

**23 May 2013**  
**[08-13]**

## **Call for submissions – Application A1083**

### **Maximum Residue Limits for Blueberries and Raspberries**

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FSANZ has assessed an Application made by the Australian Food and Grocery Council and Patties Foods Limited to seek permission to amend maximum residue limits (MRLs) listed in Schedule 1 of Standard 1.4.2 to include Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

#### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 20 June 2013**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand  
PO Box 7186  
CANBERRA BC ACT 2610  
AUSTRALIA  
Tel +61 2 6271 2222

Food Standards Australia New Zealand  
PO Box 10559  
The Terrace WELLINGTON 6143  
NEW ZEALAND  
Tel +64 4 978 5630

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### Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1083maxi5839.cfm>

SD1 Supporting document SD1: Dietary exposure estimates – Application A1083  
Maximum Residue Limits for Blueberries and Raspberries

## 1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Food and Grocery Council and Patties Foods Limited on 13 March 2013. The Application sought the inclusion of maximum residue limits (MRLs) for the agricultural chemicals Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries in Standard 1.4.2 in the *Australia New Zealand Food Standards Code* (the Code).

Standard 1.4.2 lists the MRLs for agricultural and veterinary chemical residues which may occur in foods in Australia. Limits prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported.

FSANZ estimated the dietary exposure of the Australian population to these chemicals, which indicated that the proposed limits for the residues do not present any public health and safety concerns in relation to the health-based guidance values.

The potential benefits of including the MRLs in the Code outweigh the possible costs and will permit the import and sale of foods which may contain legitimate residues used as part of good agricultural practices. Agricultural and veterinary chemicals are used differently in different countries around the world where pests, diseases and environmental factors differ and because product use patterns may differ. Further, the proposed MRL variations will harmonise the Code with international MRL standards.

FSANZ has prepared a draft variation to Standard 1.4.2 to include the relevant agricultural chemicals under Schedule 1.

## 2. Introduction

### 2.1 The Applicant

The Australian Food and Grocery Council (AFGC) is a national organisation representing Australia's food, drink and grocery manufacturing industry.

Patties Foods Limited (Patties Foods) is an Australian manufacturer, supplier and marketer of branded frozen savoury and dessert products.

### 2.2 The Application

Application A1083 was submitted by the AFGC and Patties Foods on 13 March 2013. The Application sought the inclusion of maximum residue limits (MRLs) for the agricultural chemicals Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries under Schedule 1 of Standard 1.4.2 of the *Australia New Zealand Food Standards Code* (the Code).

There are currently no MRLs listed for blueberries and raspberries under Schedule 1 for the chemicals requested. The MRLs requested (Table 1) would harmonise MRLs in the Code with other international standards including Codex Alimentarius (Codex) MRL standards and New Zealand standards (see Section 3.2.3).

**Table 1 Requested MRLs for Application A1083**

Commodity	Chemical	Requested MRL (Codex)
Blueberries	Azoxystrobin	5.0 mg/kg
Blueberries	Fenhexamid	5.0 mg/kg
Blueberries	Fludioxonil	2.0 mg/kg
Raspberries	Bifenthrin	1.0 mg/kg

### 2.3 The current Standard

Standard 1.4.2 lists the limits for agricultural and veterinary chemical residues which may occur in foods according to good agricultural practice. Limits prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products with residues exceeding the relevant limit listed in the Code cannot legally be supplied in Australia. This ensures that residues of agricultural and veterinary chemicals are kept as low as possible and consistent with the approved use of chemical products to control pests and diseases of plants and animals. FSANZ has the responsibility to ensure that there are no risks to human health as a result of changes to MRLs.

The chemicals requested for consideration in this Application are permitted for use as an insecticide (Bifenthrin) or fungicides (Azoxystrobin, Fenhexamid and Fludioxonil) under good agricultural practice in Australia for many domestically produced commodities, and have permissible MRLs for those commodities in the Code. There are currently no residues permitted for Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries because the chemicals are not used in domestic agricultural production.

