EXPLANATORY STATEMENT

Agricultural and Veterinary Chemicals Code
Instrument No. 4 (MRL Standard) 2012

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority of the Commonwealth. Amongst other things, the APVMA is responsible for ensuring agricultural and veterinary (agvet) chemicals used in Australia are not harmful to public health as a result of residues.

Subsection 6(1) of the Agricultural and Veterinary Chemicals Code (Agvet Code), which is a Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, expressly authorises the APVMA to give an approval where the Agvet Code merely refers to an approval given by the APVMA. Paragraph (f) of subclause 14(3) of the Agvet Code refers limits for residues of agvet chemical products that are approved by the APVMA. These limits are referred to as maximum residue limits (MRLs).

By this authority the APVMA approves or sets MRLs which, pursuant to s.7A of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, the APVMA must publish on an annual basis. The APVMA now produces the *MRL Standard* which contains all MRLs approved by the APVMA. The *MRL Standard* is currently published on the APVMA's website. The *MRL Standard* has been published in various forms for more than 30 years.

Recently, the APVMA decided that the *MRL Standard* meets the tests in the *Legislative Instruments Act 2003* as a legislative instrument. It is an instrument in writing made in the exercise of a power delegated by the Parliament. It is also of legislative character in that it determines the law (as opposed to merely applying it) as it sets definitively MRLs approved by the APVMA. Additionally, it imposes obligations as it sets a standard that must be complied with under State laws. Numerous State stockfood and agvet chemical control-of-use laws impose obligations not to exceed the MRLs set out in the APVMA's *MRL Standard*.

Assessment and Determination of MRLs

MRLs are regulatory standards which help to monitor that agvet chemical products are used in accordance with the approved label instructions. If an MRL is exceeded, it usually indicates a misuse of the chemical but does not normally indicate a public health or safety concern.

In evaluating the safety and performance of agvet chemicals, the APVMA's assessment also includes a determination of an MRL for the chemical in relation to relevant crops and animals. The APVMA uses data from a series of residue trials and calculates whether the application of the minimum amount of chemical that is required to achieve effective pest or disease control will leave any residue in the plant or animal commodity. In order to legitimise the presence of these residues, MRLs are established by the APVMA by entry into the APVMA's *MRL Standard*.

If there are small amounts of chemical residue in produce, the APVMA uses the toxicological evaluation and the dietary exposure assessment to examine the potential occurrence of adverse effects on human health when the produce is consumed.

Dietary exposure assessments undertaken by the APVMA as part of the registration of the relevant agvet chemical products indicate that the MRLs approved by the APVMA and included in the *MRL Standard* do not present any public health and safety concerns.

Regulatory Impact Assessment

The proposed changes to regulation to make the APVMA's *MRL Standard* a legislative instrument are minor and machinery in nature. On 22 November 2012, the Office of Best Practice Regulation provided an exemption from the need to assess if a Regulatory Impact Statement is required for the approvals of MRLs by the APVMA and the making of the APVMA's *MRL Standard* as a legislative instrument.

The MRLs are an essential consequence of the decision by the APVMA to register agvet chemical products (or to extend their approved label instructions) or to issue a permit in relation to an agvet chemical product. The setting of an MRL and its inclusion in the *MRL Standard* is a science-based outcome arising from these decisions and for which there is only very limited discretion on the part of the APVMA decision maker.

The setting of MRLs by the APVMA and their inclusion in the *MRL Standard* and the making of that Standard as a legislative instrument is unlikely to have any impact on the States, other regulatory agencies, business including primary producers, individuals, or the economy. Primary producers understand the need to use only registered agvet chemical products and to use those products strictly in accordance with approved label instructions. In doing so, produce grown will be within the MRLs set by the APVMA and included into the APVMA's *MRL Standard*. The making of the *MRL Standard* as a legislative instrument will assist the States in referring to it in their legislation.

Consultations

The APVMA seeks the wider community's involvement through public consultation as part of its evaluation process for the registration of new agvet chemical products or a major extension of the use of existing products to new crops and target animals. During this consultation phase any person may comment or raise concerns about any relevant aspect of the intended registration, sale and use of the chemical product, including proposed MRLs and the dietary exposure assessment. The APVMA addresses any concerns that were raised at the time as part of the registration and approval process.

Disallowance and Sunsetting and the Updating of the *MRL Standard*

Although the *MRL Standard* is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*, pursuant to subsections 44(1) and 54(1) it is neither subject to disallowance nor sunsetting. The Agvet Code is part of a co-operative scheme involving the Commonwealth and all States and Territories; and the *MRL Standard* is authorised by the Agvet Code. The APVMA proposes to amend the *MRL Standard* on a monthly basis to incorporate new and varied MRLs approved by the APVMA.

NOTES ON 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. 4 (MRL Standard) 2012*.

Item 2 Commencement

2. The Instrument is to commence on 1 January 2013.

Item 3 Object

3. This item provides that the object of this Principal Instrument is to make the APVMA's *MRL Standard*, as it existed when it was last amended on 4 December 2012, as a legislative instrument.

