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Biotechnology

Environment Council votes no to lifting biotech bans 2005

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Report Highlights:

On June 24, 2005 the Environment Council, consisting of the Environment Ministers of the Member States in the European Union, voted against the Commission proposal to lift the bans or restrictions imposed on GMO products in some of the MS.

This is the first time that the Council found a qualified majority against a Commission proposal on GMOs.

Includes PSD Changes: No Includes Trade Matrix: No Unscheduled Report Brussels USEU [BE2] On June 24 the Environment Council voted on a package of proposals from the European Commission concerning biotech products. The proposals required the lifting of eight bans or restrictions (so-called national safeguard clauses) imposed by Austria, France, Germany, Greece and Luxembourg on authorized GM products. The Council voted against all eight Commission proposals. A number of these eight safeguard clauses include bans or restrictions on cultivation, while others include bans on imports and use in food and feed. (For more detailed information see table at the end of the report).

The proposals to lift the "national safeguard measures" concerned the biotech maize varieties T25 and MON810 banned in Austria, biotech maize Bt176 banned in Austria, Germany and Luxembourg, the oilseed rape varieties MS1/RF1 banned in France, and Topas 19/2 banned in France and Greece.

In November 2004, EU member states met in a regulatory committee to review the Commission's proposal recommending the lifting of the bans. The Commission based its recommendation on EFSA opinions asserting that there was no scientific basis for the member state bans. Nevertheless, the regulatory committee failed to reach a decision and the Commission referred the matter to the Council.

The Council voted against lifting the eight bans and the only member state (MS) that voted for lifting all of the bans was the UK. See table for the reported voting breakdown. Spain, which is the only MS with an important production of biotech corn, voted against lifting the bans. This move is somewhat surprising from the EU's only member state with significant biotech cultivation and is seen by some analysts as more of political message in favor of flexibility for member states rather than an anti-biotech vote.

| Product | Member State | Votes in favor | Votes | Member State Votes* |
|------------------|-----------------|----------------|---------|----------------------------------|
| | | | against | |
| Maize T25 | Austria | 42 | 262 | UK and NL in favor, Finland and |
| | | | | Sweden abstained |
| Colza | France | 42 | 250 | UK and NL in favor, Finland, |
| NS1BnxRF1Bn | | | | Sweden and (poss.) Portugal |
| | | | | abstained |
| Colza Topas 19/2 | France, | 42 | 250 | UK and NL in favor, Finland, |
| • | Greece | | | Sweden and (poss.) Portugal |
| | 0.000 | | | abstained |
| Maize Bt176 | Germany, | 29 | 275 | Only UK voted in favor, Finland |
| | Austria, | | | and Sweden abstained |
| | Luxemburg | | | |
| Maize MON810 | Austria | 54 | 234 | UK, NL and Portugal in favor, |
| | | | | Finland, Sweden and other MS |
| | | | | adding up to 16 votes abstained. |

*According to sources

The vote is seen as a sharp rebuff for the European Commission, which had wanted the ministers to endorse an order to lift the bans within 20 days. EU law provides for national bans if the government can justify the prohibition. 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 authorizations process. Therefore, from the European Commission's perspective, the bans were not justified under EU law.

This is the first time that the Council found a qualified majority against a Commission proposal on biotech. And the vote was also the EU's first agreement by qualified majority

either for or against a biotech issue since 1998, when the Union begun its de facto moratorium on approving biotech foods and crops. Syngenta's Bt11 sweet corn for human consumption was authorized for marketing in May 2004. Monsanto's NK603 herbicide tolerant corn was authorized in November 2004 for import for both food and feed uses. Both decisions were taken on the Commission's own authority after no qualified majority could be found for or against in the Council.

The fact that the Council rejected all eight proposals raises a host of questions. EU Environment Commissioner Dimas stated that what is certain is that these votes send a political signal that Member States may want to revisit some aspects of the existing approvals system.

The Commission now has three options:

- ? to resubmit the existing proposals back to the Council.
- ? to amend the proposals and submit to the Council.
- ? to present a legislative proposal on the basis of the Treaty.

The latter option is reportedly deemed unlikely, but the Commission expressed concern about what Friday's vote could mean for the WTO case on biotech approvals brought by the US, Canada and Argentina. The US, Canada and Argentina argue that the EU has imposed a moratorium on the approval of biotech products since 1998 without any justification, blocking a number of marketing applications already in the pipeline. Last Friday's votes could strengthen the hand of the three complainants in the case.

