

12 December 2001
06/02

INITIAL ASSESSMENT REPORT
(Preliminary Assessment s.13)

APPLICATION A427

**CAFFEINE IN WATER-BASED NON-ALCOHOLIC
BEVERAGES**

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

SUMMARY

- This report is based on available information provided by the applicant. The initial assessment is designed to assist in identifying the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include information from public submissions. Public submissions are therefore invited on this initial assessment report.
- An application has been received from the Australasian Soft Drink Association Ltd (ASDA) to amend the *Food Standards Code* to permit the addition of caffeine to soft drinks and to other non-alcoholic beverages where the addition of flavourings is permitted. Specifically, the applicant requests permission to add caffeine to the following categories of non-alcoholic beverages (as specified in Standard 1.3.1 Food Additives in Volume 2 of the *Food Standards Code*):
 - carbonated, mineralised and soda waters;
 - fruit drinks; and
 - water based flavoured drinks.
- Currently, the *Food Standards Code* only allows caffeine to be added as flavouring to kola type drinks, although under the New Zealand *Food Regulations (1984)*, caffeine is permitted in non-alcoholic beverages as an artificial flavouring substance (no maximum use level prescribed), and in artificial drinks at a maximum level of 200 mg/kg.
- In considering the proposed amendment to the *Food Standards Code* that is the subject of this Application, ANZFA will seek to fulfil the following objectives, as specified (in descending priority order) in section 10 of the *Australia New Zealand Food Authority Act 1991*:
 - the protection of public health and safety;
 - the provision of adequate information relating to food to enable consumers to make informed choices; and
 - the prevention of misleading or deceptive conduct.
- In addition to these objectives, ANZFA has also developed a set of inherently cautious principles to be used as a basis for regulatory decisions regarding caffeine. These principles were developed on the basis of current information and ANZFA's previous experience in considering this issue, and also have regard to the level of community concern about caffeine. This current application will be assessed according to these principles.
- In assessing the application, ANZFA will focus on considering:
 - (i) whether extending the permissions for caffeine, so that it may be added to a broader range of non-alcoholic beverages manufactured in Australia, raises any additional public health and safety concerns, particularly in relation to children;
 - (ii) whether the addition of caffeine as flavouring to a broader range of non-alcoholic beverages is technologically justified; and
 - (iii) whether the current labelling provisions are adequate to inform consumers and address community concerns.

1. PROBLEM

Currently in Australia, the use of caffeine as a flavouring substance is restricted to kola type drinks where the maximum use level prescribed is 145 mg/L. This contrasts to the situation in New Zealand where caffeine is permitted in a much broader range of soft drinks, namely in non-alcoholic beverages in general as an artificial flavouring substance, with no maximum use level prescribed (i.e., with good manufacturing practice (GMP)¹ use levels), and in artificial drinks at a maximum level of 200 mg/kg.

At present there is only one non-kola soft drink product on the New Zealand market that contains caffeine. This product, called Mountain Dew, contains caffeine at a level of 152 mg/L. This product is not currently available in Australia, although a non-caffeinated version may be purchased.

The application received from the Australasian Soft Drink Association (ASDA) seeks to broaden the permissions for caffeine in Australia and thus harmonise with those currently in place in New Zealand. The application requests an amendment to the *Food Standards Code* to permit the use of caffeine as a flavouring in all soft drinks at a maximum level of 145 mg/kg or 200 mg/kg (as appropriate), and in other non-alcoholic beverages where the addition of flavourings is permitted. Specifically, permission is being sought to add caffeine to the following categories of non-alcoholic beverages (as specified in Standard 1.3.1 Food Additives of Volume 2 of the *Food Standards Code*):

- carbonated, mineralised and soda waters;
- fruit drinks (part of the fruit and vegetable juice products category); and
- water based flavoured drinks.

