Part II

FORMAT OF THE SUMMARY OF APPLICATIONS FOR GENETICALLY MODIFIED PLANTS AND/OR DERIVED FOOD AND FEED

A. GENERAL INFORMATION

1. Details of application

a) Member State of application: United Kingdom
b) Application number Not available at the time of application
c) Name of the product (commercial and other names): Grain of genetically modified rice (*Oryza sativa*) with tolerance to glufosinate ammonium, derived by traditional breeding methods from crosses between GM rice transformation event LLRICE62 (OECD code ACS-OSØØ2-5) and non-GM rice cultivars. In the countries where seed will be marketed, seed bags will be labeled with the LibertyLink® trademark associated with the name of the rice hybrid or variety.
d) Date of acknowledgement of valid application Not available at the time of application

2. Applicant

a) Name of applicant: Bayer CropScience
b) Address of applicant: Bayer CropScience GmbH Industriepark Höchst, K 607 D-65926 Frankfurt a. M. E-mail address : info@bayercropscience.com
c) Name and address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the applicant (Commission Decision 2004/204/EC Art 3(a)(ii)): LLRICE62 will be imported and processed in the EU by the same groups who import, process and distribute commodity rice today.

3. Scope of the application

☐ Cultivation (Part C of Directive 2001/18/EC)

☒ Import and processing (Part C of Directive 2001/18/EC)

☒ Use as food/food ingredient (Regulation 1829/2003)

☒ Use as feed/feed material (Regulation 1829/2003)

4. Is the product being simultaneously notified within the framework of another regulation (e.g. Seed legislation?)?

Yes ☐	No ☒
If *yes*, specify	

5. Has the GM plant been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes ☐	No ☒
If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

6. Has the GM plant or derived products been previously notified for marketing in the Community under Part C of Directive 2001/18/EC or Regulation (EC) 258/97?

Yes ☒	No ☐
If *yes*, specify: 2001/18/EC notification No. C/GB/03/M5/3. Positive assessment report from UK compentent authority publically available at **www.gmoinfo.jrc**	

7. Has the product been notified in a third country either previously or simultaneously?

Yes ☒	No ☐
If *yes*, specify: Authorisations granted for cultivation and commercial use in USA, and requested for cultivation and commercial use in Brazil and Argentina. Authorizations granted or requested for import and commercial use in Canada, Mexico and the Russian Federation.	

8. General description of the product

a) Name of the recipient or parental plant and the intended function of the genetic modification:

The recipient plant belongs to the species, *Oryza sativa* L. The genetic modification intends to confer the tolerance to the herbicide glufosinate ammonium through the genetic locus defined as LLRICE62 . LibertyLink® rice varieties are developed by traditional breeding methods from crosses between LLRICE62 and non-GM rice adapted for planting in the temperate rice production regions of the Americas.

Herbicide tolerance is based upon the *bar* gene, a bialaphos resistance gene, isolated from the soil microorganism, *Streptomyces hygroscopicus*. The *bar* gene encodes the production of the enzyme, Phosphinothricin-Acetyl-Transferase (PAT). The specific enzymatic action of the PAT protein is tolerance to glufosinate ammonium herbicide.

Agricultural production of rice requires weed control and successful weed control depends upon combinations of management practices. For temperate rice production, farmers use the planting of weed-free seed, crop rotation to break weed cycles, precision land leveling to aid irrigation, seed bed preparation, conservation tillage programs, irrigation management to suppress weeds and the application of one or more herbicides.

In many regions of temperate rice production and, especially in the Americas, severe weed infestations have removed land from economic rice production. In many cases, high clay soils of rice farm land are not suitable for other crops. In the Southern USA states of Texas and Louisiana, as well as in the southern Brazil state of Rio Grande do Sul, former rice land is being grazed for the lack of efficacious red rice control. These rural economies would be enhanced if rice cultivation were able to return, especially to small farmers that have no resources to change the cropping system or to rent new land.

Growing LibertyLink rice allows; 1) more options to rotate herbicides for weed resistance management programs, 2) removal of difficult to control, conspecific weeds, i.e. red rice and rice mimic, 3) control of currently identified biotypes of herbicide resistant weeds, and 4) less reliance upon water management to control weeds, thus more options for crop management and positive implications for water conservation.

b) Types of products planned to be placed on the market according to the authorisation applied for:

LLRICE62 grain will be imported, processed and distributed in the European Union for all uses as any other rice (food, feed and industrial uses) excluding cultivation.

c) Intended use of the product and types of users:

Rice grain is consumed by humans as either a whole grain food or as an ingredient in processed food and rice grain and the by-products of rice milling can be incorporated in animal feed. Grain containing LLRICE 62 will be used by the same users as any other rice.

d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for:

No mandatory restrictions for use, storage and handling are proposed as a condition of the authorisation. All standard practices applicable to rice today remain adequate for the handling of glufosinate ammonium-tolerant, LLRICE62 varieties.

If genetically modified rice is co-mingled with non-genetically modified rice during use, storage and handling, the corresponding batch will be labelled and handled according to the legislation in application in the EU, in particular the Regulation 1830/2003 (EC)

e) Any proposed packaging requirements: Grain containing LLRICE62 will be packaged as any other rice.
f) Any proposed labelling requirements in addition to those required by Community law (Annex IV of Directive 2001/18/EC; Regulation 1829/2003 art. 13 and 25): LLRICE62 does not harbour characterictics that require specific labelling. Hence, no additional labelling is proposed.
g) Unique identifier for the GM plant (Regulation (EC) 65/2004; does not apply to applications concerning only food and feed produced from GM plants, or containing ingredients produced from GM plants): ACS-OSØØ2-5
h) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for. Any type of environment to which the product is unsuited: No restrictions are necessary as LLRICE62 is suitable for food, feed and industrial use in all regions of the European Union.

9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

A spill of paddy rice in transit might introduce viable rice seed into the environment. However, the biological limitations of this domesticated crop which include, no seed dormancy and a requirement for irrigated agricultural conditions, will prevent rice from forming an invasive plant colony. In case of germination of grain, the plants may be killed with a total herbicide different from glufosinate ammonium.

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name

a) Family name:	*Poaceae*
b) Genus:	*Oryza*
c) Species:	*sativa*
d) Subspecies:	*japonica*
e) Cultivar/breeding line:	Bengal
f) Common name:	rice

2a. Information concerning reproduction

(i) Mode(s) of reproduction

a) Autogamous; cultivated rice is basically propagated by seeds that are produced by self-pollination. Wind can move rice pollen, however the life span of pollen is short (3 to 5 min) and the most cultivated rice have stigma that do not extrude from the glums.
b) Vegetative; may be propagated by tiller buds.

