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Testbiotech comment on the Scientific Opinion on an application (EFSA-GMO-NL-2005-24) for the placing on the market of the herbicide tolerant genetically modified soybean 40-3-2 for cultivation under Regulation (EC) No 1829/2003 from Monsanto

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Zusammenfassung

- Die Rückstände der Spritzmittel in den Pflanzen wurden bei der Abschätzung gesundheitlicher Risiken außer acht gelassen.
- Die Daten über die Lebensmittelsicherheit umfassen nicht alle relevanten Produkte. So fehlen Untersuchungen zu Sojasprossen und Sojamilch.
- Verschiedene Dokumente, die von der EFSA verfasst wurden, zeigen die Notwendigkeit einer besonderen Risikoabschätzung für Kleinkinder und VerbraucherInnen mit erhöhter Allergie-Anfälligkeit. Doch die EFSA missachtet diese Probleme in ihrer Stellungnahme.
- Die EFSA hat nicht berücksichtigt, dass der dauerhafte Verzehr der Sojabohnen, die laut gesetzlichen Vorgaben mit bis zu 20 mg/kg Glyphosat belastet sein können, zu gesundheitlichen Problemen durch Veränderungen der Darmflora bei Mensch und Tier führen können.
- Es gibt viele Untersuchungen, die Veränderungen in der Zusammensetzung der Inhaltsstoffe der gentechnisch veränderten Soja zeigen, wenn diese mit Glyphosat gespritzt werden. Die meisten dieser Untersuchungen wurden von der EFSA nicht berücksichtigt.
- Zu den Risiken für bestäubende Insekten wie Bienen gibt es keine Daten, obwohl sogar die EFSA derartige Untersuchungen als essentiell für die Risikoabschätzung ansieht.
- Die EFSA stellt fest, dass negative Auswirkungen auf Bodenorganismen und Pflanzenkrankheiten zu befürchten sind, kommt dann aber zu der Schlussfolgerung, dass dies ein eher unerhebliches Risiko sei.
- Die EFSA stellt fest, dass herbizidresistente Unkräuter ein globales Problem sind, aber anstatt dieses Risiko ausreichend ernst zu nehmen, spekuliert die Behörde darauf, dieser Entwicklung nur durch Fruchtwechsel vorzubeugen.
- Die EFSA stellt fest, dass der Anbau der Sojabohnen zu erheblichen Auswirkungen auf die biologische Vielfalt führt, zieht daraus aber nicht die naheliegende Konsequenz, sich gegen eine Zulassung auszusprechen.
- Die Auswirkungen von extremen klimatischen Bedingungen auf die Genregulation der Pflanzen wurde nie getestet, obwohl entsprechende Wetterlagen im Rahmen des Klimawandels immer häufiger werden.

Summary

Some points criticised by Testbiotech are:

- The functional stability of the gene construct was never tested under extreme climate conditions such as drought and flooding which are likely to occur more often under the ongoing climate change.
- Many investigations show changes in the plants´ composition after spraying with glyphosate. But most of these studies were not assessed by EFSA.
- The data concerning food safety of the processed food and feed do not cover all relevant products. For example, data on products such as soybean sprouts prepared from soybeans and soybean milk are missing.
- Residues from spraying and potential health effects that those compounds might cause were completely left out of EFSA risk assessment.
- EFSA overlooked that permanent ingestion of the soybeans that can show up to 20 mg/ kg of residues from spraying (as allowed by pesticide legislation) might affect microbial flora in the gut of consumers or farm animals.
- Several documents produced by EFSA emphasise the need for specific risk assessment of genetically engineered plants in regard to infants and other groups of consumers more susceptible to allergic reactions. However, in its opinion, EFSA has disregarded this problem completely.
- No data are available for risks of pollinators such as honey bees, which even EFSA considers an essential part of environmental risk assessment.
- EFSA acknowledges that negative effects on soil organisms and plant diseases have to be expected, but then comes to the contrary conclusion that these effects are of only minor relevance.
- EFSA acknowledges that the increase of glyphosate resistant weed is a problem on global scale, but instead of taking the risk seriously, EFSA assumes that these effects can be avoided by crop rotation.
- EFSA states that cultivation of the soybeans can cause severe harm to biodiversity, but at the same time omits evidence that the cultivation of glyphosate tolerant plants is already endangering populations of protected butterfly species in the US.

