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[2-09]

PROPOSAL P1002

HYDROCYANIC ACID IN READY-TO-EAT CASSAVA CHIPS

FIRST REVIEW REPORT

Executive Summary

On 10 November 2008, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Proposal P1002. The Ministerial Council requested that FSANZ review the decision to approve the draft variations for Proposal P1002 on the grounds that it places an unreasonable cost burden on industry or consumers, and it is difficult to enforce and/or comply with in both practical or resource terms.

FSANZ prepared Proposal P1002 to assess the public health risks associated with total hydrocyanic acid (hydrogen cyanide) in ready-to-eat cassava chips. As a result of this assessment, FSANZ considered that regulatory measures in the *Australia New Zealand Food Standards Code* (the Code) were required to reduce levels of total hydrocyanic acid in ready-to-eat cassava chips in order to protect public health and safety. This decision was based on the best available scientific evidence and followed a re-assessment of the risks to public health and safety following public comment. The decision had regard to issues raised in public submissions.

The food regulatory measures included a maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips. Compliance with this maximum level would reduce dietary exposure to hydrocyanic acid from ready-to-eat cassava chips and would address the potential public health implications that have been identified with these foods arising from high consumption levels over a short period of time (acute dietary exposure).

Decision

Re-affirm the variations to Standard 1.4.1 – Contaminants and Natural Toxicants to include a maximum level of 10 mg/kg for ‘hydrocyanic acid, total’ in ‘ready-to-eat cassava chips’ and; to facilitate compliance monitoring, a definition of ‘hydrocyanic acid, total’ for ‘ready-to-eat cassava chips’.

Reasons for Decision

- Food regulatory measures in the Code for total hydrocyanic acid in ready-to-eat cassava chips are considered necessary to minimise dietary exposure to hydrocyanic acid and confidently protect public health and safety.

- A maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips is considered to be necessary to confidently protect public health and safety. Based on the best available scientific evidence and the risk assessment conducted by FSANZ, a maximum level higher than 10 mg/kg is not considered adequate to protect public health and safety. The preliminary data from the 2007 National Children's Nutrition and Physical Activity Survey support the estimated consumption of cassava chips derived from the 1995 National Nutrition Survey, and the conclusion that children consuming cassava chips are potentially at risk of exceeding the acute reference dose.
- The maximum level of 10 mg/kg is also considered to be practical and reasonably achievable with proper processing of cassava or with specific cassava selection, and therefore generates the greatest net benefit for the community by protecting public health and safety. The maximum level of 10 mg/kg is also consistent with the level in the international (Codex) standard for edible cassava flour (another processed cassava product for direct human consumption).
- FSANZ has given careful consideration to the submissions and representations from manufacturers of cassava chips, including those provided at a meeting of certain manufacturers with FSANZ staff on 6 February 2009 and a letter from Tixana Pty Ltd dated 12 January 2009. FSANZ particularly notes the manufacturers' concerns that a maximum level of 10 mg/kg will effectively require them to cease business. However, while this consideration weighed heavily in FSANZ's deliberations, ultimately FSANZ considers that the correct and preferable approach is to protect public health and safety. As mentioned, FSANZ considers that the only way that this can be confidently achieved is to adopt a maximum level of 10 mg/kg.
- Even if the maximum level of 10 mg/kg were unachievable, FSANZ considers that that level is still preferable because in FSANZ's view the costs to business are outweighed by the risks to public health and safety if a higher maximum level were to be adopted.
- FSANZ considers that the maximum level should come into effect upon gazettal and that the usual 'stock in trade' transitional arrangements not apply. FSANZ does not consider that transitional arrangements are appropriate because of the potential acute public health implications associated with the levels reported in some ready-to-eat cassava chips.
- FSANZ does not consider that it is practical or necessary to prescribe a method of analysis for hydrocyanic acid in ready-to-eat cassava chips, as effective compliance monitoring is achieved by defining the substances to be analysed (i.e. hydrocyanic acid, total). FSANZ considers that there are more efficient and appropriate mechanisms for resolving implementation issues than by prescribing specific food regulatory measures in the Code. In this case, FSANZ does not consider it necessary to delay the relevant food regulatory measures while implementation issues are resolved.
- FSANZ acknowledges that the potential public health implications are also relevant to other foods containing cyanogenic glycosides. FSANZ intends to discuss these issues with other food regulatory agencies and will include this activity on its work plan. FSANZ has also noted that the issues associated with certain varieties of cassava are also under discussion at an international level within the Codex Alimentarius Commission.

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1. Introduction

On 10 November 2008, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Proposal P1002. This Proposal sought to include a maximum level (ML) for total hydrocyanic acid in ready-to-eat cassava chips of 10 mg/kg in Standard 1.4.1 – Contaminants and Natural Toxicants of the *Australia New Zealand Food Standards Code* (the Code).

FSANZ approved this ML to reduce acute dietary exposure to hydrocyanic acid from ready-to-eat cassava chips and address the potential public health implications that had been identified with these foods.

FSANZ was required to review the decision by 10 February 2009.

2. Objectives of Review

The objective of this Review is to reconsider the draft variation to Standard 1.4.1 in light of the Ministerial Council's grounds for review as outlined in Section 3 below.

3. Grounds for the Review requested by the Ministerial Council

The Ministerial Council has requested that FSANZ review the decision to approve the draft variations for Proposal P1002, including a maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips was sought on the grounds that:

- it places an unreasonable cost burden on industry or consumers; and
- it is difficult to enforce (and/) or comply with in both practical or resource terms.

The public notice for the review request is at

<http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-request-reviews>.

3.1 Summary of Ministerial Council's Reasons for Requesting a Review

3.1.1 *It places an unreasonable cost burden on industry or consumers*

The Ministerial Council identified the following issues in relation to the regulatory measures placing an unreasonable cost burden on industry and consumers:

It is believed that a maximum level (ML) of 10 mg/kg for 'hydrocyanic acid, total' is a conservatively derived figure.

It is suggested that there are more than sufficient redundancies in its derivation to be comfortable with the alternative ML of 25 mg/kg which the industry indicates it can meet.

It has been suggested that:

- there is a long history of apparently safe consumption of these products in Australia at levels of total HCN which are likely to be typically higher than 25 mg/kg;
- a higher ML of 20/25 mg/kg would still protect public health and safety, without having significant adverse impact on the cassava chip industry;

- there is limited evidence provided to support the assumption that the consumption of potato crisps (and other salty snacks) and cassava chips would be the same and the assumed intake pattern for cassava chips in the sensitive group of 2-4 years is exceedingly high and a more realistic consumption pattern would be 50 g of cassava chips, which at 25 mg hydrocyanic acid/kg, is unlikely to exceed about 30% of the Acute Reference Dose (ARfD);
- evidence is required to substantiate the statement in the Approval Report that Additional results provided to FSANZ indicate that a number of other cassava containing foods also contain less than 10 mg/kg total hydrocyanic acid.;
- a recommendation for no transitional arrangements is questioned on the basis that no regulatory action is currently being taken by compliance agencies in Australia, not aware of any complaints or health concerns or cases being reported and this approach is another costly imposition on the industry;
- there are concerns with consultation with industry and clarification is sought on an industry submission;
- no Australian or New Zealand manufacturer of ready-to-eat cassava chips is understood to be currently complying with the Standard proposed by FSANZ or that they expect to be able to in the future;
- the Codex Standard for Sweet Cassava is selectively referenced in the Approval Report;
- in relation to international standards and requirements, other countries have not regulated this food; and
- this Proposal unfairly targets one specific type of food without equal concern for other food stuffs which also contain hydrocyanic acid.

