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SmartStax:
How the EU Commission is misleading public opinion

Testbiotech e. V.
Institute for Independent Impact Assessment in Biotechnology

On 20 of June, the EU Commission sent a reply to Testbiotech in response to the e-mails they received concerning “Stop SmartStax” (http://www.testbiotech.de/node/834). Testbiotech is of the opinion that the reply is misleading and is likely to damage the credibility of the EU Commission. It looks like the Commission, while pushing for market authorisation, is giving preference to commercial interests rather than a scientific argumentation. Despite the EFSA having provided risk assessment of SmartStax as far back as 2010, the Commission only recently started the process of market authorisation after there were reports about SmartStax being imported illegally. Stopping these imports would conflict with the interests of feed industry and companies like Monsanto which are producing these plants.

Reply of the EU Commission	Comment Testbiotech
Thank you for your email of 3 June 2013 addressed to Commissioner Borg, in which you outline your concerns regarding GM food/feed coming in particular from SmartStax maize. The Commissioner asked me to reply on his behalf.	This letter was written by Dorothée André, head of the GMO Unit of Commissoner Tonio Borg. But in the end it is the Commissioner to be held responsible for the decision making on SmartStax.
Let me begin by reassuring you that the Commission considers the protection of human and animal health and of the environment as a top priority and is committed to ensuring that GM seed, food and feed are allowed in the EU only when it has been established, on the basis of a thorough examination, that they do not have adverse effects on human health, animal health or the environment.	This statement is not based on facts. The risk assessment of SmartStax shows the opposite is true: There was no “thorough examination” in this case.
This risk assessment is performed by the European Food Safety Authority (EFSA), which evaluates the studies submitted by the applicants on the basis of the provisions of Regulation (EC) 1829/2003, and also studies performed by independent experts.	EU Regulation 1829/ 2003 requires that “genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority, of any risks which they present for human and animal health and, as the case may be, for the

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	environment.” (Recital 9). These requirements are not fulfilled in this case. Representatives of this industry themselves claim that some of their methods used for investigating the crops are only preliminary and admit that for several of the relevant dossiers, the standards for Good Laborartory Practise (GLP) are not met. And: Neither the EFSA nor the industry itself initiated any independent study for the market authorisation of SmartStax.
Regarding the draft Commission Decision on SmartStax presented at SCFCAH *[which is the Committee of the Experts of the EU Member States]* on 10 June 2013, I would like to stress that it has a favourable opinion from EFSA. The risk assessment follows the requirements of the relevant EFSA guidance documents for the risk assessment of GM food/feed and of stacks *[stacked events are plants which are produced by crossing of several genetically engineered plants]*.	The opinion of the EFSA suffers from substantial flaws such as: • The possible interactions between residues from spraying with the complementary herbicides and the various insecticidal proteins produced by SmartStax were not investigated. • Risks for the immune system were not investigated but simply disregarded as “unlikely” . • No feeding studies to investigate health effects for human and animal were carried out. • During field trials SmartStax showed several significant differences in its composition when compared with plants derived from conventional breeding. These differences should have been investigated in much more detail. However the EFSA dismisses these findings as irrelevant by referring to a database used by the industry that is known not to be reliable. The decision of the Commission is not bound by this flawed opinion of the EFSA. To the contrary, Regulation 178/2002 clearly states that the Commission should also to take into consideration other relevant findings before any decision is taken.
Regarding the pollen, EFSA also gave a favourable opinion on the application for placing on the market of maize MON810 pollen as or in foods. It concluded that the genetic modification in this GM maize does not constitute additional health risk if maize MON810 pollen is to replace pollen from non-GM maize as or in foods.	The EFSA clearly stated that there are hardly any specific data on risks of pollen from MON810. Therefore the EFSA ´s opinion is largely based on assumptions and not on real investigations.
I would like to stress that the European system for authorising GMOs is considered to be the strictest in the world as regards the protection of human and animal health and the environment. If	Very often the industry refers to what they call strictest testing in the EU when their plants are sold in other parts of the world. However, the risk assessment performed by the EFSA is actually not adquate to sufficiently exclude adverse effects on humans, animals and the enviroment - as

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authorised, the GMOs are further subject to strict requirements for environmental monitoring once they are placed on the market. Furthermore, EFSA continuously monitors and analyses the relevant scientific literature on authorised products and GMOs in general, and the Commission can take appropriate follow up measures if new or additional information on potential safety risks related to a product are identified.	exemplified in the case of SmartStax Furthermore, contrary to what is suggested by the EU Commission, there is no monitoring of health impacts due to the consumption of genetically engineered plants, despite requirements in EU regulations. Finally there are several findings in published literature that show that relevant health risks have been understimated (open letter). But so far none of these publications caused the EFSA to request further investigations.
I hope you are assured on the commitment of the Commission to ensure that GMOs can be authorised in the EU for food/feed uses only if they demonstrate their safety for health and the environment.	For readers who are more familiar with this issue, the credibility of the EU Commisson is seriously lacking It looks like the Commission, while pushing for market authorisation, is only taking into account commercial interests: The EFSA provided a risk assessment of SmartStax as early as 2010. Nevertheless, the Commission only started to proceed with market authorisation in 2013 after there were reports about SmartStax being imported illegally.