cost to consumers and in particular to at-risk consumers could be high.

An approach similar to Canada's could be considered where the non-regulatory approach could be trialled for a period and then evaluated to assess its effectiveness. If the non-regulatory approach was not effective, regulatory measures could be considered. It is ANZFA's understanding that Canada is still in the process of evaluating the effectiveness of its program and therefore it is too early to conclude whether the non-regulatory approach has been a success.

Conclusion

A non-regulatory approach could be trialled for a period, but its effectiveness would need to be assessed.

Option 3 – All fruit and vegetable juices to be subjected to a 5-log pathogen reduction process or be labelled with a mandatory advisory statement

This option is similar in approach to the applicant's proposal. However, it differs from the applicant's proposal in the following ways:

- it applies to all fruit and vegetable juices;
- it specifies the food safety outcome to be achieved through the processing of the juice i.e. a 5-log reduction in the most resistant pathogen of concern likely to occur in the juice; and
- it does not specifically exempt freshly squeezed juices for immediate consumption from the processing and labelling requirements.

This option extends to all fruit and vegetable juices as the risk assessment (Attachment 5) concludes that all untreated fruit and vegetables juices potentially pose an increased food safety risk as compared to treated juices.

This option specifies a 5-log reduction process instead of the pasteurisation or equivalent process specified by the applicant, as it would be difficult to determine equivalence to pasteurisation if a food safety outcome is not stated. The 5-log reduction process is the process specified by the US Food and Drug Administration (FDA) and has been determined to be adequate to achieve the safety of juices.

Freshly squeezed juices for immediate consumption have not been specifically exempted from the processing and labelling requirements in this option because if this option is preferred, they would automatically be exempted from labelling requirements by virtue of paragraph 2(1)(c) of Standard 1.2.1 Application of Labelling and Other Information Requirements. This paragraph exempts food that is sold from the premises where it was made and packaged.

Processing

All juices would need to have been subjected to a process capable of achieving a 5-log reduction in the most resistant pathogen of public health significance likely to occur in the juice or be labelled as ‘unpasteurised’. The FDA has concluded that target pathogens must be chosen on the basis of historical association with a product and the way in which the product is processed. The majority of outbreaks from juice have been caused by *E. coli* O157:H7, *Salmonella* spp. and *Cryptosporidium parvum*. The FDA has indicated that producers may also wish to consider *Listeria monocytogenes*. While this organism has not been associated with any outbreaks, it is ubiquitous and can have serious health consequences for the elderly and pregnant women.

Producers would be most likely to achieve the 5-log reduction process through pasteurisation. However, this option would enable manufacturers to use alternatives to pasteurisation that can still achieve the 5-log reduction such as ultra-high pressurisation. Other possible options would be the use of UV radiation, pulsed light and sodium benzoate. The FDA has also indicated that citrus fruits could be subjected to surface treatments to achieve all or part of the 5-log reduction process. At this stage, other fruits would need to rely on additional treatments to surface treatment, due to the risk of contamination becoming internalised into the fruit and carried into the juicing step.

With this option, producer of juices will effectively be able to exempt themselves from the processing requirements, provided they label the juice as ‘unpasteurised’. However, some producers would also be exempted from the labelling requirements (see discussion below).

Labelling

All packaged juices that have not undergone a process capable of achieving the 5-log reduction would need to be labelled as ‘unpasteurised’.

In accordance with the new Code requirements, juices that are made and packaged from the premises where they are sold, such as those that are freshly squeezed for immediate consumption, would need to include a statement to the effect that the juice had not been pasteurised in connection with the display of the food or provide the information to a purchaser upon request.

This means that freshly squeezed juices sold from retail establishments, markets, fairs, roadside stalls etc would not need to be labelled. However, if asked, the business would need to inform the purchaser that the juice had not been pasteurised.

Regulatory impact of option

Consumers

Consumers would benefit from being able to distinguish those packaged products on the marketplace that have not been treated as they would be labelled as ‘unpasteurised’. This will enable at-risk consumers to avoid purchasing these products, thereby lowering their chance of becoming ill from packaged unpasteurised juices.

However, juice that is sold from the premises where it was squeezed is likely to be unpasteurised and will not be labelled. Therefore consumers may not know that these juices are likely to be unpasteurised. They may also not know to ask the seller of the juice whether or not the juice is pasteurised. Advice from the juice industry is that the majority of unpasteurised juice sold is sold from the premises where it was squeezed.

This option also does not include any strategies for lowering the contamination levels in untreated juice.

Therefore, this option may enable at-risk consumers to avoid untreated packaged juices on the marketplace but will not assist consumers to identify the unpackaged, untreated juices sold through retail establishment, markets etc, which makes up the majority of the untreated juice sold. At-risk consumers could therefore continue to unwittingly purchase unpackaged untreated juices, which could be contaminated.

Industry

Producers of packaged 'untreated' juice will incur the costs of labelling untreated juices. The actual cost of labelling products is expected to be relatively small. One company estimated that it would cost approximately \$300 to redesign a label to include the word 'unpasteurised'. The total cost is then dependent on how many labels the company has to modify. However, the greater cost may be a reduction in sales if consumers choose to no longer purchase the packaged untreated product. Small businesses which manufacture and package juice on the premises from where it is sold would be exempt from the labelling provision and would incur no labelling costs.

Alternatively producers of packaged 'untreated' juice could opt to pasteurise or otherwise treat the juice to avoid the labelling requirement. In the New Zealand retail news bulletin, *Retail Today* in June 2001, it was reported that the leading New Zealand juice manufacturer, Frucor Beverages, has already opted to spend more than \$480,000 (Aus) to install a pasteuriser and clean room system in response to this Application. The company believes pasteurisation is the best option because it reduces the risk of pathogens, which can cause food poisoning. The Australian company who sold the contaminated juice responsible for the Salmonella outbreak in early 1999, spent \$110,000 installing a pasteurisation unit following this outbreak.

A benefit of this option for industry is that it should enable at-risk consumers to identify and therefore avoid untreated packaged juices in the marketplace, reducing the risk of these consumers becoming ill from these juices.

However, this benefit would not extend to the unpackaged juices, as they are unlikely to be labelled and there is no strategy for informing at-risk consumers of potential risks of these juices nor how to identify them in the marketplace. Therefore at-risk consumers may continue to unwittingly purchase these juices.

This option also does not include any strategies for lowering the contamination levels in untreated juice.

If an outbreak occurred from unpackaged juices, the company affected would incur costs and if it is a small company, it could cause the closure of the business. However, it could also cost the fruit juice industry as a whole if consumers perceive juices to be a risky product and purchase less of it.

Government

Government would incur the cost of enforcing the labelling requirements. Government would benefit if this management strategy is effective for the packaged juices and at-risk consumers avoid purchasing these juices and therefore no illness occurs. However, government would incur the health and management costs associated with any outbreaks from the unpackaged juices.

While the probability of a person becoming ill from unpackaged juices is low, the severity of the illness could be high. For example, if a young child was infected with enterohaemorrhagic *E.coli*, the child could develop Haemolytic Uraemic Syndrome, which can cause renal failure and death. Survivors of Haemolytic Uraemic Syndrome may require long term health treatment including dialysis and kidney transplants, which are very costly to treat.

Assessment of option

This option may effectively manage the risks associated with packaged untreated juices, as these juices will need to be labelled if they have not undergone a 5-log reduction process.

However, this option does not adequately manage the risks associated with the untreated juices that are sold unpackaged. Under this option, these juices would not be required to comply with any process requirements and would also not need to be labelled.

Consumers would therefore not be informed about the potential risks of these juices and may continue to unwittingly purchase these juices. While the probability of consumers becoming ill from these juices is low, the consequences could be high, particularly for at-risk consumers.