3.1.2 *It is difficult to enforce (and/) or comply with in both practical or resource terms*

The Ministerial Council identified the following issues about the maximum level for hydrocyanic acid in ready-to-eat cassava chips, including in relation to the ability to enforce or comply with it in both practical or resource terms.

The development of a standard and the implementation and enforcement of that standard are complementary. It is considered unacceptable for a standard to be developed without an appropriate scientifically validated methodology for testing a product against the standard determined and agreed to.

It has been suggested that:

- while it is acknowledged that FSANZ do not ordinarily prescribe testing methodologies, in this instance, a prescribed method of HCN analysis with equivalence recognition would assist in alleviating much of objection in relation to results of analysis;
- without a robust and reliable analytical method any proposed ML is of dubious value; and
- it is imperative there be no further consideration of a standard until the matter of methodology is resolved.

4. Background

In 2008, food regulatory agencies in Australia and New Zealand found that certain cassava-based foods (some chips or crackers) contained higher than expected levels of hydrocyanic acid (hydrogen cyanide). These results prompted the national recall of the implicated products in Australia by one manufacturer and further investigation by food regulatory authorities.

FSANZ prepared Proposal P1002 to:

- consider the potential public health and safety risks associated with the consumption of ready-to-eat cassava chips; and
- develop appropriate risk management strategies to manage these risks, including the need for a maximum level in the Code for hydrocyanic acid (hydrogen cyanide) and/or its precursors in these foods.

Based on a risk assessment, FSANZ considered the elevated¹ levels of total hydrocyanic acid reported in ready-to-eat cassava chips to be of public health and safety concern. The current regulatory measures in the Code do not address the potential for raw cassava containing less than 50 mg/kg of total hydrocyanic acid to be dried, minimally processed and then sold as a ready-to-eat food.

As a result of this assessment, FSANZ considered that regulatory measures in the Code were required to reduce levels of total hydrocyanic acid in ready-to-eat cassava chips to protect public health and safety. This decision was based on the data available and followed a re-assessment of the risks to public health and safety following public comment. The decision also had regard to the issues raised in public submissions.

The food regulatory measures included definitions for 'ready-to-eat cassava chips' and 'hydrocyanic acid, total' and a maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips. Compliance with these measures would reduce dietary exposure to total hydrocyanic acid from ready-to-eat cassava chips and would address the potential public health implications that have been identified with these foods arising from high consumption levels over a short period of time (acute dietary exposure).

5. Conclusions from the Approval Report

FSANZ approved the variations to Standard 1.4.1 to include a maximum level of 10 mg/kg for 'hydrocyanic acid, total' in 'ready-to-eat cassava chips' and to facilitate compliance monitoring, a definition of 'hydrocyanic acid, total' for 'ready-to-eat cassava chips'. The Executive Summary and the reasons for the decision, which were approved by the FSANZ, are provided in this Report at **Attachment 2**.

6. Issues addressed in First Review

6.1 It places an unreasonable cost burden on industry or consumers

The Ministerial Council's first ground for review was that it places an unreasonable cost burden on industry or consumers. The Ministerial Council identified the following issues in relation to the regulatory measures placing an unreasonable cost burden on industry and consumers:

¹ The levels are elevated in the context of what is understood to be readily achievable.

It is believed that a maximum level (ML) of 10 mg/kg for 'hydrocyanic acid, total' is a conservatively derived figure.

It is suggested that there are more than sufficient redundancies in its derivation to be comfortable with the alternative ML of 25 mg/kg which the industry indicates it can meet.

6.1.1 Long History of Apparently Safe Consumption

It has been stated that there is a long history of apparently safe consumption of cassava chip products in Australia at levels of total HCN which are likely to be typically higher than 25 mg/kg.

The primary toxicological endpoint of concern for hydrocyanic acid (HCN) is inhibition of mitochondrial oxidation, which may rapidly lead to death if the level of exposure to HCN exceeds the capacity of normal physiological detoxification mechanisms. Death in humans has been reported from HCN doses as low as 0.58 mg/kg bodyweight (bw). Clinical manifestations of acute cyanide poisoning, especially non-lethal doses, are often non-specific and mainly reflect those of oxygen deprivation of the heart and brain. Typically these effects include headaches, dizziness, stomach pain, or mental confusion.

These symptoms closely resemble that of over indulgence or mild gastro-intestinal tract disturbance. As these symptoms would not occur until some hours after ingestion of cassava chips, individuals exposed to dangerous levels of HCN may not recognise warning symptoms before consuming a lethal dose. This is likely to be particularly true for young children. Sub lethal exposures leading to clinical signs of intoxication would not be expected to lead to presentation at hospital emergency departments or general practitioners, and therefore would not be reported in most instances.

On this basis, it is questioned whether a 'long history of apparently safe consumption' can be assumed. In addition, FSANZ has noted that it has been suggested that 'Reported cases of health effects from members of the public consuming cassava chips have been at HCN levels between 80 mg/kg to 145 mg/kg in cassava chips with intakes of at least 200 g of cassava chips by individuals much older than the most at risk group'.

HCN is a lethal acute toxin with a steep dose response curve. Doses slightly higher than those producing relatively non specific symptoms can be fatal. Toxicity across species is similar and animal models have clear relevance to estimation of safe human exposures. An Acute Reference Dose (ARfD) based on death as the primary endpoint in hamsters was determined for linamarin. The principal cyanogenic glycoside in cassava is linamarin. Toxicity studies have been conducted directly on linamarin so that an extrapolation from HCN studies to the toxicity of linamarin, with associated adjustments for pharmacokinetics, is not necessary. As total HCN levels are more readily determined than linamarin levels, the linamarin ARfD is converted to an ARfD for total HCN measured in cassava, as an analytical convenience.

For linamarin, an ARfD of 0.7 mg/kg bw was established on the basis of death in hamsters at doses greater than 70 mg/kg bw and applying a 100-fold uncertainty factor to account for intra-species variability and inter-species extrapolation.

The use of studies in hamsters as the basis for the establishment of an ARfD for linamarin was criticised by some stakeholders. No experimental species is an ideal substitute for humans under all circumstances, with every animal model diverging from human anatomy and/or physiology in some regard. Nonetheless, studies in experimental animals, primarily rodents, form the basis of risk assessment for most industrial, food, agricultural and cosmetic chemicals and 'first in man' clinical trials on new pharmaceuticals, around the world.

These studies have proved to be broadly predictive of human effects, when interpreted correctly, and appropriately conservative health values derived from such studies have proved to be protective for humans.

Comments from some stakeholders suggesting that the presence of a forestomach in hamsters invalidated this species as a model for human toxicity were noted and considered. Consideration of anatomical and physiological differences between experimental animals and humans is a routine aspect of toxicological evaluation and the situation with linamarin in cassava is not different to other food contaminants in that sense.

FSANZ acknowledges that the available data set is suboptimal, a situation which is in no way unusual for food contaminants, however the agency is obliged to use the best *available* scientific evidence in preparing its risk assessments. Appropriately conducted studies in hamsters are considered suitable. For this reason, these studies have been used in determining the ARfD. FSANZ is always ready to discuss with stakeholders potential study designs that they may wish to commission which would address key data deficiencies. In the current context such studies would relate to the pharmacokinetics of the linamarin in cassava based foods, and its rate of conversion to HCN, in human subjects, as this constitutes the key data deficiency of the current dataset.

