

**Clausola di salvaguardia della Germania secondo l'articolo 23 della direttiva 2001/18 EC
Marzo 2009.**

I. Order

1. Until a decision is handed down pursuant to Article 23 in conjunction with Article 30 paragraph 2 of Directive 2001/18/EC by the European Commission or the Council of the European Union; at the latest, however, until the decision is handed down pursuant to Article 11 in conjunction with Article 8 paragraph 4 or pursuant to Article 23 in conjunction with Article 20 paragraph 4 of Regulation (EC) No. 1829/2003 by the European Commission or the Council of the European Union, it is hereby ordered, pursuant to Section 20 paragraph 2 of the *Gentechnikgesetz* (German Act on Genetic Engineering) and Article 34 of the Regulation (EC) No. 1829/2003, that the written consent issued by the Minister for Agriculture and Fisheries of the French Republic dated August 3rd, 1998 as to the introduction and trading on the market of genetically modified corn (*Zea mays* L. T 25 and MON810) (published in *Journal officiel de la République française* on August 5th, 1998, p. 11985) be suspended to the extent this permit allows the cultivation of the MON810 variety of corn.
2. It is hereby ordered that the present order be enforced immediately.

II. Reasoning for Item 1.

According to Section 20 paragraph 2 of the *Gentechnikgesetz* (German Act on Genetic Engineering), the [respectively] responsible German higher federal authority is authorized to order that the permit be suspended, either as a whole or in part, until the European Commission or the Council of the European Union has handed down its decision pursuant to Article 23 in conjunction with Article 30 paragraph 2 of the Directive 2001/18/EC. [It may do so if], after a permit has been issued for the [product in question] to be introduced and traded on the market (*Inverkehrbringensgenehmigung*), there is justified reason to assume that the genetically modified organism poses a hazard for human health or the environment, [such justified reason being] based on new or additional information becoming available that has impacts on the risk assessment to date, or on a re-assessment being made of the information available as a result of new or additional scientific findings. The same legal consequence shall likewise result from Article 34 in conjunction with Article 8 paragraph 5 of Regulation (EC) No. 1829/2003. The pre-requisites [stipulated by the laws granting authority to this Office to take actions affecting the basic constitutional rights of others] (*Ermächtigungsgrundlagen*) have been met in the present case.

1. Formal Pre-Requisites:

The formal pre-requisites for ordering the permit to be suspended in accordance with Section 20 paragraph 2 of the *Gentechnikgesetz* (German Act on Genetic Engineering) are given. According to Section 20 paragraph 2 of the German Act on Genetic Engineering in conjunction with Section 31 German Act on Genetic Engineering, the Federal Office of Consumer Protection and Food Safety is the authority responsible for issuing an order suspending the permit.

In accordance with Section 28 paragraph 2 no. 1 of the *Verwaltungsverfahrensgesetz* (VwVfG, German Administrative Procedures Act), it was possible to forgo a prior hearing because seeding is imminent and an immediate decision had to be taken in the interest of the general public. Due to the very warm weather [in Germany] during the first half of April, it will be possible to commence seeding shortly. Thus, the seeding of genetically modified corn of the MON810 line is imminent. However, had a prior hearing been held, this would have meant that it is no longer possible to order the suspension of the permit prior to cultivation of the corn, thus placing the environment at risk. Therefore, the interest of the general public required an immediate decision to be taken.

2. Pre-Requisites in Terms of Substance:

In terms of substance, the pre-requisites for ordering the suspension are likewise given. As required by the *Bundesministerium für Ernährung, Landwirtschaft and Verbraucherschutz* (Federal Ministry of Food, Agriculture and Consumer Protection), which has supervisory control over this Office [BVL], the order is based on the following reasons:

a) **Risks for the Environment**

1. Exposure [to the Bt toxin]:

It is common knowledge that the Bt toxin is able to reach higher trophic levels (Haarwood et al. 2005; Zwahlen & Andow 2005; Obrist et al. 2006; Harwood et al. 2007). The concentration of Bt toxin at higher trophic levels may be the same or even higher than that found in plant tissue (cf., for example, Dutton et al. 2002 concerning *Tetranychus urticae*; Obrist et al. 2006 concerning *Frankiniella tenuicornis*). Obrist et al. (2005) conclude that arthropods might be subjected to the Bt toxin should they suck dew or honeydew from plant tissue that has been contaminated by thrips feces. In the aggregate, the available data show that non-target organisms of various functional and taxonomic groups are subject to long-term exposure to Cry1Ab in the field.

