

Approval procedure for genetically engineered maize LY038 stopped for safety reasons?

Monsanto and Cargill withdraw joint application after EFSA concerns
Tuesday, 1 December 2009
Munich, Parma

The company of Renessen (a Monsanto and Cargill international joint venture) withdrew its application for market authorisation of the genetically engineered maize LY038. The decision was taken in April 2009, but was made public just recently by several stakeholders. According to documents received by Testbiotech e. V., the European Food Safety Authority, EFSA, raised safety concerns related to the maize. Prior to the withdrawal the EFSA wrote several letters to Renessen asking for more information on the risk assessment of this product. The maize shows several unintended changes in its composition.

The EFSA raised some crucial points related to a possible impact on human health. In its last letter of 24 March 2009 to Renessen it is even requested that animal feeding trials with rats should be repeated as known so far the EFSA has never asked for such a procedure before. In the feeding trials presented rats had shown some significant changes in blood parameters as well as in their urine. But this study was rejected by the EFSA for major methodological deficiencies. Several other EU member states had also raised health risk related issues. In 2005 experts from New Zealand expressed serious concerns for human health if the maize were ever to enter the food chain.

In its letter to the EFSA announcing the withdrawal Renessen only gave economic reasons for its decision - there was no mention of safety concerns. The product is already authorised in other markets such as the US, Canada, Australia and New Zealand. This type of genetically engineered maize produces high levels of Lysin, an amino acid meant to enhance the quality of the maize for its use in animal feed. LY038 maize is an example of the so called 'second generation' of genetically engineered plants that are supposed to create benefits beyond traits achieved so far, such as herbicide tolerance. Many of these crop plants of the 'second generation' do not prevail in the markets. It is therefore unclear whether this product failed mainly for economic reasons or whether Renessen's U-turn has in fact been caused by substantial risk problems.



The withdrawal glaringly highlights current discussions on the right concept for risk assessment of genetically engineered plants. In most cases the EFSA does not require any animal feeding studies and proceeds on the assumption that genetically engineered plants are 'substantially equivalent' to plants derived from conventional breeding. By withdrawing their application, Monsanto and Cargill effectively prevented the EFSA from taking a closer look at this specific product since they requested that all related documents be sent back. Perhaps they wanted to avoid any discussions on the safety of genetically engineered crops.

Testbiotech will continue to observe the EFSA's decisions on GMOs. The EFSA-watch newsletter is available at www.testbiotech.org [1]

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Further information: [Discussion about Maize LY038](#) [2]

Attachment	Size
 2009-03-24 - letter EFSA to applicant - stop the clock (2).pdf [3]	0 bytes
 LY038-highlylincorn-INBlsubmission_Heinemann.pdf [4]	0 bytes

Source URL: <http://www.testbiotech.org/en/press-release/approval-procedure-genetically->

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Links

[1] <http://www.testbiotech.org>

[2] <http://www.gmfreecymru.org>

[3] http://www.testbiotech.org/sites/default/files/2009-03-24%20-%20letter%20EFSA%20to%20applicant%20-%20stop%20the%20clock%20%282%29_0.pdf

[4] http://www.testbiotech.org/sites/default/files/LY038-highlysinecorn-INBIsubmission_Heinemann_0.pdf