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A1114 – Food derived from Monsanto's High Yield Corn Line MON87403: to seek approval for food derived from a genetically modified corn line MON87403 modified for increased yield for commercial planting purposes and livestock feed and food use.

MON87403 has been genetically engineered for increased ear biomass at an early reproductive phase compared to conventional corn. This alternation is achieved through expression of a truncated ATHB17 (*Arabidopsis thaliana* homeobox-leucine zipper protein 17) transcription factor encoded by the ATHB17 gene from *Arabidopsis thaliana*. When expressed in MON 87403 corn, the ATHB17 transcript is alternatively spliced to produce a variant of the ATHB17 protein lacking the N-terminal 113 amino acids. This variant is designated ATHB17Δ113. Monsanto proposes that ATHB17Δ113 alters the activity of endogenous homeodomain-leucine zipper (HD-Zip) transcription factors that regulate ear growth.

These changes were developed through the use of recombinant DNA technology.[1] It is known that small RNA sequences can alter gene expression, most commonly by silencing genes.[2] While RNA is stable, it survives digestion and can affect gene expression in mammals that ingest it. This change in gene expression can be passed on to future generations. Genetic engineering technologies can introduce new DNA combinations and mutations, which increase the likelihood that harmful regulatory RNA will be accidentally produced.

Roundup Ready soybeans produce unintentional RNA variations. A 'stop' signal is placed after the transgene, telling the cell to stop transcribing at this point. In transgenic soy, the stop is ignored, resulting in longer than intended RNA. It is transcribed from a combination of the transgene, an adjacent transgene fragment and a mutated sequence of DNA. The RNA is further rearranged into four variations, any of which may be harmful. The faulty 'stop' signal may have triggered the rearrangements. The same 'stop' signal is used in other crops, and might lead to similar read-throughs and RNA processing errors.[3]

[1] http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/mon-87403/eng/1413811339739/1413811341270. http://www.biologyreference.com/Po-Re/Recombinant-DNA.html#ixzz3mtToBtll.
[2] http://responsibletechnology.org/gmo-dangers/65-health-risks/2notes
[3] http://theopenscroll.blogspot.co.nz/2012/10/part-6-bioforming-pandemic-is-monsantos.html points 2.8 and 2.9

Numerous studies on transgenic organisms have revealed unintended changes in nutrients, toxins, allergens and small molecule products of metabolism.[4]

These demonstrate the risks associated with unintended changes that occur due to the processes used in genetic engineering technologies. Safety assessments are not adequate to guard against potential health risks associated with these changes

There are potential adverse health effects that can result from the insertion of novel DNA into an organism. Of primary concern are the production of new allergens, increased toxicity, decreased nutrition, and antibiotic resistance.[5]

Not all of the following potential problems can be foreseen or tested for using current testing practices.

Food allergies pose a significant public health threat. If a novel protein present in a transgenic crop has never before been consumed as a human food, this protein could elicit a detrimental response from the immune system or display toxicity.

There is concern that inserting a gene/s into a plant, foreign or otherwise, could cause it to produce toxins at higher levels that could be dangerous to humans. If other genes in the plant become altered as a result of insertional mutagenesis, the production of toxins can also result.[4] The inserted DNA construct can interfere with the metabolic pathway, causing a the plant to produce more and possibly new toxic compounds as a result.

A transgenic plant can be of lower nutritional quality than its traditional counterpart, thereby providing fewer nutrients, or possibly producing some compounds that are anti-nutrients.[6] A 2012 nutritional analysis of transgenic and conventional corn has shown substantial differences in the nutritional content of the two types of corn. Conventional corn contains 437 times more calcium, 56 times more magnesium, and 7 times more manganese than transgenic corn.[7]

Transgenic corn also contained 13 ppm of glyphosate, compared to zero in conventional corn. The EPA standard for glyphosate in US water supplies is 0.7 ppm, and organ damage in animals has occurred at levels as low as 0.1 ppm. Transgenic corn contains extremely high levels of formaldehyde - about 200 times the amount found toxic to animals.[8]

There is also concern that bacteria living in human or animal guts could take up the antibiotic-resistance gene that is present in the GE DNA construct.

Peer-reviewed studies have found harmful effects on the health of laboratory and livestock animals fed with transgenic crops. These include toxic and allergenic effects and altered nutritional values.[4]

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[4] Domingo, JL (2007). Toxicity studies of genetically modified plants: a review of the published literature. *Crit Rev Food Sci Nutr* 47:721-733
[5] 'Clinical and Laboratory Investigation of Allergy to Genetically Modified Foods'. Bernstein et al, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241560/pdf/ehp0111-001114.pdf
[6] Prescott, VE, Campbell, PM, Moore, A et al (2005). Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity. *J Agric Food Chem* 53:9023-9030
[7] http://www.momsacrossamerica.com/stunning_corn_comparison_gmo_versus_non_gmo
[8] See http://earthopensource.org/index.php/reports/58 and http://www.momsacrossamerica.com/stunning_corn_comparison_gmo_versus_non_gmo

Long-term and multi-generational studies are needed on transgenic crops used for food. These should be mandatory to establish changes that suggest harmful health effects and to see if these will develop into serious diseases, premature death, or reproductive or developmental effects. Such studies are not currently required by any regulatory agency.