Conclusion

This option does not adequately manage the risks associated with the untreated juices that are sold unpackaged. The costs of not managing this risk are therefore likely to outweigh the benefits.

Option 4 – A combination of regulatory and non-regulatory measures

This option consists of the following regulatory and non-regulatory measures:

Regulatory measures

- labelling of packaged juices as ‘unpasteurised’ if they have not undergone a process capable of achieving at least a 5-log reduction in the most resistant pathogen of public health significance likely to occur in the juice; and

- mandatory microbiological criteria for untreated juice requiring not detectable levels of *E. coli* and *Salmonella* spp.;

Non-regulatory measures

- a voluntary code of practice for the producers of untreated juices outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice; and
- consumer education to increase awareness of the potential risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace.

Processing

This option would require juice to have been subjected to a 5-log pathogen reduction process or to have not detectable levels of *E. coli* and *Salmonella* spp. in the juice. *Salmonella* species and pathogenic strains of *E. coli* have been responsible for the majority of outbreaks from untreated juice. The absence of these microorganisms in untreated juice would provide an indication (but not a guarantee) that the fruit used in the juice was not contaminated. Mandatory microbiological criteria for untreated juice would provide a more level playing field between producers of untreated and treated juice. Without this criteria, producers of treated juice may consider that producers of untreated juice are not required to take steps to minimise the risks associated with the juice and can simply label their products as ‘unpasteurised’ or for those exempted from labelling, not do anything.

Producers of untreated juices would be encouraged to comply with a voluntary code of practice to assist them achieve the mandatory microbiological criteria and meet their legal obligation to sell safe food under State/Territory and New Zealand Food Acts. It would also enable Australian producers to meet their more specific obligation to process juices safely under the new Food Safety Standards.

The code of practice would outline ways to minimise the contamination of fruit while it is being grown, harvested, stored and then processed to make juice. It would therefore cover safe practices for the farm, factory and retail and would be developed with representatives from the fruit juice industry. Similar codes have already been developed in the USA and Canada and could form the basis of an Australian and New Zealand code.

Labelling

Packaged untreated juices would need to be labelled as ‘unpasteurised’. However, juices sold from the premises where they were made and packaged would not have to be labelled as ‘unpasteurised’ but the seller would need to inform the purchaser that the juice was unpasteurised if asked. This would include ‘freshly squeezed juices’ sold by retailers and at markets etc. The labelling requirements would be supported by an education strategy which would aim to increase consumer awareness, particularly for at-risk groups about the potential risks associated with untreated juice and advice on how to distinguish between treated and untreated juices in the marketplace. In relation to product identification in the marketplace, it would aim to increase awareness that:

- freshly squeezed juices sold by retailers and at markets etc. have not been pasteurised or otherwise treated and if in doubt to ask the seller of the juice;
- some juices purchased in the refrigeration section of supermarkets may not have been pasteurised or otherwise treated and to check the label to determine whether it is labelled as ‘unpasteurised’; and
- juices purchased unrefrigerated have been pasteurised.

An education strategy would need to be developed to determine how best to raise consumer awareness of the potential risks with untreated juices. Approaches that could be considered include:

- posting consumer information on ANZFA’s website;
- having written information available to consumers in the form of a leaflet or brochure;
- encouraging the media to highlight the potential risks through newspapers, magazines and health/lifestyle television programs; and
- disseminating key information to at-risk groups through childcare, aged care and health associations as well as bodies involved in nutrition education.

Regulatory impact of option

Consumers

Consumers would benefit, through the labelling and education strategy, of having an increased understanding of the potential risks associated with untreated juices and how to distinguish these products in the marketplace. These products would be identified as ‘unpasteurised’. This will enable at-risk consumers to avoid these juices.

While the probability of these consumers contracting an illness from these juices is low, the effects could be severe or life threatening. Therefore any reduction in the possibility of at-risk consumers becoming seriously ill from untreated juices will provide a significant benefit. For example, if the labelling and the education strategy results in a parent not giving his/her child an unpasteurised juice contaminated with a strain of enterohaemorrhagic *E. coli*, it could save the life of the child.

Consumers generally will also potentially benefit from safer untreated juices, if the producers of these juices comply with the microbiological limits and voluntary code of practice.

Industry

If the education strategy is successful in increasing consumer awareness of the potential risks associated with untreated juices and how to distinguish these products in the marketplace, this option is likely to benefit producers of treated juices through increased sales and cost producers of untreated juices through a reduction in sales. Producers of packaged untreated juice will also incur the cost of labelling, though this is likely to be less costly than the loss of sales. If these producers wished to avoid the labelling requirement, they would incur the cost of installing a pasteurising unit or other alternatives treatments. These costs are discussed under option 3. Small businesses which manufacture and package juice on the premises from where it is sold would be exempt from the labelling provision and would incur no labelling costs.

All producers of untreated juice may incur costs associated with the microbiological criteria and complying with the code of practice, if they choose to comply with it. Costs associated with the microbiological criteria could include regular batch testing of the juice for the pathogens, *E. coli* and *Salmonella*. However, these costs would not be mandatory. It would be the decision of the business whether to test or not. Cost to comply with the code of practice would vary depending on whether a business needed to up-grade its operations to meet the code. Costs could include up-grading equipment and facilities, purchasing better quality fruit and improving cleaning and sanitation procedures.

However, overall the juice industry should benefit from a decreased likelihood of a serious food-borne illness outbreak occurring from untreated juices thereby avoiding an incident, which could potentially damage consumer confidence and therefore sales in juice.

Government

Government will incur the cost of enforcing the new labelling and microbiological criteria requirements, developing a code of practice and assessing its effectiveness and developing and implementing a consumer education strategy.

The cost to enforce the new labelling requirements is expected to be small as the vast majority of packaged juice sold is pasteurised and therefore only a small number of products will be affected.

The cost to enforce the microbiological criteria would include taking samples of juices and getting them analysed.

The cost to produce a code of practice would also be small but the cost to assess whether it is being complied with would be much larger. Enforcement officers would need to individually assess whether the businesses covered by the code are complying with it. While this could be done as part of a routine inspection of the business, the inspection would take longer.

The cost of an education strategy will vary depending on its size. The approach suggested for the strategy is discussed earlier in this option. The main cost for the suggested approach would be the development, printing and dissemination of a consumer brochure.

Government would benefit from a decreased likelihood of a serious food-borne illness outbreak occurring from untreated juices thereby avoiding the costs associated with managing and investigating such an outbreak. It would also avoid the health care costs associated with an outbreak.

Assessment of option

This option is similar to option 3 but has the advantage of addressing option 3's shortcomings by including additional strategies to minimise the risks associated with the production of untreated juice and by increasing consumer awareness of these risks and how to identify treated and untreated products in the marketplace. This is achieved through the mandatory microbiological limits for untreated juices, the voluntary code of practice for the production of untreated juice and the consumer education strategy.

While producers of untreated juice and government will incur costs with this option, it has the benefit of reducing the likelihood of at-risk consumers becoming ill from drinking untreated juice. It also has the benefit of protecting the fruit juice industry as a whole from another outbreak. While the likelihood of an at-risk consumer contracting an illness from an untreated juice is small, the consequences of the illness could be severe or even life threatening. Mandatory microbiological limits may place a high compliance burden on industry, particularly small businesses, but the benefits outweigh the costs.

Conclusion

Through its combination of regulatory and non-regulatory measures, this option has the potential to minimise the potential risks associated with untreated juice. However, there will be costs for producers of untreated juice and government.

Option 5 – Require juice manufacturers to implement a HACCP system that includes a 5-log pathogen reduction process

This is similar to the current FDA requirement. However, the FDA requirement does not take effect until early 2002 and small businesses will have longer to comply. The FDA has also not applied the HACCP requirement to retail producers of juice i.e. those that squeeze juice on the premises where the juice will be sold.