(ii) Specific factors affecting reproduction

a) Self-pollination: Pollen formation and fertilization of rice are affected by low and high temperature, flooding and drought. Low temperature affect the microspore stage and high temperature can affect anthesis.
b) Vegetative: favorable water and temperature conditions

(iii) Generation time

4 to 6 months.

2 b. Sexual compatibility with other cultivated or wild plant species

There is no evidence of genetic transfer and exchange with other organisms than those with which rice is able to produce fertile crosses through sexual reproduction. In Europe, *O. sativa* is present in two forms; the cultivated rice in Bulgaria, France, Greece, Hungary, Italy, Portugal, Romania and Spain, and the introduced weed, red rice, which is present in some fields of cultivated rice.

3. Survivability

a) Ability to form structures for survival or dormancy

Rice is cultivated annually. Seed are formed as structures enhancing survival. However rice plants can grow vegetatively and continuously under favourable water and temperature conditions. Rice is adapted to the humid tropics as a semi-aquatic plant.

Wild rice and older cultivars are noted for ease of seed shattering, however modern cultivars developed for machine harvesting have been selected for lack of shattering. Most cultivated rice has been selected for seed expressing a weak dormancy that can be broken with a short period of dry afterripening. Seed dormancy can be important to allow ripening of the grain and harvest without precocious germination.

The panicles of red rice biotypes easily shatter and have strong seed dormancy, becoming a weed problem in rice fields. Red rice seed, when buried in the soil can remain viable for many years and thus create a recurring weed problem.

b) Specific factors affecting survivability

As a vegetative plant, rice does not survive in dry, cold climates.

Seed survival is affected by soil conditions such as temperature and moisture content.

4. Dissemination

a) Ways and extent of dissemination

Three developmental stages are susceptible for dispersal: pollen, seed and vegetative.

- Pollen may be carried by the wind, however, the short life of pollen in cultivated rice (3 to 5 minutes) and the narrow window of female receptivity limit wind as a means of effective dissemination.
- Seed may be dispersed during transport, at sowing and essentially before and during harvest.
- Water seeded rice plants may be up-rooted by wind before the roots establish good contact with the soil. Up-rooted plants may be dispersed by wind on the water surface within the irrigation system.

b) Specific factors affecting dissemination

Rice seed has no structural modifications to facilitate transfer by animals. Dissemination is mainly the result of human activity.

5. Geographical distribution and cultivation of the plant, including the distribution in Europe of the compatible species

Rice is grown worldwide and is a staple food for half of the world's population. Annually about 530 million tons of rice are harvested from the fields of 146 million hectares world-wide. More than 90% of the world rice production comes from Asia, 5% from the Americas, 3% from Africa, and another 1% from Europe and Oceania.

The domestication of rice is considered to have likely occurred in the eastern part of India or in the Yunnan district of China and then widely distributed as a crop. Cultivated rice is recognized to have two varietal groups based upon adaptation, Indica and Japonica. In very general terms, the Indica form is more adapted to tropical, rain-fed agriculture. The Japonica form is found more in temperate, irrigated agriculture, however, Japonica rice is often grown in the upland fields of tropical regions. The two major grain types of rice produced in the USA (long and medium grain) are based upon Japonica germplasm. The preferred grain type of Brazil and Argentina is based upon Indica germplasm.

At present the northern limit of rice cultivation is the border of China and Russia (lat. 53°N.) and the southern limit, Australia (lat. 30°S) and central Argentina (lat. 51°S.) Rice can be adapted to environmental extremes, however US rice varieties are dependent upon irrigation and temperate climates. The northern limit of US rice cultivation is lat. 39°N. In Europe, the main production area, the Po River delta of Italy, is lat. 45°N.

There is no *O. rufipogon* in Europe, the tropical wild relative of *O. sativa*. There are introduced weedy strains of rice, *O. sativa,* known as red rice which are found in the cultivated rice fields in many temperate rice growing areas, including Italy and Spain.

6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Rice is cultivated in eight EU Member States (Bulgaria, France, Greece, Hungary, Italy, Portugal, Romania and Spain). Italy and Spain represent the primary regions for irrigated rice production in Europe.

Rice is found in a variety of ecosystems. Natural habitats of wild rice are swampy places, such as ditches, irrigation canals, or marshlands. The perennial types are found in deep water, while annual types grow in seasonal swamps. The distribution of so-called low land and upland rices can overlap. They have been found in the same marsh, but have different niches in the same habitat. In Asia and West Africa, where rice has been cultivated since ancient times, wild rice populations inhabit disturbed areas. In tropical America and Australia, rice remains in a natural state. The most common predator of rice habitat is man. Draining of wetlands to build housing has destroyed wild rice habitat in Asia, Africa and the Americas. Sensitivity to photoperiods and tolerance to low temperature, drought, flooding, salt and parasites can dictate the habitats of rice. Ecotypes of wild rice include lowland, upland, deep-water and floating. Cultivated rice habitats are either irrigated or upland, rainfed.

7. Other potential interactions, relevant to the GM plant, of the plant with organisms in the ecosystem where it is usually grown, or used elsewhere, including information on toxic effects on humans, animals and other organisms

Rice has a long history of safe cultivation as a crop of mankind. Rice does not produce nectar however, it can be visited by foraging insects to collect pollen. A number of insects (*e.g.* rice water weevil, *Leptocorixa oryzophilus*, rice stink bug, *Oebalus pugnax*, grasshoppers, *Conocephalus fasciatus* and *Melanopsis differentialis*, rice stalk borer, *Chilo plejadellus* and diseases (*e.g.* sheath blight, *Rhizoctonia solani*, blast, *Prycularia oryzae*, and stem rot, *Sclerotiorum oryzae*) may infest the crop.

