

# **PUBLIC COMMENTS ON MON531**

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**Organisation: None**  
**City: 57002 STOCKARYD**  
**Country: Sweden**

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**a. Assessment:**  
**3. Environmental risk assessment**

The monoculture that GMO-crops is a part of is direct toxic to the biodiversity in the nature. By permitting this you will most probably be responsible for a mass death of insects, and as an effect of that, other animals. The biodiversity will be seriously disturbed, maybe irreparable.

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**4. Conclusions and recommendations**

Do not approve this GMO cotton. It will destroy the nature.

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**Organisation: Förbundet Sveriges Småbrukare (ass for small farmers in Sweden**  
**City: 38891 vassmolosa**  
**Country: Sweden**

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**a. Assessment:**  
**3. Environmental risk assessment**

The recent decision from the European Court that GMO pollen in honey needs to be regulated has serious implications for beekeepers around the world. It is absolutely necessary that the pollen in genetically modified cotton MON531 (and all other GMO crops) is tested for its food safety. This is necessary in all countries where this cotton is grown in order to ensure that beekeepers around the world are able to maintain the important pollination services that their bees provide and that honey continues to be a healthy food product that consumers will buy. The spread of GM modified cotton genes to their wild relatives (study published in October edition of Molecular Ecology) and the risk of horizontal gene transfer to the lactic bacteria in the honey stomach of bees and to the bacteria in the gut of animals needs to be studied to ensure that bees and other animals are not harmed by Bt GMO crops. More research is required to understand how these crops can affect the animals that consume them,

the environment and the essential ecosystem services such as pollination upon which we humans are dependent.

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#### **4. Conclusions and recommendations**

The precautionary principle should be applied and no GMO crops should be grown or, in the name of solidarity, imported until these risks are properly studied.

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#### **6. Labelling proposal**

If approval is given, despite the risks outlined above, then feed and food products, as well as products from animals fed such feed should be labelled

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**Organisation: MTVSZ / Friends of the Earth Hungary**

**City: H-1091 Budapest**

**Country: Hungary**

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##### **a. Assessment:**

##### **Molecular characterisation**

We object the use of the npt-II ARM gene in these GM seeds, because of the danger of developing antibiotic resistance (Wögerbauer M. (2007). Risk Assessment of Antibiotic Resistance Marker Genes in Genetically Modified Organisms, BMGFJ – Forschungsberichte der Sektion IV, Band 5/2007). According to WHO (Critically important antibacterials for human medicine for risk management - Categorization for the Development of Risk Management Strategies to contain Antimicrobial Resistance due to Non-Human Antimicrobial Use, Department of food safety, zoonoses and foodborne diseases: 34. [http://www.who.int/foodborne\\_disease/resistance/antimicrobials\\_human.pdf](http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf)) and EMEA kanamycin and neomycin are categorised as highly important antibiotics to cure multi-resistant tuberculosis (MTB), a disease which is on the increase all over the World.

Article 4 of Directive 2001/18/EC indicates the will of the Member States and the Commission to phase out of the use of antibiotic resistance transgenes from GM crops without any further specification relating to the type of AR gene, or specifying any exemptions, therefore without discrimination.

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**Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)**

We object the choice of comparator for establishing the existence of any toxic, allergenic or other harmful effects of MON 513 on human or animal health arising from the GM food/feed. For all experiments the only proper comparator in this case is the non-GM parent line Coker 312 used for the gene transfer. The use of any other commercial lines cannot be scientifically justified.

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**b. Food Safety Assessment:  
Toxicology**

The safety evaluation of recombinant proteins, as well as the protein degradation test by stimulated gastric and intestinal fluids in vitro, were performed with bacterial recombinant proteins instead of the ones isolated from the GM plants. This is not acceptable.

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**Allergenicity**

There are indications in the scientific literature that some of the Cry genes might be allergenic, immunogenic, able to survive digestion by the gut and get into systemic circulation of the consumer (Aris, A. & Leblanc, S. (2010) Maternal and fetal exposure to pesticides associated to genecally modified foods in Eastern Township of Quebeck, Canada. *Reproductive Toxicology* 31: 528-533). Therefore, it would be very important to take MON 531 cotton out of the food and feed chain as soon as possible.

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**Nutritional assessment**

During processing the seeds are destroyed and their transgenic DNA is freed and easily available for the bacteria living in the alimentary canal or for host cells. This way the chance of horizontal gene transfer into the gut bacteria of humans (Netherwood, T. (2004) Assessing the survival of transgenic plant DNA in the human gastrointestinal tract. *Nature Biotechnology*, 22, 204-209) and animals, – especially with ruminants - (Chowdhury, EH., et al (2003) Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11. *Journal of Animal Science* 81, 2546-2551.) cannot be excluded and the risks of horizontal gene transfer is very real.

Nutritional equivalence needs to be established and not assumed.

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**Others**

It needs to be established by measurements if there were detectable levels of GM proteins present or not in highly processed foods. It is not enough to presume only that highly processed foods do not contain detectable levels of the GM protein.

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### **3. Environmental risk assessment**

Bacteria are capable of absorbing plants genes generally and are capable of exchanging genetic material directly between each other (even across species boundaries) via bacterial plasmids. Therefore the spread of npt-II resistance cannot be ignored in the bacterial population (Heinemann, J. A. (1999). How antibiotics cause antibiotic resistance. *Drug Discov. Today* 4, 72-79, and Heinemann, J. A., Ankenbauer, R. G. and Amábile-Cuevas, C. F. (2000). Do antibiotics maintain antibiotic resistance? *Drug Discov. Today* 5, 195-204.).

According to general observation, during transport and processing there are always live plant cells and plant parts (seeds) which get in the soil, making gene transfer to soil bacteria easy.

Cotton is a weak competitor in the wild, and cannot survive outside cultivation. However, during transport and processing the small GM cotton seeds can easily escape into the environment and develop to GM plants able to pass on their genetic materials via pollen or seeds. There are parts of Europe where cotton can be grown at present, and with global warming and hot, long summers other parts of Europe, such as Hungary might become suitable for the growth of escaped GM cotton seeds. Although Point 4(c) of the dossier issues an assurance that GM cotton cannot survive outside cultivation, the same assurance was given for maize as well as for canola. Both plants have been found in the wild growing without cultivation (Shafer, MG, Ross, AA, Lonto, PP, Burdick, CA, Lee, EH, Travers, SE, Van de Water, PK and Sagers, CL. (2011) *Plos One* 6: e25736).

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### **4. Conclusions and recommendations**

We do not support the continued marketing of foods and food ingredients, food additives, feed material and feed additives produced from MON 531 cotton. We would prefer to apply the precautionary principle in case of the MON 531 cotton. There is still scientific uncertainty considering its safety as human food and animal feed, as well as a source of genetic contamination for the environment.

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