



Australian Pesticides &  
Veterinary Medicines Authority

**Guidance on  
Submission of Relevant Information to the  
Australian Pesticides and Veterinary  
Medicines Authority  
(under s160A and s161 of the Agvet Code)**

**Version 1**

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## **Introduction**

Section 161 of the *Agricultural and Veterinary Chemicals Code Act 1994* (the AgVet Code) requires that 'interested persons' and holders of permits submit 'relevant information' to the APVMA as soon as possible (Attachment 1).

Under the law, interested persons and permit holders need to provide information to the APVMA if information becomes available that alters or might alter the conclusions that the APVMA would have made about the product had the information been available at the time of registration or issue of permit. Such information can become available as a result of:

- new studies being conducted that show different information to that previously available
- experiences obtained as a result of manufacture, supply or use of the product, eg. adverse experience reports, residues monitoring, epidemiological studies.

Without this information, the APVMA would be unable to assess the impact the information would have on its previous considerations about the product.

Similar requirements are imposed by section 160A of the AgVet Code on provision of relevant information that might become available whilst a product or active constituent is undergoing APVMA consideration for registration or approval (Attachment 1). Notification of relevant information under s161 and s160A is mandatory and failure to notify is subject to penalties.

### **Scope**

This document has been prepared to assist applicants, approval and permit holders and registrants to comply with the requirements of s161 and s160A.

This document is a guidance and should not be considered a substitute for competent legal advice. The reader is encouraged to refer to the relevant legislation and seek legal opinion as necessary.

The focus of the document is on requirements under s161, with later guidance on s160A and guidance for permit holders.

The prime focus is on information that is not favourable to the interested person. A person may choose to submit favourable data under s161 but is more likely to submit such data under an application, for which data protection may apply.

You may find it difficult to decide whether information in your possession should be submitted to the APVMA to comply with s161 or s160A. You should contact the APVMA if you are unsure. An APVMA contact list is provided at the end of the document [Attachment 2].

### **What definitions are used in this document?**

Terms used in this document have the same meaning as terms in the AgVet Code.

### **Who is an ‘interested person’?**

The definition of ‘interested person’ from Section 3 of the AgVet Code Act 1994 is copied in Attachment 1.

### **What is ‘relevant information’?**

The definition of ‘relevant information’ from s160A and s161 of the AgVet Code is copied in Attachment 1.

Note that ‘relevant information’ is in relation to an approved active constituent or in relation to a chemical product or any of its constituents.

See Attachment 3 for examples.

### **What other legislation applies to information?**

- s38 [Suspension of approval or registration for failing to give information to APVMA] (Attachment 1)
  - if an interested person fails, without reasonable excuse, to comply with section s160A or s161
- s32(2) [APVMA may give notice of proposed reconsideration] (Attachment 1)
  - information required during a reconsideration is covered here;
  - information provided may be studies performed by registrants (or other parties) in support of registration or in response to data call-ins by the APVMA
- s34B [Limits on use of information] (Attachment 1)
  - the APVMA must not (for a certain period ) use information that an interested person for a registered chemical product gives the APVMA under s161 in connection with the product to make another decision for an active constituent or product (under s14 or s29) or a decision for a review (s34)
  - this only applies if the information given to the APVMA under s161 is in connection with a chemical product that was registered as a result of an application submitted after January 1, 2005
- s34D(4) [Exceptions on limits on use of information] (Attachment 1)
  - APVMA can use information that meets a condition in s161(2)(b) or (c) (regarding adverse effects or being ineffective) whether or not information was given under s161

### **Does data protection apply to my data submitted under s161?**

Yes, to the extent described in s34B and s34D(4). For further information, refer to the last page of *The New Data Protection Provisions and the AgVet Chemical Industry* ([http://www.apvma.gov.au/registration/data\\_protection\\_provisions.pdf](http://www.apvma.gov.au/registration/data_protection_provisions.pdf)), noting that you must ask for data protection when data is submitted.

Data protection does not apply to data submitted in respect of a permit.

## What information should I report?

Examples of information that the APVMA would expect to be reported are provided in Table 1. Specific examples are provided in Attachment 3.