One mole of linamarin can release a maximum of one mole of hydrocyanic acid following hydrolysis and on this basis the linamarin ARfD equates to an ARfD for HCN in cassava of 0.08 mg/kg bw. In a separate study the lowest reported fatal absorbed dose for HCN in humans was 0.58 mg/kg bw. The ARfD for hydrocyanic acid of 0.08 mg/kg bw provides a margin of exposure of seven from the lowest fatal absorbed dose used in this study. Given the steep dose response curve for HCN toxicity, this is considered to be appropriate.

Following best practice, where significant uncertainties in the data exist, conservative assumptions were used to ensure that the dietary exposure assessment did not underestimate exposure.

The reported probabilities of exceeding the ARfD reflect the conservatism inherent in the exposure assessment and the ARfD. The probability of exposure above the ARfD at total HCN levels of 10 mg/kg of cassava chips for all subgroups in the population was determined to be low. At levels of HCN in excess of 10 mg/kg the likelihood of an adverse outcome begins to increase, especially for the most vulnerable group, 2-4 year old children.

For children aged 2-4 years, reducing the mean concentration of hydrocyanic acid in Cassava chips from the *status quo* to 10 mg/kg will reduce the potential incidence of exposures above the ARfD by 93-97%. Reducing the concentration to 25 mg/kg would lead to a lesser reduction of 61-70%. On this basis, a maximum level of 25 mg/kg is not considered an acceptable option for minimising the dietary exposure to hydrocyanic acid from ready-to-eat cassava chips. This is because a level of 25 mg/kg is not considered to be sufficient to confidently protect public health and safety.

The HCN concentration at which potentially tragic and irreversible consequences could arise from a single instance of a young child consuming a moderate quantity (50 - 100 g) of cassava chips is difficult to determine because of the absence of suitable data regarding the release and absorption kinetics of linamarin in humans. The nature of glycoside toxicity is such that intake-limiting, and therefore protective, warning symptoms do not occur. On this basis, a degree of conservatism is warranted and has been built into the risk assessment underpinning the proposed maximum level for total HCN.

The risk assessment including the ARfD, is based on FSANZ's assessment of the best available scientific evidence and has been peer-reviewed.

In the future, if additional studies were planned to fill any data gaps, FSANZ could make its expertise available to assist in the experimental design of an appropriate kinetic study in humans. As with any food regulatory measure, if additional data is generated and provided to FSANZ then FSANZ would be prepared to consider these data and if necessary, review the risk assessment.

6.1.2 Dietary Exposure Assessment Assumptions

It has been suggested that “There is limited evidence provided to support the assumption that the consumption of potato crisps (and other salty snacks) and cassava chips would be the same and the assumed intake pattern for cassava chips in the sensitive group of 2-4 years is exceedingly high and a more realistic consumption pattern would be 50 g of cassava chips, which at 25 mg hydrocyanic acid/kg is unlikely to exceed about 30% of the ARfD.”

The risk assessment used well established methodology and the best available scientific evidence for estimating dietary exposure to an acute hazard.

There are two basic, fundamentally different types of exposure assessments: *chronic* and *acute*. The appropriate type of exposure assessment depends on the toxicological properties of the assessed chemical. In the case of hydrocyanic acid, *acute* effects following dietary exposure to cyanogenic glycoside compounds in cassava-based foods are the primary concern. For this reason, best practice therefore mandates an acute dietary exposure assessment is appropriate.

The relevant reference health standard is the *Acute Reference Dose*, i.e. an estimate of the amount of the chemical in food, expressed on a bodyweight basis that can be ingested during one meal or one day, without appreciable health risk to the consumer. In acute dietary exposure assessment, the risk assessor estimates the exposure that ‘high-end’ consumers could experience on a single eating occasion or over a single day, where ‘high-end’ is a plausible estimate of exposure for those individuals at the upper end of the consumption distribution. This is usually the 97.5th percentile consumption.

The risk assessment for hydrocyanic acid in ready-to-eat cassava chips was focussed on estimating whether a *single day exposure* above the reference health standard could result from consumption of the food in question and how likely this would be. Following best practice, where significant uncertainties in the data existed, conservative assumptions were used to ensure that the dietary exposure assessment did not underestimate potential dietary exposure.

The best available scientific evidence supports the assumption that the consumption of potato crisps (and other salty snacks) is a reasonable estimate of cassava chips consumption.

Consumption of cassava chips was not reported in the Australian 1995 NNS² or the New Zealand 1997 NNS. Instead, data on the consumption of ready-to-eat cassava chips was estimated using FSANZ’s dietary modelling computer program, DIAMOND, from combined food consumption for consumers of crisps, chips, extruded snacks, and other salty snacks (see Tables 1 and 2 in the Dietary Exposure Assessment Report attached to the Approval Report). These data were used as a proxy for consumption of ready-to-eat cassava chips.

In the absence of data on the actual consumption of cassava chips, this approach gave the best possible estimate of the consumption of ready-to-eat cassava chips because:

² NNS – National Nutrition Survey

1. Ready to eat cassava chips are very similar to other salty snacks, such as vegetable crisps and chips.
2. It is highly unlikely that consumers of a particular salty snack e.g. potato crisps, would never consume any other type of salty snack.
3. The assessment is based on a single eating occasion. It is a reasonable assumption that on a single occasion a consumer of one bag of salty snacks (i.e. approximately 100 g) would instead consume one bag of cassava chips of similar size.
4. While consumption of cassava chips is estimated from the combined consumption of a range of proxy foods, individual consumers did not necessarily report consuming more than one of the proxy foods. High-end consumers of salty snacks typically consumed large amounts of a single type of snack, even though the particular food reported may have been a crisp, chip, extruded snack or other salty snack.
5. Preliminary data from the National Children's Nutrition and Physical Activity Survey broadly support the finding of the Dietary Exposure Assessment.

The estimated consumption for cassava chips for 2-4 year old children reflects eating patterns typical of this age group.

The purpose of the dietary exposure assessment is to estimate the exposure that 'high-end' consumers could experience on a single eating occasion or over a single day.

While high consumption amounts in 2-4 year old children represent uncommon events they form part of the eating pattern typical of this age group. Eating behaviours of children may vary, ranging from 'picky' eating to irregular eating, overeating, and disinhibited or binge eating. This type of behaviour may further increase the likelihood of consuming 100 g or more of cassava chips and therefore the risk for 2-4 year olds exceeding the Acute Reference Dose on occasions.

The 97.5th percentile of consumption is a plausible basis to estimate exposure for 2-4 year old children.

Dietary exposure to hydrocyanic acid represents a potential acute hazard and therefore requires an acute dietary exposure assessment. The 97.5th percentile is a plausible estimate of exposure for those individuals at the upper end of the consumption distribution. The 97.5th percentile consumption for salty snacks is approximately 100 g (male and female combined) for 2-4 year old children and this quantity of snack is readily consumable in a single sitting. For this reason, it has been used to estimate the acute dietary exposure that 'high-end' consumers could realistically experience on a single eating occasion or over a single day. It is not intended to represent 'typical' or 'average' consumption amounts.

Based on the dietary exposure assessment, some children may exceed the Acute Reference Dose by consuming 50 g of cassava chips containing 25 mg hydrocyanic acid/kg.