Agricultural and veterinary chemicals are used differently in different countries around the world where pests, diseases and environmental factors differ and because product use patterns may differ. Residues in imported foods may therefore legitimately differ from those in domestically produced foods.

Application A1083 has been raised to enable continued trade between Australia and major producers of individually quick frozen (IQF) berries where these agricultural chemicals are used as part of good agricultural practice in that country.

The Application would also serve to harmonise MRLs in the Code with those in Codex MRL standards.

## **2.4 Reasons for accepting Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2);
- it related to a matter that warranted the variation of a food regulatory measure;
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected;
- there was no other relevant matter to consider.

## **2.5 Procedure for assessment**

The Application is being assessed under the General Procedure.

# **3. Summary of the assessment**

## **3.1 Risk assessment**

To assess the public health and safety implications of chemical residues in food, FSANZ estimates the dietary exposure to chemical residues from potentially treated foods in the diet and compares the dietary exposure with the relevant health-based guidance value, for example the acceptable daily intake (ADI) or the acute reference dose (ARfD).

The ADI and ARfD for individual agricultural and veterinary chemicals are established by the Office of Chemical Safety and Environmental Health (OCSEH) following an assessment of the toxicology of each chemical. In the case that an Australian ADI or ARfD has not been established, a Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) ADI or ARfD may be used for risk assessment purposes.

FSANZ conducts and reviews dietary exposure assessments using the best available scientific data and internationally recognised risk assessment methodology. Variations to limits in the Code will not be supported where estimated dietary exposures to the residues of a chemical indicate a potential public health and safety risk for the population or a population sub group.

The steps undertaken in conducting a dietary exposure assessment are:

- determining the residues of a chemical in a treated food

- calculating dietary exposure to a chemical from relevant foods, using residue data and food consumption data from national nutrition surveys
- completing a risk characterisation where estimated dietary exposures are compared to the relevant health-based guidance value.

FSANZ has performed a dietary exposure assessment on the agricultural chemicals Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries, taking into account MRLs in the Code for these chemicals under Schedule 1 of Standard 1.4.2 for other commodities and the proposed MRLs do not present any public health and safety concerns. The results of the dietary exposure assessment have been provided in the supporting document (SD1).

Further information on how FSANZ conducts dietary exposure assessments is available at <http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/dietaryexposureandin4438.cfm>

## 3.2 Risk management

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.
- any relevant New Zealand standards
- any other relevant matters.

Two options were considered:

1. prepare a draft variation to Schedule 1 of Standard 1.4.2 to include MRLs for the agricultural chemicals Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries under the Code; or
2. reject the Application.

FSANZ has decided to prepare a draft variation to Standard 1.4.2 because the potential benefits of approving the variation outweigh the potential costs, and because the dietary exposure assessment has shown no public health or safety concerns resulting from consumption of the relevant foods.

### 3.2.1. Cost/benefit analysis

The Office of Best Practice Regulation (OBPR) has advised that Application A1083 is covered under the standing exemption from the need to contact OBPR regarding applications relating to maximum residue limits (ID 12065). Therefore, no further analysis in the form of a Regulation Impact Statement is required.

A consideration of the cost benefit issues of the regulatory options was considered as part of the assessment process found in 3.2.1.1 below. This section is not intended to provide a quantitative dollar analysis of the options but to highlight some of the potential qualitative impacts to consumers, government and industry.

### **3.2.1.1 Option 1 – Prepare a draft variation to Standard 1.4.2**

Consumers: There would be continued year-round availability of imported IQF blueberries and raspberries and products made with IQF blueberries and raspberries.

Government: There would be no potential for trade disruption on regulatory grounds for products which have been previously imported without issue.

The proposed MRLs would harmonise with the Codex Alimentarius Commission, New Zealand and trading partner standards and would give regard to the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry, as stated under paragraphs 18 (2) (b) and (c) of the *Food Standards Australia New Zealand Act 1991*.

These variations would therefore benefit Australian Government, state and territory agencies, in that they serve to further harmonise agricultural and food standards. Achieving further consistency between agricultural and food legislation will minimise compliance costs to primary producers and assist in efficient enforcement of regulations.