Processing

This option would require all juice manufacturers, including retail manufacturers to implement a HACCP system that included a 5-log reduction process.

Labelling

Labelling would not be required as there would not be a need to distinguish between juices in the marketplace, as all juices would have been subjected to the same process requirements.

Regulatory impact of option

Consumers

Consumers, and in particular, at-risk consumers, would have the benefit of only having juice available in the marketplace that had been processed to minimise potential hazards with the juice. Therefore, the likelihood of becoming ill from consuming this juice would be greatly reduced. However, this benefit would come at a cost. Consumers would be likely to pay more for juice that had been processed under a HACCP system and would be restricted to the type of juices they could purchase. Freshly squeezed juices, normally sold through retail establishments, would be unlikely to be available.

Industry

This option would benefit larger commercial manufacturers of pasteurised juice that may already be operating under a HACCP system or would have little difficulty in meeting HACCP requirements. These manufacturers would benefit from having minimal compliance costs and potentially an increase in market share if smaller manufacturers decide to cease operating. Smaller manufacturers of pasteurised juice would incur the costs associated with implementing a HACCP system but would have lower compliance costs than producers of untreated juice.

This option would cost producers of untreated juices. These producers would incur the costs of validating a 5-log reduction process, which would be difficult and expensive if pasteurisation is not used. Therefore, the majority of retail establishments are likely to cease selling freshly squeezed juice.

Manufacturers of juice that remain would benefit from the reduced likelihood of illness occurring from the consumption of the juice. The juice industry would therefore be unlikely to suffer the costs of an outbreak.

Government

Government would incur the cost of enforcing the new HACCP requirements. The benefits for Government of a reduced likelihood of any illness occurring from the consumption of juices would include fewer costs from investigation of outbreaks and reduced health care costs associated with outbreaks.

Assessment of option

This option would be very effective in minimising the food safety risks associated with juice but it would come at a high price. The likely result is that freshly squeezed juices would no longer be sold by small businesses. This high price is unlikely to be acceptable to smaller producers of untreated juices and the majority of consumers.

Mandating HACCP would also be inconsistent with current government policy. The Food Safety Standard 3.2.1 Food Safety Programs has been gazetted as a 'model' standard and specifies requirements for the implementation of programs based on HACCP. However, this Standard does not apply to any food business unless a State or Territory opts to require it. At this stage, the State of Victoria is the only jurisdiction implementing mandatory food safety programs. Nationally, mandatory food safety programs are unlikely to be considered until the Commonwealth Department of Health and Ageing completes its studies on the costs and efficacy of food safety programs.

Conclusion

While this option would be the most effective in controlling the food safety risks associated with untreated juices, the cost of the option makes it prohibitive.

Option 6 – similar to option 4 but with a more comprehensive labelling requirement, a permission for citrus fruit to utilise surface treatments, a requirement for the 5-log reduction process to take place within a single facility and no mandatory microbiological criteria

This option consists of the following regulatory and non-regulatory measures:

Regulatory measures

- labelling of packaged juice with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’, if the juice has not undergone a process capable of achieving at least a 5-log reduction of the most resistant pathogen of public health significance likely to occur in the juice;
- the 5-log reduction process would need to be conducted on the juice itself with the exception of citrus fruits. Surface treatments could be applied to citrus fruits after the fruit is cleaned (i.e. washed) and culled (i.e. damaged or dropped fruit is removed); and
- all 5-log reduction processes would need to be conducted within a single facility.

Non-regulatory measures

- a voluntary code of practice for producers of untreated juices outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice; and
- consumer education to increase awareness of the potential risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace.

Processing

This option would require juice to have been subjected to a 5-log reduction process or, if it is packaged, to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. Producers of juice made from citrus fruit would be permitted to utilise surface treatments as part of the 5-log reduction process. All 5-log reduction processes would need to be conducted within a single facility.

All producers of untreated juices would be encouraged to comply with a voluntary code of practice to assist them meet their legal obligation to sell safe food under State/Territory and New Zealand Food Acts. It would also enable Australian producers to meet their more specific obligation to process juices safely under the new Food Safety Standards.

The code of practice would outline ways to minimise the contamination of fruit while it is being grown, harvested, stored and then processed to make juice. It would therefore cover safe practices for the farm, factory and retail and would be developed with representatives from the fruit juice industry. Similar codes have already been developed in the USA and Canada and could form the basis of an Australian and New Zealand code.

It is also recommended that the code of practice include guideline microbiological criteria. These criteria could include pathogens as well as indicator organisms and would provide producers with an indication as to whether their processes are minimising the level of contamination in the untreated juice.

Labelling

This option requires a more comprehensive labelling statement than outlined in option 4. Untreated packaged juice would need to be labelled with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’. This option also includes the same consumer education strategy outlined in option 4.

Regulatory impact of option

The option is being considered to overcome the perceived shortcomings identified within option 4 as a result of the submissions received and further consideration by ANZFA. The costs and benefits are similar to option 4. However, it includes a more comprehensive labelling statement, permits citrus fruits to utilise surface treatments, requires the 5-log reduction process to be conducted within single facility and does not include mandatory microbiological limits. The costs and benefits of these changes for consumers, industry and government as they differ from option 4, are discussed below.

Consumers

The inclusion of a more comprehensive labelling statement in this option is likely to benefit consumers. Labelling untreated juices with a statement to the effect that ‘the product has not been pasteurised or treated to achieve the equivalent result’ is likely to enhance consumer understanding that there are two categories of juice in the marketplace. The two categories being those that have been pasteurised or treated in a manner equivalent to pasteurisation and those that have not been subjected to any form of treatment. The more comprehensive labelling statement will also make it easier to explain these two categories in the consumer education strategy. This will enable at-risk consumers to have more confidence in purchasing those juices that have been subjected to alternative treatments and hence provide them with a wider range of choice.

The permission for producers of juice made from citrus fruits to utilise surface treatments will potentially benefit consumers by providing them with a wider range of choice for treated juices.

The requirement for the 5-log reduction process to be conducted with a single facility potentially benefits consumers by providing a greater level of assurance of safety with treated juices. If producers were able to split the 5-log reduction process over more than one facility, there is a greater chance of further contamination occurring, which may not be able to be removed.

It is unlikely that the absence of mandatory microbiological limits will lower the safety of untreated juices and therefore negatively impact on consumers. As the majority of untreated juice that will be available to consumers will be freshly squeezed juice sold for immediate consumption, the absence of mandatory microbiological criteria is likely to have little impact. Consumers will still potentially benefit from safer untreated juices, if producers of these juices comply with the code of practice. It is also proposed to include guideline microbiological limits in this code.

Industry

Producers of untreated juice will incur greater costs to comply with the extended labelling statement, as it will cost more to include the additional words on the label. However, the extended labelling statement will potentially benefit producers of juice that has been treated using alternative treatments to pasteurisation through increased sales, as consumers are likely to have a better understanding that these products are safe to consume.

The permission for producers of juice made from citrus fruit to utilise surface treatment will benefit producers who wish to make use of this permission. ANZFA is aware of one producer within Australia who is already using surface treatments and if this permission was not included, this producer would no longer be able to sell its juice unless it was labelled with the required labelling statement for untreated juice.

The requirement for the 5-log reduction process to be conducted within a single facility is likely to have only a minimal impact on industry. Pasteurisation processes already occur within a single facility and as far as ANZFA is aware, producers utilising alternative treatments also apply these treatments within a single facility. However, if a producer were applying a number of treatments to the fruit and/or juice to achieve the 5-log reduction process over more than one facility, it would incur the costs of moving all the treatments to the one facility.

