1. EXECUTIVE SUMMARY

This Preliminary Inquiry to Proposal 154 assesses the regulatory requirements for royal jelly, bee pollen and propolis, and their food products following action taken, as a matter of urgency in 1997, under section 37 of the Australia New Zealand Food Authority (ANZFA) Act 1991. The action strengthened the former warning statement in the label of royal jelly presented as food, and food products containing royal jelly to refer to the risk of fatality, consistent with the warning required for royal jelly regulated as therapeutic goods. The scope of this Proposal, was originally confined to foods presented as, and containing royal jelly but was expanded in 1999 to include propolis, bee pollen and their food products, because of separate safety assessments available in the intervening period for these substances from the Australian Therapeutic Goods Administration (TGA) and the New Zealand Ministry of Health (NZ MOH).

Given that bee products cross the regulatory spectrum as foods or therapeutics in Australia; and foods including dietary supplements in New Zealand; this Proposal, while applying only to foods, aims ultimately to facilitate clarification of the regulatory status of royal jelly products and to achieve a coordinated approach to the labelling requirements for all regulated bee products. NZ MOH has indicated that the warning labelling statements adopted for food, also would be made mandatory for dietary supplements, as foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. For New Zealand, this consultation applies to both foods and dietary supplements (refer section 11.2 and Attachment 10 for details).

Although this Proposal considers royal jelly, bee pollen and propolis and their food products, it does not refer to such substances when naturally present in a food (i.e. bee pollen naturally present in honey) or in cases where their presence is due to unintentional contamination.

1.1 Assessment of risk

There is a general consensus that, although reactions to royal jelly are rare, they occur more readily than reactions to propolis or bee pollen and are more severe and serious. The population subgroup that suffers from asthma and related allergies is most at risk. A targeted warning statement in the label of royal jelly and its food products is
necessary in order to inform susceptible people of the risk of consumption of such products because they are not common and are promoted as health foods. Consumers generally take royal jelly for its therapeutic benefits and would not expect a severe allergic reaction from such a product.

In relation to bee pollen, there is no evidence to suggest that bee pollen causes severe life threatening reactions. However, bee pollen has been implicated in allergic reactions and therefore the requirement to declare its presence in a food will alert those people who are aware of their allergy to avoid bee pollen.

Similarly, there is evidence to suggest that propolis may cause serious adverse reactions; however, such reactions are very rare and there is little evidence to warrant a warning or advisory statement on propolis food products. However, propolis has been implicated in allergic reactions and therefore the requirement to declare its presence in a food will alert those people who are aware of their allergy to avoid propolis.

1.2 Conclusions in relation to food standards

This report concludes that, on the basis of assessed risk to public health, a warning statement in the label of a food presented as royal jelly or containing royal jelly remains justified because of the considerable potential for royal jelly to cause severe allergic reactions, including life threatening reactions, as assessed by the TGA’s Complementary Medicines Evaluation Committee (CMEC), and the New Zealand Report on the Findings of the Bee Products Warning Review Working Group, August 1999 (Working Group). The wording of the statement is proposed to be amended to omit reference to “fatalities”, consistent with the assessed risk. It is also proposed to require definitions of royal jelly, propolis, bee pollen and pollen, as well as the declaration of all three bee products in the label of foods containing such ingredients.

Therefore this report proposes amendments to:

Standard K2 – Honey and Related Products, of the Australian Food Standards Code; and

Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations of the draft Joint Australia New Zealand Food Standards Code.

The proposals relevant to Standard K2 of the Australian Food Standards Code are to:

a) Reaffirm the present requirement for royal jelly and its products to carry a warning statement that alerts consumers, particularly asthma sufferers to a potential health risk; but to amend the wording of the warning statement consistent with the assessed risk, as follows:

ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS.
ASTHMA SUFFERERS ARE MOST AT RISK
b) Retain the existing definitions of pollen and royal jelly and insert new definitions for bee pollen and propolis;
c) Require the presence of royal jelly, bee pollen and propolis to be declared in the label of foods containing these substances, at all times, including irrespective of their concentration in the final product, and when declared on small packages; and
d) Delete the present warning statement required in the label of pollen products.

The proposals relevant to Standard 1.2.3 of the draft Joint Australia New Zealand Food Standards Code are to:

a) Reaffirm the present requirement for royal jelly and its products to carry a warning statement that alerts consumers, particularly asthma sufferers, to a potential health risk; but to amend the wording of the warning statement, consistent with the assessed risk, as follows:

ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS.
ASTHMA SUFFERERS ARE MOST AT RISK

b) Confirm insertion of definitions for royal jelly, pollen, bee pollen, and propolis as proposed by P161; and
c) Confirm requirement for the presence of royal jelly, bee pollen or propolis to be declared in the label of foods containing these substances at all times, including irrespective of their concentration in the final product, and when declared on small packages, as proposed by P161.

1.3 Recommendations to other agencies

This Proposal recommends to the TGA that it finalises the draft proposal issued in 1998 under section 7 of the Therapeutic Goods Act 1989 to declare royal jelly presented in capsule, phial or powder form to be a therapeutic good.

Because royal jelly in capsule, vial or powder form in New Zealand is regulated as a food including dietary supplements under the New Zealand Food Act 1981, the above recommendations made for royal jelly, pollen and propolis as foods should also relate to royal jelly, pollen and propolis sold as dietary supplements in New Zealand. The NZMOH has proposed that any warning statement for royal jelly and labelling requirements for bee pollen and propolis that result from this consultation process, also applies to dietary supplements containing these substances (refer section 11.2 and Attachment 10 for details).

1.4 Regulatory impact statement

A Regulatory Impact Statement has been prepared for the amendments to the Food Standards Code, the New Zealand Food Standards 1996, and the draft Joint Australia New Zealand Food Standards Code (each Code). The conclusion of this impact statement indicates that:
provisions should be included in each Code to require that where royal jelly is
presented as a food, or used as an ingredient in food, a warning statement must
appear in the label of that food as stipulated by each Code; and
where royal jelly is presented as a food, or where foods contain royal jelly, bee
pollen or propolis, the presence of these substances should be declared in the
label of the food.

1.5 TBT Notification

There are no standards for royal jelly, propolis or bee pollen in Codex or other
international food regulations. These recommendations will be submitted to the WTO
as a Technical Barrier to Trade notification.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

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

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

• **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

• **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 the Authority 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*.

Any person or organisation may apply to the Authority to have the *Australian Food Standards Code* amended. In addition, the Authority may develop proposals to amend the *Australian Food Standards Code*. The Authority can provide advice on the requirements for applications to amend the *Australian Food Standards Code*.

**FURTHER INFORMATION**

**Submissions:** Written submissions containing technical or other relevant information which will assist the Authority in undertaking an inquiry into the draft variations to standards prepared at full assessment, including consideration of its regulatory impact, are invited from interested individuals or 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 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 - Proposal P154** at one of the following addresses:

<table>
<thead>
<tr>
<th>Australia New Zealand Food Authority</th>
<th>Australia New Zealand Food Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO Box 7186</td>
<td>PO Box 10559</td>
</tr>
<tr>
<td>Canberra Mail Centre</td>
<td>The Terrace WELLINGTON 6036</td>
</tr>
<tr>
<td>AUSTRALIA</td>
<td>NEW ZEALAND</td>
</tr>
<tr>
<td>Tel (02) 6271 2222</td>
<td>Fax (04) 473 9855</td>
</tr>
<tr>
<td>Fax (02) 6271 2278</td>
<td>Fax (04) 473 9855</td>
</tr>
</tbody>
</table>

Submissions should be received by **27 September 2000**.

**Further information** on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

<table>
<thead>
<tr>
<th>PO Box 7186</th>
<th>PO Box 10559</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canberra Mail Centre</td>
<td>The Terrace</td>
</tr>
<tr>
<td>ACT 2610</td>
<td>WELLINGTON 6036</td>
</tr>
<tr>
<td>AUSTRALIA</td>
<td>NEW ZEALAND</td>
</tr>
<tr>
<td>Tel (02) 6271 2258</td>
<td>Tel (04) 4739942</td>
</tr>
<tr>
<td>email: <a href="mailto:slo@anzfa.gov.au">slo@anzfa.gov.au</a></td>
<td>email: <a href="mailto:anzfa.nz@anzfa.gov.au">anzfa.nz@anzfa.gov.au</a></td>
</tr>
</tbody>
</table>

Requests for copies of the preliminary inquiry report for P154 or for other information papers should be addressed to the Authority's Information Officer at the above address, or Email info@anzfa.gov.au
INTRODUCTION AND BACKGROUND – PRELIMINARY INQUIRY

Proposal P154 was developed in 1997 as a matter of urgency under section 37 of the *Australia New Zealand Food Authority Act* 1991 after the NSW Coroner found royal jelly to be the cause of death of a 23-year-old female. The Coroner recommended a ban on the sale of royal jelly; but after consultation with the Therapeutic Goods Administration (TGA) and advice from the then Parliamentary Secretary to the Minister for Health, the Australia New Zealand Food Authority (ANZFA) instead recommended an amendment to Standard K2 of the Food Standards Code to include a revised warning statement in the label of royal jelly products that included reference to ‘fatalities’. The recommendation came into force in Australia on 31 December 1997 through Amendment No. 38 to the Food Standards Code.

This warning statement served as an interim measure until the safety of royal jelly, and the need for such a statement, had been assessed. The *ANZFA Act* requires ANZFA to conduct an Inquiry into the amended regulation, which must include one round of public comment. The development of this (Preliminary) Inquiry report has been delayed due to complementary investigations and assessments of the matter by government agencies in Australia and New Zealand, the conclusions of which are discussed later in this document. In addition, because of the need to review the current warning statement applicable to bee pollen products in the Food Standards Code and the inclusion of propolis in some of the scientific reviews, ANZFA agreed in 1999 to incorporate assessment of bee pollen and propolis within the scope of P154.

Tables 1 and 2 below show the recent history of the regulation of royal jelly in Australia and in New Zealand. Further details are given at Attachment 4.
Table 1: Summary of Regulatory Actions in Australia Concerning Royal Jelly

<table>
<thead>
<tr>
<th>Initiator of action</th>
<th>App/Prop, Date</th>
<th>Action</th>
<th>Date of effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Dept WA</td>
<td>A139, 1992</td>
<td>Introduce definition and composition of royal jelly to Standard K2</td>
<td>Amendment 16, July 1993</td>
</tr>
<tr>
<td>TGA request after Coronial inquiry into death of 11 year old girl</td>
<td>P115, 1994</td>
<td>Introduce to Standard K2 under s37, single warning statement for royal jelly “WARNING – NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS”</td>
<td>Amendment 20, May 1994</td>
</tr>
<tr>
<td>ANZFA P115 Inquiry</td>
<td>P115, 1994</td>
<td>Revise to two warning statements in Standard K2 to apply to: 1. Royal jelly presented as a food “WARNING – NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS”; and, 2. Foods containing royal jelly (equivalent to that required by TGA) “WARNING – THIS PRODUCT CONTAINS ROYAL JELLY AND IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS”</td>
<td>Amendment 28, January 1995</td>
</tr>
<tr>
<td>ANZFA review P161 - Specific Labelling Statements</td>
<td>P161, early 1997</td>
<td>Public comment sought,</td>
<td>early 1997</td>
</tr>
<tr>
<td>Coronal Inquiry into death 23 year old female, request for review; Parliamentary Secretary directive for review, June 1997</td>
<td>P154 extracted from P161, July 1997</td>
<td>Revise Standard K2 under s37 to single warning statement (equivalent to that required by TGA) “THIS PRODUCT CONTAINS ROYAL JELLY WHICH HAS BEEN REPORTED TO CAUSE SEVERE ALLERGIC REACTIONS AND IN RARE CASES FATALITIES, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS”</td>
<td>Amendment 38, December 1997</td>
</tr>
<tr>
<td>ANZFA P154 Preliminary Inquiry</td>
<td>P154, September 2000</td>
<td>Revise single warning statement in Standard K2; and propose for draft Standard 1.2.3, consistent with Aust and NZ risk assessment “ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS. ASTHMA SUFFERERS ARE MOST AT RISK”</td>
<td>n/a</td>
</tr>
</tbody>
</table>
### Table 2: Summary Timeline of Events in New Zealand Concerning Royal Jelly

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>New Zealand Ministry of Health encouraged all manufacturers and importers of royal jelly products to put warning statements on their products.</td>
</tr>
<tr>
<td>June 1997</td>
<td>ANZFA wrote to Australia New Zealand Food Standards Council members (including the New Zealand Minister of Health) seeking agreement for additional labelling as a matter of urgency</td>
</tr>
<tr>
<td>July 1997</td>
<td>ANZFA made a recommendation to the Australia New Zealand Food Standards Council that an additional warning statement be required in the label of Royal Jelly and Royal Jelly products sold in Australia. (Standard K2 - Honey and Related Products) and Royal Jelly and Royal Jelly products sold in New Zealand which are made in compliance to the Australian Food Standards Code. This proposal did not extend to the products or foods produced and sold under New Zealand Food Regulations 1984, or those regulated by Dietary Supplements Regulations 1985 which is outside the scope of the joint food standards arrangement.</td>
</tr>
<tr>
<td>November 1997</td>
<td>The Ministry of Health distributed a discussion document for comment on two proposals for labelling of bee products. This discussion document detailed ANZFA’s proposed warning statement (P154) and a Ministry of Health proposed food standard requiring a warning for royal jelly, bee pollen and propolis on all food products, including dietary supplements.</td>
</tr>
<tr>
<td>October 1998</td>
<td>Ministry of Health made recommendations to Associate Minister of Health for mandatory warnings. Use of ‘fatalities’ warning optional for royal jelly.</td>
</tr>
<tr>
<td>December 1998</td>
<td>The Minister of Health issued Amendment No.11 to the New Zealand Food Standard 1996. Amendment No 11 contained requirements for new mandatory warning statements on labels of foods, including dietary supplements, containing royal jelly, bee pollen and propolis. This amendment was published in the <em>Gazette</em> on 17 December 1998 and was to come into force on 17 February 1999.</td>
</tr>
<tr>
<td>January 1999</td>
<td>Damien O’Conner MP wrote to the Regulations Review Committee complaining about New Zealand Food Standard 1996 Amendment No. 11.</td>
</tr>
<tr>
<td>February 1999</td>
<td>Minister of Health delayed the date New Zealand Food Standard 1996 Amendment No. 11 comes into force until 17 April 1999.</td>
</tr>
<tr>
<td>February 1999</td>
<td>The Regulations Review Committee resolved to proceed with an investigation of the complaint by Damien O’Conner MP.</td>
</tr>
<tr>
<td>July 1999</td>
<td>Associate Minister of Health established an Expert Working Group to Review Bee Product Warnings.</td>
</tr>
<tr>
<td>July 1999</td>
<td>Regulations Review Committee reported to the House with a recommendation that the Government revoke New Zealand Food Standard 1996 Amendment No. 11.</td>
</tr>
<tr>
<td>September 1999</td>
<td>Government responded to Regulations Review Committee report, saying that it would wait until the expert working group reported before considering making an amendment to the Standard.</td>
</tr>
<tr>
<td>October 1999</td>
<td>Expert Working Group to Review Bee Product Warnings reported.</td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>November 1999</td>
<td>Associate Minister of Health released the Expert Working Group report, including sending a copy to ANZFA.</td>
</tr>
<tr>
<td>February 2000</td>
<td>NZMOH and ANZFA agreed to work together to progress the issue, as is within the scope of the Agreement Between the Government of New Zealand and the Government of Australia Establishing a System for the Development of Joint Food Standards (the Treaty).</td>
</tr>
</tbody>
</table>

2.1 Relation to other regulatory regimes

In Australia currently, royal jelly, propolis and bee pollen may be regulated as foods or therapeutic goods depending on their intended purpose. In 1998, the TGA issued a draft proposal to declare royal jelly in capsule, phial and powder form as a therapeutic good. Subject to that proposal being realised, royal jelly would be regulated as a food only when it is used as a food ingredient. Propolis and bee pollen are not standardised under the Australian Food Standards Code and their intended use would determine whether they are regulated as a food or a therapeutic good.

In New Zealand, bee products may be sold either as foods or as dietary supplements depending on their intended purpose. However, most royal jelly, bee pollen and propolis products are sold as dietary supplements, which are regulated as foods under the Food Act 1981. Warning statements for royal jelly, bee pollen and propolis (whether sold as foods or dietary supplements) are contained in New Zealand Food Standard 1996 Amendment No. 11, which is mandatory.

Given that bee products cross the regulatory spectrum as foods or therapeutics in Australia; and foods including dietary supplements in New Zealand; this Proposal, while applying only to foods, aims ultimately to facilitate clarification of the regulatory status of royal jelly products and to achieve a coordinated approach to the labelling requirements for all regulated bee products. NZ MOH has indicated that the warning labelling statements adopted for food, also would be made mandatory for dietary supplements, as foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. For New Zealand, this consultation applies to both foods and dietary supplements (refer section 11.2 and Attachment 10 for details).

3. RISK ASSESSMENT / RISK MANAGEMENT AND SUMMARY OF SCIENTIFIC REPORTS ON THE SAFETY OF BEE PRODUCTS

Assessment of the risks that bee products pose to the general population and/or subpopulations is essential to determine if there is a need for regulatory action and the most appropriate risk management strategy. To assess these risks, ANZFA has reviewed two scientific reports and other documentation on the potential risks that royal jelly, bee pollen and propolis pose to the general population and/or subpopulations, plus obtained additional expert advice on that material to ensure appropriate coverage and accurate interpretation of the literature.
The following reports on the safety of royal jelly, bee pollen and propolis have been received by ANZFA since 1997:

1) Extracted Ratified Minutes, Item 5, Royal Jelly safety review, and associated documents from December 1997 meeting of Complementary Medicines Evaluation Committee (CMEC), which provides advice to the TGA in Australia (see Attachment 5).


Collectively these reports assess the risk that royal jelly, bee pollen and propolis pose to the general population and/or subpopulations in Australia and New Zealand. Of these, the New Zealand Report on the Findings of the Bee Product Warning Scientific Review Working Group, 1999, contains the most up to date and comprehensive analysis of all related risks. The report also proposes risk management options for all three bee products.

3.1 Complementary Medicines Evaluation Committee (CMEC) Report

The Complementary Medicines Evaluation Committee (CMEC), which provides advice to the TGA, met in December 1997 on the request of the then Parliamentary Secretary to discuss the safety and quality of royal jelly. The safety of royal jelly was discussed generally and in relation to royal jelly regulation. The Committee’s assessment is reproduced below.

