

# Maximum Residue Limits/MRLs

## MAXIMUM RESIDUE LIMITS

A 'maximum residue limit' or MRL is one of the measures used to make sure that food is produced in the best way. Because any MRL also must meet strict safety standards, compliance with the MRL ensures that the food remains safe to eat. Breaches of the MRL do not mean that the food is unsafe, but simply that it could have been produced in a better way.

An MRL is the maximum concentration of an agricultural compound (see box at right) marker residue (expressed as mg/kg) that is legally permitted in food products or agricultural produce. These maximum concentrations are specified in a food standard pursuant to the New Zealand Food Act 1981. They are put into the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002* (the MRL standard), established under section 11C of the Food Act.

In New Zealand, the responsibility for administering domestic MRLs under the Food Act rests with the Agricultural Compounds and Veterinary Medicines (ACVM) Group, which is part of the New Zealand Food Safety Authority (NZFSA). (For more about this organisation, see our fact sheet entitled *NZFSA's ACVM Group*.) The NZFSA Food Residues Co-Ordination Group, with members from most sections of NZFSA, provides input on residues for all NZFSA-administered legislation, including the Food Act 1981, the Agricultural Compounds and Veterinary Medicines Act 1997, the Animal Products Act 1999 and the Dairy Industry Act 1952.

## Process of setting MRLs

The methodology of the MRL setting process established by the World Health Organisation (WHO) and the Codex Alimentarius Commission is used in New Zealand.

### 1: Request for MRL to be set

A request for the establishment of a domestic MRL is put to the ACVM Group. The request for the setting of an MRL generally comes from one of three sources:

- An applicant for the registration of an agricultural compound or veterinary medicine may have identified the need for an MRL during the trialling (including crop residue analysis) of their proposed product.
- The ACVM Group may identify the need for an MRL during the assessments carried out as part of the registration process.
- The NZFSA may identify the need to establish or change an MRL. One reason for this may be to ensure that New Zealand's access to its markets is not compromised. Such requests will usually seek the same MRLs as those set by the Codex Alimentarius, or by the regulatory authorities in the countries to which New Zealand seeks to export its produce.

### 2: Good agricultural practice withholding period established

Good Agricultural Practice (GAP) is established as the best practical way of using an agricultural compound or veterinary medicine that is safe and effective.

GAP is determined by looking at:

- the necessary application/dose rate and method
- frequency and timing of applications/doses
- the most appropriate interval between the last treatment and harvest/ slaughter.

This preharvest/slaughter interval is then established as the withholding period (WHP) for each product. At this point the process splits into two separate evaluations.

### 3a: Toxicology evaluation

An evaluation is carried out, usually by the Environmental Risk Management Authority (ERMA NZ), on the toxicology data submitted by the applicant in order to establish an acceptable daily intake (ADI) and/or an acceptable daily exposure (ADE). The ADE is the amount of a substance, expressed on a bodyweight basis, that is the total daily exposure over a lifetime without appreciable health risk.

## What is an 'agricultural compound'?

The Agricultural Compounds and Veterinary Medicines Act 1997 defines an agricultural compound as:

*any substance or mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land or water on or in which the plants and animals are managed, for the purposes of –*

- a. *Managing pests, including vertebrate pests; or*
- b. *Maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or*
- c. *Fulfilling special nutritional requirements; or*
- d. *The manipulation, capture, or immobilisation of animals; or*
- e. *Diagnosing the condition of animals; or*
- f. *Preventing or treating conditions of animals; or*
- g. *Enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or*
- h. *Marking animals*

*and includes any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfection of raw primary produce, and any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2).*

ADE = Lowest No Observed Adverse Effect Level (NOAEL)  
Uncertainty Factor

Potential daily exposures (PDEs) are then established for each potential route of exposure, e.g. food, air, water, skin contact. The sum of the PDEs for a substance must not exceed the ADE for that substance.

