30 May 2001
15/01

FULL ASSESSMENT REPORT AND REGULATION IMPACT ASSESSMENT

APPLICATION A419

SORBIC ACID IN EDIBLE COLLAGEN CASINGS

EXECUTIVE SUMMARY

- An application was received on 19 June 2000 from Devro-Teepak Pty Ltd to allow the use of sorbic acid and its salts in edible collagen casings. Sorbic acid and its salts are already permitted in a variety of other foods therefore this application is for an extension of use.

- Sorbic acid and its more water-soluble potassium, sodium and calcium salts are collectively known as sorbates and are used widely as anti-microbial agents in various foods. They are most effective against yeasts and moulds.

- The edible casings produced by the applicant are of the type preferred for coarse cut sausages such as butcher's style and bratwurst. A clear casing is preferred for these products because it maximises the visual appeal of their coarse texture. The only preservative currently permitted in Australia and New Zealand for use in edible casings is sulphur dioxide, which is unsuitable for use in the manufacturing process used by the applicant.

- The proposed use of sorbic acid as a preservative in the manufacture of edible collagen casings to a maximum level of 100 mg/kg in the final casing is technologically justified.

- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated sorbic acid in 1973 and allocated an Acceptable Daily Intake (ADI) for humans of 0 – 25 mg/kg. Sorbic acid and its salts exhibit low acute and chronic toxicity and are metabolised rapidly in the body.

- The proposed use of sorbic acid in edible collagen casings represents only a very small fraction of the total intake of sorbates and only a negligible proportion of the current ADI and does not raise any apparent public health and safety concerns.

- The Regulation Impact Statement concludes the benefits to consumers, industry and governments of permitting sorbic acid in edible collagen casings outweigh any costs.

BACKGROUND AND ISSUES

The Authority received an application from Devro-Teepak Pty Ltd on 19 June 2000 to allow the use of sorbic acid and its salts as a preservative in edible collagen casings.

Sorbic acid is a naturally occurring straight-chain unsaturated fatty acid. Sorbic acid and its more water-soluble salts, especially potassium sorbate, are collectively known as sorbates and are classed as food additives. They are used widely throughout the world as preservatives in a variety of foods.

Currently, there are no provisions in either Volume 1 or Volume 2 of the *Food Standards Code*, or the New Zealand *Food Regulations* that permit the use of sorbic acid in edible collagen casings, therefore this application requests an extension to the use of sorbic acid.

The edible collagen casings produced by the applicant are of the type preferred for coarse cut sausages such as butcher's style and bratwurst. These sausage products are generally of a high quality and are differentiated from other sausages by the presence of visible meat pieces and herbs. A clear casing is preferred for these products because it maximises the visual appeal of their coarse texture. To produce a clearer casing, the collagen dough must be processed over several days to achieve the required fine structure. During this time the dough is susceptible to mould growth and this results in a casing of poor quality.

Sulphur dioxide is permitted for use as a preservative in edible casings in Australia and New Zealand however the conditions required in clear casing production (low pH and vacuum) render sulphur dioxide unsuitable for use. The applicant considers sorbic acid to be the preservative of choice for their manufacturing process because the additive has wide acceptance as a preservative, is already used in edible casings in the United States and European Union and also has a relatively high ADI.

OBJECTIVE

The objective, in consideration of extending the use of sorbic acid to edible collagen casings, is to allow for innovation in product development, which is technologically justified, but does not compromise public health and safety.

RELEVANT PROVISIONS

Regulation 248 (7) of the New Zealand *Food Regulations* 1984 (NZFR) permits a maximum residue of 400 parts per million of sulphur dioxide in sausages but does not permit sorbic acid and its salts.

Standard C1 – Meat, Game Meat and Related Products of Volume 1 of the *Food Standards Code* permits edible casings to contain not more than 500 mg/kg sulphur dioxide but does not permit sorbic acid and its salts. Fermented uncooked processed manufactured meat and dried meat products are permitted to contain sorbic acid.

Standard 1.3.1 – Food Additives of Volume 2 of the *Food Standards Code* permits edible casings to contain sulphur dioxide and sodium and potassium sulphites up to 500 mg/kg and additives in Schedules 2, 3 and 4 in accordance with good manufacturing process (GMP) but does not currently permit sorbic acid and its salts.

Sorbic acid and its sodium, potassium and calcium salts have been allocated the International Numbering System (INS) numbers of 200, 201, 202 and 203, respectively. At the recent 33rd session of the Codex Committee on Food Additives and Contaminants, draft recommendations were issued for sorbic acid, potassium sorbate, sodium sorbate and calcium sorbate for use in a range of foods. Levels consistent with GMP are proposed when sorbates are used as additives in making edible sausage casings.

The European Union 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 United States Food and Drug Administration lists sorbic acid, sodium sorbate, calcium sorbate and potassium sorbate as generally recognised as safe (GRAS) as a direct additive, when used in accordance with GMP.

PROPOSED CHANGES

This application will, if successful, result in amendments to Standard 1.3.1 Food Additives of Volume 2 of the *Food Standards Code*.

PUBLIC CONSULTATION

Invitations for public comment were advertised in the Australian and New Zealand press on 27 September 2000, with a comment period of six weeks. Submissions were received from Frank Peddie of the Food Science and Technology Centre of the University of South Australia, the National Meat Association of Australia, Queensland Health and the Australian Food and Grocery Council. A detailed summary of the submissions appears at Attachment 6 to this report.

OPTIONS

Non-regulatory options, such as self-regulation and co-regulation through codes of practice or industry guidelines, are not considered appropriate with regard to an extension of use of a food additive. Food additives are specifically regulated under the *Food Standards Code* and any new entries for food additives, or extensions of use (as is the case with sorbic acid) are required to undergo an evaluation to ensure that there are no apparent public health and safety concerns. The standard is intended to reflect current use, and to prohibit inappropriate use, of food additives. Non-regulatory options will therefore not be considered in this assessment.

The regulatory options are:

1. Maintain the *status quo* and not permit the use of sorbic acid and its salts as a preservative in edible collagen casings.

2. Amend the *Food Standards Code* and permit 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. The food industry, specifically manufacturers of edible collagen casings and producers and retailers of premium sausage products.

2. Consumers of premium sausage products.

3. Government agencies enforcing the food regulations.

ASSESSMENT

Scientific and technical evaluation

Toxicology Report (Attachment 3 of the report)

The toxicology of sorbic acid is well characterised. Sorbic acid demonstrates low acute and chronic toxicity, and does not exhibit any carcinogenic activity or produce any adverse effects in studies of reproductive and developmental toxicity. The low toxicity of sorbic acid is explicable by the fact that it is metabolised rapidly in experimental animals to carbon dioxide and water, in an analogous manner to other fatty acids. Although the metabolism of sorbic acid has not been studied specifically in humans, it is expected to be metabolised in the same way. These results support the relatively high ADI of 25mg/kg set by JECFA in 1973.

The only concerns that have been raised in the literature regarding the toxicity of sorbic acid relate specifically to stored sodium sorbate solutions, which are found to exhibit weak genotoxic potential. This probably relates to the fact that aqueous sodium sorbate is sensitive to oxidation and stable for only a few weeks. This is not a cause of major concern because sodium sorbate is generally not used by the food industry and the applicant has confirmed that they will not be using sodium sorbate in the production of their casings.

Under certain conditions sorbic acid is known to react with nitrite to produce potentially mutagenic by-products. However, under the manufacturing conditions used for edible collagen casings, such a reaction is considered unlikely, and moreover, the casings are intended primarily to be used for raw, unprocessed meat sausages which are not permitted to contain nitrites.

Overall, the toxicity data on sorbic acid does not indicate there is any cause for concern regarding its extension of use to edible collagen casings.