2. OBJECTIVE OF THE APPLICATION

The objective, in addressing the issue of permitting the addition of caffeine to a broader range of non-alcoholic beverages, is to allow for new product development by the food industry without compromising public health and safety or the provision of adequate information to consumers to enable informed choice.

3. ISSUES RELEVANT TO THE APPLICATION

Previous consideration

ANZFA had previously considered the issue of adding caffeine to a broader range of soft drinks under Application A344. The applicant (Kensington Swan) withdrew the application in December 2000 before ANZFA could complete its assessment. A new application from ASDA was subsequently received by ANZFA in January 2001.

As part of considering Application A344, ANZFA undertook a significant amount of work in relation to identifying the potential adverse effects of caffeine, estimating the dietary exposure to caffeine, assessing the potential health risk for different sectors of the population, as well as investigating the technological justification for extending the use of caffeine to a broader range of soft drinks. Much of this work remains relevant to assessment of the current application therefore ANZFA will draw heavily upon the outcomes of this previous work, and will update where required.

¹ Under GMP, the amount of caffeine added should be the minimum amount necessary to produce the intended effect (i.e. flavouring).

Principles for regulating caffeine addition to foods

On the basis of current information and ANZFA's previous experience in considering this issue, and having regard to the level of community concern about caffeine, ANZFA has developed a set of inherently cautious principles to be used as a basis for regulatory decisions regarding caffeine. These principles are:

1. Where there is uncertainty regarding the potential for adverse health effects, particularly in children, a cautious approach should be taken regarding the broadening of any permission to add caffeine to food;
2. When caffeine is added to a food other than one in which it occurs naturally, its presence, regardless of the source, should be identified on the label and, if appropriate, the approximate quantity in the product stated;
3. Where caffeine is added to a food for its stimulant effect (i.e., at levels greater than necessary for flavouring), mandatory advisory statements that are additional to those applying to general foods would normally be required.

The current application will be assessed according to these principles.

Public health and safety

As indicated, ANZFA recently undertook a significant amount of work in relation to assessing the adverse effects that may be associated with caffeine consumption. This work includes an extensive risk assessment of caffeine which was undertaken as part of Application A344, as well as the convening of an Expert Working Group to broaden the scientific input into the risk assessment and to further address community concerns regarding the effects of caffeine, particularly in relation to behavioural effects in children. The task and terms of reference for the Expert Working Group were to examine the potential for acute toxicological and pharmacological effects at low doses of caffeine, the potential for addictive effects and identification of any other caffeine-related hazards particularly in children. The conclusions from ANZFA's draft risk assessment for caffeine (from Application A344) can be found at Attachment 1 to this report and the Executive Summary from the Expert Working Group's report can be found at Attachment 2 to this report (the full report can be downloaded from ANZFA's website ²).

The applicant has submitted that caffeine has been a normal constituent of the human diet for a considerable period of time due to its natural presence in a number of plant products such as tea, coffee and cocoa and its use as a flavouring substance in kola type drinks. The safety aspects of caffeine as a food constituent and additive has been demonstrated over this long period of dietary intake and from numerous research studies and reviews that have been undertaken in recent years.

The applicant has further submitted that the major source of caffeine in the diet is from the consumption of tea and coffee and that the contribution from kola type drinks represents only a small fraction of the total intake. The applicant states that, as kola type soft drinks currently dominate the market, the introduction of new products would not be expected to have any significant effect on current market shares, therefore they argue that the intake of caffeine from its use in any new beverage products would have very little impact on the overall dietary intake of caffeine.

² www.anzfa.gov.au/whatsinfood/caffeine

In assessing the public health and safety implications of this current application, ANZFA will undertake the following:

- extensive dietary modelling to estimate the potential dietary exposure to caffeine that may result from permitting caffeine in a broader range of non-alcoholic beverages, as compared to the dietary exposure from current sources of caffeine (kola type drinks, coffee, tea, chocolate, energy drinks etc); and
- a review of the risk assessment that was undertaken for Application A344, taking into account the latest dietary modelling, the report of the Expert Working Group, and any more recent studies that may be available, particularly in relation to children.

