

20 December 2019
[106-19]

Approval report – Application A1181 Maximum Residue Limit (MRL) – Imazapyr in Barley Grain

Food Standards Australia New Zealand (FSANZ) has assessed an application made by BASF Australia Limited to align the MRL for imazapyr in barley in Schedule 20 of the Australia New Zealand Food Standards Code with that currently listed in the APVMA MRL Standard.

On 9 October 2019 FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation on 4 December. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 19 December 2019.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at:

<http://www.foodstandards.gov.au/code/applications/Pages/A1181.aspx>

SD1 Risk Assessment – Application A1181

Executive summary

BASF Australia Limited applied to amend the Australia New Zealand Food Standards Code (the Code) to align the maximum residue limit (MRL) for the agricultural chemical imazapyr in barley in Schedule 20 of 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 related 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.

The Application sought an increase in the MRL for imazapyr in barley in Schedule 20 of the Code from 0.05 mg/kg to 0.7 mg/kg. The increase was to align the MRL in the Code with the APVMA MRL that was gazetted by the APVMA in November 2018. The APVMA did not have the appropriate legislative trigger from their amendment process to directly amend Schedule 20 of the Code and align the two domestic MRLs. The increase would 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 to the proposed increase in the MRL for imazapyr in barley and related foods in the food supply 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 in the MRL presents negligible health and safety risks to consumers. Details of the risk assessment is provided in supporting document 1 (SD1).

Domestic stakeholders will benefit from alignment of the MRL for imazapyr in barley in Schedule 20 with the APVMA MRL as it provides a consistent domestic MRL for compliance and enforcement purposes. For FSANZ's international stakeholders, alignment with the Codex MRL liberalises food trade.

For these reasons, FSANZ approved the draft variation to Schedule 20 of the Code to increase the MRL for imazapyr in barley in that Schedule from 0.05 mg/kg to 0.7 mg/kg.

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 soil nutrient management.

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 imazapyr in barley and increase it from 0.05 mg/kg to 0.7 mg/kg. This increase would align the MRL with that of:

- the Australian Pesticides and Veterinary Medicines Authority (APVMA) Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019; and
- the Codex Alimentarius Commission (Codex).

Although Section 82 of the FSANZ Act (March 2011) provides the APVMA with the delegation of power to directly amend Schedule 20, it is limited to specified legislative triggers which are new chemical approvals, registrations, variations or permits proposed under the Agricultural and Veterinary Chemicals Code (Agvet Code). In this instance, the increase to the APVMA MRL for imazapyr was based on additional relevant data provided by the registrant for the current use pattern of the chemical as permitted by the APVMA. It therefore did not carry the appropriate legislative trigger for the APVMA to directly amend Schedule 20 of the Code to align the two domestic MRLs.

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 following their approved use in food production and is an Australian only standard. The chemical 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 agvet chemical residues exceeding the MRLs in the Code are in breach 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 approved uses to control pests/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 presented for sale on the Australian market.
 2. The APVMA MRL Standard Instrument 2019 sets out the maximum residues of permitted and approved agvet chemicals in treated food commodities under the Agvet Code. The APVMA MRL standard is for domestic purposes and used by the jurisdictions to manage the use of the chemicals beyond the point of retail sale.

- Imazapyr is permitted for use on barley in Australia by the APVMA and is currently listed in Schedule 20 of the Code. The current MRL in Schedule 20 is 0.05 mg/kg and was the same as the APVMA MRL until November 2018. It applies to domestically produced and imported barley.
- 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 a risk assessment 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 Codex MRL for imazapyr in barley is also 0.7 mg/kg (see Table 1).
- Codex MRLs (also referred to as CXLs) are recognised by Australia and primarily intended to facilitate international trade and accommodate differences in good agricultural practice (GAP) employed by various countries based on differing climates, growing conditions, pests and diseases.

Table 1: Current 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

1.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2); and
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal.

The related 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

One domestic submission was received from a government department in Victoria.

Table 1: Summary of issue

Issue	Raised by	FSANZ response (including any amendments to drafting)
Supports progression of the application	Victorian Department of Health and Human Services, and the Victorian Department of Jobs, Precincts and Regions	Noted.

