

Definition of terms used in MORAG

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1. Acceptable daily intake (ADI)

The daily intake of a chemical which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time.

The ADI is expressed in milligrams of the chemical per kilogram of body weight per day (mg/kg/day). It is derived from the no-observable-effect level observed in the most sensitive animal species, utilising an appropriate safety factor.

2. Active constituent

The substance or substances in a formulated product that are primarily responsible for the biological or other effects that make the product an agricultural or veterinary chemical product.

2.1. Active constituent where a full chemistry assessment is required

A full chemistry assessment is expected to be required for products that contain a new active constituent which meets any of the following criteria:

- active constituent manufactured by chemical synthesis
- highly purified and well-characterised active constituent derived from plants or animals
- semi-synthetic active constituent manufactured by the chemical modification of a highly purified and well-characterised intermediate derived from plants or animals
- semi-synthetic active constituent manufactured by the chemical modification of an intermediate produced by conventional fermentation
- active constituent produced by conventional fermentation or using recombinant DNA technology (excluding most veterinary biologicals)
- active constituent produced by transgenic technology (excluding most veterinary biologicals)
- growth regulators, antibiotics and polypeptides
- some animal tissue extracts and some plant extracts/oils.

2.2. Active constituents in household/industrial chemicals

Certain solvents, surfactants and oils used to dilute or spread other agricultural chemicals, some disinfectants, and biocides used to control moulds and fungi in agriculture, may also be commonly used household or industrial chemicals. If these chemicals are well known, in common use and have a history of safety in the context of use, they may qualify for reduced chemistry assessment.

2.3. Existing active constituent

An active constituent that has been approved by the APVMA or entered into the register of products in Australia.

2.4. New active constituent

An active constituent that has never before been approved by the APVMA or entered into the register of products in Australia.

2.5. New source of (agricultural) active constituent

A new manufacturing source of an approved agricultural active constituent where the source is not currently approved by the APVMA, or

A new manufacturing source of an approved veterinary ectoparasiticide active constituent, for which there is no compendial standard, where the source is not currently approved by the APVMA. Active constituents included in this definition are listed in Chemistry and Manufacture (Part 2) in Volume 3, *Data Requirements and Guidelines*.

3. Acute reference dose (ARfD)

The estimate of the amount of a substance in food or drinking water that can be ingested in one meal or during one day, without appreciable health risk to the consumer, on the basis of all known facts at the time.

The ARfD is expressed as milligrams per kilogram of body weight.

4. Applicant-supplied overseas or health assessment report

The provision of a comprehensive toxicological assessment report on the active constituent, which is of OECD-acceptable quality and dated from 1 July 2005, would enable classification of the application as a Level 3 toxicology assessment. Note that summary reports would not be sufficient to modify the level of assessment required.

5. Biological chemical product

A biological chemical product is one where the active constituent comprises or is derived from a living organism (plant, animal, micro-organism etc), with or without modification.

Biological chemical products may be either agricultural or veterinary chemical products.

6. Biotechnology chemical product

A biotechnology chemical product is one that is developed by means of one of the following biotechnological processes:

- recombinant DNA technology
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells
- hybridoma and monoclonal antibody methods.

7. Closely similar products

Agricultural products

For an agricultural product to be considered closely similar to a reference product:

- i) the active constituent/s must be the same substance/s (the same APVMA-approved active constituent/s) and the concentration of active constituent/s must be the same; and
- ii) other ingredients in the formulation may be different from those in the reference product but must perform similar functions (eg emulsifier, surfactant, dye, solvent etc); and
- iii) the formulation type must be the same; and
- iv) the label must have the same crops/situations and pests (ie no additional uses) and must include similar use and precautionary/safety instructions *.

* There may be fewer or reduced claims compared with the reference product.

Veterinary products

For a veterinary product to be considered closely similar to a reference product:

- i) the active constituent/s must be the same substance/s (the same APVMA-approved active constituent/s) and the concentration of active constituent/s must be the same; and
- ii) the non-active constituents must be the same or equivalent substances at the same or equivalent concentrations *; and
- iii) the product specifications (release and expiry limits and test methods) and physicochemical properties (including pH, particle size and crystal form) must all be the same or equivalent *; and
- iv) the dose form/formulation type must be the same; and
- v) the use pattern (including target animal species, dose rates, route of administration, withholding periods), label claims and label instructions must all be the same **.