Food Technology Report (Attachment 4 of the report)

Sulphur dioxide is the only permitted additive in edible collagen casings in the *Food Standard Code*, but cannot fulfil its antimicrobial role in applicant's process of collagen homogenisation because of the low pH environment and repeated vacuuming. Sorbic acid and its salts are highly effective in suppressing microbial growth as demonstrated in the trial data submitted by the applicant. The proposed inclusion of sorbates as permitted additives in the manufacture of edible collagen casings is therefore technologically justified as an alternative to sulphur dioxide. Residual sorbic acid levels are expected to be below 100 mg/kg in sausage casings and below 1 mg/kg in sausages.

The proposed inclusion of sorbates as permitted additives in edible collagen casings is consistent with the international classification of sorbates, as additives in the manufacture of edible sausage casings, by Codex Alimentarius, European Union and the United States. The permission for sorbates as additives rather than as processing aids in edible collagen casings is also consistent with the existing permissions for preservatives, i.e., sulphur dioxide in edible collagen casings and specific permissions for sorbates, in the joint Australia New Zealand *Food Standards Code*.

Dietary Exposure Assessment Report (Attachment 5 of the report)

A dietary exposure assessment was conducted using ANZFA's dietary modelling computer program, DIAMOND. The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with current permitted levels of sorbates as well as the proposed levels of use of sorbates in edible collagen casings.

The dietary modelling indicates that the consumption of sausages, made with edible collagen casing containing sorbates, would make a negligible contribution (less than 0.01% of total exposure) to the estimated total dietary exposure to sorbates for both the whole population and children for both Australia and New Zealand. This suggests the inclusion of sorbates in edible collagen casings, at the levels specified by the applicant, would have only a very small impact on current dietary exposure to sorbates.

Current dietary exposures to sorbates from all food groups for the whole population for both Australia and New Zealand are below the ADI even when it is assumed that foods contain sorbates at the maximum permitted level, and all foods in a group contain sorbates. Estimated dietary exposure for children indicates a potential for the ADI for sorbates to be exceeded but it is unlikely that this will occur in reality. The recent review into food additives (ANZFA Proposal P150) did not identify sorbates as a potential risk to public health and safety as a result of dietary modelling.

Overall, it is concluded there would be no additional risk to public health and safety if the extension of use were granted.

Issues raised by public submissions

1. Potential for toxic by-products from sorbic acid

Queensland Health expressed concerns about the potential formation of mutagenic agents when sorbic acid and its salts are interacted with nitrite. They also requested that the toxicology assessment examine the effects of temperature, concentration, pH and blocking agents in the above reaction.

Evaluation

This issue was addressed in the toxicology report (Attachment 3). The conditions in which sorbic acid is likely to react with nitrite to form potentially mutagenic by-products are high equimolar concentrations together with high temperature (60-90°C) over a prolonged storage period. It was the conclusion of the toxicological evaluation, using information from the food technology report that such reactions are unlikely to occur in either the manufacture of the edible collagen casings or in the production of the final sausage product.

Furthermore, the edible collagen casings are intended primarily for use in the production of high quality coarse cut sausages such as butcher's style and bratwurst, which are not permitted to contain nitrites.

2. Sorbic acid as a processing aid versus a food additive

The Australian Food and Grocery Council submits that sorbic acid should be considered as a processing aid in collagen casings analogous to bleaching agents, clarifying and filtration agents and other miscellaneous processing aids, rather than as a food additive. The submission states that although high levels of sorbic acid are used during the manufacture of the casings, residual levels in the casings are less than 100 mg/kg and that at these low levels sorbic acid is no longer effective as a preservative. They recommend that sorbic acid be permitted for use as a processing aid in edible collagen casings with a maximum permitted residue not exceeding 100 mg/kg.

Evaluation

The *Food Standards Code* defines a food additive as a substance that is intentionally added to a food to achieve one or more of a number of technological functions, e.g., preservative, flavouring, humectant. In contrast, a processing aid is defined as a substance used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing but does not perform a technological function in the final food.

According to these definitions sorbic acid could be classed as a processing aid in the manufacture of the edible collagen casings if it performs no technological function in the final food. However, sorbic acid is considered to perform a technological function in the final food (the casing), and as such should be regulated as a food additive. This is consistent with the international classification of sorbates. The use of sorbates as general additives and sulphur dioxide as a specific additive in edible collagen casings are prescribed in Standard 1.3.1 Food Additives of the *Food Standards Code*.

During the manufacture of the casings the conditions are optimum for the anti-microbial activity of sorbates. Once the casing has been produced it is then washed which reduces the sorbate levels to 100 mg/kg or less as well as increases the pH of the final product. The finished casing retains its susceptibility to mould growth and this is typically controlled through water activity, refrigeration and modified atmosphere packaging. The presence of even relatively low levels of sorbic acid would however contribute to the provision of additional hurdles to suppress microbial growth in the final casing, particularly when the casing is being handled (i.e., is removed from the hermetically sealed container and is exposed to a wet environment) during the sausage making process. Therefore sorbic acid may perform a technological function in the final food.

Another issue that is relevant to ANZFA's consideration of this matter is labelling. If sorbic acid in edible casings is regulated as a processing aid there will be no requirement to declare its presence in the ingredient label for edible casings, which could be sold as such whereas as a food additive its presence must be declared. ANZFA considers that if there is no mandatory requirement to declare the presence of sorbic acid in the edible casing consumer deception may result. This is because if a sausage manufacturer is not aware of the presence of a preservative in the casing they may mistakenly declare the final sausage product as "preservative-free".

Regulating sorbic acid as a food additive will ensure that end users of the casing are aware of the presence of a preservative in the product and this will assist them in determining whether a "preservative-free" label on the final sausage product is appropriate.

3. Reaction of sorbic acid with chlorinated water

Frank Peddie (Food Science and Technology Centre, University of South Australia) submitted that he has preliminary evidence that food grade sorbic acid or potassium sorbate reacts with chlorine at levels typically found in potable water and that chlorinated by-products may be produced. Although the toxicological implications of these by-products are unknown, he believes it is advisable to recommend that solutions of sorbic acid or potassium sorbate for food use should be prepared in chlorine-free water.

<u>Evaluation</u>

The details provided by the submitter are insufficient at this stage for ANZFA to be able to consider them in this assessment. The submitter was contacted by ANZFA and invited to submit full details once the study is completed. If it were subsequently confirmed that chlorinated by-products are produced after reaction of sorbic acid with chlorine it would still remain to be established that such by-products have the potential to be harmful at the levels found. This issue has relevance to all uses of sorbic acid, and as such is not specific to this application.

Regulation impact analysis

Option 1

Maintain the *status quo* and not permit the use of sorbic acid in edible collagen casings.

AFFECTED PARTY	BENEFITS	COSTS
Food Industry	No benefits could be identified.	Erosion of market share and restriction of competition – the applicant submits that they have lost business to gut casings on the basis of their inability to produce a clearer casing. Producers and retailers of coarse cut, butcher-style sausages will not have access to a high quality alternative to gut casings.

Consumers	No benefits could be identified.	Loss of better quality premium products
Government	No benefits could be identified.	No costs could be identified.

Option 2

Amend the *Food Standards Code* and permit the use of sorbic acid and its salts as a preservative in edible collagen casings.

AFFECTED PARTY	BENEFITS	COSTS
Food Industry	More cost-effective production – the use of sorbic acid is expected to reduce production costs (less waste) associated with the manufacture of edible casings. More marketable products – the use of sorbic acid enables the production of a better quality product (clearer casings). Greater competition – more cost-effective production combined with the production of a more marketable product will enable manufacturers of edible collagen casings to compete more effectively with manufacturers of alternative products (gut casings). The applicant submits that the current market for casings is $14,000,000 p.a. The applicant anticipates that their ability to produce a clearer casing (through the use of sorbic acid) might enable them to increase their market share by 1-2%.	No costs could be identified
Consumers	Use of sorbic acid will allow a wider range of casings to be produced thus offering the market superior alternatives. Greater competition may lower the cost of products.	Some individuals may object to an increase in the number of preservatives that may be used in sausage casings.
Government	A more competitive food industry may increase employment in the food sector – the applicant claims that permission to use sorbate will enable them to consolidate their position in the market and allow future opportunity for expansion.	No costs could be identified

Evaluation

Option 1, which maintains the *status quo*, appears to provide no significant benefit to government, industry and consumers. Option 1 denies the food industry access to sorbic acid as a preservative in sausage casings, the use of which may contribute to lower production costs (less waste) as well as the production of a higher quality product.

