Australian Government

Australian Pesticides and Veterinary Medicines Authority

Varying relevant particulars and conditions

6A Guideline

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6A Guideline: Varying relevant particulars and conditions

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 set out the principles and processes APVMA decision-makers should follow in relation to performing our functions and exercising our powers relating to varying relevant particulars and conditions under the Agvet Code.
3. The guidance provided in this document is for a delegate authorised under an instrument of delegation made by the CEO of the APVMA. All decision makers should ensure the function or power they are intending to exercise is one delegated to them prior to exercising it.
4. Variations to relevant particulars or conditions can take place in the following ways:
    a) Notified variations of relevant particulars, under Division 2AA of Part 2 of the Agvet Code.
    b) Prescribed variations of relevant particulars under Division 2A of Part 2 of the Agvet Code.
    c) Varying relevant particulars and conditions under Division 3 of Part 2 of the Agvet Code.
5. The provisions of the Agvet Code and the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Code Regulations) covered by this guideline are summarised in the Annexure to this guideline.
6. 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.
7. 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.
8. This revised guideline commenced on 17 March 2023.

2. Notified variations of relevant particulars

What are ‘notifiable variations’?

9. Division 2AA provides that certain relevant particulars of an approval or registration may be varied by way of notice given to the Australian Pesticides and Veterinary Medicines Authority (APVMA) by the holder of the approval. These variations are called ‘notifiable variations’.
10. Section 6 of the Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019 sets out the relevant particulars which can be varied by notice including, but not limited to:
    a) Variations of the name of the manufacturer of an active constituent or chemical product, or the address at which a product is manufactured.

b) Variations of the distinguishing name of a chemical product.

c) Certain variations concerning the instructions for use of a chemical product, or the net contents of an agricultural product.

How are 'notifiable variations' made?

11. To vary relevant particulars the holder of approvals or registrations may, in writing, lodge notice with the APVMA of one or more notifiable variations of the relevant particulars of an approval or registration. The notice must meet the notice requirements (section 26AB). Note: Section 26AD(1) of the Agvet Code defines the notice requirements.

12. Once a compliant notice has been lodged with the APVMA under section 26AB concerning the relevant particulars, the APVMA will, under section 26AC of the Agvet Code:

    a) vary the relevant particulars as proposed in the notice, with effect from the day when the notice was lodged

    b) within 14 days after the notice is lodged, record the variation of the particulars in the relevant APVMA file, as well as in the Record and the Register.

13. Notifiable variations are submitted to the APVMA via the APVMA Online Services Portal. Further information is available under 'Minor variations' on our website.

Rules of general application

14. A notice may contain more than one notifiable variation. The number of notifiable variations contained in a single notice does not alter the application fee.

15. If a notice contains multiple variations and at least one of the variations is not a notifiable variation (for example, it is a 'prescribed variation'), then the APVMA delegate will determine that the notice does not meet the notice requirements (section 26AB). The APVMA will not be able to proceed with the remaining variations in the notice. The APVMA will write to the person that made the notification, explaining why the notice did not meet the requirements and the person may then choose to re-submit the variations using the correct pathways.

16. A holder may attach, or be required to attach, information to a notice, such as a draft label. In the event that the attached information contradicts the information contained in the notice, the APVMA will only act on the information contained in the notice.

17. The APVMA will amend the Register so that a product is no longer noted to be a 'listed chemical product' if the relevant particulars of that listed chemical product are varied in such a way that the product, or any approved label for the product, does not comply with the 'established standard' for the product.

3. Prescribed variations of relevant particulars

What are ‘prescribed variations’ of relevant particulars?

18. Division 2A of the Agvet Code provides for prescribed variations of relevant particulars of approvals and registrations. Section 26B(6) provides for the APVMA to determine, by legislative instrument, the types of variations that will be prescribed variations.
19. Prescribed variations of relevant particulars are certain variations of the name of a manufacturer of a chemical product, the address of each site where the product is manufactured, and certain variations of the constituents included in chemical products, as set out in section 5 of the Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019.
20. The APVMA must not determine a variation to be a prescribed variation unless it is satisfied that, with the particulars so varied:
    a) For an active constituent, it would meet the safety criteria; and
    b) For a chemical product, that the product would:
        i. meet the safety criteria, the trade criteria and the efficacy criteria; or
        ii. comply with the established standard for the product; and
    c) For a label for a chemical product, that the label would:
        iii. meet the labelling criteria; or
        iv. comply with the established standard for the product.

