

**30 May 2001**  
**15/01**

## **FULL ASSESSMENT REPORT AND REGULATION IMPACT ASSESSMENT**

**APPLICATION A411**

### **PASTEURISATION OF ORANGE JUICE & LABELLING OF UNPATEURISED 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. 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 this report is to assess the public health risks associated with orange juice and other juices and if a risk is identified, to propose an appropriate management strategy to address this risk.
- The risk assessment concludes 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 concludes 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 are considered for managing the risks associated with untreated juices, 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.
- The preferred option is option 4 as it outlines the most cost effective way of managing the potential risks associated with untreated juice and is in line with ANZFA's section 10 objectives. Option 4 is a combination of regulatory and non-regulatory measures. These measures are outlined below.

#### *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.

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 does need to be 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.

## **BACKGROUND AND ISSUE**

In March 2000, the South Australian Department of Human Services made an application to vary Standard O7 - Orange Juice and Related Products, in the *Food Standards Code*. The applicant proposes a provision in Standard O7 requiring all orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises, to either:

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

This Application was prompted by a food poisoning outbreak in South Australia in early 1999 from contaminated unpasteurised orange juice. The orange juice was contaminated with *Salmonella typhimurium* phage type 135a and affected over 500 people. Following this outbreak, 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 the proposal by the South Australian Department of Human Services to make an application to ANZFA to amend Standard O7 of the Code.

A preliminary assessment was conducted in May 2000 and public comment was sought on the proposal. In response to the proposal, eleven submissions were received. Submissions were received from associations representing juice manufacturers in Australia, New Zealand and the US together with other stakeholders.

Generally, submitters supported the introduction of processing requirements for all juices, not just orange juice and some form of labelling to enable unpasteurised juices to be identified.

In February 2000, the ANZFA Board approved a request to extend the time for consideration of this application by a period of six months. This request was granted on the basis of high demands on staff within the Food Safety Program to complete existing projects related to the finalisation and implementation of the Food Safety Standards.

## **ISSUE**

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 easily 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. 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.

## **OBJECTIVE**

The objective of this report is to assess the public health risks associated with orange juice and other juices and if a risk is identified, to propose an appropriate management strategy to address this risk.

## **RELEVANT PROVISIONS**

There are no requirements in Australia, New Zealand or Codex to pasteurise or otherwise process juices to reduce pathogens that may be present in the juice to safe levels. New Zealand and Codex generally require juice to be manufactured in accordance with good hygienic practice. There are also no requirements in Australia, New Zealand or Codex for juice that has not been pasteurised or otherwise treated, to be labelled as such.

However, both the US and Canada have introduced management strategies for addressing the risks associated with juices, the US a regulatory approach and Canada a non-regulatory approach.

In August 1997, the US Food & Drug Administration (FDA) proposed a comprehensive program to address the incidence of food-borne illness related to consumption of fresh juices. The proposed program consisted of:

1. initiating a mandatory Hazard Analysis Critical Control Point (HACCP) program for some or all juice products;
2. requiring the labelling of juice products not specifically processed to prevent, reduce, or eliminate pathogens to bear a warning statement informing consumers of the risk of illness associated with consumption of the product; and
3. initiating several educational programs to minimise the hazards associated with consumption of fresh juices.

In January 2001, the FDA adopted final regulations mandating the application of HACCP principles to the commercial processing of fruit and vegetable juices. Retail establishments that sell juice directly to consumers are not required to comply. Commercial producers must implement a HACCP program that includes, as part of the program control, measures that will produce, at a minimum, a 5-log (i.e. 100 000-fold) reduction in the most resistant microorganisms of public health significance likely to occur in the juice. This rule does not take effect until January 2002 with smaller businesses being given until 2003 or 2004 to comply, depending on the size of the business.

In July 1998, the FDA had finalised a labelling proposal requiring packaged untreated juice to bear a warning statement<sup>1</sup> informing at risk consumers of the hazard posed by untreated juices. The labelling requirement for juice does not apply to juice processed in a manner that will achieve a 5-log reduction in the most resistant microorganisms of public health significance likely to occur in the juice. It will therefore not apply to commercial manufacturers of juice, as they will be required to include such a process in their HACCP programs.

Packaged juices sold by retailers will continue to be required to be labelled with a warning statement and unpackaged juices sold for immediate consumption will continue to be exempted from the warning statement. FDA intends to provide recommendations for implementing measures that will assure safe juice made and sold by retail establishments.

In July 2000, Canada released a non-regulatory approach for reducing the possibility of contamination in all unpasteurised fruit juice and cider<sup>2</sup> sold in Canada. The approach consists of:

1. implementation and use of the *Code of Practice for the Production and Distribution of Unpasteurized Apple and Other Fruit Juice/Cider in Canada*. This Code of Practice outlines the steps that should be implemented by producers, processors, distributors and retailers to reduce the possibility of contamination of unpasteurised juices;

---

<sup>1</sup> The warning Statement required is 'WARNING: This product has not been pasteurised and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems'.

<sup>2</sup> In the US and Canada, cider is unfiltered and unclarified apple juice. It is not a fermented alcoholic drink.

2. labelling unpasteurised juice/cider products as 'unpasteurised' to allow consumers to be aware of the nature of the product; and
3. development and implementation of an education campaign to objectively inform consumers in general, and more specifically children (including parents and guardians), the elderly and people with weakened immune systems, of the risks associated with the consumption of unpasteurised fruit juices/cider.

This non-regulatory approach will be evaluated by Health Canada to determine its effectiveness.

## **PUBLIC CONSULTATION**

A preliminary assessment was conducted in May 2000 and public comment was sought on the proposal. Three options were considered in the preliminary assessment report:

1. maintaining the status quo and not requiring any juice to be either pasteurised or labelled as unpasteurised;
2. including a requirement, as requested by the applicant, to require orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises, to:
  - undergo a pasteurisation process that would kill pathogenic bacteria or another process which provides an equivalent safety outcome; or
  - be labelled to ensure consumers are informed that the product is unpasteurised and are made aware of the risks associated with its consumption.
3. as per option 2 but applying it to all fruit and vegetable juices.

In response to the proposal eleven submissions were received. Submissions were received from associations representing juice manufacturers in Australia, New Zealand and the US together with other stakeholders. Generally, submissions supported the introduction of processing requirements for all juices, not just orange juice and some form of labelling to enable unpasteurised juices to be identified.