To estimate the dietary exposure of 2-4 year old children to hydrocyanic acid from consuming a 50 g package of cassava chips, the portion of chips is divided by the individual body weights for each child. These values are then averaged for each population subgroup to provide a mean estimated consumption of chips per kg of bodyweight. This approach is described in section 3.5 of the Dietary Exposure Assessment Report in the Approval Report. Based on the assumptions that:

- a consumer may eat a whole bag of cassava chips (i.e. 50 g), and
- the maximum hydrocyanic acid concentration of the chips is 25 mg/kg,

the estimated mean acute dietary exposure would be 96% of the Acute Reference Dose for all the 2-4 year old children that consumed chips, 101% for boys, and 90% for girls.

Preliminary data from the National Children's Nutrition and Physical Activity Survey broadly support the finding of the Dietary Exposure Assessment.

Currently, FSANZ cannot carry out dietary exposure assessments using the 2007 National Children's Nutrition and Physical Activity Survey as work on incorporating this new data set into our computer program is not yet complete. However, it is possible to derive preliminary data on the consumption of foods by examining the data set. These data were not available at the time when the Approval Report was developed and have been used to assess the validity of the assumptions made in the Dietary Exposure Assessment Report of the Approval Report.

The National Children's Nutrition and Physical Activity Survey was conducted between February and August 2007 by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the University of South Australia (UniSA), on behalf of the Commonwealth Department of Health and Ageing (DoHA), the Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Food and Grocery Council (AFGC). Food, beverage, dietary supplement, food habits, demography, anthropometry and objectively and self-reported physical activity were measured in 4487 children aged 2-16 years and nutrient intakes derived.

Based on the consumption data from the 1995 NNS, approximately one quarter of 2-4 year old children (i.e. 150,000 children in Australia) consume salty snacks on any given day. In the 2007 survey, approximately 50% of children were reported as consuming various types of chips. The maximum consumption reported was 300 g. The mean consumption of chips was approximately 34 g or 1.0 g/kg body weight. This mean consumption is very similar to the estimated consumption that was based on the 1995 NNS and included in the Approval Report.

In the 2007 survey, a small number of children (38) were reported as consuming cassava chips³. Of these, ten children were reported as consuming 50 g or more of cassava chips, and six consumed 100 g of cassava chips, including 2-4 year old children. These data support the estimated high consumption amount of 100 g that was based on the 1995 NNS and included in the Approval Report.

Based on these data, it is likely that at concentrations of total hydrocyanic acid above 10 mg/kg some children consuming 100 g of cassava chips could be exposed to hydrocyanic acid in excess of the Acute Reference Dose.

In summary, in broad terms, the 2007 preliminary consumption data confirms the findings in the Approval Report which, in turn, were based on the 1995 consumption data. These data indicate that some consumers of cassava chips are potentially at risk of exceeding the Acute Reference Dose for total hydrocyanic acid at concentrations above 10 mg/kg. Limiting the concentrations to a mean of 10 mg/kg substantially reduces the probability of dietary exposures above the Acute Reference Dose.

³ Data were collected on two occasions from 4,487 participants or their caregivers from February to August 2007.
[http://www.health.gov.au/internet/main/publishing.nsf/Content/66596E8FC68FD1A3CA2574D50027D886/\\$File/childrens-nut-phys-survey.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/66596E8FC68FD1A3CA2574D50027D886/$File/childrens-nut-phys-survey.pdf)

6.1.3 Achievability

In order to confidently protect public health and safety, producers of ready-to-eat cassava chips need to achieve a maximum level of 10 mg/kg of total hydrocyanic acid. It has been suggested that no Australian or New Zealand manufacturer of ready-to-eat cassava chips is understood to be currently complying with the standard proposed by FSANZ or that they expect to be able to in the future.

- FSANZ considers the maximum level of 10 mg/kg to be practical and reasonably achievable with proper processing of cassava, specific cassava selection or the use of a processed raw material such as cassava flour. Through proper processing of cassava, total hydrocyanic acid content can be reduced to a safe level of 10 mg/kg in cassava-based products, such as ready-to-eat cassava chips. Further detail about cassava processing and ready-to-eat cassava chips was in Attachment 5 of the Approval Report⁴.

Basic puffed cassava chips made from cassava flour or starch, using properly processed cassava starch or flour that meets international standards, should enable manufacturers to achieve a level of total hydrocyanic acid below 10 mg/kg. The simplest control for ready-to-eat cassava chips to achieve a total hydrocyanic acid level below 10 mg/kg is to use cassava ingredients containing less than 10 mg/kg. Total hydrocyanic acid levels in dried raw cassava ingredients can be reduced through various processing techniques. The manufacturing process of ready-to-eat puffed cassava chips may have the potential to reduce hydrocyanic acid in the chips. However, if the total hydrocyanic acid level in the dried raw cassava ingredients is greater than 40 mg/kg, then it is very unlikely that the final cassava chips will contain total hydrocyanic acid below 10 mg/kg.

Some puffed cassava chips may contain ingredients such as 'cassava' in addition to cassava flour. This 'cassava' component could consist of milled or pulverised dried cassava chips or pellets, and is claimed by the manufacturers to provide a special cassava flavour and texture to the puffed chips. Other types of cassava chips are not puffed and are raw (and/or dried) sliced cassava which is fried directly in hot oil until crisp; a product similar to potato chips. These types of chips have much higher potential for containing total hydrocyanic acid above 10 mg/kg because the less processed dried raw cassava may contain higher levels of total hydrocyanic acid than cassava flour. To comply with a limit of 10 mg/kg, these types of chips need to be produced from low total hydrocyanic acid cassava or the cassava must be processed sufficiently to reduce the levels of total hydrocyanic acid in the cassava.

As stated in the Approval Report, results provided to FSANZ demonstrate that some ready-to-eat cassava chip producers would already comply with a limit of 10 mg/kg for total hydrocyanic acid, including certain brands of products stated as originating in Australia.

The data provided to FSANZ indicates that there are few products that contain between 10 and 25 mg/kg of total hydrocyanic acid i.e. could comply with 25 mg/kg but could not comply with 10 mg/kg. Additional results provided to FSANZ indicate that a number of other cassava containing foods also contain less than 10 mg/kg total hydrocyanic acid. The basis for these statements is the information provided in submissions from two jurisdictions. This information has been compiled into a single attachment (**Attachment 3**).

⁴http://www.foodstandards.gov.au/_srcfiles/P1002%20Hydrocyanic%20acid%20in%20cassava%20chips%20AppR%20FINAL.pdf

On the basis of the information above, FSANZ considers that compliance with the maximum level is achievable and generates the greatest net benefit for the community by protecting public health and safety.

In the Approval Report, FSANZ acknowledged that these measures are likely to increase costs for some producers of ready-to-eat cassava chips because the selection of low total hydrocyanic acid cassava may be difficult to guarantee, and additional processing of cassava with higher levels of total hydrocyanic acid will therefore require additional resources.

Even if the maximum level of 10 mg/kg were unachievable, FSANZ considers that that level is still preferable because in FSANZ's view, the costs to business are outweighed by the risks to public health and safety if a higher maximum level were to be adopted.

6.1.4 Hydrocyanic Acid Content of Cassava Containing Foods

Evidence has been requested to substantiate the statement in the Approval Report that *Additional results provided to FSANZ indicate that a number of other cassava containing foods also contain less than 10 mg/kg total hydrocyanic acid.* As stated above under 6.1.3 and as stated in the Approval Report, results provided to FSANZ demonstrate that some ready-to-eat cassava chips and other cassava containing foods contain less than 10 mg/kg of total hydrocyanic acid (**Attachment 3**).