Rice has a long history of safe use in human food and animal feed in various forms including whole and milled grain, flour and bran. Rice contains a small number of antinutritional factors, all of which are concentrated in the bran fraction. The antinutritional factors include phytic acid, trypsin inhibitor, and hemagglutinin (lectin). With the exception of phytic acid, all of the antinutritional factors are subject to heat denaturation. Rice bran is typically subjected to a dry or moist heat treatment to denature lipases that otherwise would cause the rice bran to become rancid very quickly. Some segments of the population have been identified to have an allergenic reaction to rice. The major allergenic factor is a 16 kDa globulin.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

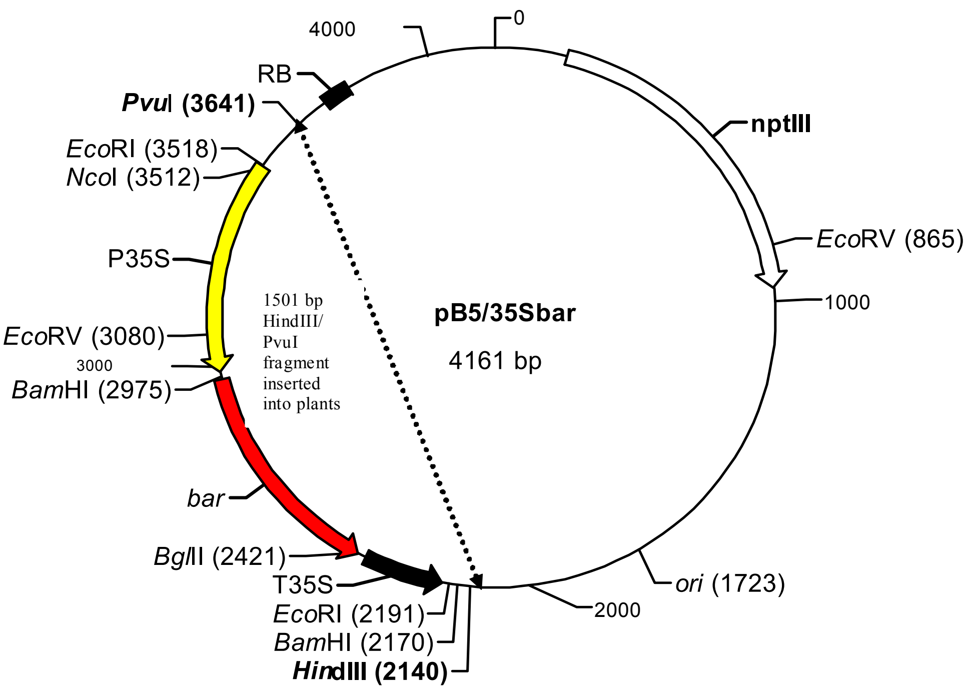
1. Description of the methods used for the genetic modification

The transformation (DNA delivery) was performed by particle bombardment using a purified plasmid fragment containing the *bar* cassette.

2. Nature and source of the vector used

A fragment of the plasmid, pB5/35S*bar*, containing the *bar* cassette (Fig. 1) was gel-purified. The plasmid, pB5/35Sbar is a derivative of the plasmid pUC19, which was derived from *Escherichia coli*.

Figure 1 **Plasmid map of pB5/35S*bar***
The 1501bp HindIII/PvuI fragment of plasmid pB5/35S*bar*, used in the transformation, contains one open reading frame, *bar*, which is intact and functional in transformation event LLRICE62. Included on the map are the restriction endonucleases used in Southern blot analysis to demonstrate that a single copy and no plasmid backbone were inserted by the transformation process.



3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion

To obtain the transforming DNA, the plasmid pB5/35S*bar* was digested with restriction enzymes Pvul and HindIII (Figure 1), and the resulting restriction fragments were separated on an agarose gel. The cleavage position of the restriction enzymes in pB5/35S*bar* for HindIII is at nucleotide 2140 and for PvuI at nucleotide 3641. The 1501 bp HindIII/PvuI fragment contained the *bar* cassette (P35S-*bar*-T35S) and was purified from the gel, and used in transformation of the parental line, rice cultivar Bengal, to generate transformation event LLRICE62. The *nptIII* gene was not included in the transforming DNA fragment.

The size, source and intended function of each constituent are listed in Table 1.

Table 1. Genetic elements of the inserted DNA component of the Vector pB5/35S*bar*

Abbre-viation	Definition	Source	Size (bp)	Accession nº or reference	Function
		Sequence derived from pUC19	44	Yanisch-Perron *et al*. 1985	Restriction site Hind III
	Polylinker sequence	Synthetic	9		Plasmid cloning site
T35S	Terminating signal of bar gene	Cauliflower Mosaic Virus	203	Franck et al., 1980; Pietrzak *et al*., 1986	Stop signal
	Polylinker sequence	Synthetic	18		Plasmid cloning site
Bar	Glufosinate ammonium tolerance bar gene	Streptomyces hygroscopicus	552	Thompson *et al*., 1987 X05822	Herbicide tolerance and selectable marker
	Polylinker sequence	Synthetic	17		Plasmid cloning site
P35S	Promoter	Cauliflower Mosaic Virus	529	Franck *et al*., 1980; Pietrzak *et al*., 1986)	High level constitutive expression
		Sequence derived from pUC19	125	Yanisch-Perron *et al*., 1985	Restriction site Pvu I

D. INFORMATION RELATING TO THE GM PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified

All LibertyLink® crops are tolerant to commercial herbicides based upon glufosinate ammonium (active form is L-glufosinate). Their herbicide tolerance is based upon the naturally occurring *bar* gene, isolated from soil microbes that produce L-phosphinothricin, a bacterial metabolite with antimicrobal and herbicidal activity. Glufosinate ammonium is the synthetic salt of this natural herbicide. Activity of the *bar* gene protects the microbe as it makes L-phosphinothricin. In a similar manner, expression of the *bar* gene in plants allows survival after a foliar spray with glufosinate ammonium herbicide. The *bar* gene codes for the enzyme Phosphinothricin-Acetyl-Transferase (PAT) that acetylates L-phosphinothricin (also known as L-glufosinate) to an inactive form. The PAT protein is a highly specific enzyme with only this one function. If left in its L-isomer form, phosphinothricin disrupts the normal process of amino acid synthesis and results in a lethal build-up of ammonium in the microbe or plant cell. In a manner not unlike an inadvertent over-fertilization of a plant, glufosinate ammonium herbicides cause sensitive plants to release internal ammonia, leading to rapid plant death.

Rice varieties with the genetic insertion LLRICE62 make the PAT protein mainly in their green leaves. When sprayed with glufosinate ammonium herbicides, the LLRICE62 plants can continue to grow while surrounding weeds rapidly die.

Several formulations of glufosinate ammonium are commercially used in many regions of the world. Registered names include Liberty®, Ignite® Finale® and Basta®. Registered uses in Europe include non-selective weed control in the floor of orchards and vineyards and desiccation of potatoes and oilseed rape prior to harvesting.. LibertyLink® crops currently on the market in certain areas include varieties of corn, cotton, canola and soybean. None of them are cultivated in the European Union yet.

2. Information on the sequences actually inserted or deleted

a) The copy number of all detectable inserts, both complete and partial

Southern blot, PCR and sequence analysis demonstrated that the glufosinate ammonium-tolerant, rice event LLRICE62 contains one copy of the *bar* gene cassette.

b) In case of deletion(s), size and function of the deleted region(s)

A deletion of 18 base pairs was identified at the transgenic locus of LLRICE62. Analysis of the native sequence at the insertion site found this region of chromosome six is not expressed.

c) Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination

Based upon Southern blot and genetic segregation analysis, it was demonstrated that the DNA has integrated in a single genetic locus in the rice nuclear genome (chromosomes). Further analyses have demonstrated that this locus is located on chromosome six.

d) The organisation of the inserted genetic material at the insertion site

The characterization of the inserted sequences in event LLRICE62 confirmed the presence of one copy of the *bar* gene cassette, and also the absence of vector backbone. There are no ARMs present in LLRICE62.

3. Information on the expression of the insert

a) Information on developmental expression of the insert during the life cycle of the plant

The amount of PAT protein in the leaves of LLRICE62 during the vegetative life cycle of the plant has an upper limit of approximately 150 µg/g fresh weight. The amount of PAT protein in seed is 12 µg/g fresh weight.

b) Parts of the plant where the insert is expressed

Linked to the plant promoter, 35S, the expression of the *bar* gene is mostly targeted to green tissue of the plant. Expression level was measured by PAT protein specific ELISA. It was found that PAT protein constitutes 12 µg/g fresh weight of roots, 30 µg/g fresh weight of stems (culm) and 90 µg/g fresh weight of leaves. PAT protein comprises an average of 0.23, 0.19 and 0.13% of the total crude protein in roots, stems and leaves respectively, of rice event LLRICE62. ELISA reactive PAT protein was not found in the non-transgenic control rice organs. The limit of detection of the assay for the different matrices was 3.37 ng/g for roots, 0.22 ng/g for stems and 4.59 ng/g for leaves. Tissue samples were harvested from field-grown rice at the late vegetative/panicle development stage.

From published experience with the 35S promoter in rice, we expected LLRICE62 plants to show high levels of PAT protein in the leaves and lesser amounts in the other organs. Indeed, we found the following order of PAT expression leaf blade>>stem (culm)>>roots, seed (grain) >>>>>>pollen (not detected). .

4. Information on how the GM plant differs from the recipient plant in

a) Reproduction

The trait of herbicide tolerance had no effect as the mode and rate of reproduction is by seed production and is the same as for conventional rice.

b) Dissemination

Three developmental stages are susceptible for dispersal: pollen, seed and vegetative. No differences in dissemination capacity have been observed between Genetically Modified LLRICE62 and non-genetically modified rice. Studies show that the genetic modification did not modify the characteristics of the rice that could impact dissemination.

- no difference in pollen characteristics including; viability by vital stain, fertility in crosses as either a male or female parent, and floral structure;
- no difference in pollen dispersal to cultivated rice and to red rice under field conditions;
- no difference in seed morphology or fecundity measured as number of seed per panicle, grain biomass and 1000 seed weight;
- no difference in shattering, germination, length of dry after ripening requirement or dormancy as measured by standard laboratory rice seed physiology tests;
- no impact on tillering capacity that could be associated with an increase in vegetative dispersal as in certain rice wild species.

c) Survivability

For cultivated rice, survival is most determined by seed characteristics. There is no indication of changes in the seed characteristics as a result of the genetic modification.

d) Other differences

The only biologically significant difference observed in field evaluations is that rice varieties based upon transformation event LLRICE62 are tolerant to Liberty® herbicide, active ingredient glufosinate ammonium.

5. Genetic stability of the insert and phenotypic stability of the GM plant

The trait is inherited as a single dominant gene. To demonstrate the stability of the inserted DNA, Southern blot analysis was completed for different generations grown under different environmental conditions and for crosses into different genetic backgrounds.
The isolated DNA was digested with the EcoRV restriction enzyme, which has only one restriction recognition site in the transgene. Probing EcoRV restricted genomic DNA with the *bar* gene cassette showed the two expected bands in all rice event LLRICE62 samples. These bands represent the junctions between transgenic sequences and plant DNA sequences upstream and downstream of the insert and were identical in all samples.
The resulting Southern blots demonstrate the molecular stability of the rice event LLRICE62 at the genetic level over multiple generations, different locations and in four distinctive genetic backgrounds.
Phenotypic stability was demonstrated by Mendelian inheritance.

6. Any change to the ability of the GM plant to transfer genetic material to other organisms

a) Plant to bacteria gene transfer

No aspect of the nature of the genetic elements used give any indication that a transfer from LLRICE62 to bacteria could occur.

b) Plant to plant gene transfer

Genetic transfer possible only to rice. There is no evidence of genetic transfer and exchange under natural condition with organisms other than those with which rice is able to produce fertile crosses through sexual reproduction. There are no indications that the potential for successful exchange of genetic material has changed due to the genetic modification.

7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

7.1 Comparative assessment

Choice of the comparator

Compositional analysis for grain compared LLRICE62 and its derived variety, Bengal.

7.2 Field trials

a) number of locations, growing seasons, geographical spreading and replicates

The geographic range included the Southern United States rice growing regions of Louisiana, Arkansas and Mississippi. Grain samples were collected from two growing seasons (1998 and 1999), 14 locations, three treatments from almost every location, and a 3-fold replication per treatment. The three treatments consist of: a) non-transgenic rice grown using conventional herbicide weed control, b) transgenic rice grown using conventional herbicide weed control, and c) transgenic rice grown with Liberty® herbicide weed control.

b) the baseline used for consideration of natural variations

Published literature was consulted to establish a range of values to be expected for each nutritional component and ranges built from the values of the non-transgenic, reference variety, Bengal.

7.3 Selection of compounds for analysis

Bayer CropScience undertook a systematic review of the composition of the grain derived from LLRICE62. The components selected for compositional and nutritional analyses comprise the important nutrients of rice. Raw grain samples were analyzed for proximate, amino acids, fatty acids, micronutrients, such as vitamins and minerals, and antinutrients, such as phytic acid, trypsin-inhibitors and lectins.

Some of the nutrients in rice can be best measured in processed products, for example;

a) The light brown colour of brown rice is caused by the presence of bran layers, which are generally high in minerals and vitamins, especially the B-complex group. The vitamin determinations show an excellent correspondence for brown rice and parboiled brown rice samples. Rice storage proteins (albumin, globulin, glutelin and prolamin) and the rice allergenic protein were analyzed in samples of brown rice.

b) Rice bran gives brown rice its colour and nutty flavour. Bran is used as an ingredient in cereals and mixes as well as in vitamin concentrates. The minerals and vitamins of the transgenic rice bran samples are similar to the respective conventional rice bran sample and within the ranges reported for the literature.

c) Rice bran oil is a high quality cooking oil and the lipid profile is preserved in LLRICE62. The fatty acid values for the nontransgenic and transgenic samples agree with each other. The unsaponifiable lipid constituents in unbleached rice bran oil (tocotrienols, tocopherols, oryzanol) showed very little difference in content between the non-transgenic and transgenic rice samples.

