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European Commission

European Commissioner for Health and Consumer Policy
Mr. Tonio Borg
Health & Consumers Directorate-General
B – 1049 Brussels
Belgium

Munich, 14 June 2013

Dear Mr Borg

New evidence that the genetically engineered maize SmartStax is a risk to health

There are several publications showing that risks posed by SmartStax to human and animal health have so far been underestimated and incorrectly assessed by EFSA:

Scientists recently fed genetically engineered maize to pigs and found it had significant effects on their health. The feed used in the trial had a similar mixture of residues from spraying with herbicides and insecticidal toxins to that of SmartStax. It is currently not known if SmartStax could have similar effects. There has, in fact, been no feeding study to investigate effects on health carried out with SmartStax, which produces a mixture of six insecticidal toxins and was made resistant to two herbicides.

Further, a print version of a scientific publication has just become available. This publication (Mesnage et al., 2013) reports on the unintended effects on human cells due to insecticidal toxins similar to those produced by SmartStax. The effects were observed at a relatively high concentration. According to data from industry, the content of the insecticidal toxins produced by SmartStax is highly variable and can add up to quite high levels (see Testbiotech, 2010). In the case of Bt toxins, standardised protocols to measure the content of Bt toxins in a way that the results can be reproduced by other laboratories are largely missing (Székács et al., 2011). Therefore, it is impossible to know the true concentration of the toxins.

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These findings have to be interpreted in the light of key findings by Walsh et al. (2011) showing that the protein Cry1Ab can be found in the colon of pigs with an 80% success rate. It appears that the Cry proteins can have a much higher stability in monogastric species than predicted by current in vitro digestion experiments. This higher stability can influence potential toxicology as well as immune reactions that may underlie the findings made by Carman et al (2013). There are several studies showing immune reactions in animals after being fed with Bt plants, none of which EFSA (2010) took into account. Examples include fish (Sagstad et al., 2007), pigs (Walsh et al., 2011), mice (Finamore et al., 2008), and rats (Kroghsbo et al. 2008).

It also should be acknowledged that the EFSA opinion on safety of maize SmartStax is based mostly on assumptions about the mode of action of Bt toxins that are not sufficiently based on scientific evidence. There are several modes of action described and not just one theory about how these toxins function. Some of these publications show that selectivity cannot be assumed without detailed testing, others show that synergistic interactivity has to be taken into account (for overview see, Then 2010).

Testbiotech is of the opinion that the new publications make it necessary to stop the process of authorisation. We would also once more like to draw your attention to our previous report on the flaws of the risk assessment performed by EFSA (Testbiotech, 2010).

With kind regards



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