



Trade Advice Notice

on broflanilide in the product Cimegra Insecticide for use on  
brassica vegetables and leafy vegetables

APVMA product number 91936

September 2023

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Assistant Director, Communications  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: [communications@apvma.gov.au](mailto:communications@apvma.gov.au).

This publication is available from the [APVMA website](http://www.apvma.gov.au).

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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 APVMA is considering an application to vary the use of an existing registered agricultural 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 to register Cimegra Insecticide 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 Thursday 5 October 2023 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](https://apvma.gov.au/node/72856)).

Please lodge your submission using the [public consultation coversheet](https://apvma.gov.au/node/72856), 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](mailto: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](http://www.apvma.gov.au).

# Introduction

The APVMA has before it an application from BASF Australia Ltd to register Cimegra Insecticide, an SC formulation containing broflanilide, for use on brassica vegetables and leafy vegetables. This will be the first use of broflanilide in food producing situations in Australia and a summary of the residues and trade assessment is presented in this Trade Advice Notice.

Currently broflanilide products are only registered in Australia for insect control in non-food producing situations[[1]](#footnote-2). The use of broflanilide on a number of crops including brassica vegetables was considered by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 2022[[2]](#footnote-3).

# Trade considerations

## Commodities exported

Brassica vegetables and leafy vegetables are not considered to be major export commodities[[3]](#footnote-4). The applicant has proposed the following risk mitigation statement which is considered appropriate and acceptable for brassica vegetables and leafy vegetables:

**Export of treated commodities**

Growers should note that Maximum Residue Limits (MRLs) or import tolerances do not exist in all markets for labelled crops treated with Cimegra Insecticide. Additionally, some export markets have established MRLs different to those in Australia. If you are growing crops for export, please check with BASF Australia Ltd for the latest information on MRLs and import tolerances BEFORE using this product.

Commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated brassica vegetables and leafy vegetables, are considered to be major export commodities. Residues in these commodities resulting from the use of Cimegra Insecticide may have the potential to unduly prejudice trade. It is noted that a grazing restraint has been proposed for treated brassica vegetables and leafy vegetable crops.

## Destination and value of exports

While brassica vegetables and leafy vegetables are not considered to be major export commodities, available export statistics for crops within these crop groups are presented below for completeness[[4]](#footnote-5).

Australian exports of fresh broccoli/baby broccoli were 1,648 t valued at $8.4 million in 2021–22. Exports of cauliflower were 225 t valued at $0.9 million. Major markets for fresh broccoli and cauliflower were Singapore, Hong Kong, Malaysia, the Philippines and Brunei Darussalam. Exports of fresh Brussels sprouts were 298 t valued at $1.8 million. The major markets were Korea, Singapore, Hong Kong, Japan and Malaysia. Exports of cabbage were 364 t valued at $1.2 million. The major markets were Singapore, Malaysia, Hong Kong, Brunei Darussalam and Vietnam.

Exports of fresh English spinach, silverbeet and kale were 322 t valued at $2.7 million in 2021–22. Major markets were Malaysia, Hong Kong, Singapore, Thailand and Taiwan. Exports of head lettuce were 413 t valued at $1.2 million. Major markets were Singapore, New Caledonia, Hong Kong, Fiji and New Zealand. Exports of leafy salad vegetables were 816 t valued at $7 million. Major markets were Singapore, Hong Kong, Thailand, Malaysia and Brunei Darussalam.

The significant export markets for Australian beef, sheep, pig meat and offal are listed in the APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B)3.

Australian exports of dairy products totalled 549.9 kt ($2,879 million) from July 2022 to March 2023. Of this total, Australian exports of fresh milk totalled 194.8 kt ($251.7 million) from July 2022 to March 2023.[[5]](#footnote-6) The major markets for Australian dairy products include China, Japan, Korea, Indonesia, Malaysia, Philippines, Vietnam, Thailand and Singapore[[6]](#footnote-7).

## Proposed Australian use pattern

Cimegra Insecticide (100 g/L broflanilide).

The proposed Australian use pattern for Cimegra Insecticide containing 100 g/L broflanilide is shown in Table 1 below.

