Maize NK603 x T25

Organisation: The European GMO-free Citizens
Country: The Netherlands
Type: Others...

---

a. Assessment:
Molecular characterisation

See b. Food Safety Assessment: Toxicology

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

See b. Food Safety Assessment: Toxicology

---

b. Food Safety Assessment:
Toxicology

b. Food Safety Assessment:
Toxicology

GLA and glyphosate. In 1987, the following article was published: Thomson, C. J. et al., 'Characterisation of the herbicide-resistance gene bar from S.hygroscopicus', EMBO Journal Vol. 6 No 9, pages 2519-23. It described how phosphinothricin-acetyltransferase also has glutamic acid as a substrate, by mixing the two substances and demonstrating the reaction product. Hoechst contested this in a report (93-01) by Dr Arno Schulz: 'L-phosphinothricin N acetyltransferase biochemical characterisation'. Glufosinate had been exposed, TOGETHER with a seriously excessive amount of glutamic acid (and other amino acids) to the effects of the acetyltransferase. Schulz had been unable to demonstrate ANY reaction product with glutamic acid and thus concluded that glutamic acid was not a substrate. THIS IS INCORRECT AND HIGHLY MISLEADING because • in situations in which the acetyltransferase (present in the modified plant) could have a toxic effect, as in our gastro-intestinal tract, large quantities of glufosinate are not simultaneously present (see Thomson). Unbelievable! • it is only logical that, under Schulz's test conditions, the acetyltransferase would acetylate the glufosinate using not only the added acetyl source but also acetylated glutamine acid as an acetyl source (because the transferase has a higher affinity for

glufosinate). In a MIXTURE a reaction product will be produced only with the substrate for which it has the highest affinity.

A VERY MISLEADING REPORT. We object to the development of a GMO containing this gene product. 1. According to Hoechst, it is not teratogenic. E. Ebert et al.: 'Summary of safety evaluation toxicity studies of glufosinate ammonium', 1989/1990. Defects found in rabbit progeny were brushed under the carpet by Hoechst, which claimed that they were the result of 'maternal toxicity'!! The toxic effect on the mother was claimed to prevent her giving birth to healthy progeny. We believe they are playing fast and loose with the words they use. We would put forward instead the research data of Tomoko Fujii et al., from 1996: 'Alterations in the Response to Kainic Acid in Rats Exposed to Glufosinate Ammonium, a Herbicide, during Infantile Period', a study sponsored by the Japanese Ministry of Education, Science, Sports and Culture. 'Exposure to GLA, even in low doses (1 mg/kg) during Infantile Period in the rat, induces alterations in the kainic receptor in the brain'. T. Watanabe, 1996: 'Apoptose induced by GLA in the neuroepithelium of developing mouse embryos in culture'. Programmed cell death as a result of the secretion of substances which destroy the cell from within; this 'suicide' is regulated by a suicide gene which appears to be activated by GLA. T. Watanabe et al., 1997: 'Developmental and dysmorphogenic effects of GLA in mouse embryos in culture'. Deformities. 2. It is not considered to be sensitising. Ms L. Eijsten discovered for herself the exact opposite of GLA's 'non-sensitising properties', something she has reported previously. In 1992, she - and her dog - became sensitised: a parks department employee carried on spraying the edges of the grass in a park, where she was sitting reading on a bench, with Finale SL 14. Nothing apparently amiss. However, a year later she was walking her dog by grass which had shortly before been sprayed with the same herbicide and promptly, seven hours later, her legs were covered in eczema. She walked the same route the next day, this time in a sleeveless blouse, and within no time her arms and face were also covered in eczema (the dog too had red patches on its stomach). She has reported on this many times already. The serious thing is, however, that every attempt is made to brush these facts under the carpet, arguing that her symptoms were caused by a food allergy (letter of 10 June 1996 from Mr Top / Ms Terpstra at the Netherlands Ministry of Health, Welfare and Sport (VWS); a very scientific communication. The photograph sent showed clearly that the eczema was on unprotected parts of Ms Eijsten's body. And there was no eczema on the back of her hands - logically, because she had washed her hands after the contact. A dermatologist carried out tests involving patches with Vaseline to which the herbicide had been added. This meant that a hydrophilic substances was being tested using a hydrophobic substance. It was logical that no effect should be visible after the test. The dermatologist carried out tests in the same way three times, despite Ms Eijsten's request that a hydrophilic substances, such as lanolin, be used, or that the herbicide be tested on her skin by itself. His argument was that he always worked that way, thus making his incompetence clear. He had previously told her that he did not know the herbicide in question and had asked her to bring some with her. That was strange, because Finale had already been in use for some 20 years. This was also why she collected various articles about Finale and showed the dermatologist an American book describing methods for demonstrating sensitisation. EU LEGISLATION prescribes many methods for demonstrating sensitisation. Ms Eijsten constantly wondered why the dermatologist did not want to carry out any different tests. She found this all very improper. If all dermatologists in the Netherlands took the same approach as 'her dermatologist', no cases of eczema resulting from GLA would ever be found! Why should the correct tests not be done? We believe that everything possible is being done to cover up the harmful effects of GLA. The annual report of the organisation *Consument en Biotechnologie* for 1996/1997 reported that Fujii's 1996 report stated that high doses had been found to cause brain damage.