Technological issues

ANZFA had previously considered the technological justification for broadening the permissions for caffeine under Application A344. The conclusions of this assessment can be found at Attachment 3 to this report.

The applicant has submitted that caffeine is a unique flavouring or bittering compound and is an important constituent of the taste and flavour quality of tea and coffee as well as being an integral component of the flavouring systems for kola type drinks. The applicant further submits that its use in new beverage products would contribute to the development of unique and new flavour systems and that there are currently no other approved flavour ingredients that have the same bitter type characteristics and the same taste profile as caffeine, or that provide the same flavour modifying effects and impact on the flavour profile of a complex flavour system.

ANZFA will review the technological justification for adding caffeine to a broader range of non-alcoholic beverages, taking into account the previous assessment undertaken for Application A344.

Labelling

Currently, the *Food Standards Code* (Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations) requires kola drinks to carry an advisory statement to the effect that the product contains caffeine. Should caffeine be permitted in a broader range of non-alcoholic beverages, this provision would require amendment so that it applied to any other categories of non-alcoholic beverages permitted to contain caffeine.

As part of the assessment of this application, ANZFA will also examine the adequacy of the current labelling provisions to provide information to consumers and to address community concerns regarding caffeine.

Formulated caffeinated beverages (“energy drinks”)

Recently, the Ministerial Council approved a new standard (Standard 2.6.4) for the regulation of formulated caffeinated beverages (FCBs). FCBs are a special class of non-alcoholic water-based flavoured beverages to which caffeine is added as a stimulant at levels between 145 and 320 mg/L. In this case, the label on the product must indicate the caffeine content in milligrams, and carry a mandatory advisory statement to the effect that the product “contains caffeine”; and “this food is not recommended for children, pregnant or lactating women and individuals sensitive to caffeine”.

As the addition of caffeine to FCBs goes beyond a technological purpose (i.e. its added as a stimulant, rather than as a flavouring substance) these beverages are regulated separately to other non-alcoholic beverages.

The beverage products being proposed in this current application do not fall within the scope of FCBs.

Potential regulatory impact

The applicant states that approval of caffeine for use as a flavour ingredient in a broader range of non-alcoholic beverages, rather than just kola type drinks, would provide food manufacturers with the opportunity to develop new and innovative beverage products and that consumers would benefit by having a greater choice of products. The applicant further states that approval of the application will provide beverage manufacturers in Australia with the same regulations and product opportunities that currently exist for manufacturers in New Zealand and other countries and that this will ultimately benefit consumers.

The applicant submits that the development and marketing of new beverages may have some effect on the growth of the beverage sector and on individual product brand share, however they consider the overall effect in terms of product cost, profitability and pricing would be negligible. The applicant considers the main regulatory impact would be to harmonise with regulations currently in New Zealand and to more closely align with that in various countries in Europe, North America and Japan and that, as a consequence, new products developed in Australia may be suitable for overseas markets and would thus provide export opportunities. Similarly, some products presently on the market in these countries may be suitable for marketing in Australia.

Relevant provisions for caffeine addition to food

Volume 1 of the *Food Standards Code*³

Standard A6 – Flavourings and Flavour Enhancers, clause 5(1), caffeine must not be added to food except where permitted by Standards O1 and O4.

Standard O4 – Soft Drinks and Soft Drink Products, clause 2(3), permits caffeine in 'kola type soft drink' to a maximum level of 145 mg/kg.

Standard O1 – Cordials, Syrups and Toppings, clause (3)(d), permits caffeine in 'kola type syrup and cordial for sale other than retail' to a maximum level of 145 mg/kg when diluted according to directions.

Volume 2 of the *Food Standards Code*⁴

Standard 1.3.1 – Food Additives, Schedule 1, permits caffeine to be added to kola type drinks to a maximum level of 145 mg/L.

New Zealand Food Regulations 1984

Regulation 252A(1)(c) – Permitted Flavourings, permits caffeine as a flavouring in non-alcoholic beverages. No maximum level of use is prescribed. (*Regulations 214* - Fruit Flavoured Drink, and

³ Formerly referred to as the Australian *Food Standards Code*.

⁴ Also referred to as the joint Australia New Zealand *Food Standards Code* (the joint Code).

Regulation 216 - Drink Flavour or Drink Concentrate, permit the addition of 'permitted flavouring substances')

Regulation 211(3)(e) – Artificial Syrup or Artificial Cordial, permits caffeine as a flavouring substance in a proportion not exceeding 1000 ppm.

Regulation 215(2)(e) – Artificial Drinks, permits caffeine as a flavouring substance at a maximum level of 200 mg/kg.

Codex standards

There is currently no Codex standard for caffeine.

Other countries

European Union – there are no Council Directives that relate to the use of caffeine or flavourings in food and beverages, however a number of European countries have their own regulations for caffeine addition to non-alcoholic beverages. These include:

- France – permitted according to GMP
- Germany – authorised without limitation
- Netherlands – permitted at 150 mg/kg in brown coloured soft drinks
- Spain – permitted at 150 mg/kg in kola drinks
- United Kingdom – not regulated

Canada – permitted up to 200 mg/kg in kola type beverages. Health Canada is currently considering an extension of use to permit caffeine up to a maximum of 200 mg/kg in non-alcoholic carbonated citrus-based beverages.

Japan – natural caffeine can be used as a bittering agent in food or beverages without restriction on use level.

USA – caffeine is considered GRAS (generally recognised as safe) when used in kola type beverages in accordance with GMP at levels up to 200 mg/kg.

4. OPTIONS TO ADDRESS THE APPLICATION

At this stage of the assessment ANZFA considers that a regulatory measure (such as an amendment to Standard 1.3.1 Food Additives) would be a more appropriate mechanism for the control of caffeine addition to foods than other types of measures (e.g. a Code of Practice). The following regulatory options have therefore been identified:

Option 1. Maintain the *status quo* and not permit the use of caffeine in a broader range of non-alcoholic beverages.

Option 2. Permit the addition of caffeine to a broader range of non-alcoholic beverages and apply the current labelling provisions, that is, any such beverage to display the statement “CONTAINS CAFFEINE”.

Option 3. Permit the addition of caffeine to a broader range of non-alcoholic beverages with additional labelling provisions. These could take the form of labelling as for option 2 but also including additional information for consumers (e.g. the actual milligram amount of caffeine added, comparisons with caffeine content in coffee, etc).

Option 2 or 3 could be adopted in conjunction with an information program on caffeine, which could take the form of leaflets distributed at supermarkets etc comparing the caffeine content of soft drinks with tea, coffee, chocolate, energy drinks etc and advising on the health effects when consumed at various levels.

5. IMPACT ANALYSIS

Parties affected by the options outlined above include:

1. Those sectors of the food industry involved in the manufacture, marketing, import or export of non-alcoholic beverages.
2. Consumers who may benefit from a greater range of caffeine containing beverage products, or conversely, consumers who would be concerned about a greater availability of caffeine-containing beverages.
3. Government agencies responsible for enforcing the food regulations.

The following is an initial assessment by ANZFA of the costs and benefits of the three regulatory options identified so far. This is based on information supplied by the applicant and experience ANZFA has gained from consideration of a previous application (A344 Caffeine in Non-Alcoholic Beverages), which was withdrawn by the applicant before completion of Final Assessment (Inquiry – section 17). Your comments are also invited on the costs and benefits identified for the options below.

