Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on sulfoxaflor for use on faba beans

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

About this document

This Trade Advice Notice indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural or veterinary chemical.

It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application for a permit for use of sulfoxaflor on faba beans should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 19 December 2022 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or organisation name (if relevant)
- email or postal address (if available)

- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Further information on Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The APVMA has before it a minor use permit application from Pulse Australia Limited for the use of sulfoxaflor on faba beans, for the control of faba bean aphids and green peach aphids.

The applicant has not submitted residues data in support of the application but referred to previously evaluated relevant data in a Trade Advice Notice (TAN)[1] related to the residues evaluation of the proposed use of Expedite Full Insecticide (Product No. 65464) on pulses and other crops. At the time of the trade consultation for that application, which proposed a Maximum Residue Limit (MRL) for VD 0070 Pulses [except soya bean (dry)] at 0.7 mg/kg, concern was raised by two stakeholders concerning the risk of breaching tolerance levels of export markets. Registration was therefore subsequently restricted to just adzuki beans, mung beans and navy beans, which were the pulse crops covered by the Codex Beans (dry) MRL.

It is noted that the registered use patterns on adzuki beans, mung beans and navy beans are the same as that currently proposed for faba beans.

[1] Australian Pesticides and Veterinary Medicines Authority, *Sulfoxaflor in the product Expedite Full Insecticide*, APVMA website, 4 August 2016, accessed 10 October 2022.

Trade considerations

Commodities exported

Faba beans are considered to be a major export commodity[2], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated faba beans. Residues in these commodities resulting from the use of sulfoxaflor may have the potential to unduly prejudice trade.

No amendments to the current edible animal commodities have been proposed, thus risk to trade arising from animals that have been fed feeds containing sulfoxaflor, remains unchanged to that previously assessed. The risk to trade with respect to the proposed use on faba beans is considered below.

Destination and value of exports

Australian exports of pulses (lupins, field peas, chickpeas, faba beans, mung beans, navy beans and lentils) totalled 1,520 kt, 1,731 kt and 2,560 kt (value $1015 m, $ 1,263 m and $1647 m) respectively, in 2018-19, 2019–20 and 2020–21[3].

The major markets for faba beans are countries in the Middle East, specifically Egypt, Saudi Arabia and the United Arab Emirates.[4] The applicant has indicated that the major market for Australian faba beans is Egypt, with up to 60% of faba beans exported there in the past[5].

Proposed Australian use pattern

Table 1: Proposed use pattern for faba beans being considered by the APVMA

Transform Isoclast active Insecticide (P64101) containing 240g sulfoxaflor/L as the only active constituent.

Expedite Full Insecticide (P65464) containing 500g sulfoxaflor/kg as the only active constituent.

Crop	Pest	Rate	Critical comments
Faba beans	Faba bean aphid	240 g/L product: 100 mL/ha (=24 g a.i./ha)	Apply as a foliar cover spray following first signs of pest infestation. Apply using a boom sprayer in a minimum spray volume of 50 L/ha by ground and 30 L/ha by air.

[2] Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Guidelines – Data Guidelines: Agricultural data guidelines – Pesticides: Overseas trade (Part 5B)*, APVMA website, 20 July 2020, accessed 10 October 2022.

[3] Department of Agriculture, Fisheries and Forestry, Agricultural Commodity Statistics 2021, *Agricultural commodities and trade data - DAFF*, DAFF website, accessed 8 September 2022.

[4] Grains Research & Development Corporation, *Faba bean Section A Introduction*, GRDC website, accessed 11 October 2022.

[5] Pulse Australia, Part 1 Application Overview, August 2022, p.8.

Crop	Pest	Rate	Critical comments
	(*Megoura crassicauda*) Green peach aphid (*Myzus persicae*)	500 g/kg product: 50 g/ha (=25 g a.i./ha)	Droplets for ground and aerial spraying should be no smaller than medium category according to nozzle manufacturer specifications that refer to the ASABE S-572 Standard. DO NOT apply more than 2 applications per crop with a minimum re-treatment interval of 14 days. DO NOT apply this product while bees are foraging in the crop to be treated. Refer to the Protection of Honey Bees and other Insect Pollinators statement on the product label.

Withholding periods:

Harvest: DO NOT harvest for 14 days after application.

