Bundesamt für
Verbraucherschutz und
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Position statement of the ZKBS on the decision of the BLV (partial suspension of approval for placing genetically modified maize MON810 on the market) from 27 April 2007

1. Introduction

In its decision from 27 April 2007, the BVL ordered the partial suspension of the written agreement by the Minister for Agriculture and Fisheries of the Republic of France from August 3 1998, about placing genetically modified maize (*Zea mays* L. T 25 and MON810) on the market (Journal officiel de la République français from August 5 1998, p. 11985) until the decision of the European Commission or Advisory Body of the European Union based on Article 23 in connection with Article 30 Para. 2 of Directive 2001/18/EG, or at least until the decision of the European Commission or Advisory Body of the European Union based on Article 11 in connection with Article 8 Para. 4, or Article 23 in connection with Article 20 Para. 4 of Regulation (EG) No. 1829/2003.

This decision was justified with new, additional information that affects the risk assessment, as well as reevaluation of existing information based on new or additional scientific knowledge providing justified reasons for supposing that cultivation of MON810 maize represents a hazard to the environment.

An enquiry from the chairperson of the National/Federal States Working Committee on Genetic Engineering (LAG) requested the ZKBS to take a position on the following questions:

1. Does the ZKBS share the assessment of the BVL that there are justified reasons for supposing that cultivation of MON810 maize represents a hazard to the environment?
2. Is the ZKBS of the opinion that particularly the studies cited in the decision of the BVL and their reevaluation lead to such a conclusion?
3. If yes, does the ZKBS consider that further measures are necessary to protect the environment and health, or do they share the opinion of the BVL that putting forward a monitoring plan is sufficient?

II ZKBS position statement

1. The ZKBS does not share the assessment of the BVL that a justified reason exists for supposing that cultivation of MON810 maize represents a hazard to the environment.
2. The ZKBS is of the opinion that the studies cited in the decision of the BVL and their reevaluation do not lead to such a conclusion.
3. The ZKBS does not consider that further measures are necessary.
4. In addition, the ZKBS is of the opinion that the BVL did not include all the available information in its position statement. In particular, the results of the BMBF biological safety research, investigating the potential risk of cultivating Bt-maize MON810 in various projects, was not taken into account in the decision of the BVL (e.g. Pagel-Wieder et al., 2004; Rauschen et al., 2004; Baumgate and Tebbe, 2005; Eckert et al., 2006; Gathmann et al., 2006; Toschki et al., 2007).

Reasons

1. It is correct that food chain members at a higher tropic level (predators or parasitoids) can be exposed to the Bt protein through the food chain, but this represents no new information. This theme has been investigated in numerous laboratory, partial release and deliberate release field studies. However, the ZKBS can discern no specific (detrimental) effect of MON810 maize on the environment from the cited publications.

2. The cited review article from Lövei and Arpaia (2005) evaluated a total of 44 laboratory tests designed to investigate possible effects of genetically modified plants, or caused by the genetically modified components produced by them, on higher food chain members (predators or parasitoids). In 26 studies, negative effects were observed with predatory arthropods for 41% of the parameters, although statistical support of the results was only possible in 30% of cases. 18 of the 26 studies used different Bt proteins (Cry1Ab, Cry1Ac, Cry3Bb) expressed in various cultivated plants (cotton, potatoes, maize, rice). The other studies analyzed protease and trypsin inhibitors or snowdrop toxins. Furthermore, it should be considered that many of the observed effects are autocorrelated, since in several studies a number of parameter such as life-span, weight gain, fecundity or mortality were recorded in one experiment; i.e. a toxic effect is reflected in a number of parameters, which results in a quantitative over-evaluation of the effect. Negative effects in experiments with Cry1Ab were only detected in the studies with predatory lacewing larvae *Chrysoperia carnea* (lacewing).

   18 studies investigated possible effects of genetically modified plants and insecticide compounds produced by genetically modified plants on parasitoids. Altogether, significant negative effects could only be observed for about 40% of the 128 parameters. The Bt protein Cry1Ab was only investigated in 2 of the studies. A negative effect could only be determined in one of these two studies, affecting one parasitoid, and this can be traced back to a reduced nutritional quality of the host (see next paragraph).