3.1.1 CMEC Assessment

There is an established market for royal jelly in Australia and an established industry for the importation and exportation of royal jelly. Lack of proven efficacy has been no barrier to the proliferation of perceived benefits and widely held beliefs. A possible placebo effect due to confidence in royal jelly cannot always be separated from reputed mechanisms of therapeutic effect.

Royal jelly could not be described as a toxic substance but is an allergen, and as such, is associated with severe and sometimes fatal reactions. These reactions occur mainly in atopic or allergic patients, particularly asthmatic individuals, but it cannot be stated that reactions are exclusive to these groups.

The regulation of royal jelly for the protection of public health and safety has to take account of the potential harm in balance with the potential benefit. This is difficult in the case of royal jelly because of the lack of rigorous evidence of benefit, albeit with recognition that some lines of research are worth pursuing, and because of the idiosyncratic nature of the reactions associated with royal jelly. A solution has to be found which provides protection to users of royal jelly even if the potential number for whom consumption is dangerous is small and which increases the public confidence in the industry.
The industry needs to take responsibility for the royal jelly standards. Products marketed as royal jelly or containing royal jelly are associated with adverse reactions but there is doubt about what is actually in some of these products.

A number of submissions recommended that the supply of royal jelly be restricted to competent and qualified health professionals. At present this would restrict access to doctors and pharmacists as there is currently no formal mechanism for regulating and identifying other appropriately qualified practitioners.

In the absence of any kind of market restriction, warnings are certainly required and education and monitoring of consumers by a professional have to be encouraged.

3.1.2 Recommendation of CMEC to TGA

1. Permit royal jelly to be included in listable products, provided:
   - the labelling of the products includes the current warning statement;
   - the products are not promoted for any condition which might be a symptom of an allergic or hypersensitivity condition eg, hay fever, rhinitis or asthma; and
   - the products are not promoted for children and the labelling includes a warning specifying that the product is not suitable for children.

2. Develop a specific standard for royal jelly as a therapeutic good because:
   - it seems likely that some of the products, marketed as royal jelly, could be worker jelly;
   - royal jelly appears to be relatively unstable and therefore the quality of royal jelly products is likely to be variable;
   - from the available information, royal jelly products on the market could be adulterated or contaminated; and
   - it would ensure royal jelly products on the market do not contain allergens such as bee pollen.

3. The warning statement needed to be more direct and while the potential for adverse reactions is not confined to asthma and allergy sufferers, the message should be particularly directed to them.

4. A Section 7 declaration be made under the Therapeutic Goods Act 1989 to declare royal jelly presented in capsules, phials and powders, to be therapeutic goods because:
   - the contribution to nutritional requirements of capsules, phials and powders does not justify nutrition being considered a principal role for these goods; and
   - there is a widely held community perception that royal jelly has therapeutic benefit.
CMEC stated that the Section 7 declaration has implications for royal jelly as a food that could mean that Standard K2 of the Food Standards Code should be amended to exclude royal jelly in the forms recognised as therapeutic goods.

3.2 Report on the Findings of the Bee Products Warning Scientific Review Working Group

The New Zealand Working Group (Working Group) conducted a separate risk analysis for royal jelly, bee pollen and propolis. The Working Group classified the adverse effects according to the WHO framework for hazard characterisation. The term 'severe' was defined by the Working Group as the intensity (severity) of a specific event; the event itself, however, may be of relatively minor medical significance. The term 'serious' was defined by the Working Group as death, hospitalisation, persistent/significant disability, or being life threatening.

3.2.1 Summary of findings

A. Royal jelly

The Working Group:

- defined royal jelly as a substance produced by special glands in worker honeybees and used as both a food for developing larval bees and to feed the queen bee;
- stated that royal jelly is high in protein, has a range of bioactive effects and is available in raw form and in capsules, tablets, vials, creams, soaps and shampoos;
- claimed that royal jelly may cause contact dermatitis, rhinitis, gastrointestinal symptoms, bronchospasm, anaphylaxis, asthma, urticaria and rhinitis; and of these
- considered bronchospasm, asthma and urticaria reactions to be severe and serious, and the anaphylaxis and gastrointestinal reactions to be serious.

The Working Group then reviewed the evidence surrounding three Australian cases where death resulted after ingestion of royal jelly. In the case of the death of a 21-year-old man, the Working Group was unable to assess the claimed association with the ingestion of royal jelly so this case was excluded from the risk characterisation. In the second case of a death of an 11-year-old girl, the Working Group could find inadequate information to support the findings of the Coroner on the claimed association between the ingestion of the royal jelly and the death. This was due to the lack of supporting analytical data. The Working Group therefore excluded this report from the risk characterisation. In the third case of the death of a 23-year-old woman, the Working Group considered the evidence and concluded that there was a strong association between the ingestion of royal jelly and the development of an acute asthmatic episode with a fatal outcome.

The Working Group concluded that there was insufficient information to establish a quantitative risk estimate but serious adverse health effects (including 'fatal outcome'), while very uncommon, appeared to occur at a frequency considerably
higher than that for other bee products. Thus a *qualitative* risk characterisation ranked royal jelly as a bee product presenting higher risk, both in terms of probability of occurrence and seriousness of reactions, compared to propolis and bee pollen. It is important to note that the Working Group stated that:

“In itself, the possibility of one reported death does not alter the risk characterisation by the Working Group, as death is a potential outcome of any serious adverse reaction. …the Working Group did not distinguish between serious reactions where the outcome was death or recovery.”

**B. Bee pollen**

The Working Group:

- defined bee pollen as pollen grains collected by worker bees from flowering plants, modified by bees and, then, used as the honeybee colony’s only source of protein;
- stated that bee pollen has nutritive value and also a range of bioactive effects and it is available in granules, tablets, capsules, creams, soap and shampoo;
- noted that bee pollen might cause anaphylaxis, gastrointestinal symptoms, asthma, angioedema/urticaria and hypoglycaemia;
- considered that, of these, anaphylaxis, asthma and angioedema might be severe, although there does not appear to have been any deaths associated with the use of bee pollen;
- indicated that there are strong indications of a high level of exposure on a per capita basis in the general population, however there is insufficient data to generate exposure estimates on a per capita basis;
- stated that the world literature indicated that the frequency of serious adverse health effects following ingestion of bee pollen is extremely low; and
- concluded that despite evidence of high levels of exposure on a worldwide and Australasian basis there are an extremely small number of cases of serious (and potentially life-threatening) adverse effects, therefore, on any qualitative scale the risk is extremely low.

**C. Propolis**

The Working Group:

- defined propolis as a resinous substance collected by worker honey bees from the growing parts of trees and shrubs, modified by the bees and then used by the bees to seal their hive;
- indicated that propolis is antimicrobial and is available in the form of syrup or lozenges. It is also available in a variety of creams and soaps
- considered propolis in its oral and in its topical form. Note that the topical form is outside the scope of this Preliminary Inquiry report; and
- concluded that there is some evidence of serious adverse health effects linked to ingestion of propolis, but this is very limited in extent. Despite the probability of high levels of exposure on a worldwide and Australasian basis there are an extremely small number of cases. Therefore, on a qualitative scale the risk is extremely low.
3.2.2 Risk management strategy suggested by the New Zealand Working Group on Bee Products

The Working Group investigated a number of risk management options for bee products. These options were examined from a viewpoint of feasibility and practicality. The risk management options that were available and which could reasonably be applied were judged by the Working Group to be:

- mandatory labelling;
- voluntary labelling with a code of practice;
- voluntary labelling; or
- no action.

Public health was clearly identified as the primary determinant in decision-making.

A. Risk Management of royal jelly

The Working Group considered that, although the risk of adverse reaction was low, reactions, when they do occur are serious. The Working Group considered that the risks could be significantly reduced by implementation of appropriate risk management measures.

The Working Group noted that there is a greater prevalence of adverse reactions to other foods than there is to royal jelly, however they believed that consumers have a greater expectation for safety of ingested foods presented in the form of dietary supplements like capsules of royal jelly.

The Working Group was not in a position to evaluate the claimed benefits of royal jelly so did not include benefit parameters in the risk management framework.

The use of mandatory health warnings was thoroughly examined. It was considered that any benefits to public health from mandatory health warnings in terms of the general population would be negligible. However, the risk management process identified that asthmatics represent a population that is more susceptible to serious adverse health effects than the general population. A specific mandatory health-warning label for products containing royal jelly could qualitatively be expected to reduce this risk.

The Working Group concluded that there was a need for ingredient labelling of all products containing royal jelly. This could be achieved through voluntary labelling and a self regulated industry Code of Practice or through mandatory labelling.

In addition, to reduce the risk to population sub-groups more susceptible to adverse health effects from royal jelly than the general population, the working group recommended the following [warning] statement on all food products and dietary supplements containing royal jelly:
"Royal jelly may cause serious allergic reactions. Most reports have been in asthma sufferers"

B. Risk management of bee pollen

The Working Group concluded that the only risk management activity required for bee pollen was ingredient labelling of all products containing bee pollen. This could be achieved through voluntary labelling and a self regulated industry Code of Practice or through mandatory labelling. The Working Group did not anticipate any measurable reduction in the already extremely low level of risk as a consequence of this activity; rather it is a measure that is consistent with general public health expectations.

C. Risk Management of propolis

The Working Group concluded that the only risk management activity required was ingredient labelling of all products containing propolis. This could be achieved through voluntary labelling and a self regulated industry Code of Practice or through mandatory labelling. The Working Group did not anticipate any measurable reduction in the already extremely low level of risk as a consequence of this activity; rather it is a measure that is consistent with general public health expectations.

4. EXPERT ADVICE ON SCIENTIFIC REPORTS

The CMEC documents, and the New Zealand Working Group report summarised above are collectively considered to be comprehensive. However, the reports suggest different levels of risk management particularly for royal jelly. In the case of bee pollen and propolis the only information available is provided by the Working Group report. It was considered appropriate for ANZFA to seek expert advice on the information presented in these reports to ensure appropriate coverage and accurate interpretation of the literature.

ANZFA does not have the expertise to analyse the recommendations of the scientific reports summarised above. Therefore, ANZFA sought advice on these recommendations from two expert immunologists who were not involved in the development of the reports: Dr Sheryl van Nunen¹, from Australia, and Dr Penny Fitzharris², from New Zealand. ANZFA is satisfied that the two experts provided independent advice. ANZFA developed options for regulation based primarily on the recommendations of the scientific reports summarised above, and used the advice from Dr Fitzharris and Dr van Nunen to substantiate the validity of these reports.

¹ Dr Sheryl van Nunen - Convenor of the Clinical and Laboratory Practices Committee (CLPC) of the Australasian Society of Clinical Immunology and Allergy (ASCIA), Head of the Department of Allergy at Royal North Shore Hospital and a Visiting Medical Officer at the North Shore Private and Sydney Adventist Hospitals in Sydney.

² Dr Penny Fitzharris - Senior Lecturer in Clinical Immunology and Allergy at the Wellington School of Medicine and a consultant clinical specialist for Capital Coast Health in treatment of allergic diseases for 12 years. New Zealand representative member on the ANZFA Expert Panel on Specific Labelling for Allergens in 1996 (Proposal 161)
The advice provided to ANZFA by Dr van Nunen and by Dr Penny Fitzharris is summarised below. (See Attachments 9 and 10 respectively)

4.1 Dr Sheryl van Nunen

4.1.1 Royal jelly

Dr van Nunen indicated that the reports clearly showed a risk of severe allergic reactions to royal jelly, which occurred more commonly in those with asthma. Dr van Nunen stated that a similar range of reactivity was seen in individuals allergic to peanuts, fish and other food allergens.

Dr van Nunen further indicated that the reports showed that qualitatively, royal jelly presented a higher risk of serious reactions than other bee products. However, there seemed to be no means of definitely determining those at risk of life-threatening reactions to royal jelly as reactions seemed to have occurred with the first exposure to royal jelly. Due to these factors, and the fact that royal jelly may be perceived by many in the community as a health tonic, Dr van Nunen's opinion was that royal jelly products should be clearly labelled with a warning that they contain an ingredient that may provoke life-threatening reactions especially in those with a history of asthma or allergy.

4.1.2 Bee Pollen

Dr van Nunen indicated that the scientific reports showed that reactions to bee pollen were rare but there was some evidence that bee pollen ingestion might result in anaphylaxis in people with a history of allergic rhinitis. The reports clearly indicated however that bee pollen posed a lesser risk of life-threatening allergic reactions than royal jelly.

Dr van Nunen stated that, in her opinion, a warning regarding bee pollen’s potential for causing allergic reactions should suffice.

4.1.3 Propolis

Dr van Nunen stated that propolis was a well-recognised cause of contact dermatitis. The reports indicated that life-threatening reactions to propolis were possible, however, such reactions were extremely rare and the mechanism of these reactions had not been definitely established. Dr van Nunen indicated that the size of the population at risk was unknown and, in her opinion, labelling noting the products’ rare propensity for life-threatening reactions and declaring the presence of propolis would seem prudent.

4.1.4 Summary

Dr van Nunen apparently agreed with the risk assessment conclusions of the reports presented by CMEC and the New Zealand Working Group, however she suggested as
a risk management strategy, more stringent labelling requirements than is currently the case in Australia.
4.2 Dr Penny Fitzharris

Dr Fitzharris stated that, once allergy to a particular substance had been reported in the literature, additional reports were likely to be published only if they added to the understanding of the pathogenesis of the condition or identified new clinical features. Therefore, the published literature should not be taken to represent the world experience of the problem, nor should reporting of adverse reactions be considered complete when reporting is voluntary.

4.2.1. Royal jelly

Dr Fitzharris stated that the reports indicated that reactions to royal jelly are typically in asthmatic subjects, that they could be rapid in onset and severe, and may occur after the first known exposure to royal jelly. She stated that the reports clearly indicated that although this problem may not be common, reactions could be life threatening.

Dr Fitzharris stated that it seemed likely that royal jelly could induce a similar range of reactions as typical food allergies such as peanut allergy.

It is Dr Fitzharris's view that the scientific published literature and reported cases fully justified a warning statement in the label of royal jelly products as suggested in the Working Group’s report.

4.2.2. Bee pollen

Dr Fitzharris indicated that the reviewed reports suggested that there were fewer reports of reactions to bee pollen than to royal jelly; that it is difficult to assess the frequency of adverse reactions; and it seemed the overall risk from these products was relatively low.

Dr Fitzharris agreed with the advice of the Working Group that ingredient listing through voluntary labelling and a self-regulated industry Code of Practice or through mandatory labelling was appropriate.

4.2.3. Propolis

Dr Fitzharris indicated that propolis is well known as a cause of contact dermatitis. There seems to be a small amount of evidence that propolis may cause adverse reactions such as angioedema/urticaria and bronchospasm.

Dr Fitzharris agreed with the Working Group’s advice for ingredient listing and a warning statement on skin preparations that contain propolis.

5. ASSESSMENT OF FINDINGS

The recommendations from CMEC, the Working Group, Dr Sheryl van Nunen and Dr Penny Fitzharris are assessed as follows:
5.1 Royal jelly

There seems to be a consensus that royal jelly has the potential to cause severe, life-threatening, adverse reactions in rare cases and those particularly at risk are people with a history of asthma. There also seems to be consensus that reactions could occur at the first exposure to royal jelly. All sources recommend that warning statements targeted to people with asthma should appear in the label of royal jelly products, although advice differed as to the strength of the warning statement. CMEC and Dr Sheryl van Nunen indicated that this warning should state that reactions may be fatal or life threatening. The Working Group and Dr Penny Fitzharriss suggested that a statement is needed but only to the extent that the product may cause allergic reactions in people with asthma or allergies.

5.2 Bee pollen

There is consensus that reactions to bee pollen are rare in the general population and may occur in people with allergic rhinitis, however serious reactions are extremely rare. There is agreement in all reports that products containing bee pollen should list bee pollen in the label however, there was little support for a warning or advisory statement in the label of bee pollen products.

5.3 Propolis

There is consensus that serious reactions to propolis may occur, however, these are rare. The main risk associated with propolis is contact dermatitis from skin preparations that contain propolis. There is agreement in all reports that products containing propolis should list bee pollen in the label. There was no support to require a mandated warning statement.

6. SUMMARY OF SUBMISSIONS AND CORRESPONDENCE to ANZFA and NZMOH REGARDING THE SAFETY OF ROYAL JELLY, BEE POLLEN AND PROPOLIS

In addition to the scientific reports summarised above, ANZFA has received numerous representations from the bee product industry and other stakeholders over the past three years. A more comprehensive summary of these submissions or representations is presented in Attachment 3.

The main issues raised in these submissions are summarised below.

- Royal jelly and bee pollen products were being singled out from other foods that may produce allergic reactions, such as peanuts.
- Under the WTO the inclusion in the Food Standards Code of mandatory label warnings is and would be, a departure from relevant international standards.
- The evidence of reactions to royal jelly is flawed and does not justify prescriptive warning statements.
- The nutritive and therapeutic benefits of royal jelly need to be taken into account.
An option for non-prescriptive advisory labels should be provided. Royal jelly products are foods with therapeutic effects; they are not drugs and should not be classified as drugs.

Two articles cited by TGA, ANZFA and the Coroners Inquiry into the death of a 23-year-old female were duplicated and revoked from the journals in which they were published and should not be used as justification for the warning statements.

The linking of royal jelly with fatalities has seriously damaged the royal jelly industry in Australia and New Zealand.

The industry agrees with the findings of the New Zealand Working Group and recommends that these recommendations be implemented.

Professional and consumer groups believe a mandatory statement in the label of bee products regarding their potential to cause adverse reactions is justified on the basis of protection of public health and safety, however, less severe wording was considered appropriate.

6.1 ANZFA’s response to issues raised in submissions and correspondence to ANZFA and the NZMOH

6.1.1. Royal jelly and bee pollen products were being singled out from other foods that may produce allergic reactions, such as peanuts.

Proposal P161- Specific labelling statements was developed in 1997 to review the issue of allergens in food. This proposal was completed in 1999 and recommended that a list of foods that are known to cause severe adverse reactions be included in the draft Australia New Zealand Food Standards Code and that a mandatory requirement for the presence of these foods to be declared in food labels be included in the draft Code.

The final list that now appears in the draft Australia New Zealand Food Standards Code is as follows:

- Cereals containing gluten
- Crustacea and their products
- Egg and egg products
- Fish and fish products
- Milk and milk products
- Nuts and sesame seeds and their products
- Peanuts and soybeans and their products
- Sulphites in concentrations of 10mg/kg or more.