## **ASSESSMENT OF THE RISK OF FRUIT AND VEGETABLE JUICES**

A risk assessment assessing the risk of all fruit and vegetable juices both treated and untreated is included at attachment 3. This risk assessment concludes 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 concludes 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.

## **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 processed 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 beginning 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 affect 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*

There would be no new regulatory costs for industry. However, if an outbreak of illness were to occur, juice sales could decrease if consumers are concerned about the safety of juices.

### *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. Consumers would continue to consume untreated juices as they are not aware of the risks and they could therefore contract a food-borne illness. At-risk consumers could contract a severe 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 Uremic Syndrome, which can cause renal failure and death.

### *Government*

There would be no new enforcement costs for government. However, if an outbreak of illness were to occur, health care costs could be significant, especially for severe illnesses. 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, it does not address the risks associated with untreated juices. The risk assessment (attachment 3) 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 and consequently could become ill from consuming these juices.

## **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. 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 campaign 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 campaign 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. 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 campaign, as it would raise awareness about the potential risk of untreated juices. However, this campaign 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.

### **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. However, there may still be a percentage of producers who choose not to comply. 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 trialed 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 trialed for a period, but 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 (included at attachment 3) concludes that all untreated fruit and vegetable 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 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 it is considered appropriate to exempt these juices, they could 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 carry 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'. However, juices sold through retail establishments and markets etc would not be labelled and 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. Therefore, this option will enable at-risk consumers to avoid unpasteurised packaged juices on the marketplace but will not assist consumers to identify the unpackaged, untreated juices sold through retail establishment, markets etc.

### *Industry*

Producers of 'untreated' juice will incur the costs of labelling untreated juices. However, labelling will not be mandatory for juice that is produced and packaged from the premises from where it is sold e.g. freshly squeezed juice sold by retailers. Producers of 'untreated juice', particularly the packaged juices, may incur costs associated with a fall in sales, if certain consumers choose to no longer purchase these juices as these juices would need to be labelled.

The main 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. The fruit juice industry should therefore benefit from a reduced likelihood of a serious or even life threatening food poisoning outbreak with the packaged juices. However, this benefit would not extend to the unpackaged juices, as they are unlikely to be labelled and therefore at-risk consumers may continue to unwittingly purchase these juices.

### *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.

### **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. This option also provides those producers of juice that wish to treat their products with the flexibility to choose a pathogen control process that best suits their needs. This will enable producers to utilise processes other than pasteurisation such as high pressure and UV radiation.

However, this option does not effectively 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.

### **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 US 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 campaign 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 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 and to check the label to determine whether it is 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 dietician associations.

## **Regulatory impact of option**

### *Consumers*

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

untreated juices and therefore minimise the risk of contracting a severe or even life threatening food-borne illness from these juices. 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*

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 and 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.

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 requirements, developing a code of practice and developing and implementing a consumer education campaign. 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.

### **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 will incur costs with this option, it has the benefit of reducing the likelihood of at-risk consumers contracting severe or even life threatening food-borne illness from untreated juice. It is therefore considered that this benefit to consumers outweighs the cost to the producers of untreated juice.

### **Conclusion**

Through its combination of regulatory and non-regulatory measures, this option has the potential to minimise the potential risks associated with untreated juice without high costs to industry.

### **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 cost 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. The FDA has indicated that at this stage citrus fruit is the only fruit that can be subjected to just surface treatment and still comply with the 5-log reduction process. Other fruit would need to be subjected to additional treatments and while alternative treatments to pasteurisation are available, they would still need to be validated and are likely to be expensive. Therefore, manufacturers of citrus fruit could continue to sell unpasteurised juice if they could validate a surface treatment that was capable of achieving a 5-log reduction in pathogens of concern. However, other manufacturers would need to introduce pasteurisation or no longer sell juice. The majority of retail establishments would therefore 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. It would also incur the cost of food businesses and consumers that do not support the new requirements. Food businesses that have been forced to spend a significant amount of money to comply with the requirement or go out of business are unlikely to be very supportive of government nor are consumers who are unhappy with increased prices for juice and/or reduced product range.

Government would have the benefit of a reduced likelihood of any illness occurring from the consumption of juices.

### **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. This high price is unlikely to be acceptable to 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 and as yet this has not occurred. Nationally, mandatory food safety programs are unlikely to be considered until the Department of Health and Aged Care 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.

## **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**

This option is similar to option 4 but does not require mandatory labelling or microbiological limits for untreated juices. A complete non-regulatory approach could be trialed 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 same as for option 4, but so also will be the costs. Therefore as the costs would be similar for option 4 for this option to be successful, option 4 is preferred. Option 4 will ensure strategies to minimise the risks associated with untreated juices are implemented quickly.

### **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 and 5, 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 pasteurised and untreated juices in the marketplace through a targeted education campaign.

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 enable 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.

#### **Preferred option**

Option 4 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.

## **ASSESSMENT OF PUBLIC COMMENT RECEIVED**

Following is a summary and assessment of the issues raised in submissions received in response to the preliminary assessment of this application. A summary of issues raised by each submitter is included at attachment 4.

### **Application of the requirements**

#### *Extending the requirements to all juices*

Submissions that supported mandatory requirements also supported extending the requirements to all juices. The Australian Fruit Juice Association and the NZ Juice Association both supported the extension of requirements to all fruit and vegetable juices. The National Food Processors Association in the US also supported requirements for all juices as experience in the US with apples, mamey, strawberries and raspberries show that other fruits may be contaminated with pathogenic microorganisms that can be incorporated into any juice prepared from the fruit. Queensland Health supported the pasteurisation of all fruit and vegetable juice if a risk assessment indicates there is a need for such a requirement.

The risk assessment report (attachment 3) concludes that any fruit or vegetable juice can be a source of food-borne illness and fruit and vegetable juices that have not been pasteurised or otherwise treated to reduce pathogens to a safe level, pose a greater risk of causing illness. The illnesses caused by untreated fruit and vegetable juices have also been severe, especially in young children. It is therefore considered appropriate to extend any proposed requirements to all fruit and vegetable juices.

#### *Exemption for small manufacturers*

If requirements for orange juice were to be included, Charlie's Trading Company supported an exemption for any in-store juicing machine producing less than 200 000 litres pa under a HACCP program and which has a 'consume by' date no later than 4 days after production<sup>1</sup>.

