

EUROPEAN FEDERATION OF BIOTECHNOLOGY

Mr Stavros Dimas Commissioner for the Environment European Commission Rue de la Loi 200 1040 Brussels Belgium

Brussels, 28 November 2007

Dear Commissioner Dimas,

The European Federation of Biotechnology, EFB, is very concerned to read about your draft decisions to reject two Bt maize product submissions based on discredited scientific arguments that have not been reviewed by your own independent scientific body, the European Food Safety Authority.

We consider that the draft decisions do not have a scientific basis and seem to be made without considering the consequences for Europe or the fact that similar varieties have been growing in Europe for the past 9 years with high adoption rates with no adverse environmental effects and in coexistence with conventional and organic farming.

Concerning the scientific studies contained in your draft decisions, that claim to demonstrate environmental risks presented by Bt maize, nine out of the eleven publications actually confirm the environmental safety of Bt maize cultivation and in fact do not identify any environmental risk with respect to the cultivation of Bt maize in the EU.

Only two of these publications (Hilbeck et al., 2006, & Rosi-Marshall et al., 2007) allege potential environmental risks; the former being a philosophical approach, rather than scientific data, and the latter is a questionable extrapolation from laboratory tests. Indeed the Rosi-Marshall et al. paper is based solely on laboratory experiments, whereas the field data of the same authors demonstrates no Bt effect on aquatic organisms (as shown on their own website). As far as the field test is concerned, it lacks decisive data on which transgenic maize plants were used and the entire experimental documentation appears sloppy and not meriting peer reviewed publication¹. In contrast to the theoretical risk projections of Hilbeck, other authors have published a meta-analysis, of all available studies carried out with Bt crops based on real, scientifically acquired data that confirm there is no indication of ecological risk arising from the cultivation of Bt maize (Marvier et al., 2007; Romeis et al., 2007). There is no new scientific evidence to contradict the conclusions reached by the GMO Panel of the EFSA on the safety of Bt maize cultivation in the EU. Furthermore, in July 2007, the OECD published a consensus document² on safety information of transgenic plants expressing Bt.

Legal Address :Place du XX, août 7, 4000 Liege Belgium VAT BE0876997883 Central Office: Pg. Lluis Companys 23, 08010 Barcelona, Spain Tel (+34) 93-2687703 Fax (+34) 93-2684500 This document thoroughly reviews and confirms the safety and high degree of specificity of the Bt proteins expressed in Bt maize, including the protein expressed in line 1507.

Another inconsistency of your draft decisions is that they fail to draw on a substantial body of scientific data accumulated over several years and published in the last 12 months that highlight the economic, environmental and consumer benefits of Bt maize. A total of 63 peer-reviewed publications attest to the fact that Bt toxin does not accumulate in the soil and does not affect aerial and soil-based non-target organisms, on the contrary, there is ample evidence that non-target insects are severely threatened and reduced in their populations by spraying pesticides.

In considering the environmental safety of Bt maize, it is pertinent to note that *Bacillus thuringiensis* has been widely used as an insecticide spray for the control of European corn borer in Europe since 1938, when the first commercial Bt preparation (Sporeine) came onto the market in France. Given that Bt is a commonly used insecticide in <u>organic agriculture</u> and given the current trend in the expansion of organic farming in Europe, and the year-on-year northward spread of European corn borer, it is inevitable that Bt spraying will be on the increase. The scientific data accumulated over recent years as part of biosafety assessment dossiers compiled on the various Bt crop varieties for commercial release will provide useful evidence for assessing the environmental impact of organic farming. As for the present time these environmental assessments of Bt sprays with their much higher concentrations have not been properly carried through, and also not published in peer reviewed journals – this in contrast to the many peer reviewed papers testifying no negative effects in soil and agricultural environment of GM Bt crops.

Agriculture is vital to the European economy, and Europe stands to gain much by the cultivation of new high performance crop varieties. Bt maize ensures productivity in years of heavy infestations and reduces the need for pesticides. In 2006, GM maize varieties including these two products were planted on 25.2 million hectares around the globe, and on 62,187 hectares in Europe. Spain has grown Bt maize for 9 years, and the benefits of Bt maize to Spanish farmers are well documented: average yield benefits have often been 10% and sometimes higher, which adds €15 million income to Spanish growers. Recent field trials in Italy showed that Bt maize performed better than conventional varieties with yield increases of between 28 and 43 percent. These trials demonstrated that Bt maize can not only be more profitable for farmers, but is healthier because of lower contamination with hazardous fungal mycotoxins which represent a significant health threat to humans and animals when present in the food chain (Regulation (EC) No 1881/2006).

Farming systems are very diverse, from conventional to organic or genetically modified (GM). This ensures that agriculture provides an abundant and affordable supply of healthy food and feed, and offers consumers more choice. The EU's explicit policy is that 'No form of Agriculture should be excluded from the Union', and the European Commission asks Member States to develop rules for the coexistence of different production systems, like Bt maize and non-GM maize, all long term scientific coexistence studies on maize demonstrate the feasibility of coexistence.

It is important that the consequences of any obstacles to the cultivation of GM maize varieties such as these are carefully evaluated, since a number of alarming indicators point to a future collapse of the EU livestock production due to the unavailability of imported feedstuffs.

The Portuguese Council Presidency has recently called for an open debate on the impact of the EU GM policy on food and feed security, in the light of an extra cost of \in 2 Bio for EU-livestock producers resulting from de-facto import bans on feed maize and corn gluten feed from GM corn producing countries.

The draft Commission Decisions are totally unacceptable, not only for European farmers and consumers, but also set a terrible example for other parts of the world that presently draft guidelines for the cultivation of GM crops, since they look to Europe as an example. This is especially true in the developing world where there is an urgent need of new technologies to raise agricultural productivity. Other GM strains of maize are under development that will have enhanced nutritional quality or tolerance to drought, and must be given the chance to reach those who need them the most. It is a proven fact that in developing countries Bt maize is healthier due to its much lower content of mycotoxins, which have dramatic detrimental effect on human health (cancer, spina bifidis).

In conclusion, Commissioner, your proposals to not approve the two Bt maize lines for cultivation based on discredited scientific arguments would not only undermine the EU's own scientific advice and risk assessment procedure but would also represent a significant threat to the competitiveness of European farmers.

To impose such bans is economically wrong, and pesticide use for controlling European corn borer would continue, It is also wrong on grounds of human health considerations. European farmers would be denied a valuable economic choice and Europe would import more grain to meet demand, but from where. It would do nothing to support the choice of feed producers or consumers. Such a move would violate EU procedures and without scientific evidence to support them would ultimately be rejected.

As European scientists we urge you to reconsider and return to a reasoning based on science and experience. The consequences of approving these draft Decisions and the precedents they would set would be the marginalisation of science in Europe, the discrediting of the European Food Safety Authority and the collapse of the EU-livestock industry.

Yours sincerely,

Emeritus Professor Marc Van Montagu President of the European Federation of Biotechnology

The European Federation of Biotechnology - The European Federation of Biotechnology is the non-profit association of all national and cross-national Learned Societies, Universities, Institutes, Companies and Individuals interested in the promotion of Biotechnology throughout Europe and beyond.

¹ More detailed comments on the study can be visualized at http://pubresreg.org/index.php?option=com_smf&Itemid=27&topic=9.0 ² http://www.agbios.com/docroot/articles/07-214-001.pdf

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