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European Commission

European Commissioner for Health and Food Safety Mr Vytenis Andriukaitis Health & Consumers Directorate-General B – 1049 Brussels Belgium

open letter

30 April 2015

Dear Mr Andriukaitis

Time to stop cultivation of MON810

We are writing to ask you to stop the cultivation of MON810 in 2015. Overwhelming evidence has emerged that current practices in the cultivation of MON810 do not comply with EU regulations:

- (1) Monsanto is not fulfilling its obligation to monitor the MON810 crops, and say that they will not do so in future.
- (2) There is new evidence that gene expression in MON810 is not predictable.
- (3) There are considerable flaws in EFSA risk assessment, which have once more been highlighted in findings from recent studies on pollen dispersal in the environment.

In more detail:

(1) According to EU Directive 2001/18, if genetically engineered plants are cultivated for commercial reasons, the company has to regularly produce a monitoring report on potentially adverse effects on human health and the environment. According to EFSA, Monsanto failed to produce a comprehensive report for 2013, and EFSA experts have therefore said that they "cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810



Impact Assessment in Biotechnology

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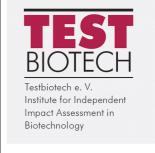
in 2013" (www.efsa.europa.eu/en/efsajournal/doc/4039.pdf). There are some particular concerns that the cultivation of MON 810 could affect rove beetles of which there are a large number of different species, some of which are rare and many of which are characterised as useful predators. EFSA has repeatedly criticised Monsanto on the issue of its monitoring.

In 2013, the company presented even less information and announced that in future it would not be willing to fulfil requests from EFSA

(http://ec.europa.eu/food/plant/gmo/reports_studies/docs/report_2013_mon_810/report_2013_mon_810_en.pdf).

Further, in a letter to the Commission dated November 2014, Monsanto stated that in future they are not able to monitor the cultivation of MON810 at all (www.testbiotech.org/node/1222). It appears that the company has failed to establish networks that would have allowed the monitoring of the crops after the patent expired. Since Monsanto is the holder of the EU authorisation, it is obliged to provide the legally required information. If no reliable monitoring information can be made available, cultivation must be stopped.

- (2) In April 2015, scientists from Switzerland and Norway published the results of an investigation into MON810 and its interaction with changing environmental conditions (Trtikova et al., 2015). Two varieties of maize MON810 were grown in climate chambers and subjected to defined stress conditions i.e. cold/wet and hot/dry. The results show that the reactions of maize MON810 are not predictable in reliable way. There are, hardly any data at all on how genetically engineered plants could react to ongoing climate change. Reliable data on the Bt content are needed to assess potential toxicity in non-target organisms. For example, risks for non-target organisms such as soil organisms or the larvae of protected butterflies can be much higher than assumed if the Bt content shows a high range of variations. It should also be taken into account that immune reactions due to the consumption of food and feed derived from transgenic plants have been observed in several feeding studies. It is likely that these effects are dose-dependent, and therefore the content of the Bt toxins also plays a decisive role in the risk assessment for food and feed. If the gene expression of MON810 is not predictable, it cannot be allowed for cultivation.
- (3) The European Food Safety Authority, in a letter dated 16 December 2014, announced a new investigation into the safety of genetically engineered Bt maize currently being grown in Europe, or which might soon be grown. The reason is new research from Germany. Hofman et al. (2014) collected data and monitored over a 10-year period how far maize pollen can travel. The new research has



found that maize pollen can, in fact, travel up to several kilometers. It concludes that, "previous risk assessments and conclusions regarding distances, potential exposure, and effects on non-target organisms should be revised in the light of these findings".

Now that the EU Commission is aware of the new evidence it should, as the responsible risk manager, take action to stop the cultivation of MON810.

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With best regards

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References:

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