The removal of mandatory microbiological criteria potentially means lower costs to producers of untreated juices, as these producers will no longer have to comply with these criteria. While mandatory microbiological criteria does not in itself require producers to test their products, the deletion of this requirement may mean producers will decide not to test product or to test product less often.

Government

The extended labelling statement is unlikely to result in additional costs to option 4, as there should be similar enforcement costs.

The permission for surface treatments to be applied to citrus fruit potentially benefits government because it allows producers to utilise alternative treatments that have already been recognised. Surface treatments on citrus fruits are permitted in the USA as they have been shown to be effective and therefore it would have been difficult for the government to justify not allowing these surface treatments.

Government is unlikely to incur greater costs to enforce the requirement for the 5-log reduction process to be conducted within a single facility, as it appears that this is already occurring.

There are potentially lower enforcement costs with the removal of the mandatory microbiological criteria. Government would no longer be obliged to take samples of untreated juice to assess whether it was complying with these criteria.

Assessment of option

The option overcomes the perceived shortcomings identified within option 4 as a result of the submissions received and further consideration by ANZFA.

The inclusion of a more comprehensive labelling statement will cost more for producers of untreated juice. However, it will provide greater benefits for consumers over option 4 as it will better enable consumers to identify alternatively treated juices and understand that these juices are also safe. This will potentially benefit producers of juice that has been alternatively treated through increased sales.

The permission for producers of juice made from citrus fruits to utilise surface treatments provides a clear benefit to these producers as without this permission, as it the case under option 4, they would no longer be able to sell their product unless it was labelled with the required labelling statement.

The requirement for the 5-log reduction process to be conducted within single facility should have a minimal impact, as it appears this is already occurring. However, if it is not, the producer will need to move its processes under the one facility, providing a greater level of assurance of safety in this product, which benefits the consumer.

The removal of the mandatory microbiological criteria has the benefit over option 4 of not including the costs to industry to comply with these criteria or to government to enforce it. This lowering in costs is unlikely to adversely impact on the safety of juice and therefore consumers as the majority of untreated juice will be drunk before it can be tested.

Overall assessment of options and regulatory impact

Option 1

This option includes no new costs for industry but it is unlikely to address the potential risks associated with untreated juices, as consumers will not be informed of the potential risks and will not be able to distinguish the different products on the marketplace. At-risk consumers could therefore unwittingly expose themselves to a risk that could easily be avoided. This makes this option too costly for consumers.

Option 2

A complete non-regulatory approach could be trialled for a period and then evaluated to assess its effectiveness. If this approach was shown to be ineffective, regulatory measures could be introduced. The disadvantage of opting for a non-regulatory approach is that if compliance is low, at-risk consumers could be unnecessarily exposed to risks while the approach is being implemented and evaluated. If compliance is high, the food safety benefits will be the similar as for those options that include regulatory components (options 3-6), but so also will be the costs. Therefore as the costs would be similar for the options that include regulatory components, these options are preferred over this one.

Option 3

Option 3 will require labelling of packaged untreated juice as ‘unpasteurised’ but it does not address all potential issues with the labelling and processing of these juices. Specifically it effectively exempts untreated juice from any processing requirements, provided they are labelled. It also does not include any consumer education strategy to increase consumer awareness of the potential risks of untreated juices and how to distinguish between the treated and untreated juices in the marketplace especially where labelling is not required.

While this option will be cheaper for both industry and government than options 4, 5 and 6, the cost to consumers is considered to outweigh this benefit.

Option 4

This option includes the mandatory labelling outlined in option 3 but has the advantage of including additional measures to address option 3's shortcomings. These measures are:

- encouraging producers of untreated juice to minimise contamination of this juice by adhering to mandatory microbiological criteria and complying with a voluntary code of practice; and
- increasing consumer awareness of the risks associated with the untreated juices, particularly for at-risk groups and advice on how to distinguish between treated and untreated juices in the marketplace through a targeted education strategy. The nature of this strategy would be finalised after undertaking further consultation.

These additional measures will benefit consumers as it has the potential to increase the safety of untreated juices, increase consumers awareness of the risks associated with untreated juices and assist at-risk consumers to identify untreated juices in the marketplace unlike options 1 and 3. This should result in a reduced likelihood of food-borne illness occurring from untreated juices. It also has the benefit of allowing consumers to choose between treated and untreated juices in the marketplace, unlike option 5.

This option will be more costly than options 1 and 3 for producers of untreated juice as it may result in reduced sales of their product and they are likely to incur costs to comply with the microbiological criteria and code of practice. However, it will be less costly for these producers, than option 5 where untreated juices could not be sold. This option would have similar costs to option 2, if there was high compliance with the non-regulatory approach outlined in this option.

This option is more costly for government than options 1 and 3 but less costly than option 5. It may also be less costly than option 2, which is likely to include extra costs to encourage compliance and evaluate the effectiveness of the non-regulatory approach. This option provides greater benefits than options 1 and 3, similar benefits to option 2 and less benefits than option 5.

The benefits of this option to consumers are considered to outweigh the costs to producers of untreated juice and government.

Option 5

Option 5 addresses the potential risks associated with untreated juice by requiring all juice to be produced under a HACCP system that includes a 5-log reduction process. This would mean that untreated juice could not be sold. This option provides the greatest food safety benefit to consumers by ensuring untreated juices are not sold but will deny consumers the choice to purchase these juices. This option will be the most expensive for the juice industry due to the high compliance costs and the loss of market in the sale of untreated juices. This option may also be costly to government if industry and consumers are not supportive of this strict approach. It is therefore considered that the cost of this option outweighs the benefits.

Option 6

This option will provide similar benefits to option 4 but will overcome the perceived shortcomings of option 4 identified through submissions and further consideration by ANZFA. The changes necessary to overcome these perceived shortcomings would have the greatest impact on consumers and industry.

Consumers will benefit by having a better understanding of the two categories of juices on the marketplace, those that are pasteurised or alternatively treated and those that are untreated. This is likely to assist consumer understanding that both pasteurised juice and juice that has undergone an equivalent process are safe for at-risk consumers to drink. Under option 4, untreated juices would be labelled as 'unpasteurised' and consumers may therefore have concluded that only pasteurised juices were safe to drink.

Parts of industry will potentially benefit from this option and others will incur greater costs over option 4. Producers of alternatively treated juices will potentially benefit through increased sales if there is increased consumer understanding that these juices are also safe to consume. Producers of juice made from citrus fruits will benefit by being able to utilise surface treatments. Producers of untreated juices are likely to have greater costs to include the longer labelling statement.

The increased benefits to both consumers and parts of the juice industry over option 4 are considered to outweigh the increased costs to the producers of untreated juice. This option is therefore the preferred option.

Preferred option

Option 6 is the preferred option as it outlines the most cost effective way of managing the potential risks associated with untreated juice.

The drafting changes to the *Food Standards Code* necessary to make effective the proposed regulatory measures are included at Attachment 1.

It is recommended that the regulatory measures not commence until six months after the gazettal of the requirements to provide producers of juice sufficient time to become familiar with the requirements and if necessary, make labelling changes and change any of their processing practices.

Risk Assessment of Fruit and Vegetable Juices

Scope

This risk assessment assesses the risk of all fruit and vegetable juices (including concentrates) both treated and untreated. It also includes all shelf-stable, frozen and refrigerated products.

It primarily assesses the microbial risks associated with these juices, but also assesses the physical and chemical hazards.

Hazard Identification

The hazards associated with fruit and vegetable juices can be categorised as physical, chemical and microbiological and are identified under these three categories below.

Physical

A physical hazard in juice is considered to be any physical matter present in the juice that could cause harm to a person who consumes this juice. Examples include, glass, plastic, metal, and stones.

