



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

3-07

23 May 2007

INITIAL ASSESSMENT REPORT

APPLICATION A602

EXTRANEOUS RESIDUE LIMIT IN HONEY (PARADICHLOROBENZENE)

For information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

Standard 1.4.2. – Maximum Residue Limits stipulates the requirements for residues of agricultural and veterinary chemicals in food. The Standard includes a separate Schedule for Extraneous Residue Limits (ERLs). An Extraneous Residue Limit (ERL) is the maximum permitted limit of a pesticide residue, arising from environmental sources other than the use of a pesticide directly or indirectly on the food.

An Application was received from the Australian Honey Bee Industry Council (AHBIC) on 21 March 2007 to include an ERL for paradichlorobenzene in honey in Schedule 2 of Standard 1.4.2. The limit requested is 0.1 mg/kg and is the same as the default limit¹ that the New Zealand Food Safety Authority has used to manage residues of paradichlorobenzene in honey in New Zealand. The Applicant has also requested that the limit apply for a finite period of five years.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (the Treaty), excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary

Low level residues of paradichlorobenzene have been found in honey from some producers as a result of the ‘leaching’ of residues from contaminated waxes in hives. According to the Applicant, this contamination has occurred as a result of the previously approved and historical use of paradichlorobenzene. Incorporating the proposed ERL would allow implicated apiarists to identify and dispose of contaminated combs in hives in an orderly and economically viable timeframe.

FSANZ has identified three main options for considering the impact of various regulatory (and non-regulatory) options on all sections of the community:

Option 1 – Do not incorporate an ERL for paradichlorobenzene in honey.

Option 2 – Incorporate an ERL of 0.1 mg/kg for paradichlorobenzene in honey for a period of five years.

Option 3 – Incorporate an ERL of 0.1 mg/kg for paradichlorobenzene in honey without specifying a timeframe.

The Application relates to a matter that may warrant a variation of a food regulatory measure and there is no similar previous Application. FSANZ has taken these matters into account and accepts the Application.

FSANZ will undertake a risk assessment of the residues of paradichlorobenzene in honey as part of the Draft Assessment.

¹ All imported and domestically-produced food sold in New Zealand (except for food imported from Australia) must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards (the MRL Standards) and amendments. The MRL Standards list the MRLs for a range of agricultural compounds, but also include a provision for residues of up to 0.1 mg/kg for agricultural compound/food combinations not specifically listed.

Under section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ decided to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. It was satisfied that that the Application raised issues of minor significance or complexity only.

Purpose

The purpose of the Application is to amend Standard 1.4.2 – Maximum Residue Limits to include an ERL for paradichlorobenzene in honey in Schedule 2 of Standard 1.4.2 for a period of five years.

Reasons for Assessment

The Application has been assessed against the requirements in section 13 of the FSANZ Act and FSANZ recommends accepting the Application for the following reasons:

- The Application relates to a matter that may warrant a variation of a food regulatory measure and there is no similar previous application.
- If Standard 1.4.2 was varied as a result of the Application, the likely outcome would be a reduction in costs to certain members of the honey industry.
- Other measures would not be appropriate in addressing the problem raised by the Applicant.
- At this stage no other relevant matters are apparent.

Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act, to omit inviting public submissions in relation to the Application prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only.

FSANZ will seek public comment following Draft Assessment in order to proceed to Final Assessment of this Application.

CONTENTS

INTRODUCTION	2
1. BACKGROUND.....	2
2. THE ISSUE	3
3. OBJECTIVES	3
4. KEY ASSESSMENT QUESTIONS	3
RISK ASSESSMENT	4
5. SAFETY ASSESSMENT.....	4
6. DIETARY EXPOSURE ASSESSMENT	4
RISK MANAGEMENT	4
7. OPTIONS.....	4
8. IMPACT ANALYSIS	4
8.1 <i>Affected Parties</i>	4
8.2 <i>Benefit Cost Analysis</i>	5
COMMUNICATION	5
9. COMMUNICATION AND CONSULTATION STRATEGY	5
10. CONSULTATION.....	5
10.1 <i>Public consultation</i>	5
10.2 <i>World Trade Organization (WTO)</i>	6
CONCLUSION	6
11. CONCLUSION AND RECOMMENDATION	6

INTRODUCTION

An Application was received from the Australian Honey Bee Industry Council (AHBIC) on 21 March 2007 to include an Extraneous Residue Limit (ERL) for paradichlorobenzene in honey in Schedule 2 of Standard 1.4.2 – Maximum Residue Limits for five years. An ERL is the maximum permitted limit of a pesticide residue, arising from environmental sources other than the use of a pesticide directly or indirectly on the food.

The limit requested is 0.1 mg/kg and is the same limit that the New Zealand Food Safety Authority (NZFSA) has used to manage residues of paradichlorobenzene in New Zealand.

The honeybee industry is very concerned about the detection of residues of paradichlorobenzene in honey and the industry is also concerned that the honey from some small primary producers will not be accepted by honey processors, unless a limit is established to recognise the presence of these residues.

1. Background

Standard 1.4.2. stipulates the requirements for residues of agricultural and veterinary chemicals in food. The Standard includes a separate Schedule for ERLs.

Paradichlorobenzene is a chlorinated organic substance that has been used to control moths in hives. According to the Applicant, the previously approved and historical use of paradichlorobenzene has resulted in contamination of the wax in previously treated hives.