Option 2, which proposes to amend the *Food Standards Code* to extend the use of sorbic acid to edible collagen casings, appears to impose no significant costs on government, industry or consumers and may be of benefit to all sectors, but especially to manufacturers of edible collagen casings and producers and retailers of sausage products.

The assessment of the costs and benefits of Options 1 and 2 indicate there would be net benefit in extending the use of sorbic acid to edible casings.

ANZFA section 10 objectives

(a) the protection of public health and safety; and

The overall toxicity data on sorbic acid and its salts does not indicate there is any cause for concern regarding its extension of use to edible collagen casings. The proposed use of sorbic acid in edible collagen casings represents only a very small fraction of the total intake of sorbates and only a negligible proportion of the current ADI of 25mg/kg body weight established by JECFA in 1973.

(b) the provision of adequate information relating to food to enable consumers to make informed choices; and

Sorbic acid and its sodium, potassium or calcium salts are preservatives and are considered to function as food additives in the casing.

In general, the presence of additives in food must be declared in the ingredient list, however in this case sorbic acid is not an additive of the final food, but rather is an additive of one of the ingredients (the casing). In relation to the labelling of the sausages, the provisions of compound ingredient labelling apply (Clause 5 (e) of Standard A1 of Volume 1 and Clause 6 (2) of Standard 1.2.4 of Volume 2 of the *Food Standards Code*). Sausages made with the edible casings containing sorbic acid will not be required to be labelled as containing sorbic acid because the casing will comprise less than 5% of the final food. Edible casings that are sold at retail, however, will have to be labelled to indicate the presence of sorbic acid as a preservative.

(c) the prevention of misleading or deceptive conduct

Claims that a food is “preservative free” are subject to the Australian Trade Practices Act 1974 and the State and Territory Food Acts, and the Western Australian Health Act, and in New Zealand to the Fair Trading Act 1986 and the Food Act. The current advice from enforcement agencies is that a claim that a food is ‘free’ of an ingredient or constituent should only be used when there is no detectable quantity of the ingredient or constituent in the food. This applies also to compound ingredients.

Although sausages made with casings containing sorbic acid are not required to be labelled to indicate the presence of sorbic acid, there are still likely to be detectable residues of sorbic acid in the final sausage product. Hence, it would be regarded as misleading or deceptive conduct if sausages made with such casings were labelled as “preservative free”. This issue will be considered in the development of proposed guidelines for the labelling of meat and meat products.

CONCLUSIONS

It is concluded that:

- extending the use of sorbic acid to edible collagen casings at the level of 100 mg/kg is technologically justified and poses no significant risk to public health and safety;

- sausages made with casings using sorbic acid as a preservative should not be labelled as "preservative-free".

- there is a net benefit to all sectors, but especially to manufacturers of edible casings and producers and retailers of sausage products, from extending the use of sorbic acid to edible collagen casings;

- the proposed amendment should take effect upon gazettal.

ATTACHMENTS

1. Variations to the *Food Standards Code*
2. Explanatory Notes
3. Toxicology report
4. Food technology report
5. Dietary exposure assessment report
6. Summary of public comment

ATTACHMENT 1

VARIATION TO VOLUME 2 OF THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

APPLICATION A419

SORBIC ACID IN EDIBLE COLLAGEN CASINGS

To commence: On gazettal

Standard 1.3.1 *of Volume 2 of the Food Standards Code is varied by inserting into Item 8.4 in Schedule 1 - Edible casings** *and before the entry for Sulphur dioxide and sodium and potassium sulphites –*

200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	100 mg/kg

ATTACHMENT 2

EXPLANATORY NOTES

APPLICATION A419

SORBIC ACID IN EDIBLE COLLAGEN CASINGS

The Australia New Zealand Food Authority (ANZFA) had before it Application A419 (received on 19 June 1999) from Devro-Teepak Pty Ltd to amend the *Food Standards Code* to permit the use of sorbic acid as a preservative in the production of edible collagen casing.

ANZFA has completed a full assessment of the application and has prepared draft variations to Standard 1.3.1 - Food Additives of Volume 2 of the *Food Standards Code*.

Sorbic acid and its more water-soluble salts, especially potassium sorbate, are collectively known as sorbates. They are used widely throughout the world as preservatives in a variety of foods including dairy products, bakery items, fruit and vegetable products, edible fat emulsion products, certain meat and fish products, sugar and confectionery items.

The edible collagen casing being produced by the applicant is of the type preferred for coarse cut sausages such as butcher's style and bratwurst. The casing is clearer than other casings and its use maximises the visual appeal of the coarse texture of the butcher style sausages, as well as enabling them to be differentiated from other sausages. To produce a clearer casing, the collagen dough must be processed over several days to achieve the required fine structure. During this time it is susceptible to mould growth and this results in a casing of poor quality. Sulphur dioxide is permitted for use as a preservative in edible casings however the conditions required in clear casing production (low pH and vacuum) render sulphur dioxide unsuitable for use. The applicant has requested that sorbic acid be permitted as an alternative preservative for use in collagen casings.

The full assessment report concludes that the proposed inclusion of sorbates as permitted additives in the manufacture of edible collagen casings is technologically justified as an alternative to the currently permitted additive – sulphur dioxide – and also poses no significant risk to public health and safety. The residual sorbic acid levels are expected to be below 100 mg/kg in sausage casings and below 1 mg/kg in sausages.

VARIATION TO VOLUME 2 OF THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

APPLICATION A419 - SORBIC ACID IN EDIBLE COLLAGEN CASINGS

To commence: On gazettal

Standard 1.3.1 *of Volume 2 of the Food Standards Code is varied by inserting into Item 8.4 in Schedule 1 - Edible casings****** *and before the entry for Sulphur dioxide and sodium and potassium sulphites –*

200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	100 mg/kg

REGULATION IMPACT ANALYSIS

ANZFA 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.*

Consideration of the Regulatory Impact for this application concludes that amending the *Food Standards Code* to extend the use of sorbic acid to edible collagen casings, imposes no significant costs on government, industry or consumers and may be of benefit to all sectors, but especially to manufacturers of edible collagen casings and producers and retailers of sausage products. Therefore the benefits to consumers, industry and governments of permitting sorbic acid in edible collagen casings outweigh any costs.

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 are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter does not need to be notified to the WTO as a Sanitary or Phytosanitary notification or a Technical Barriers to Trade (TBT) notification because it represents a minor technical matter involving the extension of use of a food additive.

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 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code)* of the *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 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code),* of the *Food Standards Code,* but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code)* of the *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 *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 solely with Volume 1 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code),* of the *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*.

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has completed a full assessment of the application, prepared a draft variation to the *Food Standards Code* and will now conduct an inquiry to consider the draft variation and its regulatory impact.

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. ANZFA'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 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.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A419** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **11 July 2001.**

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>.

ATTACHMENT 3

TOXICOLOGY REPORT

APPLICATION A419

SORBIC ACID AND ITS SALTS IN EDIBLE COLLAGEN CASINGS

1. Background

Devro-Teepak Pty Ltd has submitted an application requesting approval to use sorbic acid and its salts as a preservative in the production of edible collagen casings. Sorbic acid and its salts are already permitted for use in Australia and New Zealand as a preservative in a variety of other foods.

2. Physical and chemical properties

Sorbic acid ($C_6H_8O_2$) is a straight-chain unsaturated fatty acid (2,4-hexadienoic acid) with a molecular weight of 112.13.