Chemical

A chemical hazard in juice is considered to be any chemical substance present in the juice that could cause harm to a person who consumes this juice. Examples include:

- pesticides and fungicides or other agricultural chemicals present at unsafe levels;
- heavy metals and other metals present at unsafe levels such as lead and cadmium;
- non-metal chemical contaminants such as cleaning chemicals;
- natural toxicants such as patulin; and
- food additives present at high levels or present when they should not be.

Microbiological

Microbiological hazards found in juices include those from bacteria, viruses and parasites. Table 1 lists food-borne illness outbreaks that have occurred from juice contaminated with microorganisms. Two outbreaks have occurred in Australia, one from a Norwalk-like virus and another from *Salmonella typhimurium*. The majority of the outbreaks have been caused by *E.coli* O157:H7 and *Salmonella* spp. The outbreaks listed in the table have occurred from both heat-treated and non heat-treated juice.

Prior to the 1990s, it was commonly thought that pathogenic bacteria were of minimal concern for fruit juice processors.⁵ In recent years, however, the relationship between pathogenic bacteria and fruit juices has received increased attention due to a series of well publicised disease outbreak from juices.⁵

While juices are acidic, certain species of pathogens including an *E. coli* O157:H7 strain (ATCC 43895) can survive exposure to extremely acidic (pH <3) environments. Most juices, including apple (pH = 3.4-4.0), orange (pH=3.6-4.3), grapefruit (pH = 3), prune (pH = 3.7), tomato (pH = 4.1 – 4.2), and pineapple (pH = 3.5), are not acidic enough to guarantee pathogen inactivation. Sugar concentrations are also probably too low to ensure safety. Parasites and human viruses will not multiply in juice, but will not be inactivated.¹⁰

A study by Parish suggests that salmonellae, which might contaminate orange juice could survive sufficient time to cause illness. This study showed that salmonellae could survive in detectable numbers in orange juice up to 27 days at pH 3.5, 46 days at pH 3.8, 60 days at pH 4.1 and 73 days at pH 4.4. Parish concluded when present in sufficient numbers in orange juice, *Salmonella serovars* may survive long enough to cause illness in susceptible persons.¹

Bacterial pathogens will not reproduce in typical fruit juices due to the low pH. However, they can survive in the juice. The survival time for bacterial pathogens in juice depends on juice pH, storage temperature and the physiological state of the microorganisms. In general, survival increases at higher pH levels and under chilled storage conditions.⁵ Evidence suggests that pathogens in low pH systems die more rapidly at temperatures approaching room temperatures than under very cold (non frozen) conditions.²

Year	Disease vehicle	Causative micro and no. of cases	Possible cause	Country	References
1922	Infected apple cider* Unpasteurised	<i>S. typhi</i> , 24 cases reported	Contaminated stream water used to rinse apples	France	2, 5
1944	Orange juice	<i>S. typhi</i> , 18 cases reported	Asymptomatic food handler	USA	2, 5, 9
1962	Orange juice Reconstituted	Hepatitis A, 24 cases	Asymptomatic food handler	USA	2, 5
1967	Orange juice Reconstituted	Gastroenteritis agent, 5200 cases reported	Contaminated water added to juice concentrate	USA	2, 5, 10
1975	Apple cider* Unpasteurised	<i>S. typhimurium</i> , 296 cases reported	Faecal contamination of apples	USA	2, 5, 10
1980	Apple cider* Unpasteurised	<i>E. coli</i> O157:H7, 14 cases, one death	Faecal contamination of apples	Canada	2, 5, 16
1989	Orange juice Reconstituted	<i>S. typhi</i> , 69 cases reported	Asymptomatic food handler	USA	2, 5, 10
1991	Apple cider* Unpasteurised	<i>E. coli</i> O157:H7, 23 cases (4 HUS)	Faecal contamination of apples	USA	2, 5, 10
1991	Orange juice Reconstituted Unpasteurised	Norwalk-like virus, >3000 cases reported	Contaminated water added to juice concentrate	Australia	8
1991	Coconut milk, unpasteurised	<i>Vibrio cholerae</i> O1, 4 cases reported	Contamination during manufacture	USA (product manufactured in Thailand)	10
1992	Orange juice Unpasteurised	Enterotoxigenic <i>E. coli</i> , unknown no. of cases	Poor sanitation and facility design	India	2, 5

1992	Orange Julius drink	<i>Salmonella agona</i> , 25 cases reported		USA	10
1993	Apple cider* Unpasteurised	<i>Cryptosporidium parvum</i> , 160 cases reported	Faecal contamination	USA	2, 5
1993	Orange juice	Yeast or unknown toxicant, 23 cases reported	Improper storage time and container	USA	10
1993	Watermelon drink Unpasteurised	<i>Salmonella spp.</i> , 18 cases	Home-made	USA	10
1994	Orange juice	<i>Bacillus cereus</i> ; yeast, 85 cases reported	Fermented; juice left at room temperature	USA	10
1995	Orange juice Unpasteurised	<i>S. Hartford</i> , <i>S. gaminara</i> , <i>S. rubinslaw</i> , 62 cases reported	Environmental contamination from factory surrounds	USA	2, 5, 6, 10
1995	Orange juice Unpasteurised (freshly squeezed)	<i>Shigella flexneri</i>	Contamination from hands of staff squeezing the oranges	South Africa	7
1996	Orange juice Unpasteurised	Virus suspected, 2 cases reported	Symptomatic food handlers	USA	5
1996	Apple juice Unpasteurised	<i>E. coli</i> O157:H7, 70 cases reported (14 HUS, 1 death)	Faecal contamination of apples	USA	2, 4, 5, 10, 4
1996	Apple cider* Unpasteurised	<i>E. coli</i> O157:H7, 14 cases reported (3 HUS)	Faecal contamination of apples	USA	10
1996	Apple cider* Unpasteurised	<i>E. coli</i> O157:H7, 6 cases reported	Cider made at church event	USA	10
1996	Apple cider* Unpasteurised	<i>Cryptosporidium parvum</i> , 31 cases reported	Contaminated wash water	USA	2, 5, 10
1998	Apple cider* Unpasteurised	<i>E. coli</i> O157:H7, 10 cases	Two farm families that used dropped apples	Canada	16
1999	Orange juice Unpasteurised	<i>Salmonella muenchen</i> , 423 cases reported	Imports of Mexican orange juice that contained melted ice	USA	13, 14, 15, 16
1999	Orange juice Unpasteurised	<i>Salmonella Typhimurium</i> phage type 135a, >500 cases reported	Contaminated oranges from packing shed	Australia	5, 12, SA Health
1999	Apple juice Unpasteurised	<i>E. coli</i> O157:H7, 8 cases reported	Unknown	USA	5
1999	Imported frozen mamey** puree Unpasteurised	<i>Salmonella typhimurium</i> , 13 cases of typhoid fever	Unknown	USA	16
2000	Orange juice Unpasteurised	<i>Salmonella enteritidis</i> , 88 cases	Unknown	USA	15

* In the US, apple cider is unfiltered and unclarified apple juice. It is not a fermented alcoholic drink.

** Mamey is a traditional fruit used in Caribbean drinks

In addition to the outbreaks listed in the table above, there have been other isolated cases of food poisoning associated with juice in the USA. There were four isolated cases of *Clostridium botulinum* from homemade tomato juice, between 1976 to 1983, one case of *C. botulinum* from home-made carrot juice in 1993 and one suspected case of *E. coli* O157:H7 in 1996 likely to have been caused from cow manure on clothes of a farmer making cider.¹⁰

Hazard Characterisation

Physical

Juice may become contaminated with physical hazards at any stage of its production. Sources of physical contaminants include processing equipment (broken pieces of equipment), food handlers (hair, jewellery, hair clips) and materials used to package the juice (glass and plastic). The raw fruits may contain physical contaminants such as dirt and stones but these are likely to be washed or filtered away during the production process.