1. Molecular characterisation

The expression of the gene construct and the functional stability of the gene construct were not tested under extreme climate conditions such as drought and flooding which are likely to occur under the ongoing climate change. Investigations under controlled environmental conditions are necessary to determine the actual range of variation and to identify relevant impact factors.

Further, the effects of the additional genes (and non-functional sequences) on the activity of the plants´ genome and the plants´ metabolism should have been investigated using methods such as metabolic profiling. EFSA did not evaluate existing publications.

The methods for measuring the content of the additional protein in the parts of the plants were not

evaluated by independent laboratories. It was not shown that the data presented by Monsanto are reliable.

2. Comparative assessment (for compositional analysis and agronomic traits and GM phenotype)

The data provided by Monsanto show some significant differences between the genetically engineered soybeans and their conventional counterparts in composition and agronomic performance. For example, a considerable yield suppression seems to be associated with the introduced trait (Elmore et al. 2001). These differences have been declared non-relevant by referring to historical data from the ILSI Database which is known to be unreliable. Instead of using these historical data, the actual differences should have been investigated further under various defined environmental conditions, and using methods such as metabolic profiling.

Much more data would be also be needed from the receiving environment – the only available field data from EU countries were generated in 2005 in Romania.

EFSA did not assess a whole range of publications (see below) providing evidence of changes in compositional analysis after spraying the genetically engineered crops with glyphosate. Most of these studies were not even mentioned by EFSA. Some of the studies point to a change in fatty acid content and composition as well as in levels of micronutrients – changes that might impact the quality of food derived from RR soy.

Overall, there is no scientific basis for claiming substantial equivalence of the Soy. By not assessing the existing data correctly, further steps in risk assessment based on the assumption of substantial equivalence are necessarily flawed.

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3. Toxicology

3.1 Missing risk assessment of relevant food products

EFSA states that soybeans are used

> "for human consumption, including flours, soybean protein concentrates and various textured products simulating meats, seafoods and cheeses. (…) Whole soybeans are used to produce soy sprouts baked soybeans, and roasted soybeans".

But the data on anti-nutrients and food safety of the processed food and feed only cover a small range of the relevant products. For example, data on soybean sprouts, soymilk and baby food are missing. Without such data, no conclusion can be drawn on food safety.

Replying to concerns voiced by Belgian experts, this is what EFSA had to say about missing data on baby food:

> "The EFSA GMO Panel does not know what type of ingredients producers of infant formula use."

This is by no means a satisfactory answer.

EFSA also overlooked the review article by Magaña-Gómez et al. (2009). The authors come to the conclusion that in quite a few of the studies with soybean 40-3-2, there were observable signs of possible effects on health:

> "(...) a tendency towards microscopic and molecular changes was observed, suggesting some kind of cell damage. These studies should be used to support further experiments using profiling techniques to screen for potential changes at different cellular levels: gene expression, protein translation, or metabolic pathways."

3.2 Residues from spraying omitted by EFSA

Residues from spraying and their potential effects on health were left out of the EFSA risk assessment all together. But in the Council meeting on 4 December 2008, Member States requested

a revision of current EU regulations to close the loopholes between the pesticide regulation and the regulation on genetically engineered plants http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressdata/en/envir/104509.pdf) . This demand is not confined to the usage of the genetically engineered plants in agriculture but includes all relevant products, which might be authorised on the market:

> "(...) the mandate includes examination of the criteria and requirements for assessing all GMPs, including GMPs that produce active substances covered by directive 91/414/EEC and herbicide-tolerant GMPs with a view to reviewing them if necessary; (…) RECALLS that the use of plant protection products implies authorisations at national level and EMPHASISES THE NEED for competent authorities involved with the implementation of Directive 2001/18/EC and of Council Directive 91/414/EEC concerning the placing of plant protection products on the market, within the Commission and at national level, to co-ordinate their action as far as possible;"

A recent legal dossier, commissioned by Testbiotech (Kraemer, 2012) also shows that from a legal point of view, the residues from spraying with complementary herbicides need to be taken into account in the risk assessment of genetically engineered plants.

