

# Soybean MON 87708 x MON 89788

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**Organisation: GeneWatch UK**

**Country: United Kingdom**

**Type: Non Profit Organisation**

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

For the information on expression of the inserts, plants were grown at eight locations (four replicate blocks each) under field conditions in 2009 in the USA. Gene-environment interactions can affect food safety but the crops studied were grown only in the US, not in other potential export markets i.e. South America, so the analysis is incomplete. The potential production of novel dsRNA should also have been investigated.

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

Based on the agronomic and phenotypic characteristics of soybean MON 87708 × MON 89788 under the tested conditions (treated and not treated with both intended herbicides), differences (non-equivalence) in some fatty acids and in trypsin inhibitor were observed in soybean MON 87708 × MON 89788 compared with its non-GM comparator. It is unclear why these differences were assumed to have no relevance to food safety or nutrition. These potential impacts of these differences should have been investigated further.

Again, field sites were limited to eight sites within the soybean cultivation areas in the USA, which is insufficient to examine gene-environment interactions, which were identified as of importance to many of the endpoints.

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

### **Toxicology**

Studies of the combined effects of the two herbicide residues have been omitted, as discussed further below.

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### **Nutritional assessment**

The risk assessment wrongly states that the nutritional characteristics of soybean MON 87708 × MON 89788-derived food and feed are not expected to differ from those of conventional soybean varieties, when in fact significant differences were detected in fatty acid composition during the compositional analysis. The impacts of these differences should have been assessed.

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## Others

The two-event stack GM soybean MON 87708 × MON 89788 was produced by conventional crossing of two GM crops to produce soybean tolerant to dicamba (3,6-dichloro-methoxy-benzoic acid) and glyphosate (N-(phosphonomethyl)glycine)-based herbicides. A major area of public interest will be the presence of residues of dicamba and glyphosate and their metabolites on the crop entering the food chain, due to blanket spraying of the plants. Impacts on human and animal health due to these changes in management must be considered in the risk assessment according to Directive 2001/18/EC. The assessment completely omits this aspect of the analysis. From a food safety perspective, this means that the increased levels of dicamba- and glyphosate-based herbicides on the GM herbicide-tolerant soybean product being considered for approval have not been assessed.

Dicamba-tolerance is achieved by the expression of dicamba mono-oxygenase (DMO) proteins, which demethylates dicamba, producing 3,6-dichlorosalicylic acid and formaldehyde. However, information about the impacts of formaldehyde have been omitted, although it is a known carcinogen, implicated in some food safety alerts (e.g. <http://www.foodsafetynews.com/2013/09/formaldehyde-detected-in-supermarket-fish-imported-from-asia/#.Unu3I-K7R0M> ).

For 3,6-dichlorosalicylic acid and dicamba residues, EFSA refers to the expertise of the EFSA Pesticides Unit in setting acceptable daily intakes (ADIs) and Maximum Residue Levels (MRLs). The Pesticides Unit has published a "Reasoned opinion on the modification of the MRL for dicamba in genetically modified soybean" (EFSA Journal 2013;11(10):3440) which states that "since the relevant component of the residues in dicamba-tolerant soybean was identified as the metabolite 3,6-dichlorosalicylic acid (DCSA) while dicamba was not detected at harvest, EFSA proposed to set a specific import tolerance of 0.4 mg/kg for the metabolite DCSA in soybean, and not to change the current MRL of 0.05\* mg/kg set for dicamba". However, there are numerous gaps in information and thus little data to support the ADIs or how the relationship between the ADIs and MRLs has been set, especially as the metabolism pattern of the active substance in genetically modified plants was shown to be different and the available data did not allow EFSA to conclude whether dicamba and DCSA act through the same toxicological mode of action. Another metabolite, DCGA, was identified but there was insufficient toxicological data to set a specific ADI.

For glyphosate, a recent IARC publication identifies glyphosate as a probable human carcinogen (Guyton, K. Z., Loomis, D., Grosse, Y., El Ghissassi, F., Benbrahim-Tallaa, L., Guha, N., Scoccianti, C., Mattock, H., Straif, K. (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. International Agency for Research on Cancer). This evidence was not taken into account when EFSA assessed MON 89788. EFSA cannot therefore rely on that earlier assessment. There is also evidence that glyphosate-based herbicides may be endocrine disruptors (e.g. Romano, R. M., Romano, M. A., Bernardi, M. M., Furtado, P. V., & Oliveira, C. A. (2010). Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology. *Archives of Toxicology*, 84(4), 309–317. <http://doi.org/10.1007/s00204-009-0494-z> ). Glyphosate residues are known to accumulate in glyphosate-tolerant soybeans (Bøhn, T., Cuhra, M., Traavik, T., Sanden, M., Fagan, J., & Primicerio, R. (2014). Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans. *Food Chemistry*, 153, 207–215. doi:10.1016/j.foodchem.2013.12.054). In addition the effects of

adjuvants should have been considered. Many toxicological studies conducted with human, mouse and rat cells confirm findings from aquatic non-target organisms which suggest that looking at the effects of glyphosate alone is insufficient for a comprehensive assessment of the cultivation of glyphosate on human health (e.g. Young, F., Ho, D., Glynn, D., Edwards, V. (2015). Endocrine disruption and cytotoxicity of glyphosate and roundup in human Jar cells in vitro. Integrative Pharmacology, Toxicology and Genotoxicology. Vol. 1(1): 12-19. doi: 10.15761/IPTG.1000104. ).