Pollen introduces the Cry1Ab-toxin from the MON810 line of corn into the surrounding area (Hofmann 2007). It should be noted in this context that the introduction of pollen is in fact considerably higher than has been assumed to date. Other than is the case for Bt preparations, the Bt protein contained in pollen does not seem to be affected by UV radiation.

Several studies (Tapp & Stotzky 1998, Crecchio & Stotzky 1998, 2001) show that Bt protein persists in soil at high rates (for longer than 200 days). Analyses of the degradation of Bt corn in the field in moderate climatic conditions (Zwahlen et al. 2003) likewise indicate that the Bt protein persists in the soil for a period of 200 days. For Germany and Canada, similar results were presented by Baumgarte & Tebbe (2005) and Hopkins & Gregorich (2004). Zwahlen et al. (2003) point out in their paper that plowing may delay the transfer of Bt protein and that Bt protein is not degraded during the wintertime.

Bt is introduced into aquatic eco-systems by material being washed into them from agricultural fields, as detritus and as pollen deposits. Recent scientific research has shown that water and sediment may transport considerable amounts of Bt toxin from the cultivation of Bt corn (Douville et al. 2007; Rosi-Marshall et al. 2007).

2. Ecotoxicology

- Epigaeic organisms

In a meta analysis of the field data available on corn with the Bt toxin Cry1Ab, Marvier et al. (2007) concluded that the impacts of Bt corn on arthropods are lower than those of the routine application of insecticides, but higher than those of corn lines that have not been genetically modified and that were not treated using insecticides.

- Lepidoptera

The protein Cry1Ab affects not only the target organism *Ostrinia nubilalis*; it also impacts further butterfly species. The Bt protein is introduced by pollen into areas more than 2 km [away from the source] (Hofmann 2007). Corn pollen is dispersed on the host plants by butterflies outside of the field. As a result, larvae feeding off of the leaves of their host plants may ingest corn pollen. It has already been shown that corn cultivation areas overlap with butterfly habitats and the development stages of butterflies in Germany and Austria (Schmitz et al. 2003; Traxler et al. 2005). For a number of species, it was proved that non-target organisms react sensitively to Cry1 toxins (Losey et al. 1999; Hansen-Jesse

Obyrcki 2000; Hellmich et al. 2001; Zangerl et al. 2001; Felke et al. 2002; Dively et al. 2004; Mattila et al. 2005; Lang & Vojtech 2006). Although corn pollen of the MON810 line seem to have a low content of Cry1Ab, impacts on non-target organisms have been proven (Dively et al. 2004). Furthermore, studies performed by the *Biologische Bundesanstalt für Land- und Forstwirtschaft* (Federal Biological Research Center for Agriculture and Forestry) (now named the Julius-Kühn-Institut) have shown that a single[, non-recurrent] ingestion of five to ten (5-10) grains of pollen from genetically modified corn (Bt176) will cause sub-lethal effects in sensitive Lepidoptera larvae (Felke & Langenbruch 2001, 2003, 2005; Felke et al. 2002). The results of this work group have also shown that two butterfly species (*Inachis io* and *Aglais urticae*) react sensitively whose habitats are adjacent to corn fields. Data on the sensitivity to Cry1Ab are also available for the European swallowtail butterfly *Papilion machaon*. Lang & Vojtech (2006) have shown its high sensitivity to Bt pollen (Bt176). Their results have indicated that fourteen (14) days after the larvae had ingested a mere 9.9 pollen [grains], on average, 30% of them died. Moreover, the LD30/LC50 values were about twice as high as the LD50/LC50 values, while other important parameters for the viability of full-grown butterflies such as their wingspan were impaired (Lang & Vojtech 2006). Marvier et al. (2007) have shown that non-target butterfly species were significantly decimated by Cry1Ac cotton.