The preferred option, discussed in the section the above, is for all juice to be subjected to a process capable of achieving a 5-log reduction in the most heat resistant pathogen of concern reasonably likely to be present in the juice. Packaged juices that have not undergone this process will need to be labelled as 'unpasteurised' unless the juice is made and packaged on the premises from where it will be sold. Therefore, no labelling requirements will apply to retail juicers unless the juice is to be packaged and sold at another premises. However, the preferred option is for all producers of untreated juice to comply with mandatory microbiological criteria and adhere to a voluntary code of practice outlining ways to minimise contamination of the untreated juice.

---

<sup>1</sup> Charlie's supplies machinery, training and marketing support to several supermarkets in NZ which use fruit supplied under its HACCP program to prepare juice in-store for consumers to take home or consume immediately.

### *Support for no regulation*

Food Safety Victoria supporting maintaining the status quo and therefore not introducing any requirements for juice. However, this support was on the proviso that manufacturers continuously maintain good manufacturing practices.

Maintaining the status quo is discussed under option 1 in the section above, where it is concluded that this will 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. 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, no new compliance costs for industry and enforcement costs for government.

### **Processing requirements**

#### *Support for processing requirements with exemptions*

The majority of submitters support requiring juice to be pasteurised or otherwise processed to reduce pathogens to safe levels unless the product is labelled as 'unpasteurised' or is freshly squeezed product sold for immediate consumption. Submitters that supported this approach included the Australian Fruit Juice Association, Queensland Health and the National Council of Women of Australia as well as the National Council of Women of New Zealand. The New Zealand Fruit Juice Association also supported this approach but there was one dissenting member who did not support mandatory processing or labelling requirements.

However, a number of submitters, including the New Zealand Fruit Juice Association indicated that alternatives to pasteurisation should be expressly permitted as alternative technologies may become economically viable in the future. Food Science Australia also indicated that any process requirement must specify that the juice be heated to a time and temperature that can be demonstrated to produce a 5-log reduction in the most resistant micro-organism of public health significance likely to occur in the product and also allow an equivalent process to be used that does not rely on heat to effect the pathogen reduction. Food Science Australia also stated that fruit and vegetables should be considered separately to enable the nomination of a specific time/temperature schedule to obtain a 5-log reduction of the pathogen of concern separately for fruits and vegetables.

As outlined in options 3 and 4 above, it is agreed that alternatives to pasteurisation should be permitted and that instead of specifying a process or processes that must be undertaken, a processing requirement for juice should specify the food safety outcome to be achieved. Manufacturers can then determine how they wish to achieve this food safety outcome. As currently required in the US, it is recommended that fruit and vegetable juices be subjected to a process that is capable of affecting a 5 log reduction in the most resistant micro-organism of public health significance likely to occur in the product.

#### *Support for processing requirements with no exemptions*

The US National Food Processors Association did not support providing an exemption from processing even if products are labelled with a warning statement, as there is no scientific justification for exempting any juice products from the requirement for pasteurisation or an equivalent process. The FPA states that a label warning statement should be sanctioned only as a necessary short-term alternative for unpasteurised juices, until pasteurisation or an equivalent process is universally required for all juices in the shortest possible time frame.

It is agreed that labelling should not be used as an alternative to the safe processing of a food product. All manufacturers of juices, whether retail or commercial establishments, are legally obligated to sell safe food and in Australia will also be required to comply with the new food safety standards.

Clause 7 of Standard 3.2.2 - Food Safety Practices and General Requirements, obligates food businesses to use a process step that is reasonably known to achieve the microbiological safety of the food, where such a step is needed to reduce to safe levels any pathogens that may be present in the food. Therefore, if juice manufacturers choose not to treat juice, they need to have a high level of assurance that fruit to be juiced is not contaminated with pathogens of concern.

To assist producers of untreated juice to meet their general obligation to sell safe food and for Australian producers, their more specific processing obligations under the new food safety standards, the preferred option is for these producers to comply with mandatory microbiological criteria and adhere to a voluntary code of practice. This is outlined in detail in option 4 in the section above.

No food sold can be guaranteed to be safe. However, some foods have a higher probability of being unsafe than others, particularly if they have not undergone any form of pathogen reduction step. Even if a manufacturer of untreated juices does all it reasonably can to minimise contamination of the product, it will still be more likely to contain pathogens than a treated product. However, consumers should be permitted to purchase untreated juices, provided they are aware of the increased risks this product poses.

#### *No exemption for freshly squeezed juices from processing*

Charlie's Trading Company and one member of the NZ Juice Association did not support the exemption of freshly squeezed juices sold for immediate consumption from any processing requirements. Charlie's stated that exempting any juice made for immediate consumption involves risk and therefore queried why they should be exempt. The member of the NZ Juice Association stated that if pathogenic bacteria can be internalised into the flesh of oranges, there should be no exclusion for freshly squeezed juice for immediate consumption.

The US National Food Processors Association stated that if an exemption is to be provided for 'freshly squeezed orange juice for immediate consumption on the same premises', it must be worded so that it is clear that consumption is to be on the same premises where the 'squeezing' takes place.

It is not proposed to require all juices to undergo a process capable of achieving a 5-log reduction in the most resistant pathogen likely to occur in the juice. It is therefore not necessary to include an exemption for freshly squeezed juices whether for immediate consumption or not. Juices that have not undergone the 5-log reduction will need to be labelled unless an exemption already applies in the *Food Standards Code*. This means that juice that is sold from the premises where it was made will not be required to be labelled as per paragraph 2(1)(c) of Standard 1.2.1 *Application of Labelling and Other Information Requirements* in the new joint Code.

### *Support for no processing requirements*

Two submitters did not support the inclusion of a mandatory pasteurisation requirement for juices - Charlie's Trading Company Ltd and one member of the NZ Juice Association. Reasons provided included the good safety record of juices in NZ, the expense of pasteurisation equipment, the restriction of consumer choice, and that a properly constructed 3<sup>rd</sup> party HACCP based food safety plan addresses all areas of risk to food safety.

It is agreed that a mandatory requirement for the pasteurisation of juice should not be included. However, juices that have not been treated in some way to reduce pathogens to safe levels should be labelled as 'unpasteurised' unless it is evident to consumers that the product is untreated. It is proposed that juice that has been squeezed on the premises from where it will be sold not be labelled, as consumers are likely to know that this juice is untreated, for example, juice that is freshly squeezed at a retail establishment for immediate consumption by the purchaser.

