Australian Government
Australian Pesticides and
Veterinary Medicines Authority

Requesting information from applicants

6A Guideline

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6A Guideline: Requesting information from applicants

1. What is this guideline about?

1. This guideline is made pursuant to section 6A of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (Agvet Code). It provides guidance in relation to the following matters under subsection 6A(3):
   a) 6(3)(b)(i) the approval of active constituents for proposed or existing chemical products; and
   b) 6(3)(b)(ii) the registration of chemical products; and
   c) 6(3)(b)(iii) the approval of labels for containers for chemical products; and
   d) 6(3)(b)(iv) the variation of relevant particulars and conditions; and
   e) 6(3)(b)(v) the issue of permits and licences.
2. The purpose of this guideline is to set out the principles and processes APVMA decision-makers must have regard to when exercising any of the powers or functions provided for in this guideline.
3. If, when considering the circumstances of the decision to be made, a decision-maker feels it is appropriate to depart from the principles or process in this guideline, they should carefully explain their reasons and document their decision for that departure.
4. All decision makers must ensure the function or power they are intending to exercise is one delegated to them prior to exercising it.
5. If unsure seek assistance from your manager or the Legal Team.
6. This guideline commenced on 8 June 2023.

2. Introduction

7. APVMA staff may request information as part of their ordinary dealings with applicants and registrants.
8. The Agvet Code requires holders and applicants to provide certain information as part of their application within specified timeframes, but also restricts what information can be considered by the APVMA.
9. Under the Agvet Code, there are 3 main provisions that can be used by staff to request information from applicants during the assessment of an application:
   a) Preliminary Assessment Defect notice (ss 11(3), 28(3), 110A(3))
   b) Updating or clarifying information (under section 8C(a)(iii) and regulation 8AHAA taken together)
   c) Notice of requirement of additional information, report or sample (s 159).
10. There is no limit to the number of requests for information under regulation 8AHAA and section 159.
11. Written submissions invited in response to a notice of proposed refusal under section 8S of the Agvet Code are not included in this guideline, as the application has been determined at this time and the

decision-maker has come to a decision. Section 8S is included in the 6A Guideline *Approvals and registrations*.

3. Guidelines

Section 11(3) – Defects that can be reasonably rectified at preliminary assessment for applications for approval and registration

Explanation: After completing a preliminary assessment, if it appears to the APVMA that the application does not meet the application requirements but that the defects in the application can be reasonably rectified, the APVMA must give written notice to the applicant within 14 days requiring the defects to be rectified within one month.

12. In determining whether the defect/s can be reasonably rectified, the matters that the APVMA may consider include:

    a) The severity or complexity of the defect/s requiring rectification.

        i. Note: Examples may include a datalist without adequate descriptions, a missing document referred to in the Application Form, details that do not match APVMA records or an incorrect declaration.

    b) If the defect/s can be rectified within one month.

        i. Note: Section 11(3)(c) provides a statutory limit of one month within which the defects can be rectified.

    c) The number of defects requiring rectification.

        i. Note: If there are many or complex defects that are not likely to be rectifiable within the one-month statutory timeframe permitted under section 11(3)(c), the decision should be refused under section 11(3A).

Section 28(3) – Defects that can be reasonably rectified at preliminary assessment for applications for varying relevant particulars and conditions

Explanation: After completing a preliminary assessment, if it appears to the APVMA that the application does not meet the application requirements but that the defects in the application can be reasonably rectified, the APVMA must give written notice to the applicant within 14 days requiring the defects to be rectified within one month.

13. For the purposes of section 28(3) of the Agvet Code, when the APVMA is determining whether a defect can reasonably be rectified the matters that may be considered include:

    a) The severity or complexity of the defect/s requiring rectification.

        i. Note: Examples of rectifiable defects may include, a datalist without adequate descriptions, or a missing document referred to in the Application Form or details that do not match APVMA records.

b) Whether the defect/s can be rectified within one month.

   i. Note: Section 28(3)(c) provides a statutory limit of one month within which the defect can be rectified.

c) The number of defects requiring rectification.

   i. Note: If there are many or complex defects that are not likely to be rectifiable within the one-month statutory timeframe permitted under section 28(3)(c), the decision should be refused under section 28(3A).

Section 110A(3) – Defects that can be reasonably rectified at preliminary assessment for permit applications

Explanation: After completing a preliminary assessment, if it appears to the APVMA that the application does not meet the application requirements but that the defects in the application can be reasonably rectified, the APVMA must give written notice to the applicant within 14 days requiring the defects to be rectified within one month.

14. For the purposes of section 110A(3) of the Agvet Code, when the APVMA is determining whether a defect can reasonably be rectified the matters that may be considered include:

    a) The severity or complexity of the defect/s requiring rectification.

       i. Note: Examples of rectifiable defects may include, non-payment of application fees due to ineligibility under Regulation 70(8) of the Agvet Code Regulations, or missing details on the Application Form, or a missing document referred to in the Application Form, or details that do not match APVMA records.

    b) Whether the defect/s can be rectified within one month.

       i. Note: Section 110A(3)(c) provides a statutory limit of one month within which the defect can be rectified.

    c) The number of defects requiring rectification.

       i. Note: If there are many or complex defects that are not likely to be rectifiable within the one-month statutory timeframe permitted under section 110A(3)(c), the decision should be refused under section 110(4).

Regulation 8AHAA – Requesting information that clarifies or updates information in or accompanying the application, or information given under sections 157, 159 or 160A

Explanation: In determining an application, the APVMA may request information that clarifies or updates information in or accompanying the application, or information given under sections 157, 159 or 160A. The delegation to request updating and clarifying information is exercisable under Section 8C(1)(iii) of the Agvet Code.

