

# Soybean DAS 81419-2

---

---

**Organisation: Astma och allergiföreningen**

**Country: Sweden**

**Type: Individual**

---

**a. Assessment:**

**Molecular characterisation**

Because I am a diabetic, have about 40 food allergies, gluten and lactosis intolerance, I do eat a lot of vegetables. I have not eaten red meat for 4 about years. And besides, some years ago the WHO told the world about how dangerous the red meat is, how eating it means a 18 percents risk of cancer. Since the soy bean has everything the meat has, I have to enjoy it really often, like many times a week. The GM bean is a big health risk for all of us, specially for all with certain allergies, and for all of us who do not eat red meat.

---

**Allergenicity**

All GM products are a risk for those with food and other allergies.

---

**3. Environmental risk assessment**

Besides, keeping cows really pollutes the air so much.

---

---

**Organisation: NONE**

**Country: Sweden**

**Type: Individual**

---

**a. Assessment:**

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

I don't want GMO products to exist anywhere at any time. This is not making The world and the environment any better. It' S The opposite.This is all about making money for large corporations. You don't have to be scientist to figur that out. What happens to The environment when you spray toxic stuff on your GMO products? What do you think happens to The birds and The bees? We are Killing our selves with this shit.

---

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

Don't use GMO products! Please

---

**Organisation: My own**  
**Country: Sweden**  
**Type: Others...**

---

**a. Assessment:**  
**Others**

No GMO:s in EU or on earth for that matter.

---

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

Yes of course.

---

**Organisation: myself**  
**Country: Sweden**  
**Type: Others...**

---

**a. Assessment:  
Molecular characterisation**

I am scared to death in this matter. I am a very allergic person and must think of everything I put in my mouth. If I don't know what is in the food I am eating I can be very sick. I have to prepare all my foods myself. What if you alter the food, what if I can't eat anything in the future?

Why do I have this food allergy? Probably because we are doing things to our food that is not natural, our body can't coop with it. I do not dare to eat any soya now a day.

---

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

I am scared to death in this matter. I am a very allergic person and must think of everything I put in my mouth. If I don't know what is in the food I am eating I can be very sick. I have to prepare all my foods myself. What if you alter the food, what if I can't eat anything in the future?

Why do I have this food allergy? Probably because we are doing things to our food that is not natural, our body can't coop with it. I do not dare to eat any soya now a day.

---

**b. Food Safety Assessment:  
Toxicology**

I am scared to death in this matter. I am a very allergic person and must think of everything I put in my mouth. If I don't know what is in the food I am eating I can be very sick. I have to prepare all my foods myself. What if you alter the food, what if I can't eat anything in the future?

Why do I have this food allergy? Probably because we are doing things to our food that is not natural, our body can't coop with it. I do not dare to eat any soya now a day.

---

**Allergenicity**

I am scared to death in this matter. I am a very allergic person and must think of everything I put in my mouth. If I don't know what is in the food I am eating I can be very sick. I have to prepare all my foods myself. What if you alter the food, what if I can't eat anything in the future?

Why do I have this food allergy? Probably because we are doing things to our food that is not natural, our body can't coop with it. I do not dare to eat any soya now a day.

---

### **Nutritional assessment**

I am scared to death in this matter. I am a very allergic person and must think of everything I put in my mouth. If I don't know what is in the food I am eating I can be very sick. I have to prepare all my foods myself. What if you alter the food, what if I can't eat anything in the future?

Why do I have this food allergy? Probably because we are doing things to our food that is not natural, our body can't coop with it. I do not dare to eat any soya now a day.

---

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

If we grow this things are going to be spread to other plants and we probably get a lot of allergic people that can't eat anything. You can't have this plant separated from the nature.

---

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

If we grow this things are going to be spread to other plants and we probably get a lot of allergic people that can't eat anything. You can't have this plant separated from the nature.

---

### **5. Others**

If we grow this things are going to be spread to other plants and we probably get a lot of allergic people that can't eat anything. You can't have this plant separated from the nature.

---

### **6. Labelling proposal**

Please don't alter what nature givs us.

---

---

**Organisation: Ramedco ab**  
**Country: Sweden**  
**Type: Others...**

---

**a. Assessment:**  
**Molecular characterisation**

well done.

---

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

well done.