7.4 Agronomic traits

Throughout the field testing history of LLRICE62 there were no differences observed that could be attributed to pleitropic effects of the *bar* gene insertion. Neither did LLRICE62 differ from the recipient in nutritional, agronomic or reproductive characters. The agronomic evaluations included a detailed phenotypic analysis based upon plant variety description, agronomic performance evaluations common to yield trials, pest resistance evaluations and agronomic practice evaluations to determine plant nutrition requirements. Field studies were conducted in Brazil and Argentina in the 1998-1999 and 1999-2000 seasons. The Southern US variety development program began replicated agronomic evaluations in 1999 and continued for three years in Arkansas, Louisiana, Texas and Mississippi. A summary of the comparisons between LLRICE62 and its parent rice variety, Bengal, is provided in Table 2. Only two differences were noted :

a) A shorter plant height, which was a result of plant breeder selection, not the LLRICE62 genetic modification.

b) The agronomic performance evaluations observed some yield differences across locations and with different agronomic practices. This is not unexpected as the GM rice is a derived line from the reference variety. It is not uncommon that closely related lines of rice vary in their yield, in fact lines containing LLRICE62 were found to yield more or less or the same as the reference. Differences in yield were one critiera used to select lines for advancement in the variety development program. The range of variation of yield is within the normal distribution during field testing of commercial varieties.

There is no indication in the data of agronomic performance that LLRICE62 is unlike rice that is currently grown and consumed.

Table 2: Summary of parameters evaluated in the comparison of varieties containing LLRICE62 and the recipient rice variety, Bengal.

Characteristic	Parameters	Findings
Plant morphology using PVP standards	Maturity Culm Flag leaf Ligule Panicle Spikelet Fertility Germination and vigor in cold	Same as recipient variety
Grain morphology using PVP standards	Endosperm color Aroma Shape class defined by L/W ratio Amylose values Alkali spreading value	Same as recipient variety
Field performance	Emergence and stand establishment Rate of growth (first and 50% tillering date) Vigor Height Yield	Same as recipient variety, (See 7.4).
Grain performance	Whole grain milling yield Grain moisture Duration (days) of optimum harvest	Same as recipient variety
Reproduction	Date of first flower (heading) Date of 50% and last heading Date of grain maturity	Same as recipient variety
Disease resistance	Severity rating for naturally occurring pathogens	No changes in disease reaction compared to recipient variety
Fecundity	Seed per panicle 100 seed weight Empty florets	Same as recipient variety
Shattering	Shatter rating of mature panicles	Same as recipient variety and not like weedy rice.
Dormancy	Dry afterripening Germination rate Survival of imbibed seed	Same as recipient variety and not like weedy rice.
Persistence	Census of volunteers in subsequent season	Same as recipient variety.
Nutritional composition of grain and straw	Proximates, amino acids, minerals, vitamins, fatty acids	Same as recipient variety
Anti-nutritional components	Phytic acid, trypsin inhibitor, and hemagglutinin (lectin)	Same as recipient variety
Rice allergenic protein	16 kDa protein sera screen	Same as recipient variety
Rice storage proteins	Albumin, globulin, glutelin, prolamine	Same as recipient variety

7.5 Product specification

Glufosinate ammonium-tolerant rice transformation event LLRICE62 has been conventionally bred with rice varieties having grain types common in the diet of the European Community (LLRICE62 varieties). The derived food is rice and the derived feed can be ground whole grain or the by-products of rice milling. LLRICE62 varieties belong to the species, *Oryza sativa* L. and are distinguished from other rice only by tolerance to the herbicide, glufosinate ammonium, the genetic locus defined as LLRICE62 and the presence of the PAT protein.

7.6 Effect of the production and processing

The LLRICE62 varieties are grown using the agronomic practices of the region of production and the grain is harvested, transported, stored and milled using the same processes as rice currently in commerce. Upon chemical analysis, the nutritional composition of whole grain and processed grain (brown rice, parboiled brown rice, milled rice, bran, flour and rice bran oil) were found to be equivalent to other rice.

Processing using heat, like parboiling and cooking degrades the PAT protein, but not the DNA. In rice bran oil, the PAT protein is not detected, while DNA can be detected.

7.7 Anticipated intake/extent of use

The intake of rice in the diet of the European Community is not anticipated to change with the introduction of LLRICE62 varieties. Grain derived from LLRICE62 varieties is not different in grain quality or nutritional composition from the rice now consumed. No change in the use patterns for rice is anticipated. No potential dietary and nutritional impacts have been identified for rice grain derived from LLRICE62 varieties.

The per capita consumption of rice for the European diet is 4.4 kg/year. The extremes of rice consumption in the member States include 16 kg/person/yr in Portugal down to 2 kg/person/yr for the UK population. The principal contribution of rice in the human diet is carbohydrate for energy.

7.8 Toxicology

7.8.1 Safety evaluation of newly expressed proteins

The PAT protein is not toxic for mammals and does not possess any of the characteristics associated with food allergens. Findings to support this conclusion include:

- The coding sequence of the *bar* gene is derived from a common soil microbe not known to be a pathogen.
- The PAT protein is quickly degraded and denatured in gastric and intestinal fluids of domestic animals and humans.
- The PAT enzyme is highly substrate specific. It acts on its target, glufosinate ammonium but it does not act on glutamate, the closest structural analogue of L-glufosinate.
- There were no adverse effects found in mice, even at a high dose level of the PAT protein, after intravenous administration.

7.8.2 Testing of new constituents other than proteins

No constituent other than the PAT protein is novel and no changes in composition of rice was discovered by chemical analysis

7.8.3 Information on natural food and feed constituents

Natural constituents of rice have not been changed in LLRICE62. . See section 7.9 for discussion of the rice allergenic protein. Equivalence in the raw grain was demonstrated for all proximates, fiber compounds, and the total amino acids. Statistical quivalence was not proven for calcium, iron, and three of the vitamins, however, the mean values calculated for the transgenic samples are within the reference range reported in the literature for rice in commerce and in some cases, were higher than those of the non-transgenic reference.
Good agreement between the findings for LLRICE62, the comparator and the baseline support the conclusion of compositional equivalence to rice currently in commerce.