Industry: Importers of IQF berries would benefit by bringing imported berries into compliance with the Code, allowing continued market access and choice in raw materials.

The applicant has stated that Australian berry production does not fill the needs for shelf stable or IQF berry products for industry or for sale to the consumer. These variations would therefore benefit industry by allowing them to fill a demand that cannot be met by local production alone.

Retailers may be able to continue to offer food products manufactured using imported IQF berries.

### **3.2.1.2 Option 2 – Reject application**

Consumers: There may be possible restrictions of the availability of berries and products produced using imported berries.

Government: There may be a potential barrier to trade with international trading partners due to the lack of MRLs in the Code for agricultural chemicals with legitimate use in growing blueberries and raspberries.

This may result in potential issues with World Trade Organization (WTO) obligations; promotion of consistency between domestic and international trading partners; and the promotion of fair trading in food.

Industry: The importation of IQF berries and berry containing products would be restricted from countries where these chemicals are used as part of legitimate agricultural practices.

There is potential for the supply of foods manufactured using imported IQF berry products to be discontinued.

The potential benefits of approving the variation outweigh the potential costs. Based on the conclusions of the safety assessments there are no reasons to reject the Application.

### **3.2.2 Other measures**

There are no measures that could achieve the same result other than an amendment to Standard 1.4.2.

### **3.2.3 Relevant New Zealand standards**

New Zealand has its own standards for chemical residues set out in the *New Zealand* (Maximum Residue Limits of Agricultural Compounds) *Food Standards* (the MRL Standards) and amendments, and the New Zealand Government enforces these standards.

Limits in the Code and in the New Zealand MRL Standards may differ for a number of legitimate reasons including differing use patterns for chemical products as a result of varying pest and disease pressures and varying climatic conditions.

Foods imported into New Zealand must comply either with the New Zealand MRL Standards or with Codex MRLs (except for food imported from Australia).

Further information about the New Zealand MRL Standards is available on the New Zealand Ministry for Primary Industries website at <http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/>.

The MRLs set out in the New Zealand MRL Standards for Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries refer to MRLs in Codex standards shown in Table 1. The proposed changes in this Application would harmonise the Code with Codex and New Zealand standards.

### **3.2.4 Any other relevant matters**

There are no other relevant matters to consider in relation to A1083.

### **3.2.5. Addressing FSANZ's objectives for standards-setting**

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### **3.2.5.1 Protection of public health and safety**

Inclusion of MRLs for Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries has been assessed using internationally accepted procedures for estimating dietary exposure to food chemicals. FSANZ concluded that in relation to current health-based guidance values, setting the limits as proposed does not present any public health and safety concerns.

#### **3.2.5.2 The provision of adequate information relating to food to enable consumers to make informed choices**

Country of origin labelling requirements under Standard 1.2.11 will continue to be required allowing consumers to make informed choices when purchasing berry products.



There are no specific labelling requirements for agricultural chemicals and this is not a consideration for this Application.

### **3.2.5.3 *The prevention of misleading or deceptive conduct***

In Australia, compliance with the Code for all foods is monitored by authorities in the states and territories. Testing for agricultural chemical residues will ensure that imported foods are in compliance with MRLs in the Code.

### **3.2.6 *Subsection 18(2) considerations***

FSANZ has also had regard to the matters listed in subsection 18(2):

- the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ's primary role in developing food regulatory measures for residues of agricultural and veterinary chemicals in food is to ensure that estimated dietary exposures to potential residues are within health-based guidance values. As described in Section 3.1, FSANZ conducts and reviews dietary exposure assessments using the best available scientific data and internationally recognised risk assessment methodology.

- the promotion of consistency between domestic and international food standards

The proposed MRL variations would remove inconsistencies between MRLs in the Code and those in Codex and other international trading partner standards, removing trade barriers.

- the desirability of an efficient and internationally competitive food industry

The proposed MRL variations ensure openness and transparency in relation to the residues that could reasonably occur in food and will minimise potential costs to primary producers and importers by permitting the sale of food containing legitimate residues.

