

Brussels/Luxembourg, 24 June 2005

GMOs: Commission reaction on Council votes on safeguards and GM maize MON863

The Environment Council voted today on a package of proposals from the Commission concerning genetically modified organisms (GMOs). The proposals require the lifting of bans or restrictions (so-called national safeguard clauses) imposed by Austria, France, Germany, Greece and Luxembourg on 8 authorised GM products. The Council voted against all 8 Commission proposals. This is the first time that Council found a qualified majority against a Commission proposal on GMOs. It is thus a new situation in terms of subsequent action. The Commission will have to carefully consider the legal and scientific bases that underpin any further proposals, as well as the implications for EU internal market and trading partners. In a separate proposal involving the authorisation of placing MON863 maize on the European market for import, processing and feed use, the Council did not find the required qualified majority for or against. This case will now go back to the Commission for a final decision.

Stavros Dimas, Commissioner for the Environment, said, "The Commission has a legal obligation to make sure that the existing regulatory framework governing the release of GMOs is correctly applied by Member States. That is why we proposed to lift the current bans or restrictions on certain GMOs in Austria, France, Germany, Greece and Luxembourg. The fact that the Council rejected all 8 proposals raises a host of questions. What is certain is that today's vote sends a political signal that Member States may want to revisit some aspects of the existing system."

The Commission now has three options: to re-submit the existing proposals back to the Council, to amend the proposals and submit to the Council, or to present a legislative proposal on the basis of the Treaty. Commissioner Dimas said that the Commission will now reflect on all legal and scientific aspects related to the 8 decisions in order to decide on the best way forward.

Background on safeguard clauses

The proposals to lift the so-called "national safeguard measures" on certain authorised genetically modified organisms concern the GM maize varieties T25 and MON810 banned in Austria, GM maize Bt176 banned in Austria, Germany and Luxembourg, the oilseed rape varieties MS1xRF1 banned in France and Topas 19/2 banned in France and Greece (see table in annex).

A number of these eight safeguard clauses include bans or restrictions on cultivation whilst others include bans on import and use in food and feed. The responsible Scientific Committees deemed that the information submitted by the Member States as justification for the bans did not change the original risk assessments which had been carried out as part of the authorisation process.

In December 2003, then Environment Commissioner Margot Wallström submitted letters to the above Member States requesting that they re-consider their safeguard clauses in view of the new regulatory framework and if necessary, to re-submit them under Article 23 of Directive 200/18/EC on the deliberate release of GMOs in the environment (which replaced Directive 90/220/EEC). In view of this request, Greece and Austria submitted, in the first quarter of 2004, further information in support of their bans but no response was received from the other Member States.

This additional information potentially impacted on all eight cases and was submitted to EFSA for opinion. In its opinion of July 2004, EFSA concluded, as for all previous arguments and information, that the additional information did not invalidate the original risk assessments for the GMOs in question. Consequently, the Commission was required to submit draft decisions, initially to the Regulatory Committee, requesting the Member States concerned to lift their national safeguard measures.

The Regulatory Committee composed of Member States representatives, on 29 November 2004, failed to reach qualified majority either in favour or against any of these draft decisions. Draft proposals were subsequently transmitted, on 26/27 April 2005, to the Council for opinion.

Background on MON 863

A request to market a genetically modified maize product (line MON863), with resistance to corn rootworm, was submitted by Monsanto to the competent authority of Germany for assessment. The requested uses of the product included import, processing and feed use but not use in food or for cultivation.

The German competent authority concluded that there was no scientific evidence that indicated any risk for human health or the environment for the requested uses. However, other Member States raised and maintained objections in terms of molecular characterisation, allergenicity, toxicity, an inadequate monitoring plan, accidental spillage, presence of an antibiotic resistance marker gene and detectability. The European Food Safety Authority (EFSA) was consulted and delivered its opinion on 16 April 2004 concluding that the MON863 maize was as safe as conventional oilseed rape and unlikely to produce adverse effects.

Consequently, a draft Commission Decision to place the product on the market was presented to the Regulatory Committee for vote on 20 September 2004. However, on 17 September 2004, the German competent authority submitted to the Commission and to the Member States, a re-evaluation of a rat-feeding study included in the original application.