Furthermore, for the stacked trait MON 87708 × MON 89788 the combined residues of glyphosate-based and dicamba-based herbicide residues on human and animal health have not been considered, including potential synergistic effects. This is a very significant omission from the Opinion.

No information has been provided on how compliance with MRLs can be maintained over time as weeds will inevitably develop resistance to both glyphosate and dicamba (Mortensen, D. A., Egan, J. F., Maxwell, B. D., Ryan, M. R., & Smith, R. G. (2012). Navigating a Critical Juncture for Sustainable Weed Management. BioScience, 62(1), 75–84. doi:10.1525/bio.2012.62.1.12). In addition, no data has been provided regarding the potential use of other herbicides (especially as resistance develops) or the effects of consuming mixtures of the product with other products (such as RoundUp Ready soybeans).

No information was provided in the framework of this application on the effect of processing on the nature of dicamba or glyphosate residues.

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

The risk assessment is incomplete and inadequate to support approval of the product.

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#### **5. Others**

If the product were to be approved, extensive monitoring of herbicide residues (including metabolites) would be needed. However, it is unclear how this would be done in practice.

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**Organisation: The European GMO-free Citizens**

**Country: The Netherlands**

**Type: Others...**

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

see 5

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**Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)**  
see 5

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**b. Food Safety Assessment:**  
**Toxicology**  
see 5

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**Allergenicity**  
see 5

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**Nutritional assessment**  
see 5

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**Others**  
see 5

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**3. Environmental risk assessment**  
see 5

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

On 14 July, a new scientific study was published which shows that genetically modified (GM) soya accumulates formaldehyde and contains considerably less glutathione. Formaldehyde is carcinogenic and glutathione is an antioxidant; antioxidants are needed for cell detoxification. The natural breakdown of formaldehyde in cells is also blocked.

This accumulation of formaldehyde could perhaps be characteristic of GM crops and definitively puts an end to the equivalence principle, on the basis of which GM crops have been authorised.

As the press release states, the results indicate that further research is needed.

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#### **5. Others**

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific  
WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class 1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (<http://www.integrativesystems.org/systems-biology-of-gmos/>). Contact Information: Nathan Nye: [nnye@fenton.com](mailto:nnye@fenton.com) (<http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com>), (910)876-2601; Alison Channon: [achannon@fenton.com](mailto:achannon@fenton.com) (<http://www.prnewswire.com/news-releases/mailto:achannon@fenton.com>), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: <http://www.prnewswire.com/news-releases/systems-biology-group-international->

center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

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## **6. Labelling proposal**

Do not authorise. More research needed.

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**Organisation: The European GMO-free Citizens**

**Country: The Netherlands**

**Type: Others...**

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### **a. Assessment:**

#### **Molecular characterisation**

This is supplementary information.

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

#### **Toxicology**

[http://articles.mercola.com/sites/articles/archive/2015/07/05/glyphosate-cancer.aspx?e\\_cid=20150705Z2\\_DNL\\_art\\_1&utm\\_source=dnl&utm\\_medium=email&utm\\_content=art1&utm\\_campaign=20150705Z2&et\\_cid=DM78981&et\\_rid=1017974367](http://articles.mercola.com/sites/articles/archive/2015/07/05/glyphosate-cancer.aspx?e_cid=20150705Z2_DNL_art_1&utm_source=dnl&utm_medium=email&utm_content=art1&utm_campaign=20150705Z2&et_cid=DM78981&et_rid=1017974367)  
Researcher Reveals Monsanto Has Known Since 1981 That Glyphosate Promotes Cancer  
[http://mercola.fileburst.com/PDF/ExpertInterviewTranscripts/Anthony\\_Samsel-May2015\\_transcript1.pdf](http://mercola.fileburst.com/PDF/ExpertInterviewTranscripts/Anthony_Samsel-May2015_transcript1.pdf) Institute of Science In Society Report 24/03/15 Glyphosate 'Probably Carcinogenic to Humans' Latest WHO Assessment [http://www.issis.org.uk/Glyphosate\\_Probably\\_Carcinogenic\\_to\\_Humans.php](http://www.issis.org.uk/Glyphosate_Probably_Carcinogenic_to_Humans.php) July 05, 2015 Dicamba is one of the PAN Bad Actors are chemicals that are one or more of the following: highly acutely

toxic, cholinesterase inhibitor, known/probable carcinogen, known groundwater pollutant or known reproductive or developmental toxicant.

[http://www.pesticideinfo.org/Detail\\_Chemical.jsp?Rec\\_Id=PC32871](http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC32871) Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

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systems biology approach." The full study can be read here (<http://www.integrativesystems.org/systems-biology-of-gmos/>). Contact Information: Nathan Nye: [nnye@fenton.com](mailto:nnye@fenton.com) (<http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com>), (910)876-2601; Alison Channon: [achannon@fenton.com](mailto:achannon@fenton.com) (<http://www.prnewswire.com/news-releases/mailto:achannon@fenton.com>), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: <http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde--disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html> Check the box to include the list of links referenced in the article.

