

**9 October 2019**  
**[98-19]**

## **Call for submissions – Application A1181**

### **Maximum Residue Limit (MRL) for Imazapyr in Barley**

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FSANZ has assessed an application made by BASF Australia Limited to align the MRL for imazapyr residues in barley in Schedule 20 of the Code with the MRL currently listed in the APVMA MRL Standard 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 we accept as confidential, 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 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) 24 October 2019**

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:

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### Supporting document

The [following document](#) which informed the assessment of this Application is available on the FSANZ website.

Supporting Document 1 (SD1)      Risk assessment on proposed increase in maximum residue limit for imazapyr residue in barley

## Executive summary

This Application seeks to align the maximum residue limit (MRL) for the agricultural chemical imazapyr in barley in Schedule 20 of the Australia New Zealand Food Standards Code (the Code) with the MRL set by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 (the APVMA MRL Standard).

The Application relates only to Australia as the Agreement between the Government of Australia and the Government of New Zealand concerning the *Joint Food Standards System* (the Treaty) excludes MRLs for agricultural chemicals in food from the joint food standards.

MRLs are legal limits that apply to all foods sold in Australia whether produced domestically or imported. They are determined through good agricultural practice based on the amount of a chemical that is needed to control pests and/or diseases.

The Application is to increase the MRL for imazapyr in barley in Schedule 20 of the Code from 0.05 mg/kg to 0.7 mg/kg. This increase will align the MRL with the APVMA MRL Standard that was gazetted by the APVMA in November 2018. The APVMA does not currently have the legislative power to directly amend Schedule 20 to align the MRLs.

The increase will also align the MRL for imazapyr in barley in Schedule 20 of the Code with the international MRL set by the Codex Alimentarius Commission (Codex).

The Australian population's dietary exposure through the food supply to the proposed increase in the MRL was extensively assessed by the APVMA before the new MRL was published in the APVMA MRL Standard. FSANZ also undertook an independent dietary exposure assessment following receipt of the application. The risk assessment indicated that the proposed increase to the MRL presents a negligible health and safety risk to consumers. The risk assessment for the proposed increased MRL is detailed in Supporting Document 1 (SD1).

Domestic and international stakeholders will benefit from alignment of the MRL for imazapyr in barley with the APVMA MRL and Codex standards, providing a consistent national MRL for enforcement purposes.

FSANZ has therefore prepared a draft variation to amend Schedule 20 to increase the MRL for imazapyr in barley from 0.05 mg/kg to 0.7 mg/kg. FSANZ now seeks public submissions in relation to its assessment and the draft variation.

# 1 Introduction

## 1.1 The Applicant

BASF Australia Limited is a leading company in the Australian crop protection industry and has a broad portfolio of fungicides, insecticides, herbicides, seed treatments and pest control products. It also provides biological crop protection products and solutions for improving plant health and nutrient management in the soil.

## 1.2 The Application

The application was lodged on 17 May 2019 and paid for on 13 August 2019. It sought to amend the maximum residue limit (MRL) in Schedule 20 of the Code for residues of the agricultural chemical imazapyr in barley by increasing it from 0.05 mg/kg to 0.7 mg/kg. This increase was to align the MRL with:

- the MRL for imazapyr in barley set by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019; and
- the MRL for imazapyr in barley set by the Codex Alimentarius Commission (Codex).

Section 82 of the FSANZ Act provides the APVMA with the power to directly amend Schedule 20 only when making new chemical approvals, registrations, variations or permits under the Agricultural and Veterinary Chemicals Code (Agvet Code). In this situation, the increase to the APVMA MRL standard was due to additional data being provided by the registrant for the current use pattern of imazapyr. As a result the APVMA did not have the legislative power to directly amend Schedule 20 of the Code as the appropriate legislative trigger was not satisfied.

## 1.3 The current standard

Schedule 20 of the Code lists the MRLs for agricultural and veterinary (agvet) chemical residues which may occur in foods. This is an Australia only standard. The pesticide residue limits prescribed in Schedule 20 constitute a mandatory requirement that apply to all food products of a particular class, whether produced domestically or imported. Food products with residues exceeding the MRLs listed in the Code are non-compliant and cannot legally be sold in Australia. This approach ensures that residues of agvet chemicals in food are kept as low as possible, are consistent with the approved uses to control pests and diseases of plants and animals, and are at levels that have been assessed as safe for human consumption.