* Minor differences in formulation, specifications, and physicochemical properties may be acceptable if they do not have adverse implications for product quality or biological activity such as efficacy, safety or residues. Efficacy/safety/residues data will not be required to demonstrate similarity of the proposed product to the reference product.

** There may be fewer or reduced claims compared with the reference product.

8. CODEX

The Codex Alimentarius Commission (CODEX) was created in 1963 by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) to develop food standards such as MRLs, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of this program are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting co-ordination of all food standards work undertaken by international governmental and non-governmental organisations.

9. Direct-fed microbial

A product that contains viable micro-organisms for oral administration.

10. Enzyme

High molecular weight proteins with catalytic effect, composed of amino acids, produced by living cells. Enzymes may also contain non-protein parts such as carbohydrates, lipids, phosphate groups and metals.

11. Export Interval (EI)

Export intervals are advisory times that should be observed, allowing exporters of food commodities to meet the residues standards of a trading partner. They relate to the time between the last administration or feeding of a chemical product to livestock, or last application to crops, and the slaughter or harvesting of those livestock or crops for export.

The EIs include export slaughter intervals (ESI), export harvest intervals (EHI), export animal feed intervals (EAFI), and export grazing intervals (EGI).

12. Food-producing animal species

Any animal used to produce food for human consumption, or which is used as food for human beings, and includes any buffalo, cattle, deer, fish (other than ornamental fish), goat, kangaroo, pig, poultry, rabbit, sheep, bee, crustacean or mollusc.

13. Fibre-producing animal species

Any animal used to produce fibre (including wool and mohair) for human use.

14. Full assessment

A full assessment of chemistry, toxicology, residues and trade, OHS, environment, efficacy and host crop/animal safety, or special data comprises assessment of data sets that are listed in the corresponding column 2 of the module tables in Volume 3, 'Module levels for modular categories'.

15. Image products

Products containing approved active constituents, where the product is closely similar to an APVMA-registered reference product.

16. Immunobiological chemical product

Products which, when administered to the host, provide, induce or change an immune response to a target chemical or biological entity. Immunobiological products include vaccines, antisera and other immunobiologicals (eg antibodies and cytokines).

New immunobiological veterinary products are generally exempt from requirements for toxicological and OHS assessments except in the case of new adjuvants or other excipients of OHS concern. Aerosolised vaccines may require toxicological and OHS assessment.

Vaccines containing genetically modified organisms require evaluation by the Office of the Gene Technology Regulator (OGTR) and environmental assessment.

17. Limited assessment

A limited assessment of chemistry, toxicology, residues and trade, OHS, environment, efficacy and host crop/animal safety, or special data comprises assessment of data sets that are listed in the corresponding column 2 of the module tables in Volume 3, 'Module levels for modular categories'.

18. Limit of Quantitation (LOQ)

The minimum concentration of analyte in a test sample which can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test.

19. Major change

A change to a registered product or its label that is expected to require data for technical assessment of potential risks to safety of humans, the environment, the host crop/animal, or efficacy, or Australian trade. Technical assessment may be required of data for toxicology, OHS, residues and trade, environment, efficacy or host crop/animal safety.

20. Major food crop

Any crop that is widely consumed in Australia by humans or livestock, and includes:

Crop group	Individual crops
Grasses	Barley, maize, oats, rice, sorghum, triticale, wheat, sugarcane
Citrus fruit	Oranges, mandarins
Pome fruit	Apples, pears
Stone fruit	Apricots, plums, peaches, nectarines, cherries
Berries and other small fruit	Grapes (wine and table), strawberries
Assorted tropical & sub-tropical fruit (inedible peel)	Avocados, bananas, mangoes, pineapples
Bulb vegetables	Onions
Brassica vegetables	Broccoli, cabbages, cauliflowers
Fruiting vegetables (cucurbits)	Melons, pumpkins, cucumbers
Fruiting vegetables (other than cucurbits)	Peppers (capsicums), mushrooms, tomatoes
Leafy vegetables	Lettuce
Legume vegetables and pulses	Beans (French and runner), chick-peas, field peas, green peas, lupins
Root and tuber vegetables	Carrots, potatoes
Stalk and stem vegetables	Asparagus
Tree nuts	Almonds, macadamias
Oilseeds	Cotton, canola, sunflowers
Pastures grown specifically for the purpose of being grazed by, or fed to, livestock	Lucerne, medics, clovers and grasses, whether for grazing or seed crops

21. Major food-producing animal

Cattle, sheep, pigs and chickens are major food-producing animal species.