Physical hazards can cause harm. For example, sharp objects could cause cuts, hard small objects could damage teeth and other foreign objects could cause choking. However, the presence of a foreign object in a food such as juice does not automatically mean that this object will pose a hazard. The majority of foreign objects in food do not cause any harm. If an injury did occur, it is likely to be minor and not life threatening. To ANZFA's knowledge there are no documented cases of foreign objects in juice causing harm in Australia and New Zealand.

The likelihood of a physical hazard occurring in a juice product appears small. Since 1990 there have been nine recalls of juice and juice products in Australia, with only two of these recalls as a result of foreign matter, one due to glass and the other due to metal shavings. Manufacturers normally have effective systems in place to minimise the risk of physical hazards. In the manufacture of juice, physical hazards are likely to be minimised by washing of fruit, use of filters and metal detectors, maintaining equipment in good order and enclosing production lines.

Chemical

Juice may become contaminated with chemicals when the fruit for the juice is being grown and during production. Fruit could become contaminated as it is grown from contaminated water and soil, fertilisers and pesticides. During production, juice could become contaminated with chemicals used within the manufacturing plant such as cleaning chemicals. Food additives may also be added accidentally or at incorrect levels. Natural toxicants such as patulin can occur by the use of rotten or partially rotten fruit to make the juice.

Chemical hazards can cause acute and chronic illness. Acute illness may occur if a chemical contaminant is present in high concentrations. However, the effect of chemical contamination is normally chronic, with the ill effects not becoming apparent for a number of years. For example, pesticide residues (at unsafe levels), consumed for many years, may be large enough to lead to chronic health problems such as cancer.

The likelihood of a chemical contaminant being present in juice appears small. Of the nine recalls of juice and juice products in Australia since 1990, three were chemical related, one product had high sulphur dioxide levels, one product was contaminated with refrigerant and another product contained undeclared sulphur dioxide. Orange juice was one of the foods tested in *The Australian Market Basket Survey* (1996) for pesticides and other contaminants. In this survey no levels of pesticides were detected in the orange juice tested and concentrations of arsenic, cadmium, lead and mercury were within safe limits.

Microbiological

Juice may become contaminated with pathogens from the fruit itself or during processing. Contamination with pathogens is unlikely to occur once the juice is processed and packaged for sale but may occur when the juice is opened. Fruit surfaces, equipment, and employees are the more common sources of pathogens. However, dusts, insects and other pests, and anything that might come into contact with fruit or surfaces that may come into contact with the juice must also be considered possible pathogen sources.² Ways in which fruit juice could become contaminated with pathogens have been listed below for the raw product and during processing.^{10, 5}

Raw Product

airborne pathogens
fertilizers, pesticides, herbicides
wild or domestic animal faeces (increased likelihood of fruit being contaminated if dropped or deteriorated/damaged fruit used)
agricultural water use (especially where poor quality water directly contacts fruit close to harvest)
during transportation
humans

During processing

unsanitary wash water
contaminated water added to concentrated juice
contaminated food surfaces of equipment
contaminated packaging materials
airborne contamination if juice exposed during processing
food handlers

The majority of the outbreaks that have occurred from juice have been attributed to the use of fruit that has been contaminated with animal faeces. Orchards are often located near livestock or wildlife with the potential for microbial contamination. Contamination of the outside of the fruit is more likely to occur if the fruit drops to the ground, hence coming into contact with the faeces. *E. coli* O157:H7 has been cultured from the faeces of deer, sheep, pigs, goats, dogs, birds, flies and a horse.¹⁰

Due to contamination normally being present on the outside skin or peel of the fruit or vegetable, contamination of juice is more likely to where the skin or peel of the fruit is in intimate contact with the juice during processing.² However, pathogens can become internalised through natural plant structures or through decayed or damaged sites on the fruit or vegetable. Submerging warm harvested fruit in cold water also increases the potential for pathogens to infiltrate into susceptible produce.¹⁵

Many of the outbreaks have also occurred from food handler contamination. Food handlers that are suffering or carrying a food-borne disease can transfer pathogens to the juice if they are in contact with it directly or indirectly through surfaces coming into contact with the juice. Outbreaks from juice have been caused by food handlers infected with the Norwalk virus, Hepatitis A, *Shigella flexneri* and *Salmonella typhi*. In many of these instances the food handlers were unlikely to have been aware they were suffering or carrying the disease, as they were asymptomatic.

In the two documented outbreaks of food-borne illness due to contaminated juice in Australia, one was caused by a Norwalk-like virus and the other *Salmonella typhimurium*. In both circumstances the contaminated juice was unpasteurised orange juice. In the 1991 Norwalk-like virus outbreak, the orange juice became contaminated when contaminated water was used to reconstitute the juice. The water within the factory became contaminated through faulty piping that allowed the potable water supply to come in contact with a sewerage line. In the 1999 *Salmonella* outbreak, the oranges used to manufacture the juice were contaminated. These oranges became contaminated in a packing shed, the likely source being a fungicide that the oranges were dipped in. The fungicide dipping tank was open to environmental contamination from birds and other pests and was not cleaned.

The effect of consuming juice contaminated with pathogenic microorganisms could vary from no effect, to severe illness and even death. The effect will depend on the pathogen present in the juice, the number of pathogens present, and the susceptibility of the person consuming the juice.

Of the pathogens that have caused illness in juice, *E. coli* O157:H7 has led to the most severe human health consequences, including haemolytic uraemic syndrome and death.¹⁰ *Salmonella* spp., *Cryptosporidium parvum* and Hepatitis A can also cause severe illness. In particular, *Salmonella typhi* leads to a severe illness (typhoid fever), which may last several weeks and usually requires hospitalisation. The case fatality rate is 6 percent.¹⁰

In the two outbreaks that occurred in Australia from juice, there were no reported deaths.

The numbers of pathogens that need to be present in the juice to cause illness will vary, depending on the pathogen. For example, viruses can cause illness in very small numbers. However, it is likely that all the pathogens that have been responsible for illness in juice were present in low numbers, whether viral or bacterial. Juice is not able to support the growth of bacterial pathogens due to the low pH but can survive in substantial numbers for days to weeks.⁵ In general, survival increases at higher pH levels and under chilled storage conditions.

Some persons are more susceptible to food-borne illness. Infants, small children, the elderly and immunocompromised persons represent those risk populations typically affected when juice borne outbreaks occur.² In one of the outbreaks of apple juice contaminated with *E. coli* O157:H7 in the USA in 1996, the majority of persons affected were young (56% were ≤ 5 year of age). This outbreak also caused serious illness with 36% of cases requiring hospitalisation, 20% developing haemolytic uraemic syndrome and 1 death.⁴

The likelihood of a juice being contaminated with pathogens will depend on how the juice has been processed. If a juice is pasteurised or otherwise heat-treated, pathogens that may have been present in the fruit are likely to be destroyed. If the juice does not undergo any form of heat treatment, pathogens that may have been present on the fruit or introduced during processing, may be able to survive in the juice. Of the 29 outbreaks listed in table 1, 22 were attributed to unpasteurised juices or 76%. Pasteurised juices can also cause illness if they are contaminated after processing. For example, a food handler suffering or carrying a food-borne illness could contaminate juice after pasteurisation, if in contact with the juice itself or a surface that will come into contact with the juice such as a packaging material.

