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AUSTRALIA NEW ZEALAND FOOD AUTHORITY'S RESPONSE ON FURTHER INFORMATION ON GM SOYBEANS – APPLICATION A338

Glyphosate Tolerant Soybean GTS 40-3-2

In May 2000, Monsanto Australia submitted additional data on application A338 to the Australia New Zealand Food Authority (ANZFA) on the detection of additional DNA in their glyphosate tolerant (Roundup Ready) soybean GTS 40-3-2. The company had detected the additional DNA as a result of their routine quality control program. Roundup Ready soybean was previously approved by ANZFA in 1999 for sale as food in the Australian marketplace. ANZFA's recommendation on this application will be considered by the Australia New Zealand Food Standards Council (ANZFSC) on 28 July 2000. ANZFA scientists conducted a rigorous evaluation of the supplementary data and identified no human health or safety risks. The new information demonstrates that the additional DNA was present in the original seeds approved in 1999 and in all other progeny derived from the original line.

The GTS 40-3-2 soybean line was created through direct DNA transformation by microparticle bombardment of plant cells. The plasmid used for transformation contained the EPSPS encoding gene from the common soil bacterium, *Agrobacterium sp*. CP4. The original molecular analysis of GTS 40-3-2 determined that one functional CP4 - EPSPS expression cassette had integrated into the genome. Recent data submitted in May 2000 revealed that additional DNA sequences are present in GTS 40-3-2. Specifically, a 250 bp segment of CP4 EPSPS DNA located adjacent to the termination element of the previously described EPSPS insert and a second insert comprising a 72 bp segment of CP4 EPSPS DNA were detected. Further analysis demonstrated that only the full length CP4 EPSPS mRNA and protein is expressed in GTS 40-3-2 and that the presence of the two additional DNA sequences does not result in the expression of any RNA or protein. In summary, the newly detected sequences are constituents of the plasmid DNA that was used in the original transformation of the soybean and are not different genes to those originally inserted into the soybean genome.

In addition, the data submitted in May 2000 does not raise any evidence regarding the nutritional quality or the levels of trypsin inhibitor, lectins or isoflavone glucosides because the additional fragments of DNA were present within the soybeans used in all of the original safety testing. Furthermore, the additional data

does not raise concerns regarding the toxicity or potential allergenicity of the soybean because the DNA fragments do not result in the expression of any new proteins.

Based on the additional data supplied on food derived from GTS 40-3-2 by Monsanto in May 2000, ANZFA's review concluded that there are no risks related to human health and safety and the approval status of GTS 40-3-2 remains unchanged.

The assessment process for genetically modified foods set in place by ANZFA under Standard A18 – *Food produced using gene technology* ensures that a full and thorough safety evaluation of all genetically modified food is done. ANZFA looks at the nature of the genes introduced and their function, and whether the genetic modification changes the toxicity, allergenicity or nutritional value of the food. Food producers must provide evidence to show that toxicity and allergenicity risks have not been increased and that the nutritional value of the food has been maintained. Food producers use standard benchmark biological techniques to provide much of the evidence, computer databases to compare new proteins in the foods with known toxins and allergens and, in some cases, animal studies.

The information provided to ANZFA is comprehensive and includes the raw data from every experiment so that ANZFA scientists can undertake an independent evaluation of the application, a practice which is standard for all regulatory agencies, including those dealing with drugs and chemicals. The ANZFA process is at the forefront of international best practice and based on principles developed by the World Health Organisation, the Food and Agriculture Organisation of the UN and the OECD. ANZFA's scientists check the scientific material provided by the companies against the world literature and confer with other experts and other organizations before preparing their assessment report.

Subject to approval by the Ministerial Council, there are no objections to the sale of foods derived from Glyphosate tolerant soybean event 40-3-2 in Australia. ANZFA notes that similar conclusions were determined by Health Canada, the US FDA and the UK Food Standards Agency.

Further information may be obtained from the ANZFA Project Manager, Dr Paul Brent, on (02) 6271 2279.