



# **GMO-Approval by the EU-Commission is not in line with the Precautionary Principle**

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## Argumentation 1: Common sense



Up till now scientist do only know how to shoot  
a synthetic gene into a plant.

They do not know how to remove a synthetic  
gene from a plant.

Every error in the risk assessment of GMOs is  
persisting several generations (at least).



i.e. Errors in the risk assessment are  
not allowed

But ...



# Mistakes in risk assessment are inevitable

## DDT

1940

Authorization (before 1948)

- insect resistance (1947)

1950

- DDT in mother's milk (1950)

- Bioconcentration in tissue  
and food chain (1951)

1960

1970

1980

1990

- Authorization revoked  
(1992)

2000

- hormonal effects (1995)

2010

2020

## Methyl Bromide

- Authorization (1965)

- human toxicity (1976)

- Destruction of  
ozone layer (1994)

1998: Production  
stopped (2005)  
2005: 30% von 1991

## Vinclozolin

- Authorization (1984)

- hormonal effects  
(1994)

- Authorization  
revoked (2004)



- As long as scientist do not know how to remove a synthetic gene from a plant
- The approval of GMOs is incompatible with the precautionary principle



## Argumentation 2: ***detailed analyses***



## Legal requirements for the safety assessment of GMOs

- ***EU-Directive 2001/18/EC***
  - ***Decision 2002/623/EG Risk assessment principles***
- ***Regulation (EC) Nr. 1829/2003 (GM Food Feed)***
- ***Regulation (EC) Nr. 178/2002 European Food Safety***



## EU Regulation 178/2002 Article 14

- *In determining whether any food is injurious to health, regard shall be had:*
- *(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also*
- *on subsequent generations;*
- *(b) to the probable cumulative toxic effects*





# EFSA methods

Method	Comment
<ul style="list-style-type: none"> <li>Comparative chemical analyses of protein, amino acid content, ash content etc.</li> </ul>	<ul style="list-style-type: none"> <li>No scientific basis of how to translate results into human toxicity assessment</li> </ul>
<ul style="list-style-type: none"> <li>Sequence Analyses</li> </ul>	<ul style="list-style-type: none"> <li>Almost identical sequences can show differences in function monkey/human DNA</li> </ul>
<ul style="list-style-type: none"> <li>28 days study with the protein</li> </ul>	<ul style="list-style-type: none"> <li>Short term toxic studies are useless, and must be avoided from terms of animal rights</li> </ul>
<ul style="list-style-type: none"> <li>Comparative 90 day study with rats ( NK603 and Mon863 but not in GT73)</li> </ul>	<ul style="list-style-type: none"> <li>Subchronic study, not able to extrapolate to chronic effects (cancerogenicity, immuno toxicity)</li> </ul>



## EFSA ignores Legal requirements

- **NO assessment of long term risks (730 days -Test)**
- **NO assessment of risks on future generations**
- **NO assessment of cumulative toxic effects**



EFSA ignores first early warnings



## EFSA phrases on statistical significant differences between GMO and Non-GMO plants

### phrases

### source

1. Minor differences in some plant constituents are **not considered to be biologically significant**
2. slight increase of lymphocyte counts, slight decrease in kidney weights are **not considered to be meaningful**
3. Lower incidence of mineralized kidney tubules **are not considered as concern.**
4. Reported findings are **considered as incidental and not treatment related**

Mon 863 (Monsanto)  
EFSA Journal 2004,  
50:1-25





## EFSA phrases on statistical significant differences between GMO and Non-GMO plants

### phrases

### source

**1. Altered level of linolenic acid is considered as not biologically significant, greater differences between GT73 and Westar but without statistical analyses**

**Rape GT 73** (Monsanto)  
EFSA Journal 2004, 29:1-19

- 1. no consistent differences,**
- 2. no biological significance,**
- 3. artifactual differences** of corbuscular haemoglobin values (90 days feeding study)
- 4. No conclusive** differences of chemical constituents

**Maize NK 603**  
(Monsanto) EFSA Journal 2003, 9:1-14





EFSA is always in line with the  
argumentation of the Biotech-industry  
Legal requirements such as long term  
tests are ignored by EFSA



## Wording from Monsanto and EFSA e.g. NK603

Data interpretation of	Judgement by <b>Monsanto</b>	Judgement by <b>EFSA</b>
observed differences found in the subchronic 90 days toxicity study	<b>absence of biologically relevant differences</b>	<b>"The applicant concludes that these findings are of no biological significance. The panel accepts this as a reasonable interpretation of the data."</b>
safety claims of CP4 EPSPS-Protein	the <b>long history</b> of safe consumption of similar proteins	humans have a <b>long history</b> of dietary exposure to the protein. No adverse effects associated with its intake have been identified.