A manufacturer of juice that will not undergo any form of processing such as pasteurisation to destroy pathogens that may be present, must ensure contamination of the product is minimised so that unsafe levels of pathogens are not present in the final product. This will require implementing controls at each step of the manufacturing process that minimise the risk of microbiological contamination occurring. These controls would need to be monitored to ensure they are being followed and corrective action taken if the controls are not working. This system would need to begin from when the fruit is being grown to when the juice is packaged for sale. Controls systems the manufacturer would need to consider at each stage of the manufacturing process include the following.²

Growing of fruit

- animal manures not used unless certified pathogen free
- harvesting practices that yield high-quality, clean fruit that avoid fruit/ground contact must be employed
- livestock not permitted to graze where fruit is being grown
- wildlife, to the extent that is possible, kept away from fruit
- water used for irrigation has minimal faecal contamination and is not sprayed onto fruit
- pesticides not contaminated with pathogens

Transportation of fruit

- fruit to be transported in clean covered containers

Packing/storage sheds

- fungicides not to be contaminated with pathogens
- fruit to be stored in clean covered containers
- water used for cleaning fruit not to be contaminated with pathogens
- sheds to be free from pests

Processing plant

- fruit inspected and damaged, deteriorated fruit not used
- extensive cleaning and sanitation of all fruits with uncontaminated water
- extensive cleaning and sanitation of all food contact surfaces
- enclose production lines if possible or protect exposed juice from contamination during extraction, pressing and packaging and any other steps that may be included in the process such as filtration and de-aeration
- ensure food handlers follow safe hygiene practices and do not work when ill
- ensure plant is well maintained, clean and free from pests

While a manufacturer of non-heat treated juices can take steps such as the ones listed above to reduce the microbial contamination of fruits and vegetables, but it is impossible to eliminate microbial pathogens from all raw fruits and vegetables. In the USA in 1996, an outbreak of *E. coli* O157:H7 occurred from unpasteurised commercial apple juice.⁴ The factory where this juice was produced was described as a state-of-the-art plant.⁴ However, despite implementing controls to minimise the risk of applies becoming contaminated, this outbreak still occurred.

The source of the contamination was never found but when the plant was investigated several unsatisfactory practices were identified. These were:

- the company provided a written statement advising suppliers that it would accept only handpicked applies, but it had no mechanism to ensure compliance;
- the procedure of not using decayed apples was not always strictly followed; and
- a phosphoric acid-based solution used to wash the apples was not appropriate for waxed apples and was also sometimes used at concentrations below the recommended level.⁴

The application of heat to juice is an effective way of destroying pathogens that may be present in juice. The majority of commercial juice produced in Australia and New Zealand is pasteurised by subjecting the juice to high temperatures for a short time. However, the application of heat will alter the flavour of juices and there is a market for juices that taste 'fresh'.

In the future, juice manufacturers may be able to utilise methods other than pasteurisation, to reduce pathogens that may be present in juice to safe levels. Non-thermal pasteurisation of fruit juices is technologically feasible but not yet commercially practical. Isostatic high pressure, pulsed light, pulsed electric field and filtration are a few of the non thermal methods investigated by researcher for applications to foods.²

A study by Slifko et al (2000) evaluated the effectiveness of high hydrostatic pressure (HHP) on *Cryptosporidium* oocysts. This study demonstrated that HHP efficiently rendered the oocysts nonviable and non-infectious after treatment at 5.5×10^8 Pa. By exposing foods to pressure for a short time, foods can achieve the benefits of pasteurisation without the undesirable effects of heat. High pressure is now well documented as a food disinfection process and is currently being tested with fruit juices. High pressure processing can result in a decrease of microbial contaminants without significantly affecting texture, flavour and colour.³

Exposure Evaluation

Data from the Australian 1995 National Nutrition Survey (NNS) indicates that fruit juices and drinks are consumed in significant quantities by a large sector of the population. Approximately 35% of all respondents to the Australian 1995 NNS consumed fruit juices and drinks with the mean consumption being 250 ml (see attachment 3A). The highest consumption rates of fruit juices and drinks in the Australian population on the day of the survey were reported by 16-18 year-old males consuming 420 ml, and 16-18 year-old females consuming 395 ml. Alternatively, the lowest consumption rates of fruit juices and drinks were reported by 65+ year-old males consuming 190 ml, and 65+ year-old females consuming 180 ml.

In addition it was reported that over 60% of 2-3 year-old male children consumed over 300 ml of fruit juices and drinks and over 53% of 2-3 year-old female children consumed over 310 ml.

Approximately 20% of the consumers in the New Zealand 1997 NNS consumed fruit juices and drinks with the mean consumption being 250 ml (see attachment 3B). The highest consumption rates of fruit juices and drinks in the New Zealand population on the day of the survey were reported by 15-18 year-old males consuming 545 ml, and 19-24 year-old females consuming 365 ml. Alternatively, the lowest consumption rates of fruit juices and drinks were reported by 65+ years males consuming 165 ml, and 65+ years females consuming 150 ml. Note that, children 15 years and under were not surveyed in the New Zealand 1997 NNS.

The consumption rates of both countries indicate that fruit juices and drinks consumption peaks in adolescence and then decreases through to the elderly population.

The consumption data does not provide information on how much untreated juice is consumed by the population. The Australian Fruit Juice Association believes that approximately 95% of juice sold has undergone some form of pasteurisation process.

Conclusion

As indicated in the NNSs, a high proportion of the population in Australia and New Zealand report to consume fruit juices and drinks, though the vast majority of the juice consumed is likely to have been pasteurised. However, if pathogens were present in fruit juices and/or their associated products, a relatively high proportion of all age groups would be exposed.

Children, elderly people and individuals with a compromised immune system are especially vulnerable to the severe illness arising from the potential microbiological hazards associated with fruit juices and drinks (for example *Salmonella* spp. and *E. coli* O157), which may result in long term sequelae or death.

Risk Characterisation

Physical hazard

The overall risk of physical hazards in juice is considered small as the hazard is unlikely to occur due to effective controls by manufacturers and while there is the potential for some physical hazards to cause serious harm, this has not yet occurred in Australia, or to ANZFA's knowledge in New Zealand.

Chemical hazards

The overall risk of chemical hazards in juice is considered small as the hazard is unlikely to occur due to effective controls by manufacturers and while there is the potential for some chemical hazards to cause serious harm, this has not yet occurred in Australia, or to ANZFA's knowledge in New Zealand.

Microbiological

There is the potential for any fruit or vegetable juice to be contaminated with pathogens. The number of outbreaks that have occurred from juice is evidence of this potential. Food-borne illness has occurred from orange, apple, watermelon, tomato and carrot juice. The pathogens that have been responsible for these outbreaks are not able to grow in the juice, but are able to survive and cause illness, even in low numbers.

Pathogens can be controlled in juice by the use of heat as occurs with pasteurisation. If no heat process is applied, steps can be taken to reduce the likelihood of juice being contaminated but contamination cannot be eliminated.

While juice that has been pasteurised may be contaminated after the pasteurisation has taken place, the use of the heat process greatly assists in ensuring the safety of this juice. One of the two juice outbreaks that have occurred in Australia was caused by unpasteurised juice and of the documented outbreaks from juice listed in Table 1, approximately 75% have been caused by unpasteurised juice.

In the USA's preliminary investigation into the morbidity and mortality associated with the consumption of fruit and vegetable juice, it is concluded that non-heat treated juices are much more hazardous than heat-treated juices. The main evidence provided to support this conclusion is that in the USA' non-heat treated juices accounted for 76% of the food-borne illness related to juice reported in 1993-1996, while accounting for slightly more than 1% of juice consumption.¹⁰

While it can be concluded that juice that has not been heat-treated is more likely to be contaminated with pathogens than untreated juices, there has only been one documented outbreak of food-borne illness from unpasteurised juice in Australia and none, which ANZFA is aware of, in New Zealand. While there may have been other cases of food-borne illness from unpasteurised juice, there is no documented evidence of such cases. It could therefore be concluded that there is a low risk of unpasteurised juice in Australia and New Zealand being contaminated with pathogens.