7.8.4 Testing of the whole GM food/feed

Two animal feeding studies were conducted to supplement the safety evaluation; a 42-day feeding study was performed in male broiler chickens and a 96-day growing-finishing study in swine. Poultry were selected to evaluate the effects of a feed component over an entire life span and under conditions of rapid growth, thus the assay is highly sensitive for nutritional deficiencies or toxic effects. In contrast, swine represent a close approximation to the human food preferences and digestive processes. No differences were identified for nutritive value of the grain and no indications of toxic or adverse effects were associated with any of the sources of rice in either of the tested animal species.

7.9 Allergenicity

7.9.1 Assessment of allergenicity of the newly expressed protein

The PAT protein does not possess any of the characteristics associated with food allergens.

The PAT protein has no homology with any known allergens, toxins or antinutrients.

The PAT protein has no glycosylation sites present on certain food allergens.

The PAT protein forms only an extremely minor part of the crude protein fraction in LLRICE62, making it unlikely to become a food allergen, which tend to be major proteins

7.9.2 Assessment of allergenicity of the whole GM plant or crop

Rice is not considered a major food allergen by *Codex Alimentarius*. There are naturally occurring allergenic proteins in rice, principally the 14-16 kDa alpha-amylase/trypsin inhibitor, which are food allergens for certain populations. Two studies were designed to evaluate the endogenous allergenic proteins in LLRICE62. A collection of blood sera from rice-allergic subjects was challenged with brown rice extract and no difference in IgE antibody binding was observed. Using a antibody-based assay (ELISA technique), the amount of 14-16 kDa endogenous allergenic proteins was quantified and found to be the same for LLRICE62 and the comparator.

The results of both studies affirm that there are no changes in the total endogenous rice allergens content of LLRICE62 when compared to its counterpart thus demonstrating no increased risk of allergenic potential. LLRICE62 is just like other rice in these direct tests for allergenicity.

7.10 Nutritional assessment of GM food/feed

7.10.1 Nutritional assessment of GM food

The introduced trait in LLRICE62 is intended for agronomic benefit. No change in the nutritional composition was intended and upon extensive analysis, none was found.

Raw rice grain was analyzed for the key nutrients for which rice can be the principal dietary source; carbohydrates, protein, iron, calcium, thiamine, riboflavin and niacin. The data demonstrate that rice containing the genetic locus LLRICE62 has the same nutritional composition as its non-transgenic counterpart, and values for nutritional components fall within the range of values reported for rice commodities in commerce (see section 7.8.3).

Rice grain derived from LLRICE62 is not different in nutritional profile from rice currently in the European consumers' diet. Thus, the introduction of rice derived from LLRICE62 is not expected to change the pattern of rice consumption or result in nutritional imbalances.

7.10.2 Nutritional assessment of GM feed

The by-products of rice milling (bran and rice hulls) can be used in animal feed. Rice contains a small number of antinutritional factors, all of which are concentrated in the bran fraction. The antinutritional factors include phytic acid, trypsin inhibitor, and hemagglutinin (lectin). With the exception of phytic acid, all of the antinutritional factors are subject to heat denaturation. Rice bran is typically subjected to a dry or moist heat treatment to denature lipases that otherwise would cause the rice bran to become rancid in storage. Antinutritional factors common to rice were best measured in LLRICE 62 bran and are well below acceptable levels. In addition, two studies using two animal species (chickens and pigs) raised no concerns about the nutritional value of the LLRICE62.

7.11 Post-market monitoring of GM food/feed

No post-market monitoring plan is required for LLRICE62. A traditional comparator, the rice variety, Bengal, was used in the comparative analysis (D.7.1-3). The intent of the genetic modification was for agronomic benefit (D.7.4), no change in the nutritional composition or value was intended and no change was identified (D.7.6,10). No health claims are intended and LLRICE62 will not be marketed as an alternative to or replacement for traditional rice (D7.5). LLRICE62 has no specific properties that might increase the dietary intake compared to traditional rice (D.7.7). There is no evidence that the long term nutritional and heath status of some individuals of the European population could be impacted by the marketing of LLRICE62 (D.7.8-10).

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

Not applicable. There are no target organisms.

9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

9.1 Persistence and invasiveness

A review of the reproductive and vegetative fitness finds that LLRICE62 compares to its parent variety Bengal in all aspects except the tolerance to glufosinate ammonium herbicide. Subsequent season monitoring for volunteers has found no indication of increased persistence or invasiveness of LLRICE62.

9.2 Selective advantage or disadvantage

None. USDA concludes that PAT protein does not confer a selective advantage. Agronomic performance shows no disadvantage. The only circumstance in which a selective advantage could happen would be if some plants from escaped grain would be sprayed with glufosinate ammonium. The likelihood that some escaped grain would germinate is very low because most of the imported grain is non-viable. In addition the herbicide glufosinate ammonium is not likely to be used in the vicinity of grain storage facilities, processing plants or roadways, areas where such an escape might occur.

9.3 Potential for gene transfer

Plant to bacteria gene flow. In order for any horizontal gene transfer to lead to a new type of micro-organism and therefore to introduce a significant impact, some of the following conditions will have to be fulfilled:

- the uptake should result in the incorporation of complete undegraded DNA
- the plant targeted genes should result in significant expression in a prokaryotic background
- the expression should represent a significant increase over the background level
- the traits should convey a competitive advantage to the strain in which they are incorporated.

Sequence analysis of elite event LLRICE62 confirmed (Section D.2), the insertion of one copy of the *bar* gene cassette only and also the absence of vector backbone sequences. LLRICE62 does not contain either the origin of replication of plasmid pB5/35S*bar* or any sequences responsible for an enhanced frequency of recombination. Further more the introduced *bar* gene is under the control of the 35S promoter, which is not functional in bacteria. Considered altogether, these facts make the possibility of gene transfer from plants of LLRICE62 to bacteria to be unlikely.

Plant to Plant gene flow. Gene flow to red rice or other crop rice is possible in rice producing areas of Europe. Studies find the potential to be small. Impacts of outcrossing to other cultivated rice can be managed with modest isolation distances in commercial production. Prudent use of glufosinate ammonium herbicide can control red rice before it can flower, thus eliminating the opportunity of cross-pollination. In cases where red rice does flower in field production, subsequent monitoring has not found hybrids. The self-pollinating nature of rice and red rice serve as a barrier to cross pollination.