**Table 1. Examples of information that the APVMA expects to be reported**

<b>Legislative basis If the information .....</b>	<b>Examples of information that the APVMA expects to be reported, would be ..... (but is not limited to these examples)</b>
contradicts any information given to the APVMA under this Code (s161(2)(a))	<ul style="list-style-type: none"> <li>• Information that would be given as part of an application including study data generated by or on behalf of your company</li> <li>• Supply of product after unplanned manufacturing errors, usually batch-limited including out-of-specifications, for which a recall is proposed</li> </ul>
shows that the use of, or any other dealing with, the constituent or the chemical product in accordance with the instructions for its use or for such a dealing that the APVMA has approved may be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues ((s161(2)(b))	<ul style="list-style-type: none"> <li>• Australian adverse experience reports</li> <li>• Residues monitoring data (excess residues) where trace back indicates use according to instructions approved by the APVMA eg. on label or in permit</li> <li>• Field or experimental occupational health and safety or residues study data generated by or on behalf of your company (adverse OH&amp;S data or excess residues) when used according to instructions approved by the APVMA eg. on label or in permit</li> <li>• Supply of product after unplanned manufacturing errors, usually batch-limited including out-of-specifications, for which a recall is proposed</li> </ul>
shows that the use of, or any other dealing with, the constituent or the chemical product in accordance with the instructions for its use or for such a dealing that the APVMA has approved: may be likely to have an effect that is harmful to human beings (s161(2)(b))	<ul style="list-style-type: none"> <li>• Australian adverse experience reports</li> <li>• Field or experimental toxicology study data generated by or on behalf of your company (new or more severe toxicological responses; epidemiological or exposure studies of human population groups; information on metabolites, degradates, contaminants or impurities that may be of toxicological concern)</li> <li>• Supply of product after unplanned manufacturing errors, usually batch-limited including out-of-specifications, for which a recall is proposed</li> </ul>
shows that the use of, or any other dealing with, the constituent or the chemical product in accordance with the instructions for its use or for such a dealing that the APVMA has approved may be likely to have an unintended effect that is harmful to animals, plants or things or to the environment	<ul style="list-style-type: none"> <li>• Australian adverse experience reports</li> <li>• Environmental monitoring reports generated by or on behalf of your company (excess residues in surface, ground or drinking water)</li> <li>• Field or experimental crop safety, animal safety or environmental study data generated by or on behalf of your company (toxic or adverse effects to non-target organisms) when used according to instructions approved by the APVMA eg. on label or in permit</li> <li>• Supply of product after unplanned manufacturing errors,</li> </ul>

(s161(2)(b))	usually batch-limited including out-of-specifications, for which a recall is proposed
shows that the use of the product in accordance with the instructions for its use that the APVMA has approved may be ineffective according to criteria determined by the APVMA for the product (s161(2)(c))	<ul style="list-style-type: none"> <li>• Australian adverse experience reports</li> <li>• Field or experimental efficacy study data generated by or on behalf of your company (showing lack of efficacy) when used according to label instructions</li> <li>• Supply of product after unplanned manufacturing errors, usually batch-limited including out-of-specifications, for which a recall is proposed</li> </ul>
would have had to be given to the APVMA in connection with the application for the approval, registration, listed registration or permit if the applicant had been aware of the information when the application was made. (s161(2)(d))	<ul style="list-style-type: none"> <li>• Any required information listed in the Manual of Requirements and Guidelines including study data generated by or on behalf of your company or information that has led to a change in the registration status of the product as a result of regulatory action by other regulators</li> </ul>