6.1.5 Transitional Arrangements

A recommendation for no transitional arrangements has been questioned on the basis that no regulatory action is currently being taken by compliance agencies in Australia, there are no complaints or health concerns or cases being reported, and this approach is another costly imposition on the industry.

FSANZ considers that the maximum level should come into effect upon gazettal and that the usual 'stock-in-trade' transitional arrangements not apply after that point. This is because transitional arrangements are not considered appropriate given the potential acute public health implications associated with the levels reported in some ready-to-eat cassava chips.

In addition, FSANZ has noted that it has been suggested that 'Reported cases of health effects from members of the public consuming cassava chips have been at HCN levels between 80 mg/kg to 145 mg/kg in cassava chips with intakes of at least 200g of cassava chips by individuals much older than the most at risk group.' FSANZ has also noted that over 12 months has elapsed since the issue of total hydrocyanic acid in ready-to-eat cassava chips was originally raised with FSANZ.

6.1.6 Consultation with Industry

There are concerns with consultation with industry and clarification is sought on an industry submission.

Proposal P1002 was assessed under the General Procedure. The *Food Standards Australia New Zealand Act 1991* requires one round of public consultation for a general procedure proposal. In addition, FSANZ extended the initial formal consultation following the Assessment stage to allow potentially affected businesses more time to prepare their submissions. FSANZ is of the view that a limit of 10 mg/kg as proposed at Assessment, as approved by FSANZ and as subsequently notified to Council, was necessary to confidently protect public health and safety.

As the limit had not changed between Assessment and Approval, and was based on a risk assessment, FSANZ did not specifically consult individual businesses again after the initial consultation period.

FSANZ has given careful consideration to the submissions and representations from manufacturers of cassava chips, including those provided at a meeting of certain manufacturers with FSANZ staff on 6 February 2009 and a letter dated 12 January 2009 from Tixana Pty Ltd. FSANZ particularly notes the manufacturers' concerns that a maximum level of 10 mg/kg will effectively require them to cease business. However, while this consideration weighed heavily in FSANZ's deliberations, ultimately FSANZ considers that the correct and preferable approach is to protect public health and safety. As mentioned, FSANZ considers that the only way that this can be confidently achieved is to adopt a maximum level of 10 mg/kg.

Some concern was expressed about whether a submission from Unique Food Group had been adequately summarised in the Approval Report for Proposal P1002.

FSANZ considers that the comments from the particular submitter have been correctly summarised in the summary of submissions attached to the Approval Report, including the issue surrounding the method associated with these comments.

It should also be noted that FSANZ has not wholly or heavily relied on this submission in forming a view that 10 mg/kg total hydrocyanic acid in ready-to-eat cassava chips is achievable. FSANZ has relied on its food technology assessment and the data provided in all submissions in forming the view that 10 mg/kg total hydrocyanic acid in ready-to-eat cassava chips is achievable.

6.1.7 International Standards/Requirements

It has been suggested that the Codex Standard for Sweet Cassava is selectively referenced in the Approval Report and that in relation to international standards and requirements, other countries have not regulated this food.

While the Codex standard for 'sweet cassava' was referenced as background for Proposal P1002, it is not relevant to the maximum level for total hydrocyanic acid in ready-to-eat cassava chips. The Codex Standard of most relevance to Proposal P1002 is the Codex standard for edible cassava flour in which the level of total hydrocyanic acid in the flour must not exceed 10 mg/kg.

The maximum level of 10 mg/kg of total hydrocyanic acid in ready-to-eat cassava chips is consistent with the level in the Codex Standard for edible cassava flour (another processed cassava product for direct human consumption).

In the Approval Report, FSANZ emphasised that 'bitter cassava' and derivatives of bitter cassava (e.g. dried bitter cassava) are currently prohibited from sale in Australia and New Zealand. FSANZ has also noted that the issues associated with certain varieties of cassava are under discussion at an international level within the Codex Alimentarius Commission.

The issue with total hydrocyanic acid in ready-to-eat cassava chips arose as a result of actions taken by authorities in Japan. The results and the decisions by Japanese authorities are available from their website <http://www.mhlw.go.jp/english/topics/importedfoods/>. These actions have occurred even though issues associated with cassava and cyanogenic glycosides in food are under development internationally.

Evidence indicates that Japan has taken steps in relation to cassava chips containing cyanide, including action in relation to cassava chips manufactured in Australia.

6.1.8 Other Foods Containing Hydrocyanic Acid

It has been suggested that this Proposal unfairly targets one specific type of food without equal concern for other food stuffs which also may contain hydrocyanic acid. In the Approval Report, FSANZ acknowledged that the potential public health implications are also relevant to other foods containing cyanogenic glycosides (e.g. apricot kernels, linseed products) and will include this task on its work plan for future activity. FSANZ considers that the potential acute public health implications associated with consuming readily available, ready-to-eat cassava chips warrants specific food regulatory measures for these chips. The actions with cassava chips arose because of the potential acute adverse health effects for vulnerable groups (i.e. children) consuming 100 g-200 g cassava chips containing 80-145 mg/kg of total hydrocyanic acid in one sitting. This scenario does not apply to other foods such as apricot kernels which are not considered to be consumed by children to the same degree as cassava chips.

FSANZ does not consider that a maximum level for total hydrocyanic acid in ready-to-eat cassava chips should be delayed while other foods are investigated.

As stated in the Approval Report there are insufficient data available in relation to additional food regulatory measures for other foods. Further data on total hydrocyanic acid in food is proposed to be generated as part of the surveillance and monitoring activities that are overseen by the Implementation Sub-Committee of the Food Regulation Standing Committee. While this means that, at this time, FSANZ is not in a position to consider further regulatory measures, FSANZ will continue to monitor the situation. It should also be noted that the general provisions in food legislation in relation to safe food apply to all foods and that these provisions give enforcement agencies the ability to act quickly if hydrocyanic acid is considered to be an issue for other foods. Furthermore, there are existing food regulatory measures for total hydrocyanic acid in certain other foods in the Code.

6.1.9 Cost Burden on Industry or Consumers Conclusion

In conclusion and as stated in the Approval Report, FSANZ acknowledged that the food regulatory measures to confidently protect public health and safety are likely to increase costs for some producers of ready-to-eat cassava chips. This was on the basis that the selection of low total hydrocyanic acid cassava may be difficult to guarantee, and additional processing of cassava with higher levels of total hydrocyanic acid will therefore require additional resources. Based on the best available scientific evidence, a maximum level of 10 mg/kg total hydrocyanic acid in ready-to-eat cassava chips is considered necessary to confidently protect public health and safety. Based on information provided to FSANZ, it is a level that at least some producers are currently achieving and should be achievable for all producers.

While higher levels may be more achievable for industry, FSANZ considers that a higher maximum level would not be sufficient to confidently protect public health and safety.

6.2 It is difficult to enforce (and/) or comply with in both practical or resource terms

The Ministerial Council's second ground for review is that the food regulatory measures for total hydrocyanic acid in ready-to-eat cassava chips are difficult to enforce or comply with in both practical or resource terms. The Ministerial Council identified the following issues in relation to the ability to enforce or comply with it in both practical or resource terms.

The development of a standard and the implementation and enforcement of that standard are complementary.