And it should be noted that it was Ms Eijsten who sent the report in question to *Consument en Biotechnologie*, at their request. The report concerned precisely the fact that the work had been done using very small doses (1 mg/kg). When she complained, they promised to correct the errors. Recently she was informed that no correction is to be made. No reason was given. This twisting of the truth is an example of false lobbying. We believe that the above information on sensitisation has to be communicated once again, against the background of the dangers which arise when herbicides are sprayed and as a result of drift when herbicide-resistant crops are cultivated, be it on a large or a small scale. Murphy's law. http://www.gentechvrij.nl/rvs9907.html, extract from: Objection to a draft decision on herbicide resistance by J. van der Meulen, L. Eijsten (ISIS). ISIS Announcement 20/08/15 Announcing ISIS Special Report Banishing Glyphosate Glyphosate/Roundup, falsely claimed by Monsanto to be safe and harmless, has become the world's most widely and pervasively used herbicide, especially with glyphosate tolerant GM crops; it has brought rising tides of birth defects, cancers, fatal kidney disease, sterility, and dozens of other illnesses. Read the devastating evidence & ban glyphosate herbicides from you home and local community Dr Eva Sirinathsinghji & Dr Mae-Wan Ho with Dr Medardo Ávila-Vázquez, Dr Don M. Huber, Dr Rosemary Mason, Ib Borup Pederson, Prof Peter Saunders, & Dr Nancy Swanson Sign the Independent Scientists Manifesto on Glyphosate here: http://www.i-sis.org.uk/Independent_Scientists_Manifesto_on_Glyphosate.php Download the report here (11mb) http://www.i-sis.org.uk/Banishing_Glyphosate.pdf Glyphosate was released as an herbicide in 1974, and rapidly became the world's most popular herbicide especially since the introduction of genetically modified (GM) glyphosate-tolerant crops in the 1990s. Currently, 85 % of GM crops are herbicide-tolerant, with glyphosate-tolerant crops making up the vast majority of those planted. In the US for example which is the largest producer of GM crops, 93 % of soybean and 85 % of maize crops are glyphosate-tolerant. A total of 137 glyphosate-tolerant varieties have been approved by May 2015 (see Supplement Table 1 Approved glyphosate tolerant crops). There are 19 varieties of cotton, 115 of soybean and 81 of maize; and in addition, 1 wheat, 2 sugar beet, 4 potato, 3 Polish canola, 8 Argentine canola, 1 creeping bentgrass and 3 alfalfa. 80 % of these crops are stacked, containing additional traits such as tolerance to glufosinate and 2,4-D herbicides and/or pesticidal properties. Of the glyphosate-tolerant crops generated, over 99 % of those grown belong to only four species - soybean, maize, cotton and canola. According to the new yearly report from industry funded International Service for the Acquisition of Agri-Biotech Applications (ISAAA) [1], "18 million farmers in 28 countries planted more than 181 million hectares [of GM crops] in 2014, up from 175 million in 27 countries in 2013." This has spurred huge sales of glyphosate, giving it a market value of US$5.4 billion in 2012 with a total demand of 718 ooo tonnes [2]. Globally it is a key ingredient in more than 700 products [3] and is also used to control weed in gardens, along roadsides in commercial and residential areas, and on millions of hectares of farmland. Its presence is pervasive, in the air, in the soil, in our food and drinking water (see Chapter 1). Underlying its success has been the repeated claim that the chemical is benign for human health, that its killing mechanism for plants works via an enzyme that does not exist in animals and is therefore safe for both human and animals. This claim goes counter to evidence that existed right from the start. Studies revealed both carcinogenicity and teratogenicity as far back as the 1980s, but were buried by industry with the support of regulatory bodies such as the US Environmental Protection Agency and the European Food Safety Authority (see Chapter 5 and [4] EU Regulators and Monsanto Exposed for Hiding Glyphosate Toxicity, SiS 51). Meanwhile, overwhelming evidence of glyphosate toxicity across the globe has come to light. Everywhere, people are seeing steep rises in cancers, birth defects and other serious illnesses as glyphosate use increases. The World Health Organisation's recent re-assessment of glyphosate as a 'probable carcinogen'

