Scientific Analysis of Publications Cited by DG ENV

Nine out of the eleven publications cited by DG ENV are consistent with 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. A brief scientific analysis of these publications is presented below:

Andow and Zwahlen (2006) argue against a prescriptive environmental risk assessment (e.r.a.) and propose a general model for tiered risk assessment, with a view to applying it to future transgenic crops that may pose greater challenges for risk assessment than current types of Bt maize. While their approach is of philosophical interest, their proposal does not constitute any evidence of a potential environmental risk from Bt maize cultivation.

Butler et al. (2007) present a generic risk assessment framework for the prediction of bird species' conservation status and bird population growth rate based on past changes in agriculture. Their assessment of the future potential impact of genetically modified (GM) crops on biodiversity uses the conclusions from the Farm Scale Evaluations (Zeki, 2003) and is therefore limited to herbicide-tolerant (HT) crops, and in particular to HT sugar beet and oilseed rape. There is no mention of Bt maize. Furthermore, the results of the Farm Scale Evaluations regarding herbicide tolerant crops confirmed that any potential impact on organisms depends on the consumption of weeds. Thus, any potential effect on higher trophic levels is directly correlated to the efficacy of the herbicide applied, within common agricultural management practices, to control weeds in cultivated areas. Furthermore, genetically modified T25 maize also used in the Farm Scale Evaluations showed a significant two-fold increase in weed biomass, as well as a significant two-fold greater weed seed return resulting in more nectar resources for pollinators and more weed seed resources for granivorous birds.

Douville et al. (2007) measure the persistence and distribution of transgenic DNA in aquatic environments and found that it was rarely detected. There is no reason to expect that transgene DNA would be any different in persistence than any other DNA from maize. In addition, the transgenic DNA would represent a negligible part of the total DNA already in the maize field. DNA is environmentally benign and thus does not represent any environmental risk from Bt maize cultivation. A recent publication not cited by DG ENV indicates that the potential for DNA in the environment to be transferred to a living organism is extremely small even under circumstances that would unrealistically favour such transfer (Smalla and Vogel, 2007).

Farria et al. (2007) report increased numbers of aphids on Bt maize. Plants are well known to produce chemicals that protect them against aphids in response to stress. Well protected Bt maize plants would be expected to produce less of these chemicals due to less damage from caterpillars. One of the benefits of excellent pest control is the reduction in secondary plant compounds that can be detrimental to both pest and human health (Mattsson 2000, 2006). In fact, the main effect reported by the authors is that more honeydew produced by the aphids may sustain greater populations of beneficial organisms and therefore may be a benefit of the Bt maize. In any case, the magnitude of the difference they measured between the Bt and non-Bt maize was smaller than the magnitude of the

difference among different varieties of non-GM maize. Therefore, the effects reported in this publication are neither unexpected nor do they represent any environmental risk from Bt maize cultivation.

Johnson et al. (2007) present a philosophical discussion on the difference between risk assessment and risk analysis. However, their comments do not constitute any evidence of a potential environmental risk from Bt maize cultivation and indeed support the environmental risk assessment methodology followed by EFSA where they concluded that 1507 maize cultivation was safe.

Mulder et al. (2006) report that soil obtained from a field cultivated with Bt maize expressing the Cry1Ab protein shows transient differences in microbial activity compared to soil from a non-GM maize field. One might expect that maize tissue protected from insect pest damage would reduce stress related factors and lessen invasion from pathogens that could lead to differences in utilization by soil microbes. Therefore, a transient difference in soil microbial activity is neither unexpected nor does it represent any environmental risk from Bt maize cultivation. In addition, the reduction in soil compaction and pesticide inputs that would result from shifting to Bt maize could also improve the microbial activity in field soils.

Nguyen and Jehle (2007) report variable expression of Cry1Ab protein in Bt maize. This is expected, especially when measured on a fresh-weight basis. The water content of plant tissues varies widely which is why plant constituents are commonly measured on a dry-weight basis. Variation in protein levels (including Cry1F as well as all other maize proteins) amongst varieties, environments and tissues is expected. The variation in Cry1F expression in 1507 maize was measured and reported to EFSA. High-end exposure estimates based on maximum expression levels were used in the margin of exposure calculations used in ecological testing. Therefore, the effects reported in this paper are neither unexpected nor do they represent any environmental risk from Bt maize cultivation.