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### **Allergenicity**

Unfortunately the US framework for regulating GE crops like Dicamba Soy is broken. As the USDA considers legalizing GE crops, it only asks whether or not the crop poses the risk to other plants, but not farmers. more <http://grtv.ca/2012/12/monsantos-latest-poison-dangers-dicamba>

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### **Nutritional assessment**

Animal products, such as milk, meat or eggs, from livestock fed GM plants, do not have to be labelled. Many producers exploit this and give preference to GM feed. By doing so, they promote the cultivation of GM crops in the USA and Latin America, where fatal effects have already been observed. For example, the cultivation of GM plants which are resistant to certain insecticides has resulted in more and more pesticides being used. According to research by the US agronomist, Charles Benbrook, pesticide use in the USA increased by 63 000 tonnes between the beginning of the 1996 growing season and 2004. Furthermore, farmers are compelled to use increasingly toxic pesticides, such as 2.4-D and Dicamba. Greenpeace rejects GM plants on account of the dangers they entail. Most recently, on 22 June 2005, the environmental organisation published documents, confidential up to that point, from the genetic engineering company Monsanto, on tests on rats using GM maize. The rats showed signs of damage to health after being fed with Monsanto's GM maize, MON 863, which produces an insecticide. They suffered damage to their internal organs and to their blood count. As a rule, documents on risk assessments for GM plants are kept secret by the companies involved. Greenpeace persuaded the Higher Administrative Court in Münster that the Monsanto report should be released.

[http://presseservice.pressrelations.de/standard/result\\_main.cfm?aktion=jour\\_pm&r=196470&quelle=0&pfach=1&n\\_firmanr\\_=101150&sektor=pm&detail=1](http://presseservice.pressrelations.de/standard/result_main.cfm?aktion=jour_pm&r=196470&quelle=0&pfach=1&n_firmanr_=101150&sektor=pm&detail=1) Fragment

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### **Others**

As a legal dossier compiled by Professor Ludwig Kraemer shows, EU regulations require the monitoring of effects on health at the stage of consumption. Directive 2001/18 and Regulation 1829/2003 both require that potential adverse effects on human health from genetically modified plants are monitored during use and consumption stage. Therefore, EFSA's opinion that monitoring the effects on health is unnecessary contradicts current EU regulations.

References Kraemer, L. (2012) The consumption of genetically modified plants and the



potential presence of herbicide residues, legal dossier compiled on behalf of Testbiotech, [http://www.testbiotech.de/sites/default/files/Legal\\_Dossier\\_Kraemer\\_Pesticide\\_RA\\_PMP.pdf](http://www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf)

Amsterdam, 7 March 2000

In your dreams

There have been a lot of reports, articles and letters in the media recently on the subject of the genetic modification of food crops in particular.

Both those in favour (such as the US Ambassador) and those against (such as Greenpeace) have had something to say.

Phrases like 'twisting the facts' are bandied around willy-nilly but what facts are being twisted in NOT stated. This takes the place of any explanation of the advantages or analysis of the criticisms of the advantages claimed, or any critical appreciation of the disadvantages.

This is also a sign of the public relations adage that '.. if the interests at stake and thus the available PR budget are big enough, any untruth you want can ultimately be made acceptable. Do the government and the other parties involved sufficiently understand this advertising aspect of paid repetition?', as Dr Paul E. Metz asks in the 'Chemisch Weekblad' of 26 February 2015. We see advocates endlessly repeating certain 'arguments'.

We would like to set down a couple of these 'arguments' and take a critical look at them.

- Genetic modification can (sic!) can make a valuable contribution to the world food problem. Our criticism of this: how that might happen is never explained. It is just taken for granted that listeners will accept it as fact (if you give the matter any consideration, you will not know how, either!). It has always been claimed that herbicide and insecticide-resistant crops will produce higher yields, but this has never been demonstrated conclusively. The corn borer causes a 4% world-wide harvest loss (joint Commodity Boards, March 1999), but that is not something you want to shout from the rooftops.

Herbicide-resistant crops are just another way of keeping weeds at bay. In comparison with alternatives their ability to increase yields is illusory. The alternatives are perhaps more expensive in terms of money or manpower, but that is not the issue. The issue is crop yields. And in the meantime, the herbicide residues end up on our plates.

There are alternative ways of combating insects too, such as using hoverflies or introducing sterile males. We really are not waiting with bated breath for herbicide-resistant or insect-resistant crops.

Moreover, the fact that, in the Netherlands, agricultural land is to be returned to nature and, in Brazil, sugar cane is being turned into alcohol to replace petrol for motor vehicles is rather starkly at odds with the vague contention that genetic modification might be a solution to a world food problem.

Specifically: nothing is being done to increase production, it is simply a question of changing production. The aim is to increase the income of seed merchants and chemical giants, even if this is at the expense of a reduction in production in real terms.

Moreover, food production could be increased enormously by cultivating crops (existing varieties), large parts of which are edible, such as cabbage and potatoes, instead of wheat, and more edible seeds. This can also be done in a traditional manner.

For the time being, however, the world market is being flooded with an ever greater range of food, the prices of which continue to plummet, while premiums are paid for leaving agricultural land fallow (in the USA).

We plough our way through the literature searching for validated publications in recognised scientific journals on these subjects (increasing world population and crop yields) but find no reports that hold water.

- Another claim that we frequently encounter is that genetic modification works in a very precise, highly targeted and predictable manner: predictable, that is, in the sense that the only effects relate to the gene introduced.

This is not confirmed by practice. Avebe's amylopectin potato provides a simple example. A gene from that very potato was inserted in the antisense direction, together with many other genes, as part of a gene construct.

That the genetic modification would involve a single, well-defined characteristic and a single gene for that characteristic is yet another misconception.

In the case of Avebe there were a number of transformations (events): they were all different. Two of them, involving differences in inflorescence and leaf shape, were the varieties Apriori and Apropos. They can be identified in the field by their leaves and inflorescence. Now, was that difference in inflorescence in comparison with the parent stock predicted?