How are ‘prescribed variations’ made?

21. The holder may apply to the APVMA for one or more prescribed variations of the relevant particulars of an approval or registration. The application must meet the application requirements (section 26B). Note: ‘meets the application requirements’ is defined under section 8A of the Agvet Code.
22. Under section 26C(1)(a) if the APVMA is satisfied that the application meets the application requirements, it must vary the relevant particulars as proposed in the application. If it is not so satisfied, the APVMA must refuse the application (section 26C(1)(b)).
23. Section 26D provides that the variation of particulars will take effect when the APVMA records the variation (including the relevant particulars as varied and the date of the variation) in the Record, the Register or the relevant APVMA file.
24. If relevant particulars of a listed chemical product are varied, and those variations cause the product or an approved label from the product not to comply with the established standard for the product, the APVMA must amend the register so that the product is no longer noted as a listed chemical product.
25. Applications for prescribed variations applications are submitted to the APVMA via the APVMA Online Services Portal. Further information is available under ‘Minor variations’ on our website.

4. Applying for a variation

Preliminary assessment

26. If a variation being sought by an applicant is not a notifiable or prescribed variation, the applicant will need to apply for variation under Division 3 of Part 2 of the Agvet Code.
27. Applicants must, when lodging an application to vary relevant particulars or conditions of an approval or registration, ensure that the application contains or is accompanied by all relevant information such that the application 'meets the application requirements'. Note: Section 8A of the Agvet Code defines 'meets the application requirements'.
28. We will undertake a preliminary assessment of applications for variation. Further information on the preliminary assessment process can be found on the APVMA website.
29. For the purposes of section 28(4) of the Agvet Code, we may alter an application, after it has passed preliminary assessment, and with the written consent of the applicant. Further information on altering applications can be found on the APVMA website.

How will the APVMA determine applications for variation?

30. The APVMA must be satisfied of the relevant matters in section 29 of the Agvet Code before we can vary the relevant particulars or conditions of an approval or registration. All applications for variations must meet the application requirements. Depending on whether the application is with respect to an active constituent, chemical product or label for a chemical product, we will also need to be satisfied:
    a) For an active constituent, that if the particulars were varied as requested that the constituent would meet the safety criteria.
    b) For a chemical product, that if the if the particulars were varied as requested the product would meet the safety criteria, the trade criteria and the efficacy criteria, or comply with the established standard for the product.
    c) For a label for a chemical product, that if the particulars were varied as requested the label would meet the labelling criteria, or comply with the established standard for the product.
    d) We will take into account Section 6A Guidelines in performing this function.

5. Varying on our own initiative

31. Under section 29A of the Agvet Code, we may, on our own initiative, and with the written consent of the holder, vary the relevant particulars or conditions of an approval or registration. No fee is payable in relation to a variation made under this section.

6. Annexure – relevant legal provisions

32. Division 2AA of Part 2 of the Agvet Code provides for the variation of certain relevant particulars by notice to the APVMA. Section 26AA provides an overview of Division 2AA. Section 26AB of the Agvet Code deals with notices of notifiable variations (see also Section 6 of the Agricultural and Veterinary Chemicals Code (Notifiable Variations) Instrument 2019). Section 26AC requires the APVMA to vary the relevant particulars in accordance with notices. Section 26AD sets out the notice requirements for notices of notifiable variations.
33. Division 2A of Part 2 of the Agvet Code provides for the variation of certain relevant particulars by application to the APVMA. Section 26A provides an overview of Division 2A. Section 26B deals with applications for prescribed variations (see also section 5 of the Agricultural and Veterinary Chemicals Code (Prescribed Variations) Instrument 2019). Section 26C requires the APVMA to make a decision concerning prescribed variations on an application. Section 26D deals with how the prescribed variation will take place.
34. Division 3 of Part 2 of the Agvet Code provides for the variation of relevant particulars or conditions of an approval or registration. Section 27 of the Agvet Code deals with applications to vary a relevant particular or condition. Section 28 deals with preliminary assessment of the application (see also regulation 19AD of the Agvet Code Regulations). Section 29 deals with assessment of an application for a variation. Section 29A gives us the power to vary a relevant particular or condition on our own initiative, with the consent of the holder. Section 29B sets out how a variation takes place.

The 6A Guidelines are published on the APVMA website.