Survey of GM in Soy-based Infant Formula

Summary

In September 2010, Food Standards Australia New Zealand (FSANZ) initiated an independent analysis of a single brand of soy-based infant formula following consumer concerns and several media reports suggesting the presence of unlabelled genetically modified (GM) ingredients in this product. Six samples of the soy-based infant formula were purchased with each sample analysed by two independent accredited laboratories for GM DNA commonly used in GM plants.

The results of the survey do not allow for any firm conclusions to be drawn. One laboratory did not detect GM DNA in any of the six samples, while the second laboratory detected GM in all samples at very low levels close to the lowest amount that can be measured with accuracy. This variation demonstrated the difficulty in detecting low level GM DNA in foods. While the results of this survey are inconclusive, the levels detected by one laboratory were all below the threshold level of 1% required for mandatory labelling when GM is present unintentionally in food, as outlined in Standard 1.5.2 of the Australia New Zealand Food Standards Code (the Code).

Background

In September 2010, the Australian Government asked FSANZ to consider conducting an independent analysis of a single brand of soy-based infant formula following consumer concerns and several media reports, including reports on testing undertaken by Greenpeace, suggesting the presence of unlabelled GM ingredients in this product. FSANZ was also aware of these concerns and recognising the consumer sensitivities associated with infants and infant formula, determined that it would be in the public interest to conduct a small scale independent survey of this product.

According to Standard 1.5.2 – Food Produced Using Gene Technology, where GM material is present unintentionally up to the level of 1% (per ingredient), foods are exempt from GM labelling. This exemption applies to packaged foods where the manufacturer has actively sought to use non-GM ingredients in their products. When GM material is unintentionally present, it must be a GM food ingredient that is approved for use in Australia and New Zealand. Unapproved GM food ingredients in any quantity is prohibited. Compliance with the Code is a matter for enforcement agencies within the State and Territory Governments of Australia and the New Zealand Government.

The threshold level of 1% of an approved GM ingredient in a product is acknowledgement that a small amount of cross-over between bulk food consignments could reasonably be expected to occur on a regular basis. Thresholds for unintended GM presence exist in many overseas countries where labelling is mandatory, although the levels differ. For example, in the European Union and Japan the levels are set at 0.9% and up to 5% respectively (Agrifood Awareness Australia, 2004; DAFF, 2010; Foster, 2010).

Objectives

The objectives of this survey were:

- to determine the presence of approved GM ingredients in a single brand of soy-based infant formula available in Australia; and
- to assess whether there were any public health and safety risks associated with GM ingredients where levels were detected in soy-based infant formula.

Methodology

In October 2010, six samples of a single major brand of soy-based infant formula, with different 'use by' dates and batch codes, were purchased 'off the shelf' from a number of supermarkets in the Australian Capital Territory.

Advanced Analytical Australia and Dairy Technical Services (DTS) Food Laboratories were engaged to conduct independent duplicative analysis, given the difficulties in analysing and detecting genetic material at very low levels (0.1%). Advanced Analytical Australia received the unopened samples and, prior to analysis, dispatched approximately 100 grams of each sample to DTS Food Laboratories for separate analysis. Each laboratory conducted an independent National Association of Testing Authorities Australia (NATA) accredited GM screen. The laboratories used similar Polymerase Chain Reaction (PCR) methods of analysis, testing for the detection of the 35S promoter and NOS terminator, common DNA elements used in GM plants. Where positive detections were reported by a laboratory, an extended screen was conducted to identify the specific GM event. Samples were analysed as received in the powder form.

Results

A summary of the results obtained by the two laboratories is presented in Table 1. A description of the terms used in the Table is also provided.

Advanced Analytical Australia did not detect the 35S Promoter or the NOS regulatory elements in any of the six samples of soy-based infant formula. The Limit of Detection (LOD[1]) was 0.03-0.08% (Table 1, shaded blue).

Where GM components are detected, further analysis is required to quantify the amounts present. The lowest amount that can be quantified is known as the Limit of Quantification (LOQ[2]). The LOQ of the testing method in this case is 0.1% GM material. Given that there were no detectable GM components present in the infant formula samples tested by Advanced Analytical Australia, no further analysis was necessary.

The results obtained from DTS Food Laboratories detected the 35S and NOS regulatory elements in all six samples of soy-based infant formula (Table 1, shaded purple). Given that all samples tested positive in the qualitative test, DTS Food Laboratories carried out quantitative testing for one particular GM food, known as Roundup Ready™ soybean (line 40-3-2). Two samples returned a positive result at the level of 0.1%; four samples returned a positive result at the level of 0.2%.

Discussion

It is generally accepted that the technical limitations and extreme sensitivity of using PCR methods to analyse for GM material means that both false positive and false negative results are possible. In order to minimise variable results, accredited laboratories use appropriate GM reference material and can adopt practices such as extracting and testing all samples in duplicate, only reporting a detection if the replicates give a consistent result.

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[1] The LOD is the lowest amount that can be detected using a specific testing method, and reflects the technical sensitivity of the method.