Grazing: DO NOT graze or cut for stock food for 14 days after application.

Restraints: DO NOT apply more than 2 applications per crop with a minimum re-treatment interval of 14 days.

DO NOT apply this product while bees are foraging in the crop to be treated.

Export of treated produce - Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with sulfoxaflor. If you are growing produce for export, please check with the permit holder for the latest information on MRLs and import tolerances before using sulfoxaflor.

Results from residues trials presented to the APVMA

Faba beans

It was noted in the TAN[1] related to the residues evaluation of the proposed use of Expedite Full Insecticide on pulses and other crops that:

"*Six new Australian trials on field peas, lentils and faba beans are supported by 19 previously submitted overseas trials on soybeans and six on dry beans.*

Residues of sulfoxaflor in pulse grain at harvest 14 days (or more) after the last of 2 applications at 24 g ai/ha (1× proposed) were 0.02, 0.04, 0.04, 0.06, 0.29 and 0.32 mg/kg. The STMR is 0.05 mg/kg. The OECD MRL calculator recommends an MRL of 0.7 mg/kg.

In trials in the USA and Brazil residues of sulfoxaflor in soybeans at a 7-day harvest interval after 4 applications at 100 g ai/ha (4× proposed) were: <0.01 (8), 0.01, 0.02 (3), 0.03 (2), 0.04 (3), 0.09, and 0.21 mg/kg.

In 6 trials on dry beans in Brazil, Germany and Spain, following 4 applications of sulfoxaflor at a total rate of 0.350 to 0.365 lb a.i./A (~400 g a.i./ha), residues of sulfoxaflor were 0.02, 0.05, 0.09, 0.09, 0.10 and 0.11 mg/kg in/on dried beans harvested at a 7 day PHI."

Based on these data a sulfoxaflor MRL for VD 0071 Beans (dry) was established at 0.7 mg/kg to cover residues arising in adzuki, mung and navy beans from the registered uses.

As the proposed use pattern for sulfoxaflor on faba beans (VD 0523) is the same as and based on the registered uses on adzuki, mung and navy beans and all 4 crops are members of the APVMA Crop subgroup 015A, Dry beans[6], it is considered appropriate to estimate an MRL for the proposed use on faba beans based on the residues data previously considered for registration of the other 3 crops.

It is noted that under the new APVMA Crop Groups, the MRL for VD 0071 Beans (dry) only covers Phaseolus species and cultivars. As faba beans are classified as Vicia rather than Phaseolus, it is appropriate to establish a separate (temporary) MRL for VD 0523 Broad bean (dry) at the same level, 0.7 mg/kg, for the proposed use on faba beans.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. Codex CXLs are primarily intended to facilitate international trade and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Sulfoxaflor has been considered by Codex.

[6] Australian Pesticides and Veterinary Medicines Authority, *Crop Group 015: Pulses*, APVMA website, accessed 11 October 2022.

Table 2: Relevant international MRLs for sulfoxaflor on dry beans

Commodity	Tolerance for residues arising from the use of sulfoxaflor (mg/kg)							
	Australia	EU[7]	Codex[8]	Japan[9]	Korea[10]	USA[11]	China[12]	Taiwan[13]
Broad bean (dry)	T0.7 (proposed)	–	–	0.2 (Broad beans)	–	–	–	–
Beans (dry)	0.7	0.3 (Beans)	0.3	0.3	0.2 (Beans)	0.20	-	0.3 (Other dry beans except cotton seed and rapeseed)
Soya bean (dry)	0.3	–	0.3	–	–	0.20	T0.3	–

Current and proposed Australian MRLs for sulfoxaflor

Table 3: Current relevant MRLs for sulfoxaflor in Table 1 of the MRL Standard

Compound		Food	MRL (mg/kg)
Sulfoxaflor			
VD	0071	Beans (dry)	0.7
MO	0105	Edible offal (mammalian)	0.5
PE	0112	Eggs	*0.01
MM	0095	Meat (mammalian)	0.2
ML	0106	Milks	0.1

[7] European Commission, *EU Pesticide residue(s) and maximum residues levels (mg/kg)*, European Commission website, accessed 11 October 2022.