### *Support for permission to bulk ship unpasteurised juice*

The US National Food Processors Association requested ANZFA allow for the bulk shipment of unpasteurised juice to another location for pasteurisation and consumer packaging provided the shipping documents adequately reveal the fact that the juice is not pasteurised and must either be pasteurised or bear the warning statement for unpasteurised juice as per the FDA.

The proposed requirements would allow unpasteurised juice to be transported to another location for pasteurisation. However, this juice would need to be labelled as 'unpasteurised'. The receiver of this juice would then need to process this juice to reduce any pathogens that may be present to safe levels (i.e. a 5-log reduction) or sell the juice as 'unpasteurised'.

## **Labelling**

### *Support for labelling untreated juice as 'Unpasteurised'*

The majority of submitters supported the labelling of untreated juice as 'unpasteurised' including the Australian Fruit Juice Association and the NZ Juice Association (with the exception of one dissenting member). The National Council of Women of New Zealand supported labelling as it provides increased protection for public health and safety and enables consumers to make more informed choices regarding the purchase of unpasteurised juice. Queensland Health supported the use of a warning statement for unpasteurised product as per the statement for milk i.e. 'warning: unpasteurised'.

The Food Technology Association of Victoria supported the labelling of all fruit and vegetables juices with the statement 'unpasteurised' but did not support any statements about possible risks. In contrast, the Australian Fruit Juice Association supports requiring additional labelling to highlight the risks associated with consuming unpasteurised juice as per the FDA warning statement if the manufacturer of such products is not 3<sup>rd</sup> party HACCP certified.

Charlie's Trading Company did not support labelling but requested that if labelling is proposed, the opportunity be provided to assess the style and wording of the particular word/statement, before implementation.

The Food Technology Association of Victoria stated that unpasteurised juice will have to be labelled as such in an ingredient list.

The preferred option, option 4, proposes that untreated packaged juices be identified as 'unpasteurised'. This option also recommends that the labelling requirement be supported by a consumer education campaign to increase consumer awareness of the potential risks associated with untreated juices and to provide advice on how to distinguish between the treated and untreated juices in the marketplace.

A warning statement on the label as per the FDA statement has not been considered. Requiring untreated juices to be labelled with a statement to the effect that it is 'unpasteurised' is consistent with labelling requirements for unpasteurised juice.

#### *Support for no labelling requirement*

Three submitters did not support the labelling of untreated juices - Charlie's Trading Company, one member of the NZ Juice Association and Food Science Australia. The US National Food Processors Association also only supported labelling as a short-term measure to requiring all juice to be pasteurised or otherwise processed using an equivalent system.

The reasons provided by Charlie's Trading Company and the one member of the NZ Juice Association for not supporting mandatory labelling are summarised below as dot points followed by a response.

- NZ juices have a good safety record

ANZFA is not aware of any reported cases of food-borne illness from unpasteurised juices in New Zealand. The risk assessment (attachment 3) concludes that the likelihood of unpasteurised juice causing illness is low but if it does cause illness, the effects can be very severe and in extreme cases could cause death. Young children and the elderly have died from consuming untreated juice overseas.

- Labelling moves the risk/liability from the manufacturer/vendor to the consumer, exposing consumers to greater risks and reducing the incentives on manufacturers and suppliers to 'be safe'.

Producers of untreated juices are still legally obligated to sell safe food and must do all they reasonably can to minimise the likelihood of the juice becoming contaminated. The preferred option is for producers of untreated juice to comply with mandatory microbiological criteria and adhere to a voluntary code of practice. However, the likelihood of untreated juices being contaminated with dangerous pathogens is still higher than for treated juices and consumers need to be aware of these increased risks.

- Warning statements of any description will convey a message to consumers that citrus products are inherently unsafe – a message that is not true.

An effective management strategy for minimising the risks associated with the consumption of untreated juices is reliant on increasing consumer understanding of the relative risks associated with these juices. A communication strategy should not convey to consumers that these products are inherently unsafe. It should indicate that these products have a good safety record but there is a possibility they could pose a risk, especially to certain sectors of the community.

- The labelling requirement may well be fatal to our business, as it will suggest to customers and supermarkets that we have not considered the risk and hazards. In fact, nothing is further from the truth. We are not aware of any processor that has a HACCP program as well developed or as comprehensive as our own (Charlie's).

The labelling requirements will not preclude producers of untreated juice communicating to consumers the steps that have been taken to minimise the risks associated with the juice.

- Labelling assumes the reader is competent to make judgements about the issue. Consumers are not often well enough educated or informed to make sensible decisions based on the information on a label.

It is agreed that any labelling requirement needs to be underpinned by an education campaign so that consumers are better able to interpret what the labelling means.

- Labelling product as 'unpasteurised' will operate as an entry barrier as it favours the pasteurised product.

The education campaign will clarify that for the majority of the community, untreated juices pose a minimal risk. It is likely that most consumers will continue to purchase untreated juices for taste reasons or for perceived health and nutritional benefits.

Food Science Australia did not support labelling, as fruit juices would be risk categorised with milk, which is inappropriate. Food Science Australia also stated that labelling would discriminate against fruit juices, as a number of other foods implicated in food poisoning incidents do not require labelling when they are not pasteurised.

It is not suggested that unpasteurised juices pose the same risk as unpasteurised milk. It is important that labelling be required when there are two different products on the market, of which one poses a greater risk, and the one that poses the greater risk cannot be identified. Without labelling, consumers may have difficulty distinguishing which packaged products are treated and which products are not. The labelling of untreated juices as 'unpasteurised' is consistent with the labelling for unpasteurised milk.

### **Use of the term 'fresh'**

Several submitters indicated that the term 'fresh' would need to be defined if an exemption for 'freshly squeezed juice' is included. The Australian Fruit Juice Association's support for including requirements for juice were on the proviso that a pasteurised product, which contains no added concentrate, no added preservatives and has a maximum shelf-life of 21 days, may still be labelled as 'fresh'. The Association stated that a precedent has been set by the Australian dairy industry in calling their pasteurised milk as 'fresh'. Food Science Australia stated that if the term 'unpasteurised' is to be mandated for those juices, which have not received the appropriate heat treatment, the term 'fresh' should not be permitted to be used in relation to these juices.