Sorbic acid forms colourless flakes or needles when crystallized. It has a weak but characteristic acrid odour and acid taste. Potassium sorbate can be manufactured in the form of a powder or granules. Sodium sorbate is a white fluffy powder and is commercially available as an aqueous solution that is sensitive to oxidation and stable for only a few weeks. Sodium sorbate is generally not used by the food industry (Würgler *et al* 1992). The calcium salt forms a white odourless and tasteless powder.

3. Current limits for oral intake

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed the toxicological data on sorbic acid and its salts in 1973 when an acceptable daily intake (ADI) of 0 – 25 mg/kg body weight was assigned (WHO 1974).

4. Kinetics and metabolism

Sorbic acid is metabolised in mammals in a manner similar to that of other fatty acids and thus can serve as an energy source. In the presence of adequate metabolisable carbohydrate, the major end products are CO_2 and H_2O.

In metabolism studies using [^{14}C] sorbic acid in the rat, sorbic acid is rapidly absorbed and metabolised. About 85% of the radio-labelled carbon occurred as CO_2 in expired air, with about 2% appearing in the urine as [^{14}C] urea and [^{14}C] carbonate with the remainder found in tissues as normal constituents. At doses of 60 to 1200 g/kg body weight the metabolic half-life was 40 – 110 minutes.

5. Review of toxicology studies

The following is a summary of the JECFA report on sorbic acid (WHO 1974) supplemented with more recent reports on the toxicity of sorbic acid, as appropriate.

Acute toxicity

Sorbic acid has a very low acute oral toxicity. The median lethal dose (LD_{50}) of the free acid or its sodium salt is > 8 g/kg body weight in the mouse and 7 – 10 g/kg body weight in the rat. The LD_{50} of the potassium salt is 4 – 7 g/kg body weight in the rat.

Short-term toxicity

A large number of short-term (repeat dose) toxicity tests have been done on sorbic acid in mice, rats, rabbits and dogs. In rats, short-terms tests of 90 – 120 days duration have been done at levels of sorbic acid up to 8 – 10% of the diet. The only effects reported were reduced weight gain and increased liver weight. There was no evidence of accompanying gross abnormalities or histological changes in any of the tissues. In dogs, potassium sorbate at a dietary level of 2% for 3 months was not associated with any adverse effects and a study with rabbits also indicated that daily doses of sorbic acid of 3300 mg/kg are tolerated without adverse effects.

Chronic toxicity and carcinogenicity

At least four long-term studies have been done in the rat at dietary levels of sorbic acid up to 10%. All of these studies show that sorbic acid has low chronic toxicity with treatment-related changes occurring at the highest dose level only. No increase in tumour incidence was observed in any of the studies. When administered at 5% of the diet, no adverse signs or histopathological effects were observed.

Reproductive and developmental toxicity

The effects of sorbic acid on reproduction and development have been studied in mice and rats. In both species, sorbic acid at dietary levels up to 10% did not produce any adverse effects on reproductive function or foetal development.

Genotoxicity

The genotoxicity status of sorbic acid, potassium sorbate and sodium sorbate has recently come under investigation following the observation by Hasegawa *et al* (1984) that these substances exhibit positive genotoxicity *in vitro*.

Hasegawa *et al* (1984) found sodium sorbate gave a weak positive result in *in vitro* assays for sister chromosome exchanges, gene mutation and chromosome aberrations in mammalian cells, while potassium sorbate gave a small increase in chromosome aberrations at the highest dose level tested. Munzner *et al* (1990), on the other hand, failed to find any genotoxicity activity in *in vitro* or *in vivo* assays, although they noticed there was a weak increase in clastogenic activity by increased chromosome aberrations and micronuclei when stored sodium sorbate was tested. There was no similar positive result with stored potassium sorbate. Further investigations by Schiffman and Schlatter (1992) revealed no genotoxic activity of fresh sodium or potassium sorbate in *in vitro* micronucleus or cell transformation assays, while stored sodium sorbate gave weak positive results in both assays. This result was further confirmed by Schlatter *et al* (1992) who concluded that stored sodium sorbate may have a weak genotoxic potential.

Both sorbic acid and its potassium salt gave negative results in long-term carcinogenicity assays, but no similar assay has been performed with sodium sorbate.

The results above indicate a weak genotoxic potential for stored sodium sorbate solutions but a lack of genotoxicity for sorbic acid and its potassium salt. The applicant has indicated that sodium sorbate is not required in making edible collagen casings, and sorbic acid and its calcium and potassium salts satisfy the technological needs (Devro-Teepak 2001).

Reaction with nitrite

Sorbic acid has been proposed as a partial replacement for nitrite in curing, since it inhibits *Clostridium botulinum* and also reduces formation of nitrosamines (Ivey 1977). This practice however may lead to other toxicological concerns since sorbic acid has been found to react with nitrite to yield mutagenic reaction products (Hayatsu *et al* 1975). Ethyl nitrolic acid and 1,4-dinitro-2-methyl pyrrole have been identified among these products (Namiki and Kada 1975, Kito et al 1978) and the former has been shown to be mutagenic in the rec-assay using *Bacillus subtilis*. However, the conditions under which these compounds were shown to be formed – 60-90°C and high equimolar concentrations over a prolonged storage period – do not represent those obtained in curing brines, and negative results have been obtained in mutagenicity assays on curing brines containing sorbic acid (Walker 1990).

Edible collagen casings are manufactured at temperatures of 15ºC and the applicant proposes using levels of sorbic acid of 1000 mg/kg. Also, once the casing is made it is washed which removes a substantial amount of the sorbic acid typically reducing its levels to well below 100 mg/kg casing and in the final sausage product the level of sorbic acid is not expected to rise above 1 mg/kg. Therefore the two conditions of high temperature and high equimolar concentrations are unlikely to occur.

Sausage casings may be used on frankfurters, saveloys, salamis, soy-based analogues and other forms of “sausage”, some of which could contain nitrates/nitrites. However, the applicant has submitted that the edible collagen casings are used exclusively for fresh meat sausages (butcher-style) and that there is no product advantage and thus no demand for such casings in making frankfurters and other coloured sausages. Furthermore, for sausages containing raw, unprocessed meat, nitrite is not a permitted additive. Thus it is highly unlikely there would be any potential for reaction between sorbic acid and nitrite.

6. Conclusion

The toxicology of sorbic acid is well characterised. Sorbic acid demonstrates low acute and chronic toxicity, and does not exhibit any carcinogenic activity or produce any adverse effects in studies of reproductive and developmental toxicity. The low toxicity of sorbic acid is explicable by the fact that it is metabolised rapidly in experimental animals to $CO_2 + H_2O$, in an analogous manner to other fatty acids. Although the metabolism of sorbic acid has not been studied specifically in humans, it would be expected to be metabolised in the same way. These results support the relatively high ADI of 25mg/kg set by JECFA in 1973.

The only concerns that have been raised in the literature regarding the toxicity of sorbic acid relate specifically to stored sodium sorbate solutions, which are found to exhibit weak genotoxic potential. This probably relates to the fact that aqueous sodium sorbate is sensitive to oxidation and stable for only a few weeks.

This is not a major cause of concern because sodium sorbate is generally not used by the food industry and also the applicant has confirmed that they do not use sodium sorbate.

Under certain conditions sorbic acid is known to react with nitrite to produce potentially mutagenic by-products. However, under the manufacturing conditions used for edible collagen casings, such a reaction is considered unlikely, and moreover, the casings are intended primarily to be used for fresh (raw, unprocessed) meat sausages which are not permitted to contain nitrites.

Overall, the toxicity data on sorbic acid does not indicate there is any cause for concern regarding its extension of use to edible collagen casings.

7. References

Devro-Teepak Pty. Ltd. 30 March 2001, Supplementary information submitted by Devro-Teepak Pty. Ltd.

Hasegawa, M.M., Nishi, Y., Ohkawa, Y. and Inui, N. (1984). Effects of sorbic acid and its salts on chromosome aberrations, sister chromatid exchanges and gene mutations in cultured Chinese hamster cells. *Food Chem. Toxicol*. **22:** 501-507.

Hayatsu, H., Chung, K., Kada, T. and Nakajima, T. (1975). Generation of mutagenic compounds by a reaction between sorbic acid and nitrite. *Mutation Res.* **30:** 417 – 419.

Münzner, R., Guigas, C. and Renner, H.W. (1990). Re-examination of potassium sorbate and sodium genotoxic potential. *Food Chem. Toxicol*. **28:** 397-401.

Schiffman, D. and Schlatter, J. (1992). Genotoxicity and cell transformation studies with sorbates in Syrian hamster embryo fibroblasts. *Food Chem. Toxicol*. **30:** 669-672.

Schlatter, J., Würgler, F.E., Kränzlin, R., Maier, P., Holliger, M.E. and Graf, U. (1992). The potential genotoxicity of sorbates: effects on cell cycle *in vitro* in V79 cells and somatic mutations in Drosophila. *Food Chem. Toxicol*. **30:** 843-851.

Walker, R. (1990). Toxicology of sorbic acid and sorbates. *Food Additives and Contaminants* **7:** 671 – 676.

WHO (1974). Sorbic acid and its calcium, potassium and sodium salts. In: *Toxicological evaluation of some food additives including anti-caking agents, antimicrobials, antioxidants, emulsifiers and thickening agents*. Food Additive Series No. 5, World Health Organisation, Geneva, pp 121 – 129.

Würgler, F.E., Schlatter, J. and Maier, P. (1992). The genotoxicity status of sorbic acid, potassium sorbate and sodium sorbate. *Mutation Res*. **283:** 107-111.

ATTACHMENT 4

FOOD TECHNOLOGY REPORT

SORBIC ACID AND ITS SALTS

1. Chemical nature of sorbic acid and its salts

Sorbic acid is a naturally occurring compound that was first isolated from the berries of the mountain ash tree in 1859. Sorbic acid and its more water-soluble salts, especially potassium sorbate, are collectively known as sorbates and are used widely throughout the world for their antimicrobial activity in various foods [1]. Sorbic acid ($C_6H_8O_2$ or $CH_3CH{=}CHCH{=}CHCOOH$) is a straight-chain, trans-trans unsaturated fatty acid (2,4-hexadienoic acid) with a molecular weight of 112.13. The carboxyl group of the sorbic acid is highly reactive and can form various salts and esters. The conjugated double bonds of sorbic acid are also reactive and can be influential in its antimicrobial activity. Commercially available salts include calcium, sodium, and potassium sorbates [1, 2].

Sorbic acid forms colourless flakes or needles when crystallized; it is available as a white free-flowing powder or as granules. It has a weak but characteristic acrid odour and acid taste. Potassium sorbate can be manufactured in the form of a powder or granules. Sodium sorbate is a white fluffy powder and is commercially available as an aqueous solution that is sensitive to oxidation and stable for only a few weeks. The calcium salt forms a white odourless and tasteless powder [2].

The solubility of sorbic acid in water at 20^{o}C is only 0.15 g/100 ml. Solubility increases with temperature and/or pH of the solution. The salts of sorbic acid may find more frequent applications in food because of their greater solubility in water. Calcium sorbate has a water solubility of 1.2 g/100 ml and is insoluble in fats. The sodium salt has a water solubility of 32 g/100 ml. Potassium sorbate constitutes the most soluble form (58.2 g/100 ml of water at 20^{o}C), and its stability and ease of manufacture make potassium sorbate the most widely used form in food systems [2].

2. Antimicrobial activity of sorbates

The pK_a of sorbic acid is 4.75, and the antimicrobial activity of sorbic acid is greatest when the compound is in the undissociated state. Antimicrobial activity of sorbic acid is greatest as the pH decreases and is essentially non-existent at pH > 6.0 [1.] Other studies suggest sorbic acid is an effective antimicrobial agent at pH values as high as 6.5 to 7.0 [2].

The primary inhibitory action of sorbates is against yeasts and moulds. Food-related yeasts, inhibited by sorbates include species of *Brettanomyces, Byssochlamys, Candida, Cryptococcus, Debaryomyces, Endomycopsis, Hansenula, Oospora, Pichia, Rhodotorula, Saccharomyces, Sporobolomyces, Torulaspora*, and *Zygosaccharomyces*. Food-related mould species inhibited by sorbates belong to the genera *Alternaria, Ascochyto, Aspergillus, Botrytis, Cephalosporium, Fusarium, Geotrichum, Gliocladium, Helminthosporium, Humicola, Mucor, Penicillium, Phoma, Pullularia, Sporotrichum*, and *Trichoderma*. Certain species of yeast are more resistant, and some acquire a resistance to sorbates. Certain moulds are also resistant to sorbates, which results in occasional spoilage of foods [1]. Sorbates are not effective agents against bacteria, especially lactic acid bacteria [3]. A number of studies however, reported sorbate inhibition on the growth of the following bacteria:

Salmonella, *Clostridium botulinum*, and *Staphylococcus aureus* in cooked and uncooked sausage; *S. aureus* in bacon; *Vibrio parahemolyticus* in crab meat and flounder homogenates; *Salmonella*, *Staphylococcus aureus* and *E. coli* in poultry; and *Yersinia enterocolitica* in pork[1].

The inhibitory effect of sorbates on microorganisms may be lethal as well as static. The mechanism by which sorbic acid inhibits microbial growth may be due to its effect on enzymes such as dehydrogenases involved in fatty acid oxidation; and sulfhydryl enzymes including fumarase, aspartase, succinic dehydrogenase and yeast alcohol dehydrogenase. Other studies found that sorbic acid interferes with the microbial cytoplasmic transport mechanism [1, 2].

The antimicrobial effectiveness of sorbates depends on factors such as microbial species, pH, water activity, presence of other additives, contamination level, processing conditions, packaging, storage temperature, storage length, sanitation and substrate composition. There are various practices for sorbates incorporation into food products including dipping, spraying, dusting, direct addition, and incorporation into food wrapping [1].

3. Applications of sorbates in food manufacturing

Sorbic acid and its salts are some of the most widely used food preservatives in the world. The most commonly used forms include sorbic acid and its potassium salt. The compounds find application in human foods of all types, animal feeds, pharmaceuticals, cosmetic products, packaging materials, and technical preparations that come in contact with foods or the human body. Sorbic acid is a metabolisable fatty acid [2].

Available data, primarily sourced from literature in USA indicate that major groups of foods that may be preserved with sorbates include dairy products, bakery items, fruit and vegetable products, edible fat emulsion products, certain meat and fish products and confectionery items. Amounts of sorbates used in foods are in the range of 0.02 - 0.3% (200 – 3,000 mg/kg). These concentrations have no major impact on food quality, but higher levels may cause taste changes [2]. Potassium sorbate at a level of 0.1% by weight (1,000 mg/kg) is used as a preservative in margarine. Potassium sorbate may be used to protect dry sausages from mould spoilage by dipping the casing in a 2.5% (25,000 mg/litre) solution either before or after stuffing in USA. A 10% aqueous spray (100,000 mg/litre) or 5% dip solution (50,000mg/kg) is also used to extend the shelf life of salted and smoked fish [1].

In Australia and New Zealand, sorbates are used in a wide range of foods with permissive levels varying from 375 mg/kg to 3,000 mg/kg (Standard 1.3.1. of Volume 2 of the *Food Standards Code*).

As is the case with all food preservatives, sorbates are not a substitute for good sanitation or agents to be used to improve the quality of partially spoiled or degraded foods. They are considered adjuncts to good sanitation and hygiene.

4. Regulatory status of sorbates

Data in Table 1 illustrate the maximum level of sorbates permitted in various foods in Australia and New Zealand.

