EXPLANATORY STATEMENT

Agricultural and Veterinary Chemicals Code
Instrument No. 3 (Assessment Periods for Applications
where Additional Information is Submitted Voluntarily) 2008

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory authority of the Commonwealth operating on a full cost-recovery basis and within certain statutory timeframes. The APVMA is responsible for ensuring that agvet chemicals entering into the Australian market pose no hazard to humans, target animals and plants and the environment, are effective for their approved use and pose no threat to Australian trade.

Subsection 32(1) of the Agricultural and Veterinary Chemicals (Administration) Act 1992 provides that the Chief Executive Officer of the APVMA is to manage the affairs of the APVMA and in doing so, may exercise any of the powers and perform any of the functions of the APVMA.

Subsection 165(1A) of the Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (the Agvet Code Act) provides that the APVMA may make a legislative instrument setting out criteria for working out which period stated in, or determined in accordance with, the regulations applies in a particular case. This period is the period within which the APVMA must determine an application made to it.

Amendments to the Agvet Code and the Agricultural and Veterinary Chemicals Code Regulations 1995 (the Agvet Code Regulations) in 2005 provided for new cost recovery arrangements for the APVMA, including a revised fee structure for applications made to the APVMA. The periods within which the APVMA must determine particular applications were also revised. The revised fee and timeframes structure for applications commenced on 1 July 2005 and is set out in an amended Part 2 of Schedule 6 of the Agvet Code Regulations.

The APVMA believes that, overall, the new fee and timeframes structure is much fairer and more equitable. It is concerned, however, with the number of applications for which additional information is being submitted – estimated at almost half of the 550 more complex applications received each year. It is not uncommon for the APVMA, after extensive evaluation and assessment of a particular application, to decide to refuse or severely restrict a proposed use of a chemical product. In these circumstances the applicant, rather than have the particular use applied for refused or restricted by the APVMA, may decide to submit a substantial amount of additional data in an endeavour to support the particular chemical use of concern. This necessitates not only the APVMA thoroughly evaluating this additional information, but on many occasions, existing assessments have to be substantially revised or redone.

Under current arrangements the APVMA is allowed no more time in which to perform the extra work associated with additional information and must determine the
application within the same period of time. The purpose of the Agricultural and Veterinary Chemicals Code Instrument No. 3 (Assessment Periods for Applications where Additional Information is Submitted Voluntarily) 2008 is to set out criteria for working out which particular periods specified in the Agvet Code Regulations and within which the APVMA must determine an application, are to apply to those applications where additional information is voluntarily submitted to the APVMA.

This proposal is only a minor issue that has arisen from the ongoing monitoring of the 2005 revised fee and timeframes structure for the APVMA. The proposal has been endorsed by the APVMA’s Audit Committee and is part of an overall efficiency package to ensure that timeframe performance for applications is in line with cost recovery principles.

The APVMA has consulted with the pesticides and veterinary medicines industry on the proposal to amend the period of time within which the APVMA must determine applications containing additional information. While the industry, of course, seeks to minimise, to the extent possible, the timeframes for completion of applications, there is broad acceptance of the necessity of increasing timeframes where additional information requires the APVMA to undertake significant amounts of extra work.

The Agricultural and Veterinary Chemicals Code Instrument No. 3 (Assessment Periods for Applications where Additional Information is Submitted Voluntarily) 2008 is a legislative instrument for the purposes of the Legislative Instruments Act 2003.
NOTES TO ITEMS

Part 1 Preliminary

Item 1 Name of Instrument
1. This item states that the full name of the Instrument is the _Agricultural and Veterinary Chemicals Code Instrument No. 3 (Assessment Periods for Applications where Additional Information is Submitted Voluntarily) 2008._

Item 2 Commencement
2. This item provides that the Instrument will commence on the day after it is registered on the Federal Register of Legislative Instruments (FRLI).