In a separate proposal involving the authorization 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, as was the case with the last two approvals. The fact that the Council failed to make a decision on MON863 (which means the Commission will probably approve it) during the same meeting at which it blocked lifting the MS bans implies that the vote on the bans was more about Member State rights, rather than biotech per se.

To read the Commissions press release on the votes go to: http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/793&type=HTML&aged=0&language=EN&guiLanguage=en

To read the press release from the Luxemburg Presidency go to: http://www.eu2005.lu/en/actualites/communiques/2005/06/24env01/index.html

| Member | Product details and date of | Justification for | Additional information |
|---------------------|---|---|--|
| State and | Scientific Opinion concerning | bans | and date of reception |
| date of invocation | original information to justify bans | | |
| 1. FR | Swede rape resistant to | Negative effects on | FR: 16.02.04 (holding |
| (20.11.98) | glufosinate MS1/RF1 | human health, the | reply); 27.08.04 renewal of |
| | Head, gultivation for broading | environment and | prohibition until 17.10.06 |
| | Uses: cultivation for breeding activities (seed production) | agriculture; Clarification issues re | |
| | Product approval: 1996 | dissemination, | |
| | Scientific Committee Opinion: | volunteers, gene flow | |
| | 18.05.99 | and accumulation of resistance genes | |
| 2. AU | Bt-maize tolerant to | Effects of BT-toxins | AU: 09.01, 09.02, 17.02.04 |
| (14.02.97) | glufosinate ammonium (Bt- | on non-target | Information concerning |
| 3. LX | 176) | organisms and | potential environmental |
| (17.03.97) | Uses: All uses (cultivation, food | development of resistance to toxins | impact of Bt-toxin and allergenic and toxicological |
| | and feed, processing) | by target organisms | risk assessment |
| 4. DE | Product approval: 1997 | | LUX: 19.05.2004 |
| (28.02.00) | Scientif. Committees Opinion: | Risks associated with ampicillin antibiotic | Information concerning potential |
| | 21.03., 10.04., 12.05.97 (AU); | resistance market | impact of Bt-toxin and |
| | 09.11.00 (DE) | gene | antibiotic resistance genes as |
| | EFSA: 08.07.04 (AU) | | well as allergenic and |
| 5. EL | Swede rape tolerant to | Issues concerning | toxicological risk assessment FR: 16.02.04 (holding |
| (05.11.98) | glufosinate (Topas 19/2) | dissemination, | reply); 27.08.04 renewal of |
| (ED | Uses: import, storage and | persistence, | prohibition until 17.10.06 |
| 6. FR (20.11.98) | processing (no cultivation) Product approval: 1998 | volunteers and gene flow in the | EL: 05.03.04 Information concerning |
| (20.1.1.70) | Troduct approval. 1976 | environment (arising | environmental risks, |
| | Scientific Committee Opinion: | from spillage or | consumer protection and co- |
| | 18.05.99 | unintended release) | existence (out-crossing with wild relatives, which are |
| | EFSA: 08.07.04 (EL) | | consumed by humans in |
| | | | Greece; enhanced capability |
| | | | of rape, wild relatives and |
| | | | hybrids to survive/spread, potential for multi-resistant |
| | | | wild plants and weeds) |
| 7. AU | Maize expressing the Bt | Effects of BT-toxins | AU: 09.01, 09.02, 17.02.04 |
| (01.06.99) | cryIA(b) gene (MON 810) | on non-target organisms and | Information concerning |
| | Uses: All uses (cultivation, food | development of | potential environmental |
| | and feed, processing) | resistance to toxins | impact of Bt-toxin and |
| | Product approval: 1998 Scientific Committee Opinion: | by target organisms | allergenic and toxicological risk assessment |
| | 24.09.99 EFSA: 08.07.04 | | 1131. 0330331110111 |
| 8. AU | Maize tolerant to glufosinate | Risk of out-crossing | AU: 09.01., 09.02., 17.02.04 |
| (08.05.00) | (T25) Uses: All uses (cultivation, food | with wild relatives and conventional | Information concerning |
| | and feed, processing) | crops as well as in | allergenic and toxicological |
| | Product approval: 1998 | sensitive areas | risk assessment. |
| | Scientific Committee Opinion: | No monitoring | |
| | 30.11.00 (AU) replaced 20.07.01 EFSA: 08.07.04 | | |
| L | LI 3/1. 00.07.07 | l . | |

Source: European Commission

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