22. Major formulation change

For the purposes of agency assessment (toxicology, OHS, environment, residues) a major formulation change is a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents, such that safety to humans, the environment and/or target species may need separate assessment. Some examples are:

- where there has been a significant increase in the concentration of active constituent which could affect the hazard potential, poison scheduling, safety directions or residues
- where a major change in non-active constituent significantly affects the performance, stability or other attributes of the product
- where the formulation has been changed significantly to accommodate a new application method/use pattern (eg changing from a wettable powder to an emulsifiable concentrate; changing from an oral drench to a topical pour-on dosage form).

For the purposes of efficacy and safety assessment a major formulation change is a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents, such that efficacy and/or safety to the host crop/animal requires assessment. Some examples are:

- where there has been a significant change in the concentration of active constituent and where the application/dose rate to the crop/animal is changed
- where a major change in non-active constituent significantly affects the performance, stability or other attributes of the product
- where there has been a significant change in product specifications
- where the formulation has been changed significantly to accommodate a new application method/use pattern (eg changing from a wettable powder to an emulsifiable concentrate; changing from an oral drench to a topical pour-on dosage form)
- where the new formulation is not identical, not closely similar, and not similar to a registered reference product.

Major changes in formulation are expected to require assessment under Module 8.1. However, applicants may provide valid scientific argument regarding submission of relevant efficacy/safety data to justify a different level of assessment. For example:

- if the change in formulation is likely to affect only efficacy or safety, then assessment under Module 8.3 could be appropriate
- data to demonstrate comparable efficacy/bioequivalence with the previous formulation could be assessed under Module 8.3.

23. Maximum residue limit (MRL)

The maximum concentration of a chemical residue that is legally permitted in or on a food or food commodity when that chemical is applied according to Good Agricultural Practice or Good Practice in the Use of Veterinary Drugs.

The MRL is expressed in milligrams of the residue per kilogram of the food (mg/kg).

MRLs are gazetted before inclusion in the APVMA's *MRL Standard* and referred to Food Standards Australia New Zealand (FSANZ) for incorporation into Standard 1.4.2 of the Food Standards Code. The Food Standards Code is adopted by various State laws.

The *MRL Standard - Maximum residue limits in food and animal feedstuff* is published by the APVMA and lists the maximum residue limits recommended by the APVMA for agricultural and veterinary chemicals registered for use in Australia. It is available at http://www.apvma.gov.au/residues/mrl_standard.shtml

24. Minor change

A change that is not a major change.

25. Minor food-producing animal

Animal species that are not major food-producing animal species, including buffalo, deer, fish (other than ornamental fish), goat, kangaroo, rabbit, bee, crustacean and mollusc.

26. Non-active constituent (excipient)

Any ingredient other than an active constituent which is part of a formulated product. Non-active constituents are added at the time of manufacture for various reasons, eg to improve formulation characteristics such as stability, solubility and spreadability.

27. Non-major food crop

Any crop that is not a major food crop.

28. Permit

A document issued by the APVMA under section 112 or section 114 of the Agvet Code that allows a person to possess, supply or use a chemical product, which would otherwise be an offence under the Agvet Code.

29. Pest

A pest is defined in the Agvet Code Act as:

- (a) in relation to an animal, plant or thing — any animal, plant or other biological entity that injuriously affects the physical condition, worth, or utility of the first-mentioned animal or plant or of that thing;
- (b) in relation to a place — any animal, plant, or other biological entity that injuriously affects the use or enjoyment of that place.

30. Public Release Summary (PRS)

A published report which summarises the APVMA's evaluation of an agricultural or veterinary chemical product and its proposed determination on safety, efficacy and suitability of the product for registration.