The provision for declaration of these foods simply requires them to be declared in the label of the food. A declaration of the presence of the food in the ingredient list would suffice. The P161 assessment concluded that people with severe allergies would know from a young age that they are allergic to these common foods and would be advised by medical professionals to avoid them in the diet. A simple declaration of the presence of the ingredient is enough to warn people with an allergy to these foods that they should avoid the food.
ANZFA also had to review the need for the warning statements in the label of royal jelly and bee pollen products because there were provisions in the Food Standards Code put in place in Australia in 1994 for warning statements in the label of royal jelly and bee pollen products. There were no warning statements required for other foods that contain allergens.

The scientific reports reviewed and advice from Dr Sheryl van Nunen indicated that IgE mediated reactions to royal jelly, bee pollen and propolis are similar to those caused by peanuts, fish and other food allergens. ANZFA agrees that the prevalence of reactions to royal jelly, bee pollen and propolis would be far less than the prevalence of reactions to other food allergens. ANZFA believes this could be due to the fact that the consumption of royal jelly would be considerably smaller than the consumption of other food allergens because they are not a staple or common food. The food allergens listed above are staple foods and are generally included in the diet of people in Australia and New Zealand from a young age.

Knowledge of an allergic response to a food cannot be determined unless the person consumes the food. A person usually needs to be sensitised to a food initially before they will react to it. Therefore they do not generally have a reaction the first time they eat the food. There is no practical way to predict if a child will react to a foodstuff until they eat it. Parents and carers of infants are educated to introduce foods to children in small amounts to see how they react to them—a trial and error process.

Placing a warning statement on all products that contain nuts, soybeans, sesame seeds, cereal products, milk, crustacea, fish and sulphites would mean that a large majority of foods on the supermarket shelf would carry a warning statement. This would diminish the impact of the statement, be impractical and would not necessarily protect the health of the general population.

Reactions to these staple foods are still prevalent because unpackaged foods, restaurant meals and meals cooked in the home or social environment may contain foods to which an individual is allergic without his or her knowledge. Labelling statements cannot assist this problem.

In comparison, royal jelly, bee pollen and propolis are not staple foods. They may be classified as foods by the health food or dietary supplement industry, but the majority of consumers in Australia and New Zealand would not classify royal jelly, bee pollen and propolis as a staple or common food. Royal jelly, bee pollen and propolis are generally sold from health food stores and are promoted for their nutritional and therapeutic benefits. A consumer would not expect to have a reaction to a product that is promoted as a health food.

Bee products other than honey are not generally included in the diet at a young age\(^3\); they are usually consumed by choice later in life for their therapeutic benefits. It is not possible to determine who will react to common staple food allergens at a young age and trial and error is the only process to determine if a reaction will occur.

\(^3\) While bee products are not included in the diet at a young age, children may be unintentionally exposed to traces of royal jelly, bee pollen and propolis in honey.
Although the risk of reaction to royal jelly is considered low, reactions may be serious and they may occur at the first exposure to royal jelly. A declaration in the label of royal jelly products that indicates people with allergies and asthma may react to the products would greatly assist in protecting their health, particularly because royal jelly may be perceived as a health food.

ANZFA does not believe there is adequate evidence to require a statement in the label of bee pollen or propolis food products because the risk of reaction is very rare.

6.1.2. Under the WTO the inclusion in the Food Standards Code of mandatory label warnings is and would be, a departure from relevant international standards.

Departure from international standards such as Codex is permitted under the WTO if the measure is considered necessary to protect public health.

According to the Asthma Association of NSW and the Asthma and Respiratory Foundation of New Zealand, Australia and New Zealand have a very high rate of asthma in the world that is exceeded only by the United Kingdom. Approximately one in six people in New Zealand has asthma and one in seven people in Australia has asthma. The prevalence of asthma seems to be highest in English speaking countries. The Asthma and Respiratory Foundation of New Zealand states that there is a tendency for a higher prevalence of asthma in more economically developed countries.

Although reactions to royal jelly are rare, there have been more reports of reactions to royal jelly in Australia and New Zealand than in any other country. There is some evidence that people with asthma are at a higher risk of reacting to royal jelly and although reactions are rare, reactions when they do occur are serious. Therefore, ANZFA believes there is justification under the WTO to require more stringent requirements for royal jelly in Australia and New Zealand.

The same argument could not be made for bee pollen and propolis products however, because there is no evidence of higher reactions to these in Australia and New Zealand and there is no evidence that people with asthma are particularly at risk.

This issue will be notified to the WTO as a TBT notification.

6.1.3. The evidence on reactions to royal jelly is flawed and does not justify prescriptive warning statements.

Industry stated that the evidence used to implement the warning statement for royal jelly is flawed because it was based on two journal articles that were subsequently revoked because of duplicated publication. ANZFA did not rely on the aforementioned journal articles to implement Amendment No. 38 to the Food Standards Code. The warning statement for royal jelly was implemented after consideration of the NSW Coronial Report on the death of a 23-year-old woman. In 1997, until the safety of royal jelly was assessed, it was necessary to require a warning statement in the label of foods that contain royal jelly, as an interim measure, to
ensure consumers were informed that royal jelly might be a risk to health. The scientific reports reviewed in this report indicate that royal jelly does pose a risk to public health especially for people with asthma.

6.1.4. The nutritive and therapeutic benefits of royal jelly need to be taken into account

ANZFA does not have a position on the matter because neither ANZFA nor the scientific reports available to ANZFA assessed the nutritive or therapeutic benefits of royal jelly.

ANZFA’s main aim is the protection of public health and safety. Where a food poses a risk to health ANZFA must investigate the need to protect the public from that risk. This is the case for any food and is not dependent on whether or not the food has nutritive or other benefits.

The fact that royal jelly is promoted as having therapeutic benefits concerns ANZFA because there is also a risk that it may cause severe adverse reactions despite the benefits. Consumers with asthma in particular must be made aware of this risk especially if they are consuming royal jelly for its claimed therapeutic benefits.

6.1.5. An option for non-prescriptive advisory labels should be provided.

Non-regulatory alternatives to mandatory labelling were not considered initially in P154 because it was implemented as a matter of urgency as an interim measure. Options for non-regulatory alternatives are considered in section 10 of this report.

6.1.6. Royal jelly products are foods with therapeutic effects; they are not drugs and should not be classified as drugs.

Royal jelly is classified as a food or therapeutic good in Australia and as a food or dietary supplement in New Zealand.

In Australia food products are not generally permitted to carry ‘health claims’ in the label. Therefore, royal jelly products classed as foods in Australia are not permitted to claim their prophylactic or therapeutic benefits in the label or advertisements. If royal jelly were regulated as a complementary medicine under TGA legislation, substantiated therapeutic claims would be permitted in the label. ANZFA considers that it may be of benefit to the royal jelly industry if royal jelly were considered to be a therapeutic good in Australia rather than a food.

Currently, the use of health claims on food labels and in food advertising (including dietary supplements) is prohibited in New Zealand. Products allowed to carry a health claim - including the advertising of those products - require the consent of the Minister of Health, under the Medicines Act 1981. The proposed Healthcare and Therapeutic Products Bill will regulate all products used for an intended health or therapeutic benefit under the broad categories of medicines, medical devices and health care products. Healthcare products is a general descriptor that includes dietary supplements currently regulated under the Dietary Supplements Regulations 1985.
The proposed legislation will establish an appropriate framework to assess the efficacy of products. This framework will relate the level of evidence to the level of claim, i.e. if the product wishes to make a high level claim, then the company would be expected to be able to provide clinical evidence that supports the claim. For a low level claim, the company would be expected to provide evidence at that appropriate level. This is part of the evidence and risk-based approach to be developed for the Bill.

6.1.7. The industry agrees with the findings of the NZ Working Group and recommends that these recommendations be implemented.

ANZFA notes that the industry agrees with the recommendation of the New Zealand Working Group and has taken this view into consideration in this assessment of the issues.

6.1.8. Professional and consumer groups believe a mandatory statement in the label of bee products regarding their potential to cause adverse reactions is justified on the basis of protection of public health and safety, however, less severe wording was considered appropriate.

ANZFA agrees that there is a need for a statement in the label of royal jelly products that is targeted to people with asthma and allergies. Although reactions to royal jelly are rare, they are serious and may occur at the first exposure. People with asthma are particularly at risk. Royal jelly is marketed as a health food and people with asthma may not expect that there is a risk of severe reaction from the product.

The wording of the proposed statement is discussed later in this paper.

7. CONCLUSION BASED ON ASSESSMENT OF SCIENTIFIC REPORTS, EXPERT ADVICE AND REPRESENTATIONS FROM INTERESTED PARTIES

ANZFA concludes the following based on the evidence presented in the CMEC advice to TGA, the Bee Product Warning Scientific Review Working Group, the expert advice of Dr Sheryl van Nunen and of Dr Penny Fitzharris, and representations made by the bee product industry and other interested parties.

7.1 Royal jelly

There is a general consensus that, although reactions to royal jelly are rare, they occur more readily than reactions to propolis or bee pollen and are generally severe and serious. The population subgroup that suffers from asthma and related allergies is most at risk. There is a consensus that a targeted warning statement in the label of royal jelly and food that contains royal jelly is necessary in order to inform susceptible people of the risk of consumption of royal jelly because these foods are not common and are promoted as health foods. Consumers generally consume royal jelly for its therapeutic benefits and would not expect a severe adverse reaction from
such a product. The regulatory options and wording for this statement are discussed later in this paper.

7.2 Bee Pollen

There is little evidence that bee pollen causes severe adverse reactions. A prescribed statement in the label of bee pollen products is not justified. There is some evidence that bee pollen may cause allergic reactions that are not considered serious in people with allergic rhinitis. For the benefit of these people, the presence of bee pollen should be declared in the label at all times, including irrespective of its concentration in the final food, and when declared on small packages so that the food may be avoided if desired. The regulatory discussed later in this paper.

7.3 Propolis

There is some evidence that propolis may cause serious allergic reactions; however, such reactions are extremely rare and do not justify the need for a prescribed statement in the label of food products. Serious reactions to propolis should be monitored and this issue reconsidered in the future if necessary. Declaration of the presence of propolis in the ingredient list of food, regardless of its concentration, will be necessary for people who are aware that they may react to propolis and wish to avoid it. The regulatory options for declaration of propolis in the label of food are discussed later in this paper.

8. WARNING STATEMENT IN THE LABEL OF ROYAL JELLY PRODUCTS

8.1 ANZFA policy framework for the use of warning and advisory statements

As a part of the Review of Food Standards ANZFA developed Proposal P161 – Specific Labelling Statements. P161 proposed definitions and conditions for specific labelling statements including warning and advisory statements.

1. A specific labelling statement should be provided on the label of a food when the food itself, a characteristic of the food, a component of the food, an ingredient of the food, or inappropriate use of the food, poses a potential, significant public health and safety risk to the general population or a specific population group. A specific labelling statement can either be a warning or an advisory statement.

2. A warning statement should be required if the risk to health is life threatening and it can be reasonably assumed that the general population or the specific target group is unaware of the potential risk to their health and a statement is needed to alert them to the risk.

3. An advisory statement should be required when the general public or the sub-population is exposed to a significant potential risk to health but the risk is not life threatening, or when guidance about use of a food is needed to protect public health and safety.
4. All warning and advisory statements should be mandatory. The form of a warning statement should be prescribed, whereas the form of advisory statements need not.

This policy is essential in determining the need for a warning or advisory statement in the label of bee products.

8.1.1 Application of policy to determine the appropriate type of statement on royal jelly

It has been determined that the food or a characteristic of the food, in this case royal jelly, may cause a significant public health and safety risk to a specific population group, i.e. people with asthma and allergies.

According to the above policy, the required statement should be a warning statement rather than an advisory statement because it has been determined that there may be a risk to health that is life threatening and people with asthma are not generally aware of the potential risk to their health.

The ANZFA policy states that warning statements must be mandatory and the form of the statement should be prescribed. This means that the exact words of the statement should be prescribed in the food standard.

8.2 Options for wording of the warning statement

The four essential elements of the statement should be to:

- apply to royal jelly presented as a food as well as to foods containing royal jelly as an ingredient;
- refer particularly to the at-risk target group, but also to others at risk;
- describe an appropriate level of risk, but emphasise that risk particularly for the target group; and
- be meaningful and succinct.

Following are options for the wording of the warning statement taken from former regulation or based on the recommendation of the Working Group.

Option 1

THIS PRODUCT CONTAINS ROYAL JELLY WHICH MAY CAUSE SEVERE ALLERGIC REACTIONS AND IN RARE CASES, FATALITIES, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS

This is the current warning statement required since 1997 as an interim measure on royal jelly and food products containing royal jelly. The word ‘fatalities’ in the statement has caused controversy and is opposed by the bee product industry as being draconian.

Option 2
WARNING – NOT RECOMMENDED FOR ASTHMATICS OR ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’

This is the original warning statement required on royal jelly and food products containing royal jelly. There was no opposition to this statement in Australia when introduced in 1994.

Option 3

ROYAL JELLY MAY CAUSE SERIOUS ALLERGIC REACTIONS. MOST REPORTS HAVE BEEN IN ASTHMA SUFFERERS

The above statement is recommended by the New Zealand Working Group. The bee product industry in Australia and New Zealand has supported the wording of this statement.

Option 4  Preferred option

Although all of the above options satisfy the essential elements to some extent, another option was devised based on the wording from Option 3, but crafted to convey a more consumer-oriented meaning.

ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS. ASTHMA SUFFERERS ARE MOST AT RISK

Two significant changes from Option 3 are proposed to:

- introduce the term ‘very’ to emphasise to consumers that the allergic reactions may extend to life threatening situations; and
- modify the emphasis of the second sentence from a scientific and objective statement, to one that can be appropriated by members of the target group but which does not exclude other susceptible individuals.

The statement is considered to be applicable to the label of foods presented as royal jelly, and to foods containing royal jelly.

9. REGULATORY OPTIONS FOR ROYAL JELLY, BEE POLLEN AND PROPOLIS

9.1 Australia and New Zealand

Although the scope of this Proposal covers royal jelly, bee pollen and propolis food products, it does not extend to such substances when present in a food naturally (i.e. bee pollen naturally present in honey) or when their presence is due to unintentional contamination.

9.1.1 Royal jelly
The majority of royal jelly products on the Australian market is in the form of capsules, phials or powders, which suggests that these products are more likely to be therapeutic goods, however, the existence of provisions for royal jelly in the Food Standards Code creates some confusion if only from a regulatory point of view. Royal jelly may also be presented as a food, or be added to foods.

P161 has already proposed the inclusion of the current definition of royal jelly and the requirement for mandatory declaration of royal jelly in the label of a food presented as royal jelly or containing royal jelly. These requirements contained in draft standard 1.2.3 are confirmed and, together with proposed warning statement, are proposed to be reflected in Standard K2 of the Food Standards Code and the New Zealand Food Standard 1996.

The current compositional requirements in Standard K2 and the New Zealand Food Standard 1996 Amendment No 11 are considered unnecessary because they address quality issues rather than protect public health and safety and are not needed to prevent fraud and deception. For this reason, no compositional requirements are proposed to be included in draft Standard 1.2.3. If the name of a food includes the name ‘royal jelly’ or a food claims to contain royal jelly then this name or claim cannot be false, misleading or deceptive under food law or fair trading law. Therefore the current compositional requirements for royal jelly are proposed to be deleted.

9.1.2 Bee pollen

Bee pollen can be used as a food, as well as an ingredient in foods and therapeutic goods. P161 has already proposed the inclusion of the current definition of pollen and a new definition of bee pollen and the requirement for mandatory declaration of bee pollen in the label of bee pollen food products. These requirements contained in draft standard 1.2.3 are confirmed and are proposed to be reflected in Standard K2 of the Food Standards Code and in the New Zealand Food Standard 1996.

Consistent with the assessed levels of risk to public health, it is proposed that draft Standard 1.2.3 not require a warning statement in the label of foods containing bee pollen and thus the statement presently required by Standard K2 and the New Zealand Food Standard 1996 Amendment No 11 is proposed for deletion.

9.1.3 Propolis

Propolis may be used as an ingredient in foods and therapeutic goods. P161 has already proposed a new definition of propolis and the requirement for mandatory declaration of propolis in the label of a food containing propolis. These requirements contained in draft standard 1.2.3 are confirmed and are proposed to be reflected in Standard K2 of the Food Standards Code and in the New Zealand Food Standard 1996.

9.2 New Zealand

In New Zealand, royal jelly products may be sold as a food or a dietary supplement depending on the intended purpose of the product. The requirements for royal jelly,
bee pollen and propolis are given in the New Zealand Food Standard 1996 Amendment No. 11, that applies to foods, including dietary supplements. General composition and other labelling requirements are contained in the Dietary Supplement Regulations 1985, the Food Regulations 1984, or the Australian Food Standards Code, recognised as alternative standards in New Zealand. The general safety requirements for foods, including dietary supplements, are specified in the Food Act 1981, that food for sale, including dietary supplements, must not be harmful. However, there are no specific provisions in the Dietary Supplement Regulations, 1985, or the Food Regulations 1984, that apply to these products.

9.3 TGA Section 7 Declaration

In December 1998, after receiving advice from CMEC, the TGA proposed under section 7 of the Therapeutic Goods Act 1989, to declare goods containing royal jelly which are presented in the form of capsules, phials or powders to be therapeutic goods. The purpose of a section 7 declaration is to provide certainty to industry and regulatory bodies about the appropriate regulatory classification of a group of goods in instances where confusion exists as to the boundary between food and drugs. The rationale for the proposal was that, when sold in the form of capsules, phials and powders, royal jelly is clearly presented in the form of a therapeutic good and promoted for its therapeutic value.

The submission period for the section 7 declaration closed on 12 February 1999. After consideration of submissions received, the TGA stated that the declaration would take effect at the time of the removal of the relevant provisions for royal jelly within the Food Standards Code, should this be a consequence of Proposal P154.

10 REGULATORY IMPACT STATEMENT

10.1 Problem

To assess the risk to public health from royal jelly, bee pollen and propolis food products; also to assess the potential for insufficient or misleading information or consumer deception in relation to these risks, and to determine the costs and benefits of various regulatory options to deal with these.

10.2 Objective

The protection of public health and safety, provision of adequate information to consumers and prevention of misleading information and fraud and deception.

10.3. Options for regulation

All options relating to Standard K2 of the Food Standards Code also apply to the New Zealand Food Standard 1996, and draft Standard 1.2.3 of the joint Australia New Zealand Food Standards Code. Depending upon their intended purpose, royal jelly, bee pollen and propolis products would continue to be classed as foods or therapeutic goods in Australia and as foods or dietary supplements in New Zealand, until such
time as ANZFA’s recommendation to TGA to clarify the regulatory status of these products was respectively implemented.

