

Press release (in German):

http://www.bvl.bund.de/nn_1004662/DE/08__PresseInfothek/01__InfosFuerPresse/01__PI__und__HGI/GVO/mon__810.html

--- unofficial translation by Antje Lorch ---

From: Federal office for consumer protection and food safety

To: Monsanto Europe S.A.

27 April 2007

I. Notification

Until the decision of the EU Commission or of the EU Council according to article 23 in connection with article 30 para. 2, Directive 2001/18/EG, but at the most until a decision of the EU Commission or the EU Council according to article 11 in connection with article 8 para. 4 or according to article 23 in connection with article 20 para. 4 of Regulation (EG) 1829/2003, the written approval of the Minister of Agriculture and Fishery of the Republic of France from 3 August 1998 on the deliberate release of genetically modified maize (*Zea mays* L. T25 and MON810) (Journal officiel de la Republique francaise from 5 August 1998 p. 11985) has been ordered to suspend, in as far as the written approval concerns the cultivation of genetically modified maize of the event MON810 in Germany and in as far it does not make MON810 subject to the following condition:

The release of seed of genetically modified maize of the MON810 event to third parties for commercial cultivation may only take place after the permission holder has submitted a monitoring plan for the environmental effects, in terms of Annex VII of Directive 2001/18/EG, to the Federal Office for Consumer Protection and Food Safety. The plan needs to comply with Annex VII of Directive 2001/18/EG as well as decision 2002/811/EG and particularly needs to take the following points into account:

- a) exposure of germinable maize seeds in the environment (loss during harvest, transport and processing),
- b) exposure of the Bt toxin in the environment (e.g. through pollen, silage, plant residues in the soil),
- c) fate of the Bt toxin in the soil of the area under cultivation; effects on soil organisms and soil functions,
- d) effect on non-target organisms in the area under cultivation and in affected habitats in the surroundings of the area under cultivation,
- e) long-term and large-scale effects on the biodiversity,
- f) fate of transgenes (persistence and accumulation) in organisms and in environmental media,
- g) development of secondary pests,
- h) changes in pesticide applications (type of the pesticide, volume, frequency and date),
- i) effects on food webs.

The notice comes into force immediately.

II. Grounds

According to §20 para. 2 of the law on genetic engineering, the competent federal authority can order the total or partial suspension of the approval until the decision of the Commission or the Council according to Article 23 in connection with Article 30 para 2 of Directive 2001/18/EG, if based on new or additional information that have

influence on the risk assessment or based on a new assessment of available information on the basis of new or additional scientific knowledge after the deliberate release approval was given, legitimate reason exists to assume that the genetically modified organism poses a danger for the human health or the environment.

1. Risks for non-target organisms

It only became obvious with recent studies that and to what degree the Bt toxin of the plant arrive in higher members of the food chain (Harwood et al. 2005, *Molecular Biology*, 14, 2815-2823; Zwahlen & Andow 2005, *Environmental Biosafety Research*, 4, 113-117; Obrist et al. *Ecological Entomology*, 31, 143-145). The exposure of non-target organisms such as predators or parasitoids to the Bt toxin are therefore proven.

In their review of tests relevant for Bt plants, Lövei & Arpaia (2005, *Entomologia Experimentalis et Applicata*, 114, 1-14) come to the conclusion that 41% of the parameters studied for predatory insects in laboratory studies showed negative effects; these including amongst others the survival, development time, lifespan and reproduction (30% of which were significantly negative). Other important groups of organisms such as predatory flies, wasps, ants, Staphilinidae or spiders, that play an important role on the field in the natural pest control, are not yet or only poorly studied.

Effects of Cry1 proteins, as they are produced by MON810, clearly show negative effects when butterfly larvae are exposed to them (cp. Hansen-Hesse & Obrycki 2000, *Oecologia*, 125, 241-248; Hellmich et al. 2001, *PNAS* 98: 11925-11930; Zwangerl et al. 2001, *PNAS* 98, 11908-11912; Mattila et al. 2005, *Entomologia Experimentalis et Applicata*, 116, 31-41; Romeis et al. 2006, *Nature Biotechnology*, 24, 63-71). Even though MON810 compared to other Bt-maize events produces relatively little toxin in the pollen, negative effects on non-target butterflies were also shown for non-target butterflies (Dively et al. 2004, *Environmental Entomology* 33, 1116-1125).