It is proposed not to include a specific exemption for 'freshly squeezed juice'. Juice that is sold from the premises from where it was made will not be required to be labelled by virtue of the general labelling exemptions listed in paragraph 2(1)(c) of Standard 1.2.1 - Application of Labelling and Other Information Requirements in Volume 2 of the *Food Standards Code*. Therefore, there is no need to define 'fresh' or 'freshly squeezed' for this Application. As per

the outcome from the review of juice standards within Volume 1 of the *Food Standards Code*, the term 'fresh' and 'freshly squeezed' will be regulated by general offences in State/Territory Food Acts and fair trading legislation which prohibit false, misleading and deceptive claims in labels.

'Unpasteurised juice' could be labelled as 'fresh'. The education strategy for this Application should alert consumers that 'fresh' juice and particularly 'freshly squeezed' juice is unlikely to have been treated.

## **Nutrition**

Several submitters provided comments relating to the nutritional content of treated and untreated juices. These comments are summarised below in dot point form, followed by a response.

- The National Council of Women of Australia supported a requirement for treated juices to have the content of Vitamin C restored to no less than 400mg/L.

Volume 1 of the *Food Standards Code* requires orange juice to contain not less than 400mg/L of Vitamin C. The fortification of juices was considered as part of the development of the new Joint Code (now Volume 2), and it was determined unnecessary to require orange juice or any other juice to contain a minimum amount of Vitamin C. This decision was made on the basis that most recent National Nutrition Surveys conducted in Australia and New Zealand indicate the populations of the two countries have a more than sufficient dietary consumption of Vitamin C. However, if this circumstance changes, the re-introduction of mandatory fortification could be considered.

- InforMed Systems requested that the proposal in Standard 1.3.2 (Volume 2 of the *Food Standards Code*), which permits folate addition to fruit juices be implemented immediately to address the issue of folate destruction from pasteurisation.

This Standard has now been implemented meaning that manufacturers can now fortify juice with folate.

- Charlie's Trading Company recommended that pasteurised juices be labelled to inform consumers that, 'as natural vitamin C is destroyed on pasteurisation XX mg/ml is added'.

Any processing of food has the potential to reduce levels of vitamins present in a food. While pasteurisation will reduce the amount of Vitamin C present in juice, the Vitamin C content of freshly squeezed juice will also reduce over time, the rate dependent several conditions; including packaging, temperature and storage conditions. The ingredient list of juice is required to indicate whether Vitamin C or any other Vitamins have been added.

- One member of the NZ Juice Association did not believe that the dietary considerations had been fully explored as many nutrients are diminished or destroyed during the thermal treatment of juice, including beta-carotene and valuable enzymes.

The mandatory processing of juice is not being proposed. Untreated juice can continue to be sold and consumers can make a choice between the two products. The consumer education strategy will stress that juice does have a good safety record and that it is only certain sectors of the community that should avoid untreated product. It will only be those untreated juices

that the consumer may not be able to identify that will need to be labelled. This means packaged juices that are sold from different premises to where they were produced.

## **ANZFA SECTION 10 OBJECTIVES**

An assessment of the preferred option against the section 10 objectives of ANZFA's Act is discussed below. The Authority must have regard to these objectives when developing food regulatory measures. The objectives are listed in descending priority order.

### *Protection of public health and safety*

The risk assessment for fruit and vegetable juices concludes that juice that has not undergone any form of treatment is more likely to be contaminated with pathogens than treated juice and 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. This report proposes that this potential risk be addressed through the following measures:

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

These measures protect public health and safety by minimising the likely contamination of juice with pathogens, increasing consumer knowledge, particularly at-risk consumers of the potential risks with untreated juices and providing these consumers with advice on how to identify untreated juices in the marketplace. This should reduce the likelihood of consumers, and in particular at-risk consumers, from contracting severe or even life-threatening illnesses from untreated juice.

### *Provision of adequate information relating to food to enable consumers to make informed choices*

It is important that at-risk consumers can identify untreated juices in the marketplace so they can choose to avoid purchasing these juices. To achieve this objective, the following measures are proposed:

- 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
- 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 consumer education strategy would seek to increase consumer awareness of the following:



- freshly squeezed juices sold by retailers and at markets etc. have not been pasteurised 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 and to check the label to determine whether it is unpasteurised; and
- juices purchased unrefrigerated have been pasteurised.

The mandatory labelling requirement for packaged juices will enable consumers to identify the chilled packaged juices in the refrigerator sections that are untreated. Without this information, consumers are likely to have difficulty distinguishing between the refrigerated packaged juices.

It is considered that the combination of mandatory labelling and consumer education will provide consumers with sufficient information to enable them to make an informed purchase choice.

#### *Prevention of misleading or deceptive conduct*

At preliminary assessment it was proposed to exempt ‘freshly squeezed juices sold for immediate consumption’ from the labelling requirements. This raised issues in relation to the use of the terms ‘fresh’ and ‘freshly squeezed’ with juice. The use of these terms in relation to juice is contentious as these terms were previously defined under the Australian Food Standards Code but will not be defined in the new joint Code. Instead, these terms will be regulated by the general offences in State and Territory Food Acts and trade practices legislation, which prohibits claims on labels that are false, misleading or deceptive. Significantly, manufacturers of pasteurised juice used the regulation of ‘fresh’ in the Australian Food Standards Code to justify referring to this juice as ‘fresh’. This practice is likely to be made more difficult under the new Code as it does not include a definition for ‘fresh’ in relation to juice.

It is no longer proposed to include a specific exemption for ‘freshly squeezed juices sold for immediate consumption’ as these juices are already exempted from labelling requirements by virtue of paragraph 2(1)(c) of Standard 1.2.1 in the new joint Code. The education campaign will alert consumers that juices that are ‘freshly squeezed’ have not been pasteurised. Untreated packaged juices will need to be labelled as ‘unpasteurised’ regardless of whether they are referred to as ‘fresh’ or not.

The Authority must also have regard to the following when developing food regulatory measures.

#### *The need for standards to be based on risk analysis using the best available scientific evidence*

A risk assessment of fruit and vegetable juices is included at attachment 3. This risk assessment draws upon the best available scientific evidence on the hazards associated with juice.

#### *Promotion of consistency between domestic and international food standards*

The Codex standards do include specific processing or labelling requirements for untreated juice. However, it is unlikely that such an issue would be addressed in a Codex standard as there is no or limited international trade in these juices due to their short shelf life. The proposed requirements are therefore unlikely to have any effect on imported food.

The proposed requirements are similar in approach to the measures introduced in the US and Canada to address the potential risks associated with untreated juice. However, the US measures are more stringent and the Canadian measures less stringent.

