Australian Government

Australian Pesticides and Veterinary Medicines Authority

Approach to managing confidential commercial information

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Introduction

What this document is about

The Australian Pesticides and Veterinary Medicines Authority (APVMA) receives and holds a large amount of information that may be commercially or personally sensitive or have a significant commercial value to the person or entity providing it.

This document explains the:

- APVMA's approach to identifying, using and disclosing this type of information, and
- various legislative protections that may apply to it.

As part of the Commonwealth, the APVMA has obligations under the Australian Government's Protective Security Policy Framework[1] (PSPF) to ensure that it develops, documents, implements and reviews appropriate security measures to protect information from unauthorised use or accidental modification, loss or release. When information is provided to the APVMA that appears to be commercially sensitive or valuable, it is treated as Official Information[2] and the APVMA is required to take measures to protect it under the PSPF.

The Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (Agvet Code) and Agricultural and Veterinary Chemicals Code Regulations 1995 (the Regulations) also contain additional protections about the use and disclosure of information provided to, or held by, the APVMA, including confidential commercial information.

Finally, the APVMA must comply with other legislation that may affect the collection, use or disclosure of information.

This document refers to the agvet legislation as it applies from 1 May 2021. It provides general summary information only and should not be relied upon as legal advice or advice relating to particular circumstances.

[1] The Protective Security Policy Framework (PSPF) provides the appropriate controls for the Australian Government to protect its people, information and assets, at home and overseas.

[2] Under the PSPF, Official Information is defined as 'all information created, sent or received as part of the work of the Australian Government'.

Official information

The APVMA complies with the Australian Government's PSPF when handling information.

The PSPF defines Official Information as "*All information created, sent or received as part of the work of the Australian Government.*"

All information created, sent or received by the APVMA that is not publicly available will be treated as Official Information. The APVMA is required to take measures to protect this information. The APVMA classifies Official Information using the classification system under the PSPF into one of the following categories:

- Unofficial – for use only on information when its compromise will cause no business impact and no damage.
- Official – for use only on information when its compromise will have low business impact and no or insignificant damage.
- Official Sensitive – for use only on information when its compromise will have low to medium business impact and limited damage to an individual, organisation or government generally.
- Protected – for use only on information when its compromise will have high business impact and damage to the national interest, organisations or individuals.
- Secret – for use only on information when its compromise will have extreme business impact and serious damage to the national interest, organisations or individuals.
- Top Secret – for use only on information when its compromise will have catastrophic business impact and exceptionally grave damage to the national interest, organisations or individuals.

Official Information that meets the definition of 'confidential commercial information' in the Agvet Code and/or is subject to limitations or restrictions on use under the agvet legislation is likely to be classified 'OFFICIAL SENSITIVE'.

Access to Official Information

A person may seek to access Official Information held by the APVMA through:

- applying for copies of documents held by the APVMA under the Freedom of Information Act[3]

[3] If the document relates to an approved active constituent or registered chemical product, the request should be made under section 8W, 17(5) or 18(5) of the Agvet Code.

- inspecting, or seeking a copy or extract of part of, the Record of Approved Active Constituents for Chemical Products[4]
- inspecting, or seeking a copy or extract of part of, the Register of Agricultural and Veterinary Chemical Products[5]
- applying to the APVMA for a copy of, or extract of, a document relating to an approved active constituent or registered chemical product[6].

Fees may apply to requests for access to some information.

[4] Under subsections 17(4) and (5) of the Agvet Code.

[5] Under subsections 18(4) and (5) of the Agvet Code.

[6] Under subsection 8W(1) of the Agvet Code.

Confidential commercial information (CCI)

What is CCI?

The Agvet Code defines CCI[7] in relation to a constituent or chemical product as:

- trade secrets
- information that has a commercial or other value that would be (or could reasonably be expected to be) destroyed or diminished if it were disclosed
- information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking, relating to manufacture, distribution or supply, that (if disclosed) could unreasonably affect the person, organisation or undertaking.

These definitions all refer to potential damage from release of the information, rather than the circumstances in which it was obtained or made available.