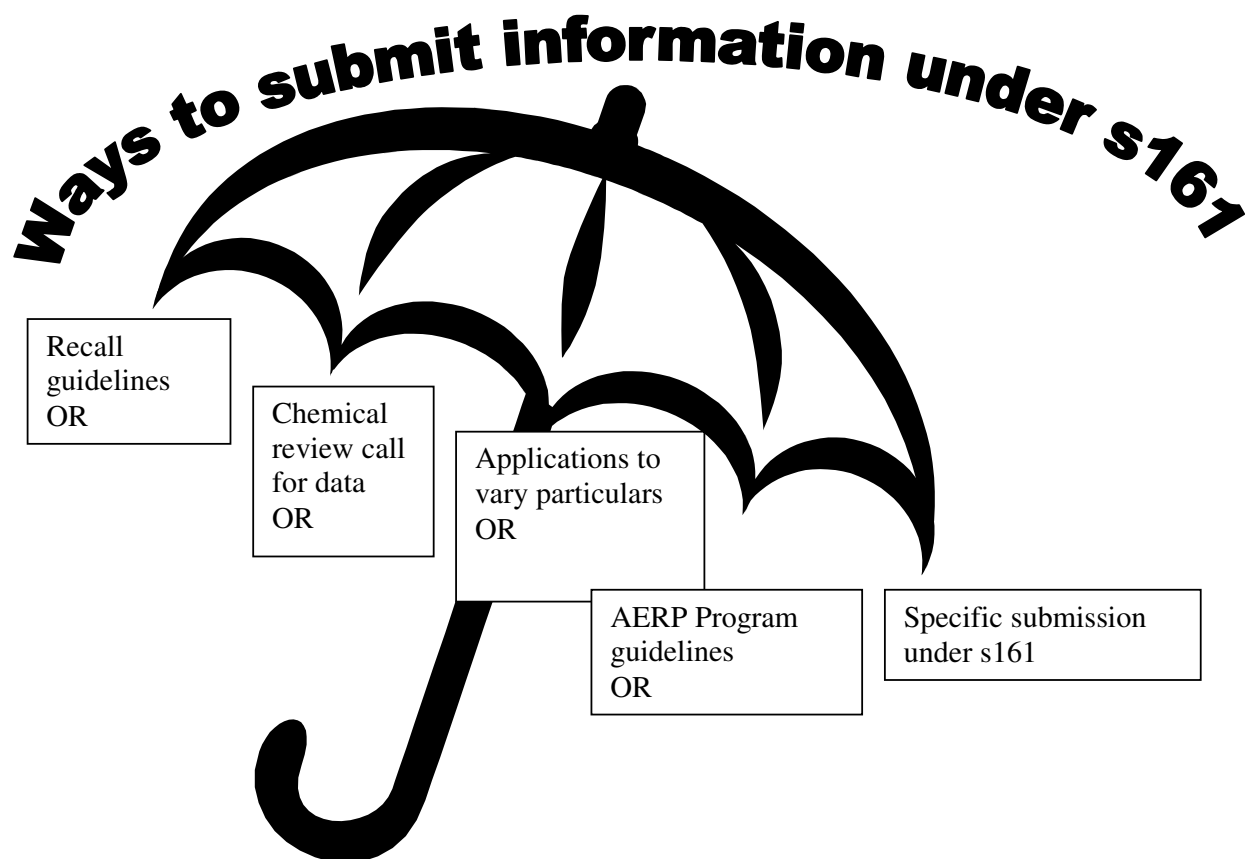
**Are there types of information that the APVMA does not expect me to submit under s161?**

- information in the public domain that would reasonably be expected to be available to the APVMA (such as, but not limited to, information that is accessible in the published scientific literature or through the world wide web)
- information when a product is not used according to instructions approved by the APVMA eg. on label or in permit
- information about suspected breaches of control-of-use legislation
- information about unregistered products, excluding products supplied or used under APVMA permit
- information previously submitted to the APVMA
- media articles
- product complaints other than Australian adverse experience reports
- market basket surveys
- in-house market research
- accidents in transport and storage of chemical products or at manufacturing sites
- scientific study data published by organisations other than your company or not on your behalf and that are in the public domain

**Are there types of information expected to be submitted under section 161 but can be submitted to the APVMA by other mechanisms?**

Your obligations to submit relevant information can be met by different ways, depending on the nature of the information. The APVMA considers a range of information is covered by the phrase “relevant information” under the statutory scope of s161. Figure 1 shows a range of mechanisms by which relevant information can be submitted. The APVMA considers that a person submitting information under these mechanisms would be in compliance with s161.

Figure 1 The range of mechanisms by which “relevant information” can be submitted to the APVMA



Registrants or permit holders can submit some types of “relevant information” in a variety of ways to the APVMA and still comply with s161. The APVMA does not expect such information to **also** be submitted using a specific s161 form. Such types of information include that:

- submitted through the APVMA Adverse Experience Reporting Program
- submitted in an APVMA application for approval of planned variations to registered products, approved actives or approved labels (only if such information is submitted in an APVMA application for approval)
- called-in under the APVMA Chemical Review Program for the purposes of addressing identified deficiencies in data available to the APVMA, and generated for that purpose during the time of review
- on supply of product after unplanned manufacturing errors, submitted under a Notification of a Potential or Actual Recall of an Agricultural or Veterinary Chemical Product See *Guidelines for Recall of Agricultural & Veterinary Chemicals* ([http://www.apvma.gov.au/qa/recall\\_guidelines1.shtml](http://www.apvma.gov.au/qa/recall_guidelines1.shtml))

Any relevant information that is inappropriate to be submitted under one of these 4 mechanisms can be submitted using the attached form (Attachment 4)

## **How do I report information?**

If you plan to submit under s161, the attached form (Attachment 4) or a letter clearly identifying the submission as a submission under s161 could be used. Irrespective of whether a form is used or not, it is in your best interest to clearly identify information that is being submitted under s161.