Item 4 Background

4. This item contains four subclauses.

5. Subclause (1) provides that the *MRL Standard* as set out in the Schedule to the Instrument lists MRLs of substances arising from the approved use of those substances. In most cases the substances are agvet chemical products registered by the APVMA for use in accordance with the relevant label instructions for the product approved by the APVMA.

6. Subclause (2) notes that the APVMA sets (that is, approves) MRLs for agvet chemicals in agricultural produce, particularly produce entering the food chain. The subclause further notes that MRLs are set at levels which are not likely to be exceeded if the agvet chemicals are used in accordance with their label instructions approved by the APVMA. Additionally, for the MRLs approved, the APVMA has completed a dietary exposure evaluation to ensure the residue levels do not pose an undue hazard to human health.

7. Subclauses (3) and (4) note that the MRL Standard includes all current MRLs set by the APVMA and its predecessor the NRA (National Registration Authority for Agricultural and Veterinary Chemicals) from 15 March 1994. For many years prior to then MRLs were recommended by the Chemicals Safety Unit (CSU) of the then Department of Human Services and Health. Before then, MRLs were recommended by a technical committee to the then National Health and Medical Research Council.

Item 5 Interpretation

8. Subclause (1) of this item provides that an expression used in this Instrument has the same meaning as in the Agvet Code. Strictly, the provision is unnecessary as paragraph (b) of subsection 13(1) of the *Legislative Instruments Act 2003* provides that expressions used in an Instrument have the same meaning as in the enabling legislation.

9. Subclause (2) of this item defines several terms such as maximum residue limit (MRL), the *MRL Standard*, feed additive, good agricultural practice, and primary feed commodity.

Item 6 The *MRL Standard*

9. This item provides that the Schedule to this Instrument sets out the *MRL Standard*.

Schedule — the *MRL Standard*

Part 1 — Preliminary

Item 1 Explanation

10. Subclauses (1), (2) and (3) of this item explain certain letters and symbols used in the Tables to the *MRL Standard*.

11. Subclause (4) of these items explains the food commodity designations and their codes used in the Tables to the *MRL Standard*. These have been adopted from Codex Classification of Foods and Animal Feeds (Part 4 of the Guide to Codex Recommendations Concerning Pesticide Residues, second edition, 1989) with minor modifications. Codex codes are included in the *MRL Standard* entry to assist in associating Australian MRLs with Codex MRLs.

12. Subclause (5) notes that MRLs set for 'groups' of commodities are applicable to all members of the group as designated in the Codex classification. For example, a group MRL for "VC 0045 Fruiting vegetables, Cucurbits..." applies to all cucurbit vegetables listed in the Codex classification under this group; for example, melons, cucumber and squash.

13. Subclause (6) explains appropriate method of analysis for measuring residues in food commodities. For many compounds, appropriate sources of methods are available in the Guide to Codex Recommendations Concerning Residues. While the analyses are not confined to any particular method, they are subject to the necessary quality control procedures.

14. Subclause (7) explains in precise detail how an MRL shall be considered to have been exceeded.

15. Subclause (8) explains that for a food containing or manufactured from several specified foods, such as fruit juice, the presence of residues not greater than the respective MRLs of each of the ingredient foods is acceptable only where there is no concentration. Where there is evidence of concentration, separate MRLs for the food commodity may be set (for example, wine).

16. Subclause (9) explains how MRLs (and extraneous residue limits (ERLs)) are expressed. The number set out in the *MRL Standard* for an MRL is in milligrams per kilogram of the food, agricultural commodity, or animal feed. For liquids, MRLs are expressed in milligrams per litre.

17. Subclause (10) explains that MRLs on food commodities in Table 1 are expressed on a "fresh weight" basis; whereas MRLs for animal feeds in Table 4 are normally expressed on a "dry weight" basis. Certain technical consequences of this difference are explained.

18. Subclause (11) explains that it has been the consistent policy of the APVMA and the other bodies which have set MRLs over the years not to set MRLs for tobacco and certain agricultural commodities primary used for fibre production such as wool.

19. Subclause (12) explains that usually, MRLs are not set for residues in agricultural commodities primarily used for human or veterinary drug or medicine production. This is because it is assumed that processing under good manufacturing practices will remove any residues which might constitute a toxicological hazard to human health.

Item 2 Meat and Milk [in the fat]

20. Subclause (1) of this item explains that where a MRL is determined for meat or milk and the chemical concerned is fat soluble, the commodity is designated with the qualification '[in the fat]'.

21. Subclauses (2) and (3) of this item explains that 'meat' MRLs are expressed on a fat basis rather than on a whole product basis. The approach followed in the *MRL Standard* is that a portion of adhering fat is analysed and the MRLs apply to the clean, dry fat.

22. Subclause (4) of this item explains that when a MRL for cattle milk or milks is qualified by '[in the fat]', the MRL applies to the fat portion of the milk. Thus, MRLs are expressed on a fat basis. In a derived or manufactured milk product with a fat content of 2% or more, the MRL also applies to the fat portion. For a milk product with a fat content of less than 2%, the MRL applied should be 1/50 of that for 'milk [in the fat]' and should apply to the whole product.