#### *The desirability of an efficient and internationally competitive food industry*

The proposed requirements will not unnecessarily impede industry efficiency or competitiveness. Untreated juice will continue to be permitted to be sold, and the education campaign will focus on the potential risks to the at-risk consumers to minimise sale losses.

The labelling requirement will not apply to juices that have been subjected to a process capable of achieving a 5-log reduction in pathogens of concern. Therefore, manufacturers will have the flexibility of choosing any process method for juice, provided it achieves the 5-log reduction food safety outcome. This will enable manufacturers to make use of new technologies such as high pressure and fruit surface treatments.

#### *The promotion of fair trading in food*

At preliminary assessment, the preferred option was for juices to be labelled as 'unpasteurised' unless they had been pasteurised or otherwise processed using an equivalent method. Some submitters had concerns with this approach indicating that it effectively exempted untreated juices from having to process this juice safely and that labelling should not act as a substitute for safe processing. The proposal also exempted the freshly squeezed juices from any processing or labelling requirements.

It is agreed that labelling should not exempt producers of untreated juice from meeting their obligations to sell safe food and all producers of untreated juice should take steps to minimise the risks associated with these juices. To achieve this, this report recommends mandatory microbiological criteria for untreated juice and that all producers of untreated juice should adhere to a voluntary code of practice, which will outline ways of minimising contamination of untreated juice. This is a fairer approach, as it requires all producers of juice to take steps to minimise the potential risks associated with this food.

## **CONCLUSION**

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, if it is, 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 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.

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.

### **Attachments to the Report:**

1. Draft variation to volume 2 of the *Food Standards Code*
2. Explanatory Notes
3. Risk Assessment of Fruit and Vegetable Juices
4. Summary of Public Comment Received

**DRAFT VARIATION TO VOLUME 2 OF THE *FOOD STANDARDS CODE***

**APPLICATION A411**

**PASTEURISATION OF ORANGE JUICE AND LABELLING OF UNPASTEURISED JUICE**

**To commence: Six 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 that 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
--	---

[2] *Standard 1.6.1 of Volume 2 of the Food Standards Code is varied by –*

[2.1] *inserting in columns 1, 2, 3, 4 and 5 respectively of Schedule 2 of Standard 1.6.1, immediately before the entry for Dried milk –*

Untreated fruit juice or vegetable juice	<i>Escherichia coli</i> /ml	5	0	0
	<i>Salmonella</i> /25g	5	0	0

## EXPLANATORY NOTES

### APPLICATION A411

#### PASTEURISATION OF ORANGE JUICE & LABELLING OF UNPASTEURISED JUICE

In March 2000 the Australia New Zealand Food Authority (ANZFA) received an application from the South Australian Department of Human Services to vary Standard O7 - Orange Juice and Related Products, in the *Food Standards Code*. The applicant proposes a provision in Standard O7 requiring all orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises, to either:

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

This application was prompted by a food poisoning outbreak in South Australia in early 1999 from contaminated unpasteurised orange juice. The orange juice was contaminated with *Salmonella typhimurium* phage type 135a and affected over 500 people. Following this outbreak, 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 the proposal by the South Australian Department of Human Services to make an application to ANZFA to amend Standard O7 of the Code.

A preliminary assessment was conducted in May 2000 and public comment was sought on the proposal. In response to the proposal, eleven submissions were received. Submissions were received from associations representing juice manufacturers in Australia, New Zealand and the US together with other stakeholders. Generally, submitters supported the introduction of processing requirements for all juices, not just orange juice and some form of labelling to enable unpasteurised juices to be identified.

In February 2000, the ANZFA Board approved a request to extend the time for consideration of this application by a period of six months. This request was granted on the basis of high demands on staff within the Food Safety Program to complete existing projects related to the finalisation and implementation of the Food Safety Standards.

#### DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

##### To commence: Six 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 that 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
--	---

[2] **Standard 1.6.1** of Volume 2 of the Food Standards Code is varied by –

[2.1] inserting in columns 1, 2, 3, 4 and 5 respectively of Schedule 2 of Standard 1.6.1, immediately before the entry for Dried milk –

Untreated fruit juice or vegetable juice	<i>Escherichia coli</i> /ml	5	0	0
	<i>Salmonella</i> /25g	5	0	0

## ASSESSMENT OF THE RISK OF FRUIT AND VEGETABLE JUICES

The full assessment report includes a risk assessment assessing the risk of all fruit and vegetable juices both treated and untreated. This risk assessment concludes 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 concludes 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.

## REGULATION IMPACT ANALYSIS

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community, which includes the consumers, food industry and governments in both countries. The regulation impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice*.

The following five options were considered for managing the risks associated with untreated juices:

1. Maintaining the status quo.
2. A non-regulatory approach that encouraged producers of unpasteurised juice to follow a code of practice and to label their products as 'unpasteurised'.
3. Requiring all fruit and vegetable juices to be subjected to a 5-log pathogen reduction process or be labelled as 'unpasteurised'.
4. A combination of regulatory and non-regulatory measures.
5. Requiring juice manufacturers to implement a HACCP system that includes a 5-log pathogen reduction process

Consideration of the Regulatory Impact for this application concludes that option 4 is the preferred option as it outlines the most cost effective way of managing the potential risks associated with untreated juice and is in line with ANZFA's section 10 objectives. Option 4 is a combination of regulatory and non-regulatory measures. These measures are outlined below.

#### *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.

### **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).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter will be notified to the WTO as a Technical Barriers to Trade (TBT) notification because there is a possibility that imported product may come under the scope of the proposed requirements and there are no similar requirements specified by Codex. If untreated juice were to be imported into the country it would need to be labelled as 'unpasteurised' and would need to comply with the mandatory microbiological criteria for untreated juice. However, it is ANZFA's understanding that this is unlikely to occur as juice imported into the country comes in a concentrated form. Concentrated juice has been heat-treated and therefore this juice would not need to be labelled or comply with the microbiological criteria.

## FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australia 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 *Australia New Zealand Food Standards Code* is the sole Code between Australia and New Zealand, the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (previously known as *Australian Food Standards Code*) or Volume 2 (also known as the *Australia New Zealand Food Standards Code*) of the *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 (previously known as *Australian Food Standards Code*) or Volume 2 (also known as the *Australia New Zealand Food Standards Code*), of the *Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (previously known as *Australian Food Standards Code*) or Volume 2 (also known as the *Australia New Zealand Food Standards Code*) of the *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 *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 solely with Volume 1 (previously known as *Australian Food Standards Code*) or Volume 2 (also known as the *Australia New Zealand Food Standards Code*), of the *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 *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

## INVITATION FOR PUBLIC SUBMISSIONS

ANZFA has completed a full assessment of the application, prepared draft variations to the *Food Standards Code* and will now conduct an inquiry to consider the draft variations and its regulatory impact.