- This is not the type of an independent risk assessment.
- Moreover EFSA-Panel Members has given statements on the Food safety of GMOs in promotional videos from the Biotech-industry. (see FOE -Report "Throwing Caution to the Wind")
- The lack of consumer trust into the European Food Safety Policy is clearly linked to the lack of taking consumers interests before Biotech-industry interests



## Further Legal Requirements not addressed by EFSA

„Description of uncertainties  
e.g. assumptions made in the risk assessment, and of  
the known limits of mitigation measures“

EG decision 2002/623

EFSA does not address scientific  
uncertainty in any of its opinions







# Scientific uncertainties on the effects of synthetic DNA/RNA on the human immune system





- We eat thousand of genes.
- The DNA form the Transgene is the same as the DNA of normal plants.
- DNA from a transgene is not a risk

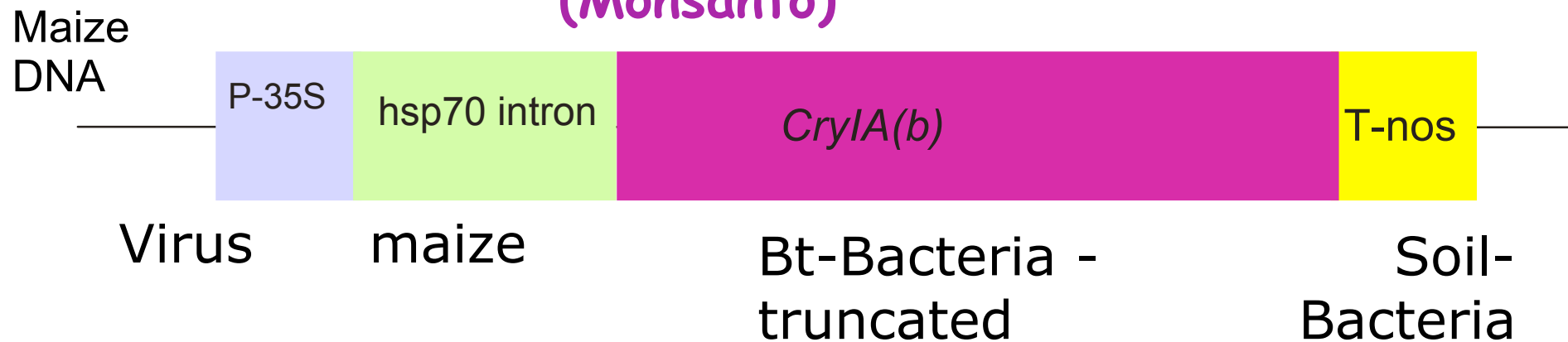
Effects of synthetic DNA from transgenes are not addressed during the risk assessment by EFSA.  
Although:





## Synthetic Gene – new to the human immune system

### Mon810 maize- *YieldGard™* (Monsanto)



→

Synthetic Gene = man made gene  
no naturally living organism has such genes



# Synthetic genes causes unintended effects on the genome

CHARACTERISATION OF COMMERCIAL GMO INSERTS: A SOURCE OF USEFUL MATERIAL TO STUDY GENOME FLUIDITY.



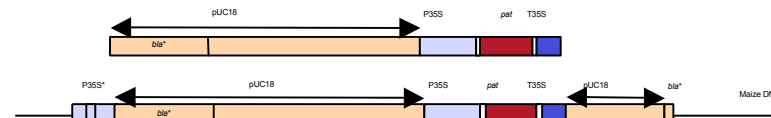
## T25 maize - Libertylink™ (Bayer)

Tolerance to herbicide glufosinate, Peg-mediated transformation

Construct content : truncated *bla* gene (*bla*\*), pUC cloning vector (pUC), synthetic *pat* gene (*pat*), CaMV 35S promoter and terminator (P35S, T35S).

Sequence expected  
(public data)

Sequence observed



(Presence of cloning vector + the 5' first bp of *bla* on the 3' end)

→ DNA rearrangement: presence of a second truncated and rearranged P35S on the 5' end.  
Insertion site: the 5' and 3' ends of the insert show homologies with Huck retrotransposons.

