



CHEMICALS AND FOOD SAFETY

Before an agricultural or veterinary chemical product can be legally supplied, sold, or used in Australia it must be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The agricultural and veterinary chemicals legislation under which the APVMA operates requires it to be satisfied that when the product is used according to the label directions it will not result in any appreciable risk to:

- consumers
- other persons handling, applying or administering the chemical
- the environment
- target crops or animals; or
- trade in an agricultural commodity.

The APVMA is also required to be satisfied that every product works effectively against the pest(s), disease(s) or condition(s) claimed on the label.

Assessment of agricultural and veterinary chemicals in food to ensure any potential residues are within safe limits is an important part of the regulatory process. There are three main assessment steps:

1. The toxicological evaluation;
2. The Maximum Residue Limit (MRL) evaluation; and
3. The dietary exposure evaluation.

The Toxicological Evaluation

Scientists from the Department of Health and Ageing undertake toxicological evaluations and provide their recommendations to the APVMA. Scientists review results from a wide range of experiments including the effects of short-term, medium-term and long-term dosing studies on animals of various ages, together with studies to determine the potential for formation of tumours, birth defects and effects on genetic material. This information is used to determine:

The No Observable Effect Level (NOEL)

The evaluation of each toxicity study includes the determination of a NOEL—the dose that does not cause any detectable (usually adverse) effect in the test animal. The NOEL used to set the acceptable daily intake for a chemical is generally the NOEL in the most sensitive species of test animal.

The Acceptable Daily Intake (ADI)

The ADI is the amount of chemical that may be consumed every day for an entire lifetime without causing an appreciable risk to health. The ADI is usually calculated by dividing the appropriate NOEL by a safety factor (often 100).

The Acute Reference Dose (ARfD)

The ARfD is an estimate of the maximum amount of a substance in food or drinking water, expressed as milligrams per kilogram of body-weight, that can be ingested in one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of the evaluation. The ARfD is calculated by dividing the appropriate NOEL by a safety factor (usually 100).

The Department of Health and Ageing recommends ARfDs for new chemicals and chemicals being considered in the APVMA's Chemical Review Program.

Health authorities also recommend first aid instructions and warning statements for chemicals, and safety directions for products.

Based on the toxicological evaluation produced by the health authorities, the National Drugs and Poisons Schedule Committee determines the poison schedule classification for the chemical.

Recommendations relating to toxicity and/or occupational health provide for the inclusion of information on the product label that gives instructions on the safe use of the product. These statements include "Poison", "Keep Out of Reach of Children", "do not swallow", "will irritate the eyes" or "if skin contact occurs, remove contaminated clothing and wash skin thoroughly". It is important to note that no agricultural

or veterinary chemical product will be registered if human health and safety concerns identified in the toxicological evaluation cannot be adequately addressed by measures designed to reduce exposure to an acceptable level.

The Maximum Residue Limit (MRL) Evaluation

The Maximum Residue Limit (MRL) is the highest concentration of a residue of a particular chemical that is legally permitted or accepted in a food or animal feed. The concentration is expressed in milligrams of the chemical residue per kilogram (mg/kg) of the commodity.

MRLs are regulatory standards which help to monitor that the product has been used as directed on the approved label. 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 determines an MRL after a comprehensive evaluation of a chemical product's chemistry, metabolism, analytical methodology and residue trial data. When evaluating chemical products, the APVMA uses data from a series of residue trials and calculates whether the application or administration 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.

Based on the residue trial data, the APVMA also sets an appropriate withholding period.

A withholding period is the shortest time that must elapse between the last treatment with a chemical product and the harvest of a crop, or the grazing of a commodity by livestock, or the slaughtering of an animal for human consumption. By observing the withholding period, growers permit the residues in plant or animal commodities to deplete to levels below the MRL.

Dietary Exposure Evaluation

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

The short and long-term dietary exposures to a chemical are estimated by calculating the National Estimated Daily Intake (NEDI) and the National Estimated Short Term Intake (NESTI) respectively. The NEDI and NESTI are calculated using methods that are consistent with those developed and used internationally.

Information used in the calculation of the NEDI and NESTI includes:

- food consumption data from subgroups of the population provided by Food Standards Australia New Zealand (FSANZ);
- all known uses of the chemical concerned;
- expected residue levels in raw commodities; and
- data showing depletion or concentration of residue levels during storage, washing, peeling, cooking and other processing.

The APVMA ensures that MRLs for agricultural and veterinary chemicals are determined at levels that should result in long-term (chronic) human exposures below the ADI, and short-term (acute) human exposures below the ARfD.

Models used to estimate dietary exposure are very conservative and overestimate exposure to chemicals. The best estimates of long-term dietary exposure are based on surveys of foods (such as the Australian Total Diet Survey, previously known as the Market Basket Survey) in retail shops. Such surveys have shown that the actual concentrations of chemical residues in our food are negligible. That is, the exposure is a small fraction of the ADI.

