SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

INQUIRY INTO THE
FOOD STANDARDS AUSTRALIA NEW ZEALAND AMENDMENT BILL 2010

ANSWERS TO QUESTIONS ON NOTICE

1. **Please explain what role, if any, the Department of Health and Ageing undertakes with respect to the setting of Maximum Residue Limits for agricultural chemicals.**

The Office of Chemical Safety and Environmental Health (OCSEH), within the Department of Health and Ageing, conducts human health risk assessment of agricultural and veterinary chemicals for the Australian Pesticides and Veterinary Medicines Authority (APVMA). This involves the establishment of Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs). The APVMA considers this, among other matters (including a dietary risk assessment), when establishing a Maximum Residue Limit (MRL). From time to time the OCSEH advises the APVMA on whether a particular MRL is appropriate.

Acceptable Daily Intakes (ADI)
The acceptable daily intake (ADI) for humans is considered to be a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health. The ADI is expressed in milligrams of the chemical per kilogram of body weight per day (mg/kg/day).

To determine an ADI, toxicity studies on animals are assessed to determine the NOEL (No Observable Effect Level), which is the highest administered dose which does not cause any detectable (usually adverse) effect in each study, are carried out. The overall NOEL, is then used to estimate the ADI.

The ADI is calculated by dividing the overall NOEL for the chemical, determined in the most sensitive species from the animal studies, by a safety factor. The magnitude of the safety factor is selected to account for uncertainties in extrapolation of animal data to humans, variation between humans, the completeness of the toxicological data base and the nature of the potential adverse effects.

The most common safety factor used is 100, which takes into account that humans may be 10 times more sensitive to the chemical than experimental animals and that a proportion of the population may be 10 times more sensitive than the average person.

The ADI for a chemical set by OCSEH is considered by the APVMA in setting an MRL for that chemical, but it is only one of the matters considered.

Acute Reference Dose (ARfD)
The Acute Reference Dose (ARfD) is the amount of a substance in food and/or drinking water, normally expressed on a body-weight basis, that can be ingested in a period of 24 hours or less, without appreciable risk to the consumer, The ARfD is expressed as milligrams per kilogram of body weight.

The establishment of an ARfD is normally considered for all chemicals if the toxicity data contains an appropriate toxicology endpoint relevant to acute exposure.

The proposed legislation will not change these established processes.

2. The department has noted in its submission that the proposed legislation will not compromise public health and safety. Please explain to the committee why the department is certain of this and provide any relevant background information that the department has used to come to this conclusion.

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has agreed to the revised arrangements for setting MRLs in the Food Standards Code that will be implemented by the Food Standards Australia New Zealand Amendment Bill 2010 (the FSANZ Amendment Bill).

Public health and safety will not be compromised under the proposed legislation because the legislation does not modify the scientific assessment process upon which a decision to set an MRL is based. Further detail on the protections for public health and safety are outlined below.

1. Under the current arrangements to assess applications or proposals to vary the MRL Standard in the Food Standards Code, FSANZ, in consultation with the APVMA, determines the public health and safety implications of chemical residues through a dietary risk assessment. This involves comparing the dietary exposure with the relevant reference health standard, as established by OCSEH (see answer to question 1 above). The proposed legislation maintains FSANZ's role in conducting the dietary risk assessment. Where FSANZ has agreed for another person or body to undertake the dietary exposure assessment, FSANZ is required to comment on that final assessment., The APVMA must consider FSANZ's assessment, or comments, when approving the registration or permit for use of an agvet chemical (Item 5 of the FSANZ Amendment Bill) and varying the MRL Standard in the Food Standards Code (Item 14, amending Subsection 82(5) of the FSANZ Amendment Bill).
2. The protection of public health and safety is a requirement under the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). In approving the registration or a permit for use of an agvet chemical product, the APVMA must satisfy itself that the approval of an agricultural and veterinary chemical product:

   > (i) would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
   >
   > (ii) would not be likely to have an effect that is harmful to human beings…
   >
   > *(Sections 14(3)(e) and Section 112(2)(f), with reference to registrations and permits respectively.)*

   The protection of public health and safety is also an objective of FSANZ, in developing or reviewing food regulatory measures, as set out in the *Food Standards Australia New Zealand Act 1991*.
3. The Food Standards Code will retain its current structure whereby no chemical residue in food is legal, unless there is a relevant prescribed MRL standard in the Code. MRLs are specific to the chemical product and to the produce on which the product may be used.
4. Under the provisions outlined in Section 95 of the FSANZ Act, FSANZ has the power to make urgent variations to the Food Standards Code for the purposes of protecting public

health and safety. The Ministerial Council also has the power to request a review of any food standard, including the MRL Standard, where the Ministerial Council considers a standard meets one or more of the criteria set out in Paragraph 3(e)(b) of the Food Regulation Agreement. These criteria include that a standard does not protect public health and safety (3(e)(b)(iii).

5. In the more-than-ten years of its operation, FSANZ and the Ministerial Council have never disagreed with an MRL proposed by the APVMA on the basis of public health and safety.