



# Section 6A Guideline: remitting certain application fees under the Agvet Code

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# Section 6A Guideline: remitting fees under the Agvet Code

# What is this guideline about?

- 1. This is a guideline for the purposes of section 6A of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Cth)* (Agvet Code).
- 2. The purpose of this guideline is to set out the Australian Pesticides and Veterinary Medicines Authority's (APVMA) principles and processes in relation to remitting fees under subsection 164(8)(a) of the Agvet Code.
- 3. This guideline is limited to the *remission* of application fees under the Agvet Code and the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Regulations) in circumstances where the application has been withdrawn in writing and signed by the applicant in accordance with section 8D of the Agvet Code.
- 4. This guideline does not apply to the *waiver* of fees under s164(8) of the Agvet Code. It also does not apply to the remission or waiver of a fee in any of the circumstances prescribed by the Agvet Regulations pursuant to section 164(8)(b) of the Agvet Code.
- 5. APVMA officers who have a delegation under s164(8)(a) of the Agvet Code must have regard to this guideline when deciding whether to remit an application fee to which this guideline applies, however strict adherence is not mandatory.
- 6. If making a decision that does not follow the principles set out in this guideline, delegates should include in their documentation the reasons why they decided to deviate from this guideline. The applicable facts, evidence and circumstances should be included with those reasons.
- 7. This guideline is not intended to be exhaustive of all circumstances or scenarios where the APVMA may remit fees.
- 8. A decision under section 164(8) of the Agvet Code to refuse to remit the whole or part of a fee is a reviewable decision (ss 166(1)(b) and 167(1).
- 9. This guideline commences on 26 November 2024.

# **Principles for remitting fees**

- 10. Remission of fees is discretionary.
- 11. For the purpose of this guideline fees have been divided into two categories:

**Modular assessment fees** being application fees that are described as modular assessment fees in column 5 of Schedule 6 to the Agvet Regulations.

Note: Regulation 70A and Schedule 7 to the Agvet Regulations (Schedule 7) make provision for different types and levels of assessment modules. Column 3 of Schedule 7 specifies the relevant fee for each type and level of modular assessment.

**Fixed application fees** being application fees that are for a fixed amount as set out in column 5 of Schedule 6 to the Agvet Regulations.

## 12. Principles for remitting Modular Assessment Fees

- a. The preliminary assessment fee specified in column 3 of Item 1 of Schedule 7 to the Agvet Regulations (Schedule 7) should usually be retained in full for all applications.
- b. If any work has commenced on a module level specified in items 2.1 10.3 inclusive in Schedule
   7, the corresponding fee in column 3 of Schedule 7 should usually be retained in full.
- c. The fee for the relevant final assessment module type specified in items 11.1 to 11.3 inclusive in Schedule 7 should usually be retained in full unless the application is withdrawn before or soon after preliminary assessment is complete.
- d. If the application requires a limits on use of information module as specified in item 12 of Schedule 7 the corresponding fee in column 3 of Schedule 7 should usually be retained in full.
- e. The fee for a module level specified in items 2.1-10.3 inclusive in Schedule 7 may be remitted if no work on that module has commenced.

## 13. Principles for remitting Fixed Application Fees

- a. The preliminary assessment fee specified in column 3 of Item 1 of Schedule 7 should usually be retained in full for all applications.
- b. If the application involves an assessment that is considered equivalent to a modular assessment of a level specified in modules 2.1 -10.3 inclusive in Schedule 7 and work has commenced on any such module, an amount equal to the fee in column 3 of Schedule 7 for the equivalent assessment should usually be retained in full.
- c. If the application requires an assessment that is considered equivalent to a finalisation assessment of a type specified in modules 11.1-11.3 inclusive in Schedule 7, an amount equal to the fee in column 3 of Schedule 7 for the equivalent finalisation assessment should usually be retained in full, unless the application is withdrawn before or soon after preliminary assessment is complete.
- d. If the application requires a module considered equivalent to a limits on use of information module as per item 12 module in Schedule 7 an amount equal to the fee in column 3 of Schedule 7 for module 12 should usually be retained in full.
- e. The balance of any fee remaining may be remitted.

# 14. Examples for Fixed Fee Applications

# Example 1

An application of a type specified in Item 12 of Schedule 6 to the Agvet Regulations involves assessments considered equivalent to a preliminary assessment and a finalisation assessment. It does not involve an assessment considered equivalent to a modular assessment of a level specified in items 2.1-10.3 inclusive or item 12 in Schedule 7.

In accordance with the principles stated in paragraphs 13 a. and 13 d., the full fee should usually be retained unless the application is withdrawn soon after preliminary assessment is complete, in which case, a refund of the total fee less the preliminary assessment fee may be remitted.

## Example 2

An application of a type specified in Item 5 of Schedule 6 to the Agvet Regulations involves assessments considered equivalent to the following levels and types specified in Schedule 7:

Item	Module
1	Preliminary assessment
2.3	Chemistry – level 3
8.3	Efficacy and safety – level 3
11.2	Finalisation – type 2
12	Limits on use of information

If a preliminary assessment has been completed and work has commenced on the item 2.3 module but no work has commenced on the item 8.3 module, the following principles and outcomes will usually apply:

- (i) The preliminary assessment fee should be retained in accordance with the principle stated in paragraph 13 a.;
- (ii) An amount equal to the fee for an item 2.3 module should be retained in accordance with the principle stated in paragraph 13 b.;
- (iii) An amount equal to the fee for an item 11.2 module should be retained in accordance with the principle stated in paragraph 13 c;
- (iv) An amount equal to the fee for an item 12 module should be retained in accordance with the principle stated in paragraph 13 d.;
- (v) After the amounts for preliminary assessment and the item 2.3, 11.2 and 12 modules have been deducted the balance of the fee remaining may be remitted.