Regarding the conclusion of this paper - Bt concentration in insect-resistant maize is not the same in every plant - Greenpeace has carried out measurements to check this and found that the Bt levels varied considerably. Greenpeace claims that the legal basis for the EU approval has not been fulfilled. The results were in contrast with the conclusions of a three-year research project in which Bt levels in genetically modified MON810 maize were measured. Over a period of three years with extreme weather differences, the variations measured in the project were 3-10 times smaller overall than those in the one-year Greenpeace measurements. See more on: http://www.gmo-safety.eu/en/news/568.docu.html

Prafsifka et al. (2007) show that anthers from Bt maize expressing the Cry1Ab protein affect monarch butterfly larvae when sprinkled on milkweed leaves in the laboratory. Larval wandering is a common response to Cry proteins among sensitive Lepidoptera as an avoidance response and serves to reduce the exposure of the insects to the Cry protein. Similar to those from Losey et al. (1999), the laboratory findings are not relevant to field situations (Sears et al., 2001). Behavioral changes are not likely to occur on milkweed plants in the field because

the anther density tested is rare and natural feeding behaviors already reduce exposure to Bt anthers (Anderson et al., 2004; EFSA, 2005 and 2006). Thus this study does not present any new evidence of potential environmental risk from Bt maize cultivation. In addition, Hellmich *et al.* (2001) had confirmed that Cry1F protein expressed in 1507 maize is relatively non-toxic to larvae of the monarch butterfly compared to other Cry proteins.

Rose et al. (2007) conducted laboratory and field studies to investigate the effects of Bt maize pollen on honey bees. These studies show no adverse effects to honey bees, which strongly substantiates the conclusions on the safety of Bt maize cultivation as previously predicted from laboratory studies. Furthermore, this work supports the tiered risk assessment followed by EFSA as being appropriate for the evaluation of the environmental safety of Bt maize cultivation in the EU.

Only two of the eleven publications cited by DG ENV allege potential risks that may arise from cultivation of Bt maize. However neither of these publications contain data that would change the conclusions of safety reached by the EFSA GMO Panel on Bt maize cultivation in the EU:

Hilbeck et al. (2006) present a philosophical approach, rather than scientific data, concerning risk. Their conclusions have been discussed previously in other scientific publications and found to be speculative opinions rather than useful in making regulatory decisions (EFSA, 2005; 2006). In contrast to the philosophical questions posed by Hilbeck, other authors have published a meta-analysis of all available studies carried out with Bt crops that confirms that there is no indication of ecological risk arising from the cultivation of Bt maize (Marvier et al., 2007).

Rosie- Marshall et al. (2007) attempt to extrapolate from minor effects seen in two laboratory tests conducted under unrealistic exposure conditions and speculate that entire aquatic ecosystems might be affected by Bt maize cultivation. However, when these authors looked for effects in actual streams located within maize fields, they found no effects on either individual species or on the aquatic ecosystems. This indicates that the conclusions derived from their extrapolations from their laboratory based studies were incorrect and that the effects did not occur under realistic field situations (see Chambers et al., 2007; and, Pokelsek et al., 2007). In addition, an isogenic control was not included in the studies making it impossible to know what was the effect that the transgene had on caddisflies. (For additional details, please refer to a letter to the editor of the publishing journal by academic experts from several different countries that details some of the serious shortcomings with this work: http://pubresreg.org/index.php?option=com_smf&Itemid=27&topic=9.msg24).

To conclude, 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, the OECD published in July 2007 a consensus document on safety information on transgenic plants expressing *Bacillus thuringiensis* (Bt) derived insect control proteins. This document thoroughly reviews and confirms

the safety and high degree of specificity of the Cry proteins expressed in Bt maize, including the Cry1F protein expressed in 1507 maize.