**Option 1a - retain the status quo in both Australia and New Zealand**

This option would retain the current requirements for royal jelly, bee pollen and propolis food products in the Australian Food Standards Code, which include compositional requirements for royal jelly and the current warning statements for royal jelly and pollen. In New Zealand warning statements (variations from the Australian wording) are required for all three bee products regulated as food including dietary supplements. This option recognises that a different range of warning statements are currently required in Australia and New Zealand, and that no reference is made to recommendations to TGA to clarify the regulatory status of royal jelly, bee pollen and propolis products.

**Option 1b – retain the status quo in Australia but New Zealand adopt the Australian requirements**

This option would retain the current requirements for royal jelly, bee pollen and propolis food products in the Australian Food Standards Code, which include compositional requirements for royal jelly and the current warning statements for royal jelly and pollen. The New Zealand Food Standard 1996 Amendment No 11 would be amended to adopt those same provisions. In addition, this option explores the regulatory impact of New Zealand adopting the current Australian regime to apply to foods and dietary supplements, consistent with the Treaty. This option recognises that no reference is made to recommendations to TGA to clarify the regulatory status of royal jelly, bee pollen and propolis products.

**Option 2 - Change regulations consistent with assessed level of risk – Amended warning statement for royal jelly only; mandatory declaration of royal jelly, bee pollen, and propolis.**

This option would introduce amended requirements into the Australian Food Standards Code for royal jelly, bee pollen and propolis food products as explained in sections 9.1.1 –9.1.3, and consistent with the assessed level of risk to the Australian and New Zealand populations, including vulnerable at-risk subpopulations. This option also includes ANZFA’s recommendations to TGA to clarify the regulatory status of royal jelly, bee pollen and propolis products.

**Option 3 – non-regulatory approach to develop an industry Code of Practice – advisory statement for royal jelly only; mandatory declaration of royal jelly, bee pollen, and propolis**

Option 3 considers a non-regulatory approach to the development of a Code of Practice that would need to be subsequently supported and administered by industry. Such a Code of Practice would be expected to achieve the same public health and information outcomes as regulation including the use of an appropriate voluntary advisory statement on royal jelly products. It could also cover good manufacturing practice for royal jelly, bee pollen or propolis food products. This option includes
ANZFA’s recommendations to TGA to clarify the regulatory status of royal jelly, bee pollen and propolis products.

10.4 Impact statement

Affected parties - Consumers of royal jelly, bee pollen and propolis food products, manufacturers and importers of these products, regulatory authorities (government).

Option 1a - Retain status quo in both Australia and New Zealand

<table>
<thead>
<tr>
<th>Affected party</th>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>No foreseeable additional costs. Consumers may unnecessarily avoid products in response to the current royal jelly and pollen warning statements, which, for royal jelly sold in Australia, and other bee products, may be overstating the recently assessed levels of risk to public health.</td>
<td>High protection of at-risk consumers through the advice contained in the strong Australian and milder New Zealand warning statements (royal jelly) and the bee pollen (Aust and NZ) and propolis product (NZ only) warning statements.</td>
</tr>
<tr>
<td>Manufacturer s/Importers</td>
<td>On-going cost of labelling and compliance with the regulations. Continued low sales of royal jelly in Australia from a contracted industry base due to unnecessary avoidance of the product by some consumers in response to the warning statement. Potential decrease in pollen sales for the same reason. Potential decrease in bee product sales in New Zealand due to unnecessary avoidance of the product by some consumers in response to the warning statements. Differences in regulatory requirements between Australia and New Zealand and uncertainties about regulatory status as a food or otherwise, adversely impact on business and bilateral trade.</td>
<td>Low risk of complaints and legal action from Australian consumers in the event of an allergic reaction to royal jelly or bee pollen. Slightly higher risk for propolis products in Australia. Low risk of complaints and legal action from New Zealand consumers of bee products.</td>
</tr>
<tr>
<td>Government</td>
<td>Cost of enforcement particularly resulting from different regulatory requirements in Australia and New Zealand. Cost of non-compliance with WTO. Cost of duplication of standards in the food standards and therapeutic goods regulations.</td>
<td>Present level of public health and safety outcome, which has not recorded any deaths attributable to royal jelly consumption since introduction of the current Australian strong warning statement.</td>
</tr>
</tbody>
</table>
Option 1b - Retain status quo in Australia but New Zealand to adopt Australian requirements

<table>
<thead>
<tr>
<th>Affected party</th>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>No foreseeable additional costs. Consumers may unnecessarily avoid products in response to the current royal jelly and pollen warning statements, which, for royal jelly sold in Australia, and other bee products, may be overstating the recently assessed levels of risk to public health.</td>
<td>High protection of at-risk consumers through the advice contained in the strong warning statements.</td>
</tr>
<tr>
<td>Manufacturer(s)/Importers</td>
<td>On-going cost of labelling and compliance with the regulations. Continued low sales of royal jelly in Australia from a contracted industry base due to unnecessary avoidance of the product by some consumers in response to the warning statement. Potential decrease in pollen sales for the same reason. Same adverse impact on New Zealand royal jelly industry as seen in Australia due to unnecessary avoidance of the product by some consumers in response to the warning statement. No change for bee pollen products, but a potential increase in sales of propolis products due to removal of warning statement. Differences in regulatory requirements between Australia and New Zealand and uncertainties about regulatory status as a food or otherwise, adversely impact on business and bilateral trade.</td>
<td>Low risk of complaints and legal action from Australian and New Zealand consumers in the event of an allergic reaction to royal jelly and pollen products. Slightly higher risk from New Zealand consumers of propolis products.</td>
</tr>
<tr>
<td>Government</td>
<td>Smaller cost of enforcement as consistent regulatory requirements for foods than Option 1a. Cost of non-compliance with WTO. Cost of duplication of standards in the food standards and therapeutic goods regulations.</td>
<td>Present level of Australian public health and safety outcome extended to New Zealand.</td>
</tr>
</tbody>
</table>
Option 2 - Change regulations consistent with assessed level of risk – Amended warning statement for royal jelly only; mandatory declaration of royal jelly, bee pollen, and propolis

<table>
<thead>
<tr>
<th>Affected party</th>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>No foreseeable additional costs except that, compared with Option 1, fewer consumers may unnecessarily avoid consuming the products in response to the appropriately pitched royal jelly warning statement. Fewer consumers also unnecessarily avoid pollen and propolis products.</td>
<td>Consumers will be appropriately and consistently informed of the risks to susceptible individuals from consumption of royal jelly products commensurate with the assessed public health risks. Consumers of other bee products will always be informed of the presence of bee pollen or propolis in food products.</td>
</tr>
<tr>
<td>Manufacturers/Importers</td>
<td>Cost of re-labelling and on-going compliance costs. Potential for increase in sales compared with Option 1 in response to the appropriately pitched royal jelly warning statement, and only mandatory declaration of other bee product ingredients in foods.</td>
<td>Greater risk than Option 1 (but now appropriately matched to the level of risk) of complaints and legal action from consumers due to a more appropriately pitched royal jelly warning statement plus the mandatory declaration of bee products in food products. Subject to TGA’s adoption of ANZFA’s recommendations, clarification of regulatory status of bee products at Australian interface, thus facilitating trade and reducing industry costs.</td>
</tr>
<tr>
<td>Government</td>
<td>Smaller cost of enforcement than Options 1a or 1b of Trans Tasman traded products. Cost of non-compliance with WTO.</td>
<td>Public health and safety outcome maintained. Subject to TGA’s adoption of ANZFA’s recommendations, clarification of Australian regulatory status of bee products thus reducing enforcement costs.</td>
</tr>
</tbody>
</table>

Option 3 – Non-regulatory approach to develop an industry Code of Practice – advisory statement for royal jelly only; mandatory declaration of royal jelly, bee pollen, and propolis

The success of this approach is contingent on the industry and perhaps government reaching agreement on appropriate standards for good manufacturing practice, and for labelling and advertising that includes an appropriately pitched and relatively consistent advisory statement for royal jelly food products. It is also contingent upon industry’s effective administration of, and broad voluntary compliance with the Code. Such a Code would benefit from clarification of the regulatory status of these
products. The costs and benefits of such a Code for each of the affected parties entirely depend on the timeliness and level of success of implementation of the Code of Practice.

<table>
<thead>
<tr>
<th>Affected party</th>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Depending on the success and timeliness of the Code, costs would be the same as Option 2 if highly successful and implemented quickly. Additional costs may accrue through consumer confusion if there is an inconsistent approach to labelling or provision of consumer information on the safety aspects of the product, through to even higher costs due to diminished protection of public health because of inadequate information.</td>
<td>Depending on the success and timeliness of the Code, benefits would be the same as Option 2 if highly successful and quickly implemented, but would reduce in parallel with the level of adherence to the Code and any delay in its implementation. Potential for consumer confusion and increased risk to public health if disparate forms of advisory statement were used.</td>
</tr>
<tr>
<td>Manufacturer(s)/Importers</td>
<td>Depending on the success and timeliness of the Code, costs would be the same as Option 2 if highly successful and timely, but with an additional cost of administration of the Code being borne by the industry. Reliance on industry persuasion rather than strong sanctions to encourage compliance. Potential loss of consumer confidence in the product if the industry does not consistently label and inform on the safety aspects of the product.</td>
<td>Depending on the success and timeliness of the Code, benefits would be, at best, the same as Option 2 if highly successful and timely, but not be as great if the industry did not consistently adhere to the Code or implementation was delayed. Greater or equal risk than Option 2 of complaints and legal action from consumers depending on success and timeliness of Code of Practice.</td>
</tr>
<tr>
<td>Government</td>
<td>Depending on the success and timeliness of the Code, costs would be less than Option 2 if successfully implemented because of reduced enforcement costs. Some costs in developing a non-regulatory approach and monitoring the overall success or otherwise of the Code. Cost of liability if public health and safety is not adequately protected.</td>
<td>Depending on the success of the Code, benefits would be the same as Option 2 if the Code was successfully implemented in a timely manner and any advisory statement was consistently formed and applied.</td>
</tr>
</tbody>
</table>
10.5 Assessment of options

The primary benefit of Option 1b over Option 1a is for manufacturers who would be able to label their products with the same statement whether destined for Australian or New Zealand markets. Governments would incur higher enforcement costs however, because of other differences between national regulations. The benefits to consumers of Options 1 and 2 are similar. Both options would ensure that consumers were provided with adequate information about royal jelly to make an informed choice about whether they wish to consume the product. However, fewer consumers would unnecessarily avoid royal jelly and bee pollen food products under Option 2 than either of Options 1a and 1b.

Although the costs for manufacturers and importers may be greatest for Option 1a but similar under Options 1b and 2, the benefits of Option 2 considerably exceed Option 1 because of the more targeted label requirements that would result in the removal of the pollen warning statement, and a more finely honed warning statement commensurate with the recently assessed level of risk.

Options 1 and 2 would present some costs and benefits to government in the form of costs of enforcement and, in the case of option 1, costs associated with different requirements for royal jelly presented as a food and as a therapeutic good in Australia, and under Option 1a, different regulations for royal jelly between Australia and New Zealand. Nevertheless, both options would help to protect the health of individuals susceptible to severe allergic reactions to royal jelly.

Options 1 and 2 may present a barrier to trade and may breach the WTO agreement; however, this may be justified on the basis of protection of public health and safety.

Given the specific risks associated with bee product substances not commonly consumed, Option 3, development of a non-regulatory Code of Practice, appears to be inconsistent with the proposed regulatory requirements for labelling of other food allergens. Although Option 3 is potentially a viable option, its viability is contingent upon a timely introduction; the industry’s collective support for a Code of Practice; and its effective administration of, and comprehensive voluntary compliance with the Code to ensure adequate protection of consumers from potential adverse reactions. The industry would need to demonstrate that a Code of Practice could adequately mitigate the public health risks of royal jelly. ANZFA invites comment on this issue.

Preferred option

Option 2 is the preferred option because it:
- protects the public health and safety of consumers of royal jelly and other bee products in the form of food, commensurate with the assessed risk;
- provides adequate information for consumers to make an informed choice;
- provides consistent information to minimise consumer confusion;
- reduces the disincentive to consumer consumption resulting from the current strong warning statement;
- is less prescriptive than Option 1 with respect to food standards; and
ultimately aims to remove regulatory duplication in Australia and establish consistent regulations for royal jelly and other bee products in New Zealand.

11. OTHER CONSIDERATIONS

11.1 Type size

Proposal P142 - Review of Print Size and Quality has proposed that warning statements should appear in a print size of 3 mm, where the smallest letter must not be less than 3 mm. Therefore any statement in the label of a food that contains royal jelly would be required to be at least 3mm in height and must be prominent, legible and in English. Small packages are not exempt from this requirement.

11.2 Commencement and Mandatory Standards in New Zealand

This Proposal has developed two sets of drafting –

(1) a draft variation to Standard K2 of the Food Standards Code requiring a warning statement on the label of royal jelly and foods containing royal jelly and a requirement always to declare the presence of bee pollen, propolis and royal jelly in the ingredient list or elsewhere on the label of food.

(2) provisions in draft Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations for inclusion in the joint Australia New Zealand Food Standards Code (the Joint Code) which have the same effect as those provisions in the re-drafted Standard K2.

Commencement of the Joint Code

It is anticipated that the Joint Code, including those provisions in Standard 1.2.3, will be recommended to the Australia New Zealand Food Standards Council in November 2000. If adopted by the Council, the Joint Code will take effect from gazettal in January 2001. In general terms, the Joint Code will operate as an alternative to present requirements in Australia and New Zealand. Accordingly, in Australia, food will need to comply with either the current Food Standards Code or the Joint Code. In New Zealand, food will need to comply with either the New Zealand Food Regulations 1984 or the Standards in the current Food Standards Code incorporated under the New Zealand Food Standard 1996, or the new Joint Code.

Commencement of Standard K2

(1) ANZFA is considering the possibility of delaying the commencement of Standard K2 as re-drafted for a period of between three and six months to enable producers to adjust to the new labelling requirements.

(2) Additionally, New Zealand is considering whether the re-drafted Standard K2 should be declared a mandatory Standard in New Zealand. Attachment 10 to this Report sets out the ‘Regulatory Situation in New Zealand for Warning Statements for
Royal Jelly, Bee Pollen and Propolis’. This Attachment should be read in conjunction with the following commentary. **Submitters are requested to provide comment on these two issues in particular**, having regard to the following options:

1. If the commencement of Standard K2 is delayed by three or more months then, for Australian purposes, the current Standard K2 in the Food Standards Code continues to apply until January 2001, when either the current K2 in the Food Standards Code or the provisions of Standard 1.2.3 in the Joint Code will apply as alternatives. When the re-drafted Standard K2 takes effect then this Standard will operate as an alternative to the provisions in Standard 1.2.3 of the Joint Code.

or

2. If the commencement of Standard K2 is delayed by three or more months then, for New Zealand purposes, the New Zealand Food Standard 1996 Amendment No.11 continues to apply until the re-drafted Standard K2 takes effect. As the New Zealand Food Standard Amendment No.11 was issued as a mandatory standard, the relevant Joint Code provisions in Standard 1.2.3 will not apply in New Zealand until the Joint Code becomes the sole Code (in or about January 2003). Therefore, from January 2001 the New Zealand Food Standard 1996 Amendment No.11 will continue to apply in New Zealand, until such time as the re-drafted Standard K2 replaces it.

or

3. If re-drafted Standard K2 replaces the New Zealand Food Standard 1996 Amendment No 11 and is issued as a mandatory Standard in New Zealand on its commencement, then producers will be required to comply with this Standard alone. However, there is no effective difference between the re-drafted K2 and the provisions in Standard 1.2.3 of the Joint Code. Accordingly, the same labelling requirements would apply to both New Zealand and Australian producers once the re-drafted Standard K2 and Standard 1.2.3 are in place.

or

4. If re-drafted Standard K2 is not issued as a mandatory Standard in New Zealand, then until the joint Code becomes the sole Code (in or about January 2003), producers could utilise either the re-drafted Standard K2 or the provisions in Standard 1.2.3 of the Joint Code, or the New Zealand Food Regulations 1984. As the New Zealand Food Regulations do not contain provisions regulating the labelling of royal jelly, bee pollen and propolis, New Zealand producers/importers could rely on the regulations to avoid the warning statement and declaration requirements altogether. This outcome would not protect public health. Furthermore, Australian producers would be required to label their products with the warning statement and/or declarations to comply with Standard K2 as re-drafted or the provisions in Standard 1.2.3.

**12 CONCLUSIONS**
It is concluded that although reactions to royal jelly are rare, they occur more readily than reactions to propolis or bee pollen and are more severe and serious. The population subgroup that suffers from asthma and related allergies is most at risk. A targeted warning statement in the label of royal jelly and food that contains royal jelly is necessary in order to inform susceptible people of the risk of consumption of royal jelly because these foods are not common and are promoted as health foods.

In relation to bee pollen, there is no evidence to suggest that bee pollen causes severe life threatening reactions. However, bee pollen has been implicated in allergic reactions and therefore the requirement to declare its presence in a food will alert those people who are aware of their allergy to avoid bee pollen.

Similarly, there is evidence to suggest that propolis may cause serious adverse reactions; however, such reactions are very rare and there is little evidence to warrant a warning or advisory statement on propolis food products. However, propolis has been implicated in allergic reactions and therefore the requirement to declare its presence in a food will alert those people who are aware of their allergy to avoid bee pollen.

This report concludes that, on the basis of assessed risk to public health, a warning statement in the label of a food presented as royal jelly or containing royal jelly remains justified because of the considerable potential for royal jelly to cause severe allergic reactions, including life threatening reactions, as assessed by the TGA’s Complementary Medicines Evaluation Committee, and the New Zealand Report on the Findings of the Bee Products Warning Review Working Group, August 1999 (Working Group). The wording of the statement is proposed to be amended consistent with the assessed risk, and to delete reference to “fatalities”.

*ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS. ASTHMA SUFFERERS ARE MOST AT RISK*

In addition, it is proposed to require definitions of royal jelly, propolis and bee pollen, as well as the declaration of all three bee products in the label of foods containing such ingredients.

Amendments are proposed to the following standards to give effect to these conclusions:

Standard K2 – Honey and Related Products, of the Australian Food Standards Code; and
Draft Standard 1.2.3 of the draft Joint Australia New Zealand Food Standards Code.

Given that bee products cross the regulatory spectrum as foods or therapeutics in Australia; and foods including dietary supplements in New Zealand; this Proposal, while applying only to foods, aims ultimately to facilitate clarification of the regulatory status of royal jelly products and to achieve a coordinated approach to the labelling requirements for all regulated bee products. NZ MOH has indicated that the warning labelling statements adopted for food, also would be made mandatory for dietary supplements, as foods and dietary supplements that pose the same risks should
be managed so as to achieve the same outcome. For New Zealand, this consultation applies to both foods and dietary supplements (refer section 11.2 and Attachment 10 for details).