vindicates the evidence witnessed by communities, researchers, doctors and campaigners for many years. Despite rising glyphosate use and GM crop cultivation, recent data show that global GM crop adoption rates are falling, covering only 3.5 % of arable land. The markets of high-adoption rate countries are becoming saturated, while few additional countries have been cultivating GM crops, indicating that nations and farmers are turning their backs on a failing technology [5]. With the rise of weeds evolving resistance to glyphosate, US Farmers reported a decline in the effectiveness of glyphosate on almost 44 % of acres planted with soybeans in 2012. More than 47 % of those acres are in the Corn Belt, which contains the majority of soybean acreage in the United States, followed by the Northern Plains (23 %), Delta (11 %), Lake States (10 %), and Appalachia (9 %).The failure of GM crops could also have a major impact on the future of glyphosate use [6]. With its increasing lack of efficacy on top of the rising awareness of its toxicity, people across the globe are taking action to rid glyphosate from their farms, their food and their land, air, and water. Lawsuits are being filed against Monsanto both in the US for false claims of safety, and in China for hiding the toxicology documents used for registering the chemical in the country. China is the world's largest producer of glyphosate and the largest importer of GM soybeans [7] (How Grain Self-Sufficiency, Massive Soybean Imports & Glyphosate Exports Led China to Devastate People & Planet, SiS 67); and feelings are running high against both. A recent petition has even gone so far as to call for the complete overhaul of the Ministry of Agriculture, whose Agricultural GMO Safety Evaluation is deemed inadequate for ensuring that "GMOs developed abroad or within China are safe". It goes on to claim that there has been collusion between them and Monsanto, resulting in the submission of "fake samples", the carrying out of "false tests" as well as the falsification of "safety conclusions" (see [8] China's Ministry of Agriculture Accused of Colluding with Monsanto, SiS 67). The ultimate rejection of glyphosate and GM crops by the Chinese people could be a turning point not just for China but the world. Meanwhile in Argentina, a federal judge has accepted an unprecedented class action lawsuit demanding a ban on GM foods and their associated pesticides [9]. Defendants of this case include not only all the major GM crop and chemical corporations, but the Argentine national government and the Federal Council for the environment. Claiming that GMOs contribute to the trend towards monoculture, direct seeding with consequent reduction of rural labour, concentration of profit in few producers and impacts of health of rural populations and environment, the lawsuit demands the passing of a biosafety law, labelling of GM crops, and the remediation of environmental damage such as the soil in addition to the bans. The WHO declaration may well be the final nail in the coffin for Monsanto's flagship product, as it has intensified campaigns to ban the chemical. Several countries are already implementing bans of the chemical just 2 months after their assessment was published [10] (Fallout from WHO Classification of Glyphosate as Probable Carcinogen, SiS 67). Sri Lanka, suffering from an epidemic of fatal kidney disease, is the first to declare a complete and immediate ban. Earlier, Bermuda has banned glyphosate imports with immediate effect. And Colombia will no longer use it for its large aerial campaigns to destroy illegal coca plantations, a US-led war on drugs that is displacing Colombian citizens and compromising their land and water supplies. The Ecology Minister of France has ordered garden centres to stop selling it [11] and even private companies are taking the chemical off their shelves [12, 13, 14]. At a scientific UK parliament briefing on the 15 July, the Soil Association called for a ban of wheat pre-season spraying destined for bread after tests conclude that UK glyphosate use has risen by 400 % in the last 20 years [15]. Also attending was a member of the glyphosate researcher from WHO's IARC who reiterated the findings stating that glyphosate is "definitely genotoxic". Healthcare workers and campaigners are demanding action from governments that have so far supported the use of glyphosate, with Argentina seeing a recent statement backed by 30 000 healthcare professionals to ban its use completely, in line with the WHO assessment that vindicates all