Table 1 Sorbates permitted as additives in various foods in Australia and New Zealand

Food Category	Food items	Max. level
Dairy products	Cheese, Cheese products	3,000 mg/kg
Edible oils and oil emulsions	Oil emulsions	2,000 mg/kg
Ice cream and edible ices	Ice confection sold in liquid form	400 mg/kg
Fruits and vegetables	Peeled and/or cut fruit and vegetables Mushrooms in brine or water and not commercially sterile Chutneys, low joule jam and low joule spread Candied fruits and vegetables Fruit, vegetable preparations including pulp Lactic acid fermented fruits and vegetables Imitation fruit	375 mg/kg 500 mg/kg 1,000 mg/kg 500 mg/kg 1,000 mg/kg 500 mg/kg 500 mg/kg
Confectionery	Fruit filling for confectionery containing not less than 200 g/kg of fruit Sugar confectionery Icings and frostings	500 mg/kg 1,000 mg/kg 1,500 mg/kg
Cereals and cereal products	Flour products (including noodles and pasta) Breads and bakery products	1,000 mg/kg 1,200 mg/kg
Meat and meat products	Dried meat Fermented, uncooked processed comminuted meat products	1,500 mg/kg 1,500 mg/kg
Fish and fish products	Semi processed fish and fish products	2,500 mg/kg
Sugars, honey and related products	Tabletop sweeteners	GMP
Foods intended for particular dietary uses	Liquid formulated supplementary sports foods	400 mg/kg
Non-alcohol and alcohol beverages	Fruit, vegetable juices and fruit and vegetable juice products Coconut milk, coconut cream and coconut syrup Water based flavoured drinks Fruit wine, vegetable wine and mead (including cider and Perry) Mixed alcoholic drinks not elsewhere classified	400 mg/kg 1,000 mg/kg 400 mg/kg 400 mg/kg 400 mg/kg
Mixed foods	Sauces and toppings	1,000 mg/kg

Source: *Australia New Zealand Food Standards Code*, December 2000

Sorbic acid and its salts are permitted additives according to Australia New Zealand *Food Standards Code* (Schedule 1, Standard 1.3.1, Volume 2) for dried meats and fermented, uncooked processed comminuted meat products. However, in making edible sausage casings, only sulphur dioxide and its potassium and sodium salts (not exceeding 500 mg/kg) are currently permitted preservatives (Schedule 1, Standard 1.3.1 Volume 2).

In the United States, sorbic acid and its salts as food additives are considered GRAS (generally recognised as safe). These are listed in the Food and Drug Administration’s revised Code of Federal Regulations: 21CFR182.3089 for sorbic acid, 21CFR182.3225 for calcium sorbate, 21CFR182.3640 for potassium sorbate, and 21CFR182.3795 for sodium sorbate. Sorbates may be used in more than 80 US food products having federal standards of identity, and their use may be requested in any food product that allows GRAS food additives[1,2].

Sorbic acid and its salts are permitted additives for incorporation into collagen-based casings under the European Parliament and Council Directive 98/72/EC (15 October 1998). The maximum level is defined as *quantum satis*. In other words, the amount of additive should be no more than the level required to perform its antimicrobial role.

Sorbic acid and its salts are the permitted additives for making edible sausage casings according to the most recent draft of Codex General Standards for Food Additives (33rd session of Codex Committee on Food additives and Contaminants, 12-16 March 2001). Levels consistent with Good Manufacturing Practice (GMP) are proposed when sorbates are used as additives in making edible sausage casings.

5. Use of sorbates in the manufacture of edible collagen casings

Collagen is a fibrous protein, and comprises about 90-95% (dry basis) of the corium of animal skin and hides. Collagen can be dissolved and isolated from its natural sources by mild extraction with dilute acid, dilute alkali, and neutral salt solution. The film-forming ability of collagen has been traditionally utilised in the meat industry for production of edible sausage casings [4]. Edible casings from collagen were developed as a substitute for gut casings. The latter, although still in use, cannot cover all the demands of the meat processing industry. Two methods have been developed for the industrial production of collagen casings. One is known as "dry process", which was developed in Germany, and the other known as "wet process", which was developed in North America [4]. The following generic procedure for "wet process" is relevant to this application.

1. Acid- or alkaline-dehairing of hides
2. Decalcification of hide coriums and grinding into small pieces
3. Mixing of ground collagenous material with acid to produce a swollen slurry (4-5% solids)
4. Slurry homogenisation (**involving air pressurisation and vacuum cycles**)
5. Extrusion into tubular casings (8-10% solids)
6. Washing casings free of salts
7. Treatment with plasticising and cross-linking agents
8. Drying.

A potential function of edible coatings, in meats and other products, is as a carrier of antimicrobial compounds. Dipping meats or other foods in solutions of antimicrobial compounds is of limited benefit, since the preservative diffuses into the bulk of the product, lowering the concentration at the food surface. Incorporation of sorbic acid into an edible coating slows the migration of preservative into the products, increasing the duration of effective surface concentration. The permeability of the sorbic acid in the coatings is dependent on coating water activity and its pH [4].

The primary objective of the application submitted by Devro-Teepak Pty. Limited is to incorporate sorbates as antifungal agents to prevent the microbial damage that occurs during the process of collagen slurry homogenisation. According to the applicant, microbial counts can typically increase from 10 to 10,000 cfu (colony forming units) per gram of collagen in the absence of a growth inhibitor.

The applicant claims that addition of sorbic acid and/or its salts (at 1,000 mg/kg, calculated as sorbic acid) to the collagen slurry suppresses the microbial growth (the maximum count of yeast/mould after 3 days of homogenisation was < 50 cfu per gram of collagen in the presence of sorbates [5]), and results in superior quality casings. The sorbates are substantially removed during the post extrusion washing. The level of sorbates in the final casings varies between 10 and 100 mg/kg which the applicant claims would result in a final sorbate concentration in sausages between 0.055 mg and 1 mg per kg. Under the operation conditions specified by the applicant of pH 2.0 and 15^{o}C, sorbic acid or potassium sorbate would be effective as an antimicrobial additive.

An alternative antimicrobial additive for manufacturing edible collagen casings is sulphur dioxide. Sulphur dioxide and its sodium and potassium salts are the only currently permitted preservatives for use in Australia and New Zealand for making edible collagen casings (maximum level: 500 mg/kg). The pK_a values for sulphur dioxide are 1.76 and 7.20. Under the process condition of pH 2.0, a substantial proportion of sulphur dioxide is in the form of gas SO_2 [2]. Repeated vacuuming at this stage effectively removes much of this additive, thus rendering the unsuitability of sulphur dioxide as an antimicrobial agent in Devro-Teepak's method for processing collagen. In addition, excessive air exchange due to air pressurisation and vacuuming would reduce the amount of effective sulphur dioxide through oxidation, thus leading to a reduced antimicrobial efficiency. Under the current processing conditions used by the applicant, sulphur dioxide is not an effective agent to control the microbial activity during the process of collagen slurry homogenisation.

Sorbic acid and its salts in making edible collagen casings, if permitted, will be treated as food additives but not processing aids. This is determined by the preservative nature of sorbates, and is consistent with the international classifications of sorbates, as well as the convention adopted by ANZFA Food Standards Code in the classifying food additives and processing aids.

6. Hurdle Technology

According to the principles of multi-target preservation and the hurdle synergies in food preservation [6], it is more effective to use different preservatives in small amounts in a food than only one preservative in larger amounts. While sorbic acid and its salts perform a better antimicrobial role under the processing conditions employed by Devro-Teepak, the combination of two antimicrobial agents at different stages or under different process conditions of casing manufacturing is seen as a provision of additional hurdles in the production of quality edible casings. Replacement of sulphur dioxide with sorbates in the Devro-Teepak's collagen homogenisation process would effectively reduce the amount of sulphur dioxide used in making the casings, which will contribute to the overall reduction of additives in casing manufacturing.

7. Conclusions

Sulphur dioxide is the only permitted additive in edible collagen casings in the *Food Standard Code*, but cannot fulfil its antimicrobial role in applicant's process of collagen homogenisation because of the low pH environment and repeated vacuuming. Sorbic acid and its salts are highly effective in suppressing microbial growth as demonstrated in the trial data submitted by the applicant.