### 1.3.1 National standards

- There are two sets of MRL standards recognised in Australia:
  1. Schedule 20 of the Code is the main MRL standard and is adopted by the states and territories for monitoring the maximum concentration of agvet chemical residues in foods for sale on the Australian market.
  2. The APVMA MRL Standard sets out the maximum residues of permitted and approved chemicals in treated food commodities under the Agricultural and Veterinary Chemicals Code (Agvet Code).
- The agricultural chemical imazapyr is permitted for use on barley in Australia by the APVMA and is also currently listed in Schedule 20 of the Code. The current MRL in

Schedule 20 is 0.05 mg/kg and applies to domestically produced and imported barley. The same level was in the APVMA MRL Standard until November 2018.

- In November 2018, the APVMA amended the MRL for imazapyr in barley from 0.05 mg/kg to 0.7 mg/kg in the APVMA MRL Standard. The increase was based on risk assessments and evaluations undertaken following provision of additional new data by the registrant (BASF Australia Ltd). The new data was relevant to the current use pattern of the chemical and indicated that the MRL needed to be increased to 0.7 mg/kg. The current Codex MRL for imazapyr in barley is also 0.7 mg/kg (see Table 1).

Table 1: Domestic and international MRLs for imazapyr in barley

Chemical	Commodity	Current MRL (mg/kg)	Authority	Jurisdiction
Imazapyr	Barley	*0.05	Australia New Zealand Food Standards Code (Schedule 20)	Domestic – for sale
		0.7	APVMA MRL Standard	Domestic – for use
		0.7	Codex	International

Codex MRLs (also referred to as CXLs) are primarily intended to facilitate international trade and accommodate differences in Good Agricultural Practice (GAP) employed by various countries based on differing climate, growing conditions and pests and diseases.

## 1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2); and
- it warranted the variation of the specific food regulatory measure.

## 1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

# 2 Summary of the assessment

## 2.1 Risk assessment

FSANZ assessed potential public health and safety implications of increasing the MRL for imazapyr in barley for Australian consumers. In doing so, FSANZ considered the scientific assessment and residues evaluation report prepared by the APVMA in increasing the MRL in its standard from 0.05 mg/kg to 0.7 mg/kg. That report was part of the documents submitted to FSANZ by BASF Australia Ltd (the Registrant). It detailed the APVMA's risk assessment process and the decision to increase the MRL based on the new information/data submitted by the Registrant to cover the currently registered use pattern.

The MRL of \*0.05 mg/kg for imazapyr residues on barley was established in 2012 based on

trial data undertaken in 2008/09. The new data supporting the increase in the MRL to 0.7 mg/kg was based on new GLP trials on barley conducted in 2015 and 2016. The two studies of imazapyr residues in barley were considered by the World Health Organization Food and Agriculture Organization Expert Committee Joint Meeting on Pesticide Residues (JMPR) in 2017 and the recommendation was made to increase the MRL for imazapyr on barley to 0.7 mg/kg based on the new data.

Imazapyr is presently listed in Schedule 20 of the Code. Therefore FSANZ considered the residue definition used by the APVMA and that established by JMPR and other overseas regulatory bodies for the proposed increased MRL. FSANZ's assessment concluded that the residue definition as currently stated in the Code remains appropriate.

### **2.1.1 Dietary exposure assessment (DEA)**

To assess the public health and safety implications of the increased MRL for imazapyr in barley, FSANZ reviewed the DEA undertaken by APVMA and carried out its own DEA using internationally recognised risk assessment methodologies. Estimates of the chemical residue from potentially treated foods in the Australian diet were undertaken and compared with the relevant Health-Based Guidance Values (HBGVs) – the acceptable daily intake (ADI) and where required the acute reference dose (ARfD).

The Australian ADI, and where required an Australian ARfD, for imazapyr are established by the APVMA following an assessment of the toxicology of the chemical. In situations where an Australian ADI or ARfD has not been established, a JMPR or Joint Expert Committee on Food Additives (JECFA) ADI or ARfD may be used for the risk assessment. In the case of imazapyr, no ARfD was established by either the APVMA or JMPR due to its low oral toxicity and the absence of any developmental toxicity after a single dose. Therefore only an ADI was used for the HBGV.

The steps undertaken in conducting the DEA included:

- Determining the residue of imazapyr in barley
- Estimating dietary exposure to imazapyr from relevant foods, using chemical residue data and food consumption data from Australian national nutrition surveys
- Completing a risk characterisation by comparing the estimated dietary exposures to the relevant HBGV.