The definition in the Agvet Code excludes:

- permit applications, where the proposed use is minor use or emergency use
- the name of the applicant, the application number, the chemical product number, the name of each of the active constituents of the chemical product and a short description of the application and its purpose, including a description of the way in which the chemical product is intended to be used[8].

Some examples of what is likely to be considered CCI include the following:

- The identity of any source of active constituent used to formulate the end-use product. Where the source of the active constituent is a registered product, the identity of that product is also CCI.
- Formulation composition and manufacturing process. This might include active and non-active ingredients, manufacturing methods, their concentration, product specifications, common trade and chemical names.
- Active constituent specifications and product constituent specifications, including chemical and physical properties. These details may be included in a manufacturer's specification sheet.
- Details of the site of manufacture of a product of active constituent including the name and address of the business office, and any facility involved in any part of the manufacturing process including formulation, contractors, packaging and labelling, analysis and supply.
- Information about analytical trials, testing and validating methods used in manufacture, including information that would identify a validation method.
- Batch analysis results for an active constituent or product.

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[7] See section 3 of the Agvet Code.

[8] See paragraphs (d) and (e) of the definition, and Regulation 3C of the Agricultural and Veterinary Chemical Code Regulations 1995 (the Regulations).

- A study, report of a test, or analysis or any information submitted as part of an application or any report received in relation to an assessment of the information.
- Information about the volume or value of projected or actual sales of products or active constituents.
- Information or inquiries in relation to registration requirements and any details of planned applications for registrations or approvals by potential applicants.

Some examples of what would generally not be considered CCI:

- Any information published on the APVMA website for the purpose of licencing, approvals and standards or otherwise fulfilling its requirements under the Agvet Code (such as information required for Public Release Summaries or active constituent details required for the APVMA Standards for Active Constituents).
- Information that will be made public (such as active constituent names and concentrations, as they will appear on product labels).
- Information that is already in the public domain (such as company advertising and promotional material).

These examples are not exhaustive and the APVMA will apply the definition in the Agvet Code to determine whether information is CCI at a particular time (for example, if the APVMA is considering disclosing the information).

How is CCI identified?

In order to be considered as CCI at a particular time, the information should meet the definition of CCI in section 3 of the Agvet Code.

When is information determined to be CCI?

Information provided to the APVMA will be reviewed when it is received to ascertain whether it meets the definition of CCI in the Agvet Code.

When applying to the APVMA, the applicant will be asked to identify any information that they could consider to be CCI. This can be provided in the application or separately. Over time, however, information that could have been CCI on application may no longer meet that definition (for example, because it is now publicly available or it is no longer a trade secret because it is widely known).

The APVMA will apply the definition in the Agvet Code to determine whether particular information is CCI at a particular time (for example, if the APVMA is considering disclosing the information).

Disagreements about whether information is CCI

The Agvet Code sets out a process in the event that APVMA disagrees with an applicant or the holder of a registration or permit who claims that information is CCI.

Where an authorising party, applicant, or holder of a registration or approval, claims that information about an active constituent, chemical product or any of its constituents, or a label for containers for a chemical product is CCI but the APVMA does not agree, the APVMA will give notice of any decision to disclose that information before disclosure (section 163 Agvet Code). The notice will give reasons why the APVMA considers that the information is not CCI.

The APVMA will not disclose the information until at least 28 days after this notice is given. This will give the authorising party, applicant or holder an opportunity to provide the APVMA with further supporting evidence.

The basic rule against disclosing CCI

It is an offence under subsection 162(1) of the Agvet Code[9] to disclose CCI (that is, give it out or communicate it in any way).

The prohibition covers release of information about an active constituent for a proposed or existing chemical product, about a chemical product or any of its constituents, or about a label for containers for a chemical product.

It applies to a person who is or has been a Director, the Chief Executive Officer, or a member of the staff, of the APVMA, or is or has been a consultant to the APVMA, a mediator or arbitrator appointed under the Agvet Code, or a state/territory co-ordinator.

The prohibition:

- applies to both direct disclosure (telling somebody the CCI, or giving them a copy of it) and indirect disclosure (including doing or saying something that would allow that person to know the substance of the CCI, even if the CCI itself is not provided)
- applies to disclosure both within and external to the APVMA
- extends beyond a person's employment or association with the APVMA.