Table : Proposed use pattern

| Crop | Pest | Rate | Critical comments |
| --- | --- | --- | --- |
| Leafy vegetables including lettuce (head and leafy), chard, spinach, bok choy, pak choi, choi sum, kale, gai lan, leafy mustard, rocquette  Brassica vegetables including broccoli, broccolini, Brussels sprouts, cabbage, cauliflower, kohlrabi | Diamondback moth (*Plutella xylostella*)  Cabbage white butterfly (*Pieris rapae*) | 125 to 250 mL/ha (up to 25 g ai/ha) | Use in accordance with local insecticide resistance management strategy for diamondback moth  Cimegra will control all larval growth stages (instars) of diamondback moth and cabbage white butterfly. Apply a maximum of 2 sprays with a 7 to 14-day spray interval targeting a single pest generation before rotating to an alternative insecticide.  Use the higher label rate when larger larvae are present (such as 3rd/4th instar, or >5 mm length for diamondback moth and 3rd to 5th instar or >9 mm for cabbage white) and in temperatures and conditions where rapid growth is occurring.  DO NOT apply more than 50 g active ingredient (500 mL product) per hectare per year total. This includes any subsequent crop in the same calendar year.  Apply in sufficient water to ensure thorough coverage of the target crop.  Addition of a non-ionic wetter may aid in coverage, particularly in dense crops and crops with waxy leaves. Speed of knockdown and the overall control may also be improved. If using the lower label rate, the use of a non-ionic wetter is recommended. |
| Brassica vegetables | Plague thrips (*Thrips imaginis*)  Western flower Thrips (*Frankliniella occidentalis*) | 125 to 250 mL/ha + Hasten at 0.2%, or a non-ionic adjuvant at 0.02% (up to 25 g ai/ha) | Apply a maximum of 2 sprays with a 7 to 14-day spray interval before rotating to an alternative insecticide for thrips control.  The use of a 2-spray strategy for thrips is recommended, particularly where new thrips infestations may occur from surrounding crops or vegetation.  DO NOT apply more than 50 g active ingredient (500 mL product) per hectare per year total. This includes any subsequent crop in the same calendar year.  Apply in sufficient water to ensure thorough coverage of the target crop. |

### Withholding periods

#### Harvest

Do not harvest for one day after application.

#### Grazing

DO NOT allow livestock to graze crops or vegetable waste that has been treated with Cimegra Insecticide.

### Restraints

DO NOT apply by aircraft

DO NOT use in protected cropping situations

### Export of treated commodities

Growers should note that Maximum Residue Limits (MRLs) or import tolerances do not exist in all markets for labelled crops treated with Cimegra Insecticide. Additionally, some export markets have established MRLs different to those in Australia. If you are growing crops for export, please check with BASF Australia Ltd for the latest information on MRLs and import tolerances BEFORE using this product.

## Metabolism and residue definition

### Plant commodities

In food commodities from plant metabolism studies conducted on cabbage, Japanese radish, tomato, soya bean, rice and tea, the predominant residue was parent broflanilide, accounting for 66 to 84% Total Radioactive Residues (TRR) in cabbage, 77 to 82% TRR in Japanese radish leaves, 60 to 68% TRR in tomato fruit, 13 to 64% TRR in husked rice and 96 to 97% TRR in tea. In studies with wheat (seed treatment) and in Japanese radish root, TRR levels were too low for identification. In animal feed matrices, residues of broflanilide accounted for 75 to 76% TRR in soya bean forage, 67 to 71% TRR in soya bean hay, 83 to 90% TRR in rice hulls and 85 to 87% TRR in rice straw.

As broflanilide represents the major part of the residues in plant commodities, a residue definition for plant commodities, for both MRL enforcement and dietary risk assessment, as the parent compound (broflanilide) is recommended, in line with the 2022 JMPR recommendation.

### Animal commodities

In animal metabolism studies performed with lactating goats and laying hens, the predominant metabolic pathway was N-demethylation of parent broflanilide to form DM-8007. Its subsequent cleavage results in DC-DM-8007 (identified using the B-label) and hippuric acid (identified using the C-label), via the intermediate benzoic acid. Depending on the label and tissue, some percentages may appear higher/lower than truly present due to the selective radio-detection.

