18 May 2010

Project Officer Application A1035
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

FS350-117-1035

Dear Sir/Madam

Application A1035 – Food derived from Insect-protected Soybean Line MON87701 – Assessment Report

Thank you for the opportunity to comment on this application. The New Zealand Food Safety Authority has the following comments to make on Supporting Document 1 – Safety Assessment, for consideration by FSANZ in the preparation of the Approval Report. In our opinion, these issues do not detract from the overall conclusion that food from this genetically modified plant variety is as safe for human consumption as food derived from conventional soybeans.

Genetic modification

Section 3.4.4

The Assessment Report does not address the function (if any) of the soy genomic DNA insertion site. Given that the soy genome has now been fully sequenced, this should be able to be identified, and an assessment made of whether the insertion site was part of a functional gene. If so, then any potential effect of the insertion (and 32 bp deletion and 14 bp insertion) could be further assessed.

Sections 3.4.5 and 3.4.6

The wording in Sections 3.4.5 and 3.4.6 is confusing. The number of ORFs is described as either nine or six. The opening sentence of 3.4.6 talks about the possibility of mutation within a coding sequence, but does not say whether this occurred in the introduced cry1Ac gene, or if the “other 5 reading frames” were naturally occurring.

Novel proteins

The Cry1Ac protein expressed by the gene introduced into MON 87701 is described as being over 99% the same as the bacterial protein. It differs from the bacterial protein by 7 amino acids, though these are not specified. The N-terminal of the protein also has a 4 amino acid sequence added which is derived from the chloroplast-transit-peptide (CTP) from Arabidopsis. The reason for adding the sequence from the CTP is not included in A1035, but A436 included the information that this sequence is included to direct the toxin to the chloroplast, which is generally green leaf tissue and therefore most likely to be subject to insect attack. The amino acid differences between the bacterial and soy expressed proteins are not defined in the draft Assessment Report, nor the reason for adjusting the gene sequence to achieve them (possibly related to improved expression in plant tissues). A341 does include some details of the differences between the bacterial and cotton expressed Cry1Ac proteins, but it is not clear if these differences also apply for A1035.

Sections 4.2. (4.2.1 and 4.2.2.1)

The comparisons made in this section, while probably appropriate in the context of protein analyses, could look highly variable. In particular, the assertions that molecular weight differences of ≤5% (i.e. approximately 5 kDa) and densitometric variability of ±35% are acceptable, should be referenced.

Compositional Analysis

The isoflavones analytical results are more varied than the results for other analytes. The range of results for the isoflavone where a significant difference was found is large (approximately 200-800 mg/kg for daidzein in the GM plant and comparator), and the range for the commercial varieties is 200-1300 mg/kg. The difference found was discounted because the results were still within the commercial variety range. A significant difference was also found for genistein at one field site, which was discounted because the result was still within the 99% commercial tolerance interval of 0 – 1352 mg/kg. Such large tolerance intervals mean that comparisons of isoflavone levels cannot be said to add much weight to demonstrating that there is no difference between the GM plant and conventional counterpart. Instead it could be noted in the Approval Report that either these components vary markedly in their natural levels, or else the analytical method is not precise.

Yours sincerely

Jenny Reid
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Science