- Coleoptera

In a laboratory experiment, larvae of the two-spotted lady bug *Adalia bipunctata* were fed with varying concentrations of two Bt toxins (0, 5, 25, 50 µg/ml), these being Cry1Ab and Cry3Bb (Schmidt et al. 2009). These experiments, which also included the Cry1Ab that MON810 contains, indicate a significantly higher mortality rate. The conclusion suggested by these results is that the increased mortality of the larvae was caused directly by the activated Bt toxin.

- Soil Organisms

There are indications that Bt corn impacts terricoline, saprophagous larvae of dipteran fauna (Büchs et al. 2004).

- Aquatic Organisms

Two studies recently published indicate potential risks for aquatic non-target organisms. Rosi-Marshall et al. (2007) proved that when transgenic corn is cultivated, larvae of Caddis flies (trichoptera) might be exposed to Bt. It was also shown that the trichoptera larvae reacted sensitively to Cry1Ab at densities of Bt pollen in the same scale as the density given in the field (higher mortality and development periods that are up to 50% longer). Trichoptera (caddis flies), which are part of most aquatic ecosystems, play a major role in aquatic food webs and can be found in most inland waters. A second, more recent publication indicates a potential sensitivity of *Daphnia* to Cry1Ab. Bøhn et al. (2008) have observed that fitness is reduced and reproduction commences earlier in *Daphnia magna* fed with MON810 corn grains that were milled to a grain size that *Daphnia magna* are able to filter. The authors' opinion is that the toxicity they have observed is a more likely indication of a toxic effect than a low nutritional value of the MON810 corn as compared to isogenic control cells at the baseline.

- Rare and endangered and/or protected species and protected areas

Pollen is transferred from Bt corn fields to surrounding areas. The data obtained in monitoring pollen indicate that the average pollen deposit at a distance of 340 m from corn fields is 5 pollen [grains] per cm². Butterfly species are differentiated by the varying sizes of the leaf areas they feed on. It is deemed to be possible that the area is larger than a single cm² by one or two orders of magnitude. Since sublethal impacts were observed in butterflies that were exposed one single time to a mere five (5) grains of pollen (Felke et al. 2002; Felke & Langenbruch 2005; Lang & Vojtech 2006), the potential impacts of the Bt pollen on non-target butterflies in an area that is at several hundred meters' distance from corn fields must be studied. This is particularly important where endangered species are concerned, since in the highly diversely structured landscapes of Europe, areas serving agricultural use are located in the vicinity of nature conservation areas or ecologically sensitive areas, or are a part of same (Lang 2004). Seven percent (7%) of all of the large butterfly species known to exist in Germany (97 species) have their predominant habitats in agricultural fields, according to a preliminary analysis of their exposure, and thus may potentially be exposed to Bt corn pollen. Schmitz et al. 2003 have shown in a study that approximately 38% of these 97 species are rare or

endangered.

b) New Scientific Information

This new and additional information, which affects the risk assessment, or this re-assessment of the available information on the basis of new or additional scientific findings, give rise to the justified assumption that the cultivation of MON810 is a hazard to the environment. Thus, the present order serves to suspend only that part of the permit allowing the product to be introduced and traded on the market (*Inverkehrsbringensgenehmigung*) of August 3rd, 1998 that concerns the cultivation [of this line of corn] including its seeding in the environment.

In view of these circumstances, it is not necessary to wait until the risks that the cultivation of genetically modified corn of the MON810 line may entail have been fully cleared up. Rather, the precautionary principle codified in German law (Section 1 No. 1 of the *Gentechnikgesetz* (German Act on Genetic Engineering)) as well as in

European law (Article 4 paragraph 1 of the Directive 2001/18/EC and Recital 3 of the Regulation (EC) No. 1830/2003) enables [the responsible authorities] to take preliminary measures serving to protect the environment in cases such as these.

According to the adjudication handed down by the European Court of Justice, the precautionary principle means that in the event of any uncertainty being given as to whether or not risks exist to human health, or regarding their scope, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent (Judgment of the Court of September 9th, 2003 in Case C-236/01 "Monsanto", marginal number 111 and Judgments of May 5th, 1998 in Case C-157/96, National Farmers' Union et al., ECR 1998, I-02211, marginal number 63, and in Case C-180/96, United Kingdom/Commission, ECR 1998, I-2265, marginal number 99).