The GMO panel decided to leave these questions about the risk assessment of residues from spraying to the EFSA pesticide panel. There are, however, several reasons why the risk assessment of genetically engineered plants with herbicide tolerance cannot simply leave the issue of residues from spraying aside:

- Commercial large- scale cultivation of these plants means there is a strong selective pressure on weeds to develop glyphosate resistance, this increases the amount of sprayed herbicides and the load of residues. The complementary herbicides are likely to be sprayed several times during crop growth, thus the pattern of usage and the level of residues can be significantly higher compared to non-resistant crop plants.
- Herbicide tolerant plants are meant to survive the application of the complementary herbicide while most other plants will be killed after short time. Thus, residues of glyphosate, its metabolites and the additives can accumulate and interact in the plants that survive due to their additional genetic information.
- The residues are inevitable constituents of the plants' composition leading to a very specific exposure of the food chain.

A basic prerequisite for risk assessment in this context is reliable data on residue loads from spraying with glyphosate formulations. The amount of these residues depends on the specific agronomic management used in the cultivation of the herbicide resistant plants. However, reliable data covering the actual range of residue load in the plants are not available (Kleter et al., 2011). Without such data, no sound risk assessment of this product can be made.

Several experts warn that a higher toxicity can be expected for glyphosate than previously thought (Benachour, et al., 2007; Paganelli et al., 2010; PAN AP 2009). Further, several studies indicate that there are particular risks to health from genetically engineered glyphosate-tolerant soybeans and the residues from spraying with the complementary herbicide (Malatesta, et al. 2002, 2005, 2008; Cisterna et al., 2008, Magana Gomez et al., 2008)

In this context, the additive POEA also has to be taken into account, as it is even more toxic than glyphosate. In 2010, German authorities prohibited the use of certain glyphosate formulations with a high content of POEA for the production of animal feeds in order to avoid the risk of toxins being passed through the food chain

(www.bvl.bund.de/DE/04_Pflanzenschutzmittel/05_Fachmeldungen/2010/psm_anwendungsbestimmungen_tallowamin-Mittel.html). If other additives are used their residues would have to be considered, too.

The need for taking the residues from spraying into account is underlined by the fact that s significant proportion of consumers seem to have a substantial load of pesticide residues in their blood. As EFSA (2011) wrote in a letter to the European Commission (DG Sanco) asking for an opinion on the publication by Aris & LeBlanc (2011):

> "From the consumer health perspective, the observations described by the authors on the presence of glyphosate and glufosinate in non-pregnant women blood (5% and 18% of the subjects, respectively) and of 3-MPPA in non-pregnant women, pregnant women and the fetal cord blood are not unexpected. It is known that pesticides are generally well absorbed by the gastrointestinal tract and that an exposure to the two herbicides investigated through the consumption of food commodities is plausible."

3.3 Missing assessment of impact on gut organisms

As stated by EFSA it is known that the microbial community in the soil can be changed by frequent application of glyphosate during cultivation:

> „Potential consequences of frequent glyphosate applications in GMHT cropping systems comprise alterations in the microbial community and microbial-mediated processes carried out in the crop rhizosphere, and may encompass effects on potential phytopathogen antagonist interactions (…) Glyphosate released into the rhizosphere of GMHT soybean, combined with the release of high concentrations of carbohydrates and/or amino acids may favour increased fungal root colonisation and growth, including that of fungal soil borne plant pathogens, either directly or indirectly by suppressing bacterial antagonists (Johal and Huber, 2009). A number of studies have shown that glyphosate stimulates the growth of pathogenic fungi (…) Responses of individual fungal species varied depending on their sensitivity to glyphosate; some species express glyphosate sensitive forms of EPSPS and may not metabolise glyphosate (...), whilst others may readily metabolise glyphosate (...)."

EFSA completely overlooks that permanent ingestion of the soybeans that might carry a burden up to 20 mg/ kg of residues from spraying (as allowed by pesticide legislation), may in turn also affect microbial flora in the gut. There are, for example, concerns that permanent ingestion of glyphosate might be a cause of chronic botulism through interfering with the ecology of microorganisms in the gut (http://www.pan-germany.org/deu/~news-1102.html). The data from soil organisms, gives these scenarios sufficient plausibility and cannot be omitted from risk assessment.

There might be also be other relevant issues in relation to changes in the intestinal flora of human and animals related to the ingestion of these soybeans. Thus, targeted feeding studies should be conducted.

3.4 Misleading interpretation on exposure and requirements for monitoring

EFSA is propagating a completely misleading interpretation of data on the history of exposure to RR soybean in the last ten years:

EFSA is using the calculation from the applicant that 54% of the overall amount of soybean oil for

the food market might have been produced from genetically engineered soybeans. EFSA does not mention that these products would need labeling and EU food producers were consequently avoiding these products during the last decades. Further, soybean oil is only one and highly processed product derived from soybeans and cannot be used as a basis for surveillance of effects on health as far as genetically engineered soybeans in general are concerned.

On the contrary, genetically engineered soybeans were fed to animals on a large scale. However, no epidemiological data have been made available on animal health since 1996 when the first soybeans were imported. So the EFSA assumption that no effects on health were detected and that no monitoring would be necessary is simply based on a don´t look – don´t find strategy.

The fact that no monitoring at all was conducted in the EU on health effects is, in itself, a severe violation of current EU regulations (see Kraemer, 2012). The EFSA proposal that monitoring is also not required in future is an attack on the interests of farmers and consumers, and in conflict with the EU regulations that foresee monitoring/ general surveillance of health effects in any case where genetically engineered plants enter the market. The EFSA opinion can be interpreted as an attempt to subvert consumer protection as foreseen by EU regulations.

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4. Allergenicity

EFSA did not mention Yum et al. (2005) who reported the details of skin tests with the RR- and non-transgenic soybean. They found that the 40-3-2 soybean shows a different binding band compared with wild soy. Furthermore, one patient had a positive skin test result to GMO soybeans only.

To assess allergenicity of the whole food, EFSA and Monsanto refer only to one quite old study (Burks& Fuchs, 1995) that is based on only five samples from the serum of allergic patients. But, as the minutes of a meeting of the working group (WG) “Self Task on Allergenicity” from 24 September 2007 shows, EFSA experts have serious doubts about the reliability of investigations with sera from patients with known allergic reactions to soybeans as performed in this case. According to the minutes,

> “More sera from patients are needed but they also need to be well-characterised. Statistical calculations have been done showing that 60-70 well-characterised sera are needed based on variability. Since this might not be feasible, the WG has to consider the reliability od studies with a lower number of sera.”

So the Burks&Fuchs (1995) study should no longer be used to show the safety of the genetically engineered soybeans.

Further, as the cited document shows (minutes from a meeting on 24 September 2007), the authorities´ experts are aware that specific investigations would be needed to exclude risks for children:

> “Infants are more susceptible towards allergenic reactions as their gastro-intestinal tract differs from adults. A specific assessment for children might therefore be recommended. It needs however to be discussed how this specific pre-market assessment needs to be

performed. It might for instance be recommended that more research is needed on young animal models."

Similarly, the need for more detailed investigations is expressed in EFSA (2010):

> "The specific risk of potential allergenicity of GM products in infants as well as individuals with impaired digestive functions (e.g. elderlies, or individuals on antacid medications) should be considered, taking into account the different digestive physiology and sensitivity towards allergens in this subpopulation." (page 46)

However, these specific risks for infants were omitted during the EFSA risk assessment.

In this case, the weight of evidence approach used by EFSA is based on tests that are unreliable, and the necessary detailed risk assessment for infants is completely missing.

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5. Environmental risk assessment

5.1 Wrong assumption about equivalence

The EFSA conclusion „that soybean 40-3-2 has no altered agronomic and phenotypic characteristics, except for the herbicide tolerance" is not sufficiently based on scientific findings, more investigations concerning environmental risks are required. Unintended changes in plant components - such as those reported for plants sprayed with the herbicide - can lead to a wide range of unexpected ecological behaviour under specific environmental conditions, and might, for example, make plants more vulnerable to plant diseases. Without assessing the publications cited by Testbiotech under the heading „comparative analysis" and without more detailed investigations under controlled environmental conditions no final conclusion can be drawn.

5.2 Missing data on risks for pollinators

EFSA makes a strong statement about missing data being necessary to perform risk assessment on pollinators such as honey bees:

„However, no event-specific data on plant-pollinator interactions were provided by the applicant. The EFSA GMO Panel considers that these data are essential for the environmental risk assessment, and therefore scientific uncertainties pertaining to the occurrence of adverse effects on pollinators due to potential unintended changes in soybean 40-3-2 remains.“ (page 32/33)

This issue is all the more important as beekeepers may be asked to place beehives close to soybean fields in order to increase soybean yield (RIRDC 2009).

However, instead of requesting these data for risk assessment, EFSA agreed to Monsanto proposals to conduct some studies after market authorisation. It would be the first time that official risk assessment was not finalised before market authorization. This is not in line with current EU regulations. Without sufficient data, the precautionary principle must come into force and no commercial cultivation can be allowed.

5.3 Effects on Soil:

EFSA concludes that negative effects on soil organisms have to be expected:

“On the negative side, there is evidence that, depending upon the specific herbicide regimes applied at the farm level, the cultivation of GMHT crops may: (…) affect soil microbial communities.” (page 38)

Further, EFSA cites relevant literature that clearly shows the negative impact of cultivation of the herbicide tolerant crop on soil organisms, and concludes a high risk for change in the microbial ecology - at least if the soybeans are grown consecutively over several years. EFSA also points out that several investigations indicate higher risks of plant fungal diseases:

„Glyphosate released into the rhizosphere of GMHT soybean, combined with the release of high concentrations of carbohydrates and/or amino acids may favour increased fungal root colonisation and growth, including that of fungal soil borne plant pathogens, either directly or indirectly by suppressing bacterial antagonists (Johal and Huber, 2009). A number of studies have shown that glyphosate stimulates the growth of pathogenic fungi such as Fusarium, Pythium, Phytopthora, Corynespora and Sclerotinia, and can inhibit beneficial fungi. Responses of individual fungal species varied depending on their sensitivity to glyphosate; (…) In a laboratory study, growth of the plant pathogens Pythium ultimum and Fusarium solani could be stimulated or inhibited, depending on glyphosate concentration (Kawate et al., 1992). Kremer and Means (2009) reported that Fusarium spp. colonisation levels of roots of GMHT soybean receiving glyphosate were two to five times higher, compared with soybean receiving no herbicides, or a conventional herbicide, indicating that glyphosate induces fungal colonisation of soybean rhizospheres and hence affects the ability of plants to suppress potential pathogen colonisation and root infection.“ (page 44/45)

EFSA refers to other publications that found less impact on soil organisms and fungal diseases. But these studies are in no way sufficient to contradict the studies that show severe effects on soil organisms and plant diseases. EFSA even assumes the effects would be of such minor relevance that not case specific monitoring would be required. In consequence, EFSA is taking a biased position that is not sufficiently based on scientific evidence.

5.4 Resistant weeds:

EFSA acknowledges that increasing resistance of glyphosate resistant weed is a problem on global scale – caused by the introduction of Monsanto´s herbicide resistant plants:

> "contradicting the initial speculations that the evolution of glyphosate resistant weeds was unlikely (...). Currently, 21 weed species have evolved glyphosate resistant populations globally and 12 glyphosate resistant weed species (such as Amaranthus palmeri, A. rudis, A. tuberculatus, Ambrosia artemisiifolia, A. trifida, and various Conyza and Lolium spp.) have been identified in the USA , most of which evolved resistance to glyphosate in GMHT cropping systems (...). Likewise, in cultivation areas of GMHT crops in Argentina and Brazil, glyphosate resistant populations of Sorghum halepense and Euphorbia heterophylla have been reported, respectively (...)." (page42)

In other words, these effects are being observed in all regions where the genetically engineered soy is grown on a large scale for a longer period of time. Meanwhile, glyphosate-resistant weed populations have been described for at least 23 weed species (www.weedscience.org). EFSA assumes that these effects can be mitigated by crop rotation, but this assumption is not based on any experience. There are several effects described that can lead to an increase in herbicide resistance in weed. The evolutionary mechanisms behind the observed fast adoption of resistance in weed species is not fully understood. Further, it is known that resistance once established, can spread quickly amongst the weedy species. The EFSA conclusion that negatives effects can be mitigated implies a too high level of uncertainty.

The Commission should give a clear signal that based on current experience this technology cannot be regarded as promoting sustainable agriculture, and therefore cultivation of the soybeans within the EU cannot be permitted.

5.5 Effects on biodiversity

EFSA states that cultivation of the soybean can cause severe harm to biodiversity:

> "The EFSA GMO Panel is of the opinion that potential adverse environmental effects of the cultivation of soybean 40-3-2 are associated with the use of the complementary glyphosate-based herbicide regimes. These potential adverse environmental effects could, under certain conditions, comprise: (1) a reduction in farmland biodiversity; (2) changes in weed community diversity due to weed shifts; (3) the selection of glyphosate resistant weeds; and (4) changes in soil microbial communities."

However, EFSA does not include evidence that the cultivation of glyphosate tolerant plants puts populations of endangered species at risk e.g. protected butterflies. Brower et al (2011) and Pleasants & Oberhauser (2012) have shown a dramatic decline in the population of Monarch butterflies caused by a reduction in milkweed species in the regions where these genetically engineered crops are cultivated. In Europe, there could be similar hazards that would need assessment when it came to large-scale cultivation. This example shows that EFSA risk assessment is deficient in regard to even the most crucial elements in environmental risk assessment.

Furthermore, EFSA omitted potential effects on wildlife species, aquatic systems and highly suspectible organisms like amphibians (Relyea, 2012) or fish.

Consequently, the risks for biodiversity are likely to be much higher than described by EFSA, crucial data such as risk for pollinators are missing and relevant uncertainties are not mentioned in the opinion.

References:
Brower, L.P., Taylor, O.R., Williams, E.H., Slayback D.A., Zubieta, R.R. Ramirez, M.I., (2011) Decline of monarch butterflies overwintering in Mexico: is the migratory phenomenon at risk?, Insect Conservation and Diversity doi: 10.1111/j.1752-4598.2011.00142.x

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Kawate, M.K., Kawate, S.C., Ogg, A.G., Kraft, J.M. (1992) Response of Fusarium solani f. sp. pisi and Pythium ultimum to glyphostae. Weed Science, 40: 497–502.

Kremer, R.J., Means, N.E. (2009) Glyphosate and glyphosate-resistant crop interactions with rhizosphere microorganisms. European Journal of Agronomy, 31: 153–161.

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Relyea, R.A. (2012) New effects of Roundup on amphibians: Predators reduce herbicide mortality; herbicides induce antipredator morphology. Ecological Applications 22: 634-647. http://dx.doi.org/10.1890/11-0189

RIRDC (2009) Pollination, Soybean. http://www.rirdc.gov.au/programs/established-rural-industries/pollination/soybean.cfm.

Conclusion on environmental risk assessment:
When observations on large-scale cultivation of herbicide tolerant crops in countries such as Argentina and the USA are taken into account, the cultivation of these crops cannot be regarded as sustainable. The expectation that the negative impact of large-scale cultivation can be reduced by risk mitigation measures is a matter of theoretical expectation rather than one of practical experience. Cultivation of these herbicide resistant plants poses risks to biodiversity, plant health, soil fertility and enables the emergence of herbicide resistant weeds. There is substantial indication that plant diseases, e.g. increased infestation with fungal diseases are caused by the large-scale cultivation of glyphosate tolerant crops. The negative impact on plant growth and plant health can even be transmitted to other plants cultivated in the same field in the following year (Bott et al., 2011, Bott et al., 2008).

The risk manager should give a clear signal that agriculture in the EU is giving sufficient weight to sustainability in agricultural production and, therefore, the cultivation of herbicide-tolerant crops such as soybean 40-3-2 should not be regarded as an option.

References:
Bott, S., Tesfamariam, T., Candan, H., Cakmak, I., Römheld, V., Neumann, G. (2008) Glyphosate-induced impairment of plant growth and micronutrient status in glyphosate-resistant soybean (Glycine max L.), Plant Soil, 312:185–194.

Bott, S., Tesfamariam, T., Kania, A., Eman, B., Aslan, N., Roemheld, V. Neumann, G. (2011) Phytotoxicity of glyphosate soil residues re-mobilise4d by phosphate fertilization. Plant Soil, 315: 2-11. DOI 10, 1007/s11104-010-06989-3.

6. Others

As a recent legal dossier compiled by Professor Ludwig Kraemer shows, the decision not to monitor any health effects violates the requirements of EU regulations. Directive 2001/18 and Regulation 1829/2003 both require that potential adverse effects on human health of genetically modified plants are controlled during the use and consumption stage, including in those cases that such effects are unlikely to occur. Monitoring also has to include residues from spraying with the complementary herbicide.

Thus, the EFSA opinion that monitoring of health effects is unnecessary, is wrong and in contradiction to current EU regulations.

In its opinion, EFSA suggests several times that no negative effects on health have emerged after several years of using these plants in food and feed. However, it should be stated very clearly that despite the requirements of EU regulation, no systematic data were collected on human and animal health. Consequently, we have the same situation within the EU that the Commission described in a dossier forwarded to the WTO (European Communities, 2005):

> "As regards food safety, even if some GM products have been found to be safe and approved on a large scale..., the lack of general surveillance and consequently of any exposure data and assessment, means that there is no data whatsoever available on the consumption of these products – who has eaten what and when. Consequently, one can accept with a high degree of confidence that there is no acute toxicological risk posed by the relevant products, as this would probably not have gone undetected – even if one cannot rule out completely acute anaphylactic exceptional episodes. However, in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health."

It is now the time to take action to protect consumers and the environment as foreseen by EU regulations before any new decsisions are taken upon further authorisations.

Technical remark: The way that the EFSA presents its opinions causes considerable confusion. Several opinions and updates are available on this crop. In the latest EFSA opinion, some food and feed aspects were discussed broadly, even though they had been assessed previously. Other aspects that were assessed in the previous opinion were left aside. A possible solution for this situation might be that EFSA should always present all relevant findings on each event in its 'final' opinions regardless of whether these concern usage in food and feed or crop cultivation.

References:

European Communities (2005) Measures affecting the approval and marketing of biotech products (DS291, DS292, DS293). Comments by the European Communities on the scientific and technical advice to the panel. 28 January 2005, http://trade.ec.europa.eu/doclib/html/128390.htm

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

Conclusion and recommendations

The opinion of EFSA has to be rejected.