6th Dec 2012

Submission: Application A1073 Food derived from herbicide tolerant Soybean DAS-44406-6

I would like to draw attention to, and express concerns about the following aspects of the application:

1. The application "addresses food safety and nutritional issues" but excludes environmental risks or risks related to impacts on food derived from GM plants.

   There may well be secondary (or indirect) health and safety consequences that arise resulting from environmental impacts or through effects on animals. For example, if this product were to have toxicological or immunological effects in livestock, these could have effects on meat for human consumption.

   Health and safety cannot therefore be reliably guaranteed unless environmental are included in assessment

2. Three novel protein are confirmed to be produced as a result of the gene insertion. In addition, 12 "ORFs" are determined from the gene sequences of flanking regions, these may or may no be expressed, the safety of these has been determined theoretically.

   What other DNA regulation effects might occur under a range of different plant and seed conditions?

   Has this work been undertaken and if not, how can the production of allergenic and harmful proteins be excluded under differing environmental conditions.

3. 2m EPSPS and AAD-12 proteins have not been specifically assessed for allergenicity of toxicity. The conclusion of safety has been drawn from the fact that 'similar proteins" do not have these properties.

Minor differences in proteins clearly can significantly alter the potential for toxicity and allergenicity and this should be formally excluded by studies.

4. "Significant differences were noted in a number of constituents". This by itself should warrant further study to determine why there are differences. Instead the document goes on to state that the differences are due to natural variability.

   What evidence is there that this is the case? None is provided in the document. What is the purpose of doing these very preliminary investigations such as compositional analysis, if abnormal results are then dismissed?

   Conversely, it would be quite possible for compositional analysis to be very similar even if the proteins in the material being analysed were different.

   The point being, that compositional analysis only provides a rough guide to equivalence and is not exact. To then get a "significant difference" and conclude that the error is not due to real differences in composition is totally illogical.

5. It is noted that the AAD-12 protein is not identical to the native protein having an additional amino acid, alanine, inserted at position 2. It is quite possible for small changes in proteins to produce significant differences in action. This must warrant further assessment.

6. However, it is then noted that " None of the proteins are produced are produced in sufficient quantities in Soybean 44406 to isolate enough for the toxicological and biochemical studies required for a safety assessment." So these proteins are produced in a different (bacterial) system.
7. The fact that proteins can be different as a consequences of differences in transcription and protein folding that depend on cellular mechanisms in bacterial and plant cells is discussed. Differences are again noted, but what is the significance? The conclusion however is that "Based "weight –for weight" evidence", the proteins are suitable surrogates for use in safety

assessment studies. This is an assumption and one that is contrary to the precautionary principle.

8. No long term safety studies have been performed. Chronic or delayed toxicity will not be detected by the methodology used in this assessment. What are the legal liabilities should long term adverse effects become apparent? Will the Australian tax payer be shielded from these?

9. From the incomplete biological assessment process and the information provided it is difficult to conclude that health soybean DAS-4406-6 is safe for human consumption.

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