The distressing aspect is that more than enough amylopectin, the substance that the potato was intended to produce, can be obtained from waxy maize. We didn't need GM potatoes.

Another distressing aspect is the fact there is already a mutant potato with the desired characteristic. It would certainly have been possible to breed in that characteristic through traditional cultivation. We didn't need Genetic Modification.

In conclusion, we can say that extremely scant attention is devoted to public health. However, you can't leave public health to market forces. On the other hand, subsidies from the Ministry for Economic Affairs, which are interesting in themselves, do mean that the Government is 'party' to these things. We see that everywhere.

For example, there is the motion tabled by Ms Van Ardenne - where she talks about the broad debate in society on GMOs and food and the establishment of a broad-based Biotechnology Committee, to report in due course on desired and acceptable uses ... and how there has to be across-the-board support among the public (who?) ... and how getting rid of the uncertainties regarding the risks, and drawing up a list of the advantages of genetically modified foods, can contribute to greater trust in such food, etc.

SO, get rid of the uncertainties and emphasize the advantages. IN YOUR DREAMS. How do you get rid of uncertainties? Not by playing down the health risks. Consumers can see perfectly well that the balance is tipping in favour of producers!

Consumers also want to have as much information as possible on the GMOs to be cultivated. That information is kept to a minimum and absolutely no attention is paid to the subject in the media (rulings of the Council of State). The dangers are lying in wait.

As regards the genes in the construct inserted into plants, scientists warn that we should, for example, be CONCERNED about the toxin gene of *Bacillus thuringiensis* (Bt) which can get into other bacteria, with unexpected consequences for the soil fauna balance.

Let's hope the Minister will soon have an answer to some difficult questions.

J. van der Meulen, L. Eijsten. <http://www.gentechvrij.nl/rvs0005.html>

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### 3. Environmental risk assessment

Highly toxic for people who breath in the drift. What do allergens taste like? The advertisement in various newspapers (including the NRC 10/10/01) about your senses really took the biscuit! I would never have thought that the government would take supernatural advice from a medium to determine how safe our food is! Neither did I imagine that you would play on the feelings of the ignorant majority. A very weak and irresponsible way to behave.

Is your sixth sense supposed to guarantee our safety? The policy-makers are constantly changing. What does your "guarantee" actually mean? Is it some kind of contract, with government guaranteeing your recovery to health if your sixth sense runs amuck? Or are there some kind of financial arrangements? For example, in the case of a lifelong allergy triggered by sensitivity to herbicides (e.g. Liberty/Basta/Finale, or by a substance in a pesticide. I could go on).

What happens if we

1. consume Bt-maize sprayed with Btk delta endotoxin, or
2. have inhalation problems as a result of the use of Bt spray in organic agriculture?

Bt (*thuringiensis*), Bc (*cereus*), and Ba (*Anthraxis*) are closely related and I have read that the transfer of genetic material has occurred. The chances of this happening are no doubt very small but where does the anthrax come from? Since time immemorial, there have been anthrax spores here and there in the soil. Vondel even wrote a poem about it. Worms and mice can bring it to the surface.

What about the pH value in insects' intestinal tract? At a pH of more than 7, insects fall victim to delta-endotoxins. Differences in pH in various insects have an impact on the effectiveness of toxins. (A certain toxin kills a specific group of insects, according to what I've read).

I have also read that the excessive use of pesticides is making certain insects resistant. That is something else. Has enough research been done on this?

"Each of the more than 800 strains of *Bacillus thuringiensis* may exhibit toxicity to insects, rodents and humans". The Bt-sprays in GM maize apparently cause their own problems in the

long run, each in their own way. We do not yet know what may happen tomorrow, as a result of a multiplicity of interactions.

Bt. israelensis has been shown to kill rats if injected into the abdomen and the brain, and "The irritancy of Bt.i. to eyes depends on the physical characteristics of the formulation".

De delta-endotoxin from Bt.israëlsensis also caused destruction of rat, mouse, sheep, horse and human blood cells" and so on.

Regarding Bt. Kurstaki, users have reported all sorts of trouble in the event of contact with the face. Another interesting case concerns the scientist who accidentally injected himself with Bt. israelensis "and another kind of bacteria commonly found on human skin".

It is also nice that the Oregon Health Division suggested before a Bt.k. spray programme that "individuals with ... physician-diagnosed causes of severe immune disorders may consider leaving the area during the actual spraying".

And "The 1991 Material Safety Data Sheet for Foray 48B" states "Repeated exposure via inhalation can result in sensitization and allergic response in hypersensitive individuals".

And

"Inert Ingredients All Bt-products contain ingredients other than Bt. These are identified only as 'inert' ingredients and are called trade secrets by the manufacturers of the products. The 'inert' ingredients are potentially the most toxic components of the formulations". Examples follow.

Because 'inerts' are called trade secrets, there, there is little public information that is available indicates they could cause health problem. Sodium hydroxide, sulphuric acid, phosphoric acid, methyl paraben and potassium phosphate are then given as examples of 'inerts'. They constitute less than 10% of Foray 48b, 'they pose hazards'. Then follows a list with consequences: mild cases to irritation of the mucous membranes of the nose; damage of the upper respiratory tract; corrosive; severe deep skin burns, permanent loss of vision; severe bronchial constriction, and bronchitis; irritant to skin and mucous membranes; throat irritation and both methyl paraben and potassium phosphate were once registered by EPA as pesticide active ingredients. Sodium sulfite (inert) in Dipel 8AF: Up to ten per cent of asthmatics (about one million people in the United States) may react to sulfites, particularly those people who are treated with steroids. Symptoms of exposure in those sensitive to sulfites usually involve the respiratory system, and can also include nausea, diarrhea, lowered blood pressure, hives, shock, and loss of consciousness". And so on.