Part 2 — The Tables

Item 1 Table 1 - MRLs

23. Subclause (1) of this item explains how the tables are to be read. Table 1 lists residues of substances which may occur in food commodities and for which a MRL or an ERL applies. The particular food commodity is set out in column 2 of Table 1 and the MRL (or the ERL) for that food commodity is in column 3.

24. Subclause (2) of this item explains how a residue of a substance may arise.

Item 2 Table 2 - Commodity Portions

25. Subclause (1) of this item states that Table 2 lists the portion of the commodity to which the maximum residue limit applies (and which is analysed).

26. Subclause (2) of this item explains that Table 2 is derived from the Codex Classification of Foods and Animal Feeds, second edition, 1989

27. Subclause (3) of this item explains that MRLs are in most cases stated in terms of a specific whole raw agricultural commodity as it moves in trade. For some entries in Table 2 a qualification is included that describes the part of the raw agricultural commodity to which the MRL applies. Hence the portion of the raw agricultural commodity to which the MRL applies and which is to be prepared as the analytical sample for the determination of residues is as described in Table 2, unless otherwise specified.

Item 3 Table 3 – Residue definitions

28. Subclause (1) of this item explains that MRLs for a commodity are set for residues measured by a valid method of analysis and explains certain consequences of this method.

29. Subclause (2) of this item explains that Table 3 sets out the residue to which the MRL applies for each chemical compound. It is to be noted that residue definitions for compounds which no longer have entries in Tables 1, 4 or 5 have been retained in Table 3 for reference as analyses may still be required for compounds whose use is no longer permitted.

Item 4 Table 4 – Animal Feed Commodities

30. Subclause (1) of this item states that Table 4 lists MRLs and ERLs for residues of substances that may occur in animal feed commodities. The subclause also explains how a residue of a substance may arise

31. Subclause (2) of this item explains the treatment of feed commodities that are also primary human food commodities in the Table 4 and the application of MRLs for these commodities.

Item 5 Table 5 – MRLs not necessary

32. Subclause (1) of this item lists uses of substances where MRLs are not considered by the APVMA to be necessary.

33. Subclause (2) of this item explains that MRLs are not necessary in situations where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or otherwise are of no toxicological significance.

Table 1 — MRLs of agricultural and veterinary chemicals and associated substances in food commodities

34. The table sets out the MRLs for various agvet chemicals on particular foods beginning with a temporary MRL of 0.002 mg/kg for the chemical Abamectin on adzuki bean (dry).

Table 2 — Portion of the commodity to which the MRL applies (and which is analysed)

35. The table begins with Class A: Primary Food Commodities of Plant Origin; Type 1 – Fruits and provides that for citrus fruits the relevant portion is the whole commodity.

Table 3 — Residue definitions

36. The table begins with the agvet chemical Abamectin which is defined as the sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b.

Table 4 — MRLs for pesticides in animal feed commodities

37. The table sets out the MRLs for various agvet chemicals on particular animal feed commodities beginning with a temporary MRL of 0.1 mg/kg for the chemical Abamectin on almond hulls.

Table 5 — Uses of substances where MRLs are not necessary

38. The table sets out particular uses of certain substances for which an MRL is not considered by the APVMA to be necessary beginning with the substance acetic acid when used as a disinfectant for animal and poultry houses, egg hatcheries and associated equipment.

By Authority:
Chief Executive Officer
of the APVMA
Dated this seventh day of December 2012

STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012

This Legislative Instrument made by the Australian Pesticides and Veterinary Medicines Authority (APVMA) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Requirement for a Statement of Compatibility with Human Rights

This Legislative Instrument made by the APVMA is not a disallowable instrument pursuant to subsection 44(1) of the *Legislative Instruments Act 2003* and therefore the Statement of Compatibility with Human Rights is not strictly required. Nonetheless, to accord with the spirit of the *Human Rights (Parliamentary Scrutiny) Act 2011*, the APVMA provides this Statement of Compatibility.

Overview of the Legislative Instrument

This Legislative Instrument makes the APVMA's *MRL Standard*, as it existed when it was last amended on 4 December 2012, as a legislative instrument. The *MRL Standard* contains the maximum residue limits (MRLs) for agvet chemicals approved by the APVMA and other bodies for more than 30 years.

MRLs are regulatory standards which help to monitor that agvet chemical products are used in accordance with the approved label instructions. If an MRL is exceeded, it usually indicates a misuse of the chemical but does not normally indicate a public health or safety concern.

The APVMA evaluates the safety and performance of agvet chemicals before they are registered for sale in Australia. A part of this assessment also includes a determination of an MRL for the chemical in relation to relevant crops and animals.

The assessments undertaken by the APVMA indicate that the MRLs approved by the APVMA and included in the *MRL Standard* do not present any public health and safety concerns.

The approval of MRLs do not affect the rights or freedoms of any humans.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.