	Stakeholder	Benefits	Costs
Option 1	Consumers	Will alleviate the concerns of those consumers who have expressed unease about the potential for increased exposure to caffeine.	Some consumers may be denied access to a broader range of soft drinks containing the specific flavour profile that caffeine imparts. Although consumers may still be able to access these products via importation from New Zealand, the increased costs of importing these products may be passed on to consumers.
	Industry	No benefits currently identified.	May act as a trade barrier for Australian industry, who may be disadvantaged compared to New Zealand beverage manufacturers.
	Government	No benefits currently identified.	There may be a continued cost to enforcement agencies related to the need to administer two different sets of regulations.
Option 2	Consumers	Consumers will potentially have access to a broader range of caffeine-flavoured beverage products.	Potential for greater caffeine consumption by the community, in particular, children.
	Industry	The resultant harmonisation with New Zealand, and alignment with other countries, may lead to increased market and export opportunities for Australian beverage manufacturers.	If approved at the level of 145 mg/L it may disadvantage New Zealand beverage manufacturers who currently are permitted a maximum level of 200 mg/L.

	Government	No benefits currently identified	No costs currently identified.
Option 3	Consumers	Consumers will potentially have access to a broader range of caffeine-flavoured beverage products. Consumers will have access to more information about the caffeine content of non-alcoholic beverages.	Potential for greater caffeine consumption by the community, in particular, children.
	Industry	The resultant harmonisation with New Zealand, and alignment with other countries, may lead to increased market and export opportunities for Australian beverage manufacturers.	If approved at the level of 145 mg/L it may disadvantage New Zealand beverage manufacturers who currently are permitted a maximum level of 200 mg/L. May result in labelling changes to caffeine containing non-alcoholic beverages currently on the market.
	Government	No benefits currently identified.	No costs currently identified.

To further develop the analysis of the costs and benefits of the regulatory options proposed, ANZFA seeks comment on the following:

What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?

What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?

What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?

What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

6. CONSULTATION

The Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the application.

All stakeholders that make a submission in relation to the application will be included on a mailing list to receive further ANZFA documents in relation to the application. If readers of this Initial Assessment Report are aware of others who might have an interest in this application, they should bring this to their attention. Other interested parties as they come to the attention of ANZFA will also be added to the mailing list for public consultation.

At this stage ANZFA is seeking public comment to assist it in assessing this application. Comments that would be useful could cover:

- Scientific aspects of this application, in particular, information about any recent studies conducted on the safety of caffeine, particularly in relation to children;

- Parties that might be affected by having this application approved or rejected;
- Arguments in support or opposition to permitting the addition of caffeine to a broader range of non-alcoholic beverages;
- Potential costs and benefits to consumers, industry and government.

ANZFA has already consulted extensively on this issue for Application A344 and also established an external Consultative Group composed of people with expertise in the areas of public health/risk management from State/Territory/New Zealand Governments, industry, consumer organisations and the health sector. This group met on 30 August 2000 and provided feedback to ANZFA on a range of options for the regulation of caffeine in soft drinks. The options considered by this group form the basis for the regulatory options considered in this Initial Assessment report.

7. OTHER RELEVANT MATTERS

Workplan classification

ANZFA's initial consideration of this application for placement on the Workplan was Group 2, Category 4. Following Initial Assessment (Preliminary Assessment – section 13) it is recommended that this grouping is appropriate and that consequently it be confirmed (see ANZFA website for further information about the Workplan and the different groups and categories).

WTO Implications

As a member of the World Trade Organization (WTO) Australia must notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

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

Amending the *Food Standards Code* to allow caffeine to be added to a broader range of non-alcoholic beverages may significantly affect trade, i.e., increase market opportunities for Australian beverage manufacturers and increased market opportunities within Australia for overseas manufacturers. However, this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (Full Assessment – section 15) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

8. CONCLUSIONS

This application does relate to a matter that may be developed as a food regulatory measure, as provided for in section 13 of the *Australia New Zealand Food Authority Act 1991*. Costs and benefits arising from any food regulatory measure so developed will be further assessed at Draft Assessment (Full Assessment – section 15).