Item 3 Object
3. This item provides that the purpose of the Instrument is to set out criteria for working out which particular periods specified in the Agvet Code Regulations and within which the APVMA must determine an application, are to apply to those applications where additional information is voluntarily submitted to the APVMA.

Item 4 Interpretation
4. This item clarifies, consistent with section 13 of the _Legislative Instruments Act 2003_, that expressions used in the Instrument have the same meaning as in the Agvet Code Act or the Agvet Code Regulations.

5. A definition is also provided for the term “additional information”. The term means relevant information in relation to an application that is provided to the APVMA sometime after the original application was made and where the APVMA has already undertaken some assessment of the application (comprising of one or more of the twelve modules set out in Column 2 of Schedule 7 of the Agvet Code Regulations other than item 1 Screening – that is, either chemistry, toxicology including poison scheduling, residues, occupational health and safety, environment, efficacy and safety, non-food trade, special data, finalisation or data protection), and the additional information is also one or more of these modular types that requires evaluation or assessment by the APVMA.

6. The definition also requires that the submission of the additional information necessitates that an existing assessment of the application has to be revised or redone. It is also necessary that the APVMA did not give the applicant notice under section 159 of the Agvet Code requesting the additional information, or that the additional information was not submitted at a particular time after the application had been made pursuant to any agreement which the APVMA had reached with the applicant prior to the application being lodged with the APVMA.

7. This definition makes it clear that the APVMA must have begun substantial evaluation of the application, although it is not necessary that an assessment be completed. It would be sufficient if the additional information necessitated the APVMA having to go back and recommence or revise any assessment that it had already commenced. However, no additional timeframes are imposed where evaluation or assessment (other than Screening) had not commenced when the additional information was provided.
8. It is also expressly clear that any additional information requested by the APVMA under section 159 of the Agvet Code does not attract any additional timeframe period within which the APVMA must determine the application. This is because information actually requested by the APVMA (as opposed to being submitted by the applicant without invitation by the APVMA) is not included in the definition of “additional information”. Further, the submission of information pursuant to section 159 would either not be of the same modular type as an assessment already undertaken or would not require another assessment to be revised, recommenced or redone. Information submitted under section 159 would only add to an assessment that is underway or is yet to begin, but without that information it is not possible to progress or complete the assessment. In short, section 159 information fills a gap and allows the assessment of the application to go forward whereas additional information requires the APVMA to go back and revisit or rework assessments it has previously completed.

9. The general principle is where additional information requires a completed assessment for that application to be reopened and redone or where an assessment that is underway has to be recommenced or revised then it could be said that the timeframe for that particular assessment had already been utilised so that a further period for completion of an application is required to allow the APVMA to do assessment work a second time.

**Part 2 Criteria for working out a period for completion of an application with additional information**

**Item 5 The total period within which the APVMA is to determine an application containing additional information**

10. Where the applicant provides additional information in relation to a particular application then the total period within which the APVMA must determine that application is worked out by adding to the period for completion otherwise applicable (as specified in Column 3 of Part 2 of Schedule 6 of the Agvet Code Regulations including, if appropriate, any modular assessment period) the sum of the longest of any periods for the modules, levels or types of assessment specified in Column 3 of Schedule 7 (other than item 1 Screening) that the APVMA considers necessary for the application to further undergo by reason of the additional information (or which needs to be revised or redone) and any period for the type of finalisation assessment module in items 11.1 to 11.4 in Schedule 7 that the application must undergo a second time.

11. Hence, after an applicant has submitted additional data as defined (say efficacy and safety data), if the APVMA had to redo its efficacy and safety level 2 evaluation and, as a direct consequence, recommence or revise its residues level 2 evaluation, then the extra time for completion of the application would be the longest of the 4 months and 6 months periods for those evaluations – that is, 6 months. If the type 2 finalisation had to be done a second time a further 2 months would be allowable for the APVMA to complete the application – that is, a total of an additional 8 months would be allowable for the APVMA to complete the application where additional information had been submitted voluntarily.