-Likelihood of gene flow. Gene flow can occur into an adjacent rice crop and into weed red rice, however, the rate is likely to be very low because there exists a combination of genetic, botanical, geographic and agricultural barriers to gene flow. Gene flow will not occur into wild *Oryza* species, which are not present in Europe. Measurement of natural cross pollination from LLRICE62 to cultivated rice and weed red rice found the rate of outcrossing to be the same as other rice, less than 0.1% between plants in close proximity and difficult to measure at distances beyond 1 meter.

-Consequence of gene flow. Furthermore, the transfer of the *bar* gene into red rice will not exacerbate problems of weed control or adversely impact agriculture. The fitness of crop-weed hybrids would not be greater than that of red rice. No adverse impact to biodiversity was identified.

Nevertheless LLRICE62 is not intended to be grown in Europe and thus, this risk is only hypothetical. The only foreseeable chance for LLRICE62 to outcross to rice in Europe would be if imported grain spilled in transit, that grain was viable seed and plants established inside 1 meter of cultivated rice.

9.4 Interactions between the GM plant and target organisms

The introduced trait is not an insecticidal trait. There are no target organisms.

9.5 Interactions of the GM plant with non-target organisms

Three possible interactions with other organisms were examined. The genetic modification, tolerance to the herbicide, glufosinate ammonium, did not change the interaction of GM rice varieties with other organisms in the absence of herbicide application. Under agricultural conditions when the herbicide is used (a), some advantage may be gained in plant population dynamics. In habitats outside agriculture (b), the interaction with other plant communities is like any other rice. No changes could be identified in interactions with non-target organisms (c) in the environments under which glufosinate ammonium tolerant rice will be cultivated (USA, Brazil, and Argentina). Under agricultural conditions, with direct comparisons of herbicide application, insect population diversity and measures of sensitivity to natural pathogens of rice found no advantage for the transgenic event LLRICE62.

(a) Effects on biodiversity in the area of cultivation

Under pressure of selection in an area treated with glufosinate ammonium, LLRICE62 may establish in the environment and, thereby, modify the biodiversity. Furthermore it might transfer the trait via pollen flow to other cultivated rice or weed rice (red rice) or wild rice in the vicinity and contribute to their establishment and modification of the biodiversity too. However the anticipated area of cultivation is not in Europe, but rather in the USA, Brazil and Argentina.

(b) Effects on biodiversity in other habitats

LLRICE62 will be imported as mostly non-viable grain. Therefore the likelihood that some imported grain could escape from silos or lorries and germinate is very low. In addition, glufosinate ammonium is used in Europe mainly in agricultural areas (as a herbicide in grapevine and orchards, and as a desiccant in oilseed rape and potatoes). Therefore the very rare plants that might germinate would have no chance to be sprayed with glufosinate ammonium. Consequently the likelihood for LLRICE62 in the environment is not higher than conventional rice.

(c) Effects on non-target organisms

There are no non-target organisms specific to the GMHP compared to non-genetically modified rice. There are no observed effects of the herbicide-tolerant rice on non-target organisms. Field observations found no differences in insect populations or reactions to natural infestation of rice pathogens. No effect was observed on birds or small mammals. No indication of allelopathy on the germination and growth of an indicator crop planted in soil following LLRICE62.

9.6 Effects on human health

No effects on human health are indicated for people working with, coming into contact with or in the vicintity of an environmental release of LLRICE. The rice grain of LLRICE62 has the same nutritional quality and identical allergen profile as rice in commerce. The plants of LLRICE62 have the same qualities as other rice. PAT protein is not detectable in pollen of LLRICE62 plants, therefore the exposure of field workers to pollen is the same as with the traditional rice.

9.7 Effects on animal health

The primary use of rice is for human food, however rice grain and the by-products of rice milling are often included in animal diets. The nutritional composition of the grain was demonstrated to be equivalent to other rice by chemical analysis.

To support the finding of nutritional equivalence and to demonstrate bioavailability, poultry and swine were fed diets containing rice under study conditions designed to evaluate growth and health parameters. Poultry were selected to evaluate the effects of a feed component over an entire life span and under conditions of very rapid growth, thus the assay is highly sensitive for nutritional deficiencies or toxic effects. In contrast, swine represent a close approximation to the human food preferences and digestive processes. No differences were identified for nutritive value of the grain and no indications of toxic or adverse effects were associated with any of the sources of rice in either of the tested animal species.

The grain of transformation event LLRICE62 is not anti-nutritional or toxic for mammals and no effects on animal health are expected.

9.8 Effects on biogeochemical processes

Potential effects on biogeochemistry were assessed indirectly in agronomic studies designed to identify best agronomic practices for growing glufosinate ammonium-tolerant rice. For example, studies to determine nitrogen requirements found rice varieties containing the transformation event, LLRICE62 are not different in grain yield response to nitrogen levels than comparable rice varieties.

Chemical analysis of the nutritional components grain and straw found no differences in the mineral composition and thus no reason to consider mineral utilization from the soil to be different than for conventional rice.

Substantial equivalence of the rice grain derived from LLRICE62 has been demonstrated, and no effect on biogeochemical processes are anticipated that would differ from rice now in cultivation and commerce.

9.9 Impacts of the specific cultivation, management and harvesting techniques

LLRICE62 varieties will be grown in principally the United States of America (USA), Brazil and Argentina. Rice produced in the USA enters the European Union by import as commodity rice grain. Milling, processing and consumer packaging are accomplished in the EU.

In many regions of temperate rice production and, especially in the Americas, severe weed infestations have removed land from economic rice production. In regions of Texas and Louisiana, as well as in the southern Brazil state of Rio Grande do Sul, former rice land is being grazed for the lack of efficacious red rice control. These rural economies would be enhanced if rice cultivation were able to return, especially to small farmers that have no resources to change the cropping system or to rent new land.

10. Potential interactions with the abiotic environment

No interaction with the abiotic environment is foreseen that would differ from rice now in cultivation and commerce. Water conservation may be a benefit of the cultivation of LLRICE62 as farmers growing it can be less reliant upon water management to control weeds.

11. Environmental monitoring plan (not if application concerns only food and feed produced from GM plants, or containing ingredients produced from GM plants)

11.1 General (risk assessment, background information)

The scope of this application is the import of grain derived from LLRICE62 for food, feed and industrial uses, no authorization for growing is requested in the Member States of the European Union.

Environmental risk assessment for the import of LLRICE62 into the European Community identified no potential risk, however a potential adverse effect could be anticipated if pollen from LLRICE62 were to fertilize commercial rice or the weed, red rice in European rice production. The only foreseeable chance for LLRICE62 to outcross to rice in Europe would be if imported grain spilled in transit, that grain was viable seed and plants established inside 1 meter of cultivated rice. The likelihood that viable seed could be released unintentionally into the rice growing environment of the UE community is very small, as the amount of rice imported as viable grain is small and the transit routes from the ports to the mills do not pass through areas of rice cultivation.