3. Exercise of Discretion

The Federal Office of Consumer Protection and Food Safety thus may order the permit to be suspended in accordance with Section 20 paragraph 2 of the *Gentechnikgesetz* (German Act on Genetic Engineering). In so deciding on the order to suspend the permit, the Federal Office of Consumer Protection and Food Safety is entitled to exercise discretion as regards the legal consequences, and the Federal Office of Consumer Protection and Food Safety has so exercised it in keeping with its obligations.

In exercising this discretion, it was considered in favor of Monsanto Europe S.A. that Monsanto Europe S.A. will most likely not be able to sell, or, respectively, license any MON 810 seed and that it will thus suffer economic losses. Moreover, Monsanto may suffer economic damages by the fact that farmers will return seeds they have already bought, asking for their money back. In view of the low cultivation area of MON810 given in Germany, however (in 2008: 3,173 ha MON810 versus 2,081 million ha cultivated with conventional corn; this corresponds to about 0.15% of the total area on which corn is cultivated), these losses are to be deemed low. For 2009, German farmers have filed their intention to cultivate MON810 on an area of 3,596 ha with the GMO Location Register kept by the Federal Office of Consumer Protection and Food Safety. However, experience in the previous years has shown that approximately $\frac{1}{3}$ of the areas so registered is in fact not used by the farmers, so that in the end result, it was to be expected for 2009 that corn of the MON810 line would have been cultivated on an area of approximately 2,700 ha. As compared to other countries, such as the United States, to cite but one example, the cultivation of MON810 in Germany is relevant only to a marginal extent. The detrimental impacts caused by the permit being suspended are to be assessed as low, both in financial terms and as regards the number of parties affected.

Moreover, it should be considered in this context that Monsanto Europe S.A. also distributes conventional seed, so that, in many instances, Monsanto Europe S.A. will now be able to sell conventional seed instead of the genetically modified seed.

Furthermore, farmers are also affected by the permit being suspended, since they will not be able to sow the

MON810 seed they may already have bought. However, the impacts for the farmers are relatively low in view of the fact that they can use conventional seed instead. Since no seeding has taken place yet, any economic disadvantages they might have to bear will be limited to their purchasing costs for conventional seed. The potential additional expenditure for conventional seed must, however, be set off from the additional costs that the purchase of genetically modified seed entails, so that the additional expenditure – if any accrues at all – will in any case be low.

These disadvantages that Monsanto Europe S.A., and the farmers affected, will suffer, are juxtaposed by the constitutional requirement of protecting the environment and nature as stipulated by Article 20a of the *Grundgesetz* (German Constitution). There is justified cause to assume that should MON810 continue to be cultivated, detrimental impacts as described above will result. Damages to individual components of the ecological balance may have grave and irreversible consequences in the long term. Other than is the case for the consequences of the present order, environmental impacts have an effect on the general public and not just a limited group of persons. Therefore, the protection of the environment is allocated exceptional importance, in particular in the laws pertaining to genetic engineering (Section 1 No. 1 of the *Gentechnikgesetz* (German Act on Genetic Engineering)). European law as well (Article 174 paragraph 2 TEC) provides for a high level of protection for the environment in the EC. As a logical consequence, the great relevance of the protected legal interest so concerned may restrict the room for maneuver that the Federal Office of Consumer Protection and Food Safety [has in exercising its discretion] and may even reduce it to zero (reasoning provided for the *Gentechnikgesetz* (German Act on Genetic Engineering), published in: Eberbach/Lange/Ronellenfisch, Commentary on the Laws pertaining to Genetic Engineering), Volume 1, Section 20 of the *Gentechnikgesetz* (German Act on Genetic Engineering), marginal no.15).

In view of the hazards posed to the environment in the event the [corn of the line MON810] is cultivated, and the relatively slight economic disadvantage suffered by a small number of affected parties as a result of the present order, and after having balanced out the impacted legal interests, the interests of environmental protection as stipulated by constitutional law were given precedence before the legally protected interest of Monsanto Europe S.A. in continuing to distribute seed for cultivation purposes.

In balancing out the interests, any basic constitutional rights that may be affected (Articles 12 and 14 of the *Grundgesetz* (German Constitution)) were sufficiently considered. In fact, it was questionable whether Monsanto Europea S.A. actually is covered by the scope of protection stipulated by Article 12 of the *Grundgesetz* (German Constitution) since it is a foreign holding and the order does not include any tendency to regulate a profession.

