

MONSANTO



MONSANTO AUSTRALIA LIMITED  
A.C.N. 006 725 560  
LEVEL 12, 600 ST KILDA ROAD  
MELBOURNE VIC 3004 AUSTRALIA  
PHONE 61 3 9522 7109  
FAX 61 3 9522 6109  
amanda.forster@monsanto.com

Food Standards Australia New Zealand  
PO Box 7186  
CANBERRA BC ACT 2610  
AUSTRALIA

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Dear Sir/Madam

**Re: Request to instigate a change to Standard 1.4.2 – *Maximum Residue Limits***

FSANZ recently advised in a letter to the agricultural biotechnology industry's trade association CropLife Australia, dated 18 February 2011, that MRL amendments to the Food Standards Code will now be considered as a separate process from applications to vary Standard 1.5.2.

Monsanto Australia Limited has recently submitted an application to FSANZ for the inclusion of food derived from MON 87427 Maize with Tissue-Selective Glyphosate Tolerance Facilitating the Production of Hybrid Maize Seed in Standard 1.5.2 – *Food Derived from Gene Technology*.

Currently the MRL set for glyphosate on cereals (including maize) in Australia is 0.1 ppm (parts per million). Residue studies that Monsanto has conducted on grain containing the MON 87427 trait have resulted in some MRLs slightly higher than this. Residues ranged from 0.01-0.13 ppm in MON 87427 x Roundup Ready Corn 2 (Line NK603) grain, and ranged from 0.01-0.20 for MON 87427 x YieldGard VT Rootworm/ Roundup Ready Corn 2 (MON 88017) grain. However, the mean residue level from the samples analyzed for each stack is below 0.1ppm. These hybrids were selected for the residue study because MON 87427 will only be used for the production of viable commercial hybrid corn seed, through the pollination of a MON 87427 female parent inbred with a male parent inbred that has a commercially desirable and approved trait with vegetative and reproductive tolerance to glyphosate. MON 87427 will be combined with other glyphosate-tolerant maize using traditional breeding techniques and will not be released commercially as a single trait.

Monsanto Australia Limited would therefore like to request that FSANZ consider amending Standard 1.4.2 – *Maximum Residue Limits* to raise the MRL tolerance for glyphosate on maize food imports to that which is set out in the Code of Federal Regulations of the United States of

America [40 CFR 180.364(a)(2)]. In the United States, a tolerance for enforcement purposes of 5 ppm has been established for the combined residues of glyphosate and its metabolite N-acetyl-glyphosate (expressed as glyphosate) in or on corn (maize), field, grain. The Codex Alimentarius Commission has also established an MRL, defined for compliance purposes as residues of glyphosate only, of 5 ppm for the same use.

Please note, currently Australia and the United States have different MRL definitions for Glyphosate in maize. The USA definition does not contain aminomethylphosphonic acid (AMPA) because it was determined by the Agency, based on toxicological considerations, that it did not need to be regulated regardless of levels observed in foods or feeds. In addition, as a result of a competitor GM maize product, the metabolite N-acetyl-glyphosate has been added to the USA maize Glyphosate definition for purposes of MRL compliance. Monsanto's MON 87427 does not contain the genetic modification that metabolizes glyphosate to N-acetyl-glyphosate within the plant and we were, therefore, not required to analyse for N-acetyl-Glyphosate in our regulated field residue trials.

Thank you very much for considering this request. Should you require any further information, please do not hesitate to contact me.

Yours sincerely

A handwritten signature in black ink, appearing to read 'A. Forster', with a long horizontal stroke extending to the right.

Amanda Forster  
Regulatory Affairs Manager