their work documenting rising rates of cancers and other illnesses linked to widespread GM soy cultivation. Their message seems to be getting through, with the Argentinian town of Lago Puelo now taking action to ban the marketing and use of glyphosate [16]. The EU is yet to make the final decision, expected later this year, on whether it will re-approve glyphosate. The approval process by the EU commission thus far relying on a summary of data provided by a consortium of chemical companies including Monsanto that form the Glyphosate Task Force, it is time that we make sure that the EU does not continue to corrupt the approval process and instead take into account the WHO assessment as well as the many other independent studies that were omitted from the assessment by the task force (see Chapter 11). This report summarises the converging pattern of glyphosate toxicities from farm to clinic to the laboratory that leaves us in no doubt glyphosate must be banished (a combination of ban and vanish) from our homes, our cities and fields as a matter of urgency. A global ban is in order; the momentum to do so is already gathering pace. But we must start as individuals, in our family and home, our local communities. Above all, we must take this opportunity to stop poisoning people and planet with agrochemicals and shift comprehensively to sustainable, organic, non-GM agriculture that can truly guarantee food security under climate change (see [17] Food Futures Now *Organic *Sustainable *Fossil Fuel Free, ISIS Special Report) . All chapters in this report (except Chapter 9 by Professor Emeritus of plant pathology Dr Don Huber) are selected from articles published by ISIS online and in print between 2013 and 2015. Chapter 1 is updated and substantially enlarged from [18] A Roundup of Roundup Reveals Converging Pattern of Toxicity from Farm to Clinic (SiS 65) incorporating Chapter 1 of [19] Ban GMOS Now (ISIS special report). Chapter 2 is from [20] Marked Deterioration of Public Health Parallels Increase in GM Crops and Glyphosate Use, US Government Data Show (SiS 65). Chapter 3 is updated from [21] Devastating Impacts of Glyphosate Use with GMO Seeds in Argentina (SiS 66). Chapters 4 and 5 are from [22, 23] Glyphosate/Roundup& Human Male Infertility, Glyphosate & Cancer (SiS 62). Chapter 6 is updated from [24] Sri Lanka Partially Bans Glyphosate for Deadly Kidney Disease Epidemic (SiS 62). Chapter 7 is from [25] Changing from GMO to Non-GMO Natural Soy, Experiences from Denmark (SiS 64). Chapter 8 is updated from [26] USDA scientist reveals All (SiS53). Chapter 10 is from [27] How Roundup Poisoned my Nature Reserve (SiS 64). Chapter 11 is from [28] Scandal of Glyphosate Re-assessment in Europe(SiS 63). Chapter 12 is from [29] Glyphosate 'Probably Carcinogenic to Humans' Latest WHO Assessment (SiS 66). We thank all our co-authors who have contributed to separate chapters of this report, adding invaluable personal perspectives and especially first hand personal experiences of glyphosate toxicities.

