

## Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) sets maximum residue limits (MRLs) for agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. These MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. At the time that the MRLs are set, the APVMA undertakes a dietary exposure evaluation to ensure that the levels do not pose an undue hazard to human health.

The *MRL Standard* lists MRLs of substances which may arise from the approved use of those substances or other substances, and provides the relevant residue definitions to which these MRLs apply. The Standard is made up of five Tables:

- Table 1** Maximum Residue Limits of agricultural and veterinary chemicals and associated substances in food commodities;
- Table 2** Portion of the commodity to which the maximum residue limit applies (and which is analysed);
- Table 3** Residue definition;
- Table 4** Maximum residue limits for pesticides in animal feed commodities;
- Table 5** Uses of substances where maximum residue limits are not necessary

## History

In addition to the MRLs set by the NRA, (now APVMA) the *MRL Standard* includes recommendations made by the former Pesticides and Agricultural Chemicals Standing Committee (PACSC) of the National Health and Medical Research Council. It also includes recommendations by the former Chemicals Safety Unit (CSU) of the Commonwealth Department of Human Services and Health.

The CSU was responsible for recommending MRLs for agricultural chemicals in food and animal feedstuffs, and for maintaining the *MRL Standard*, from the disbandment of the PACSC until 30 June 1994, when this function was formally transferred to the NRA (now APVMA) on 1 July 1994. From 15 March 1995, the NRA (now APVMA) has set MRLs for agricultural chemicals in food and animal feedstuffs and has maintained the *MRL Standard*.

## Comments or Inquiries

Any comments or inquiries relating to this document are welcome and should be addressed to:

The Administrative Officer  
Chemistry and Residues Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box E240  
Kingston ACT 2604  
Phone: (02) 6210 4820  
Fax: (02) 6210 4840

Amendments to this *MRL Standard* are published in the Agricultural and Veterinary Chemicals Gazette, available from the Australian Publishing Service, GPO Box 84, Canberra, ACT 2601. The *MRL Standard* is also available on the internet via the APVMA web page: <http://www.apvma/mrl.shtml>.

## Introduction

### Setting of Maximum Residue Limits

The maximum residue limit (MRL) is the maximum concentration of a residue, resulting from the registered use of an agricultural or veterinary chemical. MRLs set by the APVMA are referred to Food Standards Australia New Zealand (FSANZ) for incorporation into Standard 1.4.2 of the Food Standards Code entitled "Maximum Residues Limits". The Food Standards Code is adopted by various state laws so that the MRLs become the maximum concentration of a residue, resulting from the registered use of an agricultural or veterinary chemical legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed.

MRLs are set for all types of raw food commodities (and some processed commodities) where the use of agricultural or veterinary chemicals is required for efficient practice. Such foods may be either of plant or animal origin and may be used for consumption by humans or animals. Residues can arise by either direct or indirect exposure to plants or animals. In animals, for example, feeding of grain or forage that has been treated with pesticide or has been grown in pesticide-treated soil may result in residues in animal tissues or in milk.

MRLs are set by the APVMA, during the evaluation of chemical products prior to registration. Evaluators consider detailed submissions on the use of the agricultural or veterinary chemical and other information including recommendations made by other governments and internationally-recognized organizations.

### Factors considered

When MRLs are being determined, evaluators consider the most extensive permitted use of the product. They consider 'the maximum label use pattern', which defines Good Agricultural Practice (GAP) or Good Veterinary Practice (GVP) needed to control diseases or pests. The consideration takes into account such factors as:

- how accurately the chemical and/or toxicologically significant metabolites can be measured in animal tissues and/or plant material;
- how rapidly the chemical may be processed by either plant and/or animal tissues;
- how rapidly the chemical may be degraded by soil and other environmental processes;
- how frequently and at what intervals the chemical is used, taking into account the potential for bio-accumulation;
- how close to harvesting of plants, collection of milk and eggs and/or slaughtering of livestock the chemical is used (including withholding periods);
- the acceptable dietary exposure to low levels of chemicals in food;
- the effects of processing (e.g. flour from wheat; wine and dried fruit from grapes; sugar from sugar cane); and
- any differences in MRLs and residue definitions between Australia and its major trading partners and those of the Codex Alimentarius Commission of the United Nations.

Every country registers chemicals under their own regulations and according to their domestic GAP or GVP. Differences between Australia and overseas MRLs may occur for a number of reasons. These include different use patterns (presence of pests in one country but not in another, uses on the same crop but at different concentrations for control of different pests), toxicological considerations (ADIs), analytical methodology and/or residue definition.

### **Review and Gazetting of MRLs**

Evaluations are subject to peer review. Public comment is sought, when a product containing a new active constituent is considered for registration for the first time or when a product containing an existing active constituent is first considered for registration for use on a food commodity or when there are possible trade implications arising from registration.

MRLs are gazetted by the Australian Pesticides and Veterinary Medicines Authority as amendments to the *MRL Standard*. For MRLs in human foods, the MRLs set by the APVMA are advanced to the Food Standards Australia New Zealand for incorporation into the Standard 1.4.2 of the Food Standards Code. In the case of MRLs in animal feeds, the entries in the *MRL Standard* are usually adopted into the appropriate State legislation.

### **Monitoring of chemical residues in food**

National programs such as the Food Standards Australia New Zealand's *Australian Total Diet Survey* and the Department of Agriculture, Fisheries and Forestry - Australia *National Residue Survey* monitor the residues found in food destined for human consumption within Australia or for export.

Various State, Territory, retailers and grower groups also monitor residue levels in food.

