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Supporting Document 1

Risk assessment and dietary exposure estimate – Application A1181

Maximum Residue Limit (MRL) for Imazapyr in Barley

Executive summary

This supporting document provides information relating to the results of the risk and dietary exposure assessments undertaken for the requested increase in the MRL of the agricultural and veterinary (agvet) chemical imazapyr in barley through the paid MRL Application A1181.

The dietary exposure assessment (DEA) was undertaken using the relevant health based guidance value (HBGV), which for this chemical was the Acceptable Daily Intake (ADI) established by the Australian Pesticides and Veterinary Medicines Authority (APVMA) or the Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR). The DEA method used is consistent with internationally accepted methodologies, the APVMA's risk assessment framework for approving and registering agvet 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.

The National Estimated Daily Intake (NEDI) was calculated for imazapyr residues in barley to represent chronic dietary exposure. The NEDI estimate was then compared to the ADI for imazapyr. 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 food consumption data used for the DEA were sourced from the 2011–12 National Nutrition and Physical Activity Survey (NNPAS), a component of the 2011–13 Australian Health Survey. The mean food consumption data for all survey respondents (n=7,735, aged 2 years and above) were used for the NEDI calculation. This mean value represents the average intake of a food commodity for the whole Australian population which included population sub-groups of children aged 2–6 years and women of childbearing age (16–44 years).

The dietary exposure estimate for the proposed increased MRL of imazapyr residues in barley to 0.7 mg/kg is less than 1% of the ADI, indicating negligible health and safety risks to Australian consumers. The proposed MRL change, origin of request, commodity name, comparison with Codex MRL and the dietary exposure estimate for the Australian population are given in Table 1 of this document.

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1 Introduction

This supporting document provides information about the result of risk assessment and dietary exposure estimates undertaken for paid Application A1181 submitted by BASF Australia Ltd.

The application sought to align the maximum residue limit (MRL) in Schedule 20 of the *Australian New Zealand Food Standards Code* (the Code) for imazapyr residues in barley with the MRL currently listed in the Australian Pesticides and Veterinary Medicines Authority (APVMA) Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 – (Authorised Version F2019C00757 registered 10/10/2019) and the Codex Alimentarius Committee (Codex) MRL. The two latter standards reflect current legitimate use of imazapyr in the production of barley and the amount of residue permitted on the commodity following its use according to label instructions and established good agricultural practice.

The Application has the support of the APVMA because the agency is aware of the different MRLs in the two domestic MRL standards for imazapyr in barley. In addition, the APVMA undertook extensive risk assessment and evaluation studies based on the new data provided by the registrant (BASF Australia Ltd) before it increased the MRL in the APVMA MRL Standard.

The residue definition for imazapyr remains unchanged as imazapyr, and is listed as such in both the APVMA MRL Standard and Schedule 20 of the Code. It is also the same as agreed by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 2013 and is used internationally as the definition of the residue for plant and animal commodities for compliance with MRLs and for estimation of dietary intake.

2 Dietary Exposure Assessment

3 Results of the assessment

The dietary exposure estimate for the proposed increase in the MRL for imazapyr in barley from 0.05 to 0.7 mg/kg showed the NEDI to be below the ADI for the chemical. Summary information on the DEA is shown in Table 1 below.

Table 1: Dietary exposure estimate for proposed increase in MRL for Imazapyr in barley – Application A1181

Current MRL in Schedule 20 (mg/kg)	Current Codex MRL (mg/kg)	Proposed MRL (mg/kg)	Origin of requested MRL	MRL change in Schedule 20	Australian food consumption amount (g/kg bw/day)	Estimated dietary exposure as percent of ADI
*0.05	0.7	0.7	APVMA	Increase	0.172	<1

The NEDI represents an estimate of chronic dietary exposure from the whole diet for the general population aged 2 years and above and is considered acceptable. The ARfD has not

been estimated because it is considered unnecessary due to the low toxicity of the chemical.

2.1 Background

FSANZ's risk assessment process estimated Australian consumers' dietary exposure to imazapyr using the relevant health based guidance values (HBGVs), such as the Acceptable Daily Intake (ADI) and where applicable the Acute Reference Dose (ARfD). These values are established by the APVMA or adopted from that established by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR).

The methods used for the dietary exposure estimates are consistent with internationally accepted methodologies and with the APVMA's risk assessment framework for approving and registering agricultural chemical products in Australia. It is also the process used by both the APVMA and FSANZ for establishing and reviewing MRLs in Schedule 20 of the Australia New Zealand Food Standards Code (the Code).

Variations to MRLs in the Code will not be supported where estimated dietary exposure to the residue of a chemical indicates a potential public health and safety concern for consumers.

The steps undertaken in conducting a DEA are:

- determining the residues of a chemical in the food or foods of interest
- calculating dietary exposure to a chemical from relevant foods, using residue data and food consumption data from Australian national nutrition surveys
- completing a risk characterisation where estimated dietary exposures are compared to the relevant health based guidance value (HBGV).

Further information on how FSANZ conducts DEAs is available on the [FSANZ website](#)¹

2.1.1 Australian National Nutrition and Physical Activity Survey (NNPAS)

The mean food consumption data used to estimate the dietary exposure were derived from the National Nutrition and Physical Activity Survey (NNPAS).

Consumption amounts were for all respondents that were surveyed over two non-consecutive days and the average for each respondent over the two days was calculated to derive a two-day average exposure. The approach applied a different set of sample weights to make this sub-sample of the survey representative of the Australian population.

The two-day average exposures are better estimates of longer term dietary exposure and therefore of chronic dietary exposure. The consumption data included barley reported as consumed on its own and also used in mixed foods.

2.2 Dietary Exposure estimates

A chronic estimate of dietary exposure, the National Estimated Daily Intake (NEDI) was calculated for residues of imazapyr in barley and other foods currently listed under the chemical in Schedule 20 of the Code.

The acceptable daily intake (ADI) of 2.5 per kilogram body weight per day (mg/kg bw/day) is

¹ <http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandn4438.aspx>

the relevant health based guidance value (HBGV) published in the APVMA list of the *Acceptable Daily Intakes (ADI) for agricultural and veterinary chemicals used in food producing crops or animals* (Edition 2, 2019). This value was used for the NEDI calculation in accordance with WHO Guidelines² and is a conservative estimate of dietary exposure to residues of the chemical in food. The ADI for humans is considered to be a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health. It is calculated by dividing the overall NOAEL from the animal studies by an uncertainty (safety) factor. The magnitude of the uncertainty factor is intended to account for uncertainties in extrapolating animal data to humans, variation between humans and completeness of the toxicological database.

An acute estimate of dietary exposure was not undertaken because the establishment of an acute reference dose (ARfD) for imazapyr was 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.

4 Conclusion

The NEDI for imazapyr taking into account all currently permitted uses and the proposed increased MRL is less than 1% of the ADI.

Based on the risk assessment and dietary exposure estimate conducted for this application, the proposed increase to the MRL for imazapyr in barley from 0.05 mg/kg to 0.7 mg/kg in Schedule 20 of the Code is supported by FSANZ. The estimated dietary exposure to imazapyr residues in barley does not indicate a potential public health and safety concern for the Australian population or a population subgroup.

² WHO (2008). Consultations and workshops: Dietary Exposure Assessment of Chemicals in Food: Report of a joint FAO/WHO Consultation, Annapolis, Maryland, USA, 2-6 May 2005.