PROPOSAL P154

REGULATORY REQUIREMENTS FOR FOODS COMPRISING OR CONTAINING ROYAL JELLY, BEE POLLEN AND PROPOLIS, INCLUDING THE NEED FOR LABEL WARNING STATEMENTS

First Review Report

(Under Section S.21)
1. BACKGROUND

The Food Regulation Ministerial Council has requested a review of draft variation to Standard 1.2.3 (Volume 2) of the Food Standards Code as notified to the Council on 1 July 2002 (see Attachment 2). In particular, the Council has requested review of:

- The change in legibility requirement that permits the warning statement on foods comprising or containing royal jelly to be in **Sentence case** or **UPPER CASE**, from the previous requirement to be only in upper case.

- The deletion of the requirement for foods containing bee pollen to be labelled with a warning statement.

1.1 Current Regulations

Volume 1 of the Food Standards Code prescribes warning statements in upper case for foods comprising or containing royal jelly and foods containing bee pollen, but there is no specific labelling requirement for foods containing propolis.

The New Zealand Food Standard 2001 prescribes warning statements in upper case for products (foods and dietary supplements) containing royal jelly, bee pollen or propolis.

Volume 2 of the Food Standards Code requires the mandatory declaration of royal jelly, bee pollen, or propolis on the labels of foods containing them and contains a transitional standard for the continuation of the Australian or New Zealand requirements for royal jelly, bee pollen and propolis pending finalisation of this Proposal.

2. ISSUES REQUESTED TO BE REVIEWED BY THE MINISTERIAL COUNCIL

2.1 Legibility Requirements

Warning statements are required on the labels of foods that are considered to pose a high risk to public health and safety i.e. where the risk is life threatening. Warning statements need to be highly differentiated from the surrounding labelling information so as to attract attention to the important message. Also, warning statements in relation to unpackaged foods must be displayed on or in connection with the display of the food.

In addition to the general requirements in Volume 2 of the Food Standards Code for all information on food labels to be legible, prominent and in English, warning statements must be at least 3 mm in size for packages of surface area 100 cm² or more, or at least 1.5 mm for smaller packages. This means that, for most packages, each letter of a warning statement must be at least 3 mm in size when measured from the base to the top of the letter. Upper case is no longer mandated, however this does not preclude food manufacturers from adopting upper case. None of the 10 warning statements currently prescribed in Volume 2 are written in upper case although the text of warning statements required on infant formula labels are preceded by the word ‘Warning – ’.
The minimum size of a warning statement in upper case would be uniformly 3 mm in height, but for sentence case, the equivalent total height of the statement, given that each letter is 3 mm, would be about 5-6 mm in total taking into account the length of letters that have either ascenders or descenders (see examples using different fonts in normal typeface, unbolded).

WARNING STATEMENT TEXT **warning statement text**

WARNING STATEMENT TEXT **warning statement text**

Research has shown that sentences constructed totally from upper case take 10-12 percent longer to read and are also harder to understand and recall as those of sentence or lower case (Ley (1995)\(^1\)). Protection of public health and safety demands that warning statements are not only highly noticeable but that the message is easily read and understood. These objectives are met by the originally notified Proposal.

For comparison, two statements are required on the label of royal jelly as therapeutic products (the predominant form of royal jelly in the market):

- a short statement in 3 mm type prominently displayed on the front, case unspecified “not to be taken by asthma and allergy sufferers; and

- the same warning statement as proposed for food in 1.5 mm type (half the size required on foods) anywhere on the label, case unspecified.

\(^{2.1.1}\) Conclusion

On review, it is concluded that public health and safety are protected by the originally notified Proposal i.e. the prescription of each letter of the text of the warning statement in minimum size type of 3 mm and in the more easy to read form of sentence case. Such requirements are comparable to the Australian requirements for royal jelly as therapeutic goods.

2.2. Deletion of Requirement for Warning Statement on Foods containing Bee Pollen

Products of lower risk are either subject to mandatory declaration or an advisory statement on the label. Unlike royal jelly, where fatalities have been recorded, the evidence suggests that bee pollen constitutes a lower risk, and a lesser risk management strategy is appropriate.

The proposal not to continue the Australian and New Zealand warning statement THIS PRODUCT MAY CAUSE SEVERE ALLERGIC REACTIONS on foods containing bee pollen was based on a risk analysis of bee pollen products by the New Zealand Bee Product Warning Scientific Review Working Group in 1999 and concluded that “despite evidence of high levels of exposure on a world wide and Australasian basis there are an extremely small number of cases of serious [including life threatening] adverse effects, therefore on any qualitative scale, the risk is extremely low”.

\(^1\) Professor Phillip Ley, (1995) *The assessment and improvement of the clarity of meaning of warning statements, first aid statements, and safety directions required on labels of scheduled drugs and poisons* University of Sydney.
Between 1992-9, no fatalities, 1 case of anaphylaxis and no more than 7 cases of angioedema/urticaria were reported in the two countries. A review of the current content of the Australian Adverse Drug Reactions System Database in 2002 indicated no additional cases reported.