### 3b: Residues evaluation

Evaluation of the residues under the GAP conditions for the agricultural compound or veterinary medicine that are likely to remain at harvest/ slaughter are usually based on field trials and residue decay curves.

New Zealand is a food exporter and, for some produce (mainly animal products), is required to certify that the produce meets the importing country's food standards. For this produce, recognition is also made of CODEX and other countries' national MRLs to ensure continued market access for produce being exported.

Although specific New Zealand GAP may result in MRLs that differ from those set internationally for this produce, the MRL identified in the residues evaluation as appropriate for setting in New Zealand will usually be the lowest of that indicated by either the New Zealand GAP or the international considerations.

The residue likely to be in the food is then assessed for potential dietary intake in New Zealand by calculating the National Estimate of Dietary Intake (NEDI) using the internationally accepted methodology established by the WHO.

### 4: Comparison of the NEDI and the PDE

The level of dietary risk is measured by comparing the NEDI with the potential daily exposure ( $PDE_{\text{food}}$ ). (The  $PDE_{\text{food}}$  is that portion of ADE that is allocated to food.) If the NEDI is less than or equal to the  $PDE_{\text{food}}$  then the proposed MRL is deemed acceptable and the process of formally setting the MRL in the MRL standard begins.

Where the NEDI exceeds the PDE, further work is usually necessary before the MRL can be justified. This is usually done by refining the NEDI,  $PDE_{\text{food}}$  or, if possible, adjusting the withholding period to allow more residue decline prior to harvest.

#### Refinements

The NEDI often overestimates the potential dietary intake of residues in that the residue figures assume such things as:

- 100% of the crop or animals are treated at all times
- there is no residue degradation between harvest and consumption.

More accurate estimates of the NEDI can be made, taking these overestimates into account. If the revised NEDI still exceeds the  $PDE_{\text{food}}$ , then the established GAP is reconsidered to see if a longer withholding period can be established to ensure lower residues at harvest or slaughter. If the GAP cannot be changed, then the request for an MRL will be refused.

The ADE or ADI may be revised if new toxicology data become available. This revision may increase or decrease the estimated ADE, with a similar change to the  $PDE_{\text{food}}$  and, particularly where a decrease is found to be necessary, this change could well affect established MRLs.

### 5: Audit of MRL proposal

The MRL proposal is audited in an independent process by the Food Residues Coordination Group.\* If the MRL is acceptable, the proposal is put out for public comment for four working weeks. Comments received are considered by the ACVM Group, and the final decision to set the MRL (or not) is then made. A formal recommendation to the Minister of Food Safety is prepared and, if accepted, the MRL standard appropriately amended.

\* The Food Residues Coordination Group is composed of members representing the NZFSA businesses (ACVM Group, Animal Products Group, and the Dairy and Plant Products Group), along with the Policy and Regulatory Standards Group and NZFSA Legal. They are a mixture of technical and policy people, and are charged with ensuring that any MRL proposal is acceptable from the whole of the NZFSA perspective.

### RELATED FACTORS

#### New Zealand has a Default MRL of 0.1 ppm

Registration of agricultural compounds and veterinary medicines in New Zealand cannot take place until an appropriate MRL has been set in the MRL standard. This Standard includes a default MRL of 0.1 ppm for any agricultural compound or veterinary medicine not otherwise specified. When a product is put forward for registration, the default MRL is assessed as part of the residues evaluation as to its acceptability. If it is not acceptable for any reason, including trade, an acceptable MRL is sought prior to any registration being issued.

#### Codex MRLs

The MRL standard also establishes that food imported into New Zealand can comply with either the domestic MRLs or those established by the Codex Alimentarius Commission. Codex MRLs are considered in the MRL setting process, and New Zealand now considers adoption of the Codex figures where appropriate in the MRL standard.

#### Trade

An amendment to the Food Act allows trade considerations to be taken into account when setting domestic MRLs.

**For more information visit the ACVM Group website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)) or contact the ACVM Group directly at:**

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