The APVMA has internal procedures to ensure that CCI is not disclosed in contravention of section 162(1), unless one or more of the legislative exceptions in the Agvet Code applies.

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[9] The basic rule around disclosure of CCI in subsection 162(1) of the Agvet Code is:

(1) A person who is or has been a *D*irector, the Chief Executive Officer, or a member of the staff, of the APVMA, or is or has been a consultant to the APVMA, a mediator or arbitrator appointed under this Code, or a co-ordinator designated for a jurisdiction, must not disclose, directly or indirectly, to another person any information about an active constituent for a proposed or existing chemical product, about a chemical product or any of its constituents, or about a label for containers *for a chemical product, that:*

(a) the person knows to be confidential commercial information and

(b) was acquired by the person in the performance of such functions or duties or the exercise of such powers.

Penalty: Imprisonment for 2 years.

When is it lawful for the APVMA to disclose CCI?

The Agvet Code sets out a number of situations where the general prohibition against disclosure does not apply.

Performance of functions and duties under the Agvet Code

The general rule against disclosure does not apply where disclosure is necessary to perform functions or duties, or exercise powers as an APVMA officer under the Agvet Code.

This is because the general prohibition does not apply "*to the extent that the person engages in the conduct in the performance of functions or duties or the exercise of powers, under this Code"* (section 162(1A)).

For example, an APVMA evaluator may disclose CCI to another APVMA officer for the purposes of issuing a notice or meeting the requirements to make an entry on the APVMA register or record. An APVMA officer may also disclose conditions of a permit to a state or territory coordinator which may include CCI.

The Agvet Code states, however, that the section 162(1A) exception will not permit disclosure of CCI in certain notices issued by the APVMA, including notice to an applicant that their product has or has not been registered (see section 8X of the Agvet Code). Accordingly, the APVMA will not include CCI in any of these notices unless another exception applies.

Disclosure to a court

The general prohibition does not prohibit the disclosure of information about a constituent or product to a court (including a tribunal, authority or person with power to require the production of documents or the answering of questions).

In complying with any subpoena, summons, notice to produce or discovery order, the APVMA will, however, take steps to notify the court of its obligations under section 162(2) of the Agvet Code to do all things necessary to prevent the disclosure of the CCI to any other person except for the purpose of the legal proceedings. The court must do all things necessary to prevent disclosure of the CCI to any other person except for the purpose of the proceeding.

The APVMA's approach is to notify the owner of the CCI in writing if it is required to disclose any of the CCI to a court.

Disclosure of CCI about an active constituent or chemical product under section 162(3)

A person who has been expressly authorised by the Chief Executive Officer under section 162(3) of the Agvet Code can make certain disclosures. Such a person can disclose CCI in certain circumstances, including:

- about an active constituent for a proposed or existing chemical product by disclosing a summary of an evaluation of that constituent made by the APVMA or by a prescribed authority or person
- if a product contains a new active constituent, by disclosing a summary of an evaluation that the APVMA has made of the product

- the relevant particulars of the constituent or product, for the purposes of a reconsideration of the approval of the constituent or the product
- by disclosing toxicity/residues information about an active or a product (but only if the conditions in Regulation 66 are satisfied)
- about an active constituent or a product or any of its constituents to:
    - the Commonwealth, a state or territory or their authorities, e.g. the Therapeutic Goods Administration , Office of Chemical Safety, Department of Health
    - an overseas authority having similar functions to the APVMA, or another international organisation set out in Regulation 68, but only if the APVMA has the consent of the Authorising Party or has made reasonable efforts to obtain this consent and 28 days has passed
    - the Authorising Party for the information, or where the Authorising Party has expressly authorised another person or entity to obtain the information.

The APVMA has procedures to ensure that evidence of proper consent from the relevant Authorising Party is provided before any CCI is disclosed (either directly or indirectly) under the last of the legislative exceptions listed above.