2.2 Risk assessment

The presence of residues of imazapyr in barley at low levels should not represent a public health and safety concern if the chemical is used according to label instructions. However, to ensure that this is the case, FSANZ estimated the Australian population's dietary exposure to the proposed increased MRL for imazapyr in barley and other foods for which its use is permitted.

The results of the risk and dietary exposure assessments for the proposed increased MRL for imazapyr in barley (0.05 mg/kg to 0.7 mg/kg), used the relevant health based guidance value (HBGV), the acceptable daily intake (ADI). The ADI was established by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR).

The National Estimated Daily Intake (NEDI) for imazapyr was calculated to represent the population's chronic dietary exposure to the chemical. The estimated NEDI was then compared to the ADI. The National Estimated Short Term Intake (NESTI) was not calculated for an acute (short-term) dietary exposure for imazapyr because the acute reference dose (ARfD) for imazapyr is considered unnecessary by the APVMA and the JMPR due to its low oral toxicity and the absence of any developmental toxicity after a single dose.

The dietary exposure assessment (DEA) method used is consistent with internationally accepted methodologies, the risk assessment framework used by the APVMA for approving and registering agricultural chemical products for use in Australia and the process used by both the APVMA and FSANZ for establishing and reviewing MRLs in Schedule 20 of the Code.

A summary of the dietary exposure estimate for the proposed increased MRL for imazapyr in barley requested in this application is provided in supporting document 1 (SD1). The estimated dietary exposure is less than 1% of the ADI (the relevant chronic health based guidance value), and is considered acceptable as it poses negligible health and safety risks to Australian consumers.

2.3 Risk management

FSANZ is committed to ensuring that residues of agvet chemicals that may occur in food commodities are legitimate following their use in food production according to label instructions. It also maintains the currency of the MRLs in Schedule 20 of the Code following proper risk assessment based on appropriate trial data and ensures the limits are safe for

consumers and the foods can be legally sold on the Australian market.

The application from BASF Australia Ltd to increase the MRL for imazapyr residues in barley in Schedule 20 and align it with the current MRL in the APVMA MRL Standard and Codex is to provide consistency between the two domestic food regulatory standards and the international standard.

FSANZ will only approve variations to MRLs in the Code where the risk assessment concludes that the estimated dietary exposures do not exceed 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 risks to Australian consumers.

Given the increased MRL for imazapyr in barley poses a negligible health and safety risk to consumers, the approval of the draft variation to amend the MRL for imazapyr in barley and increase it to 0.7 mg/kg in Schedule 20 of the Code is appropriate.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ notified all stakeholders to the proposed MRL change on its website and the call for submissions was notified via the FSANZ Notification Circular and a media release. Subscribers and interested parties were also notified about the availability of the report on the FSANZ website for public comment. International stakeholders were also notified through the Australian Sanitary and Phytosanitary (SPS) measures contact point.

FSANZ sought domestic public comment on the draft variation to Schedule 20 which is at Attachment A and welcomed comments on any impacts (costs/benefits) likely to result from the proposed MRL increase, potential impacts on imported foods, and any public health and safety considerations associated with the proposed change.

One domestic submission was received from a state government department in Victoria. It supported the proposed draft variation.

2.4.2 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.

Amending the MRL in Schedule 20 for imazapyr in barley facilitates international trade because the increased MRL will align with Codex. The MRL of a chemical constitutes a mandatory requirement and applies to all food products of a particular class whether produced domestically or imported. Foods with agvet chemical residues not listed in Schedule 20 or that exceed the relevant MRLs in the Code cannot legally be sold on the Australian market.

The proposed regulatory measure is trade promoting and consistent with an existing international standard, therefore FSANZ made a notification only to the WTO without a call for submissions for the Application. This is in accordance with the minimum requirements of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and for

transparency.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation has provided FSANZ with a standing exemption (ID 12065) from preparing a Regulation Impact Statement for MRL proposals and applications.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act requirements. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers either the approval or rejection of the application to amend the Code to increase the MRL for imazapyr residues in barley.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by amending the Code as requested.

FSANZ's assessment is that the direct and indirect benefits that would arise from an increased MRL for imazapyr as a result of this application outweighs the costs to the community, industry or government. The proposed increase in the MRL would benefit growers and producers, state and territory agencies and the Australian Government. It would ensure a consistent MRL for imazapyr in barley for the two domestic MRL standards, (the agricultural use and food standard) and also assist in the efficient enforcement of imazapyr residue in barley thereby minimising compliance costs to primary producers.