(Collonnier et al. (2003) Eur. Food Res. Tech. (submitted))

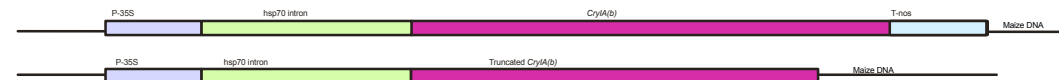
## Mon810 maize - YieldGard™ (Monsanto)

Resistance to lepidopteran insects, Bt-barbaricum

Construct content : CaMV 35S promoter (P35S), *CryIA(b)* toxin synthetic gene (*CryIA(b)*), nos terminator (T-nos).

Sequence expected

Sequence observed



DNA rearrangement: deletion of T-nos in the insert (but Tnos detected in the genome) and deletion of a part of *CryIA(b)*.

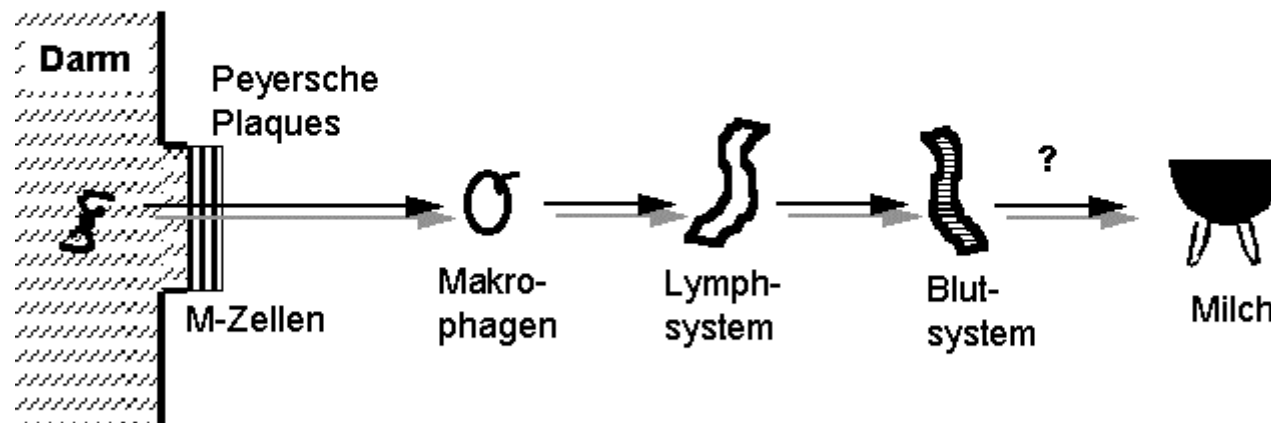
(Hernandez et al. (2003) Transgenic Res. 12: 179-189; Holck et al. (2002) Eur. Food Res. Tech. 214: 449-453)

Insertion site: the 5' end of the insert shows homology with LTR sequences of the *Z. mays* alpha Zein gene cluster. No homology between LTR sequences and the 3' end: rearrangement of the integration site.



Food-DNA has been detected in lymphocytes, blood, kidney, liver, spleen, muscles and even milk (Einspanier 2001, 2004, Mazza et al 2005, ...)

Potentielle Resorption von Nahrungs-DNA im Darm der Säugetiere



**GALT**: gut associated lymphoid tissue  
(Darm-assoziertes Lymphsystem)





## Food-DNA **interacts** directly with the immune system

- The protective **effects** of probiotics **are mediated by their own DNA** rather than by their metabolites or ability to colonize the colon
  - Rachmilewitz et al: Gastroenterology 2004 Feb;126(2):520-8





## Summary: Food-DNA **and** immune system

- Synthetic and conventional Food-DNA survives the gastro intestinal tract and can be detected in the blood
- Food-DNA has effects on the immune system
- The underlying mechanism are currently not known
- The propability the synthetic DNA from transgenic plants interacts with the immune system are high



EFSA refusal to address risk from Food-DNA to the immune system is not based on sound science



"While the duty of preventing damage to the environment is based on a known risk, the notion of precaution is based on lack of certainty." (OECD 2001)

Due to the lack of long term tests and major uncertainties

**The approval of GMOs is in contraticition to the  
Precautionary Principle of directive  
2001/18 and regulation 178/2002 und  
1829/2003**





- There has been a lot activities
  - Report from Friends of the Earth  
“Throwing caution to the wind”  
([www.foeeurope.org](http://www.foeeurope.org))
  - Letters and Consultations (National Member states, Friends of the Earth/GLOBAL2000, GREENPEACE)