The proposed inclusion of sorbates as permitted additives in the manufacture of edible collagen casings is therefore technologically justified as an alternative to sulphur dioxide. Residual sorbic acid levels are expected to be below 100 mg/kg in sausage casings and below 1 mg/kg in sausages.

The proposed inclusion of sorbates as permitted additives in edible collagen casings is consistent with the international classification of sorbates, as additives in the manufacture of edible sausage casings, by Codex Alimentarius, European Union and the United States. The permission for sorbates as additives rather than as processing aids in edible collagen casings is also consistent with the existing permissions for preservatives, i.e., sulphur dioxide in edible collagen casings and specific permissions for sorbates, in the joint Australia New Zealand *Food Standards Code*.

8. References

1. Davidson, P.M., and Juneja, V.K. 1990. Antimicrobial agents. In *Food Additives*, edited by A. L. Branen, P. M. Davidson and S. Salminen, Marcel Dekker. Inc., New York, p. 83-137

2. Sofos, J. N., and Busta, F. F., 1993. Sorbic acid and sorbates. In: *Antimicrobials in foods*, 2nd edition, edited by P. M. Davidson, and A. L. Branen, Marcel Dekker, Inc., New York, p. 49-94

3. Smith, J. 1991. Preservatives. In *Food Additive User's Handbook*, edited by J. Smith, Blackie Academic & Professional, Melbourne, p. 114-119

4. Ginnadios, A., McHugh, T.H., Weller, C.L. and Krochta, J.M. 1994. Edible coatings and films based on proteins. In *Edible coatings and films to improve food quality*, edited by J.M. Krochta, E.A. Baldwin and M. Nisperos-Carriedo, Technomic Publishing Co. Inc., Lancaster, p. 201-277

5. Experimental data of sorbate trials in making edible collagen casings, 30 March 2001, Supplementary information submitted by Devro-Teepak Pty. Ltd.

6. Leistner, L. 1995. Principles and application of hurdle technology. In *New methods of food preservation*, edited by G.W. Gould, Blackie Academic & Professional, Melbourne, p. 1-21

ATTACHMENT 5

DIETARY EXPOSURE ASSESSMENT REPORT

SORBIC ACID AND ITS SALTS

An application was received by ANZFA requesting an extension of the use of sorbic acid and its salts (herein referred to as sorbates) for use in edible collagen casings and certain sausages enclosed in edible collagen casings.

A dietary exposure assessment was deemed necessary in order to determine if the requested extension of use of sorbates from the application was of public health and safety concern.

Background

Sorbates are currently permitted in a variety of foods and beverages in the joint Australia New Zealand Food Standards Code (see Table 1). The application states that residual levels of sorbates in casings after processing would be between 10 and 100 mg/kg. This level in casings corresponds to residual levels of sorbates in sausages of between 0.055 and 1 mg/kg (depending on the diameter of the sausage).

Sulphur dioxide is currently permitted as a preservative in Australia and New Zealand in edible collagen casings, but is considered unsuitable for the conditions required in production of the specified type of casing. Sorbates would be added as a preservative to edible collagen casings to prevent the growth of microorganisms during the production process as it is considered to better serve this purpose than sulphur dioxide.

The recent review into food additives (ANZFA proposal P150) did not identify sorbates as a potential risk to public health and safety, in the risk assessment process that included dietary modelling.

Dietary Exposure Assessment provided by the applicant

Devro-Teepak provided information on dietary intake of sorbates based on the estimated consumption of 200 grams of sausages (4 large sausages) with a residual level of sorbates between 0.055 and 1 mg/kg of sausage. The estimated intake of sorbates from consuming 200 grams of sausages ranged from 0.011 to 0.2 mg per day.

The maximum estimated intake was compared to the ADI. The comparison was made for both children and adults. A child weighing 25 kg was estimated to have a maximum intake of sorbates of 0.008 mg/kg of body weight (0.032% of ADI). An adult weighing 70 kg was estimated to have a maximum intake of sorbates of 0.003 mg/kg of body weight (0.012% of ADI). These percent ADI figures assume children eat the same amount of sausage as adults.

The applicant noted that consumption data from the National Dietary Surveys was not available for use in calculations, therefore, the intake of sorbates from other sources in the diet was not considered. ANZFA conducted a detailed dietary exposure assessment to estimate the total dietary exposure to sorbates and what impact there would be if their use were extended to include addition to edible collagen casings.

Dietary Modelling

The dietary exposure assessment was conducted using ANZFA's dietary modelling computer program, DIAMOND. The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with current permitted levels and proposed levels of use of sorbates in edible collagen casings.

Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

Dietary exposure assessments were conducted for both Australian and New Zealand populations. Modelling was conducted for the whole population, as well as for children aged from 2 to 12 years of age (Australia only). An exposure assessment on children was conducted because children generally have higher levels of exposure due to their smaller body weight and are high consumers of sausages.

Sorbates Concentration levels

Two models were completed for the dietary exposure assessment. The baseline model used the current maximum permitted levels (MPLs) in the joint Australia New Zealand Food Standards Code, and manufacturers' usage levels of sorbates where available, in an attempt to gain a more accurate reflection of actual use levels. Information on manufacturers' usage levels was limited to only a small number of food categories. Where no manufacturers' usage levels were available, the MPL for that food category was used. The second model assigned a concentration of sorbates of 1 mg/kg to sausages. The concentration of 1 mg/kg of sorbates in sausages was provided by the applicant and used as a worst-case concentration. The foods and sorbates concentration levels used in the dietary exposure assessments are shown below in Table 1.

Table 1. Foods and sorbates concentration levels used in dietary modelling

Food code	Food description	Baseline model (mg/kg)	Extension of use model (mg/kg)
0.1	Preparations of Food Additives	1000	1000
1.6	Cheese and cheese products	3000	3000
2.2.2	Oil emulsions (< 80 % oil)	2000	2000
3.1.2	Ice confection	400	400
4.1.3	Peeled &/or cut fruits and vegetables	375	375
4.3.2	Fruit & veg in vinegar, oil, brine, alcohol	1000	1000
4.3.2.2	Mushrooms in brine	500	500
4.3.4.1	Fruit spreads, artificially sweetened	1000	1000
4.3.5	Candied fruits and vegetables	500	500
4.3.6	Fruit and vegetable preparations inc pulp	1000	1000
4.3.7	Fermented fruit and vegetable products	500	500
4.3.8.2	Imitation fruit	500	500
4.3.8.3	Coconut milk	1000	1000

Food code	Food description	Baseline model (mg/kg)	Extension of use model (mg/kg)
5	Confectionery	500	500
5.2	Sugar confectionery	1000	1000
5.4	Icings and frostings	1500	1500
6.4	Flour products (including noodles and p	1000	1000
6.4.1	Hotplate products	0*	0*
7	Breads and bakery products	1200	1200
7.1	Breads and related products	0*	0*
7.2	Biscuits, cakes and pastries	500*	500*
8.2	Processed meat, pltry & game prod, whole	1500	1500
8.3	Processed comminuted meat, poultry & game	1500	1500
8.3.1	*Sausages*	*0*	*1*
9.3	Semi preserved fish and fish products	2500	2500
11.4.1	Tabletop sweeteners, liquid preparation	GMP	GMP
14.1.2	Fruit & vegetable juices & fruit & veg	400	400
14.1.3	Water based flavoured drinks	400	400
14.1.3.5	Electrolyte/sports drinks	400	400
14.2.2	Wine, sparkling wine and fortified wine	200	200
14.2.4	Fruit wine, vegetable wine, mead (inc ci	400	400
14.3	Mixed alcoholic drinks not elsewhere cl	400	400
20.2.1	Desserts (non dairy)	500	500
20.2.2	Dairy desserts	500	500
20.2.4	Sauces, toppings, mayonnaises, salad dr	1000	1000
20.2.8	Fat based dips and other fat based prod	500	500

* Manufacturers use levels

Calculation of dietary exposures

The DIAMOND model allows concentrations for sorbates to be assigned to food groups. Concentrations for sorbates were assigned to sausages in addition to those food groups permitted under the joint Australia New Zealand Food Standards Code (see Table 1 for list of concentration levels used).

