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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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General information

The APVMA 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 8J(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

The APVMA Gazette is published in electronic format only and is available from the [APVMA website](#).

If you would like to subscribe to receive email notification when a new edition is published, please complete a [subscription form](#).

APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

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

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Contents

New active constituent bromethalin.....	1
Fastrac G Blox Rodenticide containing bromethalin.....	3
Fastrac Pro Blox Rodenticide containing bromethalin.....	5
Fastrac G Place Pacs Rodenticide containing bromethalin.....	7
Fastrac G Pellets Rodenticide containing bromethalin.....	9
Fastrac Pro Place Pacs Rodenticide containing bromethalin.....	11
Fastrac Pro Pellets Rodenticide containing bromethalin.....	13
Fastrac G Meal Bait Rodenticide containing bromethalin.....	15
Fastrac Pro Soft Bait Rodenticide containing bromethalin.....	17

List of tables

Table 1: Particulars of the active constituent bromethalin.....	1
Table 2: Particulars of the application Fastrac G Blox Rodenticide containing bromethalin.....	3
Table 3: Particulars of the application Fastrac Pro Blox Rodenticide containing bromethalin.....	5
Table 4: Particulars of the application Fastrac G Place Pacs Rodenticide containing bromethalin.....	7
Table 5: Particulars of the application Fastrac G Pellets Rodenticide containing bromethalin.....	9
Table 6: Particulars of the application Pro Place Pacs Rodenticide containing bromethalin.....	11
Table 7: Particulars of the application Fastrac Pro Pellets Rodenticide containing bromethalin.....	13
Table 8: Particulars of the application Fastrac G Meal Bait Rodenticide containing bromethalin.....	15
Table 9: Particulars of the application Fastrac Pro Soft Bait Rodenticide containing bromethalin.....	17

New active constituent bromethalin

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, bromethalin, for use as a new rodenticide in damp or dry situations in and around industrial, commercial, agricultural and domestic buildings.

Table 1: Particulars of the active constituent bromethalin

Common name	Bromethalin
IUPAC name	<i>N</i> -Methyl-2,4-dinitro- <i>N</i> -(2,4,6-tribromophenyl)-6-(trifluoromethyl)aniline
CAS name	<i>N</i> -methyl-2,4-dinitro- <i>N</i> -(2,4,6-tribromophenyl)-6-(trifluoromethyl)benzenamine
CAS registry number	63333-35-7
Minimum purity	950 g/kg
Molecular formula	C ₁₄ H ₇ Br ₃ F ₃ N ₃ O ₄
Molecular weight	577.9 g mol ⁻¹
Structure	
Chemical family	Diphenylamine

Summary of the APVMA's evaluation of bromethalin active constituent

The APVMA has evaluated the chemistry aspects of active constituent bromethalin (physico-chemical properties, identification, spectra, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of bromethalin, and concluded that there are no toxicological concerns regarding the approval of this active constituent. Neither an acceptable daily intake (ADI) nor an acute reference dose (ARfD) were established as bromethalin residues are not expected to be present in the food supply. A tolerable daily intake (TDI) of 0.0019 µg/kg bw/day (based on 80 kg bw) is established to serve as a guideline with which potential dietary exposure assessments can be undertaken in the event of unintentional presence in food.

Bromethalin is included in Schedule 6 Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) when present in rodent baits containing 0.01% or less of bromethalin and in Schedule 7 otherwise.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for bromethalin:

Constituent	Level
Bromethalin	Minimum purity 950 g/kg

Other compounds of toxicological significance are not expected to occur in bromethalin as a result of the raw materials and the synthetic route used.

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

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or from the contact listed below.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether bromethalin should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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.

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see [public submission coversheet](#)).

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Please send your written submission and coversheet by email or post to:

Email: enquiries@apvma.gov.au

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Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Privacy

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Fastrac G Blox Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac G Blox Rodenticide containing a new active constituent, bromethalin.

Table 2: Particulars of the application Fastrac G Blox Rodenticide containing bromethalin

Proposed product name	Fastrac G Blox Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin ready to use block bait to control rats and mice in damp or dry situations in and around industrial, commercial, agricultural and domestic buildings
Pack sizes	Net contents 150 g – 10 kg Size of block: 5 g, 10 g, 15 g, 20 g, 28 g, 113 g, 225 g blocks
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac G Blox Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac G Blox Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.
The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac G Blox Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac G Blox Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac G Blox Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac G Blox Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac G Blox Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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Fastrac Pro Blox Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac Pro Blox Rodenticide containing a new active constituent, bromethalin.

Table 3: Particulars of the application Fastrac Pro Blox Rodenticide containing bromethalin

Proposed product name	Fastrac Pro Blox Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin ready to use block bait to control rats and mice in damp or dry situations in and around industrial, commercial, agricultural and domestic buildings
Pack sizes	Net contents 150 g – 10 kg Size of block: 5 g, 10 g, 15 g, 20 g, 28 g, 113 g, 225 g blocks
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac Pro Blox Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac Pro Blox Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.
The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac Pro Blox Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac Pro Blox Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac Pro Blox Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac Pro Blox Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac Pro Blox Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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Fastrac G Place Pacs Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac G Place Pacs Rodenticide containing a new active constituent, bromethalin.

