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**AGRICULTURAL AND
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**Australian Pesticides and
Veterinary Medicines Authority**

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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The Manager, Public Affairs
The Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Email: communications@apvma.gov.au

Website: www.apvma.gov.au

GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 53(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

From February 2010, the APVMA will publish the *APVMA Gazette* in electronic format only. The *APVMA Gazette* and information about subscribing to the gazette alert service are available on the APVMA website, www.apvma.gov.au.

Copies of the *APVMA Gazette* from November 1999 until July 2009 will remain available from the APVMA website.

APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4871

For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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NOTICE—NEW AGRICULTURAL CHEMICAL PRODUCTS

Fluxapyroxad in the product MBREX Fungicide (earlier named as BAS 700 01 F Fungicide)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from BASF Australia Ltd, for registration of a new product containing the active constituent fluxapyroxad. The product is **MBREX FUNGICIDE**. The product is for use on barley.

PARTICULARS OF THE APPLICATION

Proposed Product Name):	MBREX FUNGICIDE
Applicant Company:	BASF Australia Ltd.
Name of Active Constituent:	Fluxapyroxad
Signal Heading:	Schedule 5
Summary of Proposed Use:	For the control of specific fungal diseases of barley
Pack Sizes:	5, 10, 20L
Withholding Period:	Grazing: Do not graze or cut for stock food for 14 days after application. Harvest: Not required when used as directed.

SUMMARY OF THE APVMA'S EVALUATION OF BAS 700 01 F FUNGICIDE IN ACCORDANCE WITH SECTION 14(3) (E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3) (e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of BAS 700 01 F FUNGICIDE would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Department of Health and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

The product, BAS 700 01 F Fungicide, will be imported fully formulated from overseas. Farmers and their employees will be the main users of the product. Workers may be exposed to the product when opening containers, mixing/loading, application, and cleaning up spills, maintaining equipment and entering treated areas. The main route of exposure to the products will be dermal and inhalation, although ocular exposure is also possible.

Based on the risk assessment conducted, First Aid Instructions, Warning Statements and General Safety Precautions, Safety Directions and Re-entry statements have been recommended and shown on the product label.

The APVMA accepts the findings and recommendations of the OCS evaluation.

- (iii) The APVMA is satisfied that the proposed use of BAS 700 01 F FUNGICIDE will not be an undue hazard to the safety of people using anything containing its residues provided the product is used in accordance with the proposed label directions.

The product is proposed for use for the control of various fungal diseases in barley. It is considered that a residue definition of parent only is appropriate for fluxapyroxad in plant commodities. The APVMA Pesticides Residue Section has evaluated the residues aspects of the proposed product and has recommended amendments to the APVMA MRL Standard for fluxapyroxad and for subsequent inclusion in the Food Standards Code. Recommendations in regard to the required withholding period and protection statements for livestock have been included on the label. Long term (chronic) dietary exposure as estimated by the National Estimated Dietary Intake is acceptable. Estimation of short term (acute) dietary exposure is not required as establishment of an acute reference dose was considered unnecessary.

The APVMA accepts the findings and recommendations of its advisors on these criteria.

- (iv) The APVMA is satisfied that the proposed use of BAS 700 01 F FUNGICIDE containing the active constituent fluxapyroxad is not likely to be harmful to human beings if used according to the product label directions.

Based on the findings of the acute toxicological studies evaluated, fluxapyroxad was of low acute oral, dermal and inhalational toxicity in rats. It was a slight skin but not an eye irritant in rabbits, and was not a skin sensitiser in guinea pigs.

The product BAS 700 01 F FUNGICIDE has low acute oral, dermal inhalational toxicity in rats. It is a slight skin and a severe eye irritant in rabbits, but not a skin sensitiser in guinea pigs. The new active constituent fluxapyroxad has been evaluated for approval. The appropriate signal heading is on the proposed product label. The First Aid and Safety Directions recommended by the Department of Health and Ageing have also been included on the proposed label.

The APVMA accepts the findings and recommendations of its advisors on these criteria.

- (v) The APVMA is satisfied that the proposed use of BAS 700 01 F FUNGICIDE is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

The Department of Sustainability, Environment, Water, Population and Communities has assessed data in support of the proposed use and has concluded that the risks to the environment from this use are acceptable provided that the draft label is updated to meet current requirements.

Fluxapyroxad is stable with minimal or no detectable degradation by abiotic processes (photolysis and hydrolysis). It undergoes slow degradation by biotic processes in both soil and water under laboratory conditions. However, it does dissipate rapidly from the aquatic compartment to sediment. Under field conditions it dissipates more rapidly than under laboratory conditions, but there is potential for residue carryover to the following cropping season if application is performed annually.

Fluxapyroxad is at most slightly acutely toxic to birds as well as showing some effects on reproduction. It was found to be approximately equally toxic to all aquatic species including algae and generally this toxicity could be attributed to the active constituent alone. Fluxapyroxad was considered either highly or moderately toxic to aquatic species. It was slightly or moderately chronically toxic to fish or aquatic invertebrates. Sediment dwelling organisms were also only slightly sensitive to fluxapyroxad. Terrestrial invertebrates were at most slightly sensitive to either fluxapyroxad or its formulated product. Soil organisms were not sensitive to fluxapyroxad or its metabolites and phytotoxicity was

limited. Despite its persistence and relatively low water solubility, fluxapyroxad was considered unlikely to bio-accumulate.

At the proposed rate, the major potential risk to the environment was fluxapyroxad's potential to accumulate in soil and sediment from multiple applications. Even using conservative modelling, risk to aquatic organisms was found from run-off water entering environmental waters was found to be acceptable. Similarly the risk to sediment and soil dwelling organisms from spray drift and run-off was found to be acceptable in spite of the potential of fluxapyroxad to accumulate in these environmental compartments. The risk assessment determined that fluxapyroxad is unlikely to pose an environmental risk under the proposed use pattern, provided the draft label is updated to meet current requirements.

The APVMA has considered the findings of the Department of Sustainability, Environment, Water, Population and Communities and accepts these conclusions.

- (vi) The APVMA is satisfied that the proposed use of BAS 700 01 F FUNGICIDE would not adversely affect trade between Australia and places outside Australia.

The APVMA is considering whether the proposed use of BAS 700 01 F Fungicide would not adversely affect trade between Australia and places outside Australia. Detectable residues may be expected to occur in barley and all export markets have not established appropriate tolerances. Accordingly, a determination of undue prejudice to trade or commerce should be made following the completion of the public consultation process. Any areas of concern and possible management strategies have been outlined in the Public Release Summary.

The draft label includes the following advice regarding export of treated cereals:

'Growers should note that Maximum Residue Limits (MRLs) or import tolerances do not exist in all markets for cereals treated with BAS 700 01 F FUNGICIDE. Additionally, some export markets have established MRLs different to those in Australia. If you are growing cereals for export, please check with BASF Australia Ltd or your grain exporter for the latest information on MRLs and import tolerances BEFORE using BAS 700 01 F FUNGICIDE.'

- (vii) In relation to its assessment of efficacy under section 14(3) (f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, www.apvma.gov.au/consultation/public or by contacting the person listed below.

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of BAS 700 01 F FUNGICIDE 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 include **occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy**. 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 within **28 days** of the date of this notice 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 the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address
- the date you made the submission.

All personal and **confidential commercial information (CCI)**¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the **grounds for registration** should be addressed in writing to:

Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: 02 6210 4718

Fax: 02 6210 4776

Email: pesticides@apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).