---

**b. Food Safety Assessment:**  
**Toxicology**

well done.

---

**Allergenicity**

well done.

---

**Nutritional assessment**

well done.

---

**4. Conclusions and recommendations**

All the assessments have been done very well. But it concerns only a part of the seed. I want to have long term investigation on the final product. That is how it impacts rats after 200 days to 3 generations. Also how the increase use of the chemicals influences the soil, the ground

water and the insects. Ref for studies <http://www.nature.com/nbt/journal/v25/n9/full/nbt0907-981.html> <http://www.gmoseralini.org/ten-things-you-need-to-know-about-the-seralini-study/>

---

---

**Organisation: None**

**Country: Sweden**

**Type: Individual**

---

**a. Assessment:**

**Nutritional assessment**

EU foods should focus on how to make more organic foods available for all its members. There is a reason why EU citizens are living a more healthy life than other part of the world. I know its mostly beacuse of the good kind of food we have. Please consider this very careful.

---

**3. Environmental risk assessment**

The GMO seeds are known for spreading very quickly and uncontrollably. That is a major risk for contamination of other crops.

---

**4. Conclusions and recommendations**

Labelling is the most important thing the gouvernement can do if they intruduce GMO foods to the country. It's up to every individual to make up her mind on consuming GMO foods. We all shall have the rights to know whats in our food. Right to a correct label.

---

**5. Others**

P

---

## **6. Labelling proposal**

A very clear label with the sign "GMO". No one should be felt cheated. The sign should be very obvious for all the people in different ages and reading capacity.

---

---

**Organisation: Testbiotech**

**Country: Germany**

**Type: Non Profit Organisation**

---

### **a. Assessment:**

#### **Molecular characterisation**

There are unintended structural changes in the genome: One of the gene constructs responsible for the production of the Bt toxin shows rearrangements. An additional short fragment is inserted and the genome of the soybean shows a deletion of 59 bp. There are 9 new open reading frames (ORF) in the flanking regions and several hundred ORFs within the gene constructs inserted (FSANZ 2014). Gene products from the additional open reading frames were assessed in regard to translation into potential proteins. But no assessment was made of any other gene products such as miRNA. Thus, uncertainties remain about other biologically active substances emerging from the method of genetic engineering.

The additional DNA added to the sequences of the Cry1Ac and Cry1F DNA is not meant to change its toxicity, but nevertheless the biological functions of the proteins might be changed. Further, compared to their native templates, the toxins in the plant are truncated and activated. But the protein assessment carried out by EFSA does not address these details.

The expression of the toxin was only measured under field conditions in the US. It is unclear to which extent specific environmental conditions can influence the overall concentration of the toxins in the plants. The plants should have been subjected to a much broader range of environmental conditions to obtain reliable data on gene expression and functional genetic stability. Environmental stress can also cause unexpected patterns of expression in the newly introduced DNA (see Trtikova et al., 2015).

In addition, more varieties should have been included into the field trials since it is known that the genetic background of the varieties can influence the level of gene expression (see Trtikova et al., 2015).

Further, all parts of the plants should be taken into account for risk assessment. Expression data have to be considered as one of the starting points in the risk assessment of the plant, so the assessment of the data cannot be reduced to those parts of the plants entering the food chain.

FSANZ (2014) Food derived from Insect-protected Soybean Line DAS-81419-2. Food Standards Australia New Zealand.  
<http://www.foodstandards.gov.au/code/applications/Pages/A1087-Food-derived-from-Insect-protected-Soybean-Line-DAS-81419-2.aspx>

Trtikova, M., Wikmark, O.G., Zemp, N., Widmer, A., Hilbeck, A. (2015) Transgene expression and Bt protein content in transgenic Bt maize (MON810) under optimal and stressful environmental conditions. *PLoS one*, 10(4): e0123011.

---

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

The significant changes observed were set aside without more detailed investigations of underlying mechanisms, evaluation of tendencies in the data and more targeted experiments (see comments from experts of the Member States). No data from Omics (proteomics, transcriptomics, metabolomics) were used to assist the compositional analysis and the assessment of the phenotypical changes. The additional reference varieties used for the statistical assessment were chosen without sufficient reasoning. Consequently, it cannot be ruled out that data noise may be masking biologically relevant effects. As a result, the comparative analysis suffers from many uncertainties and remains inconclusive.