Enough misery for the time being. I'll just leave you with the fact that Bt.i. formulations are especially unhealthy because the 'inerts' in the product deplete the dissolved oxygen in water. The Bt.i formulation Teknar was acutely toxic to brook trout fry, probably because of xylene used as 'inert' in the product.

There is so much in the literature about Bt and other pesticides, the formulations and their effects, that I already have a nasty taste in my mouth: the taste of allergies, sickness and death.

Yours sincerely,

L. Eijsten. <http://www.gentechvrij.nl/rvs0107.html>

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

This product should no longer be sold. More research is needed and we wonder whether this product can in fact be authorised. On 14 July, a new scientific study was published which shows that genetically modified (GM) soya accumulates formaldehyde and contains considerably less glutathione. Formaldehyde is carcinogenic and glutathione is an antioxidant; antioxidants are needed for cell detoxification. The natural breakdown of formaldehyde in cells is also blocked.

This accumulation of formaldehyde could perhaps be characteristic of GM crops and definitively puts an end to the equivalence principle, on the basis of which GM crops have been authorised.

As the press release states, the results indicate that further research is needed.

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#### **5. Others**

Amsterdam, 11 augustus 2002.

#### **SOME OBSERVATIONS**

First of all, I would like to remind you of the ruling of the *College van Beroep voor het bedrijfsleven* [Dutch Trade and Industry Appeals Tribunal] on the question of extending the authorisation for the preparation Symphonie (active ingredient: flutolanil).

The case was dismissed because - in short - '... the above-mentioned report was based purely on information which originated from the applicant itself (Aventis Crop Science) and no interested third parties were involved in the case'.

It also came to light in the same context that the amendments tabled by Ms Van Ardenne (27085) and Messrs. Feenstra and Udo on 6.11.2001, in respect of the authorisation of active ingredients (the 'inerts' in the formulation are more damaging to human health than the supposed active ingredient), had been adopted. One relevant amendment (authorisation of biocides in only one Member State means that they are also authorised in the Netherlands)

"kills two birds with one stone":

- first, maximum access is ensured, and

- second, the companies concerned are no longer dependent on the *College Toelating Bestrijdingsmiddelen (CTB)* [Pesticide Authorisation Committee].

Speeding up, under pressure, the processing of applications - which can easily compromise the care which needs to be taken to arrive at a correct risk assessment - will undoubtedly make superficial assessments more likely; in fact it is certain to do so.

I would like to draw a few brief conclusions, referred to in our objections and appeals to the Ministry of Housing, Spatial Planning and the Environment (*VROM*) (73 in total), without the names of the producers or the data from our submissions.

Tests did not look at the action of intestinal juice; only 5-day feed tests were conducted (using unsprayed rape seed), there were no 90-day feed tests; a distinction can be made using various analytical methods - so there is substantial equivalence; in our opinion, recording methods were not precise enough; large-scale supply of plant parts with this gene will very much result in increased availability and resistance in pathogens (in the intestines of humans and animals being treated for a disease (cotton seed in feed). Corn DBT contains two new detectable proteins: no substantial equivalence: product intended for feed, corn gluten, poultry. SE/96/3501: risk involved in occasional use of this potato, or cumulative risk for the community and progeny - safe?

T25xMon810: accumulation of risks from both parental lines. Impact on intestinal flora not examined. American documents missing; no chronic toxicity tests, etc. Rapeseed DE/9806: no methods/analyses to distinguish seed from other oil seed; Thompson versus A.Schulz. Toxicological impact from new toxicity data ignored - reprehensible. GA21: dubious practice in the file. GA21 - GB/97/M3/2: ACRE [Advisory Committee on Releases to the Environment] criticises scientific basis as being substandard (3.2.99); toxicity insufficiently tested, insufficient information, unreliable for the purposes of authorisation; sunflowers: umbrella constructions misleading for the public; sugar beet: where do the GLA (glufosinate ammonium) residues end up? In the molasses? Rapeseed: two different antibiotic genes, kanamycin and hydromycin. No risk assessment of other parts of the construct inserted; why are the health risks not mentioned? Sugar beet: GLA is damaging to progeny; safety aspects of beet pulp and molasses. Sugar beet 99/05: no reflections on risk; protein in beet pulp, molasses, vinasses, filter-press residues. Gets into the food chain via feed? There is no protocol for voluntary feed test. The producer's report is misleading; GLA is sensitising. Fuji, Watanabe: brain damage, apoptosis, malformations, etc. Sugar beet 99/01: risk analysis conducted before the crops were in the field. All responsibility shifted onto the Minister; various aspects left out of the risk assessment. COGEM (Dutch Committee on Genetic Modification) continues to rely on old reports. Potato 99/09: horizontal gene transfer from plant to microorganism: Schlüter/Smalla/Mercer. Problems with neomycin phosphotransferase (*npt*) III gene spectrum of 17 antibiotics. No serious risk assessment - corners cut. Maize/GLA: phosphorus-carbon compound: resistant to degradation. Harmful drift. Carrot 95/-01: extension of the period of validity of the licence increases the risk; 98/05: cabbage plants; announcement in Scotland that a product known to be toxic for such a long period would never be authorised for placing on the market (up to 2015); carrot: twisted reasoning in the application. Confidentiality is not appropriate.