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

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

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

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

Australia New Zealand Food Authority  
PO Box 7186  
Canberra Mail Centre ACT 2610  
AUSTRALIA  
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority  
PO Box 10559  
The Terrace WELLINGTON 6036  
NEW ZEALAND  
Tel (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **11 July 2001**.

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

## RISK ASSESSMENT OF FRUIT AND VEGETABLE JUICES

### APPLICATION A 411

## PASTEURISATION OF ORANGE JUICE & LABELLING OF UNPASTEURISED JUICE

### 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 *Escherichia 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.<sup>5</sup> 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.<sup>5</sup>

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.<sup>10</sup>

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.<sup>1</sup>

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.<sup>5</sup> Evidence suggests that pathogens in low pH systems die more rapidly at temperatures approaching room temperatures than under very cold (non frozen) conditions.<sup>2</sup>

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 US. There were four isolated cases of *Clostridium botulinum* from home-made tomato juice, between 1976 to 1983, one case of *Clostridium 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.<sup>10</sup>

## **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 9 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 9 recalls of juice and juice products in Australia since 1990, 3 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.<sup>2</sup> Ways in which fruit juice could become contaminated with pathogens have been listed below for the raw product and during processing.<sup>10, 5</sup>

### 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)  
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.<sup>10</sup>

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.<sup>2</sup> 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.<sup>15</sup>

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.<sup>10</sup> *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.<sup>10</sup>

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.<sup>5</sup> 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.<sup>2</sup> 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.<sup>4</sup>

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 percent. 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.<sup>2</sup>

### **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 US in 1996, an outbreak of *E. coli* O157:H7 occurred from unpasteurised commercial apple juice.<sup>4</sup> The factory where this juice was produced was described as a state-of-the-art plant.<sup>4</sup> However, despite implementing controls to minimise the risk of apples 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 apples, but it had no mechanism to ensure compliance;
- the procedure of not using decayed apples was not always strictly followed;
- 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.<sup>4</sup>

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 NZ 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.<sup>2</sup>

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  $5.5 \times 10^8$  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.<sup>3</sup>

## **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 thirty-five percent of all respondents to the Australian 1995 NNS consumed fruit juices and drinks with the mean consumption being 250ml (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 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.

Approximately 20% of the consumers in the New Zealand 1997 NNS consumed fruit juices and drinks with the mean consumption being 250ml (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 545ml, and 19-24 year-old females consuming 365ml. Alternatively, the lowest consumption rates of fruit juices and drinks were reported by 65+ years males consuming 165ml, and 65+ years females consuming 150ml. 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 US'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 US 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.<sup>10</sup>

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 non-heat treated juices are more likely to be the source of such a hazard than heat-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](http://www.plant.uoguelph.ca/safefood/micro-haz/juice-outbreaks.htm).

### Australian average daily consumption of fruit juice & 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 &amp; 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.

## SUMMARY OF PUBLIC COMMENTS RECEIVED

### APPLICATION A411

#### PASTEURISATION OF ORANGE JUICE & LABELLING OF UNPASTEURISED JUICE

Following is a summary of the submissions received in response to the preliminary assessment report released for public comment in May 2000. The options outlined in this report for comment were:

##### **Option 1**

Maintain status quo

##### **Option 2**

Require orange juice, other than freshly squeezed orange juice for immediate consumption on the same premises to either:

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

##### **Option 3**

Require all fruit and vegetable juices including cider, other than freshly squeezed juices for immediate consumption on the same premises, to either:

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

#### **1. Food Technology Association of Victoria Inc**

- Supports the labelling of all fruit and vegetables juices with the statement 'unpasteurised' and not any statements about possible risks. States that unpasteurised statement will have to be included in an ingredient list where the unpasteurised juice is used.
- The term 'fresh' needs to be addressed in the Draft Code.

#### **2. National Council of Women of Australia**

- Supports option 3.
- Supports a requirement for treated juices to have the content of Vitamin C restored to no less than 400mg/L.

#### **3. InforMed Systems Ltd**

- Supports pasteurisation of all juices, except for freshly squeezed juices.

- Requests that the proposal in draft Standard 1.3.2 which permits folate addition to fruit juices be implemented immediately to address the issue of folate destruction from pasteurisation.

#### **4. National Council of Women of NZ**

- Supports option 3 as it provides increased protection of public health and safety and enables consumers to make more informed choices regarding the purchase of unpasteurised juice.

#### **5. National Food Processors Association (USA)**

- The NFPA is the principal scientific trade association representing the \$430 billion food processing industry in the USA.
- Supports requiring juice or juice ingredients to receive pasteurisation or an equivalent process sufficient to render the juice or juice ingredients free of vegetative cells of microorganisms of public health significance.
- Supports the above requirement for all juices as experience in the US with apples, mamey, strawberries and raspberries show that other fruits may be contaminated with pathogenic microorganisms that can be incorporated into any juice prepared from the fruit.
- Does not support providing an exemption from processing even if products are labelled with a warning statement, as there is no scientific justification for exempting any juice products from the requirement for pasteurisation or an equivalent process. The FPA states that a label warning statement should be sanctioned only as a necessary short-term alternative for unpasteurised juices, until pasteurisation or an equivalent process is universally required for all juices in the shortest possible time frame.
- If an exemption is to be provided for ‘freshly squeezed orange juice for immediate consumption on the same premises’, it must be worded so that it is clear that consumption is to be on the same premises where the ‘squeezing’ takes place. Otherwise it may be construed to mean that the consumption must take place on the premises where the juice is sold to the consumer but that the juice may be squeezed elsewhere.
- Suggests that ANZFA provide for the bulk shipment of unpasteurised juice to another location for pasteurisation and consumer packaging provided the shipping documents adequately reveal the fact that the juice is not pasteurised and must either be pasteurised or bear the warning statement for unpasteurised juice as per the FDA.

#### **6. Food Science Australia – Keith Richardson**

- The wording of (i) in option 3 is totally unsatisfactory and should be reworded to specify that the juice be heated to a time and temperature that can be demonstrated to produce a 5-log reduction in the most resistant micro-organism of public health significance likely to occur in the product. It should then also allow an equivalent process to be used that does not rely on heat to effect the pathogen reduction.