[8] Food and Agriculture Organization of the United Nations, *Codex Alimentarius: 252 - Sulfoxaflor*, FAO website, accessed 11 October 2022.

[9] Japanese Food Chemistry Research Promotion Foundation, *Table of MRLs for Agricultural Chemicals*, JFCRPF website, accessed 11 October 2022.

[10] Ministry of Food and Drug Safety Korea, *Pesticide MRLs for agricultural commodities*, FSK website, accessed 11 October 2022.

[11] Electronic Code of Federal Regulations, *Tolerances and Exemptions for Pesticide Chemical Residues in Food*, eCFR website, accessed 11 October 2022.

[12] United States Department of Agriculture Foreign Agricultural Service, *China: Maximum Residue Limits for Pesticides in Foods, Global Agricultural Information Network report*, 24 August 2021, accessed 11 October 2022.

[13] Food and Drug Administration Taiwan, *Food and Drug Administration Taiwan, Standards for Pesticide Residue Limits in Foods*, accessed 11 October 2022.

Compound		Food	MRL (mg/kg)
PM	0110	Poultry meat	*0.01
PO	0111	Poultry, edible offal of	*0.01
VD	0541	Soya bean (dry)	0.3

Table 4: Current relevant MRLs for sulfoxaflor in Table 4 of the MRL Standard

Compound	Food	MRL (mg/kg)
Sulfoxaflor		
	Pulse forage and fodder	5

Table 5: Amendments to Table 1 of the MRL Standard for sulfoxaflor

Compound		Food	MRL (mg/kg)
Sulfoxaflor			
Add:			
VD	0523	Broad bean (dry)	T0.7

Potential risk to trade

Export of treated produce containing finite (measurable) residues of sulfoxaflor may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Faba beans

The proposed use of sulfoxaflor on faba beans requires the establishment of a finite TMRL at 0.7 mg/kg [HR = 0.32 mg/kg, STMR = 0.05 mg/kg for the 6 Australian pulse trials and 0.03 mg/kg for all trials including the international trials at a shorter (7 days) WHP]. There is a potential risk to trade as finite residues of sulfoxaflor may be expected in exported faba beans.

The proposed MRL for faba beans (0.7 mg/kg), which is at the same level as the established Australian Beans (dry) MRL, is higher than the MRLs for dried beans which are established in most overseas markets at 0.2 or 0.3 mg/kg, although it is noted that the STMR of all the Australian pulse data (0.05 mg/kg) is below these MRL values.

Although the Codex MRL of 0.3 mg/kg established for dry beans was established based on consideration[14] of the USA GAP [4 applications (2 consecutive) at 80 g a.i./ha, 14 days minimum re-treatment interval and a 7 days pre-harvest interval] which allows use on a number of crops including faba beans[15], it may only cover Phaseolus species. It is noted however, that the major market for Australian faba beans (Egypt), defers to EU MRLs in the absence of a relevant Codex MRL[16]. This is also the case for the United Arab Emirates[17], while Saudi Arabia defers to the lower of the EU or USA MRLs[18]. The EU MRL for dry beans at 0.3 mg/kg, which was not established at the time of the residues evaluation of the proposed use of Expedite Full Insecticide on pulses, is established at a level close to the observed HR in Australian pulses (including faba beans).

[14] Food and Agriculture Organization of the United Nations, *JMPR 2013 Report (fao.org)*, FAO website, accessed 11 October 2022.

[15] United States Environment Protection Agency, *Label for Transform WG Insecticide Isoclast Active* ,USA EPA website, accessed 19 October 2022.

[16] Northwest Horticultural Council, Washington, USA, *Egypt (nwhort.org)*, Northwest Horticultural Council website, accessed 26 October 2022.

[17] Northwest Horticultural Council, Washington, USA, *United Arab Emirates (nwhort.org)*, Northwest Horticultural Council website, accessed 26 October 2022.

[18] Northwest Horticultural Council, Washington, USA, *Saudi Arabia (nwhort.org)*, Northwest Horticultural Council website, accessed 26 October 2022.

Conclusion

Pulse Australia Limited has applied for a permit for the use of sulfoxaflor on faba beans, for the control of faba bean aphids and green peach aphids.

Comment is sought on the potential for the proposed use to prejudice Australian trade of faba beans and the ability of industry to manage any potential trade risk.