[2] The LOQ is the lowest concentration of a chemical that can be detected and quantified with an acceptable degree of certainty, using a specified analytical method and/or item of laboratory equipment.

In this survey, the results obtained by DTS Food Laboratories determined that all six samples provided by FSANZ were positive for the two regulatory elements that are common to GM foods. Subsequent analysis to identify the nature of the GM food indicated that Roundup Ready™ soybean was present in the samples at a level of 0.1 - 0.2%. This level is very close to the lowest amount that can be measured (0.05%) with accuracy, and is well below the threshold level for labelling of GM ingredients of 1% in Australia and New Zealand.

GM soybean varieties, predominantly Roundup Ready™ soy, now account for the majority of the global production of soybean. In 2002, the Food Safety Authority of Ireland reported survey results of soy-based foods on the market in Ireland. The foods involved in this survey included dried soy products, soy dairy alternatives and soy infant formulas. These products were all bought 'off the shelf'. GM soy ingredients were detected in 18 of the 37 samples tested. Of those, 11 contained only trace amounts of GM DNA, which were too low to be quantified. Variety screening identified Roundup Ready™ soy in all but three of the positive samples. Following analysis to quantify the remaining 7 positive samples, the results indicated that all samples were well below the threshold limit in the European Union of 0.9% and thus labelling to indicate GM content was not required (FSAI, 2002).

The safety of Roundup Ready™ soy has been assessed previously (in the year 2000) by FSANZ's predecessor, the Australia New Zealand Food Authority (ANZFA) prior to approval for use in Australia (Application 338). The final assessment concluded that there are no potential public health and safety concerns associated with this product for any population group, including infants, and that food derived from glyphosate tolerant soybean line 40-3-2 can be considered as equivalent to food from conventional soybeans. Roundup Ready™ soy has also been approved for use in Canada, the European Union and the United States.

Soy protein isolate is a significant ingredient in soy-based infant formula products. Where a manufacturer has not sourced non-GM soybean, it is anticipated that analytical testing would show much higher amounts of GM material corresponding to the approved GM crop in the samples. In cases where barely detectable amounts of GM material have been found, it is reasonable to assume that this is consistent with the use of non-GM crops as ingredients.

Conclusion

The results obtained in this survey of a major soy-based infant formula confirm that testing of GM components at or around the limit of detection and quantification can be inconclusive. Due to the lack of consistency between the results of Advanced Analytical Australia and DTS Food Laboratories, the presence of GM ingredients cannot be confirmed or discounted with certainty in any of the six samples of infant formula tested. This result would be consistent with the manufacturer sourcing non-GM soy in the production of soy-based infant formula.

References

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Foster M. (2010) Evidence of price premiums for non-GM grains in world markets. Australian Agricultural and Resource Economics Society (AARES). http://www.abare.gov.au/publications_html/conference/conference_10/AARES_4.pdf . Accessed 23rd December 2010.

Table 1: Analytical results for GM components in a single brand of soy-based infant formula

Sample ID	FSANZ-1	FSANZ-2	FSANZ-3	FSANZ-4	FSANZ-5	FSANZ-6
Laboratory	**ADVANCED ANALYTICAL AUSTRALIA**					
Date of Analysis	20.10.2010					
LOD	Estimated LOD: 0.03-0.08%					
35S Promoter	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
NOS Terminator	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected
Laboratory	**DTS FOOD LABORATORIES**					
Dates of Analysis	28.10.2010 - 5.11.2010					
LOD	Estimated LOD: < 20 copies of target DNA or 0.01% for seed samples					
35S Promoter	Positive	Positive	Positive	Positive	Positive	Positive
NOS Terminator	Positive	Positive	Positive	Positive	Positive	Positive
Qualitative Roundup Ready™Soy	Positive	Positive	Positive	Positive	Positive	Positive
Quantitative Roundup Ready™Soy	GMO = 0.1% (+/-) 0.08% LOQ = 0.05%	GMO = 0.1% (+/-) 0.05% LOQ = 0.05%	GMO = 0.2% (+/-) 0.05% LOQ = 0.05%	GMO = 0.2% (+/-) 0.07%, LOQ = 0.05%	GMO = 0.2% (+/-) 0.05% LOQ = 0.05%	GMO=0.2% (+/-) 0.05% LOQ = 0.05%

LOD = Limit of Detection: the lowest concentration of a chemical that can be qualitatively detected using a specified laboratory method and/or item of laboratory equipment (i.e. GM presence can be detected but is too low to accurately quantify).
LOQ = Limit of Quantification: the lowest concentration of a chemical that can be detected and quantified, with an acceptable degree of certainty, using a specified analytical method and/or item of laboratory equipment.
35S promoter = Cauliflower Mosaic Virus 35S Promoter, a regulatory element commonly used in GM plants.
NOS terminator = 3' region from nopaline synthase gene from *Agrobacterium* spp., commonly used in GM plants.
Roundup Ready™ Soy modification: specific test for glyphosate tolerant soybean (line 40-3-2).