Contents Preface 1. Converging Pattern of Toxicity from Farm to Clinic to Laboratory Studies Dr Eva Sirinathsinghji 2. Marked Deterioration of Public Health Parallels Increase in GM Crops & Glyphosate Use, US Government Data Show Prof Peter Saunders 3. Devastating Impacts of Glyphosate and GMOs in Argentina Dr Medardo Ávila-Vázquez 4. Glyphosate/Roundup & Human Male Infertility Dr Mae-Wan Ho 5. Gyphosate & Cancer Dr Mae Wan Ho 6. Sri Lanka Bans Glyphosate for Deadly Kidney Disease Epidemic Dr Eva Sirinathsinghji 7. Changing from GMO to Non-GMO Natural Soy, Farming Experiences from Denmark Ib Borup Pederson 8. Glyphosate and Metal Chelation – A Mechanism of Toxicity Dr Eva Sirinathsinghji 9. Glyphosate & Crops Diseases Old and New Dr Don Huber 10. How Roundup® Poisoned my Nature Reserve Rosemary Mason MB ChB FRCA 11. Scandal of Glyphosate Re-assessment in Europe Dr Nancy Swanson and Dr Mae Wan Ho 12. Glyphosate 'Probably Carcinogenic to Humans' Latest WHO Assessment Dr Mae-Wan Ho and Dr Nancy Swanson Download the report here (11mb) http://www.i-sis.org.uk/Banishing_Glyphosate.pdf http://www.i-sis.org.uk/Banishing_Glyphosate.php

Allergenicity

See b. Food Safety Assessment: Toxicology

Nutritional assessment

See b. Food Safety Assessment: Toxicology

Others

See b. Food Safety Assessment: Toxicology

3. Environmental risk assessment

See b. Food Safety Assessment: Toxicology

4. Conclusions and recommendations

See b. Food Safety Assessment: Toxicology

5. Others

See b. Food Safety Assessment: Toxicology

6. Labelling proposal

Not to be placed on the market, to dangerous! We don't want to eat this! The European GMO-free Citizens, www.gentechvrij.nl/thegmofreecitizens.html

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

a. Assessment:
Molecular characterisation

As EFSA states, the applicant recently provided new information regarding so-called open reading frames in maize NK603 that might lead to the expression of unintended gene products. Apparently these data provided new information that has been overlooked thus far. While previously no similarity to known allergens were detected, EFSA now states: Identity of over 35 % was found with ragweed (Ambrosia artemisifolia) homologues of the Art v 1 allergen for an ORF within the NK603 insert. The putative translation product of this ORF would be generated from the reverse strand of the CP4 epsps transcriptional units. Since ragweed is known to be highly allergenic, EFSA should have requested empirical data if such proteins are present in the plants, and not only base its opinion on a theoretical assumption about the likelihood of expression.

The emergence of new variations, combinations and concentrations of unintended small, biological active RNA molecules such as microRNA was neither assessed in the parental plants nor in the stacked events. Small biologically active RNA molecules can be passed from the plant to humans or animals at the consumption stage. Potential biological effects will depend on similarities between the cell regulation in mammals and plants (see, for example, Zhang et al., 2011; Lukasik & Zielenkiewicz, 2014). These molecules are likely to emerge as unintended side products at the insertion sites of the additional DNA, and can show specific interactions in the stacked event. Their concentration, structure and potential biological effects should be assessed before any conclusion is drawn upon safety of the plants.

Both the expression of the enzymes that confer herbicide resistance and the concentration of small biologically active RNA molecules should have been tested under a wide range of defined environmental conditions, taking into account stressful conditions that, for example, emerge under ongoing climate change. It is known that under stress conditions, genetically engineered plants can show reactions that are not obvious under normal agricultural conditions and can be very different from those of plants stemming from conventional breeding. For example, environmental stress can cause unexpected patterns of expression of the newly introduced DNA (Trtikova et al., 2015).

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.

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

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.

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

The field trials showed significant differences in several compounds. For example, in cross-site analysis, statistically significant differences were identified for 11 compositional endpoints, two in forage and nine in grain. In grain, two of the significant differences (palmitoleic acid and raffinose) were outside the range of the values for commercial varieties planted in the same field trial.

With regard to possible fitness advantages or persistence of maize NK603 x T25 in the environment, there are data gaps in the phenotypic assessment as values for seed germination, dormancy and pollen viability were omitted by the applicant.

Further, the assessment of the data shows major gaps and flaws: Material used for compositional analysis was treated with complementary herbicides, EFSA did not asses any data from non-treated plant material. Data used for agronomical and phenotypical analysis stems from plants that were not treated with the complementary herbicide. EFSA did not assess data from plants treated with the complementary herbicides.

As a result, a large part of relevant data is missing. Further, no production plan was made available, which is useful for assessing the robustness of the field trials.

