



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on a notification for marketing of herbicide tolerant GM rice

Notifier:	Bayer CropScience Ltd
Notification reference:	C/GB/03/M5/3
Product:	Rice genetically modified for herbicide tolerance, transformation event LLRICE62.
Scope:	For the import and use of grain varieties derived from rice transformation event LLRICE62 and processed products from rice originating from rice grain derived from LLRICE62. This notification excludes cultivation.
Date:	25 November 2003

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, Ministers of the Welsh Assembly Government and the Department of Environment (Northern Ireland).

Advice: ACRE has considered this notification for the import and use of herbicide tolerant rice based on transformation event LLRICE62. The Committee considers that sufficient information has been provided by the notifier to demonstrate that this GM rice does not pose a risk to human health or the environment. The marketing of this product for importation and processing in the UK will be no different from that of other rice imported for processing and animal feed purposes. In coming to this conclusion ACRE have taken account of the advice of the Advisory Committee on Animal Feedingstuffs (ACAF).

ACRE recommends that reports of post-market monitoring for general surveillance of this product be provided to the regulatory authorities on an annual basis.

Comment

This notification was received by the UK as the lead competent authority. ACRE considered this notification and the potential risks arising from importation and commercial use of this GM rice. The scope of the notification

excludes cultivation and the Committee considered this notification in this context. In arriving at its advice the Committee considered the notification against the requirements of the legislation as it relates to the UK.

Molecular characterisation

Transformation event LLRICE62 has been produced by particle bombardment of Bengal variety rice with a 1.5kb *HindIII/PvuI* fragment of plasmid pB5/35S*bar*. This DNA fragment includes a copy of the *bar* gene from *Streptomyces hygrosopicus* engineered to be under the control of the Cauliflower Mosaic Virus 35S promoter and terminator sequences. Expression of the *bar* gene, which encodes the PAT protein, confers tolerance to glufosinate ammonium herbicides.

ACRE considered the molecular information provided characterising event LLRICE62 to be of sufficient quality to allow the assessment of any potential hazards. The Committee is content that the data supports the conclusion that the inserted DNA sequences are present as a single copy on chromosome 6 and that vector backbone sequences are absent from LLRICE62. Sequence analysis concludes that the insert is identical to that of the donor plasmid and the DNA flanking sequences have been identified to 149bp 5' and 670 bp 3' of the insert. Northern blot analysis was used to demonstrate the absence of RNA transcripts from the 5' and 3' flanking sequences in event LLRICE62. ACRE requested that the notifier provide evidence to confirm the quality of the RNA used in the Northern blot analysis and was satisfactorily provided.

In addition ACRE was content that the PCR detection protocol provided is event-specific.

Animal feed safety

The safety of grain derived from LLRICE62 for use as animal feed was assessed by ACAF. The main rice fraction used as livestock feed in the EU is rice bran mainly as a feed for ruminants. In considering the safety of LLRICE62 for use in animal feed the safety of the gene products, compositional analysis and data from animal feeding studies were taken into account.

The safety of the PAT protein was demonstrated through evidence of the proteins susceptibility to proteases in simulated gastric and intestinal models and an absence of adverse responses when the PAT product was used in an acute mouse toxicity study. Confirmation was requested from the notifier that these studies were conducted using the PAT protein encoded by the *bar* gene from *Streptomyces hygrosopicus*. This was satisfactorily provided.

Compositional data were obtained from a two-year, multi-site trial design. Raw grains were analysed for their proximate composition, amino acid and fatty acid content and for a number of anti-nutritional factors. There were no significant differences found and herbicide-treatment appeared not to alter the composition of the transformed rice significantly. The main anti-nutrients in rice are phytic acid, trypsin inhibitors and lectins. On the basis of data presented concentrations in transgenic rice appear not to differ significantly

from those seen in conventional varieties, all values fell within the range reported for rice generally.

Separate comparisons were also conducted on brown and white rice, rice hulls, rice flour, bran oil and storage proteins. Nothing in this body of data suggested that the composition of LLRICE62 rice differed in any biologically significant way from that of the control variety.

Poultry and pig feeding studies were conducted to demonstrate the safety of LLRICE62 as animal feed. In the poultry study no significant differences in any of the parameters measured were identified and the results confirm that rice event LLRICE62 is nutritionally equivalent to its non-transgenic counterpart. It is noted that although two birds died during the experimental period, both were from causes recognised as common in broiler production. Similarly in the study in pigs no statistically significant differences were noted between two non-transgenic diets and the glufosinate-treated GM for weight gain, feed:gain ratio or for all but one measure of carcass composition, which appears to relate to the numerically small but higher weight gains in the glufosinate-treated GM feed group.

Overall, the compositional equivalence of the LLRICE62 raw grain to Bengal, a variety with a close genetic background used as a control, coupled with the results of the pig and poultry studies suggests that grain and rice bran from LLRICE62 would behave as any other equivalent variety of rice and would not pose a risk to livestock or consumers of livestock products.

Environmental risk assessment

ACRE considered carefully the environmental risk assessment for LLRICE62 provided by the notifier. The Committee noted that the genetic modification involves a well-established gene which has been present in the food chain for the last ten years without any adverse effects reported. LLRICE62 has been compared with the non-transgenic parent variety, Bengal, for characteristics relating to plant morphology, agronomic performance, disease susceptibility, seed germination and reproductive fitness. No differences have been observed with the exception of the new characteristic, tolerance to glufosinate ammonium.

ACRE considered the potential for gene dissemination and gene transfer from LLRICE62. No differences in dissemination capacity or increased potential for gene transfer have been observed in pollen, seed and vegetative material from LLRICE62 compared with non-GM rice. In addition and for the purpose of this notification LLRICE62 will be imported almost entirely as non-viable grain for direct use as processed products from rice. No seeds will be imported for cultivation into Europe. Therefore the likelihood that some imported grain could escape from silos or lorries and germinate is very low and the potential for gene transfer into rice crops and weed red rice is even lower. Members considered that because of the lack of viability of the rice seed in the UK there were no environmental risk problems. However, although the seed was unlikely to germinate in the UK there was a concern

over measures to deal with accidental spillage, which could be an issue for southern European countries.

Post-market monitoring

The aim of the case-specific part of the post market monitoring plan is to investigate any risks identified in the environmental risk assessment, and to test any assumptions made in the risk assessment. ACRE agrees that on the basis of the risk assessment for LLRICE62 there is no requirement for case-specific monitoring. For the purpose of general surveillance the notifier will make use of those people and their networks that are responsible for transport, processing and handling of the GM rice grain. Bayer have proposed to submit reports of the outcome of this monitoring 3, 6 and 10 years after authorisation. ACRE recommends that these reports be submitted annually.