

04/00 15 September 1999

INFORMATION SUMMARY APPLICATION A394 ENERGY DRINKS

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

PRELIMINARY ASSESSMENT REPORT

Applicant: Red Bull GmbH

Date received: 13 May 1999

PROBLEM/BACKGROUND:

Energy drinks are non-alcoholic beverages that are characterised by the addition of a number of energy enhancing ingredients. These include the addition of caffeine at levels of up to 80 mg per serve or unspecified levels of guarana, a herbal source of caffeine. The drinks usually have a number of added water soluble vitamins - usually a selection of B vitamins including niacin, pantothenic acid, vitamin B6 and vitamin B12, and other substances such as amino acids.

Energy drinks are considered to be foods rather than therapeutic goods. The product category is regulated under the New Zealand Dietary Supplement Regulations (1985), made under the New Zealand Food Act (1981), but is not regulated by the Australian *Food Standards Code*, nor the New Zealand *Food Regulations 1984*.

Until recently, it was unclear that products: 1) regulated under NZ Dietary Supplement Regulations; and 2) considered as foods rather than as therapeutic goods would be permitted to enter Australia under the terms of the Trans Tasman Mutual Recognition Arrangement (TTMRA). The recognition that such imports are not excluded by the Agreement has recently been confirmed by AQIS and the States. Australian industry however are disadvantaged by this arrangement as they are not permitted to manufacture for sale in Australia according to New Zealand food or dietary supplement regulations.

OBJECTIVE:

The application seeks development of appropriate regulatory provisions for energy drinks either generically or as part of a new standard for dietary supplements, or as part of the existing Standard R9 - Supplementary foods.

The application states that it is primarily aimed at permitting Red Bull energy drink to be marketed in Australia in compliance with a joint Australia New Zealand food standard. This would be initially achieved by a variation to the existing Australian *Food Standards Code* and later incorporation into the joint Food Standards Code.

POSSIBLE OPTIONS:**

**The suggestions in the sections below under possible options, affected parties and potential impacts are preliminary only and are based on available information or on information supplied by the applicant. These sections are designed to assist in the process of identifying the affected parties, any alternative options apart from the objective of the application, 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 comment will be invited on these matters.

Possible options are:

- 1 Accept the application and implement regulation by way of:
- developing a commodity standard for energy drinks either as part of:
 - Standard R9 Supplementary Foods, and/or
 - proposed new Standard 2.9.4 Formulated Meal Replacements and Formulated Supplementary Foods; or
 - new standard for Dietary Supplements regulated as foods.

or

• providing necessary caffeine, vitamin and mineral and additive permissions, and labelling requirements in proposed new generic standards.

Both of the options under (1) would be achieved initially by a variation to the existing *Food Standards Code* and later incorporation into the Joint Food Standards Code.

2 Reject the application according to the ANZFA Act 1991.

IDENTIFICATION OF AFFECTED PARTIES:**

- Consumers of non-alcoholic beverages including alternatives to alcoholic drinks
- Energy drink manufacturers and distributors

- Dietary supplement industry
- State and national food enforcement agencies

POTENTIAL REGULATORY IMPACTS:**

Regulation by Australian *Food Standards Code* and/or the Joint Food Standards Code would grant the energy drink manufacturers or importers in both Australia and New Zealand the same or similar regulatory provisions for this group of products. This would improve commercial opportunities and, for Australian manufacturers, permit the manufacture of product for the Australian market in direct competition with New Zealand or third country imports. The regulatory environment under TTMRA would not be completely equitable in Australia and New Zealand however, until the New Zealand Dietary Supplement Regulations were repealed.

Consumers would benefit from an expanded market and increased competition between locally produced and imported product.

Part of the assessment of the application will be to identify the issues and options around the current regulation of energy drinks in New Zealand under the Dietary Supplement Regulations and new options within the *Food Standards Code*. The Authority seeks comment, and will consulting in more detail, on this issue.

CONSIDERATION OF ISSUES UNDER SECTION 13:

This application:

- (a) relates to a matter that may be developed as a standard or as a variation to a standard; and
- (b) is not so similar to a previous application that it ought not be accepted.

Therefore the Authority would appear to have grounds to accept this application for further assessment.

OTHER RELEVANT MATTERS:

- *Codex* There are currently no Codex standards for soft drinks or non-alcoholic carbonated beverages;
- *EC* Red Bull energy drinks has been approved by 13 EU member countries;
- In the *United States* the ingredients in Red Bull are either recognised as GRAS (Generally Recognised As Safe) or the applicant has satisfied the self affirmation requirements of GRAS;
- The sale of Red Bull energy drink is currently permitted in *New Zealand* as a dietary supplement.
- Red Bull is also sold legally in a number of other countries including *Switzerland, South Africa* and *Singapore*.
- As a result of a separate application (A 344) for the permission of addition of caffeine to non alcoholic beverages ANZFA is expecting to convene a special

working group to examine the health aspects of caffeine in a range of foods. The findings of this working group would feed directly into this application for the regulation of energy drinks in the *Food Standards Code*.

CONCLUSIONS:

The above application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

If recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, a variation to the Code would develop provisions to regulate energy drinks.

REGULATION IMPACT ANALYSIS

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

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the regulation impact statement. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

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

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

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

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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

- <u>Food imported into New Zealand other than from Australia</u> must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.
- <u>Food imported into Australia other than from New Zealand</u> must comply solely with the Australian *Food Standards Code*.
- <u>Food imported into New Zealand from Australia</u> must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both.
- <u>Food imported into Australia from New Zealand</u> must comply with the Australian *Food Standards Code.* 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.*
- <u>Food manufactured in Australia and sold in Australia</u> must for most products comply solely with the Australian *Food Standards Code*.

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

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

INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from

interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

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

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

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager** - **Application A394** at one of the following addresses:

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Submissions should be received by the Authority by **27 October 1999**. General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above addresses.