



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

Overarching principles and processes for the effective and efficient regulation of agricultural and veterinary chemical products

6A Guideline

March 2023

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6A Guideline: Overarching principles and processes for the effective and efficient regulation of agricultural and veterinary chemical products

1. What is this guideline about?

1. This guideline is made for the purposes of s 6A of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). Officers and employees of the Australian Pesticides and Veterinary Medicines Authority (APVMA) are required to have regard to this guideline when performing the functions or exercising the powers to which this guideline applies as delegates of the APVMA.
2. The purpose of this guideline is to assist APVMA decision-makers by outlining our principles and processes for the effective and efficient regulation of chemical products and their constituents. It does so by setting out our approach to:
 - a) using and following the guidelines made under section 6A
 - b) performing our functions and exercising our powers under the Agvet Code and the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Code Regulations)
 - c) exercising discretion in relation to the decisions we make under the Agvet Code and the Agvet Code Regulations.
3. This guideline is not law; APVMA decision-makers must have regard to it, but from time to time may depart from it when determining the best way to handle the specifics of the matter under consideration.
4. Any reference in the guidelines to 'us' or the 'APVMA' exercising a particular power or making a particular decision should also be taken as referring to a delegate of the APVMA exercising the power or making the decision.
5. This revised guideline commenced on 17 March 2023.

2. When should I use and follow the 6A Guidelines?

6. This guideline is made for the purposes of s 6A of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). Officers and employees of the APVMA are required to have regard to this guideline when performing the functions or exercising the powers to which this guideline applies as delegates of the APVMA.
7. If a section 6A Guideline exists, APVMA staff must have regard to it in performing any relevant function and or exercising any relevant power under the Agvet Code and the Agvet Code Regulations.
8. However, a decision maker is not bound by the guidelines. They will consider each case on its merits and may depart from the guidelines in special circumstances.
9. Where we depart from the guidelines, we will make a record setting out our reasons for departing from the guidelines.

3. What is the APVMA's regulatory approach?

General principles

10. APVMA staff must perform their functions and exercise their powers in accordance with the provisions of the Agvet Code and the Agvet Code Regulations, and all other applicable laws (including the principles of administrative law).
11. We administer the Agvet Code and the Agvet Code Regulations in accordance with the best practice principles described in the [Regulator Performance Guide](#).
12. We recognise that, in performing our functions and exercising our powers, we must:
 - a) act within our power and comply with specific statutory requirements
 - b) exercise our power in good faith, and in a fair, ethical, professional and responsible manner
 - c) in making decisions, act fairly and equitably in accordance with administrative law principles, and apply our discretion in a rational and demonstrably justifiable way
 - d) manage any real or perceived conflicts of interest
 - e) apply the law with probity, balance, judgement, common sense and without bias
 - f) enforce the law equitably, fairly and swiftly.
13. We understand that failure to act in accordance with the above requirements may result in:
 - a) incorrect or invalid decision-making and inefficient administration of the Agvet Code and the Agvet Code Regulations
 - b) potential damage to stakeholders
 - c) the compromise of our regulatory efforts and the undermining of incentives for compliance with the Agvet Code and the Agvet Code Regulations
 - d) the erosion of public confidence in the APVMA.

A risk-based approach based on science

14. Our regulatory approach is:
 - a) risk-based
 - b) consultative
 - c) consistent with international best practices and leading scientific approaches, research, technologies, practices and evidence.
15. We apply our risk-based regulatory approach such that:
 - a) The likelihood and severity of potential threats to the health and safety of human beings, animals and the environment are minimised.
 - b) The likelihood and potential benefits of opportunities for Australia, the public and regulated industry are increased.

- c) Opportunities associated with new active constituents or chemical products will be considered, even if there are potential risks.
- 16. In this context, we will select scientific approaches and information that realistically identifies and assesses the potential risks and opportunities associated with agricultural and veterinary chemical products and their constituents.
- 17. In determining an application (or doing other things) under the Agvet Code or the Agvet Code Regulations, we will balance the risks we identify with granting the application against the purpose of the application, the opportunities that may arise from granting the application, the extent to which the risk can be mitigated by imposing conditions, and the practicability and cost of adopting particular risk mitigation measures.

4. Can I exercise discretion under the Agvet Code and the Agvet Code Regulations?

- 18. When making decisions under the Agvet Code and the Agvet Code Regulations, APVMA staff are often required to exercise discretion.
- 19. The requirement to exercise discretion in decision making can add a level of complexity and uncertainty to the process as the factors that the decision-maker must, may or must not take into account in making the decision (and the weight to be attributed to each factor) are not always clear or obvious.
- 20. We recognise that, where we are required to exercise discretion in our decision making, we must do so:
 - a) consistently with the objects and provisions of the Agvet Code and the Agvet Code Regulations
 - b) in line with administrative law principles
 - c) based on the nature and merits of the individual application or case
 - d) taking into account, where appropriate, special circumstances (that is, unusual or extraordinary circumstances that, if not taken into account, may result in an unjust, unreasonable or inappropriate outcome)
 - e) in a way that promotes streamlining of the regulatory process and improves its flexibility.

The [6A Guidelines](#) are published on the APVMA website.