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**23 February 2000**  
**10/00**

## **INFORMATION SUMMARY**

### **APPLICATION A400**

#### **PENTAERYTHRITOL ESTER OF WOOD ROSIN ON CITRUS FRUIT**

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**

**Applicant:** Castle Fruit Coatings

**Date received:** 30 September 1999

### **APPLICATION**

The applicants seek to amend the *Food Standards Code* to permit the use of the pentaerythritol ester of maleic anhydride modified wood rosin as a food additive on all types of citrus fruit.

### **BACKGROUND**

Citrus fruit is washed after harvest to remove residues of crop protection agents and other surface contaminants such as dirt. This process disturbs the natural protective wax coating resulting in increased loss of moisture. To counteract the drying effects of the cleaning process, citrus fruit is dipped or sprayed with a coating solution, with the required amounts varying according to the method of application.

It is expected that pentaerythritol ester of maleic anhydride modified wood rosin (also known as pentaerythritol ester of wood rosin) will be used by formulators as part of a coating emulsion containing varying quantities of other approved additives, such as shellac, carnauba wax, bees wax and water, for coating of citrus fruit by growers

and/or packers. The amount of the citrus coating solution will not exceed a rate of 250 mg/kg.

The applicant claims that the use of a citrus protective coating reduces loss of water (by up to 50% in hot weather) and improves the appearance of the fruit by reducing shrinkage and imparting a surface shine. In addition to improving the shelf life and appearance of the fruit, it is claimed that a coating containing this substance will retard the development of rind disorders and will provide less risk of chalking when blended with other permitted coating materials.

Pentaerythritol ester of maleic anhydride modified wood rosin is produced from a basic wood rosin obtained from pine trees. Reacting the rosin with pentaerythritol produces a chemical ester. The final product is produced by reacting maleic anhydride with the chemical ester.

The use of pentaerythritol ester of wood rosin is currently permitted in the United States and specified in the Code of Regulations 21CFR172.210. Currently no provisions exist in the Australian Food Standards Code or the New Zealand Food Regulations which permit this substance as a food additive in citrus coatings. In addition, there is no Codex Standard relating to pentaerythritol ester of maleic anhydride modified wood rosin.

The applicant claims that pentaerythritol ester of maleic anhydride wood rosin will present growers/packers with a more effective alternative to those currently permitted additives for the control and reduction of chalking of the surface of the fruit, when it is transferred from a cool room environment to an area of high humidity.

## **SPECIFIC OBJECTIVE**

The applicant specifically requests a variation to the current Australian *Food Standards Code* Standard N1 Fruits Generally, sub clause 7(ba) to permit the use of pentaerythritol ester of maleic anhydride-modified wood rosin as a food additive (humectant) for use in citrus fruit coatings.

The following amendment is also proposed:

Standard A11 – Specifications for Identity and Purity of Food Additives, Processing Aids, Vitamins, Minerals and Other Added Nutrients is varied by inserting in columns 1 and 2 respectively of the Schedule:  
Pentaerythritol ester of maleic anhydride modified wood rosin  
and by the inclusion of an Addendum with specifications.

Following implementation of the joint Australia New Zealand Food Standards Code which is anticipated later in 2000, a proposal may need to be raised to transport the amendments in this application to standards 1.3.1, 1.3.4 and 1.2.4 as appropriate.

## **DIETARY IMPLICATIONS**

Consumption of citrus fruit is assumed to be either fresh whole fruit or as an ingredient in marmalade jam with some minor consumption occurring as mixed fruit in baking products.

### **Citrus fruit**

The usual consumption of fresh citrus fruits involves the complete removal of the peel before the flesh is eaten and consequently no residues of wax coating would be expected to be consumed.

Approximately 10-20% of oranges to be used for juicing would be waxed, and approximately two thirds of the total being juiced would also be used in the production of peel extract. The applicant claims that production processes for peel extract would virtually remove all remaining traces of pentaerythritol ester of maleic anhydride-modified wood rosin and wood rosin waxes.

### **Marmalade**

Several large producers of jams and marmalades have verbally indicated that the fruit used for marmalade and other peel products is not waxed. This is a requirement to ensure that other agricultural chemicals such as fungicides do not carry over into these products, a particularly important issue to maintain exports to Japan. These large producers represent about 60% of the market. The source of fruit for the remaining marmalades in the market is not known.

Based on the maximum rate of coating at 250 mg/kg, the applicant has estimated that adults may ingest up to 6 mg daily of the pentaerythritol ester of wood rosin, while children may ingest up to 1 mg per day predominantly from the consumption of jams and marmalade. These dietary estimates will be reviewed against information on consumption patterns in relation to fruit spreads obtained from the National Nutrition Survey 1995.

### **Non-commercial rind**

Exposure to the wax coating would be expected from consumer use of citrus rinds prepared directly from whole fruit produce.

## **TOXICOLOGY**

The only known toxicological study is a 90 day sub-acute oral toxicity study of Pentalyn® 856 in rats completed in September 1960. Consideration will be given to the need for further data to enable the completion of a safety assessment.

## **POSSIBLE REGULATORY OPTIONS**

### **Option 1**

Maintain the *status quo* and do not permit the use of pentaerythritol ester of maleic anhydride modified wood rosin in citrus fruit coatings.

## **Option 2**

Amend the Food Standards Code as requested and permit the use of pentaerythritol ester of maleic anhydride modified wood rosin to Standard N1 sub clause 7(ba).

### **IDENTIFICATION OF AFFECTED PARTIES**

Parties affected by the options listed above include:

- consumers;
- growers, packers and retailers of citrus fruit; and
- State and Territory and New Zealand Health Departments.

### **POTENTIAL REGULATORY IMPACTS**

#### **Option 1**

Consumers may be negatively affected by the poorer appearance of citrus fruit in the marketplace, particularly fruit that has a chalky coating. Growers and packers may be negatively affected by being unable to use this substance with other additives to formulate a citrus coating with superior performance characteristics.

#### **Option 2**

Consumers may be positively affected by the availability of citrus fruit not affected by dehydration during storage and transport and with a fresh shiny appearance. Growers and packers may be positively affected by the availability of a citrus coating, which maintains the appearance and degree of hydration of the fruit without the disadvantages of using current formulations.

### **CONSIDERATION OF ISSUES UNDER SECTION 13**

- (a) This application relates to a matter that may require variations to several standards;
- (b) This application is not so similar to a previous application that it ought not be accepted;
- (c) The application contains adequate information for independent assessment.

### **OTHER RELEVANT MATTERS**

#### **Codex Regulations**

There is currently no known Codex Standard for pentaerythritol ester of maleic anhydride modified wood rosin.

#### **International Regulations**

Pentalyn® 856 Synthetic Resin (being pentaerythritol ester of maleic anhydride modified wood rosin) is in compliance with the requirements of the US Food and

Drug Administration (FDA) for the use as specified in the Code of Federal Regulations, section 172.210 'Coatings on fresh citrus fruit'.

## **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, an amendment to the Code, as suggested by the applicant, would permit the use of pentaerythritol ester of maleic anhydride-modified wood rosin as an approved ingredient in formulations for citrus coatings.

## **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. 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:

- **Food imported into New Zealand other than from Australia** 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*.
- **Food imported into Australia other than from New Zealand** must comply solely with the Australian *Food Standards Code*.
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** 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*.
- **Food manufactured in Australia and sold in Australia** 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 - Application A400** at one of the following addresses:

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The Authority should receive submissions by **5 April 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>.