NZ MOH has indicated that the labelling statements adopted for food, also would be made mandatory for dietary supplements since foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. For New Zealand, this consultation applies to both foods and dietary supplements.

This Proposal recommends to the TGA that it finalises the draft proposal issued in 1998 under section 7 of the Therapeutic Goods Act 1989 to declare royal jelly presented in capsule, phial or powder form to be a therapeutic good.

Public comment is sought on these recommendations. The bee product industry is encouraged to consider the development of a Code of Practice on good manufacturing practice for bee products and appropriate labelling or education to alert consumers to a potential risk of allergic reaction.

13. ATTACHMENTS:

2. Proposed Draft Variations

3. Statement of Reasons

4. Summary of submissions and correspondence to ANZFA since 1997.

5. Background to the current regulations


9. Report of Dr Sheryl van Nunen

10. Report of Dr Penny Fitzharris

11. Regulatory Situation in New Zealand for Warning Statements for Royal Jelly, Bee Pollen and Propolis
The Food Standards Code is amended by omitting Standard K2 and inserting -

STANDARD K2

HONEY AND RELATED PRODUCTS

Table of Provisions

1 Interpretation
2 Composition of honey
3 Labelling of bee pollen, propolis and royal jelly
4 Warning statement for royal jelly

Clauses

1 Interpretation

bee pollen means pollen collected from the legs of bees.

honey means the nectar and saccharine exudations of plants gathered, modified and stored by the honey bee.

pollen means the fine powdery substance discharged from the anthers of flowers.

propolis means the reddish resinous cement collected by bees from the buds of trees which is used to stop up crevices in hives and strengthen the cells.

royal jelly means the milky white viscous secretion from the salivary glands of honey bees.

2 Composition of honey

(1) Honey must contain no less than 600 g/kg of reducing sugars, expressed as invert sugar.

(2) Honey must not contain more than –

(a) 200 g/kg of water;
(b) 50 g/kg of sucrose naturally present;
(c) 7.5 g/kg of ash.

3 Labelling requirements for bee pollen, propolis and royal jelly
(1) Notwithstanding paragraphs (5)(e)(iii) and (iv) of Standard A1, the presence of bee pollen, propolis or royal jelly in a food must always be declared in the label on or attached to the package of the food.

(2) Where food containing bee pollen, propolis or royal jelly is offered for retail sale other than in a package the information required by subclause (1) must be –

(a) displayed on or in connection with the display of food; or
(b) provided to the purchaser upon request.

**Editorial note:**
The declaration required by subclause 3(1) may made in the ingredient list.

### 4 Warning statement for royal jelly

(1) Where royal jelly is presented as a food or present in a food the label on or attached to the package of food must include the statement, in type of 3mm, -

“ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS. ASTHMA SUFFERERS ARE MOST AT RISK”.

(2) Where royal jelly or food containing royal jelly is displayed for retail sale other than in a package, the statement required by subclause 4(1) must be displayed on or in connection with the display of food.
Standard 1.2.3

Mandatory Warning and Advisory Statements and Declarations

**Purpose**
This Standard sets out mandatory advisory statements and declarations which must be made in relation to certain foods or foods containing certain substances.

**Table of Provisions**

1. Interpretation
2. Mandatory advisory statements and declarations
3. Mandatory warning statements and declarations
4. Mandatory declaration of certain substances in food
5. Food containing polyols, isomalt, polydextrose etc to bear advisory statement

**Clauses**

1. **Interpretation**

In this Standard -

- **bee pollen** means pollen collected from the legs of bees.
- **milk substitutes** means any liquid able to be used as a substitute for milk, but does not include infant formula.

**Editorial note:**

Soy milk and rice milk are examples of milk substitutes.

- **pollen** means the fine powdery substance discharged from the anthers of flowers.
- **propolis** means the reddish resinous cement collected by bees from the buds of trees which is used to stop up crevices in hives and strengthen the cells.
- **royal jelly** means the milky white viscous secretion from the salivary glands of honey bees.
Mandatory advisory statements and declarations

(1) The label on a package of food listed in column 1 of the Table to this clause must include the advisory statement listed in relation to that food in column 2 of the Table.

(2) Where a food listed in column 1 of the Table to this clause, is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the advisory statement listed in relation to that food in column 2 of the Table, must be –

(a) displayed on or in connection with the display of the food; or
(b) provided to the purchaser upon request.

Editorial note:

Paragraph 2(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.

Table to clause 2

<table>
<thead>
<tr>
<th>Column 1 Food</th>
<th>Column 2 Advisory Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk, modified, dried, evaporated and skim milk, and milk substitutes</td>
<td>Health authorities recommend the product not be used to replace (a) breast milk or (b) infant formula products standardised in Standard 2.9.1 for infants under 12 months of age</td>
</tr>
<tr>
<td>Unpasteurised milk and liquid milk products</td>
<td>Statement to the effect that the product has not been pasteurised</td>
</tr>
<tr>
<td>Food containing aspartame</td>
<td>Statement to the effect that the product contains phenylalanine</td>
</tr>
<tr>
<td>Unpasteurised egg products</td>
<td>Statement to the effect that the product is unpasteurised</td>
</tr>
<tr>
<td>Food containing quinine</td>
<td>Statement to the effect that the product contains quinine</td>
</tr>
<tr>
<td>Kola beverages containing added caffeine</td>
<td>Statement to the effect that the product contains caffeine</td>
</tr>
<tr>
<td>Food containing guarana or extracts of guarana</td>
<td>Statement to the effect that the product contains caffeine</td>
</tr>
</tbody>
</table>

Drafting note:

The advisory statement relating to milk will be the subject of a further round of public consultation, and is presently reserved with [ ] brackets.
3 Mandatory warning statements and declarations

(1) The label on a package of food listed in column 1 of the Table to this clause must include the warning statement listed in relation to that food in column 2 of the Table.

(2) Where a food listed in column 1 of the Table to this clause, is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the warning statement listed in relation to that food in column 2 of the Table, must be displayed on or in connection with the display of the food.

<table>
<thead>
<tr>
<th>Column 1 Food</th>
<th>Column 2 Warning Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal jelly presented as a food or food containing royal jelly</td>
<td>[“ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS. ASTHMA SUFFERERS ARE AT MOST RISK”]</td>
</tr>
<tr>
<td>Food, other than food standardised in Part 2.7, which contains more than 50 mL/L of ethanol by volume at 20°C.</td>
<td>In conjunction with the declaration of alcohol content of the food - the following statement – “KEEP OUT OF REACH OF CHILDREN”</td>
</tr>
</tbody>
</table>

Drafting note:
Both warning statements in the Table to clause 3 are yet to be finalised. The statement in relation to food containing royal jelly is not yet settled as it awaits the conclusions of Proposal P154. The statement in relation to the declaration of the presence of alcohol awaits the conclusion of a Proposal.

4 Mandatory declaration of certain substances in food

(1) The presence in a food of any of the substances listed in the Table to this clause, must be declared in accordance with subclause (2), when present as -

(a) an ingredient; or
(b) an ingredient of a compound ingredient; or
(c) a food additive or component of a food additive; or
(d) a processing aid or component of a processing aid.

(2) Any substances required to be declared by subclause (1) must be –

(a) declared on the label on a package of the food; or
(b) where the food is not required to bear a label pursuant to clause 2 of Standard 1.2.1 -

(i) displayed on or in connection with the display of the food; or
(ii) provided to the purchaser upon request.

Editorial note:

Paragraph 4(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.

<table>
<thead>
<tr>
<th>Table to clause 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively</td>
</tr>
<tr>
<td>Crustacea and their products</td>
</tr>
<tr>
<td>Egg and egg products</td>
</tr>
<tr>
<td>Fish and fish products</td>
</tr>
<tr>
<td>Milk and milk products</td>
</tr>
<tr>
<td>Nuts and sesame seeds and their products</td>
</tr>
<tr>
<td>Peanuts and soybeans, and their products</td>
</tr>
<tr>
<td>Added Sulphites in concentrations of 10mg/kg or more</td>
</tr>
<tr>
<td>Royal jelly presented as a food or royal jelly present in a food</td>
</tr>
<tr>
<td>Bee pollen</td>
</tr>
<tr>
<td>Propolis</td>
</tr>
</tbody>
</table>
Editorial notes:

1. Clause 4 can be complied with by listing those substances in the Table in the ingredient list.

2. Any exemptions in relation to ingredient listing do not override the requirement to declare the presence of the substances listed in the Table to clause 4.

3. Manufacturers occasionally substitute one ingredient for another within the same class of foods. Where this involves a substance listed in the Table to clause 4 there must be an indication on the label that the substance is in the food. Manufacturers may indicate in the ingredient list that the product contains one substance or another (e.g. brazil nuts or cashew nuts) in cases where substitutions occur regularly.

4. Expressions such as ‘egg and egg product’ or ‘crustacea and their products’ include all products derived from the substance listed in the Table to clause 4.

5. Sulphites should be declared in the same manner as other food additives.

5 Advisory statement in relation to foods containing polyols or polydextrose

(1) The label on a package of food must include an advisory statement to the effect that excess consumption of the food may have a laxative effect, where the food contains any of the substances –

   (a) listed in Table 1 to this clause, either singularly or in combination at a level of or in excess of 10g/100g; or

   (b) listed in Table 2 to this clause, either singularly or in combination at a level of or in excess of 25g/100g; or

   (c) listed in Table 1 in combination with any of the substances listed in Table 2 at a level of or in excess of 10g/100g.

(2) Where food containing any of the substances referred to in subclause (1) is not required to bear a label pursuant to clause 2 of Standard 1.2.1, an advisory statement to the effect that excess consumption of the food may have a laxative effect, must be –

   (a) displayed on or in connection with the display of the food; or

   (b) provided to the purchaser upon request.

Editorial note:

Paragraph 5(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.
<table>
<thead>
<tr>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactitol</td>
</tr>
<tr>
<td>Maltitol</td>
</tr>
<tr>
<td>Maltitol syrup</td>
</tr>
<tr>
<td>Xylitol</td>
</tr>
<tr>
<td>Mannitol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
</tr>
<tr>
<td>Erythritol</td>
</tr>
<tr>
<td>Isomalt</td>
</tr>
<tr>
<td>Polydextrose</td>
</tr>
</tbody>
</table>

Table 1 to clause 5

Table 2 to clause 5
STATEMENT OF REASONS – DRAFT

PROPOSAL P154

FOR RECOMMENDING A VARIATION TO STANDARD K2 - HONEY AND RELATED PRODUCTS - TO SPECIFY THE REQUIREMENTS FOR ROYAL JELLY, BEE POLLEN AND PROPOLIS, INCLUDING THE NEED FOR LABEL WARNING STATEMENTS; AND

ADDITION OF CORRESPONDING PROVISIONS IN DRAFT STANDARD 1.2.3 – MANDATORY WARNING AND ADVISORY STATEMENTS AND DECLARATIONS OF THE DRAFT AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

The Australia New Zealand Food Authority (ANZFA) has before it a Proposal to amend the Australian Food Standards Code Standard K2 - Honey and Related Products, to include provisions for labelling requirements for foods that present as royal jelly or that contain royal jelly, bee pollen and propolis.

ANZFA recommends the adoption of the draft variation, as amended, on the basis of recent and comprehensive risk assessments of royal jelly, bee pollen and propolis, and for the following reasons:

1 Royal jelly has been implicated in severe adverse reactions and at least one death. There is a need to inform people with asthma and allergies, who are most at risk of very serious allergic reactions to royal jelly, and who may be unaware of that risk, that consumption of royal jelly when presented as a food, and as a food ingredient may pose a risk to their health and well being.

It is proposed that the following statement be mandated in the label of royal jelly when presented as a food, and of foods containing royal jelly:

ROYAL JELLY MAY CAUSE VERY SERIOUS ALLERGIC REACTIONS. ASTHMA SUFFERERS ARE MOST AT RISK

This statement fulfils the requirements for the statement to

- apply to royal jelly presented as a food as well as to a food containing royal jelly as an ingredient;
- refer to the at-risk target group, but also to others at risk;
- describe an appropriate level of risk, but emphasise that risk particularly for the target group; and
- be meaningful and succinct.
2 Bee pollen and propolis have been reported to be implicated in allergic reactions; however, these reactions are rare and are not as serious as those caused by royal jelly. There is a need to inform people who know they are allergic to bee pollen or propolis that a product contains bee pollen and/or propolis. Bee pollen and/or propolis are proposed to be declared in the label of the food at all times, for example in the ingredient list, including on small packages and irrespective of the final concentration in the food.

3 ANZFA recommends that the Australian Therapeutic Goods Administration finalises its proposal to declare royal jelly in capsule, powder and phial form as therapeutic goods, and that the New Zealand Ministry of Health considers applying the same labelling approach as proposed here for royal jelly, bee pollen and propolis products regulated as dietary supplements.

4 The requirements recommended in this Proposal refer to royal jelly when presented as a food, and royal jelly, bee pollen and propolis added to a food. It does not refer to royal jelly, bee pollen or propolis that is naturally present in a food (i.e. bee pollen naturally present in honey) or present due to unintentional contamination of products.

Definitions of royal jelly, bee pollen, pollen and propolis are proposed to facilitate the regulation of these substances.

COMMENCEMENT AND MANDATORY STANDARDS IN NEW ZEALAND

This Proposal has developed two sets of drafting –

(1) a draft variation to Standard K2 of the Food Standards Code requiring a warning statement on the label of royal jelly and foods containing royal jelly and a requirement always to declare the presence of bee pollen, propolis and royal jelly in the ingredient list or elsewhere on the label of food.

(2) provisions in draft Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations for inclusion in the joint Australia New Zealand Food Standards Code (the Joint Code) which have the same effect as those provisions in the re-drafted Standard K2.

Commencement of the Joint Code

It is anticipated that the Joint Code, including those provisions in Standard 1.2.3, will be recommended to the Australia New Zealand Food Standards Council in November 2000. If adopted by the Council, the Joint Code will take effect from gazettal in January 2001. In general terms, the Joint Code will operate as an alternative to present requirements in Australia and New Zealand. Accordingly, in Australia, food will need to comply with either the current Food Standards Code or the Joint Code. In New Zealand, food will need to comply with either the New Zealand Food Regulations 1984 or the Standards in the current Food Standards Code incorporated under the New Zealand Food Standard 1996, or the new Joint Code.
Commencement of Standard K2

(1) ANZFA is considering the possibility of delaying the commencement of Standard K2 as re-drafted for a period of between three and six months to enable producers to adjust to the new labelling requirements.

(2) Additionally, New Zealand is considering whether the re-drafted Standard K2 should be declared a mandatory Standard in New Zealand. Annex 1 of this Paper sets out the ‘Regulatory Situation in New Zealand for Warning Statements for Royal Jelly, Bee Pollen and Propolis’. This Annex should be read in conjunction with the following commentary. **Submitters are requested to provide comment on these two issues in particular**, having regard to the following options:

1. If the commencement of Standard K2 is delayed by three or more months then, for Australian purposes, the current Standard K2 in the Food Standards Code continues to apply until January 2001, when either the current K2 in the Food Standards Code or the provisions of Standard 1.2.3 in the Joint Code will apply as alternatives. When the re-drafted Standard K2 takes effect then this Standard will operate as an alternative to the provisions in Standard 1.2.3 of the Joint Code.

or

2. If the commencement of Standard K2 is delayed by three or more months then, for New Zealand purposes, the New Zealand Food Standard 1996 Amendment No.11 continues to apply until the re-drafted Standard K2 takes effect. As the New Zealand Food Standard Amendment No.11 was issued as a mandatory standard, the relevant Joint Code provisions in Standard 1.2.3 will not apply in New Zealand until the Joint Code becomes the sole Code (in or about January 2003). Therefore, from January 2001 the New Zealand Food Standard 1996 Amendment No.11 will continue to apply in New Zealand, until such time as the re-drafted Standard K2 replaces it.

or

3. If re-drafted Standard K2 replaces the New Zealand Food Standard 1996 Amendment No 11 and is issued as a mandatory Standard in New Zealand on its commencement, then producers will be required to comply with this Standard alone. However, there is no effective difference between the re-drafted K2 and the provisions in Standard 1.2.3 of the Joint Code. Accordingly, the same labelling requirements would apply to both New Zealand and Australian producers once the re-drafted Standard K2 and Standard 1.2.3 are in place.

or

4. If re-drafted Standard K2 is not issued as a mandatory Standard in New Zealand, then until the joint Code becomes the sole Code (in or about January 2003), producers could utilise either the re-drafted Standard K2 or the provisions in Standard 1.2.3 of the Joint Code, or the New Zealand Food Regulations 1984. As the New Zealand Food Regulations do not contain provisions regulating the
labelling of royal jelly, bee pollen and propolis, New Zealand producers/importers could rely on the regulations to avoid the warning statement and declaration requirements altogether. This outcome would not protect public health. Furthermore, Australian producers would be required to label their products with the warning statement and/or declarations to comply with Standard K2 as re-drafted or the provisions in Standard 1.2.3.

REGULATORY IMPACT

ANZFA has undertaken a regulatory impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that amendment to the Food Standards Code, the draft Joint Australia New Zealand Food Standards Code, and the New Zealand Food Standard 1996 is necessary to assist in the protection of public health and safety; is cost effective; and is of benefit to producers, consumers and government.

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).

This matter was notified to the WTO because it may be a TBT issue. There are no standards for royal jelly, propolis or bee pollen in international food standards therefore these requirements may constitute a barrier to trade.
ANNEX 1

REGULATORY SITUATION IN NEW ZEALAND FOR WARNING STATEMENTS FOR ROYAL JELLY, BEE POLLEN AND PROPOLIS

FOOD LAW: BACKGROUND

In New Zealand, food is regulated under the Food Act 1981 and delegated legislation under that Act. The Food Act 1981:

- defines relevant terms, such as, food and sale
- outlines prohibitions on sale (including unfit food)
- prohibits misleading labelling and advertising
- provides powers of enforcement and offences
- contains provisions to make regulations and food standards.

The Food Regulations 1984, Dietary Supplements Regulations 1985 and New Zealand food standards are made under the Food Act 1981.

A more complete description of New Zealand food law can be found on <www.moh.govt.nz>.

Dual food standards apply until the Joint Food Code is introduced

Food standards can incorporate other standards by reference. For example, the Australian Food Standards Code (AFSC) is incorporated into New Zealand law.

The AFSC is an alternative to most of the Food Regulations 1984. Under the joint food standards setting system with Australia, food sold in New Zealand must fully comply with either the Australian Food Standards Code or the Food Regulations 1984. The New Zealand Food Standard 1996 is the legal instrument that incorporates legal recognition of the AFSC into New Zealand law.