With the increasing use of ingredients in foods that were once only found in the therapeutic domain, it is possible that the Australian and New Zealand populations may be subject to higher levels of exposure to bee pollen. Because bee pollen does not exhibit a dose response relationship and, unlike major food allergens, the general community is unlikely to be aware of its allergenic potential in food, an advisory statement on the label of foods containing bee pollen would address this lack of community understanding and provide greater protection than the current mandatory declaration requirements in Volume 2 that apply to the major food allergens. The revised approach is consistent with the requirement for Australian therapeutic goods containing bee pollen to carry an advisory label statement ‘This product can cause severe allergic reactions (or words to that effect)’. Advisory statements have the intent of the message prescribed but not the actual text, nor are they subject to minimum size of type requirements, however they must be legible.

Bee pollen, as for royal jelly, may be found in trace amounts in honey, but these natural constituents are regarded for labelling purposes as contaminants not ingredients, and thus honey is not subject to these proposed labelling requirements.

2.2.1 Conclusion

On review, instead of mandatory declaration requirements for bee pollen as for major food allergens, the retention of a statement on the label of foods containing bee pollen to alert consumers to its low risk of severe reaction is appropriate so as to adequately protect public health and safety. However, because the risk is not high, as it is for royal jelly, it is appropriate that the statement be advisory, consistent with requirements for Australian therapeutic goods, to the effect that ‘this product contains bee pollen which can cause severe allergic reactions’.

3. RELATED ISSUES

3.1 Requirement for Advisory Statement on Foods containing Propolis

A review of the risk to health of consumption of propolis indicates a similar risk to that of bee pollen. The New Zealand Bee Product Warning Scientific Review Working Group concluded that “the risk to the population is considered to be extremely low and no population with increased susceptibility could be identified”. There were no deaths, and 8 cases of serious adverse health effects in Australia and New Zealand between 1992-9. Further interrogation of the Australian Adverse Drug Reactions System Database in 2002 indicated one additional case of oropharyngeal swelling reported in the 3 years since the New Zealand analysis.

Like bee pollen, propolis is also increasingly found in foods without widespread community knowledge of its potential as an allergen. The same risk management strategy of an advisory statement as for bee pollen should be applied to foods containing propolis.
Although there is no current Australian requirement to label foods containing propolis, Australian therapeutic goods for oral consumption that contain propolis must carry a label warning statement “WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use”. The New Zealand Food Standard 2001 (foods and dietary supplements) prescribes the warning statement “PROPOLIS MAY CAUSE SEVERE ALLERGIC REACTIONS”.

3.1.1 Conclusion

Given the similarities between bee pollen and propolis in level of risk and lack of community awareness of such risks from foods containing these ingredients, it is appropriate that the same type of advisory statement as for bee pollen also be required on the label of foods containing propolis i.e. to the effect that ‘this product contains propolis which can cause severe allergic reactions’.

3.2 Deletion of the Requirement for Mandatory Declaration of the Presence of Bee Pollen and Propolis, consistent with that proposed for Royal Jelly

The originally notified variation to Standard 1.2.3 proposed the deletion of the mandatory requirement for label declaration of the presence of royal jelly because the warning statement fulfilled that requirement. Similarly, the mandatory declaration requirements for bee pollen and propolis are no longer necessary because their respective advisory statements fulfil these roles.

3.2.1 Conclusion

Consistent with the proposed approach to the labelling requirements in relation to royal jelly, the mandatory requirement for the presence of bee pollen or propolis to be declared on the label is fulfilled by requirement for label advisory statements and thus a separate requirement for declaration of presence is redundant and should be deleted.

4. DRAFT VARIATIONS

The draft revised variation to Standard 1.2.3 resulting from the First Review is given at Attachment 1. The originally notified variation to Standard 1.2.3 is given at Attachment 2.

5. STATEMENT OF REASONS

The Australia New Zealand Food Authority (ANZFA) had before it a Proposal to amend Volume 2 of the Food Standards Code to include provisions for labelling requirements for foods comprising or containing royal jelly, and to consider the need for such requirements in relation to bee pollen and propolis.

After conducting a first review, Food Standards Australia New Zealand (FSANZ) recommends the adoption of the draft variation to Standard 1.2.3, as amended, on the basis of a review 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 in three deaths in Australia. There is a continuing 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 food comprising or containing royal jelly as a food ingredient may pose a risk to their health and wellbeing. It is proposed that the current warning statement (but no longer in upper case to improve readability) continue to be mandated in the label of food comprising or containing royal jelly as a food ingredient:

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

This statement fulfils the requirements for the statement to:

- apply to food comprising or containing royal jelly as an ingredient;
- refer to the at-risk target group, but also to others at risk; and
- describe an appropriate level of risk emphasising that risk particularly for the target group; and
- be easily recognised and understood.