   A different view point and assessment concerning the effects of Cry1Ab was reached by Romeis et al. (2006). Here, in the opinion of the ZKBS, laboratory, partial release and deliberate release field studies investigating the effects of Bt protein were more accurately evaluated than by Lövel and Arpaia (2005). The results of this work were not taken into account in the decision of the BVL. Romeis et al. (2006) could only detect negative effects where (1) the prey of the predators were fed with Bt proteins, and (2) the prey were sensitive to Bt protein. This meant the only food source for the predators or parasitoids were dying or altered prey or hosts. In cases where the Bt protein was fed directly to the predators as an artificial diet, no effects were observed (Romeis et al., 2006). This amounts to proof that the negative effects reported by Lövei and Arpaia (2005) can be traced back to the reduced nutritional quality of the prey or host, and not to a direct toxic effect of the Cry proteins. Moreover, a further analysis showed that lacewing larvae possess no receptors for Cry protein binding, and thus a direct effect of the Bt protein can be excluded (Rodrigo-Simón et al., 2006).

3. In laboratory experiments a detrimental effect of Cry1Ab could be detected in non-target butterflies. In this context the Bt protein amount contained in pollen, or various “Bt maize events” must be taken into account. In the case of Bt maize MON810, with an average of about 0.09 μg of Bt protein/g pollen, this is very low compared to other “Bt maize events” (e.g. Bt176, with an average of around 1.14 to 2.35 μg Bt protein/g pollen). Numerous laboratory and field studies estimate the risk associated with Bt maize MON810 as very

low for non-target butterfly species (e.g. Sears et al., 2001; Felke & Langenbruch, 2005; Wolt et al., 2003; Dively et al., 2004; Gathmann et al., 2006).

In the study by Dively et al. (2004) cited in the decision of the BVL, monarch butterflies were exposed to natural pollen under laboratory and semi-field conditions (caged with host plants). The experiment included investigating various Bt maize strains at 3 different locations. In contrast to previous investigations, exposure was carried out over 10 to 12 days – corresponding approximately to the flowering period of the maize. It was shown that up to 23.7% fewer larvae reached the pupation stage. In addition, differences in further fitness data, such as pupae weight or duration of development of the butterfly larvae were determined compared to controls. Dively et al. (2004) used a model calculation that included the ecological population data of the monarch butterfly (compare Sears et al., 2001; Wolt et al., 2003) to make a final quantitative risk assessment, which concluded that the threat to the monarch butterfly population in the USA is increasing by 0.6%. Taking into account reduced fitness, a maximum of 2.4% of the population were classified as threatened. Based on proven negative effects of insecticides or other factors on the monarch butterfly population and natural population Paffetti D. Saxena D., Stotzky G., Giannini R fluctuations, which can eliminate up to 80% of local populations, Dively et al. (2004) assessed the risk for monarch butterflies from MON810 maize as negligible.

4. A longer lasting period of Bt protein in the environment associated with transgenic plant remains should not necessarily be assessed any differently from conventional application of Bt preparations. For example, Vettori et al. (2003) showed that *Bacillus thuringiensis* supspecies *kurstaki* was still detected in the soil 88 months after treatment with conventional preparations, and the corresponding Bt protein still detected after 28 months. In the literature there is only speculation but no evidence for Bt protein accumulating in the soil (in terms of enrichment of toxicologically active Bt protein at Bt concentrations causing concern for non-target organisms). What can be considered as solid information is that low amounts of Bt protein in plant remains can survive one vegetative period. This is falsely argued to be a basis for potential enrichment of Bt protein in monoculture soil conditions. Also a discharge of biologically relevant amounts of Bt protein through root exudates is not expected with MON810 maize (see Saxena & Stotzky, 2001). Sufficient solid data on the biological breakdown of Bt proteins from transgenic plants in soil are available for a time period of 3-4 years. No accumulation can be extrapolated from these data (Hopkins & Gregorich, 2003; Baumgarte & Tebbe, 2005; Tebbe, 2004[1]) and therefore there is also no increased risk for non-target organisms.

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