It is considered unacceptable for a standard to be developed without an appropriate scientifically validated methodology for testing a product against the standard determined and agreed to.

6.2.1 Method Prescription

It has been suggested that the prescription of testing methods would assist in alleviating much of the subjection in relation to results of analysis.

FSANZ does not consider that food regulatory measures in the Code are the most appropriate or efficient mechanism for resolving debates on implementation issues.

Food regulatory measures for chemical hazards have been developed for many years without agreed validated methods being determined and agreed to in advance of the gazettal of these measures. FSANZ has also noted that there are existing maximum levels for total hydrocyanic acid in specific foods and there is no prescribed method for monitoring compliance with these existing levels. Prescribing a method in relation to total hydrocyanic acid in ready-to-eat cassava chips therefore represents a major departure from past practice.

The definition of 'hydrocyanic acid, total' clearly delineates the substances to which the maximum level applies and on this basis there is no need to prescribe a method for monitoring compliance. Based on submissions, the risk assessment and consistent with the approach used for all other specific chemical substances in food, FSANZ stipulated the substances to be monitored for compliance with the maximum level for total hydrocyanic acid in ready-to-eat cassava chips. This included those cyanogenic substances that evolve hydrocyanic acid following hydrolysis. It also reflects the range of methods that are available for monitoring total hydrocyanic acid in foods. This approach provides the certainty necessary to allow analysts and compliance agencies to develop and validate methods that are 'fit for purpose'.

Many methods are available for monitoring total hydrocyanic acid in foods. Restricting methods to a particular prescribed method or particular group of methods will therefore have costs to the community as alternative equally appropriate methods could not readily be used for compliance monitoring. This is considered unnecessarily restrictive when there are alternative means of resolving any debates on the efficacy of specific methods for compliance monitoring purposes.

FSANZ has no concern with differing methods being used to monitor cyanogenic glycosides, cyanohydrins and hydrogen cyanide in ready-to-eat cassava chips, provided that these methods monitor the substances stipulated in the definition for 'total hydrocyanic acid'.

This is the same approach used for the monitoring arrangements for other specific chemical hazards in food. Consistent with this approach and to facilitate compliance monitoring, FSANZ developed a definition of 'hydrocyanic acid, total' for the purposes of ready-to-eat cassava chips. This was based on the terminology used in the Assessment Report and the Approval Report, reflected the views in some submissions and was considered a more practical approach to ensuring the appropriate range of substances are measured for compliance than prescribing a specific method.

6.2.2 Indefinite Delay of Regulatory Measures

The Ministerial Council has advised that *It is considered unacceptable for a standard to be developed without an appropriate scientifically validated methodology for testing a product against the standard determined and agreed to.*

It has been suggested that without a robust and reliable analytical method any proposed ML is of dubious value. FSANZ is unaware of any food regulatory measures in the Code for specific chemical substances that have been approved with agreed validated methods⁵. Regulatory measures in the Code include many limits or levels for food additives, processing aids, contaminants and residues of agricultural and veterinary chemicals. FSANZ is unaware of any concerns with the implementation of these measures, including the existing food regulatory measures for total hydrocyanic acid in specific foods. On this basis, FSANZ regards the ML for total hydrocyanic acid in ready-to-eat cassava chips to be of equivalent validity as other limits or levels in the Code.

It has been suggested that it is imperative there be no further consideration of a standard until the matter of methodology is resolved. In the Approval Report, FSANZ acknowledged that there are implementation issues associated with the maximum level for total hydrocyanic acid in ready-to-eat cassava chips and agreed that these implementation issues should be considered in parallel with the development of food regulatory measures. However, these issues and the approaches to use in relation to monitoring compliance will need to be resolved by compliance agencies either individually or collectively. There are mechanisms and forums for resolving these implementation issues and FSANZ has noted that approximately twelve months have elapsed since the incident involving cassava chips was initially raised.

While the role of FSANZ does not extend to developing or validating methods, or arrangements for compliance monitoring, FSANZ does have the option of delaying the progression of a food regulatory measure while compliance agencies, industry and individual analysts address these issues to their own satisfaction.

Given the potential public health implications, FSANZ does not consider it appropriate to delay the progress of the proposed food regulatory measures in this Proposal while the implementation issues are further developed.

6.2.3 Conclusions

In summary and as stated in the Approval Report, FSANZ acknowledges that there are implementation issues associated with the maximum level for total hydrocyanic acid in ready-to-eat cassava chips. However, FSANZ considers that there are fora and alternative mechanisms for resolving these issues without resorting to unnecessarily prescriptive food regulatory measures in the Code.

In addition, as more than twelve months have elapsed since this incident first arose, FSANZ is concerned about this specific food regulatory measure being delayed while any further implementation issues are resolved, particularly given the potential public health implications.

On this basis and as methods for measuring total hydrocyanic acid are published, FSANZ considers that the food regulatory measures should progress.

⁵ Methods for monitoring pH, fluid loss or dietary fibre are not considered methods for monitoring 'specific' chemical hazards in food.

This will allow compliance agencies and any laboratories with existing capability to institute testing, while remaining laboratories develop and validate methods in accordance with their own individual circumstances.

7. Review Options

There are three options proposed for consideration under this Review:

1. re-affirm approval of the draft variation to Standard 1.4.1 of the Code as notified to the Ministerial Council; or
2. re-affirm approval of the draft variation to Standard 1.4.1 subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft variation to Standard 1.4.1 as notified to the Council.

8. Decision

FSANZ has considered the issues raised by the Ministerial Council in relation to Proposal P1002 – Hydrocyanic Acid in Ready-to-eat Cassava Chips.

The First Review concludes that the preferred review option is Option 1. FSANZ has decided to re-affirm the variation to Standard 1.4.1 of the Code to include an ML for total hydrocyanic acid in ready-to-eat cassava chips, as detailed in **Attachment 1**.

Decision

Re-affirm the variations to Standard 1.4.1 – Contaminants and Natural Toxicants to include a maximum level of 10 mg/kg for ‘hydrocyanic acid, total’ in ‘ready-to-eat cassava chips’; and to facilitate compliance monitoring, a definition of ‘hydrocyanic acid, total’ for ‘ready-to-eat cassava chips’.

Reasons for Decision

- food regulatory measures in the Code for total hydrocyanic acid in ready-to-eat cassava chips are considered necessary to minimise dietary exposure to hydrocyanic acid and confidently protect public health and safety;
- A maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips is considered to be necessary to confidently protect public health and safety. Based on the best available scientific evidence and the risk assessment conducted by FSANZ, a maximum level higher than 10 mg/kg is not considered adequate to protect public health and safety. The preliminary data from the 2007 National Children’s Nutrition and Physical Activity Survey support the estimated consumption of cassava chips derived from the 1995 National Nutrition Survey, and the conclusion that children consuming cassava chips are potentially at risk of exceeding the acute reference dose.
- The maximum level of 10 mg/kg is also considered to be practical and reasonably achievable with proper processing of cassava or with specific cassava selection, and therefore generates the greatest net benefit for the community by protecting public health and safety. The maximum level of 10 mg/kg is also consistent with the level in the international (Codex) standard for edible cassava flour (another processed cassava product for direct human consumption).