Disclosure for the purposes of seeking advice

The APVMA is able to consult with various governments, persons and bodies to seek information or advice relating to the performance of its functions (section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act*).* A person who has been expressly authorised by the APVMA to act under section 162(7) of the Agvet Code may permit another person to disclose CCI to these persons and bodies, to enable them to give advice to the APVMA. The APVMA has confidentiality agreements in place with all external contractors from which it seeks advice to protect any CCI that may be disclosed. The APVMA can also provide CCI to a state/territory coordinator to seek a recommendation about a permit application.

Recipient under confidentiality obligation

Any person who acquires CCI through a disclosure under section 162(3) or 162(7) of the Agvet Code is then personally subject to the same restrictions as the APVMA under section 162(1) of the Agvet Code.

CCI record keeping requirements

Regulation 69 of the Agvet Code Regulations imposes an obligation on the APVMA to keep records in relation to every disclosure of CCI. The APVMA must record the:

- name and address of the person to whom the information was disclosed
- nature of the information disclosed
- date of disclosure.

These records must be kept for 10 years.

The APVMA must not disclose any information contained in these records unless the person has a reasonable excuse or the permission of the Minister or a person authorised in writing by the minister.

Additional protections on use of information under the Agvet Code

What are the additional protections?

The use of information that is CCI may also be subject to additional legislative restrictions under the Agvet Code.

Any piece of information can be covered by more than one restriction. The restrictions apply to information where:

- use is restricted under Part 3 of the Agvet Code ('protected information')
- there are 'limitations on use' under Division 4A of Part 2 of the Agvet Code
- use is otherwise restricted under Part 7B of the Administration Act or section 14B of the Agvet Code.

Each of these categories is discussed further below.

Protected information under Part 3 of the Agvet Code

What is 'protected information'?

Protected information is defined under section 3 of the Agvet Code[10] and must have been given in response to a notice issued by the APVMA, either:

- seeking information in relation to a reconsideration decision
- in relation to a suspension or cancellation action.

What are the restrictions on using protected information?

An 8-year restriction applies where the active constituent or chemical product that is the subject of the protected information:

- is approved/registered

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[10] The Agvet Code defines protected information as:

protected information means information or results given to the APVMA as required under paragraph 32(1)(b) or 33(1)(a) or (c), or subparagraph 159(1)(d)(i), (ii) or (iii), that:

(a) have been obtained because of a trial or laboratory experiment and

(b) relate to:

(i) an active constituent that has been approved or

(ii) a chemical product that has been registered.

- is or was protected by a registered patent at the time of that approval or registration
- that patent has or will expire during the 8-year protection period.

Such active constituent or products are known as ‘protected active constituents’ and ‘protected chemical products’.

During the 8-year protected period, the rule is:

- the APVMA cannot use protected information about a ‘protected active constituent’ to determine whether to approve, or continue to approve, *another* active constituent
- the APVMA cannot use protected information about a ‘protected chemical product’ to determine whether to register, or continue to register, *another* chemical product.

When do the restrictions not apply?

The APVMA can use protected information if:

- the information is publicly available
- the protection period has expired
- it was previously given to the APVMA in such a way that it was not protected information (and it is not subject to restrictions under Part 4A of Division 2 of the Agvet Code)
- the current applicant and the primary holder agree on compensation for use of the protected information and have notified the APVMA of that agreement in writing
- an APVMA-appointed arbitrator has determined an amount of compensation which the current applicant agrees with and the current applicant has notified the APVMA and the primary holder of this
- it shows that the active constituent or chemical product in the current application may not meet the safety, trade or efficacy criteria
- the APVMA decides that it is in the public interest for the protected information to be used and the proper notice has been given.

Limitations on use of information

What information does the ‘limitations on use’ apply to?

The ‘limitations on use’ of information under Part 4A of Division 2 of the Agvet Code apply to all information given to the APVMA either:

- in connection with an application for approval of an active constituent, registration of a chemical product, or approval of a label, or for variation of the particulars or conditions of that approval or registration
- as a result of further information about an approved active constituent or registered product being provided to the APVMA in accordance with section 161 of the Agvet Code (which relates to new information which

contradicts the information entered on the Record or Register or Records of Permits or shows that the safety, trade or efficacy criteria may not be met).