The industry was recently alerted to the problem of paradichlorobenzene residues when residues above 0.01 mg/kg were detected by European authorities² in honey from Australia. While paradichlorobenzene use is not approved, low level residues have been found in honey from some producers as a result of the ‘leaching’ of residues from contaminated waxes in previously treated hives.

The honey industry does not wish to seek approval for the use of paradichlorobenzene or to apply to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for a permit for use of paradichlorobenzene. This is because it does not consider that paradichlorobenzene should be used and because there are more appropriate alternatives available to control wax moths. This Application for an ERL has been made to legitimise the residues in honey while ensuring that misuse of the chemical is not promoted.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (the Treaty), excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

² Under Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in products of plant and animal origin, the maximum pesticide residue level in foodstuffs is 0.01 mg/kg. This general limit is applicable 'by default', i.e. in all cases where an MRL has not been specifically set for a product or product type.

2. The Issue

Residues of paradichlorobenzene have been detected in honey. To allow the sale of honey containing these residues, an ERL is proposed for inclusion in Schedule 2 of Standard 1.4.2.

The proposed limit of 0.1 mg/kg is consistent with the limit in food legislation in New Zealand and is proposed to apply for a finite period of five years, to implement the industry strategy for phasing out residues.

Incorporating the proposed ERL would allow implicated apiarists to identify and dispose of contaminated combs in hives in an orderly and economically viable timeframe.

3. Objectives

The objective of this assessment is to ensure that any amendment of Standard 1.4.2 is consistent with the protection of public health and safety.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Key Assessment Questions

- Do the residues of paradichlorobenzene at the proposed limit pose any public health and safety issues?
- Is the limit proposed by the Applicant achievable?
- Is the proposed timeframe for the limit of five years acceptable and appropriate?

RISK ASSESSMENT

5. Safety Assessment

The safety of the residues of paradichlorobenzene in honey will be assessed at Draft Assessment.

6. Dietary Exposure Assessment

Dietary modelling will be required in the Draft Assessment Report for the residues of paradichlorobenzene in honey.

RISK MANAGEMENT

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, including consumers, food industries and governments. The regulatory options available for this application are:

7.1 Option 1 – Do not incorporate an ERL for paradichlorobenzene in honey

This option maintains the *status quo* by requiring the residues of paradichlorobenzene to be undetectable in honey.

7.2 Option 2 – Incorporate an ERL of 0.1 mg/kg for paradichlorobenzene in honey for a period of five years.

This option would require an amendment to Schedule 2 of Standard 1.4.2 to incorporate an ERL that would allow honey containing residues of paradichlorobenzene up to 0.1 mg/kg to be legally sold for five years.

7.3 Option 3 – Incorporate an ERL of 0.1 mg/kg for paradichlorobenzene in honey without specifying a timeframe.

This option would require an amendment to Schedule 2 of Standard 1.4.2 to incorporate an ERL that would allow honey containing residues of paradichlorobenzene up to 0.1 mg/kg to be legally sold until the ERL is deleted with a separate Application or Proposal.

8. Impact Analysis

8.1 Affected Parties

The parties likely to be affected by this Application include:

1. some honey producers and processors who would benefit from the variation as it would enable them to supply and process honey containing low levels of paradichlorobenzene;

2. consumers that may have concerns about residues in honey and those consumers who may benefit in relation to supply of honey, although this benefit is unlikely to be discernable; and
3. government agencies in Australia and New Zealand who ensure compliance with the Code, on the basis that these agencies may need to develop methods for monitoring paradichlorobenzene in honey.

8.2 Benefit Cost Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts. This benefit cost analysis will be undertaken at Draft Assessment.

COMMUNICATION

9. Communication and Consultation Strategy

This Application requests that an ERL of 0.1 mg/kg for paradichlorobenzene in honey be included in Schedule 2 of Standard 1.4.2 for five years.

FSANZ has applied a basic communication strategy to Application A602. This will involve advertising the availability of the Draft Assessment Report for public comment in the national press and making the reports available on the FSANZ website. During the assessment process, FSANZ will consult key stakeholders. FSANZ will seek public comment following Draft Assessment in order to proceed to Final Assessment of this Application.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the Application. If approval is recommended and the FSANZ Board approves the Final Assessment Report, FSANZ will notify the Ministerial Council. The Applicant and stakeholders, including the public, will be notified on the gazettal of changes to the Code in the national press and on the website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

10. Consultation

10.1 Public consultation

The Initial Assessment Report is not a detailed assessment of this Application but rather an assessment of whether the Application should undergo further consideration.

FSANZ decided, pursuant to section 36 of the FSANZ Act to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. FSANZ made its decision under section 36 of the FSANZ Act because it was satisfied that that the Application raised issues of minor significance or complexity only.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an Application for review of FSANZ's decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

FSANZ will seek public comment after a Draft Assessment is made in order to assist in assessing this Application at Final Assessment.

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

11. Conclusion and Recommendation

In accordance with section 13 of the FSANZ Act, FSANZ has undertaken an Initial Assessment and recommends accepting the application.

Reasons for Assessment

The Application has been assessed against the requirements in section 13 of the FSANZ Act and FSANZ recommends accepting the Application for the following reasons:

- The Application relates to a matter that may warrant a variation of a food regulatory measure and there is no similar previous application.
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