Food importers and consumers may benefit from the increased MRL following approval of the proposed draft amendment because the proposed amendment extends the options to source a wider variety of safe barley.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure amended as a result of the Application.

2.5.1.3 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 chemicals in food from the system that sets joint food standards. Australia and New Zealand, therefore, independently and separately develop MRLs for agvet chemicals in food commodities. However, under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), Australia and New Zealand accept food commodities that are legal for sale in each country, regardless of the sale-related regulatory requirements in the individual country.

All imported and domestically-produced food sold in New Zealand (except for food imported from Australia) must comply with the current [Food Notice: Maximum Residue Levels for Agricultural Compounds¹](#) and amendments. Agvet chemical residues in food must comply with the specific MRLs listed in the Food Notice including the 'default' MRL of 0.1 mg/kg where no specific MRL is listed. If a food is imported and no domestic MRL has been established, Codex MRLs can be recognised.

MRLs in the Code may differ from those in the New Zealand Food Notice for a number of legitimate reasons including different use patterns of the chemicals.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

MRLs are set to protect public health and safety. The APVMA's risk assessment conducted before the MRL for imazapyr was increased from 0.05 mg/kg to 0.7 mg/kg concluded that the new level did not pose a health and safety risk to Australian consumers.

FSANZ's own risk assessment using the best available scientific data and internationally recognised risk assessment methodologies showed that the proposed increase in the MRL posed negligible risk to the health and safety of Australian consumers. The details are shown in section 2.2 above.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

No issues were identified with this Application relevant to this objective.

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified with this Application relevant to this objective.

2.5.3 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 proposed amendment to Schedule 20 is based on risk analysis that used the best available scientific evidence and internationally recognised risk assessment methodologies. FSANZ conducted a risk assessment which concluded that the estimated dietary exposure, for the proposed increase in the MRL, based on Australian food consumption data, does not exceed the relevant HBGV, the ADI.

¹ MRLs for Agricultural Compounds in New Zealand:
<https://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm>

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

The approved amendment would remove the current inconsistency between the domestic agricultural use level and food standard and align the Code with Codex and other standards of trading partners.

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

The approved change will minimise potential costs to primary producers, rural and regional communities and importers, and permit the sale of barley containing legitimate levels of imazapyr residues.

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

No issues were identified with this application relevant to this objective.

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

FSANZ has had regard to the Forum's Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food². It forms a framework for the consideration of alternative approaches to address issues surrounding the regulation of residues of agricultural and veterinary chemicals in food.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

² The policy guideline is available on the Food Regulation Secretariat website at this [link](http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Regulation-of-Residues-of-Agricultural-and-Veterinary-Chemicals-in-Food).
<http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Regulation-of-Residues-of-Agricultural-and-Veterinary-Chemicals-in-Food>

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1181 – Maximum residue limit for Imazapyr in barley) Variation

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 limit for Imazapyr in Barley) Variation*.

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 subsection S20—3, the maximum residue limit for the food and substituting

Agvet chemical: Imazapyr

Permitted residue: Imazapyr

Barley	0.7
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Attachment B – 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.

The Authority accepted Application A1181 which seeks to align the MRL for imazapyr in barley with the Maximum Residue Limit (MRL) in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 and the MRL set by the Codex Alimentarius Commission for residues of that agvet chemical that may occur in barley. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to amend the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to the table to section S20—3 in Schedule 20 of the Code to increase the MRL for imazapyr residues in barley from 0.05 mg/kg to 0.7 mg/kg.

3. Documents incorporated by reference

The variation to Schedule 20 of the Code 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report.

Submissions were called for on 9 October 2019 for a two-week domestic consultation period. A minimum period of consultation was applied because the focus of the application was to align the MRL in Schedule 20 of the Code with the current domestic MRL for the chemical and food commodity in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 and, thereby also align it with the MRL set by Codex.

A Regulation Impact Statement was not required because the approved variation to Schedule 20 of the Code is likely to have a minor impact on businesses and individuals (OBPR reference 12065).

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 approved 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 gazetted in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 and is also permitted by Codex.