The chronic dietary exposure to imazapyr was estimated using the national estimated dietary intake (NEDI) calculation which included all current permissions for imazapyr in Schedule 20, the proposed MRL for the commodity in the Application (barley) and the mean daily dietary consumption data derived from the relevant national nutrition surveys.

The estimated NEDI for imazapyr was <1% of the ADI and it was concluded that the chronic dietary exposure to imazapyr was acceptable.

In the absence of an ARfD, a national estimate of short-term intake (NESTI) calculation was not considered necessary.

A summary of the dietary exposure estimate for imazapyr residues in barley is provided in SD1. The exposure estimate for this Application indicates that the proposed increase in the MRL poses a negligible risk to health and safety for Australian consumers.

Variations to MRLs in the Code will not be supported where the estimated dietary exposure of consumers to residues of a chemical indicate a potential public health and safety risk for

the Australian population or population sub-group.

Further information on how FSANZ conducts DEAs is available on the [FSANZ website](#)

## **2.2 Risk management**

FSANZ is committed to ensuring that residues of agvet chemicals that may occur in food commodities are legitimate following their prescribed use in food production and to maintain the currency of the MRLs in Schedule 20 of the Code. The safety of the Australian population is the key consideration in any proposed changes to MRLS in the Code.

FSANZ will only approve variations to MRLs in the Code where the risk assessment concludes that the estimated dietary exposures are within the relevant HBGVs. FSANZ may consider including MRLs in Schedule 20 to harmonise with those established by Codex or a trading partner's government authority in circumstances where the risk assessment shows they do not present health and safety concerns to Australian consumers.

As noted above, the dietary exposure estimate undertaken to increase the MRL for imazapyr in barley indicates that it will pose negligible risk to health and safety for Australian consumers. In this circumstance, and for the reasons outlined in this consultation paper, preparation of a draft variation to increase the current MRL in Schedule 20 from 0.05 mg/kg to 0.7 mg/kg is an appropriate risk management approach. FSANZ has therefore prepared a draft variation to the Code to make that amendment.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process.

FSANZ's communication strategy for this Application is to alert the community to the proposed change to the MRL for imazapyr residues in barley. FSANZ has published details about the administrative assessment and will publish submissions received and subsequent reports on its website. 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.

FSANZ is seeking public comment on the draft variation to Schedule 20 (Attachment A). FSANZ is particularly interested in comments on costs and benefits, potential impacts on imported foods, and any public health and safety considerations associated with the proposed change.

Individuals and organisations making submissions to this Application will be notified of the outcomes of the assessment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on an application is considered by the FSANZ Board. All comments are valued and contribute to the rigour of the assessment process.

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

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent

with any existing or imminent international standards. The proposed measure which increases the MRL for imazapyr in barley in the Code to 0.7 mg/kg aligns the Australian domestic MRL with that of Codex and is trade facilitative. It reduces the need for trading partners to request MRL alignment for the chemical and food commodity.

A notification, without a consultation period, will be made for this Application to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary (SPS) Measures Agreement. This provides transparency for international stakeholders and meets the minimum requirements for SPS notifications.

## **2.4 FSANZ Act assessment requirements**

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:

### **2.4.1 Section 29**

#### ***2.4.1.1 Consideration of costs and benefits***

The Office of Best Practice Regulation has provided a standing exemption (ID 12065) from preparing a Regulation Impact Statement for MRL applications and proposals. However, a limited impact analysis on stakeholders is that it benefits state and territory food regulators, primary producers and importers and maintains consistency between the two domestic MRL standards.

The direct and indirect benefits that would arise from a food regulatory measure varied as a result of the application outweigh the costs to the community, industry and Government. The proposed MRL variation benefits growers and producers, state and territory agencies and the Australian Government in that it serves to harmonise domestic agricultural and food standards for imazapyr residues in barley. Achieving consistency between domestic agricultural and food legislation assists in the efficient enforcement of regulations and minimises compliance costs to primary producers.

#### ***2.4.1.2 Other measures***

There are no other measures that would be more cost-effective than a food regulatory measure varied as a result of the Application.

#### ***2.4.1.3 Any relevant New Zealand standards***

The *Agreement between the Governments of Australia and New Zealand concerning a Joint Food Standards System* (the Treaty) excludes MRLs for agvet chemical residues in food commodities from the joint food standards system. Australia and New Zealand therefore independently develop MRLs for agvet chemical residues in food commodities.

