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Head of Cabinet to Commissioner Tonio Borg
Joanna Darmanin
Health & Consumers Directorate-General
B – 1049 Brussels
Belgium

Munich, 16 July 2013

Dear Joanna Darmanin

Your letter Ref. Ares(2013)2649696 – 12/07/2013, Assessment of health risks relevant to the genetically engineered maize SmartStax

Thank you very much for your reply regarding the risk assessment of the genetically engineered maize SmartStax, in response to our letter dated 14 June 2013. In our letter, we listed a range of publications showing a broad range of risks and uncertainties relevant to risk assessment of SmartStax. In your reply, you refer very generally to several EFSA opinions, saying the publications as listed have already been assessed. We would very much appreciate it if you could provide us with a more detailed analysis. As you know, we follow EFSA opinions very closely, but we are not aware of a sufficiently detailed assessment in this context, based upon empirical investigations. From your perspective, the publications as mentioned might not provide final evidence on health hazards, but at the very least, you should acknowledge that they are a reason for increasing concerns about health risks. For example, several of the publications as quoted add to an overall picture showing health-related impacts on the immune system. To our knowledge, EFSA has never assessed patterns of health impacts implied by stress reactions and consequent signs of inflammation. As far as combinatorial effects are concerned, we are aware of several assumptions made by EFSA, most of which are not based on real investigations.

In this context, we would like to draw your attention to a further new publication that again adds to the overall picture of health risks. Whilst Bondzio et al (2013) did not find signs that Cry1Ab is acutely toxic to porcine cells, there were identifiable signs of stress reaction in the cells that were treated. The authors are therefore arguing for more long term investigations.
In the case of SmartStax, such investigations were never carried out. We need to be aware that not only is there a much higher dosage of Bt proteins in SmartStax, but also of the possible combinatorial effects between the toxins and further stressors such as residues from spraying.

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In this context, you have an obligation to reconsider publications such as Seralini et al (2012) which raises concerns about residues from spraying with mixtures of glyphosate. There are many other scientific studies showing that at least some of the mixtures containing glyphosate, which are sprayed on genetically engineered crops such as SmartStax and Powercore, are suspected of having severe impacts on health. If you need a list of references please let us know.

In the light of publications such as Bondzio et al (2013), the Carman et al (2013) publication appears to be very relevant. It indicates a scaled stress reaction in pigs fed with a similar mix of proteins present in SmartStax and Powercore. We are aware of an initial critical analysis of the Carman et al (2013) publication presented by German authorities (BVL & BfR 2013), pointing out the scientific weakness of the publication because the pigs were kept under practical farm conditions. However, the impact on health from food and feed derived from genetically engineered plants has rarely been investigated and /or monitored under practical conditions with a realistic combination of stress factors. In conclusion, the hypothesis that SmartStax is safe for human and animal consumption must be rejected because the weight of evidence has shifted.

In any event, risk analysis under EU Regulation 178/2002, requests that the risk manager proceeds on a precautionary basis taking both the true range of uncertainties and gaps in knowledge into account. A high level of protection must be afforded to human health and the environment. In the case of SmartStax, we are seeing mounting uncertainties due to the combination of several genetically engineered plants, which already have single traits. This is creating some very serious doubts about the safety of food. Uncertainties are being revealed through scientific publications and by flaws in current risk assessment. These flaws have always been rejected in general statements and never been corrected or discussed in detail. For example the safety of the synthetical protein Cry1A.105 was never investigated in all details. As several publications show, synthetically derived and modified Bt toxins can show much higher toxicity than native proteins. Even small changes in the structure of the proteins can cause huge changes in toxicity. In the case of Cry1A.105, there is indeed evidence that toxicity is enhanced and selectivity is decreased. As a result, the toxicity of Cry1A.105 can concern a wider range of non-target organisms than expected and also might impact human or animal health. As described in Monsanto´s US patent application Patent 6,326,169, the toxicity is of Cry1A.105 is changed and enhanced in an unexpected way:

> "Another aspect of the invention further demonstrates the unexpected result that certain chimeric Cry1Ab/ Cry1F proteins maintain not only the insecticidal characteristics of the parent delta -endotoxins, but also exhibit insecticidal activity which is not displayed by either the native Cry1Ab or Cry1F endotoxins."

These findings on changes in the toxicity of the Bt protein, which were not mentioned and assessed by EFSA, show the need for much more detailed investigation into the risks of the parental plants.

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It is the political responsibility of the EU Commission to stop the market authorisation of SmartStax because the degree of uncertainty is too high. As you know, in this regard, the risk manager cannot simply rely on EFSA opinions.

We urge the Commission to stop market authorisation and send a clear signal that the protection of human health and the environment is paramount, and will not be jeopordised by commercial interests.

With kind regards

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Publications as cited:

Bondzio, A., Lodemann, U., Weise, C., Einspanier, R. (2013) Cry1Ab Treatment Has No Effects on Viability of Cultured Porcine Intestinal Cells, but Triggers Hsp70 Expression, PLOS one, Vol. 8, Issue 7, e67079, www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0067079&representation=PDF

BVL & BFR (2013), Stellungnahme von BVL und BfR zu Carman et al. 2013, http://www.testbiotech.de/node/845

Carman J.A., Vlieger, H.R., Ver Steeg, L.J., Sneller, V.E., Robinson, G.W., Clinch-Jones C.A., Haynes J.I., Edwards J.W. (2013). A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. Journal of Organic Systems 8 (1): 38-54. Open access full text: www.organic-systems.org/journal/81/8106.pdf

Seralini, G-E., E. Clair, R. Mesnage, S. Gress, N. Defarge, M. Malatesta, D. Hennequin, J. Spiroux de Vendomois (2012) Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize, Food Chem. Toxicol., http://dx.doi.org/10.1016/j.fct.2012.08.005

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