Once an MRL has been determined, the APVMA will do a dietary exposure evaluation which includes using FSANZ's Dietary Modelling of Nutritional Data (DIAMOND). FSANZ then reviews the APVMA's dietary exposure evaluation and once satisfied that any risk to public health and safety is acceptable, FSANZ undertakes public consultation in relation to incorporation of the MRL into the Food Standards Code.

Public Consultation

Before an application for registration of a new agricultural or veterinary chemical product or a major extension of use for an existing product is determined, the APVMA will seek the wider community's involvement through a public consultation process.

During the consultation phase (for a minimum period of 28 days), any person may comment or raise concerns regarding any relevant aspect relating to the intended use of the product including MRLs and dietary exposure.

Following full review of the public comments received, the APVMA will decide to either register the chemical product or subject the application for registration to further review and amendment, or to reject the application.

When the product is registered, the MRLs are notified in the APVMA's Agricultural and Veterinary Chemicals Gazette and entered into the MRL Standard (available on the APVMA website www.apvma.gov.au).

FSANZ's public consultation process is separate to that of the APVMA. However both organisations work together to run both processes in parallel. The FSANZ public consultation process involves consulting with various stakeholders including consumers, primary producers, importers of primary produce and foods, State health departments and the World Trade Organisation and is concerned with the food safety aspects of the use of agricultural and veterinary chemicals.

What Happens After Registration

Once the food safety aspects have been satisfactorily addressed in the consultation process, a recommendation is made to the Australian and New Zealand Food Regulation Ministerial Council (ANZFRMC) for incorporation of the APVMA determined MRLs into Standard 1.4.2 of the Food Standards Code.

Australian States, Territory and Governments have agencies to monitor residues in agricultural produce. The Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) has operated the National Residue Survey (NRS) since 1961 to monitor residues in meat, milk, dairy products, eggs, honey, grains, fruits, nuts, vegetables and seafood.

About 30,000 randomly selected samples are monitored each year for residues of a range of agricultural chemicals, veterinary drugs, stockfeed additives, environmental contaminants and some metals. The sampling methods and large scale sampling numbers make the NRS very effective in revealing any residue problems in the commodities tested.

Residue monitoring is a trade requirement, either mandatory or as an expectation, of importing countries allowing market access to Australian food products. Australia's NRS programs are scrutinised and approved by agricultural authorities in the USA, Canada and the European Union.

The Australian Quarantine and Inspection Service (AQIS), FSANZ, the States and Territories and rural industry groups, conduct other testing of Australian produce. FSANZ is responsible for the Australian Total Diet Survey that estimates the total dietary burden of chemicals and contaminants.

State and Territory surveys tend to focus on targeted sampling of produce with potential residue problems as well as random sampling. Industry groups such as the Australian Wheat Board, Grain Handling Authorities, State dairy marketing bodies, fruit and vegetable market authorities and meat processors also conduct targeted residue testing programs. Retail stores may also require testing of produce for chemical residues as part of Quality Assurance programs.

States and Territories Monitoring

The APVMA enters the MRLs it has determined into the MRL Standard when a chemical product is registered or a permit is approved. There may be a delay before these MRLs are incorporated into the Standard 1.4.2 of the Food Standards Code. The APVMA and FSANZ are working together to streamline this link following a recommendation in the Australian Government's Food Regulation Review.

Agricultural authorities in Queensland, Western Australia, New South Wales (veterinary chemicals), Northern Territory (horticulture), South Australia (permits) and Tasmania (permits) all reference the APVMA's MRL Standard for monitoring the use of agricultural and veterinary chemicals in agricultural produce.

The NSW government conducts trace backs for residue violations above MRL. For these purposes, the NSW agriculture authority uses the APVMA's MRL Standard.

Victoria, Northern Territory (veterinary chemicals), South Australia and Tasmania (registered products) use Standard 1.4.2 of the Food Standards Code for monitoring the use of agricultural and veterinary chemicals.



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State Food Safety Officers all use APVMA determined MRLs that have been incorporated into Standard 1.4.2 of the Food Standards Code for monitoring residue levels in food.

The action level for investigation used by all agricultural authorities except Victoria and NSW is half the MRL. Victoria and NSW use levels greater than the MRL for investigation purposes.

If monitoring reveals a potential residue problem, the source of supply is traced and action is taken to avoid further occurrences. Action may include seizure and disposal of produce, more residue testing at the cost of the producer, quarantining a property (farm) and preventing the sale of produce until the commodity has been found to be safe for consumption and fit for sale in both domestic and export markets. Auditing of users and operators, reseller feedback and implementing industry Codes of Practice are also used to augment residue monitoring.

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