

27 September 2000 06/01

INFORMATION SUMMARY

APPLICATION A419

SORBIC ACID IN EDIBLE COLLAGEN CASINGS

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 is provided below and 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

SUBJECT: APPLICATION A419

PURPOSE: TO ALLOW FOR THE USE OF SORBIC ACID AND

ITS SALTS FOR USE IN EDIBLE COLLAGEN

CASINGS AND CERTAIN SAUSAGES ENCLOSED IN

EDIBLE COLLAGEN CASINGS.

Applicant: Devro-Teepak Pty Ltd

Date received: 19 June 2000

BACKGROUND

An application has been received from Devro-Teepak Pty Ltd to allow for the use of sorbic acid and its salts for use in edible collagen casings and certain sausages enclosed in edible collagen casings.

OBJECTIVE

The objective of the application is to allow for the use of sorbic acid and its salts for use in edible collagen casings and certain sausages enclosed in edible collagen casings. The applicant requests an amendment to Standard C1 - Meat and Meat Products, to include a permission for the use of sorbic acid and its salts. Consequential amendments to the joint Australia New Zealand Food Standards Code, Standard 1.3.1 - Food Additives, to permit sorbic acid and its salts in edible collagen casing will need to be made.

REGULATORY IMPACT ASSESSMENT

The regulatory impact assessment below is preliminary only and based on available information or on information provided by the applicant. The 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. This preliminary assessment invites public comment on these areas.

Objective of the regulatory impact assessment

To assess the risks and benefits associated with adopting the proposed regulatory change to permit the use of sorbic acid and its salts in edible collagen casings.

Potential regulatory impacts

The potential impacts of the various regulatory options are as follows:

- *Option 1.* Not approve the use of sorbic acid and its salts as a preservative in edible collagen casings.
- *Option 2.* Approve the use of sorbic acid and its salts as a preservative in edible collagen casings.

Identification of affected parties

Parties affected by the options outlined above include:

- 1. Food industry wishing to use sorbic acid and its salts as a preservative in edible collagen casings
- 2. This permission would provide consumers with foods with improved clarity in collagen casings, potentially reducing the cost of premium quality sausage.
- 3. Government agencies enforcing the food regulations.

CONSIDERATION OF ISSUES UNDER SECTION 13

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, and is not so similar to a previous application that it ought not be accepted.

Costs and benefits arising for any food regulatory measure or other measures developed or varied as a result of this application, will be considered at full assessment.

OTHER RELEVANT MATTERS

Australian Food Standards Code

Standard C1- Meat, Game Meat and related products does not permit sorbic acid and its salts in sausages. Sausages may contain not more than 500 mg/kg of sulphur dioxide. Fermented manufactured meat which has not been cooked may contain not more than

1.5 g/kg, calculated as sorbic acid, or added sorbic acid, its sodium or potassium salt or a mixture thereof, with or without polyethylene (20) sorbitan monostearate (polysorbate 60), applied to the surface of the food.

New Zealand Food Regulations

248(7) permits a maximum of 400 parts per million of sulphur dioxide in sausages but does not permit sorbic acid and its salts.

Codex

The Codex Alimentarius Commission state that sorbic acid and its salts are readily metabolised by humans and have established a no effect level equivalent to 2500 mg/kg body weight. The estimate of acceptable daily intake for man is 0-25 mg/kg body weight. The applicant provided information that at the 33rd Session in March 2000, the Commission issued draft recommendations for sorbic acid and its salts for use in a range of foods. These include –

- a) Processed meat, poultry and game products in whole pieces or cuts at 2,000 mg/kg (as sorbic acid).
- b) Processed comminuted meat, poultry and game products at 2,000 mg/kg (as sorbic acid).

Approval in other Countries

The EU by Directive 98/72/EC of the European Parliament permit the addition of sorbic acid, potassium sorbate and calcium sorbate to collagen based casings with a water activity greater than 0.6.

The US Food and Drug Administration list sorbic acid, sodium sorbate, calcium sorbate and potassium sorbate as generally recognised as safe as a direct additive, when used in accordance with good manufacturing practice.

CONCLUSIONS

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, as provided for in section 13 of the *ANZFA Act 1991*. Costs and benefits arising from any food regulatory measure so developed will be assessed at Full Assessment.

Accordingly the Authority has decided to accept the application and will now make a full assessment of it.

If subsequently recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the Code would allow the addition of sorbic acid and its salts to edible collagen casings. Conditions of use such as a requirement to comply with specifications for identity and purity, and to comply with a maximum percentage addition to specific foods may be required.

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. A decision on whether to make a notification to the WTO will be made during the Authority's full assessment of this matter.

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* 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 be imported into Australia from New Zealand if it complies with the New Zealand *Food Regulations 1984* or *Dietary Supplements Regulations 1985*.

• <u>Food manufactured in Australia and sold in Australia</u> must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

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** – **Dean McCullum, Application A419** at one of the following addresses:

Australia New Zealand Food Authority

Australia New Zealand Food Authority

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The Authority should receive submissions by 8 November 2000.

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 address or by Email <info@anzfa.gov.au>.