- FSANZ has given careful consideration to the submissions and representations from manufacturers of cassava chips, including those provided at a meeting of certain manufacturers with FSANZ staff on 6 February 2009 and a letter from Tixana Pty Ltd dated 12 January 2009. FSANZ particularly notes the manufacturers' concerns that a maximum level of 10 mg/kg will effectively require them to cease business. However, while this consideration weighed heavily in FSANZ's deliberations, ultimately FSANZ considers that the correct and preferable approach is to protect public health and safety. As mentioned, FSANZ considers that the only way that this can be confidently achieved is to adopt a maximum level of 10 mg/kg.
- Even if the maximum level of 10 mg/kg were unachievable, FSANZ considers that that level is still preferable because in FSANZ's view the costs to business are outweighed by the risks to public health and safety if a higher maximum level were to be adopted.
- FSANZ considers that the maximum level should come into effect upon gazettal and that the usual 'stock in trade' transitional arrangements not apply. FSANZ does not consider that transitional arrangements are appropriate because of the potential acute public health implications associated with the levels reported in some ready-to-eat cassava chips.
- FSANZ does not consider that it is practical or necessary to prescribe a method of analysis for hydrocyanic acid in ready-to-eat cassava chips, as effective compliance monitoring is achieved by defining the substances to be analysed (i.e. hydrocyanic acid, total). FSANZ considers that there are more efficient and appropriate mechanisms for resolving implementation issues than by prescribing specific food regulatory measures in the Code. In this case, FSANZ does not consider it appropriate to delay the relevant food regulatory measures while implementation issues are resolved.
- FSANZ acknowledges that the potential public health implications are also relevant to other foods containing cyanogenic glycosides. FSANZ intends to discuss these issues with other food regulatory agencies and will include this activity on its work plan. FSANZ has also noted that the issues associated with certain varieties of cassava are also under discussion at an international level within the Codex Alimentarius Commission.

9. Implementation and review

As stated in the Approval Report, the draft variation to Standard 1.4.1 of the Code will come into effect on the date of gazettal.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Executive Summary and Reasons for the Decision from the Approval Report
3. Levels of Total Hydrocyanic Acid Reported to FSANZ

Draft variation to the Australia New Zealand Food Standards Code

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence: on gazettal

[1] **Standard 1.4.1** of the Australia New Zealand Food Standards Code is varied by –

[1.1] *inserting in subclause 5(1) –*

Hydrocyanic acid, total means all hydrocyanic acid including hydrocyanic acid evolved from linamarin, lotaustralin, acetone cyanohydrin or butanone cyanohydrin during or following enzyme hydrolysis or acid hydrolysis, expressed as milligrams of hydrocyanic acid per kilogram of ready-to-eat cassava chips.

Ready-to-eat cassava chips means the product containing sweet cassava that is represented as ready for immediate consumption with no further preparation required including crisps, crackers or ‘vege’ crackers.

[1.2] *inserting after subclause 5(3) –*

(4) Subclause 1(2) of Standard 1.1.1 does not apply to ready-to-eat cassava chips for the purposes of the Table to clause 5.

[1.3] *inserting in the Table to clause 5 –*

Hydrocyanic acid, total Ready-to-eat cassava chips	10 mg/kg
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Executive Summary and Reasons for Decision from the Approval Report

FSANZ prepared Proposal P1002 to assess the public health risks associated with hydrocyanic acid (hydrogen cyanide) in ready-to-eat cassava chips. As a result of this assessment, FSANZ considers that regulatory measures in the *Australia New Zealand Food Standards Code* (the Code) are required to reduce levels of hydrocyanic acid in ready-to-eat cassava chips to protect public health and safety. This decision is based on the data available and follows a re-assessment of the risks to public health and safety following public comment. The decision also takes into account the issues raised in public submissions.

The food regulatory measures include definitions for 'ready-to-eat cassava chips' and 'hydrocyanic acid, total' and a maximum level of 10 mg/kg for total hydrocyanic acid in ready-to-eat cassava chips. Compliance with these measures would reduce acute dietary exposure to hydrocyanic acid from ready-to-eat cassava chips and would address the potential public health implications that have been identified with these foods.

While not currently within the scope of this Proposal, additional regulatory and non-regulatory measures may be required as investigations continue into hydrocyanic acid in other foods. The inclusion of a maximum level for total hydrocyanic acid in ready-to-eat cassava chips is considered an appropriate risk management measure while these investigations continue.

Assessing the Proposal

Proposal P1002 – Hydrocyanic Acid in Ready-to-eat Cassava Chips has been assessed under the General Procedure.

In assessing the Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 59 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;
- there are no other measures that would be more cost-effective than a variation to Standard 1.4.1 that could achieve the same end;
- any relevant New Zealand standards;
- any other relevant matters.

Decision

Approve the variations to Standard 1.4.1 – Contaminants and Natural Toxicants of the Code to include a maximum level of 10 mg/kg for 'hydrocyanic acid, total' in 'ready-to-eat cassava chips' and to facilitate compliance monitoring, a definition of 'hydrocyanic acid, total' for 'ready-to-eat cassava chips'.

Reasons for Decision

- with proper preparation or processing, cassava and cassava-based foods are safe for human consumption, even though whole, unprocessed cassava contains naturally occurring cyanogenic substances⁶;
- the composition of some 'ready-to-eat cassava chips' is such that existing food regulatory measures in the Code are not considered sufficient to reduce levels of total hydrocyanic acid in ready-to-eat cassava chips and to protect public health and safety;
- following a revised risk assessment, a food regulatory measure in the Code for total hydrocyanic acid in ready-to-eat cassava chips is considered necessary to minimise acute dietary exposure to hydrocyanic acid and thereby protect public health and safety;
- a maximum level in Standard 1.4.1 is considered to be an appropriate risk management measure while additional information is gathered about other cassava based foods and other foods containing cyanogenic substances;
- a maximum level specifically for 'ready-to-eat cassava chips' only is considered necessary at this time. FSANZ considered the views in some submissions that this level should extend to all ready-to-eat foods containing cassava. At this time, FSANZ considers the level should only apply to ready-to-eat cassava chips because there are existing food regulatory measures for managing hydrocyanic acid in some other cassava based products and some other foods (see below);
- a maximum level of 10 mg/kg is considered to be necessary to confidently protect public health and safety. Based on the data available to FSANZ and the revised risk assessment conducted by FSANZ, a maximum level higher than 10 mg/kg is not considered adequate to protect public health and safety;
- the maximum level of 10 mg/kg is also considered to be practical and reasonably achievable with proper processing of cassava or with specific cassava selection. These measures are likely to increase costs for some producers of ready-to-eat cassava chips because the selection of low total hydrocyanic acid cassava may be difficult to guarantee, and additional processing of cassava with higher levels of total hydrocyanic acid will therefore require additional resources. Results provided to FSANZ demonstrate that some ready-to-eat cassava chip producers would already comply with a limit of 10 mg/kg for total hydrocyanic acid. Additional results provided to FSANZ indicate that a number of other cassava containing foods also contain less than 10 mg/kg total hydrocyanic acid. On this basis, FSANZ considers that compliance with the maximum level is achievable and generates the greatest net benefit for the community by protecting public health and safety;
- the maximum level of 10 mg/kg is also consistent with the level in the international (Codex) standard for edible cassava flour (another processed cassava product for direct human consumption). Typical production of cassava flour or starch, especially in the large-scale commercial factories, has ensured that processing steps and parameters are effective in eliminating total hydrocyanic acid from cassava.

⁶ 'Cyanogenic substances' are those substances that produce hydrocyanic acid (hydrogen cyanide) in specific circumstances.