General: only grant permission when you are convinced; you can't just say 'it doesn't appear to be harmful'. Consumer confidence. Applications sometimes concern 'imaginary plants': the money invested evaporates when the company is taken over by other countries, etc.

This kind of information is also gradually filtering through to consumers - mistrust. The views of Messrs. Feenstra and Udo and Ms Van Ardenne, who would like to keep proven effects

which are damaging to health out of the picture, are rather sad, and definitely not amusing. People forget that those negative, health-damaging effects could affect almost anybody. These are risks which cannot be insured against. That famous 'yardstick' should also be called into question. It takes no account of health effects. Are our policy-makers blind?

The elephant in the room is the mode of action of the substances in the formulation of a pesticide, the 'inerts', which are the most damaging to health. I would mention only propanediol, ethylene glycol and alkyl ether sulphate (AES). And the 'strange' thing is, none of the 150 references requested from the major libraries 'are available in Netherlands', that is to say not even the journals in which they appear! And yet, surely the purpose of life is to accumulate knowledge! And that applies to everyone; it is not selective!

Perhaps the 'speeding up' of assessments could have the fortunate side-effect of giving the CTB more time, for example to check for toxins in the 51 wells in the east of the Netherlands and in Limburg, which are listed in the Alterra report (which is to be kept secret) but 'not yet investigated', so that organic gardeners can water their lettuce using water from their wells with an easy mind. It would also be nice for consumers to know this. And they could put up a sign saying 'No Entry' or 'Do not use', or prevent public access by establishing plantations, as happened in the past when carcasses infected with anthrax were simply buried. The poor CTB! (Bt, Bc - bacillus cereus, Ba - bacillus anthracis - they are all related, can take on one another's characteristics. Soil life does not stand still!).

I therefore wonder, if I was to ask for the literature from TNO, for example, having received an offer with a price-tag attached, whether I would get value for my money! All the above-mentioned 150 references would have to come from abroad, and I can imagine that the number of documents that I would ultimately receive would depend on the price paid. This would be like valuing stamp collections: costs = 10% of the value calculated. Fortunately, I don't need those 150 references!

If I were a member of the House of Representatives [in the Dutch Parliament] I would also feel pretty wretched if I knew that I could only have some of the information I needed to make comparisons. But if you don't know enough, nor can you complain. Just relax, there is nothing serious at stake! After all, the independent experts from the *Staatstoezicht op de Volksgezondheid* [Dutch Public Health Supervisory Service] are supposed to know everything in their field, are they not? It is after all from this body that the policy-makers etc. have to get their information.

The Public Health Supervisory Service has written to me saying that propanediol is not toxic. 10% of the herbicide Finale/Liberty/Basta consists of this 'inert', which causes dermatitis. But, if the commercial tests are not up to scratch, this fact will never be known around the world.

The worst thing is that dermatologists have no choice but to admit that they do not have the expertise, because they do not know the secret composition of the herbicides (the CTB does of course).

Look, it is a matter of public interest that you should know what that composition is.

This was the judgment of Aventis Crop Science and it was included in the ruling of the Dutch Trade and Industry Appeals Tribunal. We can't just sweep this under the table, can we?

For example, AES (30% of the formula) causes vasoconstriction, among other things, while propanediol (10%) causes dermatitis.

In the commercial tests (in which I personally took part), they use a concentration of propanediol which is some 100x to 200x too low, plus vaseline (hydrophobic) as a carrier, rather than water, so that the substance to be tested cannot penetrate the skin.

Some years ago, during some warm weather, I ingested propanediol, ethylene glycol and alkyl ether sulphate - and all the other ingredients - from drift from Finale SL14 (comparable to Basta and Liberty). The result was permanent damage. This could happen to whole sections of the population. These substances must be eradicated, in the public interest. However, the public knows nothing about all this.

I am suspicious of arable crops which are genetically modified to be pesticide-resistant.

The companies introducing GM crops which are resistant against substances used in pesticides, are responsible for damage to health. The largest company in this field in the Netherlands has told me that it does not know the substances used in the herbicides against which they make their plants resistant. It's a matter for Hoechst, apparently. But Hoechst just passes the buck back.

Anyone introducing a new strain is responsible for its consequences. Even Monsanto claims that it bears absolutely no responsibility for the potential consequences of using its products in crop production. And that's OK?

A little aside: Foray 48B, a Bt-insecticide, - contains methylparaben as an "active ingredient". This was listed by the EPA back in the day as an active ingredient. This stuff can also be found in ointments, etc., which you spread on your skin to prevent chapping. Can anyone explain that to me?

L. Eijsten <http://www.gentechvrij.nl/rvs0110.html>

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## **6. Labelling proposal**

This product should no longer be sold. More research is needed and we wonder whether this product can in fact be authorised. In any case, labelling is a farce in the EU; hundreds of genetically engineered products imported direct from countries such as the USA are offered for sale unlabelled, primarily on the internet. Such labelling has no priority in the Netherlands. The NVWA [Netherlands Food and Product Safety Authority] has written as follows: 'The NVWA adopts a project-oriented approach to GMOs in food and feed. At the moment, the emphasis is on monitoring for the presence of GMOs which are not authorised in the EU. We will take your observations into account in future projects.' In supermarkets, products imported direct from the USA bear labels referring to an incorrect test (warning: American products may contain genetically modified ingredients), if they are labelled at all. [http://www.gentechvrij.nl/DossierC1000\\_1.html](http://www.gentechvrij.nl/DossierC1000_1.html)

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**Organisation: la nature**

**Country: France**

**Type: Individual**

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**a. Assessment:**

**5. Others**

I object to the spread of GM plants and seeds; they can only disrupt what NATURE has created. The financial artificialisation of the land can only result in future disaster: So, for the sake of my children, I say 'No' to GMOs and to MONSANTO: they would sell their children to make money.