2. The text and case requirements of the statement are also consistent with that required on royal jelly products regulated as a therapeutic good in Australia and the text with one of the options contained in the New Zealand Food Standard 2001 that regulates foods and dietary supplements.

3. Bee pollen and propolis have been reported to be implicated in allergic reactions; however, these ingredients constitute lower risk to public health than royal jelly. On the basis of then ANZFA’s risk assessment, a warning statement was considered to be no longer warranted in relation to bee pollen and not warranted in relation to propolis.

4. On review, given that consumers may not be aware of the allergenic potential of bee pollen or propolis in foods, it is appropriate to introduce mandatory advisory statements on these foods to the effect that ‘the product contains bee pollen [or propolis] which can cause severe allergic reactions’. These requirements are similar to those required on Australian therapeutic goods.

5. The application of the warning statement recommended in this Proposal has been clarified to reflect the intent that it does not apply in cases where royal jelly or other bee products are present naturally (in trace amounts) or due to unintentional contamination of products (eg in honey).

6. Because of the potential for some therapeutic-type bee products to be inadvertently classified and regulated as foods by virtue of the Therapeutic Goods Act 1989, the definitions for royal jelly, bee pollen, pollen and propolis have been deleted from Volume 2 of the Food Standards Code and included in the User Guide to Standard 1.2.3. No definitions for these substances were previously given in the New Zealand Food Standard 2001.
7. FSANZ recommends to the New Zealand Ministry of Health that the same labelling approach as recommended by this first review of Proposal P154, be adopted for royal jelly, bee pollen and propolis products regulated as foods under the New Zealand Food Standard 2001.

6. **REGULATORY IMPACT**

FSANZ 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 Volume 2 of the *Food Standards Code* is necessary to assist in the protection of public health and safety; is cost effective; and is of benefit to producers, consumers and government.

The variations recommended by this First Review will provide increased benefits to consumers and government through the requirement for more explicit label information to protect public health, but may impose some additional costs on manufacturers of foods containing bee pollen or propolis, however the benefits are expected to outweigh the additional costs.

6.1 **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 by New Zealand because the TBT Agreement requires that proposed regulatory measures such as technical regulations, including labelling requirements, be notified to other WTO members whenever relevant international standards do not exist and where the proposed measure may have a significant effect on trade. The agency responsible for WTO notifications in New Zealand determined that, in New Zealand’s circumstances, notification of the proposal was appropriate.

ANZFA received no submissions in response. WTO will be renotified by New Zealand because of the proposed change to the original wording of the warning statements in relation to all three bee products.
FURTHER INFORMATION

Submissions
No submissions on this matter are sought as the Authority has completed the first review at the request of the Australia and New Zealand Food Regulation Ministerial Council.

Further Information
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:

Food Standards Australia New Zealand   Food Standards Australia New Zealand
PO Box 7186                             PO Box 10559
Canberra BC ACT 2610                    The Terrace WELlington 6036
AUSTRALIA                               NEW ZEALAND
Tel (02) 6271 2258                       Tel (04) 473 9942
email: slo@foodstandards.gov.au         email: info@foodstandards.govt.nz

Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.govt.au or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@foodstandards.gov.au

ATTACHMENTS

1  Draft revised variation to Standard 1.2.3 proposed after First Review, September, 2002
2  Originally notified variation to Standard 1.2.3, 1 July 2002
ATTACHMENT 1

DRAFT REVISED VARIATION TO STANDARD 1.2.3 PROPOSED AFTER FIRST REVIEW, SEPTEMBER 2002

To commence: on gazettal

[1] Standard 1.2.3 of Volume 2 of the Food Standards Code is varied by –

[1.1] omitting clause 1, substituting –

1 Deleted

[1.2] inserting in Columns 1 and 2 respectively in the Table to clause 2 –

<table>
<thead>
<tr>
<th>Bee pollen</th>
<th>Statement to the effect that the product contains bee pollen which can cause severe allergic reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propolis</td>
<td>Statement to the effect that the product contains propolis which can cause severe allergic reactions</td>
</tr>
</tbody>
</table>

[1.3] inserting in Columns 1 and 2 respectively in the Table to clause 3 –

| Royal jelly when presented as a food; or Food containing royal jelly as an ingredient as defined in Standard 1.2.4 | 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 |

[1.4] omitting from the Table to clause 4 –

| Royal jelly presented as a food or royal jelly present in a food | Bee pollen | Propolis |

[1.5] omitting the Drafting note immediately following the Table to clause 3.
ORIGINALLY NOTIFIED VARIATION TO STANDARD 1.2.3, 1 JULY 2002

To commence: on gazettal

[1] **Standard 1.2.3** of Volume 2 of the Food Standards Code is varied by –

[1.1] **omitting** clause 1, **substituting** –

1 **Deleted**

[1.2] **inserting in Columns 1 and 2 respectively in the Table to clause 3** –

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[1.3] **omitting from the Table to clause 4** –

| Royal jelly presented as a food or royal jelly present in a food |

[1.4] **omitting the Drafting note immediately following the Table to clause 3.**