Accordingly the Authority has decided to accept the application and is seeking public comment before moving to undertake a more detailed Draft Assessment. Following completion of the Draft Assessment, the Authority may prepare a draft amendment to the *Food Standards Code* or reject the

application. If the Authority prepares a draft amendment, a further round of public consultation will be held before a Final Assessment (Inquiry – section 17) is made.

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

If the Council then adopts the draft variation to the *Food Standards Code*, Volume 2 of the *Food Standards Code* would be amended to permit the addition of caffeine to a broader range of non-alcoholic beverages. Depending on the outcome of the assessment, special labelling requirements may also be included.

9. IMPLEMENTATION AND REVIEW

This information will be provided once the Draft Assessment (Full Assessment – section 15) has been completed.

10. FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

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

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

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.

However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984*.

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

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

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

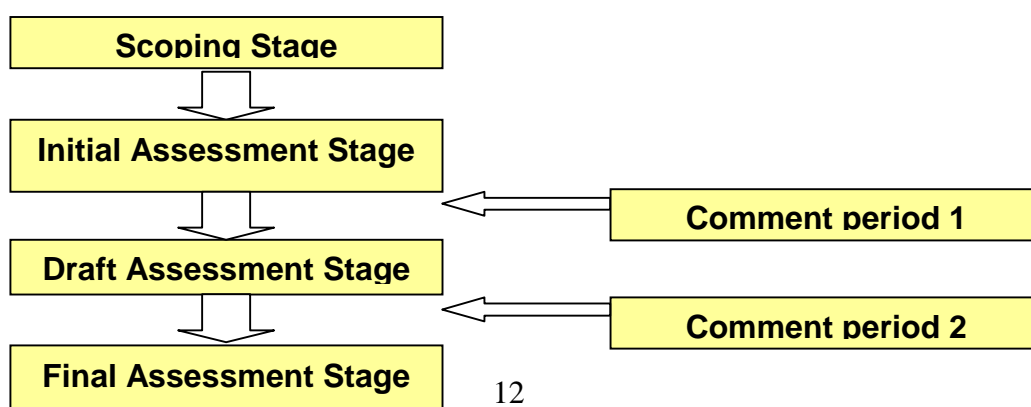
11. INVITATION FOR PUBLIC SUBMISSIONS

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

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

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

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



Content of Submissions

Written submissions containing technical or other relevant information which will assist ANZFA in undertaking an assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organizations. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant; studies, research findings, trials, surveys etc. Technical information presented should be in sufficient detail to allow independent scientific assessment.

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

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

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

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

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

Transparency

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

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

Deadlines

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

Delivery of Submissions

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

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

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

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

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

Further Information

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

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

CONCLUSIONS OF THE DRAFT RISK ASSESSMENT FOR APPLICATION A344

There are no toxicological concerns associated with caffeine at the current levels of dietary consumption and no significant concerns would be expected if there was permission to use caffeine in all soft drinks (at a maximum level of 145 mg/kg) for adults, children or teenagers.

The pharmacological and behavioural studies suggest that caffeine can have positive effects in adults when consumed in small amounts (<100 mg/day). However, as the dose is increased (>250 mg/day in adults) undesirable effects may occur. This suggests a clear dose-related increase in adverse effects following an increased intake of caffeine.

In children, the threshold dose for possible behavioural effects associated with caffeine remains unclear, although some evidence is available that behavioural effects can occur at doses of 3 mg/kg bw. In the unlikely event that maximum levels of caffeine were used in all soft drinks, high consuming children would exceed 3 mg/kg bw/day. From a public health and safety viewpoint, this is unlikely to be of significance given the varying interpretation of the behavioural changes observed at this dose level. Given the New Zealand experience where only one non-kola soft drink contains caffeine, extensive use of caffeine in non-kola drinks is not expected.

Overall, the available information indicates that the proposed extension of the use of caffeine in soft drinks would not raise additional public health and safety concerns.

