Soybean FG72

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

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a. Assessment:
Molecular characterisation

Quotes:

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Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific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 class1 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 (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: 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.

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

see 3a

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b. Food Safety Assessment:
Toxicology

see 3a

Allergenicity

see 3a

Nutritional assessment

see 3a

Others

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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3. Environmental risk assessment

see 3a

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4. Conclusions and recommendations

see 3a

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5. Others

Don't approve this. More research needed.

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6. Labelling proposal

Don't authorise it, labelling not relevant.

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.

Organisation: Citoyen
Country: France
Type: Individual

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a. Assessment:
Molecular characterisation

Insufficient is known

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

Insufficient

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b. Food Safety Assessment:
Toxicology

Bad

Allergenicity

Bad

Nutritional assessment

Insufficient

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3. Environmental risk assessment

Insufficient, the risks are too great and irreversible

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4. Conclusions and recommendations

Any introduction, marketing or use of this product, which is dangerous and unfit for use, and entails unacceptable risks, should be refused.

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

a. Assessment:
Molecular characterisation

The plants were produced using a ballistic method. There are several copies of the additional DNA inserted in the plants´ genome, showing defragmentations and other unintended characteristics in the size and orientation of the copies.

The emergence of new variations, combinations and concentrations of unintended small, biological active RNA molecules such as microRNA was not assessed. 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. 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 enzyme that confers 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). In this case, the expression data stem from another plant variety than that used in the final field trials. It seems to be unclear if these data are comparable to other plant varieties.

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)

Significant differences were found for several compounds during the comparative assessment, especially in field trials conducted in 2008 / 2009. These results were not taken into account by EFSA. Instead, the basis for risk assessment was confined to field trials from 2011 that were carried out with another genetic background (other plant variety) than that used in the previous field trials.

The results from all field trials should be assessed in detail, investigating specific interaction between the additional DNA and the genetic background of the different plant varieties as well as interaction between the environment and the genome.

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b. Food Safety Assessment:
Toxicology

The applicant failed to provide a 90-day feeding study of sufficient quality. EFSA should have requested a new study, using material that was sprayed with the complementary herbicides.

Since the feeding study was rejected, health risks stemming from feeding whole food and feed cannot be assessed. This is especially relevant for assessing potential health effects from the combination of the residues from spraying with glyphosate and isoxaflutole. 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). The US EPA found that isoxaflutole “induced liver and thyroid tumors in rats and liver tumors in mice. Isoxaflutole was therefore classified as "likely to be a human carcinogen”.” (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0845-0004) According to the draft Renewal Assessment Report prepared by Italy, liver tumours were observed in rats and mice, and thyroid tumours were seen in male rats (Directorate General for Hygiene, Food Safety and Nutrition, 2015).

The plants will contain residues from both herbicides, none of which have been tested for specific combined toxicity. Thus, 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 this event.

In general, risk assessment as performed by EFSA lacks sufficient interplay between the pesticide assessment and the GMO 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 patterns of residues that need to be assessed. In this case - according to the comments from Member States - the enzymes that confer resistance to isoxaflutole can also render tolerance to other groups of herbicides. Thus, all possible combinations and dosages needs to be taken into account in risk assessment. But no such studies were conducted.

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.

Directorate General for Hygiene, Food Safety and Nutrition (2015) Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N°844/2012. Isoxaflutole - Volume 1.
http://www.efsa.europa.eu/en/efsa_rep/repository/assessment_reports/Isoxaflutole_RAR.zip

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

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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 plant 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. This is a specific risk that needs to be addressed in the context of residues from spraying with the complementary herbicides.

Bayer presented data intended 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. Bayer 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 reactions to the soybean allergens.

Some additional testing was performed with blood samples from people known to be sensitive to soybean allergens to find out if they had a changed reaction to the genetically engineered soybeans. However, the number of samples used for testing was too small to get reliable results.

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

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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 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 to detect relevant health effects have to be defined.

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

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4. Conclusions and recommendations

Based on the data presented and assessed, risk assessment cannot be concluded. Consequently, the application should be rejected.