The DIAMOND program multiplies the specified concentration of sorbates by the amount of food that an individual consumed from that group in order to estimate the exposure to each food group. Once this has been completed for all of the food groups specified to contain sorbates, the total amount of sorbates consumed from all food groups is added up for each individual. Population statistics (mean, median and high percentile exposures) are then derived from individuals' exposures.

Estimating Risk

In order to determine if the level of exposure to sorbates is likely to be a potential public health and safety concern, the exposures were compared to an Acceptable Daily Intake (ADI). An ADI is the amount of a food additive that can be ingested daily over a lifetime without any appreciable risk to health. The ADI for sorbates is 25 mg/kg of body weight. This ADI is a group ADI, meaning it applies to sorbic acid and its salts.

Assumptions used in dietary modelling

Assumptions made in the dietary modelling include:

- all foods within a category contain sorbates at the specified level; and
- where a GMP permission is specified for a category, the model assumes this to be a zero concentration.

Limitations of dietary modelling

A limitation associated with the dietary modelling when estimating dietary exposure over a period of time is that only 24-hour dietary survey data were available. These data tend to overestimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

Results

Estimated dietary exposure to sorbates is below the ADI for all respondents and consumers for the whole population for both the baseline and extension of use models for Australia and New Zealand (Table 2). Dietary exposure estimates for children aged 2 to 12 years (Australia only) are below the ADI for mean consumers and respondents. The estimated dietary exposure for 95th percentile child consumers was above the ADI for sorbates (130.7% for baseline levels and proposed extension of use levels).

Table 2. Estimated dietary exposure to sorbates for Australia and New Zealand for both the baseline and extension of use models - % of ADI

				Consumers only†		
Country	**Age**	**Model**	**Respondent mean#**	**Mean**	**95th percentile**	**Number of consumers**
Australia	2-12	Baseline	56.7	56.8	130.7	2 077
		Extension	56.7	56.8	130.7	2 077
	all	Baseline	24.8	25.1	74.0	13 683
		Extension	24.8	25.0	73.9	13 698
New Zealand*	all	Baseline	14.9	16.2	44.4	4 500
		Extension	14.9	16.1	44.4	4 512

* New Zealand NNS surveyed people aged 15 years and above.
# All respondents includes all those people surveyed in the NNSs.
† Consumers only includes those people surveyed who have consumed a food that contains the additive.

The consumption of sausages contributed only negligibly to total estimated dietary exposure to sorbates for both the whole population and children for both Australia and New Zealand (less than 0.01%). The major contributors to total estimated dietary exposure to sorbates for the Australian population and children respectively were water based flavoured drinks (29.4% & 34.7%), cheese and cheese products (14.9% & 11.8%), and fruit and vegetable juices and products (12.4% & 18.2%). The major contributors to total estimated dietary exposure to sorbates in New Zealand were water based flavoured drinks (24.9%), cheese and cheese products (16.9%) and biscuits, cakes and pastries (9.4%).

Interpretation of results

The dietary exposure estimates for the whole population for both Australia and New Zealand are below the ADI for sorbates. This indicates that there is no potential public health and safety concern, even when it is assumed that foods contain the MPL, and all foods in a group contain the additive. Table 2 indicates that the estimated dietary exposure from the extension of use model is actually lower than exposures from the baseline model for the whole population. It would normally be expected that if an additive were permitted to be in more foods, the estimated exposures would be higher. The fact that this appears not to be the case is because first, the concentration in the sausages and the actual consumption of sausages are not significant enough to create a large increase for total dietary exposures. Second, the results between the baseline and extension models are derived from different consumer groups. The baseline model did not include sausages and had 13683 consumers, from which the estimated mean and high percentile exposures were derived. The extension of use model contained sausages and 13698 consumers, from which the exposure estimates were derived. The estimated exposures for the additional 15 consumers in the extension of use model affected the overall results.

The estimated exposure for child 95th percentile consumers (Australia only) is above the ADI for both baseline and extension of use models. However, this is not considered to be of health and safety concern because dietary exposure estimates are likely to be an overestimate of actual exposure. The dietary modelling assumes that sorbates are added to every food in each category at the concentration described in Table 1. Most of these concentrations are the maximum levels permitted to be added to foods. In reality, manufacturers would use concentrations below the MPL. More information on actual manufacturers use levels in the foods would assist in making the dietary exposure estimates more realistic.

Additionally, not every food in each category will contain the additive. There are also other preservatives available that may be substituted for sorbates in foods, so the actual use of sorbates is likely to be significantly below the levels modelled. The 95th percentile may also be an overestimate because it is based on one-day food recall data, and not necessarily representative of habitual intake over a lifetime. Therefore, in reality, estimated high consumption of sorbates in children are not expected to exceed the ADI.

Conclusions

The consumption of sausages (with sorbates added to the edible collagen casing) had negligible influence on estimated total dietary exposure to sorbates (less than 0.01% of total exposure). This suggests the inclusion of sorbates to edible collagen casings would have only a very small impact on current dietary exposure to sorbates.

The inclusion of sorbates to edible collagen casings is estimated to have negligible impact on dietary exposure to sorbates for Australian and New Zealand populations. Therefore, there would be no additional risk to public health and safety if the extension of use were granted. Estimated dietary exposure for children indicates a potential for the ADI for sorbates to be exceeded but it is unlikely that this will occur in reality. The recent review into food additives (P150) did not identify sorbates as a potential risk to public health and safety as a result of dietary modelling. Further manufacturers' use levels of sorbates for other food categories could provide a more accurate indication of actual dietary exposure to sorbates, particularly for children who may be at more risk of higher exposure.

ATTACHMENT 6

SUMMARY OF PUBLIC COMMENT

Submitter	**Comments**
Frank Peddie (Food Science and Technology Centre, University of South Australia)	- Does not state a position with regard to the application but submitted that he has preliminary evidence that food grade sorbic acid or potassium sorbate reacts with chlorine at levels typically found in potable water and that chlorinated by-products may be produced. Although the toxicological implications of these by-products are unknown, he believed it is advisable to recommend that solutions of sorbic acid or potassium sorbate for food use should be prepared in chlorine-free water.
National Meat Association of Australia	- Supports the application, requiring there is a maximum percentage addition to specific foods. - Recommends that the maximum percentage levels should be similar to the Codex Alimentarius Commission's draft recommendation levels.
Queensland Health	- Expresses concerns about the reaction between sorbic acid and nitrite, which has the potential to form direct-acting mutagens and genotoxic agents, specifically 1,4-dinitro-2-methylpyrrole and ethylnitrolic acid. - As the reaction may be limited by conditions including temperature, concentration, pH and blocking agents, requests that ANZFA advise on the relevance of this information in relation to the proposed use of sorbic acid. - Requests ANZFA's advice as to whether another evaluation of sorbic acid is planned in the near future by the Joint Expert Committee on Food Additives (JECFA), as an evaluation of current data may result in an altered acceptable daily intake (ADI) value.
Australian Food and Grocery Council	- Expresses support for the application and considers the use of sorbic acid in edible collagen casings is technically justified as a means of producing "high transparency" casings as well as consistent with the section 10 objectives of the ANZFA Act 1991. - Submits that although high levels of sorbic acid are used during the manufacture, residual levels in the casings are less than 100 mg/kg. At these low levels sorbic acid is no longer effective as a preservative and physical methods of preservation, water activity and refrigeration, take over. - Considers that sorbic acid acts as a processing aid in collagen casings analogous to bleaching agents, clarifying and filtration agents and other miscellaneous processing aids, such as potassium bromate to control malting and the use of sodium metabisulphite in the treatment of hides for gelatine production. - Recommends that sorbic acid be permitted for use as a processing aid in edible collagen casings with a maximum permitted residue not exceeding 100 mg/kg.