[cf.] *Entscheidungen des Bundesverfassungsgerichts* (BVerfGE, Rulings of the Federal Constitutional Court) 97, p. 228 (citation on p. 254); *Entscheidungen des Bundesverfassungsgerichts* (BVerfGE, Rulings of the Federal Constitutional Court) 98, p. 218 (citation on p. 258).

However, this question need not be addressed since the present order cannot be regarded to restrict the election of a profession under any circumstances and thus, the reasonable considerations made here as to the general welfare, this consisting of the protection of the environment, [sufficiently justify] the measure.

Likewise, Article 14 of the *Grundgesetz* (German Constitution) has not been violated, also not with a view to a commercial business already in place and operated. The substance and limitations of property are defined by law. Section 20 paragraph 2 of the *Gentechnikgesetz* (German Act on Genetic Engineering) allows restrictions to be imposed for reasons of protecting the environment and [human] health. This opportunity was given already at the time the permit was issued. The protection and the relevance of property were likewise considered. However, in view of the great relevance to society (*Sozialbezug*) and the potential hazards that threaten to be caused, this protection must rank behind the protection of the environment.

Moreover, the order is in keeping with the principle of proportionality. There is no milder means [available to this Office] than ordering the permit to be suspended in order to ensure that corn of the MON810 line is not introduced in the environment. This is necessary, however, in order to [avert] potential hazards for the environment should genetically modified corn of the MON810 line be cultivated.

Nor does the protection of existing rights contravene the order to suspend the permit, since the possibility of such an order being handed down was given already at the time the permit was issued, cf. Section 20 paragraph 2 of the *Gentechnikgesetz* (German Act on Genetic Engineering) in the version of its promulgation of December 16th, 1993 (*Bundesgesetzblatt* (Federal Law Gazette) [vol.] I p. 2066), modified by the law dated June 24th, 1994 (*Bundesgesetzblatt* (Federal Law Gazette) [vol.] I p. 1416).

The order is preliminary in nature. A final decision may be taken only in the proceedings governed by Article 23 in conjunction with Article 30 paragraph 2 of the Directive 2001/18/EC.

III. Reasoning for Item 2.

The immediate enforcement of the present notice is ordered pursuant to Section 80 paragraph 2 sentence 1 no. 4 of the *Verwaltungsgerichtsordnung* (VwGO, Code of Procedures before the Administrative Courts). This order is justified as follows:

In view of the hazard to the environment set out hereinabove as a result of corn of the MON810 line being cultivated, there is a particular public interest in enforcing the order immediately. There is the risk that as a result of MON810 continuing to be cultivated, detrimental impacts of the type described above may result. Damages to individual components of the ecological balance may have grave and irreversible consequences in the long term. Due to the very warm weather in early April, seeding of genetically modified corn of the MON810 line is imminent. In order to ensure that corn of the MON810 line is not introduced into the environment, this

order therefore must take effect immediately. Moreover, the Federal Office of Consumer Protection and Food Safety is under obligation, pursuant to Article 4 paragraph 1 of the Directive 2001/18/EC, to take all suitable measures to ensure that the introduction and trading on the market of genetically modified organisms does not have any detrimental impacts on human health and the environment. This is opposed by potential financial losses for Monsanto S.A. Europe and farmers; however, these are limited and temporary. Against this backdrop, the interests of the concerned parties in any suspensive effect being given must exceptionally take a lower rank until the decision is handed down by the European Commission or the Council of the European Union.

IV. Cost Ruling

The decision as to the costs will be issued separately.

V. Instructions as to the Legal Remedies Available

A complaint may be filed against the present order with the *Verwaltungsgericht* (Administrative Court) of Braunschweig, Am Wendentor 7, 38100 Braunschweig within one month of its having been served, which may be done either in writing or by recording the complaint with the records clerk of the court registry.

The complaint must set out who the plaintiff is and who the defendant, and must also specify the subject matter of the dispute. It is to contain a specific petition to the court, and the facts and evidence serving as reasoning for the complaint must be cited.

Braunschweig, dated April 17th, 2009
Bundesamt für Verbraucherschutz and Lebensmittelsicherheit
(Federal Office of Consumer Protection and Food Safety)

[signature]

Dr. Helmut Tschiersky-Schöneburg
President