Many Member States expressed concerns in terms of reaching a formal position in the Regulatory Committee meeting, pending an examination of this re-evaluation and consequently, no formal vote took place at this time. Following the meeting, EFSA was requested to evaluate the impact of the conclusions of the re-evaluated rat study on the original risk assessment concluded that it did not put into question its initial opinion on this product.

The Regulatory Committee was re-convened on 29 November 2004. The Committee, acting by qualified majority, did not deliver an opinion. The Commission consequently submitted a draft Proposal to the Council.

Further information on the regulation on GMOs in the European Union can be found at: [MEMO/05/104](#)

Member State and date of invocation	Product details and date of Scientific Opinion concerning original information to justify bans	Justification for bans	Additional information and date of reception
1. FR (20.11.98)	<p>Swede rape resistant to glufosinate MS1/RF1</p> <p>Uses: cultivation for breeding activities (seed production) Product approval: 1996 Scientific Committee Opinion: 18.05.99</p>	<p>Negative effects on human health, the environment and agriculture; Clarification issues re dissemination, volunteers, gene flow and accumulation of resistance genes</p>	<p>FR: 16.02.04 (holding reply); 27.08.04 renewal of prohibition until 17.10.06</p>
2. AU (14.02.97) 3. LX (17.03.97) 4. DE (28.02.00)	<p>Bt-maize tolerant to glufosinate ammonium (Bt-176)</p> <p>Uses: All uses (cultivation, food and feed, processing) Product approval: 1997</p> <p>Scientif. Committees Opinion: 21.03., 10.04., 12.05.97 (AU); 09.11.00 (DE) EFSA: 08.07.04 (AU)</p>	<p>Effects of BT-toxins on non-target organisms and development of resistance to toxins by target organisms</p> <p>Risks associated with ampicillin antibiotic resistance market gene</p>	<p>AU: 09.01, 09.02, 17.02.04 Information concerning potential environmental impact of Bt-toxin and allergenic and toxicological risk assessment LUX: 19.05.2004 Information concerning potential environmental impact of Bt-toxin and antibiotic resistance genes as well as allergenic and toxicological risk assessment</p>
5. EL (05.11.98) 6. FR (20.11.98)	<p>Swede rape tolerant to glufosinate (Topas 19/2)</p> <p>Uses: import, storage and processing (no cultivation) Product approval: 1998</p> <p>Scientific Committee Opinion: 18.05.99</p> <p>EFSA: 08.07.04 (EL)</p>	<p>Issues concerning dissemination, persistence, volunteers and gene flow in the environment (arising from spillage or unintended release)</p>	<p>FR: 16.02.04 (holding reply); 27.08.04 renewal of prohibition until 17.10.06 EL: 05.03.04 Information concerning environmental risks, consumer protection and co-existence (out-crossing with wild relatives, which are consumed by humans in Greece; enhanced capability of rape, wild relatives and hybrids to survive/spread, potential for multi-resistant wild plants and weeds)</p>
7. AU (01.06.99)	<p>Maize expressing the Bt cryIA(b) gene (MON 810)</p> <p>Uses: All uses (cultivation, food and feed, processing) Product approval: 1998 Scientific Committee Opinion: 24.09.99 EFSA: 08.07.04</p>	<p>Effects of BT-toxins on non-target organisms and development of resistance to toxins by target organisms</p>	<p>AU: 09.01, 09.02, 17.02.04 Information concerning potential environmental impact of Bt-toxin and allergenic and toxicological risk assessment</p>
8. AU (08.05.00)	<p>Maize tolerant to glufosinate (T25)</p> <p>Uses: All uses (cultivation, food and feed, processing) Product approval: 1998 Scientific Committee Opinion: 30.11.00 (AU) replaced 20.07.01 EFSA: 08.07.04</p>	<p>Risk of out-crossing with wild relatives and conventional crops as well as in sensitive areas No monitoring</p>	<p>AU: 09.01., 09.02., 17.02.04 Information concerning allergenic and toxicological risk assessment.</p>