### **Commodity Descriptions**

The commodity descriptions used throughout this document conform, where possible, with the *Codex Classification of Foods and Animal Feeds* (second edition, 1989) published by the Codex Alimentarius Commission. This international body, in collaboration with the World Health Organisation of the United Nations and other international bodies, sets standards for foodstuffs in international commerce.

### **Explanatory notes**

1. (\*) denotes that the maximum residue limit (MRL) has been set "at or about" the limit of analytical quantitation.
2. 'T' denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, and will be reconsidered at some future date. This symbol is also used in cases where an MRL is being phased out.
3. E' denotes an extraneous residue limit (ERL). See definition for ERL below.
4. The food commodity designations and their codes have been adopted from the *Codex Classification of Foods and Animal Feeds* (part 4 of the *Guide to Codex Recommendations Concerning Pesticide Residues*, second edition, 1989) with minor modifications. The code is included in the *MRL Standard* entry to assist in associating Australian MRLs with Codex MRLs. Where a commodity does not have a Codex classification, it is entered in the *MRL Standard* without a code. Modification of a Codex classification is denoted by [ ].

5. The portion of the commodity to which the MRL applies (and which is analysed) is given in Table 2. This table is derived from the Codex Classification of Foods and Animal Feeds, second edition, 1989. Consult that publication for further information.
6. MRLs set for 'groups' of commodities are applicable to all members of the group as designated in the Codex classification.
7. Methods of analysis for measuring residues in food commodities must be appropriate to the residues defined in Table 3. Such methods are in most cases available in published manuals or in the chemical literature. Appropriate sources of methods for many compounds 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, including adequate recovery, minimal blank, a sufficiently low limit of analytical quantitation and absence of significant interferences. The analyst may choose any method appropriate to the compound, the commodity and the equipment, facilities and expertise available in the laboratory.
8. An MRL shall be regarded as being exceeded if the result of an analysis (by an experienced residue analyst on a sample taken according to official protocols), when rounded according to the Australian Standards SAA 2706-1984 to the number of significant figures in the MRL, exceeds the level set in the standard, taking into account the accuracy of the analysis.
9. For a food which is not specified but consists of, or contains, or is manufactured from one or more of the foods specified (e.g. fruit juice), the presence of residues at a level not greater than the respective MRLs is considered acceptable where there is no evidence of concentration. Where there is evidence of concentration, separate MRLs may be set for the appropriate commodities (e.g. wine, wheat germ).
10. MRLs on food commodities (Table 1) are expressed on a "fresh-weight" or "as received" basis. MRLs on animal feeds (Table 4) are normally expressed on a "dry-weight" basis. Expression on a "dry weight" basis means that where the sample is analysed on a "fresh weight" basis, a moisture level is determined on a separate subsample and the residue is calculated as if it were all in the dried portion. However, it should be noted MRLs which apply to primary human food commodities also apply when these commodities are used as animal feed commodities.
11. As a matter of policy MRLs are not set for residues in tobacco or in agricultural commodities used primarily for fibre production, such as flax, cotton balls, hemp, wool or mohair, or hides of leather as these are not food commodities.
12. In normal practice MRLs are not set for residues in agricultural commodities used primarily for human or veterinary drug or medicine production, since it is assumed that processing under good manufacturing practices will remove any residues which might constitute a toxicological hazard to human health.

## **Definitions**

### **Extraneous residue limit (ERL)**

Extraneous residue limit (ERL) refers to a pesticide residue arising from environmental sources (including former agricultural uses) other than the use of the pesticide directly or indirectly on the commodity. ERL is defined as the maximum concentration of the pesticide residue that is recommended to be legally permitted or recognised as acceptable in or on a food, agricultural commodity or animal feed. The concentration is expressed in milligrams per kilogram of the commodity (or milligrams per litre for liquid commodities).

### **Feed additive**

Feed additive is defined as any substance or agent added to the basic feed mix for continuous long-term administration to livestock for specific purposes, for example, enhancing production or maintenance or health above the levels obtained from the basic feed, improvement of storage qualities and/or the palatability of the basic feed mix.

### **Good Agricultural Practice**

The nationally recommended, authorised or registered use-pattern of chemicals, that is necessary for effective and reliable pest control under actual conditions at any stage of production, storage, transport, distribution and processing of food commodities and animal feed.

### **Maximum residue limit (MRL)**

The maximum residue limit (MRL) is defined as the maximum concentration of a residue, resulting from the registered use of an agricultural or veterinary chemical, that is recommended to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed. The concentration is expressed in milligrams per kilogram of the commodity (or milligrams per litre in the case of a liquid commodity).

### **Meat(s) and Milk(s) [in the fat]**

Where consideration has been given to an MRL for meat or milk, and the chemical concerned is fat soluble, the commodity is designated with the qualification '[in the fat]'. '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 analyzed and the MRLs apply to the clean, dry fat. In the *MRL Standard*, when an 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 the case of a derived or a manufactured milk: product with a fat content of 2% or more, the MRL also applies to the fat portion. For a milk product with fat content less than 2%, the MRL applied should be 1/50 of that for 'milk [in the fat]' and should apply to the whole product.

**Primary feed commodity**

A primary feed commodity such as pastures, grains, forages and fodder, for the purpose of this standard, is defined as the product in, or nearly in, its natural state intended for use by:

- (a) the farmers as stockfeed which is used without further processing for livestock animals, or after silaging or similar farm processes, or
- (b) stockfeed manufacturers as a raw material for preparing compounded feeds.

Other definitions can be found in the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* and related legislation.

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