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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

– **Open letter –**

Authorisation for MON 89034 × MON 88017 maize (Monsanto) – our complaint

Munich, 2.2.2012

Dear Mr. Dalli

Thank you very much for your response to our joint complaint concerning the market authorisation of MON89034 x MON88017 we brought to your attention in July 2011.

We attach a tabled overview of our comments as elaborated by Testbiotech. Despite the reasons you present for your rejection, we are still convinced that the market authorisation of this stacked event is a violation of European Regulations. Further it shows the general need for higher standards for risk assessment of genetically engineered plants.

We are also aware of your draft new Regulation on implementing regulation on applications for the authorisation of genetically modified food and feed. On comparing this draft Regulation with the actual deficiencies in risk assessment of EFSA, we do not think it will solve

the main problems. Please see attached first analysis from Testbiotech of new draft regulation.

To show how flawed the current risk assessment of EFSA actually is, we would like to draw your attention to the way the database of the International Life Sciences Institute (ILSI) is currently used by EFSA and industry to demonstrate substantial equivalence. For example, the following explanation by Monsanto which refers to the ILSI database was accepted by EFSA to conclude that MON89034xMON88017 can be regarded as being substantially equivalent:

> *"The statistical analyses showed that all of the 366 comparisons made between the test substances, MON 89034 × MON 88017, and the conventional control corn substance, LH198 × LH172, were either: a) not significantly different, b) were significantly different ($p<0.05$) but the composition values for the test substances were within the calculated 99% tolerance interval for the population of conventional reference substances and not considered biologically relevant, or c) were significantly different ($p<0.05$) but the composition values for the test substances were within the range of values obtained from the ILSI Crop Composition Database and not considered biologically relevant. Thus, the forage and grain from MON 89034 × MON 88017 are compositionally equivalent to conventional corn forage and grain."*

(Reynolds. T., Drury, M., Nemeth, M., Trujillo, W., Sorbet, R. (2006) Amended Report for MSL-20098: Compositional Analyses of Corn Forage and Grain Collected from MON 89034 x MON 88017 Grown in 2004 U.S. Field Trials, Monsanto Company, Product Safety Center, MSL # 20404)

But as even a statement of Joe Perry, Member of the GMO panel of EFSA shows, this database is not reliable and cannot be used to demonstrate substantial equivalence:

> *"I think we're in a situation where we would be unwise at the present time (maybe in the future this will be different), but at the present time we can't trust the ILSI database. There is not sufficient environmental information from where these trials were done and that's why we insist that the commercial reference variety should be planted simultaneously with the GM and the non-GM. Otherwise I think we are in an unsafe situation and I would worry that the limits*

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would be too wide."

(Observations of Mr. Joseph Perry, Vice-Chair, at EFSA's consultative workshop on its draft guidance for the selection of Genetically Modified (GM) plant comparators, held in Brussels on 31 March 2011).

So even EFSA´s expert at least to some extent seems to share some point of view of Testbiotech and GeneWatch UK, while the Commission still is ready to defend the flawed approach chosen by EFSA.

Further, we would like to draw your attention to the fact that in the original documents as presented by Monsanto it is explicitly stated that not even the most basic standards of Good Laboratory Practise (GLP) are met. This concerns crucial issues like phenotypic evaluations and ecological observations, and the potential synergistic toxicity. Nevertheless these documents were accepted by EFSA.

As a result, we think that the standards of risk assessment are not sufficient and are concerned that also your draft Regulation will finally not overcome these deficiencies. We urge you to act against any further market authorisation on the basis of current standards and to thoroughly re-evaluate the market authorisations of genetically engineered plants as granted. Further the Commission should urgently take the initiative to strengthen the independence of EFSA that suffers severely from conflicts of interests such as close ties with ILSI.

With kind regards,

Dr. Christoph Then, Executive Director Testbiotech e.V.

Dr. Helen Wallace, Director GeneWatch UK

Attached:
TESTBIOTECH: tabled overview of arguments against market authorisation of MON89034 x MON88017 (February 2012)
TESTBIOTECH Background 25-1-2012

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