There are further flaws in the generation of the data:

Despite South America being one of the most important regions for the production of soybeans, no data have been requested from environments representing these regions.

No data representing more extreme environmental conditions, such as those caused by climate change, were generated. In addition, more varieties should have been included into the field trials to see how the gene constructs interact with the genetic background of the plants.

Furthermore, data from soybeans sprayed with the complementary herbicide should have been requested. While Dow Agro Sciences claims that they will not encourage farmers to spray glufosinate during cultivation, there is no reason why farmers in North and South America should not apply glufosinate in response to aggravated pressure from glyphosate-resistant weeds. Thus, it has to be expected that the imported soybeans will to a great extent contain residues from spraying, and might show changes in composition due to the application of the herbicide.

Finally, the choice of the components used for the assessment followed an outdated version of OECD Guidelines from 2001 instead of those from 2012.

Based on the available data, no final conclusions can be drawn on changes in the composition of the plants.

---



## **b. Food Safety Assessment: Toxicology**

There are several gaps in the risk assessment:

Despite it being known that Bt toxins can cause effects in several different ways, only one mode of action was considered (for overview: Hilbeck & Otto, 2015).

Despite it being known that Bt toxins can show synergies with each other and as well as with other compounds, no detailed investigation of combinatorial effects were conducted (for overview: Then, 2010).

There are no reliable data to assess the exposure of the food chain to Bt toxins. Soybeans can be processed in a broad range of products by using various methods for heating, germinating etc.

Interaction with plant components (such as protease inhibitors) that can delay the degradation of the Bt toxins, were not taken into account (Pardo-López et al., 2009).

No testing of the whole plant (feeding studies) was requested even though there were still several uncertainties after the comparative assessment and the molecular analysis.

As a result, the toxicological assessment carried out by EFSA is not acceptable.

Hilbeck A. & Otto M. (2015) Specificity and Combinatorial Effects of Bacillus Thuringiensis Cry Toxins in the Context of GMO Environmental Risk Assessment, *Frontiers in Environmental Science*, 3: 71.

Pardo-López, L., Muñoz-Garay, C., Porta, H., Rodríguez-Almazán, C., Soberón, M., Bravo, (2009) Strategies to improve the insecticidal activity of Cry toxins from Bacillus thuringiensis. *Peptides*, 30(3): 589–595.

Then, C. (2010) Risk assessment of toxins derived from Bacillus thuringiensis - synergism, efficacy, and selectivity. *Environ Sci Pollut Res Int*, 17(3): 791-797.

---

## **Allergenicity**

There are several relevant issues regarding allergenicity and the immune system that were left aside in EFSA risk assessment.

A range of studies found indications of adjuvant effects triggered by Bt toxins. EFSA simply referred to its earlier opinion on genetically engineered cotton 281-24-236 x 3006-201-23. This opinion from 2010 only mentions two older studies and does not take more recent findings into account (for overview see: Rubio-Infante N. & Moreno-Fierros L., 2015). Further, compared to cotton, soybeans show a much higher content of potentially allergenic proteins. Therefore, adjuvant effects have to be considered much more carefully.

The sera samples used for assessment are very low in number and there are substantial uncertainties about the outcome (see, for example, the comment made by a Expert from Belgium to EFSA).

The assessment did not take into account the risk to more vulnerable groups of people, such as infants.

Rubio-Infante N. & Moreno-Fierros L. (2015) An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals, *J. Appl. Toxicol.*, DOI 10.1002/jat.3252  
Then, C. (2010) Risk assessment of toxins derived from *Bacillus thuringiensis* - synergism, efficacy, and selectivity. *Environ Sci Pollut Res Int*, 17(3): 791-797.

---

## **Others**

Monitoring should be case specific. Exact data on exposure to the soybean should be made available. Possible health impacts have to be monitored in detail. Controls regarding residues from spraying with glufosinate have to be established. Accumulated effects that might stem from mixtures with other genetically engineered plants have to be taken into account in the monitoring plan.

---

## **4. Conclusions and recommendations**

The risk assessment undertaken by EFSA should not be accepted. It does not identify knowledge gaps or uncertainties and fails to assess toxicity, impact on the immune system and the reproductive system. The monitoring plan has to be rejected because it will not make the necessary data available.

---