There are also alternative mechanisms for submitting certain types of s161 information – via -

- the APVMA Adverse Experience Reporting Program. Adverse experience reporting is addressed in APVMA AERP Guidelines produced from time to time ([http://www.apvma.gov.au/qa/aerp\\_ag\\_vet.shtml](http://www.apvma.gov.au/qa/aerp_ag_vet.shtml)).
- an APVMA application for approval of planned variations to registered products, approved actives or approved labels (only if such information is submitted in an APVMA application for approval). Submission of an application for approval of planned variations is addressed in Manual of Requirements and Guidelines revised from time to time (MORAG; <http://www.apvma.gov.au>)
- information called-in under the APVMA Chemical Review Program for the purposes of addressing identified deficiencies in data available to the APVMA, and generated for that purpose during the time of review. Submission of Chemical Review information is addressed in APVMA web information on Chemical Reviews [*exact reference under consideration*](<http://www.apvma.gov.au/chemrev/chemrev2.shtml>)
- information, on supply of product after unplanned manufacturing errors for which a recall is proposed. Submission of such information is addressed in *Guidelines for Recall of Agricultural & Veterinary Chemicals* ([http://www.apvma.gov.au/qa/recall\\_guidelines1.shtml](http://www.apvma.gov.au/qa/recall_guidelines1.shtml))

There is no prescribed format for the information contained in your submission but scientific information could be formatted as per the Manual of Requirements and Guidelines, including a data-list in the format of Data Protection data-lists.

## **When do I need to report?**

- information submitted through the APVMA Adverse Experience Reporting Program: Follow the timelines recommended in the guidelines for reporting of adverse experiences (see [http://www.apvma.gov.au/qa/aerp\\_ag\\_vet.shtml](http://www.apvma.gov.au/qa/aerp_ag_vet.shtml))
- information submitted in an APVMA application for approval of planned variations to registered products, approved actives or approved labels: Follow application procedures
- information called-in under the APVMA Chemical Review Program for the purposes of addressing identified deficiencies in data available to the APVMA, and generated for that purpose during the time of review: Follow Chemical Review procedures
- information, on supply of product after unplanned manufacturing errors, submitted under a Notification of a Potential or Actual Recall of an Agricultural

or Veterinary Chemical Product: See *Guidelines for Recall of Agricultural & Veterinary Chemicals* ([http://www.apvma.gov.au/qa/recall\\_guidelines1.shtml](http://www.apvma.gov.au/qa/recall_guidelines1.shtml)). Follow Notification procedures. In the first instance, notify the APVMA within 24 hours of knowing about supply of product after unplanned manufacturing errors.

Apart from the above, the APVMA expects that information submitted under s161 should be reported within 30 calendar days of the interested person first becoming aware of the information.

**Is complete information required or is a summary sufficient?**

The APVMA would expect submission of complete information, not simply study summaries. However, early submission of incomplete information may be necessary if it is to be followed by submission of complete information, when available.

**Section 161 describes information that shows that the use of a product may be a hazard, or words to that effect. Who determines whether use may be a hazard?**

In order to submit information under s161 you do not have to prove that such information shows that the use of a product may be a hazard (or words to that effect). Whilst you may choose to assess whether a piece of information is relevant, the APVMA will also assess whether information shows that use of a product ‘may’ be a hazard. Examples of relevant information are provided in Table 1.

**Who in my company submits information to the APVMA?**

The ‘interested person’ would need to be identified in your company and would be responsible for submitting information to the APVMA.

**Do I need to submit task force data?**

Taskforces may be set up to generate data, using pooled resources. Interested persons involved in taskforces need to determine their legal obligations to comply with s161.

**Do I need to perform studies in order to comply with the legislation?**

Section 161 does not impose a requirement to perform studies but merely to identify and submit relevant information to the APVMA as soon as practicable.

