Monsanto's risk evaluation would not necessarily have detected unexpected effects caused by the unidentified DNA.

Introduction

The origin of the unidentified DNA in Monsanto's soya is completely unknown: it could be scrambled plant DNA or a large deletion of plant DNA during integration of the insert. It could also be a segment of DNA from an unknown source. It is possible that the unknown DNA has disrupted production of a plant protein or has led to the production of a novel or unexpected protein.

Greenpeace has previously criticised Monsanto's risk evaluation in the application for marketing of Roundup Ready soybeans under 90/220/EEC and the data submitted to the UK Advisory Committee on Novel Foods and Proteins (ACNFP). Many inadequacies were found with the data, including issues such as allergenicity and toxicity that were not dealt with fully.

Possible unintended and unexpected changes caused by the additional DNA inserts

There are several ways in which the additional inserts and the unknown DNA could result in unintended and unexpected changes to the protein chemistry of the plant:

- If the unidentified DNA is scrambled plant DNA or a large deletion of plant DNA, it may have interrupted part of a sequence that codes for one or more plant proteins. This/these protein(s) may no longer be produced by the plant, or may be produced in a modified form.

Most of the data in the field tests in the application for marketing under 90/220/EEC are visual observations made by breeders, which would only detect serious visible unintended effects. No physiological or biochemical parameters were analysed (e.g. nitrogen uptake, photosynthesis rate). Neither the effects of the genetic modification on the whole plant, nor the correct genetic functioning of the plant were assessed. Changes in plant protein production induced by the unidentified DNA may be significant but not immediately obvious and might only appear after several generations. For example, the unidentified DNA could cause non-production or modification of a plant protein produced only in response to environmental stress, such as heat or drought, in order to cope with that stress. In this case, any effects would only be seen under such environmental stress. Indeed, heat stress has been shown to cause stem splitting in GE soya possibly due to increased lignin content, although the exact cause of this is not known[1].

The data submitted to the ACNFP for food safety relied on the concept of "substantial equivalence". The use of substantial equivalence in the regulatory process has been the subject of controversy over the past few years since its introduction[2]. More recently, publication of a comprehensive study by Royal Society of Canada[3] has seriously undermined usage of the concept. The Canadian report states that current regulatory use of substantial equivalence uses a "decision threshold" interpretation. This interpretation assumes that no changes occur in the plant other than those directly attributable to the inserted gene: the food can be considered to be equivalent to its "natural" counterpart after routine chemical analysis, normally only of major constituents and those known to be potentially toxic, e.g. solanines in potato varieties. This is in contrast to a "safety standard" interpretation (recommended by the Royal Society of Canada) which would require rigorous scientific analysis to assess (and possibly attribute) all and each of the effects created by genetic engineering.

In addition, a recent report[4] on the application of "substantial equivalence" stated “An operational definition of substantial equivalence is still lacking. There is for example no minimum list of macro- and micro-nutrients, inherent plant toxins, anti-nutrients, secondary plant metabolites and allergens known to be associated with a crop species, which should be analysed, for the determination of a GM food crop as substantially equivalent. Further, discussions on valid methods to generate compositional data of a GM food crop and its ‘control’ from field trials and on their statistically analysis have not yet been completed by EC scientific committees and competent authorities of EU member states.”

Hence, any changes in protein chemistry that do not lead to immediately apparent or visible changes, but are nonetheless significant, would not have been detected in the original application for marketing and food safety assessment. These assessments would only have detected major differences between modified and unmodified soya in terms of agronomic performance and nutritional analyses. For example, since the food safety assessment, differences in phytoestrogen levels between GE and non GE soya have been found[5] which were not documented in the original food safety assessment.

- The unknown DNA could result in the production of novel proteins. The toxicity and allergenicity of any novel protein would be unknown and untested.

  -The unidentified DNA could itself code for a novel protein. E.g. if the unidentified DNA is from another organism, it could code for a protein not normally present in soya.

  -Together with the additional 250 base pair fragment of the EPSPS gene in the primary insert, the unknown DNA could produce a hybrid protein: part EPSPS and part unknown.

In Monsantos submission to the ACNFP, a technique known as SDS-PAGE (sodium dodecylsulfate -polyacrylamide gel electrophoresis) was used to identify proteins present in the soy. However, this analysis only gives a profile of the proteins present in terms of their molecular weight. It does not identify the proteins present and would only detect gross changes in protein composition.

Therefore, if the unknown DNA causes subtle changes in the protein chemistry of the plant or a novel protein were produced in small or moderate quantities, it would remain undetected. The allergenicity potential of any novel protein would also be completely unknown.

Summary

Any changes to protein chemistry (either modification/loss of a plant protein or production of a novel protein) caused by the presence of the unknown DNA would not have been detected in the original risk evaluation unless they resulted in immediately visible effects or grossly changed the composition of the soybean. Monsanto’s original risk evaluation simply did not look at the physiology and biochemistry of the plant in enough detail to ensure that any unanticipated effects were detected.

Monsanto’s RR soya contravenes EU regulations

Annex IIB of 90/220/EEC specifies information to be submitted in an application for marketing consent. The details required include:

- “copy number of the insert” - It is now known that the RR soya contains additional partial copies of the herbicide tolerance gene and this information was not included in the original risk assessment.

- “Information on the sequences actually inserted/deleted” including “information on any parts of the vector introduced in the genetically modified higher plant or any carrier or foreign DNA remaining in the genetically modified higher plant.” and “in case of deletion, size and function of the deleted region(s)” - Since the unidentified DNA in Monsanto’s RR soya could possibly be part of a large deletion, part of the vector, and the information was not included in the original risk assessment, the GE soya contravenes these regulations.

- “Genetic stability of the insert.”-the presence of unidentified DNA will undoubtedly have an influence of the genetic stability of the insert. This has not been assessed.

- “Information on any toxic or harmful effects on human health and the environment, arising from the genetic modification.” - As incomplete information about the inserts and soya DNA has been given in the original risk assessment, no conclusions can be reached regarding the toxic or harmful effects of RR soya to human health, nor the environment.

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1 Coghlan, A. (1999) Splitting headache. Monsanto’s modified soya beans are cracking up in the heat. New Scientist, 20 Nov. 1999, p. 25.

2 Millstone, E., Brunner, E. & Mayer, S. (1999) Beyond “substantial equivalence”. Nature, 401, 525-526.

3 Royal Society of Canada. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada (2001).

4 Schenkelaars Biotechnology Consultancy (2001) GM food crops and application of substantial equivalence in the European Union, The Netherlands, June 2001.

5 Lappé, M.A., Bailey, E.B., Childress, C.C. & Setchell, K.D.R. (1998/1999), Alterations in Clinically Important Phytoestrogens in Genetically Modified, Herbicide-Tolerant Soybeans. Journal of Medicinal Food, 1, 241-245.