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**Organisation: la nature**

**Country: France**

**Type: Individual**

---

**a. Assessment:**

**5. Others**

I object to the spread of GM plants and seeds; they can only disrupt what NATURE has created. The financial artificialisation of the land can only result in future disaster: So, for the sake of my children, I say 'No' to GMOs and to MONSANTO: they would sell their children to make money.

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**Organisation: Testbiotech**

**Country: Germany**

**Type: Non Profit Organisation**

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**a. Assessment: Molecular characterisation**

The molecular characterisation of the plants did not take into account the emergence of new double stranded miRNA that might be transmitted as a biologically active substance at the consumption level to humans or animals. miRNA might be transmitted to the consumer and there is indication that it interacts with gene regulation in mammalian cells (see, for example, Zhang et al., 2011; Lukasik & Zielenkiewicz, 2014). The emergence of new versions, combinations and concentrations of miRNA was neither assessed in the single plants nor in the stacked event. Uncertainties related to the emergence of these molecules were not addressed.

The gene expression of the gene constructs in some parts of the stacked plants showed substantial differences compared to those in the single plants. This is an indication of genomic effects caused by the crossing of the plants, and should have prompted further investigation

There was no assessment of the expression of the constructs in the plants under conditions that could represent the true range of environmental conditions, taking into account stressful conditions such as that caused by ongoing climate change.

Lukasik, A., & Zielenkiewicz, P. (2014) In Silico Identification of Plant miRNAs in Mammalian Breast Milk Exosomes – A Small Step Forward? PLoS ONE 9(6): e99963.

Zhang, L., Hou, D., Chen, X., Li, D., Zhu, L., Zhang, Y., Li, J., Bian, Z., Liang, X., Cai, X., Yin, Y., Wang, C., Zhang, T., Zhu, D., Zhang, D., Xu, J., Chen, Qu., Ba, Y., Liu, J., Wang, Q., Chen, J., Wang, J., Wang, M., Zhang, Q., Zhang, J., Zen, K., Zhang, C.Y. (2011) Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. Cell Research, 22(1): 107-126.

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

The outcome of the comparative analysis shows that several of the endpoints measured were significantly and consistently different. Differences were observed, for example, in the oil composition of the plants.

Further significant differences were observed for agronomic and phenotypical characteristics. In particular, differences in the 100-seed weight can be an indication for unintended genomic effects due to the genetic engineering of the plants.

Genomic x environment interactions were shown for several parameters. The effects might be much stronger under more extreme environmental conditions. However, the data presented by Monsanto only contains data from US fields (none from South America) and only for one year while the plants were grown under 'normal' agricultural conditions.

To summarise, there are indications that unintended effects are due both to the process of genetic engineering of the single plants and to the crossing of the plants. Further, environmental interactions are likely to play a role in triggering these significant differences.

Differences in plant components can indicate further changes affecting the level of anti-nutritionally, hormonally or immunologically active substances in the plant. These differences must therefore be investigated further to assess in detail their causes and biological relevance.

It is possible that some of the relevant changes in plant composition and plant characteristics may only be observed under specific environmental conditions. Thus, the observed differences should have triggered a request from EFSA for more studies, for example, to grow the plants under defined environmental extreme stress conditions. Such conditions can also reveal genetic potential for instability in the expression of the newly introduced DNA (see, for example, Trtikova et al., 2015).

However, EFSA has assumed without sufficient reason that these differences are not relevant for the food safety of soybean MON87708 x MON89788. Thus, none of these issues were assessed in detail. Instead of requesting more data, EFSA accepted that Monsanto had failed to provide data required under EFSA guidance. In fact, EFSA accepted the incomplete data based on explanations that are mostly vague and do not allow any conclusions.

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.  
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011>

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

### **Toxicology**

The outcome and quality of the 90-day feeding studies with the single plants triggered several critical comments from the experts of the Member States. This should have been followed up by a request for further feeding studies with the stacked events. Furthermore, the findings related to the composition of the plants and their agronomic and phenotypic characteristics should also have triggered further studies on potential health impacts. However, no further feeding studies with the stacked event were requested.

Even though this is the first time that a combination of two herbicides, dicamba and glyphosate, will be applied to genetically engineered soybeans in the field, EFSA has not requested any data on the combinatorial effects of the residues from spraying these two herbicides. The plants will contain residues such as 3,6-dichlorosalicylic acid (DCSA), formaldehyde (see EFSA 2013), glyphosate and AMPA, none of which have been tested for specific combined toxicity. These residues in combination should have been assessed as relevant plant constituents. According to the International Agency for Research on Cancer (IARC), a body of the World Health Organisation (WHO), both active ingredients and / or their metabolites can be regarded as having carcinogenic potential (IARC 2012, Guyton et al., 2015). Further, commercially traded herbicide mixtures such as Roundup are considered to be much more toxic than the active ingredient alone (Mesnage et al., 2013). Even though the carcinogenic potential of glyphosate is still under discussion, these two herbicides applied in combination (and as mixtures with further adjuvant ingredients) should trigger very detailed and in-depth risk assessment before any conclusion is drawn upon the safety of the stacked events.

