



# Guideline to the Type of Information the APVMA will Routinely Publish in Relation to Applications

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## Introduction

The Agricultural and Veterinary Chemicals Code (the Agvet Code), which is the schedule to the Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994* and adopted by each state, requires the APVMA to publish certain information in relation to applications for approval and registration as well as for applications to vary existing approvals and registrations. In particular, the APVMA is required to publish:

- Application summaries (sections 11A and 28B of the Agvet Code) for all applications for approval or registration and for any application for variation of approval or registration where the variation relates to the use or dealing with a product;
- Advice summaries (section 34G of the Agvet Code) where in making a decision to grant an application, the APVMA relied on advice given by a person, body or government that it consulted;
- Notices (Public Release Summaries) before deciding whether to approve a new active constituent or register a product containing a new active constituent (sections 12 and 13 of the Agvet Code).

The APVMA may also publish a Trade Advice Note in order to obtain the information it requires to meet its legislative obligations, particularly with regard to determining the risk of undue prejudice to trade from residues in edible commodities.

This guideline sets out the type of information that the APVMA may publish in carrying out its functions and duties. It is acknowledged that the publication of certain information might give rise to concern from those providing information to the APVMA in relation to applications. In discharging its statutory requirements, the APVMA will not unnecessarily include confidential commercial information<sup>1</sup>.

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<sup>1</sup> The Agricultural and Veterinary Chemicals Code provides the following definition for confidential commercial information at section 3:

**“confidential commercial information**, in relation to an active constituent for a proposed or existing chemical product, or in relation to a chemical product or a constituent of a chemical product, means:

- (a) a trade secret relating to the constituent or product; or
- (b) any other information relating to the constituent or product that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
- (c) information (other than trade secrets to which paragraph (a) applies or information to which paragraph (b) applies) that:
  - (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
  - (ii) relates to the manufacture, distribution or supply of the constituent or product; and
  - (iii) if it were disclosed, could unreasonably affect the person, organisation or undertaking in an adverse manner.”

However, sufficient detail will be included so that the notice is meaningful and consistent with a transparent regulatory process.

## **What information may be included in notices?**

### *Application summaries*

The *Agricultural and Veterinary Chemicals Code Regulations 1995* (The Regulations) (regulations 8A, 8B, 8C, 8D, 8E, 19AA, 19AB, 19 AC and 19AD) require different application summaries depending on the type of application. Application summaries will include different combinations of the following details:

- Applicant name
- Application number
- Active constituent name and number
- Product name and number
- Application purpose and description of active constituent or product use
- A list of the data that was provided with the application and required by the APVMA
- The relevant reference active constituent and/or product names and numbers.

### *Advice summaries*

The Regulations (regulations 22B and 22C) require the APVMA to publish similar details as for application summaries, however also required to be included are:

- A summary of the advice, including a summary of the results from any trials mentioned in the advice.
- A list of the information relied on in giving the advice.

### *Public Release Summaries*

Public release summaries must state that the APVMA is considering approving the active constituent or registering the product and will include the following details:

- The name of the active constituent or product
- The particulars of the active constituent or product (other than confidential commercial information)
- A summary of the APVMA's assessment, which may include a details of:
  - the toxicology of both the active and product
  - the residues and trade assessment
  - occupational exposure issues
  - environmental exposure, fate, toxicology and hazard
  - the efficacy and safety assessment
  - a copy of the label (if any) that the APVMA is considering approving.

Public release summaries are required to invite interested persons to make a written submission to the APVMA as to whether a product should be registered. Such

submissions should be based on grounds that relate to matters the APVMA is required to take into account (see s.14 of the Agvet Code). The APVMA must take into account any relevant submissions in deciding whether to approve an active constituent or register a product.

#### *Trade Advice Notes*

Trade advice notes will indicate that the APVMA is considering an application and provide a summary of the APVMA's residue and trade assessment. A Trade Advice Note will seek comment from interested persons with respect to the APVMA's assessment on trade only.

#### **Where are these notices published?**

- Application summaries are published to the APVMA website as soon as practicable after applications are accepted and a list of the application summaries that have been published each month is included in the APVMA Gazette.
- Advice summaries are published to the APVMA website where required soon after applications have been finalised (granted).
- A notice advising that a Public Release Summary is available will be included in the APVMA Gazette. Public Release Summaries are published to the APVMA website or alternatively hard copies may be obtained from the APVMA contact point detailed on the Public Release Summary web page.
- A notice advising that the APVMA is seeking comment in relation to Trade and advising that a Trade Advice Note is available will be included in the APVMA Gazette. Trade Advice Notes are published to the APVMA website or alternatively hard copies may be obtained using the contact details included in the Gazette notice.

#### **Further information**

For further information, please visit the Data Protection page of the APVMA website.