11.2 Case-specific GM plant monitoring (approach, strategy, method and analysis)

Since no risk has been identified, there is no need for case-specific monitoring plan.

11.3 General surveillance of the impact of the GM plant (approach, strategy, method and analysis)

The identification of possible unanticipated adverse effects of the GMO on human or livestock health and/or the environment, which were not anticipated in the e.r.a., can be addressed under the general surveillance. The people and their networks participating in the surveillance plan would tend, although not exclusively, to be best suited to identify possible unanticipated adverse effects of the GMO to the receiving environment and/or human or livestock health.

Background data.

Of the EU Member States that cultivate rice; Bulgaria, France, Greece, Hungary, Italy, Portugal, Romania and Spain, only Spain and Italy have imported commodity paddy rice (potentially viable seed) in the last five years in a reasonable amount (although never higher than 4% of the national production). The potential parameters determining a possible gene transfer are: a) seed spillage in ports, mills, and along transit routes. However these sites do probably not provide an opportunity for feral rice populations to establish and are generally far removed from rice cultivation, b) the application of glufosinate ammonium herbicide, which could give LLRICE62 plants an advantage, c) outcrossing happens only at a low frequency because of the self pollinating nature of rice (outcrossing is lower than 0.1% even for plants within 1 meter distance), and d) rice pollen have a very short life time.

Thus, if rice were to spill at the port or along the roadside or at a milling facility, it is very unlikely it would establish a feral population, or have an outcrossing to commercial and/or weed rice. If LLRICE62 were to spill in one of these environments, the result would be the same as for any other rice. The only difference, tolerance to the herbicide glufosinate ammonium, would not provide a survival advantage, as long as glufosinate ammonium is not applied in these environments.

Parameters to evaluate

Different parameters influence the possible occurance and/or establishment of feral or weed rice populations. Of the ones mentioned above, outcrossing possibilities and pollen viability are already discussed into detail in other papers and do not need to be repeated here. Remaining parameters to be used are: a) accidental spillage in ports, along transit routes and around milling facilities, b) occurance and/or establishment of feral Liberty Link populations of cultivated or weed rice, and c) usage frequency of glufosinate ammonium in harbors, along transport routes and around milling facilities (usage of glufosinate ammonium provides an opportunity for feral rice populations to establish).

11.4 Reporting the results of monitoring

We propose to submit general surveillance reports on an annual basis, following the initial placing on the market (first import). A final report will be made at the end of the consent. Indirect effects refer to a causal chain of events with an effect on human health and the environment. Observations of indirect effects might, in some cases, be delayed. Since surveillance will also include the observation of potential indirect and/or delayed effects, we propose to include a report covering potential indirect or delayed effects at the stage of re-evaluation or at the end of a given consent in the case where the notifier does not apply for a renewal. An evaluation of the need for additional, post-consent surveillance will be included in such a report.

If information that confirms an adverse effect which alters the existing risk assessment becomes available to the notifier from users or other sources, the notifier is required immediately to inform the Competent Authority which gave consent for marketing of the GM crop, and in collaboration with the Competent Authority, to evaluate the information and, if necessary, to take proportional measures necessary to protect human or livestock health and/or the environment. The notifier will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment.

12. Detection and event-specific identification techniques for the GM plant

A discriminating PCR (dPCR) method and control materials have been provided to the DG Joint Research Centre – Community Reference Laboratory – as defined by EU Regulation 1829/2003.

E. INFORMATION RELATING TO PREVIOUS RELEASES OF THE GM PLANT AND/OR DERIVED PRODUCTS

1. History of previous releases of the GM plant notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

a) Notification number

No releases of LLRICE62 have been made under Part B.

b) Conclusions of post-release monitoring

No release in Europe, however in the USA, no persistent volunteers that could not be managed by current agricultural practice were observed.

c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

No release in Europe, however in the USA, no human health or environmental risks were observed.

2. History of previous releases of the GM plant carried out outside the Community by the same notifier

a) Release country

Bayer CropScience has not released LLRICE62 for commercial production, pending authorizations in key export destinations (EU). Careful stewardship programs have prevented any LLRICE62 from entering commercial channels.

USA (field release since 1997, no longer regulated since 2000)
Authority overseeing the releases: United States Department of Agriculture (USDA)
Information on the releases at www.aphis.usda.gov/
Brazil (field release since 1999)
Authority overseeing the releases: Comissão Técnica Nacional de Biossegurança (CTNBio)
Information on the releases at http://www.mct.gov.br/ctnbio
Argentina (field release since 1998)
Authority overseeing the releases: CONABIA
Information on the releases at http://siiap.sagyp.mecon.ar/conabia

b) Authority overseeing the release

See E.2.a.

c) Release site

See C.7.2 and C.7.4.

d) Aim of the release

See C.7.2 and C.7.4. for a summary of the field releases for substantial equivalence studies. In addition, field releases for breeding and variety development, technical development for best agronomic practices and rice integrated pest management systems have been conducted.

e) Duration of the release The generation time for rice from planting to harvest is 4 to 6 months.
f) Aim of post-releases monitoring Volunteer LLRICE62 plants in subsequent season and indications of outcrossing to red rice.
g) Duration of post-releases monitoring One or two seasons, until no volunteers observed.
h) Conclusions of post-release monitoring Occurrence of volunteers is very infrequent and dependent upon mild conditions in the winter season. Testing of red rice in subsequent seasons gave no indication of resistance to glufosinate ammonium herbicide.
i) Results of the release in respect to any risk to human health and the environment No risk to human health or the environment has been indicated by the field release experience.

3. Links (some of these links may be accessible only to the competent authorities of the Member States, to the Commission and to EFSA):

a) Status/process of approval Bayer's response to Member State's comments and objections to be circulated to the Member States by the Commission 23 July 2004
b) Assessment Report of the Competent Authority (Directive 2001/18/EC) **www.gmoinfo.jrc** Reference notification C/GB/03/M5/3
c) EFSA opinion not yet available**.**
d) Commission Register (Commission Decision 2004/204/EC14) not yet available
e) Molecular Register of the Community Reference Laboratory/Joint Research Centre **www.gmo-crl.jrc.it/**
f) Biosafety Clearing-House (Council Decision 2002/628/EC15) **www.bch.biodiv.org/**

g) Summary Notification Information Format (SNIF) (Council Decision 2002/812/EC) **www.gmoinfo.jrc** Reference notification C/GB/03/M5/3