There was no assessment of any interaction between plant components such as immunologically or anti-nutritionally, hormonally or immunologically active substances with the residues from spraying. Besides carcinogenicity, other interactions have to be assumed as being relevant: For example, mixtures of glyphosate are suspected of inducing hormonal activity (see for example Thongprakaisang et al., 2013). Thus, these compounds might enhance the hormonal effects of the plant estrogens present in soybeans.

This case reveals major systemic flaws in current EFSA risk assessment. EFSA carries out the risk assessment of herbicide resistant, genetically engineered plants, without taking into account the specific risks that emerge from the residues from the complementary herbicides. These risks are only assessed partially within the framework of EU pesticide regulation and only for the active ingredients. However, if these herbicides are applied to herbicide resistant

plants and become plant constituents then there are additional specific risks (as shown above) that need to be assessed.

Several other genetically engineered plants with tolerance to various herbicides have pending market authorisations for the EU or have already been authorised, making a systematic approach necessary to deal with new patterns of exposure, interactions between the substances and the accumulated impact on human and animal health. Thus risk assessment of genetically engineered plants always should take into account potential interactions and accumulated effects.

Guyton, K.Z., Loomis, D., Grosse, Y., El Ghissassi, F., Benbrahim-Tallaa, L., Guha, N., ... & Straif, K. (2015) Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. *The Lancet, Oncology*, 16(5): 490-491.

IARC (2012) IARC monographs on the evaluation of carcinogenic risks to human, Formaldehyde. Monograph 100F, 1–36. International Agency for Research on Cancer, Lyon. <http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf>

Mesnager, R., Defarge, N., Spirooux, D. V. J., & Séralini, G.E. (2013). Major pesticides are more toxic to human cells than their declared active principles. *BioMed Research international*, 179691.

Thongprakaisang, S., Thiantanawat, A., Rangkadilok, N., Suriyo, T. & Satayavivad, J. (2013): „Glyphosate induces human breast cancer cells growth via estrogen receptors“. *Food and Chemical Toxicology*. [www.sciencedirect.com/science/article/pii/S0278691513003633](http://www.sciencedirect.com/science/article/pii/S0278691513003633)

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### **Allergenicity**

Most relevant for health risk assessment in this context are the naturally occurring allergens present in soybeans. A change in the plants composition might also lead to a higher concentration of the endogenic plant allergens. Further, it is known that toxicants, if applied together with the allergens, can have an adjuvant effects, triggering a stronger immune reaction to the proteins.

Monsanto presented data that are meant to show that the concentration of the endogenic proteins in the plants was not enhanced. However, soybeans are known to have a substantial variation in their natural concentrations, depending on specific varieties and on interaction with the environment. Monsanto failed to show that the level of endogenic allergens in specific varieties and/ or under specific environmental conditions is not increased. For this purpose, further crossing with other varieties should have been performed as well as subjecting the soybeans to suitable stress tests. Further, the risk assessment completely failed to take into account potential interactions between the residues from spraying and the immune reaction to the soybean allergens.

No blood samples were taken from individuals known to have allergenic reactions in order to investigate clinical effects of the stacked event. No analysis was undertaken of the risks for individuals with an impaired immune system such as the elderly or infants, as requested by the EFSA guidance (EFSA, 2010).

EFSA (2010) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. EFSA Journal 2010; 8(7):1700. [168 pp.] doi:10.2903/j.efsa.2010.1700. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

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### **Nutritional assessment**

Studies to assess nutritonal quality should have been conducted, but were not.

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### **Others**

As a legal dossier compiled by Professor Ludwig Kraemer (Kraemer, 2012) shows, EU regulations require the monitoring of effects on health at the stage of consumption in case of uncertainties. Thus for example monitoring of health effects, taking into account residues from spraying with herbicides must be required. Epidemiological parameters that are suitable to detect relevant health effects have to be defined.

The applicant should provide methods to distinct the presence of the stacked events from those of the mixture of the parental plants.

Kraemer, L. (2012) The consumption of genetically modified plants and the potential presence of herbicide residues, legal dossier compiled on behalf of Testbiotech, [http://www.testbiotech.de/sites/default/files/Legal\\_Dossier\\_Kraemer\\_Pesticide\\_RA\\_PMP.pdf](http://www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf)

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## **4. Conclusions and recommendations**

EFSA risk assessment is failing to deal properly with findings from the comparative analysis. The assessment of toxicological, hormonal and immunological effects is inadequate. Further, risk assessment does not take the many safety issues regarding the combined usage of the complementary herbicide into account. In conclusion, the application should be rejected.

A systematic approach has to be developed to deal with interactions and accumulated effects from the usage of such plants in food and feed before any further decision is taken on market authorisation of genetically engineered plants that are resistant to herbicides.

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### **Organisation:**

**Country: The Netherlands**

**Type: Individual**

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

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

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**b. Food Safety Assessment:  
Toxicology**

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**Allergenicity**

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**Nutritional assessment**

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**Others**

Could the finding of this papers taken into account:

[http://genok.no/wp-content/uploads/2015/06/010615\\_GENOK-HTIntactaBrazil-FINAL\\_web.pdf](http://genok.no/wp-content/uploads/2015/06/010615_GENOK-HTIntactaBrazil-FINAL_web.pdf)

Especially the different questions raised in that report

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**6. Labelling proposal**

It would be good to put GMO-ingredient on the foodlabel. But what information should be given to people. Foodlabling is absolutely a must. As long as people still don't agree with other, than GMO's should not enter the (EU) market. For above all, clearance on what should be put in the label should be established first. The label should be smart. We should see a food label which says about main ingredient of the GMO-modified plant. Especially the toxic one, an the allergenics and stuff which could cause an allergic reaction.

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