The PRS is released so that members of the public and relevant industry bodies may have an opportunity to raise matters of concern about human, animal and environmental safety, efficacy, and trade before a final decision on registration is made.

31. Reduced assessment

A reduced assessment of chemistry, toxicology, residues and trade, OHS, environment, efficacy and host crop/animal safety, or special data comprises assessment of data sets that are listed in the corresponding column 2 of the module tables in Volume 3, 'Module levels for modular categories'.

32. Reference product

A reference product is a chemical product registered under Part 2 of the Agvet Code, and its approved label, and does not include a product for which the registration has been cancelled.

33. Registered product

A product which is currently registered by the APVMA and has an approved product label.

34. Relevant scientific argument

The APVMA defines relevant scientific argument as:

Relevant:

- related to the active constituent and/or product
- related to the claims and use patterns

Scientific argument includes argument based on:

- accepted scientific principles
- data published in peer-reviewed journals
- relevant texts
- relevant case studies
- relevant clinical studies

35. Repack

A product which is identical in all respects to another registered product except for the product name, product number or registrant details.

36. Similar products

Agricultural products

For an agricultural product to be considered similar to a reference product:

- i) the active constituents must be the same substances (the same APVMA-approved active constituent/s); and
- ii) the formulation type must be the same; and
- iii) the label must have the same crops/situations and pests (ie no additional uses) and must include similar use and precautionary/safety instructions *.

* There may be fewer or reduced claims compared with the reference product.

Veterinary products

For a veterinary product to be considered similar to a reference product:

- i) the active constituent/s must be the same substance/s (the same APVMA-approved active constituent/s) and the concentration of active constituent/s must be the same; and
- ii) the non-active constituents must have similar properties to those in the reference product and be in similar proportions *; and
- iii) the dose form/formulation type must be the same; and
- iv) the use pattern (including target animal species, dose rates, route of administration, withholding periods), and label instructions must all be the same; and
- iv) the label claims must not exceed or be inconsistent with those of the reference product **.

* Data will be required to demonstrate similarity of the proposed product to the reference product.

** There may be fewer or reduced claims compared with the reference product.

37. Stockfood

Includes pasture, forage and fodder crops, silage, hay, straw, chaff, grain, manufactured stockfood and by-products, and other substances intended for feeding to animals, but does not include a stock medicine, a stockfood additive, a stockfood non-active constituent, or a medicated stockfood.

38. Trade Advice Notice (TAN)

A published report with respect to a chemical product proposed for registration, which gives an assessment of the impact of residues of that product on Australia's exports of:

- plant product exports derived from plants treated with the relevant chemical;
- animals and animal products that may contain residues following direct application to an animal; and
- animal products that may contain residues of the chemical following the consumption of stockfood derived from crops treated with the chemical or from stockfood that may have contained residues from spray drift.

The TAN identifies Australia's trading partners for the commodity (by name and by volume); any MRLs or tolerance levels set in these countries for the relevant chemical; and whether scientific data have been assessed to substantiate the LOQ or any proposed export interval. A TAN is made available for public comment, which are considered by the APVMA in deciding whether or not it is satisfied that registration of the chemical product will not unduly prejudice trade.

39. Use pattern

The combination of all factors involved in the use of a formulated product, including the host crop/animal species, concentration of active constituent in the preparation being applied, rate of application, method of application, frequency and duration of treatments, additives recommended and other directions which determine total quantity applied, timing of treatment, restraints and withholding periods.

40. Withholding period

The minimum period that must elapse between the last use of a product in relation to a crop, pasture or animal and the harvesting or cutting of, or the grazing of animals on, the crop or pasture, the shearing or slaughter of the animal, or the collection of milk or eggs from the animal for human consumption, as the case may be, in order to ensure that the product's residues fall to or below the Australian MRL.

Revision history

Revision date	Description of revision
1 July 2005	First edition
1 October 2005	Second edition <ul style="list-style-type: none">additional definitions sourced from Volume 3, Part 5B (Trade).
1 April 2006	Third edition <ul style="list-style-type: none">additional definitions of major and minor food-producing animalsminor change to definition of closely similar veterinary products.
1 July 2007	Fourth edition <ul style="list-style-type: none">LOQ: correct an error in the definition.