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## Commission seeks clarification on Bt10 from US authorities and Syngenta

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**IP/05/382**

Brussels, 1 April 2005

### Commission seeks clarification on Bt10 from US authorities and Syngenta

***The European Commission has written to the US authorities and to the biotechnology company Syngenta requesting clarification of the situation regarding the unauthorised genetically modified maize Bt10. According to the information received to date from the US authorities and from Syngenta, the developer of Bt10, up to 10 kg of Bt10 seed may have been exported inadvertently as Bt11 for research purposes to Spain and France. The resulting materials have all been destroyed. In addition, the Commission is informed that an estimated 1000 metric tonnes of Bt10 food and feed products may have entered the EU through the Bt11 export channels since 2001, the date from which the inadvertent release of Bt10 started. At a meeting yesterday with representatives of Syngenta, officials of the European Commission were informed that Bt10 included the gene conferring resistance to the antibiotic ampicillin.***

EU Health and Consumer Protection Commissioner Markos Kyprianou said: "The European Commission deplores the fact that a GMO which has not been authorised through the EU's comprehensive legislative framework for GMOs, nor by any other country, has been imported into the EU, and we are writing to the US authorities asking them to guarantee, by taking the appropriate measures, that present and future exports of maize to the EU do not contain GMOs which are not authorised for the EU market, including Bt10. This case again shows the importance of the European Union's comprehensive framework for traceability and labelling of GMOs."

EU Environment Commissioner Stavros Dimas said: "In order to avoid any adverse effect on human and animal health or the environment of such an accidental release, the Commission has asked Member States to carry out appropriate control measures to stop Bt10 entering their territory. Member States should also notify the state of play regarding past or current national experimental releases of Bt11, and implement any necessary monitoring and surveillance measures in the surrounding areas where these releases took place."

The Commission was first informed by the US Mission to the European Union on 22 March about an inadvertent release in the US of a non authorised genetically modified maize line called Bt10. The Commission informed the Member States without delay via the Rapid Alert System for food and feed. Moreover, the

Commission has asked the US Administration for the full safety information about Bt10 at its disposal without delay, including the full risk assessments upon which it is based as well as for an urgent audit and an official view as to the quantities exported, including the channels they may have taken in the EU.

The Commission has also asked Syngenta, the developer of the Bt10 crop, to release the full information about the molecular characterisation of Bt10 and its distinction from Bt11, as well as the specific detection method and adequate reference materials to trace Bt10. The Commission has also asked Syngenta to confirm that all Bt10 plantings and seed stock in the USA have been destroyed or isolated for further destruction. Syngenta has committed to provide this information next week.

The US government has given reassurance that no food, feed or environmental concerns are associated with the inadvertent release of this non authorised genetically modified crop, based on the fact that the Bt protein in Bt10 is similar to the one in Bt11, which is fully authorised in the US and which the EU has authorised for use in food and feed.

However, the US authorities did not inform the Commission that Bt10 contains, contrary to Bt11, the gene conferring resistance against the antibiotic ampicillin. It was only on the 31 of March that this information was given officially to the Commission by Syngenta. According to the advice of the European Food Safety Authority, the ampicillin resistance gene should not be present in crops grown commercially. However, according to Syngenta, this gene is inactive in Bt10.IP/