Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

1998/0072(COD) - 21/01/2009 - Follow-up document

By Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays L. line MON810*), it was decided that consent was to be given for the placing on the market of that product.

On 3 August 1998, the French authorities granted consent for the placing on the market of genetically modified maize. However, the Hungarian authorities informed the Commission on 20 January 2005 of their decision to provisionally prohibit the use and sale of the genetically modified maize in question and gave reasons therefore. The Commission sought the opinion of the European Food Safety Authority (EFSA), which considered that the information submitted by Hungary did not constitute new scientific evidence which would invalidate the environmental risk assessment of *Zea mays L. line MON810* and therefore would justify a prohibition of the use and sale of this product in Hungary.

The Commission took note of the declaration of the Environment Council on 24 June 2005, which, in order to indicate its opposition to a proposal requesting another Member State to repeal its safeguard clause measure on the same GMO, stated that there was still a degree of uncertainty in relation to the safeguard measure associated with the placing on the market of MON810 maize and called on the Commission to gather further scientific evidence and to further assess whether the national measure was justified and whether the authorisation of the GMO under Directive 90/220/EEC still met the safety requirements of Directive 2001/18/EC.

Therefore, the Commission consulted EFSA in November 2005 as to whether there was any scientific reason to believe that the continued placing on the market of the GMOs subject to the safeguard clause measures, including *Zea mays L. line MON810*, was likely to cause any adverse effects to human health or the environment under the conditions of consent, and requested EFSA to take account of any further scientific information that has arisen subsequent to the previous scientific opinions that assessed the safety of these GMOs. It was considered appropriate to await this new EFSA opinion on *Zea mays L. line MON810* before taking any action on the corresponding safeguard measure notified by Hungary.

In its opinion of 29 March 2006, EFSA concluded that there is no reason to believe that the continued placing on the market of *Zea mays L. line MON810* is likely to cause any adverse effects for human and animal health or the environment under the conditions of their respective consents. Therefore, the Commission prepared a draft Decision asking Hungary to repeal its measures concerning *Zea mays L. line MON810*.

The Committee established under Article 30 of Directive 2001/18/EC did not deliver an opinion on the measures laid down in a draft Commission Decision, following its consultation, so the Commission was required to submit a proposal to the Council relating to the measures to be taken. The Environment Council indicated its opposition to the proposal by qualified majority. In its Decision, the Council referred to the environmental risk assessment as provided in Directive 2001/18/EC and indicated that 'the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment'.

Hungary submitted to the Commission on 30 November 2007 additional information regarding the cultivation of *Zea mays L. line MON810* to support its measure. Consequently, EFSA was requested to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment such that detailed grounds exist to consider the above maize, for the uses laid down in the corresponding consent, constitute a risk to the environment. In its opinion of 2 July 2008, EFSA reaffirmed its previous conclusions on the safety of *Zea mays L. line MON810* and stated that it did not identify any new data subject to scientific scrutiny or scientific information that would change the previous risk assessments conducted on this product. EFSA also concluded that the Hungarian submission did not supply scientific evidence that the environment of Hungary was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU.

Under these circumstances, Hungary should repeal its safeguard measure with regard to the use and sale of *Zea mays L. line MON810*. Therefore, following the Council Decision of February 2007, and in accordance with Article 5(6)(2) of Council Decision 1999/468/EC, the Commission re-submitted its proposal relating to the measures to be taken and informed the European Parliament.