The Joint Food Code is expected to be implemented in late 2000. There will be a transitional phase before the Joint Food Code becomes the sole food code applying in New Zealand and Australia. During this time food manufacturers/importers will have the option of complying with the Food Regulations 1984, the AFSC, or the Joint Food Code, but not a combination of these.

Additionally, under the Trans-Tasman Mutual Recognition Act 1997 (TTMRA) food produced in New Zealand or imported into New Zealand that meets New Zealand’s legal requirements, may also be sold in Australia and vice versa. There are some exceptions. For example, high-risk foods listed in either country require certification or testing before being permitted entry (peanuts, soft cheeses, molluscs).

Mandatory food standards

The Minister of Health may declare a food standard mandatory for the duration of the transition period before the Joint Food Code becomes the sole food code applying in New Zealand and Australia. Mandatory food standards prevail where there is any
inconsistency between the Food Regulations 1984 and the provisions of any alternative food standards, where that inconsistency arises during the transition period.

**Dietary Supplements Regulations 1985**

Dietary supplements are “foods”, as defined under the Food Act 1981. The Dietary Supplements Regulations 1985 define “dietary supplements,” state the maximum daily doses for some nutrients, list food additive permissions and labelling requirements. As with other foods, it is the manufacturer's/importer's responsibility to ensure their products are safe and comply with the legal requirements (ie no prior approval is required to sell dietary supplements).

Dietary supplements may only be distributed for a therapeutic purpose, after receiving consent (ie as a medicine) from the Minister of Health under the Medicines Act 1981.

Dietary supplement and medicine legal requirements are not currently harmonised or mutually recognised between Australia and New Zealand. Therefore, Australia and New Zealand have separate requirements. Some foods currently sold as dietary supplement products may in the future be covered under the Australian Food Standards Code. For example, sports foods, electrolyte drinks, protein powders. The Dietary Supplements Regulations 1985 are likely to be replaced in the medium term with new legislation covering health and therapeutic products.

**REGULATION OF WARNING STATEMENTS FOR ROYAL JELLY, BEE POLLEN AND PROPOLIS**

Most royal jelly, bee pollen and propolis products are sold as dietary supplements, rather than as whole foods or food ingredients. The regulation of warning statements for these products is the same, regardless whether they are sold as foods or dietary supplements.

**Royal Jelly**

Under the Treaty New Zealand has with Australia to develop joint food standards, New Zealand is obliged (unless well defined and limited exceptional circumstances exist) to adopt changes agreed to the AFSC, that are within the scope to the Treaty. New Zealand has delayed its recognition of the changes in the AFSC to the warning statement for royal jelly, as gazetted in Amendment No. 37 to the AFSC in 1997. New Zealand’s delayed recognition is pending the outcome of the Inquiry into the change, when recognition by New Zealand of the final change to the AFSC is expected to occur. The change in warning statement was made using the urgency provisions of the ANZFA Act 1991 and in these circumstances consultation occurs after the change has been made.

The Minister of Health issued a mandatory food standard (New Zealand Food Standard 1996 Amendment No. 11) that provided New Zealand industry with two options for warning statements on royal jelly, either the warning statement in the
“6 (c) Royal jelly - The label on or attached to a package of a food, including a dietary supplement, containing royal jelly, must include, in a prominent position so that it can be easily seen by the consumer when purchasing the product, in a standard type of not less than 3 mm, the statement -

(i) in the case of a product that is comprised solely of royal jelly -

‘WARNING - THIS PRODUCT IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’; or

(ii) in the case of a product that contains royal jelly (but is not solely comprised of royal jelly) -

‘WARNING - THIS PRODUCT CONTAINS ROYAL JELLY AND IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’;

(iii) instead of the statements in 6(c)(i) and 6(c)(ii), in the case of a product that is comprised solely of royal jelly, or a product that contains royal jelly (but is not solely comprised of royal jelly) -

‘WARNING - THIS PRODUCT CONTAINS ROYAL JELLY WHICH HAS BEEN REPORTED TO CAUSE ALLERGIC REACTIONS AND IN RARE CASES, FATALITIES, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS’

Bee pollen and propolis
Prior to New Zealand Food Standard 1996 Amendment No. 11 warning statements were not required on bee pollen and propolis products. Amendment No. 11 introduced mandatory warning statement requirements for bee pollen and propolis:

(d) Bee Pollen - the label on or attached to a package of a food, including a dietary supplement, containing bee pollen, must include, in a prominent position so that it can be easily seen by the consumer when purchasing the product, in a standard type of 3 mm, the statement -

‘THIS PRODUCT MAY CAUSE SEVERE ALLERGIC REACTIONS’

(e) Propolis - the label on or attached to a package of a food, including a dietary supplement, containing propolis, must include, in a prominent position so that it can be easily seen by the consumer when purchasing the product, in a standard type of 3 mm, the statement -

‘PROPOLIS MAY CAUSE SEVERE ALLERGIC REACTIONS’

(f) Size of Package - if the size of package of any product referred to in clause 6(c), 6(d) or 6(e) is so small as to prevent the use of letters in 3 mm type, a reduced type height may be used, but no letter may have a letter height of less than 1.5 mm.
NEW ZEALAND SPECIFIC ISSUES FOR CONSULTATION

This consultation document discusses the merits of warning statements for royal jelly, bee pollen and propolis. These issues are common to both Australia and New Zealand. There are two issues that are specific to New Zealand and comment is also sought on these. These comments should be sent to ANZFA, as part of any submission on this document.

Should foods and dietary supplements be treated in the same way?

The New Zealand Food Standard 1996 Amendment No. 11 regulates foods and dietary supplements, consisting solely of or containing royal jelly, bee pollen and propolis, in the same way. The rationale for this is that foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. Having the same warning statement and ingredient listing requirements for foods and dietary supplements would achieve this. It is proposed that the warning statement finalised in the AFSC for royal jelly, and the ingredient listing requirements for bee pollen and propolis, as a result of this consultation process, apply to both foods and dietary supplements. This is because foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. Do you agree with this?

Should the food standard for warning statements and ingredient listing be mandatory?

If a food standard is mandatory it prevails over the Food Regulations 1984 and any other food standard that may be inconsistent with it. There are no specific provisions in the Food Regulations for warning statements for royal jelly, or for mandatory ingredient listing of bee pollen and propolis. If the Minister of Health issues a food standard recognising any changes to the AFSC on the outcome of consultation process and the standard is not made mandatory, then the Food Regulations would apply. This would mean that a manufacturer or importer could choose to have no warning statement or ingredient listing (in some circumstances) or to comply with the new requirements in the AFSC.

Complying with the Food Regulations, rather than the amended AFSC, will not protect public health and it is proposed to make any changes to the AFSC, which are recognised in New Zealand, mandatory. At the same time the warning statement requirements contained in New Zealand Food Standard 1996 Amendment No. 11 will be repealed. Do you agree with this?
SUMMARY OF SUBMISSIONS AND CORRESPONDENCE ON BEE PRODUCTS RECEIVED BY ANZFA BETWEEN 1997 AND 2000

1. Background

Proposal P161 - Review of Specific Labelling Statements initially looked at the issue of the need for a warning statement in the label of royal jelly and bee pollen products. However, at the same time Proposal P154 was developed as a matter of urgency to address the need for a strengthened warning statement in the label of royal jelly products as a result of the Coroners Report into the death of a 23-year-old woman. P154 subsequently introduced a new warning statement in Australia as requested by the then Minister of Health without public consultation as is permitted under Section 37 of the ANZFA Act.

P161 and P154 were circulated at approximately the same time in 1997 for public comment and confusion developed. Submissions were received from industry and consumers. Some industry organisations believed that the new warning statement had been introduced as a result of Proposal P161 and the report of the Expert Panel on Food Allergens; this was not the case. The current warning statement was introduced as a matter of urgency under P154 after the NSW Coroner found royal jelly to be the cause of death of a 23-year-old female. As a result of P161 comments were received regarding the need for a warning statement in the label of royal jelly and bee pollen products.

2. Summary of Submissions from Proposal P161

The Dietitians Association of Australia and Elaine Attwood support retention of the warning statements.

Healtheries supports the submission of the National Nutritional Foods Association (NNFA) see below. In addition they do not accept that the evidence presented supports the need for such draconian warnings.

The AFC, the NCWA and InforMed Systems support the proposal to retain the warning statement on bee pollen and royal jelly products.

The New Zealand Ministry of Health (NZMOH) proposes that the need for a standard for propolis be investigated. Five adverse reactions to propolis have been reported to the Centre for Adverse Reactions Monitoring (CARM) in New Zealand since 1993. Two of which were severe, life threatening reactions. The TGA requires a warning on propolis products as a requirement of registration. Thus to create consistency and to protect public health, as propolis may be included in food products, it is important that propolis be considered as a part of the review.

The National Nutritional Food Association New Zealand (NNFA) provided the Authority with an extensive submission on royal jelly and bee pollen products. The NNFA earlier agreed to request its members to institute voluntary warnings and even
supported mandatory warnings in its recent submissions to the New Zealand Ministry of Health but in view of investigations by a NNFA researcher it no longer considers that there is any case for warning labels for these products and for propolis.

The NNFA has since 1994 actively promoted the inclusion of voluntary warning labels on the royal jelly, bee pollen and propolis products as requested by the NZMOH. They believe that nearly three quarters of such products are being labelled with appropriate warnings. They state that bee products have been consumed by a large percentage of the world population on a daily basis for thousands of years. They ask that these products not be treated more harshly than other common food products that have proven records of adverse food reactions, eg. peanuts.

The NNFA agrees in principle with the need for appropriate product information on food products so that consumers can make informed choices. However, they challenge the scientific basis upon which the singling out of royal jelly and bee pollen has occurred. NNFA states that ANZFA is introducing policies that are out of step with international food labelling recommendations.

The NNFA state that while Bee pollen (inhaled) has been a well-recognised cause of severe asthma they have failed to find any evidence of significant adverse reactions to bee pollen (ingested) that would warrant special labelling requirements. They state that bee products have been significant dietary supplements for thousands of years and that there is mounting scientific evidence of their efficacy in providing a wide range of health benefits.

In terms of practical labelling the NNFA states that the required size of the lettering of the warning statements (3 MM) along with the number of words required would mean that in the case of some royal jelly vials 75% of the product surface would be taken up by the warning. They state that 1.5 mm lettering is consistent with the labelling on common OTC medicines.

Comvita states that they do not believe that the evidence justifies the recommendation for prescriptive warning statements on all products containing royal jelly and bee pollen. They state that there is no support for the singling out of royal jelly and bee pollen as products requiring mandatory prescriptive warnings especially in comparison to other foods with a proven high incidence and severity of adverse reactions for which no warning is recommended.

Comvita supports the conclusions of the NNFA submission. They state that the argument that a mandatory, prescriptive warning label is required for products containing royal jelly and bee pollen, because people with allergies have not been educated to avoid royal jelly and bee pollen, where as no such warning labels are required for other foods such as peanuts because people are educated by their doctors to avoid those foods, is both seriously flawed and possibly spurious.

Comvita state that under the WTO the inclusion in the Food Standards Code of mandatory warnings is and would be, a departure from relevant international standards.
**Comvita** state that there is no justification in the recommendation that a mandatory prescriptive label warning should be placed on all food products containing bee pollen. **Comvita** presented evidence in its submission that there is no linkage between respiratory allergies and food based bee pollen allergy.

In regard to royal jelly **Comvita** contends that a report by Dr Mark Donohoe, included in their submission provides an objective and well reasoned assessment of the risks and benefits to public health posed by royal jelly.

The conclusions drawn by Dr Donohoe's assessment of the international evidence and the findings of the two Australian coroners are:

- there is currently no credible scientific evidence that the ingestion of royal jelly has caused deaths in humans;
- the findings of the Australian coroners cases do not constitute scientific evidence and both cases are profoundly flawed in their findings;
- the majority of the medical literature on adverse reactions to royal jelly has originated from a small group of Australian researchers, and their work has not been independently replicated. The Australian studies also suffer from biases and irregularities which suggest that the studies should be discounted until replicated and confirmed by independent researchers; and
- the best available data at present would suggest that royal jelly has a low risk benefit ration, causes allergic reactions rarely, if at all, and has a high potential as a cost-effective therapeutic agent.

**Comvita** states that:

- no quantification of benefits or costs has been provided;
- the analysis for *bee pollen* does not include any mention of the nutritive or therapeutic benefits of the product to consumers;
- the analysis for *royal jelly* does not include any mention of the nutritive or therapeutic benefits of the product to consumers.
- the analysis for both royal jelly and bee pollen does not include any provision for losses of benefits to consumers caused by the unnecessary avoidance of these foods caused by mandatory, severe warnings.
- the risk analysis for both products does not provide an option for only including royal jelly or bee pollen in the list of ingredients, or an option of advisory, non-prescriptive labelling.

**Comvita** finally recommend the following:

- removal of the current requirement for a mandatory warning statement on product containing bee pollen from the Food Standards Code;
- that no mandatory warning statement on products containing bee pollen is adopted under the NZ Food Regulations;
- that in the interests of equity with all other foods producing allergic reactions considered in the proposal, that royal jelly and bee pollen are included in the list of foods and food additives for which a declaration is made in the ingredient list of all food products;
The New Zealand Charter of Health Practitioners Incorporated stated that royal jelly products are foods and are not drugs and as such their availability and classification as a food should be retained. They claim that such products have therapeutic effects. They indicate that if royal jelly is listed by TGA it will increase the cost and reduce the availability or royal jelly. They also state that if ANZFA proceeds to classify royal jelly products as drugs and not food they will formulate a case to be placed before the World Trade Organisation against ANZFA's administration for creating a technical barrier to trade without scientific justification.

3. Letters and representations received from industry and other stakeholders between 1997 and 2000

The Nutritional Food Association of Australia (NFAA) sent correspondence to ANZFA in 1997 expressing concern about the implications of the new warning statement as they believed the reasoning behind the statement was based on flawed evidence and that the safety of royal jelly should be considered by the Complementary Medicines Evaluation Committee of the Therapeutic Goods Committee (TGA).

Pharmatech Australiasia Pty Ltd sent correspondence to ANZFA in 1997 and made note of a reviewed notice of duplications concerning two journal articles that were published in the UK and the USA regarding Royal Jelly. These articles had been cited by TGA and ANZFA in literature reviews. Pharmatech indicated that these articles should not be used as evidence of the safety of royal jelly.

Mrs Crystal Griffiths, the mother of the 23-year-old female that died after consumption of royal jelly has made several representations to ANZFA regarding the labelling of royal jelly products urging ANZFA to take the NSW Coroners advice and ban royal jelly from sale until its safety and efficacy are assessed. Mrs Griffiths indicated in particular that to say royal jelly is the same as peanuts and other food allergens is ludicrous. She indicates that peanuts are every day foods, which are slowly introduced into the diet from a young age where the allergy can be quickly picked up and eliminated from the diet. In Mrs Griffiths opinion royal jelly is a health product, not a staple food and is not generally introduced in the diet of a child.

The Complementary Health Care Council of Australia (CHCCA) has made several representations to ANZFA in 1999 and 2000 regarding the issue of the need for a warning statement in the label of royal jelly products.

The CHCCA state that the imposition of mandatory warning statements linking royal jelly with fatalities has seriously damaged the royal jelly industry in Australia and New Zealand, that the decision to include the new warning statement in the label of royal jelly products was based on flawed evidence and that an appropriate risk assessment of the issue was not undertaken. The CHCCA support the recommendations of the NZ Working Group on Bee Product and request that these recommendations be accepted.

The National Nutritional Foods Association of New Zealand has made several representations to ANZFA regarding this issue over the past three years. They claim
that falsified information was used by ANZFA and the NZMOH to justify the warning statements on royal jelly. They refer to the duplicated journal articles on the safety of royal jelly that have been revoked and claim that the new warning statement was put in place on the basis of these journal articles.

The NNFA claim that the wording of the present warning statement, especially the word fatalities, is draconian and is in contrast to labels on aspirin and other drugs that are known to cause death yet do not contain such warnings. They have requested ANZFA carry out the Inquiry into P154 and have asked that independent assessment on all data be carried out.

The NNFA considers that equal risk should be regulated equally. They state that the overwhelming majority of food allergies are cause by 8 common foods that are not regulated. They state that during a period of three years there was no reported adverse reactions to royal jelly yet there were many cases of serious anaphylaxis to common foods and no warning statements are required on these foods. They contend that all regulations for dietary supplements such as royal jelly should be transparent, objective and equitable with that of food regulations.

The NNFA state that only a proper risk assessment such as that outlined by the WHO/UN risk management model should be used to assess the risk of bee products and the need for warning statements. The NNFA states that there are situations where the decision of a Coroner on a cause of death can be further investigated. This situation may occur if new facts or evidences have been discovered.

Mr Ron Law of the NNFA wrote an extensive submission to the NZ Parliamentary Regulation Review Committee outlining why he believed the there was a lack of evidence to prove that royal jelly and other bee products may cause severe adverse reactions. Mr Law made several errors in his submission regarding the process of the ANZFA Expert Panel on Food Allergens that was set up in 1996 to provide ANZFA with advice on Food Allergens including indicating that the current warning statement was put in place due to advice to ANZFA from the Expert Panel on Food Allergens. This is incorrect. However, his overall submission indicated that there needed to be a formal risk assessment conducted of all bee products and their need for warning statements. The NZ Parliamentary Regulation Review Committee agreed to this and the NZ Working Group on Bee Products was set up to conduct a risk assessment.

The NNFA has provided correspondence to ANZFA recently requesting that ANZFA use the Report of the NZ Working Group on Bee Products in the Inquiry for P154, as they believe it is an adequate risk assessment and agree with the groups recommended risk management strategies.

Mr Ron Law has also sent correspondence to ANZFA recently regarding the inclusion of bee pollen and propolis in the Draft Joint Australia New Zealand Food Standards Code and P154. The inclusion of these in the draft Code was only to indicate that ANZFA was considering the need for statements in the label of these products in P154 and that a decision was pending.
Golden Glow Natural Health Products agrees with the recommendations of the NZ Working Group on Bee Products that mandatory warnings on bee pollen and propolis products be removed and that the royal jelly warning statement be amended to: “Royal jelly may cause serious allergic reactions, most reports have been in asthma suffers.”


This report describes key themes from the analysis of written submissions and two public consultation meetings.

Sources of written submissions
A total of 37 written submissions were received. These include two submissions that were withdrawn and replaced. The analysis does not include the two submissions that were withdrawn.