However, if juice is contaminated with one of the pathogens that causes illness in low numbers, there is a high probability of persons who consume this juice becoming ill. This is particularly the case for persons who are young, old or immunosuppressed. The exposure data indicates that a high proportion of the population in Australia and New Zealand report to consume fruit juices and drinks including those in the at-risk category. The illnesses that have occurred from unpasteurised juice have been severe and in some cases life-threatening for persons in the at-risk groups. The pathogen that has caused the most concern in unpasteurised juice is *E. coli* O157:H7 as it has caused Haemolytic Uraemic Syndrome in young children overseas and there have been several deaths.

Conclusion

Any fruit or vegetable juice may contain a physical, chemical or microbiological hazard. However, juice is more likely to contain a microbiological hazard and untreated juices are more likely to be the source of such a hazard than treated juices. While there is a low probability of untreated juice being contaminated with dangerous pathogens, if it is, the consequences can be severe for at risk groups and in extreme cases death could occur.

References

1. Parish ME, Narciso JA and Friedrich LM, 'Survival of Salmonellae in Orange Juice', *Journal of Food Safety*, Vol 17, pp 273-281, 1997.
2. Parish ME, 'Public Health and Nonpasteurized Fruit Juices', *Critical Reviews in Microbiology*, Vol 23, No. 2, pp 109-119, 1997.
3. Slifko TR, Raghubeer E and Rose JB, 'Effect of High Hydrostatic Pressure on *Cryptosporidium parvum* Infectivity', *Journal of Food Protection*, Vol 63, No. 9, pp 1262-1267, 2000.
4. Cody SH, Glynn MK, Farrar JA, Cairns KL, Griffen PM, Kobayashi J, Fyfe M, Hoffman R, King AS, Lewis JH, Swaminathan B, Bryant GR and Vugia DJ, 'An Outbreak of *Escherichia coli* O157:H7 Infection from Unpasteurised Commercial Apple Juice', *Annals of Internal Medicine*, Vol 130, No. 3, pp 202-209, 1999.
5. Parish M, 'Relevancy of *Salmonella* and Pathogenic *E. coli* to Fruit Juices', *Fruit Processing*, Vol 10, No. 7, pp 246-250, July 2000.
6. Cook KA, Dobbs TE, Hlady WG, Wells JG, Barrett TJ, Puhf ND, Lancette GA, Bodager DW, Toth BL, Genese CA, Highsmith AK, Pilot KE, Finelli L and Swerdlow DL, 'Outbreak of *Salmonella* Serotype Hartford Infections Associated with Unpasteurised Orange Juice', *JAMA*, Vol 280, No. 17, pp 1504-1509, November 1998.
7. Thurston H, Stuart J, McDonnell B, Nicholas S and Cheasty T, 'Fresh Orange Juice Implicated in an Outbreak of *Shigella flexneri* Among Visitors to a South African Game Reserve' (Letter to the Editor), *J-Infect.*, Vol 36, No. 3, pp 350, May 1998.
8. Fleet GH, Heiskanen P, Reid I, Buckle KA, 'Food-borne viral illness – status in Australia', *International Journal of Food Microbiology*, Vol 59, pp 127-136, 2000.

9. Martinelli JJ, 'Are Enteric Infections Associated with Unpasteurised Juice?' (Letter to the Editor), *JAMA*, Vol 281, No 20, p 1892-1893, May 1999.
10. Williams R, Wilcox T, Timbo B, Street D, Nardinelli C, McCarthy P, Jackson G, Hendricks MT and Elliot E, 'Preliminary Investigation Into the Morbidity and Mortality Effects Associated With the Consumption of Fruit and Vegetable Juices', *Federal Register*/Vol. 63, No. 84/ Friday, May 1, 1998/ Proposed Rules, pp 24300-24378.
11. Lester R, Stewart T, Carnie J, Ng S and Taylor R, 'Air Travel-Associated Gastroenteritis Outbreak, August 1991', *CDI*, Vol 15, No. 17, pp 292-293, 1991.
12. Milton A, O'Brien E and Rann C (Editorial and Production Staff), 'Salmonellosis outbreak, South Australia', *CDI*, Vol 23, No 3, p 73, March 1999.
13. and 14 'Outbreak of *Salmonella* Serotype Muenchen Infections Associated with Unpasteurized Orange Juice – United States and Canada, June 1999', *MMWR*, Vol 48, No. 27, pp 582-585, July 16, 1999.
15. FDA, 'Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule', *Federal Register*/ Vol 66, No. 13, January 12, 2001/ Rules and Regulations.
16. Leudtke A and Powell D, 'Fact Sheet: A Timeline of Fresh Juice Outbreaks', sourced from www.plant.uoguelph.ca/safefood/micro-haz/juice-outbreaks.htm.

**Australian average daily consumption of fruit juice and fruit drinks
by sex and age**

Sex	Age	Number surveyed	Number consuming fruit juice (% of number surveyed)		Average amount of fruit juice consumed per day (g)
Male	2-3	170	103	(60.6)	302.8
Male	4-7	416	190	(45.7)	339.5
Male	8-11	385	167	(43.4)	356.1
Male	12-15	349	160	(45.8)	396.2
Male	16-18	215	86	(40.0)	417.9
Male	19-24	485	189	(39.0)	383.4
Male	25-44	2140	703	(32.9)	327.4
Male	45-64	1554	470	(30.2)	258.5
Male	65+	902	278	(30.8)	187.7
Female	2-3	213	114	(53.5)	314.0
Female	4-7	383	205	(53.5)	314.6
Female	8-11	354	157	(44.4)	340.8
Female	12-15	304	154	(50.7)	351.2
Female	16-18	218	103	(47.2)	393.0
Female	19-24	575	243	(42.3)	332.1
Female	25-44	2385	829	(34.8)	271.1
Female	45-64	1752	590	(33.7)	204.0
Female	65+	1058	367	(34.7)	178.0
All	2-3	383	217	(56.7)	308.7
All	4-7	799	395	(49.4)	326.6
All	8-11	739	324	(43.8)	348.7
All	12-15	653	314	(48.1)	374.2
All	16-18	433	189	(43.6)	404.3
All	19-24	1060	432	(40.8)	354.6
All	25-44	4525	1532	(33.9)	296.9
All	45-64	3306	1060	(32.1)	228.1
All	65+	1960	645	(32.9)	182.2

**New Zealand average daily consumption of fruit juice and fruit drinks
by sex and age**

Sex	Age	Number surveyed	Number consuming fruit juice (% of number surveyed)		Average amount of fruit juice consumed per day (g)
Male	15-18	109	16	(14.7)	543.7
Male	19-24	145	43	(29.7)	480.5
Male	25-44	759	161	(21.2)	303.8
Male	45-64	588	106	(18.0)	212.8
Male	65+	326	53	(16.3)	165.4
Female	15-18	137	43	(31.4)	330.0
Female	19-24	209	38	(18.2)	364.0
Female	25-44	1205	255	(21.2)	273.5
Female	45-64	667	145	(21.7)	185.2
Female	65+	491	90	(18.3)	143.7
All	15-18	246	59	(24.0)	388.0
All	19-24	354	81	(22.9)	426.3
All	25-44	1964	416	(21.2)	285.2
All	45-64	1255	251	(20.0)	196.8
All	65+	817	143	(17.5)	151.7

Notes:

- The consumption figures above were derived using ANZFA's dietary modelling computer program DIAMOND. DIAMOND contains dietary survey data from both the Australian and New Zealand National Nutrition Surveys (NNSs): The 1995 Australian NNS 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 these NNSs used a 24-hour food recall methodology to collect consumption data. DIAMOND also contains a database of recipes, used to capture the consumption of fruit juices or fruit drinks where they were included as an ingredient in mixed foods.
- Refinements made to the DIAMOND program may result in the Australian values being slightly different from those previously indicated. The New Zealand consumption values have not been previously available, as data from the 1997 New Zealand NNS were not available.