Table 4: Particulars of the application Fastrac G Place Pacs Rodenticide containing bromethalin

Proposed product name	Fastrac G Place Pacs Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin Place Packs for control of rats and mice, including those resistant to anticoagulants in and around industrial, commercial and agricultural buildings
Pack sizes	Net contents 150 g – 10 kg Primary pack contains # X 15 or 85 g place pacs
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac G Place Pacs Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac G Place Pacs Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac G Place Pacs Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac G Place Pacs Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac G Place Pacs Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac G Place Pacs Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac G Place Pacs Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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Fastrac G Pellets Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac G Pellets Rodenticide containing a new active constituent, bromethalin.

Table 5: Particulars of the application Fastrac G Pellets Rodenticide containing bromethalin

Proposed product name	Fastrac G Pellets Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin loose pellets for control of rats and mice, including those resistant to anticoagulants in and around industrial, commercial and agricultural buildings
Pack sizes	Net contents 150 g – 10 kg
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac G Pellets Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac G Pellets Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac G Pellets Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac G Pellets Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac G Pellets Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac G Pellets Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac G Pellets Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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Fastrac Pro Place Pacs Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac Pro Place Pacs Rodenticide containing a new active constituent, bromethalin.

Table 6: Particulars of the application Pro Place Pacs Rodenticide containing bromethalin

Proposed product name	Fastrac Pro Place Pacs Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin place packs for control of rats and mice, including those resistant to anticoagulants in and around industrial, commercial and agricultural buildings
Pack sizes	Net contents 150 g – 10 kg Primary pack contains # X 15 or 85 g place pacs
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac Pro Place Pacs Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac Pro Place Pacs Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.
The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac Pro Place Pacs Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac Pro Place Pacs Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac Pro Place Pacs Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac Pro Place Pacs Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac Pro Place Pacs Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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Fastrac Pro Pellets Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac Pro Pellets Rodenticide containing a new active constituent, bromethalin.

Table 7: Particulars of the application Fastrac Pro Pellets Rodenticide containing bromethalin

Proposed product name	Fastrac Pro Pellets Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin loose pellets for control of rats and mice, including those resistant to anticoagulants in and around industrial, commercial and agricultural buildings
Pack sizes	Net contents 150 g – 10 kg
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac Pro Pellets Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac Pro Pellets Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac Pro Pellets Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac Pro Pellets Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac Pro Pellets Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac Pro Pellets Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac Pro Pellets Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see [public submission coversheet](#)).

Please lodge your submission with a [public submission 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.

Please send your written submission and coversheet by email or post to:

Email: enquiries@apvma.gov.au

Post:

Executive Director Registration Management
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Privacy

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Fastrac G Meal Bait Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac G Meal Bait Rodenticide containing a new active constituent, bromethalin.

Table 8: Particulars of the application Fastrac G Meal Bait Rodenticide containing bromethalin

Proposed product name	Fastrac G Meal Bait Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin loose meal bait for control of rats and mice, including those resistant to anticoagulants in and around industrial, commercial and agricultural buildings
Pack sizes	Net contents 150 g – 10 kg
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac G Meal Bait Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac G Meal Bait Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac G Meal Bait Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac G Meal Bait Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac G Meal Bait Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac G Meal Bait Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac G Meal Bait Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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Sydney NSW 2001

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Fastrac Pro Soft Bait Rodenticide containing bromethalin

The APVMA has before it an application for registration of a new product, Fastrac Pro Soft Bait Rodenticide containing a new active constituent, bromethalin.

Table 9: Particulars of the application Fastrac Pro Soft Bait Rodenticide containing bromethalin

Proposed product name	Fastrac Pro Soft Bait Rodenticide
Applicant company	Bell Laboratories, Inc.
Name of active constituent	Bromethalin
Signal heading	Schedule 6
Summary of proposed use	Registration of a 0.1 g/kg bromethalin paste bait for control of rats and mice, including those resistant to anticoagulants in and around industrial, commercial, agricultural and domestic buildings
Pack sizes	Net contents 150 g – 10 kg Primary pack contains # X 8 or 15 g sachets
Withholding period	N/A

A summary of the APVMA's evaluation of Fastrac Pro Soft Bait Rodenticide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Fastrac Pro Soft Bait Rodenticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Fastrac Pro Soft Bait Rodenticide will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of Fastrac Pro Soft Bait Rodenticide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy 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.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. As the proposed use of Fastrac Pro Soft Bait Rodenticide is not for use in food or feed a full risk assessment of residues and trade was not required. The APVMA is satisfied that the proposed use of Fastrac Pro Soft Bait Rodenticide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Fastrac Pro Soft Bait Rodenticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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.

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