Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2016 – 2017, 19 October 2016

Ref No: SQ16-000753

OUTCOME: 2 – Health Access and Support Services

Topic: Glyphosate MRLs

Type of Question: Written Question on Notice

Senator: Rice, Janet

Question:

In setting MRLs the OECD recommends:

Scientific studies including toxicology, residue, animal transfer, processing and metabolism studies are reviewed in relation to determining MRLs. Data requirements include stringent criteria concerning rigor and independence of studies evaluated in assessments. Dietary exposure assessments conducted in determining MRLs are based on food consumption data for raw commodities derived from individual dietary records from the latest National Nutrition Survey. http://www.oecd.org/env/ehs/pesticides-biocides/45275745.pdf

The food MRLs FSANZ has set for canola and cotton have increased by 10 and 15 times respectively following the introduction of GM glyphosate resistant crops. At the same time, the World Health Organization has come to the conclusion that the evidence is now sufficient to identify glyphosate as a probable carcinogen.

What specific studies were relied on by FSANZ to justify increasing the MRLs on food for canola and cotton?

a) Please table these studies.

b) Please identify which studies addressed toxicology, residue, animal transfer and processing and metabolism.

c) How many of those studies were independent - in other words not conducted by, commissioned by or paid for by industry?

d) In addition to dietary exposure did FSANZ consider the total exposure load of Australian to glyphosate (inhalation, ingestion and skin exposure)?

Answer:

In 2015, the World Health Organization's (WHO's) International Agency for Research on Cancer (IARC) re-classified glyphosate as 'probably carcinogenic to humans' using a hazard based assessment.

In contrast, international regulators including the Australian Pesticides and Veterinary Medicines Authority (APVMA), the national agency for the approval and registration of agricultural chemicals in Australia, use a risk-based approach. The APVMA has undertaken extensive and comprehensive scientific assessment of the issue. Food Standards Australia New Zealand (FSANZ) has also reviewed the MRLs established for glyphosate which may be established for Australian uses approved by the APVMA or harmonisation requests from overseas (imported food).

The APVMA has published a report for public consultation (30 September to 30 December 2016) at http://apvma.gov.au/node/20746. The report concludes that, based on its scientific assessment, glyphosate does not pose a cancer risk to humans. This conclusion is consistent with the 2016 FAO/WHO's Joint Meeting on Pesticide Residues (JMPR) report (available at http://www.who.int/foodsafety/publications/jmpr-reports/en/) which concluded that residues of glyphosate from the uses considered, are unlikely to present a public health concern. The European Food Safety Authority, the European Chemicals Agency, Health Canada, the US Environmental Protection Agency and the New Zealand Environmental Protection Authority have also concluded that glyphosate is unlikely to pose a cancer risk to humans.

MRLs reflect the highest residue that may occur, if the product is used in accordance with the approved label directions. Although dietary exposure is considered when setting MRLs, MRLs are not safety limits. If an MRL is exceeded, it does not normally mean there is a public health or safety concern.

a) FSANZ undertook an assessment of dietary exposure in support of the MRLs on food for canola and cotton using the Health Based Guidance Value that was established by the Department of Health's Office of Chemical Safety. The other glyphosate scientific studies were assessed through the registration processes of the APVMA. A list of some of the glyphosate studies used by the APVMA can be accessed at http://apvma.gov.au/sites/default/files/publication/20701-glyphosate-regulatory-position-report-final.pdf (page 89).

b) About half of the glyphosate studies referenced by the APVMA (link provided above) relate to toxicology, residue, animal transfer and processing and/or metabolism.

c) The scientific journals in which many of the studies are published require independent peer reviews, before articles are accepted for publication. In addition, it is current practice to ask authors/researchers to declare any conflict of interest with regard to funding source and individual interests with studies presented for publication. In addition, proprietary data that have been generated by the sponsor company have to be conducted in accordance with OECD guidelines where appropriate and Good Laboratory Practice to ensure the generation of high quality reliable and reproducible test data.

d) FSANZ only considers the issue of the residues in food, for which inhalation and skin exposure is not relevant. The APVMA has responsibility for considering any issues associated with other routes of exposure. The oral, dermal and inhalational toxicity associated with glyphosate is discussed in the APVMA report referenced above.