- The application must also address the use of the term ‘fresh’ in the context of pasteurised and unpasteurised juice. If the term unpasteurised is to be mandated for those juices, which have not received the appropriate heat treatment, the term ‘fresh’ should not be permitted to be used in relation to these juices.
- Fruit and vegetables should be considered separately. If they are not considered separately, it will not be possible to nominate a specific time/temperature schedule to obtain a 5-log reduction of the pathogen of concern.
- Does not support option 2 as fruit juices would be risk categorised with milk, which is inappropriate. This option also discriminates against fruit juices as a number of other foods implicated in food poisoning incidents do not require labelling when they are not pasteurised.
- Supports option 1 if properly constructed and audited food safety programs are in place.

### **7. Australian Fruit Juice Association**

- Supports option 3. This support is on the proviso that a pasteurised product, which contains no added concentrate, no added preservatives and has a maximum shelf life of 21 days, may still be labelled as ‘fresh’. It notes that a precedent has been set by the Australian dairy industry in calling their pasteurised milk as ‘fresh’. It states the current ‘fresh’ definition in Standard O7 is based not only on industry practices, but also to protect public health and safety and to prevent consumer fraud and deception. It is a retrograde step to remove this definition and rely on the NZ Commerce Act or the Fair Trade Act.
- Supports extension of requirements to all fruit and vegetable juices.
- Supports mandatory labelling of untreated juices as ‘unpasteurised’. However, if the manufacturer of such products is not 3<sup>rd</sup> party HACCP certified, the AFJA supports requiring additional labelling to highlight the risks associated with consuming unpasteurised juice as per the FDA warning statement.

### **8. Charlie’s Trading Company Ltd**

This company supplies machinery, training and marketing support to several supermarkets in NZ, which use fruit supplied under our HACCP program to prepare juice in-store for consumers to take home or consume immediately.

Opposes mandatory pasteurisation or the labelling proposed for the following reasons:

- NZ juices have a good safety record;
- pasteurisation equipment is expensive and there is no technology or equipment that will pasteurise our ‘juice-in-store’ concept;
- pasteurisation changes the taste and flavour of juices and the nutritional value is degraded as pasteurisation substantially reduces Vitamin C content;
- it will decrease consumer choice – many consumers seek out products that are ‘pure’, ‘unprocessed’, ‘without additives’ and ‘real’. These consumers will be unhappy about natural products like vitamins being added artificially when destroyed by processing;

- labelling moves the risk/liability from the manufacturer/vendor to the consumer. Further it assumes the reader is competent to make judgements about the issue. Consumers are not often well enough educated or informed to make sensible decisions based on the information on a label;
- consumer may juice at home and this is likely to involve much higher degrees of food safety risk;
- regulation may reduce the incentives on manufacturers and suppliers to 'be safe' relying instead on a disclosed caveat emptor approach. This is likely to expose consumers to greater risks;
- company has sold over 100 000 litres of fresh orange juice without problem and have not had any evidence under the company's HACCP program of contamination. Further the product has a shelf life of 4 days so not allowing bacteria time to develop;
- the oranges are juiced without the skin contacting the juice;
- labelling product as 'unpasteurised' will operate as an entry barrier as it favours the pasteurised product;
- exempting any juice made for immediate consumption involves risk and so why exempt them from the requirements?; and
- mandatory pasteurisation or labelling will have a critical effect on the viability of our business. The labelling requirement may well be fatal to our business as it will suggest to customers and supermarkets that we have not considered the risk and hazards. In fact, nothing is further from the truth. We are not aware of any processor that has a HACCP program as well developed or as comprehensive as our own.

Supports option 1 or support option 2 provided that an exemption is also permitted for any in-store juicing machine producing less than 200 000 litres pa under a HACCP program and which has a 'consume by' date no later than 4 days after production.

Also recommends that pasteurised juices be labelled to inform consumer fully that 'As natural vitamin C is destroyed on pasteurisation XX mg/ml is added'.

Request that if labelling is proposed, that the opportunity be provided to assess the style and wording of the particular word/statement, before implementation.

## **9. NZ Juice Association**

Supports option 3. However, as alternative technologies to pasteurisation may become economically viable in the future (e.g. high pressure processing), the following should also be permitted:

'processing the juice in a way that can be demonstrated to produce a 5 log reduction in the most resistant micro-organism of public health significance likely to occur in the product'.

This view was not supported by at least one industry representative. These comments of this dissenting member were attached to the submission. This member opposes the NZ Juice

Association's preferred option for the following reasons:

- warning statements of any description will convey a message to consumers that citrus products are inherently unsafe and must be processed to make them safe – a message that is not true;
- pasteurisation is not the only mechanism available to control the safety of this product and an armoury of risk management techniques are available to processors to combat all risks to public health;
- since there are no formal and validated pasteurisation times/temperatures for orange juice, any suggested times/temperatures are purely speculative;
- post pasteurisation is still a risk;
- thermal treatment does not address risks from pesticide and herbicide residue contamination or foreign materials;
- A properly constructed 3<sup>rd</sup> party HACCP based food safety plan addresses all areas of risk to food safety. Pasteurisation is only an optional process step in an overall HACCP plan;
- products that cannot demonstrate safety should not be available for sale and labelling them as such would only serve to reduce consumer confidence in both the juice industry and the public health authority's ability to protect them;
- if pathogenic bacteria can be internalised into the flesh of oranges, we cannot accept the exclusion of freshly squeezed juice for immediate consumption; and
- many nutrients are diminished or destroyed during thermal treatment including beta-carotene and valuable enzymes.

## **10. Queensland Health**

- Supports pasteurisation as it increases the effectiveness of food safety programs, gives clear indication of critical control points and support good manufacturing practice.
- Supports pasteurisation of all fruit and vegetable juice as a risk assessment indicates there is a need for such a requirement.
- Product should be exempted that can demonstrate an equivalent outcome to pasteurisation as per the approach taken with certain unpasteurised cheeses.
- Supports the use of a warning statement for unpasteurised product as per the statement for milk i.e. 'warning: unpasteurised'.
- The exemption from the proposed pasteurisation requirement of freshly squeezed or fresh juice may be difficult to enforce if freshly squeezed and fresh juice are not more clearly defined.

## **11. Food Safety Victoria**

- Supports option 1 provided juice manufacturers continuously maintain good manufacturing practice.