The sources of the written submissions are presented in Table 1.
Table 1: Sources of written submissions

<table>
<thead>
<tr>
<th>Sources</th>
<th>Number of submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bee and dietary supplement industries</td>
<td>11</td>
</tr>
<tr>
<td>Crown Health Enterprises</td>
<td>6</td>
</tr>
<tr>
<td>Non government health organisations and individuals</td>
<td>4</td>
</tr>
<tr>
<td>Consumer organisations</td>
<td>3</td>
</tr>
<tr>
<td>Other industrial companies</td>
<td>2</td>
</tr>
<tr>
<td>Professional organisations</td>
<td>2</td>
</tr>
<tr>
<td>Other organisations</td>
<td>3</td>
</tr>
<tr>
<td>Government agencies</td>
<td>2</td>
</tr>
<tr>
<td>European Commission</td>
<td>1</td>
</tr>
<tr>
<td>Member of the public</td>
<td>1</td>
</tr>
</tbody>
</table>

Consultation meetings
Consultation meetings were held in Auckland and Wellington. The consultation meetings were attended by members of the bee and dietary supplement industries and the National Council of Women.

Key themes
Support in the written submissions for the Ministry of Health proposal differed considerably between health, consumer and industry groups. Health groups and professionals, and consumer groups strongly supported the proposal. They accepted the evidence in the discussion document of health problems associated with the use of royal jelly, bee pollen and propolis. Several referred to their own experience of dealing with consumers who had experienced negative reactions to these products.

Both the consultation meetings and written submissions from the bee and dietary supplement industries either opposed mandatory warning labels or wanted less severe warnings, particularly for royal jelly. Industry submissions argued that the number of cases of adverse health effects from bee products was very small, particularly when compared to adverse health effects from foods with known adverse health effects. The European Commission argued that a health risk statement was not appropriate.

Industry submissions did not support 3 mm lettering for labelling, especially when a small container was used.

Detailed comments on the written submissions follow.

Agreement with the proposal, in general, to have mandatory warning labels
All thirty-five submissions made an overall comment on the proposal. Twenty-seven supported the proposal in principle. Submissions from health units and professionals supported the proposal as is. While six industry submissions supported mandatory warning labels, all wanted less severe warnings. Eight submissions, all from industry, opposed mandatory health warnings. The European Commission maintained that a health risk statement was not appropriate.
Health risk of bee products
Ten submissions commented on the health risk of bee products. The two consumer
groups both reported instances of severe reactions to bee products. While asthma and
allergy suffers were seen as being most at risk there are occasional reports of
anaphylactic shock reactions to bee products from consumers who are not asthma or
allergy suffers. One health organisation wanted bee venom included as a product to
be labelled as they had received one complaint from a consumer who had reacted
adversely to bee venom. One industry submission accepted the Australian coroners
finding (unless proven wrong). The other industry submissions did not rate the risk of
adverse health outcomes as high, when compared to other food products, argued that
the number of cases per year was very small, and could not find evidence that bee
products are quoted in studies of anaphylactic shock. One industry submission argued
that the risk analysis by ANZFA is rudimentary.

Characteristics of the warning labels (general)
Seven submissions made general comments on the characteristics of warning labels.
One health unit wanted labelling statements in bold easily read letters. All other
comments came from industry. They wanted changes to lettering size or position.
For small containers 3mm was viewed as too large a size for lettering. Two industry
submissions wanted the comparable characteristics of warning label requirements as
medicines.

Proposed warning label: royal jelly
Eight submissions commented specifically on the proposed warning label. Two
agreed with the proposal. The other submissions rated the proposed label as too
severe and too wordy. Four submissions suggested alternative wording. All these
omitted reference to fatalities.

Proposed warning label: bee pollen
Five submissions commented on the proposed warning label for bee pollen, four from
industry. These submissions suggested alternative wording. One submission
disagreed with having a warning label for bee pollen.

Proposed warning label: propolis
Six submissions commented on the proposed warning label for propolis, three from
industry. Two submissions proposed alternative wording. One submission disagreed
with having a warning statement for propolis.

Commencement of the proposed food standard: overstickers
Five submissions commented on the use of overstickers. Two argued that the
proposal would act as a barrier to trade. One submission proposed that detailed
information be placed inside outer packaging.

Commencement of the proposed food standard: timing
No submissions commented on timing.
Consistency with obligations of the agreement between Australia and New Zealand and other trade issues
Two submissions commented on consistency of obligations with Australia. Both were from industry and did not support a need for consistency. Three submissions including one from the European Commission, argued that the proposal was unnecessarily trade restrictive.

Other comments
Three submissions wanted public education instead of mandatory labelling, one wanted mandatory labelling plus public education. Two submissions wanted clarification from the Ministry of Health or ANZFA whether honey and honey products should carry a warning label. Other issues raised include, a need for a standard dealing with all allergenic products, severe warnings are driven from Australia, members of the ANZFA Expert Panel have conflicts of interest and are not qualified to provide advice, an independent review of the issues was wanted, industry members would be severely harmed financially if the proposed warnings eventuate, and there were shortcomings in the consultation process.
BACKGROUND TO REGULATIONS OF BEE PRODUCTS 1992 - 2000

AUSTRALIA

In 1992 the then National Food Authority received an application from the Health department of Western Australia to amend the food standards Code to specifically provide a standard for royal jelly. It was determined the Consumer deception was occurring due to incorrect labelling of products containing royal jelly. There was at the time no accepted definition of royal jelly. The establishment of a standard for royal jelly was thought to be needed to categorise products containing royal jelly as foods or therapeutic goods. A standard for royal jelly was included in Standard K2 of the Food Standards Code. The Standard for royal jelly at that time provided a definition of royal jelly and compositional parameters indicating the amount of 10 – hydroxy – decenoic acid, protein and water that may be present. Royal Jelly was defined as the milky white, viscous secretion from the salivary glands of honeybees. The issue of royal jelly carrying potential allergens was raised and a warning statement similar to that required for bee pollen was discussed however at the time insufficient documented evidence of allergic reactions to royal jelly was available.

In February 1994 the NFA was advised by the TGA that royal jelly had been the identified as the cause of death in a recent fatality of an 11-year-old girl. In addition the Adverse Drug Reactions Section of TGA held details of several cases of asthma or other severe allergic reactions to royal jelly. These reports prompted the TGA to make an appropriate assessment of the risk of royal jelly and prepare an appropriate warning statement. They concluded that given Australia has one of the highest rates of asthma, and death from asthma, in the developed world, the public health implications of this problem were potentially very significant. They considered that all asthmatics and allergy sufferers should be warned of the potential risks to their health. Some manufacturers voluntarily labelled royal jelly with a warning statement following the death. At the time the Nutritional Foods Association stated, “It is apparent from the small number of cases and especially the fatality that a certain protein within the Royal Jelly can bring on a serious reaction in a small number of asthma sufferers. Education of the Community is therefore warranted especially the small group that is prone. Retailers are encouraged to reinforce care and caution with customers who are considering buying royal jelly.” The association agreed to consider a warning statement targeted at those at risk.

In light of the safety concerns surrounding royal jelly, the TGA was considering a warning statement. The TGA requested that the then National Food Authority (NFA) take similar action in relation to royal jelly products regulated as food. The NFA developed a proposal under Section 37 of the NFA Act to require a warning label on royal jelly products. The proposal required the following statement to be declared in the label of royal jelly products immediately following the prescribed name or appropriate designation of the product:
'WARNING – NOT RECOMMENDED FOR ASTHMATICS OR ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’.

Under Section 37 of the then NFA Act the NFA could implement a new standard as a matter of urgency without public consultation. After implementation of the new standard an inquiry including one round of public comment must be undertaken. The Council adopted the draft variation and it was published in the Gazette of 11 May 1994 as Amendment NO. 20 to the Food Standards Code. The NFA immediately called for public submissions to assist the NFA in making its Inquiry into the matter.

At the same time the Director Generals in New Zealand released a media release warning the public they should be aware of the possible health dangers associated with consuming products containing royal jelly and that they may be hazardous to people with asthma.

12 submissions were received in response to P115. The following issues were raised.

1. That the NFA and TGA warnings on royal jelly products should be identical. The drafting was revised to make provision for alternate warning statements depending on the nature of the product. Pure royal jelly standardised by K2 – Honey and Related Products was covered by the statement:

‘WARNING – NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’

The statement that was identical to the TGA required statement covering foods containing royal jelly:

WARNING – THIS PRODUCT CONTAINS ROYAL JELLY AND IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS.

It was determined that the print size should be 3mm to ensure the print is large enough to be easily read.

2. The warning should be the same as that required for bee pollen products. The warning statement for royal jelly was developed in line with the TGA statement. It was beyond the scope of this proposal, P115, to consider the bee pollen statement. But it was noted that the bee pollen statement would be considered during the review of labelling provisions.

3. The warning should be extended to infants and children. It was concluded that this was an over cautious approach and may not provide consumers with additional information.

4. Inconsistency of treatment of food that can cause allergic reaction. The NFA noted that there was a need to establish labelling policies for substances that may cause adverse effects but it beyond the scope of this proposal to consider other foods. The Authority noted that it would conduct a literature review on foods that may cause
adverse reactions and establish labelling policies in the review of the Food Standards Code.

It was concluded that the drafting should be revised to provide both a specific warning statement for pure royal jelly and to provide a specific warning statement for foods containing royal jelly that is consistent with the warning statement for therapeutic goods containing royal jelly. The NFA completed the P115 Inquiry with the amendment made to the standard as stated above in January 1995.

In 1996 Australia New Zealand Food Authority (ANZFA), previously the NFA began reviewing the labelling standards in the Food Standards Code as a part of the Review of Food Standards in Australia and New Zealand, with a view to implementing a Joint Australia New Zealand Food Standards Code. One project in this review, Proposal P161 – Specific Labelling Statements looked at the issue of declaration of foods that may cause severe adverse reactions in the label of foods. Royal jelly and bee pollen were included in the list of foods that were assessed.

A panel consisting of experts in the field of immunology and allergy from Australia and New Zealand was set up to provide ANZFA with advise as to the foods that have the potential to cause severe adverse reactions. Royal jelly and bee pollen were identified along with a list of other foods as foods that may cause severe adverse reactions in the opinions of the experts on the Panel. The initial proposal for P161 that was released for public comment in early 1997 simply called for comment on the need for warning statements in the label of these products. However, while this proposal was out for public comment other circumstances arose surrounding the issue of allergic reactions to royal jelly, i.e. the Coronial Inquest into the death of a 23-year-old woman. ANZFA was instructed to take urgent measures to protect public health and safety. This is outlined below. Therefore the issue of allergic reactions to royal jelly and bee pollen was removed from proposal P161 and a new proposal was established, (P154) to consider the urgent issue. There was some confusion about this from industry; they believed that the new warning statement was implemented as a result of P161 and advice of the expert Panel. This was not the case.

On 2 January 1996 a 23-year-old woman died in hospital after suffering an anaphylactic reaction on 31 December 1995. The Coroners Court Westmead conducted an inquest into her death and completed this Inquiry on 5 June 1997.

Having considered a wealth of evidence, medical reports and medical opinions in conjunction with the factual circumstances it was the finding of the Inquest that the cause of death was Acute Anaphylaxis due to the ingestion of a capsule of Royal Jelly.

It was recommended by the inquest that the relevant Health Authorities both for the State of NSW and the Commonwealth give urgent consideration to the withdrawal from sale of the product royal jelly and that clinical trials be undertaken and the relevant authorities satisfied before it is reintroduced for sale.

ANZFA and TGA were required by the then Senator Chris Ellison, Parliamentary Secretary to the Minister for Health and Family Services to consider this recommendation. Neither ANZFA nor TGA is in a position to dispute the findings of
a Coroners Court and must accept the findings. However, it was considered that banning royal jelly was somewhat draconian.

The Australian College of Clinical Immunology and Allergy were asked by the then Senator Chris Ellison, Parliamentary Secretary to the Minister for Health and Family Services to undertake an urgent analysis of the matter.

As an initial step in October 1996 after establishment of the Inquest, ANZFA wrote to all State and Territory Health Ministers informing them of the urgent need for effective enforcement of the labelling requirements for royal jelly products.

In June 1997 Senator Chris Ellison also wrote to all the State and Territory Health departments urging them to take extra precautions to monitor compliance with the existing warning statement on labels and informing major distributors of the concern that at-risk consumers need to be properly advised of the hazard posed by royal jelly. On 12 June 1997, State and Territory Senior Food Officers and ANZFA agreed to this course of action.

Senator Chris Ellison requested ANZFA and TGA to examine the risk that royal jelly poses to health and in the short term to explore stronger labelling requirements. In the longer term it was proposed that a detailed review be undertaken by the TGA and ANZFA as to the future regulatory status of royal jelly products with a view to restricting their availability to the outlets where adequate warnings can be given to at-risk consumers.

In June 1997 ANZFA met with the TGA and the Priority Medical Association of Australia (PMAA) and it was agreed that additional labelling be required on royal jelly products under the name of the products, the wording to be “AVOID IF ASTHMA OR ALLERGY SUFFERER”. In addition the Australasian Society of Clinical Immunology and Allergy conduct an analysis of the health risk of royal jelly; and a review of the status of royal jelly be undertaken by the Complementary Medicines Evaluation Committee at TGA.

On 23 June 1997 ANZFA received a letter from Mr David Barran – Barrister for Mrs Griffiths – the mother of the deceased, addressed to Senator Ellison. Mr Barran requested that royal jelly products be withdrawn from sale as was recommended by the NSW Coroner. He stated that further delays in implementing the Coroners recommendations has serious legal consequences for the Commonwealth and that a revised warning label is totally inadequate and that people other then people with asthma may be at risk.

Due to the legal implications surrounding this issue the TGA and ANZFA Agreed that the warning statement needed to be strengthened to indicate that life-threatening reactions may occur. The following wording was agreed to by the then Parliamentary Secretary to the Minister for Health.

"THIS PRODUCT CONTAINS ROYAL JELLY WHICH HAS BEEN REPORTED TO CAUSE SEVERE ALLERGIC REACTIONS AND IN RARE CASES FATALITIES, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS".
In July 1997 ANZFA developed P154 – Additional warning statement for royal jelly. P154 proposed the need for urgent research in to the safety of royal jelly and while this research was being carried out by CMEC an additional warning statement on royal jelly products was considered necessary to caution people with asthma and allergies. The additional labelling statement to be required was as stated above. However ANZFA soon realised that a warning statement this long in addition to the then current warning statement was not practical and amended proposal P154 to indicate that the proposed warning statement would replace the existing warning statement. The commencement date of the draft variation to Standard K2 was 1 September 1997.

In December 1997 CMEC considered the issue of royal jelly. They agreed to permit royal jelly to be included in list able products provided that the labelling of the products included a warning statement; the products are not promoted for any condition which might be a symptom of an allergic or hypersensitivity condition and the products are not promoted for children. They decided that a standard for royal jelly was necessary to protect the quality.

In regard to the warning statement CMEC stated that the message needed to be more direct and that the potential for adverse reactions is not confined to asthma and allergy sufferers and this should be reflected in the message.

CMEC agreed that TGA should develop a Section 7 declaration under the Therapeutic Goods Act 1989 to declare royal jelly presented in capsules, phials and powders to be therapeutic goods because there is a widely held community perception that royal jelly has therapeutic benefit. The Section 7 has implications for the regulation of royal jelly as a food and means that the standard for royal jelly in the Food Standards Code should be amended to exclude royal jelly in the forms recognised as therapeutic goods.

In August 1997 The Journal of Allergy and Clinical Immunology and the Journal of Clinical and Experimental Allergy agreed to publish a “Notice of Duplicate Publication” in their respective journals. Two articles published in these journals in 1995 and 1996 were submitted to the journals within days of each other in November 1994. Both manuscripts went through a peer review, and were revised and published within a month of each other. However, the authors had failed to reference the closely related article as submitted on in press and the Editors of the two journals were unaware of the other article. It was the view of the Editors that there was considerable overlap of the topic, duplicate of data essential to the conclusions, use of identical subjects and failure of the authors to reference the closely related article during the review process. The guidelines of the journals require authors to indicate that submitted manuscripts do not contain material that in whole or in part will be submitted or published elsewhere. The journals did not see any grounds to withdraw the articles but the editors considered this an example of duplicate publication and unacceptable practice.

TGA and ANZFA had used these articles in assessments without knowledge that they were duplicate articles. The outcome of this was that instead of the 19 cases that TGA
had quoted there were really only 7 cases of severe reactions to royal jelly reported in literature. ANZFA has not referred to these articles since learning of the duplication of reports. In June 1999 ANZFA sought the advice of Dr Penny Fitzharris on this issue. Dr Fitzharris indicated that there the articles were in fact a double publication and there were some inconsistencies in the data content between the two papers. However Dr Fitzharris did not believe that these defects completely abrogated the content of the papers.

NEW ZEALAND

New Zealand Ministry of Health Consultations

In August 1997 the then New Zealand Minister of Health the Hon Bill English indicated that New Zealand could not adopt the requirement for the new warning statement without conducting public consultation.

In November 1997 the NZMOH issued a discussion document entitled “Proposed Compulsory Warning Labelling for Food Products (including dietary supplement products) Containing Royal Jelly, Bee Pollen and Propolis. A Proposed Mandatory New Zealand Food Standard.” The NZMOH decided to extend the consultation to bee pollen and propolis products as well as royal jelly. The proposal called for comment on the need for warning statements in the label of royal jelly, bee pollen and propolis products and in particular it called for comment on the wording of the statement proposed for royal jelly in Australia. (See Attachment 3 for a summary of Submissions)

The NZMOH conducted two public meetings and received thirty-five written submissions to the discussion document. Following are the key issues raised during the consultation.

- Consumer groups and health professionals strongly supported the Ministry’s proposal for mandatory warning statements on foods containing bee products.

- Bee and dietary supplement industry submissions either opposed mandatory warning labels or wanted less severe warnings, particularly for royal jelly.

- Industry submissions disagreed with the Ministry’s position on the potential risk of bee products as the number of cases of adverse health effects from bee products were perceived as very small particularly when compared to other foods with recognised adverse health effects.

- The European Commission argued that a health risk statement was not appropriate because it is not consistent with the draft amendments to the Codex General Standard for labelling of Pre-packaged foods and that labelling should aim to inform consumers of the presence of bee derivatives in a food.

- Industry disagreed with the size and position of the warnings.
Implementation of requirements for warning statements in New Zealand

After assessment of the issues raised in the consultation the NZMOH considered that there was a need to include warning labels on royal jelly, bee pollen and propolis products. However, they implemented mandatory warning statements for royal jelly, bee pollen and propolis in an amendment to the New Zealand Food Standard 1996, Amendment No. 11. The warning for royal jelly differed from the new warning statement in the Food Standards Code. The new standard in New Zealand covers all food products sold in New Zealand under the New Zealand Food Regulations 1984 and, the Australian Food Standards Code and the New Zealand Dietary Supplements Regulations 1985. The statements implemented in New Zealand were as follows.