The number of the field trials was low, the range of environmental conditions and stress factors very narrow. So no conclusion can be drawn about agronomic and phenotypical characteristics and plant composition under real field conditions as, for example, those that occur due to ongoing climate change.

EFSA mostly ignored criticism of data quality made by experts of several Member States. In the “Comments and opinions submitted by Member States during the three-month consultation period”, EFSA responded to the Member States' criticism by stating: “It is correct that the application only contains compositional information on forage and grain of maize NK603 × T25 sprayed with the target herbicides glyphosate and glufosinate ammonium and not on maize NK603 × T25 not sprayed with those target herbicides. The Panel notes that the agronomic and phenotypic characteristics of maize NK603 × T25 not sprayed with target herbicides is equivalent to that of the conventional counterpart.”

and further: “The EFSA GMO Panel agreed that the optimal set of data would include information on both maize NK603 × T25 sprayed with target herbicides and maize NK603 × T25 not sprayed with target herbicides.”

We disagree with EFSA on this assumption. It is not an optimal set of data which is missing, it is the minimum set that should have been requested according to the request from experts of Member States and EFSA guidance.

---

b. Food Safety Assessment:
Toxicology

No feeding study to assess potential health effects was provided. This is especially relevant here since a combination of two herbicides, glufosinate and glyphosate, will be applied to genetically engineered maize in the field.

According to the International Agency for Research on Cancer (IARC), a body of the World Health Organisation (WHO), glyphosate can be regarded as having carcinogenic potential (IARC 2015).

Glufosinate is regarded as potentially damaging to health (EFSA, 2005). According to the German Agricultural Ministry, glufosinate will be phased out in the EU in 2017 for reasons of reproductive toxicity (BMELV, 2009).

EFSA has not requested any data on the combinatorial effects of the residues from spraying these two herbicides. The plants will contain residues from both herbicides, neither of them have been tested for specific combined toxicity. Therefore, the residues in combination should have been assessed as relevant plant constituents.

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.

This was also requested by experts from Austria who stated that “negative impacts on human and animal health described in scientific literature [...] have to be evaluated with regard to increased application rates of these herbicides. It must also not be forgotten that unidentified inert ingredients in formulations of glufosinate and glyphosate were shown to enhance the toxicity to human organ systems”

This case again 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 spraying with the complementary herbicides. These risks are only partially assessed as part of EU pesticide regulation. However, if commercially traded herbicides formulas are applied in specific combinations to herbicide resistant plants, there are specific pattern of residues that need to be assessed.

Herbicide resistance in weeds is increasingly becoming a problem in areas where genetically engineered plants are cultivated. In response, several other genetically engineered plants with

tolerance to various herbicides have been developed and are pending for market authorisation in the EU, or have already been authorised. This is making it necessary to develop a new systematic approach to deal with new patterns of exposure, interactions between the substances and the accumulated impact on human and animal health.

BMELV, Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (2009) Neue Bewertungskriterien für Wirkstoffe in Pflanzenschutzmitteln [German language only]. http://www.greenpeace.de/fileadmin/gpd/user_upload/themen/umweltgifte/BMELV-Homepage-Liste_der_18_Pestizide.pdf

EFSA (2005) Conclusion regarding the peer review of the pesticide risk assessment of the active substance glufosinate. EFSA Scientific Report 27: 1-81.

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

IARC (2015) Glyphosate Monograph. http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf

---

Others

The applicant should provide methods to distinguish the presence of the stacked events from those of a mixture of the parental plants. Without such a method no surveillance and no monitoring can be performed on the stacked event.

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 cases where there are uncertainties. Thus, for example, there must be a requirement for the monitoring of health effects that takes residues from spraying with herbicides into account. Epidemiological parameters that are suitable for detecting relevant health effects need to be defined.

Further, any spillage from the kernels has to be closely monitored.

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

---

4. Conclusions and recommendations

EFSA risk assessment is failing to deal properly with findings from the comparative analysis. The assessment of toxicological effects is inadequate. Risk assessment did not take into account relevant safety issues regarding the usage of the complementary herbicide. Further,

no interactions and accumulated effects from the use of such plants in food and feed have been assessed. Consequently, the application has to be rejected.