2. Risks for the soil

For Bt plants, the effects and the persistence period of the toxin produced by the plants are still open questions, but they hold a relatively high potential for ecological consequences. Bt maize releases the Bt toxin actively into the soil through root exudates and passively through degradation processes. Here, the toxin in an active form is bound to soil particles (mainly clay minerals) and can be detected for more than 200 days, and thereby clearly longer beyond the vegetation period (see e.g. Creccio & Stozky 2001, *Soil Biology & Biochemistry* 33, 573-581; Zwahlen et al. 2003a, *Molecular ecology* 12, 765-775). If the toxin is taken up by organisms, then it can be passed on in the food chain (Groot & Dicke 2002, *The Plant Journal*, 31, 387-406; Harwood et al. 2005, l.c.; Obrist et al. 2006, l.c.; Zwahlen et al. 2000, *Environment Entomology*, 29, 846-850). The potential hazard for non-target organisms by Bt toxin in the soil has been repeatedly emphasised by scientists (Andow & Hilbeck 2004, *BioScience*, 54, 637-649; Dale et al. 2002, *Nature Biotechnology*, 20(6), 567-574; Hilbeck 2001, *Perspectives in Plant Ecology, Evolution and Systematic*, 4(1), 43-61; Liu et al. 2005, *Plant and Soil*, 271, 1-13; Marvier 2001, *American Scientist*, 89, 160-167; Stotzky 2002, in Letourneau & Burrows, *Genetically Engineered Organisms*, p. 187-222; Zwahlen et al. 2003a, l.c. and 2003b, *Molecular Ecology*, 12 1077-1086).

This new and additional information has impacts on the risk assessment, respectively the reassessment of the available information on the basis of new or additional scientific knowledge give legitimate reason to assume that the cultivation of MON810 poses a danger for the environment.

The details above make more in-depth monitoring necessary than undertaken so far.

The approval holder asks farmers who cultivate MON810 to fill in a questionnaire in which general data about the cultivation as well as several other parameters are queried. These questionnaires are a helpful tool for a purely visual collection of agronomically relevant aspects of the area under cultivation. But they are not suitable to deliver data for the statistical analysis of environmental effects on the field and in its surroundings such as effects on non-target organisms. The questionnaires therefore are an additional element, but they cannot replace a monitoring according to Directive 2001/18/EG.

The decree complies with the condition in §§ 16c and 16d para. 1 no. 5 of the law on genetic engineering that products that consist out of genetically modified organisms or contain them have to be monitored.

The Federal Office for Consumer Protection and Food Safety is the competent authority according to §20 para. 2 in connection with §31 para 2 of the law on genetic engineering and therefore can order this decree.

A hearing did not take place, because it was not necessary due to the circumstances of the individual case. Because of the impending sowing an immediate decision was necessary in the public interest due to time reasons, according to §28 para. 2 no. 1 of the administration policy law.

Especially the following aspects were taken into account when the interests were balanced:

In favour of the approval holder it was taken into account that if the decree was ordered he would probably sell less MON810 seed resp. can licence less. However, the approval holder also distributes conventional seed so that loss should be kept within a limit.

Furthermore in his favour it was taken into account, that he needs to apply time and means to develop a monitoring plan. However this effort will be incurred anyway in the context of the European procedure to extend the approval.

The disadvantages for the approval holder stand against the subjects of the environmental and nature protection. There is especially the danger, that due to persistence and accumulation long-term and large scale effects as described above on the environment and nature will occur. Every cultivation adds to this accumulation process. Here, the great importance of the subjects for protection environment and nature have to be taken into account.

The right to continuance does not contradict the suspension of the approval because the option of such a decree already existed when the approval was given, see §20 para. 2 of the law on genetic engineering as announced on 16 December 1993 (BGBl. I p. 2066) changed by the law of 24 June 1994 (BGBl. I p. 1416).

In the overall consideration of all relevant circumstances the protection of the environment and nature had to be given priority, and the partial suspension of the approval had to be ordered.

The decree is provisional. A final decision can only be taken in the procedure according to Art. 23 in connection to Art. 30, para 2 of the Directive 2001/18/EG.

According to §80 para. 2, sentence 1 no. 4 of the administration court order the immediate execution of the notification is ordered. In balancing interested the aspects

mentioned above were taken into account. In the interest of environmental protection it is necessary to ensure an immediate execution of this decree until a decision is taken by the European Commission or by the Council of the European Union, so that cultivation only takes place under the conditions of this decree. The interest to conduct unrestricted cultivation based on the approval given for deliberate release, at present has less priority to interests of environmental protection that are relevant for this decree. Therefore there is a special public interest in an immediate execution of this order.

III. Costs

The notification about the costs will be send separately.

IV. Legal instructions

Complains against this notification can be filed within one month [...]

Bonn, 27 April 2007

Federal Office for Consumer Protection and Food Safety