15. In determining whether to request updating or clarifying information, the matters that the APVMA may consider include:

    a) If the information in (or accompanying) the application is incomplete, unclear or ambiguous.

        i. Note: For example you may request a new copy of an illegible figure, clarification of ambiguous text in a document, or proposed text for a label that requires greater consistency with the relevant labelling code.

    b) If information provided in (or accompanying) the application requires updating or clarification.

        i. Note: For example, this may include a reference to a study that was still in progress at the time the application was submitted to the APVMA. Updated information may be requested about the final outcome or results of the study referred to. However, if the information required is extensive, such as a literature review or results from a trial or experiment required to be conducted, then it may be that a notice under section 159 is more appropriate.

        ii. Note: An updated GMP certificate to replace one that has expired may also be requested under r 8AHAA provided the information does not need to be assessed again.

    c) Whether the information is likely to be provided within 14 days.

        i. Note: Regulation 8AHAA(2) provides a statutory limit of 14 days within which the information can be provided. Before requesting information, to ensure the applicant is afforded procedural fairness, you should ensure that the applicant can be given the statutory 14 days under regulation 8AHAA to provide the clarifying or updating information.

    d) Whether the APVMA will be able to assess or evaluate the information that is provided within the remaining statutory timeframe for the application.

        i. Note: The APVMA is not required to request updating or clarifying information under regulation 8AHAA, and should only do so where this is an effective and efficient way to get the information required to make a decision on an application. However, if the information is likely to be extensive, and the APVMA is likely to require additional time to assess it, it may be more appropriate to require the information by section 159 notice. A section 159 notice will extend the statutory timeframe for determining the application (provided a s159 notice has not already been issued).

Section 159 – Requirement of additional information, report or sample in certain circumstances

Explanation: The APVMA or another authority may require additional information, reports or samples, for the purposes of determining an application or deciding whether to suspend or cancel an approval, registration or permit. Section 8C of the Agvet Code specifies information to be taken into account in determining applications.

16. In determining whether to request additional information, reports or samples, the matters that the APVMA may consider include:

    a) If there is missing information in (or accompanying) the application that is required to determine the application.

        i. Note: Examples may include:

            - Additional studies if an application is lodged that refers to studies, but not all of those studies are provided.
            - Additional information if information is provided for some but not all of the proposed uses.
            - Additional information if specific information is required to assess the application however has not been provided, appears missing, or cannot be found.

    b) If there is unusable or non-compliant information in (or accompanying) the application and a new version of the information is required.

        i. Note: Examples may include:

            - A product specification with missing details.
            - A Certificate of Analysis or batch analysis for an active constituent that is not current or does not comply with the pharmacopeia or APVMA Standard, or approved composition and purity.

    c) Whether the information can be requested under regulation 8AHAA (see above).

        i. Note: For the purposes of subsection 8C(2A) of the Code, regulation 8AHAA is information that clarifies or updates existing information in or accompanying the application. Regulation 8AHAA(2) provides a statutory limit of 14 days within which the information can be provided. A request under regulation 8AHAA does not result in an extension to the timeframe for assessing the application.

    d) If the deficiency or deficiencies in the application can be rectified within the timeframe for assessing the application, as extended in accordance with Regulation 76A of the Agvet Code Regulations.

        i. Note: Regulation 76A(2) provides for an extended assessment period for an application of a kind mentioned in an item of the table in clause 2.1 of Schedule 6 of the Agvet Code Regulations, if the APVMA gives notice to the applicant under section 159 of the Code in relation to the application.

        ii. Note: If the deficiencies are not likely to be rectifiable within the statutory timeframe permitted under regulation 76A, the application can be refused under sections 14(2), 29(2) or 112(3) of the Agvet Code, noting that under section 8S of the Agvet Code the APVMA must give the applicant

written notice of what it proposes to do before it refuses an application other than on preliminary assessment, and invite written submissions from the applicant within 28 days.

e) Whether the requirement would result in the applicant needing to undertake substantial work or new work to comply.

   i. Note: The APVMA would generally not issue an s 159 notice if it would require an applicant to conduct a new study or analysis and provide the results, or if new substantial work needed to be undertaken, as this is unlikely to be possible within the statutory timeframe.

f) Whether it is more efficient to require additional information from the applicant than to propose to refuse the application under section 8S of the Agvet Code, and potentially have the applicant resubmit the application.

   i. Note: Examples of when it may be more efficient to require additional information include:

      - When the deficiency or deficiencies in the application are reasonably rectifiable.
      - When it is likely the applicant already knows or holds the required information or can source it.
      - When it is likely the applicant can give to the APVMA the required information, including the nature of and quantity of information.
      - When it is likely that the applicant would be able to comply with the requirements within the maximum timeframe that can be set for the applicant to respond in accordance with Regulation 65A of the Agvet Code Regulations.
      - When a significant amount of work has been completed by the APVMA that would need to be re-done if the application were resubmitted.
      - When the APVMA would have sufficient time to consider the applicant's response and assess the application within the statutory timeframe as extended in accordance with regulation 76A.

g) Whether the response to the first requirement could potentially result in a second requirement for additional information.

   i. Note: Although more than one s 159 notice can be issued for a single application, regulation 76A(3) of the Agvet Code Regulations specifies that an extended assessment period cannot be applied to an application if it has been previously applied.

The 6A Guidelines are published on the APVMA website.