MONSANTO

Backgrounder
Glyphosate: No Evidence of Carcinogenicity
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Regulatory authorities and independent experts around the world have reviewed numerous long-term/carcinogenicity and genotoxicity studies and agree that there is no evidence that glyphosate, the active ingredient in Roundup® brand herbicides and other glyphosate-based herbicides, causes cancer, even at very high doses, and that it is not genotoxic.

In 1986, the World Health Organization and Food and Agriculture Organization of the United Nations, in their report on pesticide residues in food stated: "The chronic toxicity of glyphosate is low; the only significant toxicity seen in a number of animal bioassays was mild hepatotoxicity at high doses in mice. There is no evidence of carcinogenicity." and "Glyphosate was without mutagenic activity both in vitro and in vivo."

The Canadian Pest Management Regulatory Agency (Doliner,1991) concluded: "Health and Welfare Canada has reviewed the glyphosate toxicology database, which is considered to be complete. The acute toxicity of glyphosate is very low. The submitted studies contain no evidence that glyphosate causes mutations, birth defects or cancer."

In 1993, the U.S. Environmental Protection Agency (EPA), after reviewing studies conducted for re-registration of glyphosate, stated: "Several chronic toxicity/carcinogenicity studies…resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study" and "Glyphosate does not cause mutations". (U.S. EPA 1993). EPA rates all pesticides according to their potential to cause cancer. In June 1991, EPA placed glyphosate in the agency's lowest cancer classification (Category E) "evidence of non-carcinogenicity for humans -- based on the lack of convincing evidence of carcinogenicity in adequate studies" .

The World Health Organization, in its 1994 review of glyphosate studies, states: "Animal studies show that glyphosate is not carcinogenic, mutagenic…" (WHO 1994)

In 2000, an international panel of toxicology experts published a peer-reviewed assessment of glyphosate studies (Williams *et al.*, 2000). They state: "Multiple lifetime feeding studies have failed to demonstrate any tumorigenic potential for glyphosate. Accordingly, it was concluded that glyphosate is noncarcinogenic.", "No genotoxic activity was observed in standard assays conducted according to international guidelines." and "On the basis of this evaluation, glyphosate does not pose a risk for production of heritable or somatic mutations."

A regulatory review was conducted by the European Commission's Health and Consumer Protection Directorate-General, after which glyphosate was re-registered for use in Europe (European Commission 2002). The EC review, like others around the world, concluded that there was "No evidence of carcinogenicity". and glyphosate is "Not genotoxic"..

In 2004, the World Health Organization and Food and Agriculture Organization of the United Nations, in their report on pesticide residues in food, stated: "Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. In the study of carcinogenicity in mice, no toxic effects were observed at up to the highest dose tested (1000 mg/kg bw per day), and there was

no evidence of carcinogenicity" and "Negative results were obtained in studies performed in compliance with current test guidelines. The Meeting concluded that glyphosate is unlikely to be genotoxic." (WHO/FAO 2004).

In 2012, two genotoxicity experts published a review of genotoxicity publications and regulatory studies (subsequent to the William's *et al*, 2000 review) of glyphosate and glyphosate-based formulations (GBFs) incorporating all of the findings into a weight of evidence for genotoxicity. The authors concluded "An overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and typical GBFs are not genotoxic in these core assays." (Kier and Kirkland, 2012).

Also in 2012 a group of epidemiologic experts reviewed seven cohort studies and fourteen case-control studies examining the association between glyphosate and one or more cancer outcomes. The authors stated: "Our review found no consistent pattern of positive associations indicating a causal relationship between total cancer (in adults or children) or any site-specific cancer and exposure to glyphosate."(Mink *et al*., 2012).

Australian Pesticides and Veterinary Medicines Authority (APVMA, 2013) review of the Earth Open Source report "Roundup and Birth Defects: Is the Public Being Kept in the Dark?"

"The APVMA currently has no data before it suggesting that glyphosate products registered in Australia and used according to label instructions present any unacceptable risks to human health, the environment and trade …" and "The weight and strength of evidence shows that glyphosate is not genotoxic, carcinogenic or neurotoxic."

Glyphosate Reevaluation Assessment Report, Germany Rapporteur Member State for the European Annex I Renewal of Glyphosate (2014) stated:"…glyphosate was considered unlikely to pose a carcinogenic risk in humans …" and "In epidemiological studies in humans, there was no evidence of carcinogencity and there were no effects on fertility, reproduction and development or of neurotoxicity that might be attributed to glyphosate**.**

References [1]

Australian Government, Australian Pesticides and Veterinary Medicines Authority (2013) http://archive.apvma.gov.au/news_media/docs/glyphosate_scitox_review_july_2013.pdf

Doliner LH. (1991) Pre-Harvest use of glyphosate herbicide [Preharvest application of glyphosate (Roundup) herbicide]. Discussion Document D91-01. 98 pp. Pesticide Information Division, Plant Industry Directorate, Agriculture Canada.
European Commission. (2002) Report for the Active Substance Glyphosate, Directive 6511/VI/99, Jan. 21.
http://ec.europa.eu/food/fs/ph_ps/pro/eva/existing/list1_glyphosate_en.pdf

Kier L, Kirkland (2012) Review of genotoxicity studies of glyphosate and glyphosate-based formulations. Crit Rev Toxicol. 2013 Apr;43(4):283-315.
http://www.ncbi.nlm.nih.gov/pubmed/23480780

Mink PJ, Mandel JS, Sceurman BK, Lundin JI. (2012) Epidemiologic studies of glyphosate and cancer: A review. Regulatory Toxicology and Pharmacology 63: 440-452.
http://www.ncbi.nlm.nih.gov/pubmed/22683395

U.S. EPA. (1993) EPA: Glyphosate. EPA-738-F-93-011. U.S. Environmental Protection Agency, Washington, DC. df

[1] All internet links were functional on November 2014.

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Williams GM, Kroes R, Munro IC. (2000) Safety evaluation and risk assessment of the herbicide Roundup® and its active ingredient, glyphosate, for humans. Regulatory Toxicology and Pharmacology 31: 117-165. http://dx.doi.org/10.1006/rtph.1999.1371

WHO/FAO. (1986) Pesticides residues in food – 1986. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR).

http://www.inchem.org/documents/jmpr/jmpmono/v86pr08.htm

WHO. (1994) Glyphosate. Environmental Health Criteria No. 159. World Health Organization, Geneva. http://www.inchem.org/documents/ehc/ehc/ehc159.htm

WHO/FAO. (2004) Pesticides residues in food -- 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR)