Letter to EU Member States concerning the vote on genetically engineered soybean 40-3-2 (Monsanto) and A5547-127 (Bayer CropScience)

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Dear representatives of the Member States

We are writing to you to make you aware of a complicated legal situation concerning the vote to be taken on the continued marketing of soybean RR 40-3-2 (Monsanto) and market authorisation of A5547-127 (Bayer CropScience). Its authorisation would not be in line with current EU legislation on pesticides and genetically engineered organisms.

(1) REGULATION (EC) NO 396/2005
Necessary data for setting and assessing the maximal residue levels (MRL) for glyphosate and glufosinate stemming from cultivation on these soybeans under the specific and recent agricultural conditions in countries like US, Brazil or Argentina are missing. Trials should have been performed, taking into account the specific agricultural practice in these countries. But so far the presence of pesticide residues stemming from plant protection practice in most relevant countries, and their cumulative and synergistic effects, have not been determined.

(2) DIRECTIVE (EC) NO 2001/18, REGULATION (EC) NO 1829/2003
The risk assessment does not fulfill the high standards of protection of human health as foreseen in the EU Regulation. For example significant changes in the composition of the plants were not assessed sufficiently, possible impact on immune system or the reproductive system were not investigated by empirical data. Although health risks are known from the usage of glyphosate and glufosinate and its metabolites produced in the plants, no specific monitoring of health effects are proposed by EFSA. Also no measures to imply general surveillance are foreseen as legally required.

We therefore kindly urge you to reject these market applications and the opinions of EFSA because they do not meet the legal requirements for the protection of consumer health within the European market.

With kind regards,

Christoph Then, Testbiotech
info@testbiotech.org, Tel: 0049 15154638040

Steffi Ober, Naturschutzbund (NABU),
Tel. + 49 (0)30.28 49 84-1612
Steffi.Ober@nabu.de

PS: Regarding the discussion about the risk assessment of “SmartStax” maize (Monsanto) we kindly ask you to take into account a recent report by Testbiotech, Then, C., Bauer-Panskus, A., 2011, How industry and EFSA have been systematically undermining the risk assessment of ‘SmartStax' http://www.testbiotech.de/sites/default/files/PR%20Testbiotech-SmartStax_2.pdf

Testbiotech Background to the letter to EU Member States concerning the vote on genetically engineered soybean 40-3-2 (Monsanto) and A5547-127 (Bayer CropScience)

(1) Pesticide regulation and its interplay with risk assessment of genetically engineered plants

Where pesticide residues are concerned, the data that are necessary to assess the actual risks stemming from the usage of these plants under the specific conditions of cultivation in the originating countries such as Brazil, Argentina are completely missing, also from the US recent data taking are lacking into account changed agricultural practise due to the rise of herbicide resistant weeds. Some of the relevant questions – such as residues and metabolites and possible synergies are quite specific for genetically engineered plants and have to be investigated in detail even if the pesticide itself is approved within the EU. The necessary interplay between risk assessment of genetically engineered plants and the pesticide regulation was omitted completely in EFSA's current opinions. Recent publication of EFSA (EFSA 2011) on Pesticide Residues gives no data on glufosinate. On glyphosate, 462 samples are mentioned, in nearly 10% residues were detected, details on imported soybeans are not given.

This data gap is also evident from recent publications. For example Kleter et al (2011) explain:

> *"While residue data from experimental studies have been used to establish the residue tolerances for the herbicide–crop combinations described above, it would be interesting to compare these tolerances with what is actually measured in the field, i.e. in commercially produced foods. No measurement of the herbicides of interest in the particular crop foods in question is apparently carried out by the centralised or federal pesticide residue monitoring programmes of the EU, the United States and Canada."*

Also EFSA (2011 b) states in a letter to the EU Commission:

> *"The risk assessment with the purpose of setting maximum residue levels (or import tolerances) in imported commodities falls within the scope of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin. Residue trials would need to be performed according to the agricultural practice relevant to the herbicide tolerant crops and an evaluation of the consumer safety is a prerequisite for the setting of any higher maximum residue level necessitated by that use."*

EFSA´s letter (EFSA, 2011 b) reflects the need for EU Regulation (EC) No 396/2005 to be obeyed when it comes to the risk assessment of herbicide tolerant events. For example Recital 26 of this Regulation reads:

> *"For food and feed produced outside the Community, different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Community. It is therefore appropriate that MRLs are set for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce."*

Since relevant data concerning the actual residue loads stemming from cultivation in countries like Brazil and Argentina, where these soybeans are allowed to be cultivated, are missing completely, the risk assessment of these products is flawed. From the aspect of consumers' safety this is not acceptable:

- Glufosinate use in transgenic plants is problematic, the substance is regarded as potentially causing health effects (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). Plants contain residues from spraying with herbicide formulations and their metabolites. Furthermore, it could be shown that the metabolite of glufosinate (called NAG) produced by the transgenic plants can be partially reconverted into the pesticide itself by gut

bacteria, leading to increased health risks for animals and consumers (Bremmer & Leist 1997).

- Several experts warn that a toxicity has to be expected in glyphosate higher than anticipated so far (Antoniou, et al., 2010; Benachour, et al., 2007; Paganelli et al., 2010; PAN AP 2009). In this context, the additive POEA also has to be taken into account as it is even more toxic than glyphosate in these plants. In 2010, German authorities even prohibited the usage of certain glyphosate formulations with a high content of POEA for the production of animal feeds in order to avoid a risk of toxins being passed through the food chain (BVL, 2010). The GMO panel decided to leave these questions concerning the risk assessment of residues from spraying to EFSA´s pesticide panel. In parallel, there is an ongoing EU process which is reviewing glyphosate under the pesticide regulation. Results are expected in 2012 but have been postponed (see EU Commission, 2002; Antoniou et al., 2011). Thus, the risk assessment of Roundup Ready soybeans suffers on two quarters – in the work of the GMO panel and the European pesticide regulation.

These aspects also have to be taken into account by post market monitoring, as legally required. Monitoring health effects has to include the risks associated with the spraying of glufosinate and glyphosate formulations and their residues in the plants. This is also underlined by the fact that a significant proportion of consumers seem to bear a substantial load of pesticide residues in their blood. As EFSA (2011c) writes in a letter to the European Commission (DG Sanco), which asked 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."*

2. On regulation concerning genetically engineered organisms

In comparison with its conventional counterparts, many significant differences in the compositional analysis and the agronomic performance were found in these plants but these were not investigated further. For example in the RR soy 40-3-2 plants the lignin content is affected (Zobiole et al., 2010a and 2010b). Instead references were made to unspecific and questionable 'historical' data from the industry unrelated to the actual field trials, e.g. the ILSI database. Since it is not sufficiently clear under which specific conditions these additional historical data were generated, this kind of comparison inevitably contains major uncertainties (Hilbeck et al., 2011). As a result, the assumption of substantial equivalence is based not on data, but mostly on statistical tricks and data manipulation.

Soybeans are known to cause severe allergic reactions. The newly introduced gene construct might for example enhance an immune response to these endogenous plant protein(s). Furthermore, soy beans are known to produce compounds with hormonal activity. The content of these compounds might be changed by interference with the newly introduced gene constructs. Despite these known risks to human health, no feeding studies were conducted with the plants from Bayer to investigate the potential negative impact on human and animal health. Some of the studies performed with soy RR 40-3-2 revealed effects that should have been investigated further (Malatesta et al., 2002a, 2002b, 2003, 2005, 2008). Instead EFSA dismissed the findings due to methodological issues without discussing their substance. In Bayer´s plants no empirical investigations were performed

concerning allergies or other impacts on the immune system. No endocrinological studies were performed to investigate potential impacts on the reproductive system

Also the risk assessment of possible accumulated effects is missing completely. These plants will be fed and might be eaten by mixing them with other genetically engineered plants. Tests have to be performed on potential accumulated effects such as combinatorial or accumulated effects.

No plan for surveillance as required by European regulation was made available such that would allow identification of particular health impacts that might be related to the use of these genetically engineered plants in food and feed.

In conclusion, the requirements of current EU legislation are not met and the applications should be rejected.

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