

**Summary of the opinion of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA-GMO-UK-2004-04) for the placing on the market of glufosinate tolerant genetically modified rice LLRICE62 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 from Bayer CropScience GmbH¹
(No EFSA-Q-2004-145)**

Opinion adopted on 30 October 2007

SUMMARY

This document provides the opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on the genetically modified rice LLRICE62 (Unique Identifier ACS-OS002-5), hereafter referred to as LLRICE62 developed to provide tolerance to glufosinate herbicides by expressing the PAT protein encoded by the *bar* gene.

In delivering its opinion the GMO Panel considered the application EFSA-GMO-UK-2004-04, additional information provided by the applicant (Bayer CropScience GmbH) and the scientific comments submitted by the Member States. The scope of the application is for food and feed uses, import and processing of LLRICE62 and does not include cultivation. The GMO Panel assessed LLRICE62 with reference to the intended uses and the appropriate principles described in the guidance document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. The scientific assessment included molecular characterization of the inserted DNA and expression of the target proteins. A comparative analysis of agronomic traits and composition was undertaken and the safety of the new proteins and the whole food/feed was evaluated with respect to nutritional quality, potential toxicity and allergenicity. An assessment of environmental impacts and the post market environmental monitoring plan were undertaken.

LLRICE62 was transformed, using particle bombardment, to express the *bar* gene, which encodes phosphinothricin acetyl-transferase (PAT). PAT acetylates glufosinate and thereby detoxifies the herbicide.

The molecular characterisation data established that LLRICE62 contains only one transgenic insert. The structure of the insert in LLRICE62 was determined by Southern analysis and DNA sequencing. No vector backbone sequences or antibiotic resistance marker genes were

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detected. Examination of the transgene locus and the plant-DNA junctions revealed 19 putative Open Reading Frame (ORF) sequences. Analysis of these ORFs was performed by bioinformatic analysis and no significant homologies were identified with known toxins or allergens or with rice genes of known function. The expression of the genes introduced by genetic modification has been sufficiently analysed and the stability of the genetic modification has been demonstrated over several generations.

The GMO Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of LLRICE62 does not raise safety concerns, and that sufficient evidence for the stability of the insert structure was provided.

Based on the results of compositional analysis of samples from a representative range of environments and seasons, the GMO Panel concluded that both rough LLRICE62 (synonym: paddy rice, including hulls), and its processed products are compositionally equivalent to those of conventional rice, except for the presence of PAT protein. In addition, field trials did not reveal any unexpected changes in agronomic performance and phenotypic characteristics.

The PAT protein induced no adverse effects in acute and repeated dose oral toxicity studies in rodents. In addition, PAT is rapidly degraded in simulated gastric fluid and inactivated during heat treatments.

A 42-day feeding study on broilers and a 96-day study on growing-finishing pigs did not indicate differences in the nutritional value of LLRICE62 compared with the non-GM comparator. These animal studies support the compositional analysis which indicated no unintended effects.

The application EFSA-GMO-UK-2004-04 concerns food and feed uses, import and processing of LLRICE62. There is therefore no requirement for scientific information on possible environmental effects associated with cultivation. Accidental release of viable GM paddy rice into the environment is possible and GM seeds could be dispersed into land cultivating rice and establish GM populations, which could outcross with non-GM cultivated or weedy rice plants. The GMO Panel concluded that there is a possibility that small numbers of GM rice plants could enter cultivation and cross-pollinate with cultivated or weedy rice. However it is unlikely that spillage will result in feral plants establishing around ports, mills, and transit routes as there is no indication of changes in fitness or behaviour of this GM rice, except in the presence of glufosinate.

The GMO Panel advised that appropriate management systems should be in place to prevent seeds of LLRICE62 entering cultivation. The monitoring plan provided by the applicant is in line with the intended uses of LLRICE62. Furthermore the GMO Panel agrees with the reporting intervals proposed by the applicant in the general surveillance plan.

In conclusion, the GMO Panel considers that the information available for LLRICE62 addresses the scientific comments raised by the Member States and that LLRICE62 is as safe as its non-GM comparator with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that LLRICE62 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

Key words: GMO, rice, *Oryza sativa*, ACS-OSØØ2-5, PAT protein, *bar* gene, herbicide tolerant, glufosinate, food and feed safety, human and animal health, environment, import, food, feed, Regulation (EC) 1829/2003, Directive 2001/18/EC.