**Do I need to certify or validate information before submission to the APVMA?**

Information does not need to be certified as being validated before submission to the APVMA. Particularly in the area of adverse experience reports, the APVMA accepts that reports may prove not to be valid. Registrants are not obligated to investigate, analyse or verify incidents before reporting them to the APVMA. However you can provide comments at the time of submission of information and the APVMA may seek your comments after you submit the information.

**Do fees apply to submission of s161 information?**

Relevant fees would only apply to a variation application that may include the submission of data. No fees apply to information submitted for chemical review, adverse experiences, recall notification or formally under s161.

**What will happen to my submitted information?**

In response to your submission, you should expect a letter, sent to you acknowledging receipt of your submission and information related to data protection [*under development*]. The APVMA will consider the data and determine whether further evaluation is required. In certain instances there may be follow up correspondence.

### **Submission of s160A data**

s160A of the AgVet Code describes the requirement for an ‘appropriate person’ to submit ‘relevant information’ to the APVMA (see Attachment 1). Notification of relevant information under s160A is mandatory and failure to notify is subject to penalties.

In general, the guidance for submission of information under s161 is relevant to s160A, and can be followed for submission of s160A information.

However the following applies specifically to s160A information:

- a) Submission of information under s160A is in respect of a pending application before the APVMA has determined the application;
- b) s160A applies if the application is for listed registration or a licence in respect of the manufacture of a chemical product (in addition to approval of an active constituent, registration of a chemical product or issue of a permit)
- c) when submitting information under s160A, please quote the relevant application number in your submission and clearly state that the information is being submitted under s 160A. You would have to observe data protection requirements
- d) as is current practice, s160A data submitted after application screening will be considered as a separate application.

### **Submission of data related to permits**

While the guidance provided in this document is also relevant to permits, there are some specific permit-related issues.

s161 of the Agvet Codes describes the requirement for a holder of a permit to give relevant information to the APVMA as soon as practicable after the person becomes aware of the information. This requirement is similar to that of an ‘interested person’ referred to in other sections of this guidance.

The prime focus is on information that is not favourable to the permit holder and that may show that continued supply and use of the product under the permit may have harmful or unintended effects. Often, permits are issued to allow research trials to be conducted with the purpose of generating data for future applications to register a product or a new use – in such cases, the permit holder would not need to submit the generated data unless the information showed that the supply and use of the product may have harmful or unintended effects during the term of the permit. However, if the use pattern described in the permit was later the subject of a registration application, or if the permit use pattern had relevance to an existing registered use pattern, then any relevant negative information discovered as a consequence of the permit would need to be submitted at the appropriate time. If you are in doubt, please discuss with the APVMA.

## Attachment 1

### The relevant AgVet Chemicals Code legislation (as per defined date of legislation)

#### 160A Notification of new information to APVMA in respect of pending application

- (1) This section applies if:
  - (a) an application has been lodged with the APVMA for:
    - (i) approval of an active constituent for a proposed or existing chemical product; or
    - (ii) registration of a chemical product; or
    - (iii) listed registration of a chemical product; or
    - (iv) a permit in respect of such an active constituent or in respect of a chemical product; or
    - (v) a licence in respect of the manufacture of a chemical product; and
  - (b) the APVMA has not determined the application; and
  - (c) an appropriate person becomes aware of any relevant information in relation to the constituent, or in relation to the product or any of its constituents.
- (2) The appropriate person must, as soon as practicable after the person becomes aware of the information, give the information to the APVMA.

Penalty: 300 penalty units.
- (3) A person is an *appropriate person* in relation to an application referred to in paragraph (1)(a) if:
  - (a) in the case of an application referred to in subparagraph (1)(a)(i), (ii) or (iii)—the person would be an interested person in relation to the constituent or product if the application were granted; or
  - (b) in any other case—the person who made the application.
- (4) Information is *relevant information* if it:
  - (a) contradicts any information given to the APVMA under this Code; or
  - (b) shows that the use of, or any other dealing with, the constituent or chemical product in accordance with the proposed instructions for its use or for such a dealing contained in the application, or shows that the use of, or any other dealing with, the chemical product in accordance with the instructions for its use or for such a dealing contained in an established standard:
    - (i) may be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; or
    - (ii) may be likely to have an effect that is harmful to human beings; or

- (iii) may be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; or
  - (c) shows that the use of the chemical product in accordance with the proposed instructions for its use contained in the application, or in accordance with the instructions for its use contained in an established standard, may be ineffective according to criteria determined by the APVMA for the product; or
  - (d) would have had to be given to the APVMA in connection with the application if the applicant had been aware of the information when the application was made.
- (5) A corporation is taken to be aware of any information if a related corporation is aware of that information.
- (6) The question whether 2 corporations are related to each other is to be determined in the same way as that question would be determined under the *Corporations Act 2001*.
- (7) Any information that a person has to give to the APVMA under this section must be given in writing signed by an approved person.