It applies to such things as reports, studies, reviews, descriptions of methods of analysis, scientific argument prepared to address relevant criteria, or other scientific work intended to inform the APVMA's assessment of relevant criteria.

What does 'limitation on use' of information mean?

The 'limitation on use' of information means that the APVMA must not use the information described to assess or make a decision on another application.

Also, the APVMA must not use this information to vary particulars or conditions of approval or registration, or to reconsider an approval or registration.

When do restrictions not apply?

The 'limitations on use' of information will not apply, and the APVMA may lawfully use the information, where:

- the authorising party has given written consent
- the APVMA is satisfied that the use is in the public interest and the process specified in the Agvet Code to make this decision is followed
- the information shows that the product may not meet the safety criteria, the trade criteria or the efficacy criteria
- it is given to the APVMA in connection with an application or reconsideration and used to assess or make a decision on that application or reconsideration
- it is 'protected information' and the protection period has expired
- it is publicly available
- a limitation period applies to the information and that limitation period has ended. The limitation periods for different types of information are set out in section 34M. These periods range from 10 years (for example, if it is given in connection with an application to register a new active constituent) to 3 years (for example, if it is given in connection with an application to register a veterinary chemical product).

Other restrictions

Part 7B of the Administration Act also places specific restrictions on when and how certain information provided with applications received between 1999 and 2004 may be used by the APVMA for other applications. It applies in very limited circumstances (for example, the restriction does not apply 5 years after the original application was determined or withdrawn).

Another restriction in section 14B of the Agvet Code applies in the specific situation where information:

- was provided to the APVMA in connection with the registration of a product containing a new active constituent (first product);

- related to the safety criteria or other prescribed matter;
- was disclosed by or on behalf of the Commonwealth (including by the APVMA) or a state or territory; and
- was not publicly available before the disclosure.

The APVMA cannot use this information to register another product on the grounds that it is the same as or similar to the first product if it would be commercially unfair and the authorising party for the second product does not consent.

The restriction will apply for 10 years after the first product was registered.

Other relevant legislation

The APVMA is also subject to other legislation that affects the way certain information provided to the APVMA, or held by it, is managed. This includes restrictions under the Australian Public Service Code of Conduct and the *Privacy Act 1988* (Privacy Act). While information may be disclosed under the *Freedom of Information Act 1982* (FOI Act), certain exemptions may apply.

Restrictions on disclosure by APVMA officers

As employees of the Australian Public Service, APVMA officers are subject to rules about the disclosure of information, including information that is CCI. It is an offence under section 122.2 of the *Criminal Code Act 1995* (Cth) to communicate information that causes or is likely to cause harm to Australia's interests. As public servants, APVMA officers are also bound by the Australian Public Service Code of Conduct, under which an employee must not make improper use of inside information in order to gain, or seek to gain, a benefit or advantage.

Privacy Act

The APVMA is bound by the *Privacy Act 1988* (Cth) (Privacy Act). The Privacy Act applies to personal information, defined as:

"personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information or opinion is true or not and

(b) whether the information or opinion is recorded in a material form or not."

The Privacy Act imposes restrictions on the collection, use and disclosure of personal information. A limited amount of personal information is received by the APVMA. In these cases, APVMA complies with the Privacy Act.

Freedom of Information Act

A person may seek documents held by the APVMA by making an application under the *Freedom of Information Act 1982* (Cth) (FOI Act). When an application is made, the APVMA must release the documents the subject of the application unless an exemption under the FOI Act applies. The reasons why the person making the FOI application has sought access to the documents is not relevant.

Documents may be exempted from disclosure under Part IV of the FOI Act. Under Part IV there are general exemptions and conditional exemptions based on public interest. Examples of general exemptions are material obtained in confidence disclosure of which would found an action for breach of confidence, disclosure of trade secrets or commercially valuable information Documents may also be conditionally exempted under the FOI Act because they disclose business, commercial or financial information and release would unreasonably impact the entity. Information that is CCI may fall within one or more of these exceptions. The APVMA will follow the processes in the FOI Act to consult with the entity that provided the information, allowing that entity to make submissions before the APVMA makes a decision whether or not to release documents.

Further information

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Information about FOI

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