EXECUTIVE SUMMARY FROM THE REPORT OF THE EXPERT WORKING GROUP ON THE SAFETY ASPECTS OF DIETARY CAFFEINE

The Australia New Zealand Food Authority (ANZFA) established an Expert Working Group (consisting of external experts) to examine the wider aspects of the safety of dietary sources of caffeine.

The task and terms of reference for the group were to examine the potential for acute toxicological/pharmacological effects at low doses of caffeine (Term of Reference A), the potential for addictive effects (Term of Reference B) and identification of any other caffeine-related hazards particularly in children (Term of Reference C).

The conclusions from the Expert Working Group are as follows:

Term of Reference A

Several variables need to be considered when interpreting studies with caffeine. These include the pharmacokinetics (eg age and sex differences, pregnancy, liver disease, diet, smoking and concomitant drug therapy), the source of caffeine (eg caffeinated beverages such as coffee may have physiological effects related to other constituents), the study design, the population studied and the sample size.

It would be valuable to have data, which would enable dose-response, and plasma concentration-response curves to be established for different effects (end-points). However, it appears that the relationship between dose and physiological response is continuous down to the lowest levels studied (although these effects are increasingly subtle as dosage is reduced). A 'no effect' level has not been identified. It is likely that caffeine causes subtle effects at very low dose levels, although their detection is ultimately dependent on the sensitivity of indicators and tests employed.

Although larger controlled studies are required to confirm the dose-related effects of low-dose caffeine, the following conclusions can be drawn from the available data:

- There are reports of enhanced performance and mood effects at doses of 37.5mg (0.54 mg/kg bw/day in 70 kg adults);
- There are reports of increased anxiety levels in children at doses of 95mg (3 mg/kg bw/day in children aged 5-12 years with a mean bodyweight of 32kg) and at 210mg in adults (3 mg/kg bw/day in 70 kg adults); and
- Caffeine has been reported to reduce the ability to sleep at doses of 100mg (1.4 mg/kg bw/day in 70 kg adults) at bedtime.

In conclusion, in addressing term of reference A, the threshold dose for possible behavioural effects in children remains unclear and it is recognised that further studies are needed to elucidate the potential effects of caffeine in children at doses that may be ingested from dietary sources.

Term of Reference B

It is concluded that caffeine at doses typically consumed in the diet may lead to withdrawal effects and some physical dependence in adults. The prevalence of such effects has been variable, as has

the interpretation and their intensity is minimal in most individuals. Further research will be required at doses typically consumed in the diet to examine whether similar withdrawal effects and physical dependency occurs in children.

Term of Reference C

It would appear that a precise link between caffeine contributing to cardiovascular disease has not been established. The published literature provides little evidence that caffeine in typical dosages consumed in the diet contributes to hypertensive disease.

If it is assumed that caffeine use in childhood lays the foundations for life-long use, there may be some grounds for concern that the consumption of caffeine-containing substances by children could be considered to be undesirable. At this stage it is not possible to conclude that patterns of caffeine consumption established early in life can contribute to negative long-term health outcomes in children and that effects observed in adults can be extrapolated to children.

CONSLUSIONS FROM THE FOOD TECHNOLOGY REPORT FOR APPLICATION A344

- The use of caffeine as a flavour in non-alcoholic beverages (where the addition of flavouring is permitted), at a maximum level of 145 mg/kg, is technologically justified. Most countries have set the maximum level of use at either 150 mg/kg or 200 mg/kg and the level currently permitted in Australia is one of the lowest in the world.
- Caffeine can depress or mask sweetness, enhance acidity and interact with other flavour components of foods and beverages. Consequently, caffeine forms part of the flavour profile that gives these beverages their unique flavour and taste sensation.
- Permission would provide manufacturers with the opportunity to develop new and innovative products and it is consistent with the objectives of the review of the Australian and New Zealand food standards.
- Industry must have regard to the concept of limited use according to good manufacturing practice (GMP). The level of caffeine used in liquid foods should be the minimum amount necessary to achieve the intended purpose, regardless of the fact that higher levels might pose no threat to public health.