#### **161 Notification of new information to APVMA**

- (1) If:
- (a) the interested person in relation to an approved active constituent for a proposed or existing chemical product or in relation to a registered chemical product or a registered listed chemical product; or
  - (b) the holder of a permit in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product;

becomes aware of any relevant information in relation to the constituent or in relation to the product or of any of its constituents, the person must, as soon as practicable after the person becomes aware of the information, give that information to the APVMA.

Penalty: 300 penalty units.

- (2) Information is relevant information if it:
- (a) contradicts any information given to the APVMA under this Code; or
  - (b) shows that the use of, or any other dealing with, the constituent or the chemical product in accordance with the instructions for its use or for such a dealing that the APVMA has approved:
    - (i) may be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; or
    - (ii) may be likely to have an effect that is harmful to human beings; or

- (iii) may be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; or
  - (c) shows that the use of the product in accordance with the instructions for its use that the APVMA has approved may be ineffective according to criteria determined by the APVMA for the product; or
  - (d) would have had to be given to the APVMA in connection with the application for the approval, registration, listed registration or permit if the applicant had been aware of the information when the application was made.
- (2A) A corporation is taken to be aware of any information if a related corporation is aware of that information.
- (2B) The question whether 2 corporations are related to each other is to be determined in the same way as that question would be determined under the *Corporations Act 2001*.
- (3) Any information that a person has to give to the APVMA under this section must be given in writing signed by an approved person.

### Section 3

***interested person***, in relation to an approved active constituent for a chemical product, a registered chemical product, a registered listed chemical product or an approved label for containers for a chemical product, means:

- (a) subject to paragraphs (b), (c) and (d), the person (the ***original applicant***) who applied for the approval, registration or listed registration or, in the case of a chemical product whose registration or listed registration has been renewed, applied for the renewal, or the last renewal, as the case may be; or
- (b) subject to paragraphs (c) and (d), if:
  - (i) the original applicant has entered into a contract with another person in relation to the constituent or product under which, or as a result of which, the other person will or may apply to the APVMA to have the other person's name entered in the relevant particulars in relation to the constituent or product, or to have a label approved in relation to containers for the product; and
  - (ii) the other person's name is entered in those relevant particulars, or such a label is approved, on the application of the other person;
 the other person; or
- (c) if the person who, apart from this paragraph, would be the interested person because of paragraph (a) or (b) was an individual who has died or is an individual whose affairs are being lawfully administered by another person—the legal personal representative of the individual or the person administering the individual's affairs, as the case may be; or
- (d) if the person who, apart from this paragraph, would be the interested person because of paragraph (a) or (b) was a body corporate—a successor in law of the body corporate.

**s38 Suspension of approval or registration for failing to give information, report or sample to APVMA**

- (1) If the interested person in relation to an approved active constituent for a proposed or existing chemical product, or in relation to a chemical product, or an approved person fails, without reasonable excuse, to comply with a requirement contained in a notice under section 159 or with section 160A or 161, the APVMA may suspend the approval or registration.
- (2) Subject to subsection (3), the APVMA must revoke a suspension imposed under subsection (1) if it is satisfied that the relevant information, report or sample has been given to it.
- (3) If the information, report or sample is not given to the APVMA within a reasonable period after the suspension takes place, the APVMA may cancel the approval or registration.

s32(2) APVMA may give notice of proposed reconsideration

- (2) The APVMA must give written notice to the interested person in relation to the constituent, product or label or an approved person:
  - (a) telling the person the matter or matters that it proposes to reconsider and its reasons for so proposing; and
  - (b) requiring the person, within a period stated in the notice that ends not earlier than 28 days after the day on which the notice is given, to give to the APVMA:
    - (i) any information of a kind stated in the notice of which either the interested person or the approved person is aware and which is relevant to the reconsideration; or
    - (ii) any information of which either the interested person or the approved person is aware that is relevant to the reconsideration; and
  - (c) inviting the person, within that period, to make a written submission to the APVMA about the matter or matters referred to in paragraph (a).
- (3) A person must comply with a requirement made of the person under paragraph (2)(b).