- the promotion of fair trading in food

Section 3.2.1 lists a number of considerations that address fair trading with respect to variations to MRLs in this proposal.

- any written policy guidelines formulated by the Ministerial Council<sup>1</sup>.

The Application has regard to the need to promote a consistent approach to MRLs for both domestic and imported foods, where appropriate, and the need to be consistent with Australia's obligations under the WTO Sanitary and Phytosanitary Agreement (SPS Agreement).

## **3.3. Risk communication**

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

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<sup>1</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation to the Code. FSANZ also places all applications and submissions on the FSANZ website. All public comments received will be reviewed and considered before approval by the FSANZ Board. The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

### **3.3.1 World Trade Organization (WTO)**

In this instance, as the amendment is a trade-liberalising measure by harmonising with international standards, FSANZ is under no obligation to notify the WTO of the amendment being proposed. However, FSANZ policy approach is in line with WTO policy to notify MRL amendments to the WTO in the interests of openness and transparency, even if they are harmonising with international standards, as there is often a strong interest in such measures among Australia's trading partners. Therefore, a notification has been made under the Sanitary and Phytosanitary Agreement.

## **4. Draft variation**

The draft variation to Standard 1.4.2 is at **Attachment A**.

A draft Explanatory Statement is at **Attachment B**.

### **4.1 Implementation**

The variation will take effect on gazettal.

## **Attachments**

- A. Draft Variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1083 – Maximum Residue Limits for Blueberries and Raspberries) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Application A1083 – Maximum Residue Limits for Blueberries and Raspberries) Variation*.

**2 Variation to Standards in the *Australia New Zealand Food Standards Code***

The Schedule varies Standard 1.4.2 in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on **the date of gazettal**.

**SCHEDULE**

[1] **Standard 1.4.2** is varied by inserting in Schedule 1 for each of the following chemicals the foods and associated MRLs in alphabetical order

<b>Azoxystrobin</b> Azoxystrobin	
“	”
Blueberries	5
<b>Bifenthrin</b> Bifenthrin	
“	”
Raspberries, red, black	1
<b>Fenhexamid</b> Fenhexamid	
“	”
Blueberries	5
<b>Fludioxonil</b> Commodities of animal origin: Sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil Commodities of plant origin: Fludioxonil	
“	”
Blueberries	2

## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1083 which seeks permission to amend maximum residue limits (MRLs) listed in Schedule 1 of Standard 1.4.2 to include Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

### **2. Purpose**

The purpose of the proposed variation to Standard 1.4.2 is to include Azoxystrobin, Fenhexamid and Fludioxonil in blueberries and Bifenthrin in raspberries which promotes consistency between domestic and international regulations and supports global trade with a net benefit to the community

Standard 1.4.2 lists the limits for agricultural and veterinary chemical residues which may occur in foods. If a limit is not listed for a particular agricultural or veterinary chemical/food combination, there must be no detectable residues of that chemical in that food. In the absence of the relevant limit in the Code the food may not be sold where there are detectable residues.

MRL variations are required to permit the sale of foods containing legitimate residues. Internationally, farmers face different pest and disease pressures and therefore agricultural and veterinary chemical use patterns, and the legitimate residues in food associated with these uses, may vary accordingly.

A dietary exposure assessment is conducted before MRLs are varied to ensure that proposed limits do not present any public health or safety concerns.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 3 of Part 1 of the FSANZ Act, the Authority's consideration of Application A1083 will include one round of public consultation following an assessment and the preparation of a draft Standard.

FSANZ will make a Sanitary and Phytosanitary notification to the World Trade Organization (WTO).

A Regulation Impact Statement was not required because the proposed variations to Standard 1.4.2 are likely to have a minor impact on business and individuals.

#### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

#### **6. Variation**

Items 1 set out proposed amendments to Schedule 1 of Standard 1.4.2 inserting new entries for the chemicals listed. The entries include the chemical name, residue definition, foods and associated MRLs. This item incorporates the new entries in alphabetical order among the chemicals listed in the Schedule.