Parent broflanilide was only detected as a minor residue in muscle, kidney and liver from lactating goats (0.5 to 6.7% TRR) and tentatively in egg white (2.1% TRR). In a cow feeding study, residues of broflanilide were detected in milk from the 10 ppm feeding level at up to 0.0018 mg/kg and in cream from the 1.5 ppm and the 10 ppm feeding levels at up to 0.016 mg/kg. In all other tissues broflanilide was not detected.

The predominant identified residue in metabolism studies was metabolite DM-8007, accounting for 21 to 100% TRR (0.01 to 3.4 mg eq/kg) in lactating goat matrices and for 57 to 100% TRR (0.013 to 19 mg eq/kg) in laying hen matrices. In a lactating cow feeding study, residues of DM-8007 were detected in milk (up to 0.12 mg/kg), cream (up to 1.2 mg/kg), fats (up to 0.79 mg/kg), liver (up to 0.078 mg/kg) and in muscle and kidney (up to 0.08 mg/kg). In matrices from laying hens, residues of DM-8007 were found in eggs, liver and fat at up to 0.023 mg/kg, 0.021 mg/kg and 0.15 mg/kg, respectively. Analytical methods which measure both broflanilide and DM-8007 in animal matrices are available.

Based on the available information, an enforcement and risk assessment residue definition as the sum of parent broflanilide plus metabolite DM-8007 (expressed as parent) is recommended for animal commodities, which is in line with the recommendation by the 2022 JMPR.

## Results from residues trials presented to the APVMA

### Brassica vegetables

The proposed use of broflanilide on brassica vegetables is for up to 2 applications, each at 25 g ai/ha, with a 7-to-14-day retreatment interval and a one-day harvest withholding period. The proposed directions for use for brassica vegetables includes the addition of Hasten at 0.2%, or a non-ionic adjuvant at 0.02%.

Australian residue trials on broccoli (2), Brussels sprouts (2), cabbage (3) and cauliflower (2) are supported by North American trials on cabbage (10) and broccoli (10). An additional Australian trial on Chinese cabbage (wombok) was on a variety representative of a head brassica. All of the available brassica vegetable trials included addition of an adjuvant except for one overseas cabbage trial.

In the Australian trials, residues at one day after the last of 2 applications at approximately 25 g ai/ha were 0.08 and 0.17 mg/kg in broccoli, 0.007 and 0.02 mg/kg in cauliflower, 0.005, 0.01 and 0.01 mg/kg in cabbage, 0.17 mg/kg in Chinese cabbage, and 0.009 and 0.03 mg/kg in Brussels sprouts.

In the North American trials, residues in cabbage without wrapper leaves at one day after the last of 2 applications at approximately 25 g ai/ha were 0.001, 0.002, 0.002, 0.002, 0.003, 0.004, 0.009, 0.009, 0.01 and 0.01 mg/kg. It is noted that Table 2 of the MRL Standard indicates that for cabbage the MRL applies to the whole commodity as marketed, after removal of obviously decomposed or withered leaves. This is in line with the sampling in the Australian cabbage trials which showed similar residues as the North American cabbage without wrapper leaves.

In the North American trials, residues in broccoli at one day after the last of 2 applications at approximately 25 g ai/ha were 0.004, 0.04, 0.07, 0.07, 0.08, 0.09, 0.12, 0.13, 0.33 and 0.45 mg/kg.

The combined dataset for MRL recommendation is 0.001, 0.002, 0.002, 0.002, 0.003, 0.004, 0.004, 0.005, 0.007, 0.009, 0.009, 0.009, 0.01, 0.01, 0.01, 0.01, 0.02, 0.03, 0.04, 0.07, 0.07, 0.08, 0.08, 0.09, 0.12, 0.13, 0.17, 0.17, 0.33 and 0.45 mg/kg. The OECD MRL Calculator recommends an MRL of 0.5 mg/kg (STMR= 0.01 mg/kg, n= 30).

An MRL of 0.5 mg/kg is recommended for broflanilide on VB 0040 Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas in conjunction with the proposed one-day harvest withholding period.

### Leafy vegetables

The proposed use of broflanilide on leafy vegetables is for up to 2 applications, each at 25 g ai/ha, with a 7-to-14-day retreatment interval and a one-day harvest withholding period.

Australian residue trials on head (2) and leafy lettuce (3) and spinach (1) are supported by North American studies on head (8) and leafy lettuce (8), spinach (11) and mustard greens (8).