#### ***2.4.1.4 Any other relevant matters***

Other relevant matters are considered below.

### **2.4.2 Subsection 18(1)**

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

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

MRLs are set to protect public health and safety.

The APVMA conducted a risk assessment before amending the APVMA MRL Standard to increase the MRL for imazapyr in that Standard from 0.05 mg/kg to 0.7 mg/kg. The APVMA concluded the new level established does not pose a health or safety risk to Australian consumers.

FSANZ's risk assessment in relation to amending Schedule 20 concluded that the proposed increase in the MRL poses a negligible risk to health and safety for Australian consumers. See section 2.1 above.

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

FSANZ is not aware of any issues relevant to this objective.

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

FSANZ is not aware of any issues relevant to this objective.

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

FSANZ has also had regard to:

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

The amended MRL in the proposed draft variation is based on a risk assessment undertaken by FSANZ using the best available scientific data.

- **the promotion of consistency between domestic and international food standards**

The proposed increased MRL for imazapyr provides a clear and transparent domestic compliance target for monitoring imazapyr residues in barley whether produced domestically or imported. It also provides consistency with the internationally established MRL for the chemical and food commodity.

- **the desirability of an efficient and internationally competitive food industry**

The draft amendment aligns the MRL for imazapyr residues in barley with that in the APVMA MRL Standard and is assessed as safe. It ensures consistent application of the MRL for the chemical and food commodity by food regulators and allows barley with this residue limit to be legally sold.

- **the promotion of fair trading in food**

FSANZ is not aware of any consumer protection or fair trading issues relevant to this Application.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The draft amendment was developed in accordance with the Policy Guideline on the *Regulation of Residues of Agricultural and Veterinary Chemicals in Food*. Particular

consideration was given to the *Specific Policy Principles* that apply to alternative approaches that FSANZ might consider to address the issue.

### **3 Draft variation**

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal. MRLs in the tables of the draft variation are expressed as mg per kg.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

#### **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 A1181 – Maximum Residue Limits for Imazapyr in Barley) 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

Dr Scott Crerar, General Manager Science and risk Assessment Branch  
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 A1181 – Maximum Residue Limits for imazapyr in barley)*

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

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

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

[1] **Schedule 20** is varied by omitting, for the following chemical in the table to section S20—3, the maximum residue limit for the food and substituting

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**Agvet chemical: *Imazapyr***

*Permitted residue: Imazapyr*

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Barley

0.7

## **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 A1181 which seeks to increase the maximum residue limit (MRL) set by the Code for imazapyr in barley from 0.05 mg/kg to 0.7 mg/kg. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to Schedule 20 of the Code.

### **2. Purpose**

The purpose of the proposed variation is to amend the table to section S20—3 to increase the MRL set by the Code for imazapyr in barley from 0.05 mg/kg to 0.7 mg/kg.

The reason for making this amendment is to align the Code's MRL for imazapyr in barley with the equivalent MRLs for imazapyr in barley set: by the Agricultural and Veterinary Chemicals Code Instrument 2019 issued by the Australian Pesticides and Veterinary Medicines Authority (the APVMA MRL Standard); and by the Codex Alimentarius Commission (Codex). As such, this amendment will ensure consistency of domestic MRLs for imazapyr in barley. It will also bring the domestic MRL for imazapyr in barley into line with the international MRL for that chemical and food commodity set by Codex.

Section S20—3 lists the MRLs for agricultural and veterinary chemical residues which may occur in foods. If an MRL is not listed for a particular agricultural or veterinary chemical/food combination, there must be no detectable residue of that chemical in that food. This general prohibition means that, in the absence of the relevant MRL in the Code, food may not be sold where there are detectable residues.

MRL variations may be required to permit the sale of foods containing legitimate residues. These are technical amendments following changes in use patterns of agricultural and veterinary chemicals available to chemical product users.

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

The variation to the food regulatory measure does not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1181 will include one round of domestic public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.4.2 is likely to have a minor impact on business and individuals and an exemption has been granted by the Office of Best Practice Regulation.

## **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**

The draft variation amends the table to section S20—3 by removing the current MRL for the chemical 'imazapyr' in barley and replacing it with a new MRL for that chemical in that food commodity. The new MRL for imazapyr in barley is 0.7 mg/kg—the value that is both gazetted in the APVMA MRL standard and permitted by Codex.