Penalty: 120 penalty units.

- (3A) An offence under subsection (3) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

- (4) Subsection (3) does not apply if, before the end of the period stated in the notice, the interested person or an approved person requests the APVMA under section 42 to cancel the approval of the constituent, the registration of the product or the approval of the label, as the case may be, and the APVMA complies with the request.

s34B Limits on use of information  
Division 4A—Limits on use of information

**Subdivision A—Preliminary**

**34B Explanation of Division**

- (1) This Division limits for a period the use the APVMA can make of information given to it:
  - (a) in connection with an application under section 10 or 27 relating to:
    - (i) approval of an active constituent for a chemical product; or
    - (ii) registration of a chemical product; or
    - (iii) approval of a label for a container for a chemical product; or
  - (b) under section 161 in connection with a registered chemical product.
- (2) During the period, the APVMA cannot use the information for granting another application, or for a reconsideration of an approval or registration, unless:
  - (a) the APVMA is given a written statement made by a person who can authorise the use of the information consenting to the use; or
  - (b) certain other conditions are met.
- (3) The object of limiting use of the information in this way is to encourage innovation by making it easier for a person who made an investment in finding out the information to get a return on that investment.

**Subdivision B—Limits on use of information**

**34C APVMA must not use some information during some periods for some purposes**

- (1) During the period described in an item of the table, the APVMA must not use information described in the item for a purpose described in the item.

<b>Limits on use of information</b>			
	<b>The APVMA must not use this information:</b>	<b>During this period:</b>	<b>For this purpose:</b>
1	Information that the applicant or an approved person gives the APVMA: (a) in connection with an application under section 10 or 27; and (b) before the APVMA makes a preliminary assessment under section 11A or 28A of the application	The period: (a) starting when the information is given; and (b) ending when the APVMA makes the preliminary assessment	Making a decision under section 14, 29 or 34 (except a decision on the application)
2	Information that the applicant or an approved person gives the APVMA: (a) in connection with an application under section 10 or 27; and (b) as required by the APVMA or section 160A	The period: (a) starting when the APVMA makes a preliminary assessment under section 11A or 28A of the application; and (b) ending when the APVMA treats the application as having been withdrawn or grants or refuses the application	Making a decision under section 14, 29 or 34 (except a decision on the application)
3	Information that: (a) was given to the APVMA by the applicant or an approved person in connection with an application under section 10 or 27; and (b) was given as required by the APVMA or section 160A; and (c) was relied on by the APVMA to grant the application	The relevant period described in section 34F	Making a decision under section 14, 29 or 34
4	Information that the interested person for a registered chemical product gives the APVMA under section 161 in connection with the product	The period: (a) starting when the person gives the APVMA the information; and (b) ending 5 years later if the product is an agricultural chemical product or 3 years later if the product is a veterinary chemical product	Making a decision under section 14, 29 or 34

*Note 1: Section 34D sets out exceptions to this subsection.*

*Note 2: Section 161 may require an interested person for an approved active constituent to give the APVMA information in connection with the constituent, even though this table does not deal with that requirement.*

- (2) This section applies only to information given to the APVMA:
  - (a) in connection with an application made after the commencement of this section; or
  - (b) under section 161 in connection with a chemical product that was registered as a result of an application made after the commencement of this section.
- (3) The use of information in contravention of subsection (1) for making a decision does not affect the validity of the decision.
- (4) An action or proceeding does not lie against any of the following for any loss directly or indirectly sustained because of the use of information in contravention of subsection (1):
  - (a) the Commonwealth;
  - (b) the APVMA;
  - (c) a person who is or has been:
    - (i) a director of the APVMA; or
    - (ii) the Chief Executive Officer of the APVMA; or
    - (iii) a delegate of the APVMA; or
    - (iii) a member of the staff of the APVMA.

s34D(4) Exceptions on limits on use of information

### **Subdivision C—Exceptions to limits on use of information**

#### **34D Exceptions**

- (1) Section 34C does not prevent the APVMA from using information for making a decision:
  - (a) under section 14 or 29 about an application; or
  - (b) under section 34 about a reconsideration of an approval or registration;if a condition in subsection (2), (3), (4), (5) or (6) of this section is met.

