

**(not official translation)**

**Ref. nr.:**

**104130/2005.**

## **A N N O U N C E M E N T**

### **I.**

Hungary announces that in accord with the decision of the Hungarian authority for gene technology (see Attachment 1.), as of 20 January 2005, on the basis of Article 23, Point 1 of Directive 2002/18/EC (12 March 2001) of the European Parliament and Council on the deliberate release of genetically modified organisms into the environment and the repeal of Council Directive nr. 90/220/EEC, it shall provisionally prohibit the production, use, sale, and import to the territory of Hungary of the seed-grains of inbred lines and hybrids originating from the MON 810 maize line. The prohibition also applies for offspring plants originating from cross-breeding with any breeds of maize purified by traditional breeding methods.

The prohibition shall not apply to the use of maize containing the MON 810 gene construction in food industry and as fodder, and for transport through the territory of Hungary without repackaging and further handling, if it can be ensured that the maize will not be released into the environment.

Hungary requests consent for the above action from the European Commission.

### **II.**

Article 23, Point 1 of Directive 2002/18/EC (12 March 2001) of the European Parliament and Council on the deliberate release of genetically modified organisms into the environment and the repeal of Council Directive nr. 90/220/EEC stipulates the following:

*„Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific*

*knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.*

*The Member state shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.*

*The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article, supplying its review of the environmental risk assessment, including whether and how the conditions of consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.”*

The national authority for gene technology has found that for the inbred lines and hybrids originating from the MON 810 maize line (which contain cryIA (b) genes originating from *Bacillus thuringiensis* subsp. *kurstaki*, controlled by a 35S promoter from the cauliflower mosaic virus and an intron, originating from a gene coding the heat shock proteine nr. 70 of maize) and for its offspring plants originating from cross-breeding with any maize varieties purified by traditional breeding methods, the conditions specified in Article 23 Point 1 of Directive nr. 2001/18/EC apply, thus providing ground for introduction of the prohibition and for initiating a safeguard clause procedure.

The detailed grounds for the decision are specified below.

## 1.

The inbred lines and hybrids of the maize containing the MON 810 gene construction were given permission for being placed on the market on **5 August 1998**, under Directive 90/220/EEC.

In 1998, the permission procedures for several GMO's were suspended, as several of the Member States were of the opinion that the possible short-term and long-term damages of GMO's to the environment and health were not sufficiently clarified at the time, or the regulations did not make it possible to conduct the necessary examinations prior to the permission of the release of new GMO species. With the coming into being of new, stricter community regulations containing more warranty elements, the permission procedures could be continued.

Consequently, Hungary conducted the accession negotiations, and submitted its observations during the codification of the Treaty of Accession while the authorisation procedures were suspended, and the inbred lines and the seed-grains of

hybrids of maize line containing the MON 810 gene construction, which were included in the individual national catalogues of varieties, could not be freely placed on the market on the territory of other Member States.

The permission procedures were continued in 2004 in such a way that the specific biogeographical features of the countries joining the EU in the meantime, and the resulting possible environmental risks were not taken into account, but instead, taking into account the permission for placing on the market issued in 1998, and the inclusion on the national catalogue of varieties, the 17 maize hybrids containing the MON 180 gene construction were included in the Common Catalogue of Varieties on **8 September 2004**.

## 2.

Independently of the inclusion in the Common Catalogue of Varieties of 17 maize varieties originating from the maize line containing the MON 810 gene construction, in 2003 Hungary launched environmental impact studies relating to a maize variety also originating from the maize line containing the MON 810 gene construction, but not included in the Common Catalogue of Varieties. **Attachment 2 contains the publications concerning the available results of constitutive studies done in Hungary, which provide new information and scientific knowledge, giving detailed grounds for considering that the inbred lines and hybrids originating from the maize line containing the MON 810 gene construction constitute an environmental risk.**

The studies conducted in Hungary under the direction of the Plant Protection Research Centre of the Hungarian Academy of Sciences concerned the maize hybrid bearing the YieldGard™ MON 810 gene construction, modified with the DK 440 BTY gene technology. Research done in laboratory and on small parcels of land showed that in the ecosystem concerned, the permanent presence of the plant can, among others, have the following damaging effects:

- The Bt maize produces 1500-2000 times more Bt-toxin than is released through the insecticide DIPEL (containing Bt-toxins) during a one-time treatment as a part of conventional plant protection.
- In other studies, the remnants of Bt-plants were decomposing more slowly than their isogenetic lines. After harvesting, 8 % of the toxin produced by the plant remained in the area, and what is more, a significant part of this toxin quantity could still be shown to be present in the soil after 11 months.
- In the soil of a field covered by transgenic plants, the complete biological activity was lower than in the control field.
- The caterpillars living on soft-stalked plants within the maize field and on its verge, which are hatched during the period of pollen dispersal, are the most affected by the toxin produced by MON 810. In Hungary, 16 % of the 187 protected species of butterflies can develop on the soft-stalked weeds living on the verge of the maize

field. According to the studies, the pollen containing Bt is the most damaging to the butterfly species *Inachis io* L. and *Vanessa atalanta* L.

### 3.

As a consequence of the inclusion in the Common Catalogue of Varieties, the 17 genetically modified maize varieties can be freely placed on the market in all Member States, but the environmental risk assessment serving as a basis for the permission for placing on the market was only done on the territory of the older member states.

The permission for maize hybrids bearing the MON 810 gene construction was given under Directive 90/220/EEC, which did not require the same extent of risk assessment as that prescribed by Directive 2001/18/EC. Attachment II of Directive 2001/18/EC states that the analysis of long-term cumulative effects with regard to release must be done for GM varieties of plants with a permission for cultivation.

According to Article 4 Point 4 of Directive 2002/53/EC on the Common Catalogue of Varieties of agricultural plants species, the deliberate release into the environment of a variety considered to be a genetically modified variety is acceptable only if all necessary actions have been taken to eliminate possible damages for human health and the environment.

The risk assessment is made especially necessary due to the fact that with Hungary's accession to the EU, a new ecological region has appeared within the boundaries of the European Union (Attachment nr. 3), which is also laid down in the Treaty of Accession. **Due to its different environmental characteristics, the Pannonian biogeographical region questions the validity of the risk assessment which takes account of the ecosystems of the older Member States.**

From the point of view of the Pannonian biogeographical region, it is indispensable that a comprehensive environmental risk assessment be made, due to the irreversible processes coming into being during the release of genetically modified organisms into the environment, taking utmost care of the principle of precaution, to ensure protection of our unique environmental characteristics.

Concerning MON 810, the environmental impact studies have been launched, but due to the adjustment to biological cycles, genuine results can only be expected over a scope of several years.

**Consequently, in view of the results of the constitutive studies referred to in Point 2, not all necessary actions have been taken to eliminate possible environmental damages, therefore there is a fundamental need for a scientifically supported risk assessment taking into account the ecosystem of Hungary as a new Member State, in accord with the objectives and obligations set in Directive 2001/18/EC.**

Budapest, „...” January 2005

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