FSANZ has conducted a "thorough safety assessment on the application, which included comparing the GM corn with a non-GM corn from a molecular, toxicological and nutritional point of view."[9] However, such an assessment has not tested the GM corn in question as a food. Without comprehensive animal feeding test data, food safety cannot be guaranteed.

Corn is used in a wide range of processed foods and food products. It is a significant source of nutritionally important amino acids, methionine and cysteine, carotenoids, and vitamin E. Corn is fed to cattle, poultry, and swine, as intact or processed grain or as dry or wet milling by-products. Corn silage is fed primarily to ruminants. Monsanto has concluded MON 87403 corn, and the foods and feeds derived from it, are as safe as conventional corn varieties and are not materially different in composition or any other relevant parameter from other corn varieties despite the obvious changes detailed above.

Any unforeseen adverse effects of GE corn (and other GE crops) may be cumulative and, as with many pharmaceutical drugs, take decades to become apparent.

In the past, it has been thought that genes were shared only between individual members of a species through reproduction. Geneticists have usually followed the inheritance of genes in what they call a 'vertical' fashion, such as breeding a male and female, following the offspring and continuing from there. Today, we recognize that genes are also shared among members of different species by means of horizontal gene transfer (HGT).[10]

Recent advances have revealed that organisms can share their genes and researchers have found sufficient evidence that meal-derived DNA fragments carry complete genes capable of entering into the bloodstream through an unknown mechanism.[11] In one such blood sample study, the relative concentration of plant DNA was higher than that of human DNA.[12]

The long-term effects of genetically engineered food crops on the human population are still unclear and need to be studied further.[12]

Our bloodstream is considered to be an environment well separated from the outside world and the digestive tract. According to the standard paradigm, large macromolecules consumed with food cannot pass directly to the circulatory system. During digestion, proteins and DNA are thought to be degraded into small constituents, amino acids and nucleic acids respectively. They are then absorbed by a complex active process and distributed to various parts of the body through the circulation system. Analysis of over 1000 human samples from four independent studies showed evidence that meal-derived DNA fragments large enough to carry complete genes can avoid degradation and enter the bloodstream through an unknown mechanism. In one blood sample the relative concentration of plant DNA was higher than that of the human DNA. The plant DNA concentration showed a surprisingly precise log-normal distribution in the plasma samples while a non-plasma (cord blood) control sample was found to be free of plant DNA.[12]

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[9] http://news.agropages.com/News/NewsDetail---15876.htm
[10] Heinemann, JA (1991). Genetics of gene transfer between species. *Trends in Genetics* 7:181-185
[11] 'Confirmed: DNA From Genetically Modified Crops Can Be Transferred Into Humans Who Eat Them', 9 January 2014, Arjun Walia, http://www.collective-evolution.com/2014/01/09/confirmed-dna-from-genetically-modified-crops-can-be-transfered-to-humans-who-eat-them-2/
[12] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0069805

Current biotech science assumes that genes are inherited in the same way when moved by vertical or horizontal gene transfer. Scientific evidence to date shows that the effects of transgenes in food crops needs much more rigorous research before we can assume their safety for consumption.

"One small mutation in a human being can determine so much, the point is when you move a gene, one gene, one tiny gene out of an organism into a different one you completely change its context. There is no way to predict how it's going to behave and what the outcome will be. It is clear that DNA from food can and does end up in animal tissues and the milk products that people eat."[13]

Studies also show that when humans or animals digest transgenes, the artificially created genes transfer into and alter the character of the beneficial bacteria in the intestine. Researchers report that microbes found in the small bowel of people with an ilestomy are capable of acquiring and harbouring DNA sequences from transgenic plants.[14]

It is normal for factory-farmed animals to have a diet that consists entirely of GE crops. Studies have linked transgenic animal feed to severe stomach inflammation and enlarged uteri in pigs.[4]

The World Health Organisation says gene transfer and the movement of genes from transgenic plants into conventional crops or related species may have an effect on food safety and food security. The consequences of such gene transfer are already apparent with widespread contamination of conventional crops with GE transgenes.

PSGR urges FSANZ to reject Application A1112 in the interests of public health and safety.

Jean Anderson
on behalf of
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[13] http://www.food.gov.uk/policy-advice/gm/gmanimal#.UsxuFPbXFGH; http://www.mindfully.org/GE/2004/Transgenes-Human-Gut1feb04.htm

[14] Nat Biotechnol. 2004 Feb;22(2):204-9. Epub 2004 Jan 18. 'Assessing the survival of transgenic plant DNA in the human gastrointestinal tract', Netherwood et al.

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