- Based on comments in submissions, edible cassava flour is an ingredient in ready-to-eat cassava chips, although not necessarily the predominant ingredient in all types of chips. Some types of ready-to-eat cassava chips have the potential to contain total hydrocyanic acid above 10 mg/kg. This is because they contain dried raw cassava, which may contain higher levels of total hydrocyanic acid than cassava flour. To comply with a limit of 10 mg/kg, these types of chips need to be produced from low total hydrocyanic acid cassava or the dried cassava used for them must be further processed to adequately reduce the levels of total hydrocyanic acid. Given the potential acute public health implications associated with total hydrocyanic acid in ready-to-eat cassava chips, FSANZ considers that all cassava based ingredients in ready-to-eat cassava chips should be processed to a level equivalent to that of edible cassava flour.
- Furthermore, it is considered necessary that the maximum level come into effect upon gazettal and that the usual 'stock in trade' transitional arrangements not apply. FSANZ does not consider that transitional arrangements are appropriate because of the potential acute public health implications associated with the levels reported in some ready-to-eat cassava chips.
- FSANZ does not consider that it is practical or necessary to prescribe a method of analysis for hydrocyanic acid in ready-to-eat cassava chips as this will restrict the flexibility of industry and compliance agencies to develop more contemporary methods for monitoring hydrocyanic acid in ready-to-eat cassava chips. To facilitate compliance monitoring, FSANZ has developed a definition of 'hydrocyanic acid, total' for the purposes of ready-to-eat cassava chips (see **Attachment 1A**). This reflects the views in some submissions and is considered a more practical approach to ensuring the appropriate range of substances are measured for compliance than prescribing a specific method.

Some submissions raised issues about existing levels for total hydrocyanic acid in the Code and that the potential public health implications are also relevant to other foods containing cyanogenic glycosides. FSANZ acknowledges these views and intends to discuss these issues with other food regulatory agencies. FSANZ has also noted that the issues associated with certain varieties of cassava are also under discussion at an international level within the Codex Alimentarius Commission.

Some submissions included comments in relation to implementing the maximum level, including the need to validate methods, concerns about variability in results and suggestions in relation to monitoring compliance. FSANZ acknowledges that there are implementation issues associated with the maximum level. However, the role of FSANZ does not extend to developing or validating methods or determining specific arrangements for compliance monitoring. These aspects will need to be implemented by compliance agencies either individually or collectively.

Consultation

This Proposal has been assessed under the General Procedure with one round of public consultation. This consultation occurred from 6 March 2008 until 3 April 2008. The consultation period was subsequently extended to 17 April 2008 to allow submitters more time to prepare their submissions.

FSANZ originally acknowledged that this Proposal would be of interest to a broad range of stakeholders and applied a general communication strategy to this Proposal. This included advertising the availability of the Assessment Report for public comment in the national press and making the reports available on the FSANZ website.

FSANZ received fifteen submissions. These were from individuals, government agencies, including an overseas agency and industry. FSANZ has had regard to the issues raised in submissions and the FSANZ response to them is in **Attachment 2**.

Amendments Following Public Consultation

FSANZ sought public comment on the draft variation at **Attachment 1C**. Following public comment and taking into account submissions on the original draft variation, FSANZ has amended the draft variation (see **Attachment 1A** - unmarked version or **Attachment 1B** - marked version).

The amendment to the draft variation is to include a definition of 'hydrocyanic acid, total' for the purposes of ready-to-eat cassava chips. FSANZ considers that this definition is necessary to facilitate compliance monitoring. This reflects the views in some submissions and is considered a more practical approach to ensuring the appropriate range of substances are measured for compliance than prescribing a specific method.

Levels of Total Hydrocyanic Acid Reported to FSANZ

Compliance of ready-to-eat cassava chips with proposed levels of total hydrocyanic acid – NSW Food Authority

Country of Origin	Brand	Level of total hydrocyanic acid (mg/kg)					
		Number of samples	Number of samples ≤25 mg/kg	Number of samples ≤10 mg/kg	Mean Level (Std dev)	Minimum	Maximum
Australia	Brand 1	193	21 (10.8%)	9 (4.7%)	66.6 (27.7)	<10	145
Australia	Brand 2	10	10 (100%)	8 (80%)	10.1 (0.8)	<10	12
Australia	Brand 3	68	1 (1.4%)	-	45.8 (14.4)	24	86
Australia	Brand 4	5	5 (100%)	5 (100%)	<10	<10	<10
China		3	3 (100%)	3 (100%)	<10	<10	<10
Indonesia	Brand 1	5	-	-	77.0 (6.9)	71	85
Indonesia	Brand 2	2	2 (100%)	2 (100%)	<10	<10	<10
Indonesia	Brand 3	3	1 (33.3%)	-	38.3 (22.0)	13	53
Indonesia	Brand 4	1	1 (100%)	1 (100%)	<10	<10	<10
Korea		5	5 (100%)	5 (100%)	<10	<10	<10
Malaysia		5	5 (100%)	5 (100%)	<10	<10	<10
TOTAL		300	54 (18%)	38 (12.7%)	55.8 (29.6)	<10	145

HCN in Cassava Food Samples – Department of Health Western Australia

All samples were tested in NSW on February 20 2008 by the Division of Analytical Laboratories (Sydney West Area Health Service). The method of analysis used was the ANU Picrate kit B2, which determines the total cyanide using analytical balance and UV-VIS Spectrophotometer.

Department Of Health Western Australia
CASSAVA FOOD SAMPLES - for HCN testing
Purchased: 31 January 2008

Code	Product	Country of Origin	Cyanide mg/Kg
Classification: Chips/ Crackers			
A01	Cassava Chips	Indonesia	57
A02	Cassava Chips - Original	Malaysia	24
A03	Cassava Chips - Curry	Malaysia	44
A04	Indonesian Prawn crackers	Indonesia	<10
A05	Kusuka Keripik Singkong Keju Bakar	Indonesia	54
A06	Chilli Tapioca with Fish	N/A	34
A07	Crispy Tapioca	N/A	77
A08	Vege chips - Herbs & Garlic	Australia	53
A09	Vege chips - French Onion	Australia	40
A10	Vege Crackers	Australia	83
Classification: Snack			
B11	Pizza Flavoured Snack Miaow Brand	Malaysia	<10
B12	Coconut Cookies	Malaysia	<10
B13	Honey Flavoured Twist Snack	Korea	<10
Classification: Noodles/ Soup			
C14	Shrimp Egg Noodles (thin)	China	<10
C15	Hand-made Amoy Flour Vermicelli	China	<10
C16	Mi Goreng Satay Indomie Instant Noodle	Indonesia	<10
C17	French Onion Soup Mix	Australia	<10
Classification: Flour			
D18	Cassava Tepung Singkong	Indonesia	<10
D19	Tapioca Starch	Thailand	<10
D20	Best Tapioca Starch	Thailand	<10
D21	Tani Tapioca Flour	Indonesia	<10
D22	Tapioca Starch	Thailand	<10
Classification: Frozen product			
E23	Frozen Pealed Cassava	N/A	15
E24	Frozen Cassava Grated	N/A	<10
E25	Frozen Cassava Whole	N/A	10
Classification: Sago			
F26	Dried Shredded Tapioca	Vietnam	<10
F27	Tapioca Pearl	China	<10
F28	Tapioca Pearl	Thailand	<10
F29	Tapioca Pearl	Thailand	<10
F30	Seed Tapioca (sago)	Thailand	<10