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European Commissioner for Health and Consumer Policy
Mr John Dalli
Health & Consumers Directorate-General
B – 1049 Brussels
Belgium

cc Experts of the member states
cc Members of European Parliament

Munich, 5. 3. 2012

Dear Mr. Dalli

Time to restart risk assessment of genetically engineered plants

The European Commission is planning to adopt new regulation on the risk assessment of genetically engineered plants used in food and feed. However, the standards are not sufficiently rigorous to exclude risks to human health and the environment. Testbiotech published a tabled overview on some deficiencies on 25 of January 2012 (http://www.testbiotech.org/en/node/613). After a meeting with the EU Commission on 14 February 2012, we continue to maintain our concerns. Some of the most evident deficiencies of your proposed regulation are:

- Comparative risk assessment is still seen as the standard procedure. Instead of comprehensive risk assessment there will only be reduced 'check up' based on a presumption that risks from genetically engineered plants can be regarded as equivalent to those derived from conventional breeding. This is like comparing apples with pears.
- The most relevant step in comparative risk assessment (the investigation of substantial equivalence) is still based on a concept that allows the introduction of flawed data (see also joined media release with GeneWatchUK, http://www.testbiotech.org/en/node/619).
- Interactions with the environment that can impact the plants composition are not tested sufficiently. There is no stress test under defined conditions to investigate the functional stability

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of the gene construct.

- Testing for health risks is still not based on a stepwise concept that entails mandatory investigations such as toxicity tests on cell cultures, targeted investigation of relevant health risks and mandatory long term and multi generational studies.
- There is no request to apply more recent technologies, such as metabolic profiling.
- Stacked events are still investigated less rigorously than single events.
- The necessary interplay with pesticide regulation is missing. Residues from spraying with complementary herbicides should be seen as constituents of the plant that have to be fully assessed during the risk assessment of the genetically engineered plants.
- Combinatorial effects should be taken into account, but the requirements for investigation of synergistic, additive and accumulated effects are not sufficiently defined.
- The need to establish fully evaluated methods to measure the expression of the newly introduced gene constructs is not mentioned.
- The need for further targeted investigations where there are uncertainties is not defined.
- Post-marketing monitoring to allow identification of negative health effects and correlation with specific products is not defined.

Furthermore, there is no overall integrated concept which takes risks as well as ethical and socio economic issues into account, and neither are any cut off criteria foreseen. We also believe that industry should bear the cost of the authorisation process and make contributions to public funds for independent risk research.

We also would like to draw your attention to new scientific peer reviewed publications that once again show deficiencies in current EFSA risk assessment. These research projects, supported by Testbiotech, address issues highly relevant for the risk assessment of genetically engineered plants but find no mention in your new regulation:

Mesnage R., Clair E., Gress S., Then C., Székács A., Séralini G.-E., 2012, Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide, Journal of Applied Toxicology, http://onlinelibrary.wiley.com/doi/10.1002/jat.2712/abstract, see also: http://www.testbiotech.org/en/node/620

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András Székács, Gabriele Weiss, David Quist, Eszter Takács, Béla Darvas, Matthias Meier, Trilochan Swain & Angelika Hilbeck (2011): Inter-laboratory comparison of Cry1Ab toxin quantification in MON 810 maize by enzyme-immunoassay, Food and Agricultural Immunology, DOI:10.1080/09540105.2011.604773, see also:
http://www.testbiotech.org/en/node/578

These publications highlight major gaps in current knowledge of Bt toxins. Meanwhile ten different Cry toxins produced by various genetically engineered plants have been authorised within the EU – both in single and in stacked events. None of them have been subjected to sufficiently rigorous testing regarding toxicity, selectivity and combinatorial effects. There are not even any fully evaluated protocols available that would allow independent measurement of the Bt content in the plant tissue. It is unacceptable that the food chain and the environment are nevertheless being exposed on such a large scale to plants producing these toxins.

We urge you to view this situation as an opportunity to restart the risk assessment of genetically engineered plants, and not simply propose minor amendments to current standards in the risk assessment process developed by EFSA.

With kind regards

Dr. Christoph Then

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