In the case of a product that is comprised solely of royal jelly:

ROYAL JELLY MAY CAUSE SEVERE ALLERGIC REACTIONS, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS.

In the case of a product that contains royal jelly but is not solely comprised of royal jelly:

WARNING - THIS PRODUCT CONTAINS ROYAL JELLY AND IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS.

Or instead of the two statements above the following statement, which is the same as the statement required in Australia may be used:

WARNING – THIS PRODUCT CONTAINS ROYAL JELLY WHICH HAS BEEN REPORTED TO CAUSE ALLERGIC REACTIONS AND IN RARE CASES, FATALITIES, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS.

Industry submissions received by the NZMOH did not support the reference to fatalities in the statement and considered that less severe wording was adequate.

The statement required for bee pollen in New Zealand was:

THIS PRODUCT MAY CAUSE SEVERE ALLERGIC REACTIONS

The statement required for propolis in New Zealand was

PROPOLIS MAY CAUSE SEVERE ALLERGIC REACTIONS.

The Amendment to the New Zealand Food Regulations (NZFR) was made on 17 December 1998 and the commencement date of the new requirements was 17 April 1999. The New Zealand Food Standard 1996 Amendment No. 11 currently requires the declaration of these statements in royal jelly, pollen and propolis products.

The New Zealand House of Representative Regulations Review Committee
In 1999 the MP Damien O'Conner complained, on behalf of the bee industry, about the new regulations to the New Zealand House of Representatives Regulations Review Committee (the Committee) on the basis that the decision to impose mandatory warnings is based on insubstantial scientific evidence and fails to take into account the benefits of bee products; it would constitute a technical barrier to trade and the wording of the labelling has not been justified on the basis of the evidence presented to the NZMOH. In addition, the bee industry indicated that the existing voluntary warnings are informative enough, are widely used and that the requirements for labelling were not consistent with that for other foods that may cause allergic reactions.

The NZMOH made a submission to the Committee contending it used risk assessment and risk management principles to develop the discussion document in 1997. However, the Committee did not agree with this and were concerned at the NZMOH’s failure to produce a substantive risk assessment for each of the three bee products and lack of a comparative risk analysis (with other foods). The Committee was also concerned that the NZMOH relied solely on the Centre for Adverse Reaction Monitoring (CARM) and Adverse Drug Reactions (ADRS) database reports. Consequently the Committee concluded that the amendments to the Food Regulations were not made in accordance with the general objects and intention of the Act because a comparative risk analysis had not been carried out and recommended that the Government of New Zealand revoke the new mandatory requirements for warning labelling in bee products. (see Attachment 7)

New Zealand Expert Working Group on Bee Products

In July 1999 the then New Zealand Associate Minister of Health established an expert working group to review the mandatory warning requirements imposed in New Zealand. The New Zealand Bee Product Warning Scientific Review Working Group (New Zealand Working Group) was set up to advise the Associate Minister of Health whether the:

- precautionary approach to warnings is appropriate;
- quality of evidence that led to the mandatory requirement was adequate; and
- quality and extent of the risk assessment and consultation was adequate and appropriate.

The New Zealand Working Group was made up of five food and public health scientists/technical experts. These experts included two members of the NZMOH Medicines Adverse Reactions Committee, two scientists/technical experts acceptable to the bee industry and one independent scientist.

The New Zealand Regulation Review Committee recommended that the Government of New Zealand revoke the new mandatory requirements for warning labelling in bee products. The New Zealand Government responded to the Committee’s recommendation by agreeing to not revoke the labelling requirements to enable the Associate Minister’s New Zealand Working Group to report.
At this time the NZMOH asked ANZFA to delay the release of the Inquiry report into P154 as it may have caused confusion in New Zealand and they stated that the outcomes of the meeting of the New Zealand Working Group that the Associate Minister had set up might be useful in the inquiry. Therefore, ANZFA agree to cease further development on P154 until the New Zealand Working Group had produced its final report.

AUSTRALIA AND NEW ZEALAND

ANZFA the NZMOH and TGA work together to develop regulatory options for bee products

The New Zealand Report on the Findings of the Bee Product Warning and Scientific Review Working Group was released in November 1999. NZMOH consulted with ANZFA in February 2000 and requested that they work together to develop an appropriate regulatory approach for bee products that would be consistent in both countries taking into account the findings of the working group. ANZFA agree to work with the NZMOH and the TGA to develop options for the regulation of bee products.
ITEM 5 FROM EXTRACTED RATIFIED MINUTES
Complementary Medicines Evaluation Committee 1

Item 5 Safety review
Item 5.1 Royal Jelly - Safety Review

In the light of the 19 reports, including 3 deaths to the Adverse Drug Reactions Advisory Committee related to the ingestion of royal jelly, and given the Government’s responsibility to protect public health and safety, and in accordance with the object and requirements of the Therapeutic Goods Act 1989, in relation to safety, quality and efficacy, the Parliamentary Secretary and the TGA sought advice from the Complementary Medicines Evaluation Committee (CMEC):

- on the safety of royal jelly generally, and
- in relation to the regulation of royal jelly;

and seeks the reasons for that advice.

Declaration of conflict of interest

Two members declared a conflict of interest: Dr Stephen Myers declared he had prepared the literature search for the Nutritional Foods Association of Australia (NFAA) and had been paid for the search. The Members agreed to permit Dr Myers to take part in discussion and to participate in any vote. Ms Val Johanson declared her role in the preparation of the NFAA submission which was to request the author to reformat the submission. The Members agreed that Ms Johanson could take part in the discussion but could not vote if voting on the issues were required.

Assessment

Members noted the following:

- There is an established market for royal jelly in Australia and an established industry for the importation and exportation of royal jelly. Lack of proven efficacy has been no barrier to the proliferation of perceived benefits and widely held beliefs. A possible placebo effect due to confidence in royal jelly cannot always be separated from reputed mechanisms of therapeutic effect.

- Royal jelly could not be described as a toxic substance but is an allergen, and as such, is associated with severe and sometimes fatal reactions. These reactions occur mainly in atopic or allergic patients, particularly asthmatic individuals, but it cannot be stated that reactions are exclusive to these groups.
The regulation of royal jelly for the protection of public health and safety has to take account of the potential harm in balance with the potential benefit. This is difficult in the case of royal jelly because of the lack of rigorous evidence of benefit, albeit with recognition that some lines of research are worth pursuing, and because of the idiosyncratic nature of the reactions associated with royal jelly. A solution has to be found which provides protection to users of royal jelly even if the potential number for whom consumption is dangerous is small and which increases the public confidence in the industry.

The industry needs to take responsibility for the royal jelly standards. Products marketed as royal jelly or containing royal jelly are associated with adverse reactions but there is doubt about what is actually in some of these products.

A number of submissions recommended that the supply of royal jelly be restricted to competent and qualified health professionals. At present this would restrict access to doctors and pharmacists as there is currently no formal mechanism for regulating and identifying other appropriately qualified practitioners.

In the absence of any kind of market restriction, warnings are certainly required and education and monitoring of consumers by a professional have to be encouraged.

Members noted that there are several issues associated with making progress with the development of a royal jelly standard for therapeutic goods. There are problems in chemically identifying royal jelly and in defining quality parameters. Acceptable levels of contaminants and break-down products would have to be determined.

**Recommendations**

1. Permit royal jelly to be included in listable products, provided:
   - the labelling of the products includes the current warning which is:
     
     *This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers;*
   
   - the products are not promoted for any condition which might be a symptom of an allergic or hypersensitivity condition eg hay fever, rhinitis or asthma; and
   
   - the products are not promoted for children and the labelling includes a warning specifying that the product is not suitable for children.
CMEC made the recommendation for the following reasons:

- the current warning together with the additional warnings are adequate to protect public health and safety;
- by limiting the claims which can be made, the risk/potential benefit ratio is improved; and
- more quality control will be achieved than at present.

2. Develop a specific standard for royal jelly as a therapeutic good.

CMEC made the recommendation for the following reasons:

- it seems likely that some of the products marketed as royal jelly could be worker jelly;
- royal jelly appears to be relatively unstable and therefore the quality of royal jelly products is likely to be variable;
- from the available information, royal jelly products on the market could be adulterated or contaminated; and
- it would ensure royal jelly products on the market do not contain allergens such as pollen.

3. A possible wording of the new warning statement to appear on the label will be developed with further input from CMEC members.

CMEC made the recommendation for the following reasons:

- the message needed to be more direct; and
- while the potential for adverse reactions is not confined to asthma and allergy sufferers the message should be particularly directed to them.

Note:

- that there is potential for a fatal reaction: and
- any requirement for a new label warning would be made with a suitable lead-in period.

4. A section 7 declaration be made under the Therapeutic Goods Act 1989 to declare royal jelly presented in capsules, phials and powders, to be therapeutic goods.
CMEC made the recommendations for the following reasons:

- the contribution to nutritional requirements of capsules, phials and powders does not justify nutrition being considered a principle role for these goods; and

- there is a widely held community perception that royal jelly has therapeutic benefit.

The proposed section 7 declaration has implications for the regulation of royal jelly as a food and could mean that Standard K2 Honey and Related Products, which includes provisions for royal jelly in the Food Standards Code should be amended to exclude royal jelly in the forms recognised as therapeutic goods.
ATTACHMENT 6

Findings of the Bee Product Warning Scientific Review Working Group, 1999
ATTACHMENT 7

Report of Dr Sheryl van Nunen

Convenor of the Clinical and Laboratory Practices Committee (CLPC) of the Australasian Society of Clinical Immunology and Allergy (ASCIA), Head of the Department of Allergy at Royal North Shore Hospital and a Visiting Medical Officer at the North Shore Private and Sydney Adventist Hospitals in Sydney.
Report of Dr Penny Fitzharris

Senior Lecturer in Clinical Immunology and Allergy at the Wellington School of Medicine and a consultant clinical specialist for Capital Coast Health in treatment of allergic diseases for 12 years. New Zealand representative member on the ANZFA Expert Panel on Specific Labelling for Allergens in 1996 (Proposal 161)
ATTACHMENT 10

REGULATORY SITUATION IN NEW ZEALAND FOR WARNING STATEMENTS FOR ROYAL JELLY, BEE POLLEN AND PROPOLIS

FOOD LAW: BACKGROUND

In New Zealand, food is regulated under the Food Act 1981 and delegated legislation under that Act. The Food Act 1981:

- defines relevant terms, such as, food and sale
- outlines prohibitions on sale (including unfit food)
- prohibits misleading labelling and advertising
- provides powers of enforcement and offences
- contains provisions to make regulations and food standards.

The Food Regulations 1984, Dietary Supplements Regulations 1985 and New Zealand food standards are made under the Food Act 1981.

A more complete description of New Zealand food law can be found on <www.moh.govt.nz>.

Dual food standards apply until the Joint Food Code is introduced

Food standards can incorporate other standards by reference. For example, the Australian Food Standards Code (AFSC) is incorporated into New Zealand law.

The AFSC is an alternative to most of the Food Regulations 1984. Under the joint food standards setting system with Australia, food sold in New Zealand must fully comply with either the Australian Food Standards Code or the Food Regulations 1984. The New Zealand Food Standard 1996 is the legal instrument that incorporates legal recognition of the AFSC into New Zealand law.

The Joint Food Code is expected to be implemented in late 2000. There will be a transitional phase before the Joint Food Code becomes the sole food code applying in New Zealand and Australia. During this time food manufacturers/importers will have the option of complying with the Food Regulations 1984, the AFSC, or the Joint Food Code, but not a combination of these.

Additionally, under the Trans-Tasman Mutual Recognition Act 1997 (TTMRA) food produced in New Zealand or imported into New Zealand that meets New Zealand’s legal requirements, may also be sold in Australia and vice versa. There are some exceptions. For example, high-risk foods listed in either country require certification or testing before being permitted entry (peanuts, soft cheeses, molluscs).

Mandatory food standards

The Minister of Health may declare a food standard mandatory for the duration of the transition period before the Joint Food Code becomes the sole food code applying in
New Zealand and Australia. Mandatory food standards prevail where there is any inconsistency between the Food Regulations 1984 and the provisions of any alternative food standards, where that inconsistency arises during the transition period.

**Dietary Supplements Regulations 1985**

Dietary supplements are “foods”, as defined under the Food Act 1981. The Dietary Supplements Regulations 1985 define “dietary supplements,” state the maximum daily doses for some nutrients, list food additive permissions and labelling requirements. As with other foods, it is the manufacturer's/importer's responsibility to ensure their products are safe and comply with the legal requirements (ie no prior approval is required to sell dietary supplements).

Dietary supplements may only be distributed for a therapeutic purpose, after receiving consent (ie as a medicine) from the Minister of Health under the Medicines Act 1981.

Dietary supplement and medicine legal requirements are not currently harmonised or mutually recognised between Australia and New Zealand. Therefore, Australia and New Zealand have separate requirements. Some foods currently sold as dietary supplement products may in the future be covered under the Australian Food Standards Code. For example, sports foods, electrolyte drinks, protein powders. The Dietary Supplements Regulations 1985 are likely to be replaced in the medium term with new legislation covering health and therapeutic products.

**REGULATION OF WARNING STATEMENTS FOR ROYAL JELLY, BEE POLLEN AND PROPOLIS**

Most royal jelly, bee pollen and propolis products are sold as dietary supplements, rather than as whole foods or food ingredients. The regulation of warning statements for these products is the same, regardless whether they are sold as foods or dietary supplements.

**Royal Jelly**

Under the Treaty New Zealand has with Australia to develop joint food standards, New Zealand is obliged (unless well defined and limited exceptional circumstances exist) to adopt changes agreed to the AFSC, that are within the scope to the Treaty. New Zealand has delayed its recognition of the changes in the AFSC to the warning statement for royal jelly, as gazetted in Amendment No. 37 to the AFSC in 1997. New Zealand’s delayed recognition is pending the outcome of the Inquiry into the change, when recognition by New Zealand of the final change to the AFSC is expected to occur. The change in warning statement was made using the urgency provisions of the ANZFA Act 1991 and in these circumstances consultation occurs after the change has been made.

The Minister of Health issued a **mandatory** food standard (New Zealand Food Standard 1996 Amendment No. 11) that provided New Zealand industry with two options for warning statements on royal jelly, either the warning statement in the
AFSC prior to Amendment No. 37, or the warning statement contained in Amendment No. 37 (effective 17 April 1999). Amendment No. 11 reads

“6 (c) Royal jelly - The label on or attached to a package of a food, including a dietary supplement, containing royal jelly, must include, in a prominent position so that it can be easily seen by the consumer when purchasing the product, in a standard type of not less than 3 mm, the statement -

(ii.) in the case of a product that is comprised solely of royal jelly -

‘WARNING - THIS PRODUCT IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’; or

(iii.) in the case of a product that contains royal jelly (but is not solely comprised of royal jelly) -

‘WARNING - THIS PRODUCT CONTAINS ROYAL JELLY AND IS NOT RECOMMENDED FOR ASTHMA AND ALLERGY SUFFERERS AS IT CAN CAUSE SEVERE ALLERGIC REACTIONS’;

(iv.) instead of the statements in 6(c)(i) and 6(c)(ii), in the case of a product that is comprised solely of royal jelly, or a product that contains royal jelly (but is not solely comprised of royal jelly) -

‘WARNING - THIS PRODUCT CONTAINS ROYAL JELLY WHICH HAS BEEN REPORTED TO CAUSE ALLERGIC REACTIONS AND IN RARE CASES, FATALITIES, ESPECIALLY IN ASTHMA AND ALLERGY SUFFERERS’

Bee pollen and propolis
Prior to New Zealand Food Standard 1996 Amendment No. 11 warning statements were not required on bee pollen and propolis products. Amendment No. 11 introduced mandatory warning statement requirements for bee pollen and propolis:

(d) Bee Pollen - the label on or attached to a package of a food, including a dietary supplement, containing bee pollen, must include, in a prominent position so that it can be easily seen by the consumer when purchasing the product, in a standard type of 3 mm, the statement -

‘THIS PRODUCT MAY CAUSE SEVERE ALLERGIC REACTIONS’

(e) Propolis - the label on or attached to a package of a food, including a dietary supplement, containing propolis, must include, in a prominent position so that it can be easily seen by the consumer when purchasing the product, in a standard type of 3 mm, the statement -

‘PROPOLIS MAY CAUSE SEVERE ALLERGIC REACTIONS’

(f) Size of Package - if the size of package of any product referred to in clause 6(c), 6(d) or 6(e) is so small as to prevent the use of letters in 3 mm type, a reduced type height may be used, but no letter may have a letter height of less than 1.5 mm.
NEW ZEALAND SPECIFIC ISSUES FOR CONSULTATION

This consultation document discusses the merits of warning statements for royal jelly, bee pollen and propolis. These issues are common to both Australia and New Zealand. There are two issues that are specific to New Zealand and comment is also sought on these. These comments should be sent to ANZFA, as part of any submission on this document.

Should foods and dietary supplements be treated in the same way?

The New Zealand Food Standard 1996 Amendment No. 11 regulates foods and dietary supplements, consisting solely of or containing royal jelly, bee pollen and propolis, in the same way. The rationale for this is that foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. Having the same warning statement and ingredient listing requirements for foods and dietary supplements would achieve this. It is proposed that the warning statement finalised in the AFSC for royal jelly, and the ingredient listing requirements for bee pollen and propolis, as a result of this consultation process, apply to both foods and dietary supplements. This is because foods and dietary supplements that pose the same risks should be managed so as to achieve the same outcome. Do you agree with this?

Should the food standard for warning statements and ingredient listing be mandatory?

If a food standard is mandatory it prevails over the Food Regulations 1984 and any other food standard that may be inconsistent with it. There are no specific provisions in the Food Regulations for warning statements for royal jelly, or for mandatory ingredient listing of bee pollen and propolis. If the Minister of Health issues a food standard recognising any changes to the AFSC on the outcome of consultation process and the standard is not made mandatory, then the Food Regulations would apply. This would mean that a manufacturer or importer could choose to have no warning statement or ingredient listing (in some circumstances) or to comply with the new requirements in the AFSC.

Complying with the Food Regulations, rather than the amended AFSC, will not protect public health and it is proposed to make any changes to the AFSC, which are recognised in New Zealand, mandatory. At the same time the warning statement requirements contained in New Zealand Food Standard 1996 Amendment No. 11 will be repealed. Do you agree with this?