#### *Evidence of consent for use*

- (2) One condition is that the applicant, an approved person or the interested person for the approval or registration gives the APVMA a written statement by the authorising party of that party's consent to the APVMA using the information for making the decision. This condition is met even if the authorising party:
  - (a) later states that it has not consented; or

(b) withdraws the consent (whether before or after the APVMA is given the statement of consent).

*Note: Chapter 7 of the Criminal Code creates offences relating to false and misleading statements and forgery.*

*Use in the public interest*

(3) Another condition is that the APVMA is satisfied, having regard to the criteria (if any) prescribed by the regulations, that the use of the information is in the public interest.

*Note: Section 34E sets out other rules that are relevant to the exception based on this condition.*

*Information does not favour the applicant or interested person*

(4) Another condition is that:

(a) the decision relates to:

- (i) a proposed or existing approval of an active constituent for a proposed or existing chemical product; or
- (ii) a proposed or existing registration of a proposed or existing chemical product; and

(b) the information meets a condition in paragraph 160A(4)(b) or (c) or 161(2)(b) or (c) (which are about showing that use or dealing with the product may have adverse effects or that the product may be ineffective), whether or not the information was given to the APVMA under section 160A or 161.

## **Attachment 2 APVMA Contact list for enquiries regarding s161 and s160A information**

A current contact list is provided at [http://www.apvma.gov.au/about\\_us/contact.shtml](http://www.apvma.gov.au/about_us/contact.shtml).

## **Attachment 3 Examples**

**Recall** - Your company realises that it has made a formulation error in a batch of product that has been supplied to the marketplace and propose to conduct a recall. They submit a recall form to the APVMA who then closely monitors their recall performance. The formulation error is considered 'relevant information'. Considering the company has submitted the information as part of the voluntary recall, there is no need for your company to submit that information again to the APVMA under s161.

**Manufacturing error** – The Quality Control officer in your company identifies, before supply to the marketplace, that the wrong label has been attached to a batch of product. No product from that batch has been supplied to the marketplace, and the batch is re-labelled with correct labels. There is no need for your company to submit information about that corrected error to the APVMA.

**Accident in transport** – Your company receives field information that a dangerous goods vehicle transporting their product has been involved in a highway accident. Whilst reporting to State authorities may be necessary, your company does not need to report this incident to the APVMA.

**Storage incident** – Your company receives field information that a substantial number of product containers are cracking or leaking despite product being stored appropriately and according to label directions. Information on this incident is considered 'relevant information' and must be submitted. Your company may choose to submit that information to the APVMA according to APVMA recall guidelines - if submitted, the information does not need to be submitted again under s161.

However the APVMA would not expect you to submit information on occasional reports of leaking containers.

**Adverse experience** - Your company receives a complaint that a person has had a severe skin reaction after using a registered product. You enter the complaint into your company's complaint register and submits an AERP report to the APVMA. This report is relevant information. Considering the information has been submitted as part of the AERP, there is no need for you to submit that information again to the APVMA under s161.

**Study data for a chemical under review** – The APVMA, undertaking a review of a chemical, identifies that there is insufficient residues data. The APVMA calls for further residues data for assessment, and your company generates data and submits it to the Chemical Review Program. This information is relevant information, has been submitted to the Chemical Review Program and does not need to be submitted again to the APVMA under s161.

**Study data** - Your company, in conducting further toxicological research on its active constituent, finds the study demonstrates that the active may be a carcinogen – previously information submitted to the APVMA did not raise such concerns. The active is not under a formal re-consideration. The study data is relevant information. The company informs the APVMA under a s161 submission.

**Change in formulator** - Your company expects to change the formulator of a product from a site in Australia to a site in China. This change in formulator is a variation to the registration particulars and requires a variation application to the APVMA to be considered before the change is made. This information is relevant information. Your company submits a variation application to change the product formulator, so there is no need for you to submit that information again as a s161 submission.

## Attachment 4 Form that can be used to submit s161 information

Information to include:

Name and address of appropriate or interested person and company

If s161: relevant APVMA product number

If s160A: APVMA application number

Summary of relevant information:

If relevant, a request for data protection:

Applicant's List of Submitted Data (see  
[http://www.apvma.gov.au/registration/data\\_protection.shtml](http://www.apvma.gov.au/registration/data_protection.shtml))

Signature by an approved person

Attached: full information sets  
(if not available – why and when available)

Note: Refer to *Guidance on submission of relevant information to the Australian Pesticides and Veterinary Medicines Authority (s160A and s161)*