In the Australian trials, residues at one day after the last of 2 applications at approximately 25 g ai/ha were 0.01 and 0.12 mg/kg in head lettuce, 0.12, 0.54 and 0.64 mg/kg in leafy lettuce and 1.05 mg/kg in spinach.

In the North American trials, residues in head lettuce without wrapper leaves at one day after the last of 2 applications at approximately 25 g ai/ha were <0.001, 0.003, 0.008, 0.009, 0.02, 0.03, 0.06 and 0.37 mg/kg.

In the North American trials, residues leafy lettuce at one day after the last of 2 applications at approximately 25 g ai/ha were 0.35, 0.38, 0.60, 0.66, 0.70, 0.72, 1.08 and 1.93 mg/kg.

In the North American trials, residues spinach at one day after the last of 2 applications at approximately 25 g ai/ha were 0.47, 0.67, 0.80, 0.89, 1.04, 1.56, 1.74, 1.76, 1.84, 1.86 and 2.58 mg/kg.

In the North American trials, residues mustard greens at one day after the last of 2 applications at approximately 25 g ai/ha were 0.38, 0.47, 0.62, 0.70, 0.92, 1.30, 1.40 and 2.40 mg/kg.

The combined dataset suitable for MRL determination is <0.001, 0.003, 0.008, 0.009, 0.01, 0.02, 0.03, 0.06, 0.12, 0.12, 0.35, 0.37, 0.38, 0.38, 0.47, 0.47, 0.54, 0.60, 0.62, 0.64, 0.66, 0.67, 0.70, 0.70, 0.72, 0.80, 0.89, 0.92, 1.04, 1.05, 1.08, 1.30, 1.40, 1.56, 1.74, 1.76, 1.84, 1.86, 1.93, 2.40 and 2.58 mg/kg. The OECD MRL Calculator recommends an MRL of 4 mg/kg (STMR= 0.66 mg/kg, n= 41). An MRL of 4 mg/kg is recommended for broflanilide in VL 0053 Leafy vegetables in conjunction with the proposed one-day harvest withholding period.

## Crop rotation

In a North American field rotational crop study conducted at 2 sites involving application to bare soil at the maximum proposed seasonal rate (50 g ai/ha) followed by planting of wheat, lettuce or radish at various intervals, residues of broflanilide were all <LOQ, except for parent broflanilide in one sample of lettuce planted at a 30-day plant back interval (PBI) which had a residue of 0.013 mg/kg.

Given that application was made to bare soil in the study, when in practice applications will be intercepted by the treated crop, the risk of residues in rotational crops from the proposed uses is considered to be low, noting also the following restraint on the draft label restricting the yearly application rate to that used in the rotational field study:

DO NOT apply more than 50 g active ingredient (500 mL product) per hectare per year total. This includes any subsequent crop in the same calendar year.

Plant back intervals or an “All other foods” MRL should not be required to manage residues in following crops.

## Animal commodities and MRLs

Kale, which can be grown as either a leafy vegetable or a fodder crop can be a feed for dairy cattle in Australia and can be fed at 40% of the diet (OECD Feed Calculator). However, the intention for this product is use on kale grown for human consumption only and the following grazing restraint is recommended to ensure this is the case:

DO NOT allow livestock to graze crops or vegetable waste that has been treated with Cimegra Insecticide.

Mammalian animal commodity MRLs are therefore recommended at the LOQ of the analytical method (\*0.02 mg/kg for tissues or \*0.002 mg/kg for milk).

Brassica vegetables and leafy vegetables are not considered to be common feeds for poultry. Poultry commodity MRLs are proposed at the combined LOQ (\*0.02 mg/kg) for the analytical method.

The Log Pow for parent broflanilide ranges from 4.4 to 5.2 at pH 4 to 10 at 25°C. The log Pow for the metabolite DM-8007 under the same conditions ranged from 5.35 to 5.75. Both compounds are therefore considered to be fat soluble and the mammalian and poultry meat MRLs will be established “in the fat”.

## Overseas registration and approved label instructions

The applicant indicated products containing broflanilide are registered for use on cabbage and Chinese cabbage in China, Japan and Korea.