But at the end still:  
All EFSA opinions are in favour of the Biotech industry



The next step

To safe human health

To restore cosumer trust in EU-Food safety policy  
des Konsumenten und zum

**To launch a case against EFSA opinions  
at the European Court of Justice by one  
ore more member states**







## scientific findings in 2005

- **Synthetische DNA from Biotech maize detected in the blood**
  - **Mazza R, Soave M, Morlacchini M, Piva G, Marocco A (2005)**  
**Assessing the transfer of genetically modified DNA from feed to animal tissues. Transgenic Research 14: 775-784.**
- **GM pea causes allergic reaction with unknown mechanism**
  - **Prescott VE, Campbell PM, Moore A, Mattes J, Rothenberg ME, Foster PS, Higgins TJV and Hogan SP (2005).**  
**Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity. Journal of Agricultural and Food Chemistry 53:9023-30.**





## scientific findings in 2005

- **Unknown RNA sequences has been detected in the Roundup-Ready Soybean**
  - **Rang A, Linke B, Jansen B (2005) Detection of RNA variants transcribed from the transgene in Roundup Ready soybean. European Food Research and Technology 220 (3 - 4): 438-443.**



## scientific findings in 2005

- **The increasing complexity of the genome**

- Carninci P, Kasukawa T, Katayama S, Gough J, Frith MC, Maeda N, Oyama R, Ravasi T, Lenhard B, Wells C, Kodzius R, Shimokawa K, Bajic VB, Brenner SE, Batalov S, Forrest AR, Zavolan M, Davis MJ, Wilming LG, Aidinis V, Allen JE, Ambesi-Impiombato A, Apweiler R, Aturaliya RN, Bailey TL, Bansal M, Baxter L, Beisel KW, Bersano T, Bono H, Chalk AM, Chiu KP, Choudhary V, Christoffels A, Clutterbuck DR, Crowe ML, Dalla E, Dalrymple BP, de Bono B, Della Gatta G, di Bernardo D, Down T, Engstrom P, Fagiolini M, Faulkner G, Fletcher CF, Fukushima T, Furuno M, Futaki S, Gariboldi M, Georgii-Hemming P, Gingeras TR, Gojobori T, Green RE, Gustincich S, Harbers M, Hayashi Y, Hensch TK, Hirokawa N, Hill D, Huminiecki L, Iacono M, Ikeo K, Iwama A, Ishikawa T, Jakt M, Kanapin A, Katoh M, Kawasaki Y, Kelso J, Kitamura H, Kitano H, Kollias G, Krishnan SP, Kruger A, Kummerfeld SK, Kurochkin IV, Lareau LF, Lazarevic D, Lipovich L, Liu J, Liuni S, McWilliam S, Madan Babu M, Madera M, Marchionni L, Matsuda H, Matsuzawa S, Miki H, Mignone F, Miyake S, Morris K, Mottagui-Tabar S, Mulder N, Nakano N, Nakauchi H, Ng P, Nilsson R, Nishiguchi S, Nishikawa S, Nori F, Ohara O, Okazaki Y, Orlando V, Pang KC, Pavan WJ, Pavesi G, Pesole G, Petrovsky N, Piazza S, Reed J, Reid JF, Ring BZ, Ringwald M, Rost B, Ruan Y, Salzberg SL, Sandelin A, Schneider C, Schonbach C, Sekiguchi K, Semple CA, Seno S, Sessa L, Sheng Y, Shibata Y, Shimada H, Shimada K, Silva D, Sinclair B, Sperling S, Stupka E, Sugiura K, Sultana R, Takenaka Y, Taki K, Tammoja K, Tan SL, Tang S, Taylor MS, Tegner J, Teichmann SA, Ueda HR, van Nimwegen E, Verardo R, Wei CL, Yagi K, Yamanishi H, Zabarovskiy E, Zhu S, Zimmer A, Hide W, Bult C, Grimmond SM, Teasdale RD, Liu ET, Brusic V, Quackenbush J, Wahlestedt C, Mattick JS, Hume DA, Kai C, Sasaki D, Tomaru Y, Fukuda S, Kanamori-Katayama M, Suzuki M, Aoki J, Arakawa T, Iida J, Imamura K, Itoh M, Kato T, Kawaji H, Kawagashira N, Kawashima T, Kojima M, Kondo S, Konno H, Nakano K, Ninomiya N, Nishio T, Okada M, Plessy C, Shibata K,

Shiraki T, Suzuki S, Tagami M, Waki K, Watahiki A, Okamura-Oho Y, Suzuki H, Kawai J, Hayashizaki Y; **FANTOM**

**Consortium; RIKEN Genome Exploration Research Group and Genome Science Group (Genome Network Project Core Group) (2005) The transcriptional landscape of the mammalian genome. Science. 2005 Sep 2;309(5740):1559-63.**