## 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. Broflanilide was considered by the Codex Committee on Pesticide Residues in June 2023 and the MRLs supported by that committee are expected to be adopted as Codex MRLs by the Codex Alimentarius Commission in November 2023[[7]](#footnote-8). The following relevant overseas MRLs have been proposed or established for broflanilide as shown in Table 2.

Table : Relevant overseas MRLs for broflanilide

| Commodity | Tolerance for residues arising from the use of broflanilide (mg/kg) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Australia | Codex[[8]](#footnote-9)[[9]](#footnote-10) | EU[[10]](#footnote-11) | Japan[[11]](#footnote-12) | Korea[[12]](#footnote-13) | Taiwan[[13]](#footnote-14) | | USA[[14]](#footnote-15) | |
| Residue definition | Animal commodities: Parent + DM-8007 expressed as parent  Plant commodities: Parent | – | – | Broflanilide | – | | – | | Animal commodities: Parent + DM-8007 expressed as parent | |
| Edible offal (mammalian) | \*0.02 (proposed) | 0.03 (proposed) | – | – | – | | – | | 0.02 (Cattle, sheep meat byproducts) | |
| Meat (mammalian)[in the fat] | \*0.02 (proposed) | 0.15 (mammalian fats, meat, proposed) | – | – | – | | – | | 0.02 (Cattle, sheep fat)  0.02 (Cattle, sheep meat) | |
| Milk fats | \*0.02 (proposed) | 0.4 (proposed) | – | – | – | | – | | – | |
| Milks | \*0.002 (proposed) | 0.015 (proposed) | – | – | – | | – | | 0.02 | |
| Brassica vegetables | 0.5 (proposed) | 2 (cabbages, head, proposed) | – | 1 (Chinese cabbage)  0.4 (cabbage)  2 (cauliflower, broccoli) | 1.5 (broccoli)  0.05 (cabbage) | | – | | – | |
| Leafy vegetables | 4 (proposed) | – | – | 10 (kale)  6 (komatsuna)  15 (Lettuce) | 3 (lettuce, leafy vegetables, spinach) | | – | | – | |

The applicant indicated that MRLs in China are in the public commenting phase but have not yet been published.[[15]](#footnote-16)

## Current and proposed Australian MRLs for broflanilide

Table 3 below shows proposed additions to Table 1 of the MRL standard for broflanilide.

Table 3: Proposed MRL Standard – Table 1

| Compound | Food | MRL (mg/kg) |
| --- | --- | --- |
| Add: | | |
| Broflanilide | | |
| VB 0040 | Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas | 0.5 |
| MO 0105 | Edible offal (mammalian) | \*0.02 |
| PE 0112 | Eggs | \*0.02 |
| VL 0053 | Leafy vegetables | 4 |
| MM 0095 | Meat (mammalian) [in the fat] | \*0.02 |
| FM 0183 | Milk fats | \*0.02 |
| ML 0106 | Milks | \*0.002 |
| PM 0110 | Poultry meat [in the fat] | \*0.02 |
| PO 0111 | Poultry, edible offal of | \*0.02 |

Table 4 below shows proposed additions to Table 3 of the MRL standard for broflanilide.

Table : Proposed MRL Standard – Table 3

| Compound | | Residue |
| --- | --- | --- |
| Add: | | |
| Broflanilide | Commodities of plant origin: Broflanilide  Commodities of animal origin: Sum of broflanilide plus 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM-8007), expressed as broflanilide. | |

## Potential risk to trade

Export of treated produce containing finite (measurable) residues of broflanilide 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.

Brassica vegetables and leafy vegetables are not considered to be major export commodities and the risk to international trade for those commodities is not considered to be undue.

Tolerances for broflanilide in animal commodities are not established in many markets, except in the USA. It is noted that the Codex Committee on Pesticide Residues has recently supported broflanilide MRLs. However, a grazing restraint has been recommended for the product for treated vegetable crops and animal commodity MRLs will be recommended at the LOQ for the analytical method. The risk to trade to animal commodities associated with the proposed use is expected to be low.

# Conclusion

BASF Australia have applied for the registration of Cimegra Insecticide containing broflanilide for use on brassica vegetables and leafy vegetables. This will be the first use of broflanilide in a food producing situation in Australia and will also require the establishment of animal commodity MRLs. Comment is sought from relevant industry groups on the potential risk to trade from the proposed uses.

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