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## **Briefing: the risks of Bayer's genetically modified LLRICE62 rice.**

The European Union is due to make a historic decision on whether or not to approve genetically modified (GM) rice for consumption in the EU. The result of this decision will not just affect European consumers – who could face the prospect of GM rice in their food – but will also determine the fate of the environment and farmers in rice producing countries. A European approval of GM rice would allow the German biotech company Bayer to promote the production of GM rice in developing countries. The consequences for the environment and the well-being of farmers in developing countries of growing this GMO has not been considered in the EU's approval process. .

Greenpeace and Friends of the Earth are strongly opposed to the approval of GM rice without full consideration of its worldwide health, environmental and social impacts. This briefing sets out the range of concerns associated with Bayer's 'liberty link' GM rice, called LLRICE62.

### **GM contamination of European rice production**

Bayer is only applying for approval to import and sell GM rice in the EU, but it has not provided any clear assurance that GM rice will not escape into the European environment. For example, grains may be dropped from transport lorries, or there could be accidental GM contamination of rice seeds sold to European farmers. Past experience indicates that such accidents are almost certain to happen. Bayer has not provided any proper plans to prevent this, even though it acknowledges the risk in its application: "*Gene flow to red rice or other crop rice is possible in rice producing areas in Europe*".<sup>1</sup> Rice is produced in six EU countries, covering an area of around 410,000 hectares<sup>2</sup>, and includes unique varieties, such as the red rice of the Camargue. Rice is also produced in the candidate states Bulgaria and Romania.

Despite the obvious risk Bayer has not provided any evidence concerning:

- how to prevent GM rice being imported into regions where rice is grown;
- how to prevent contamination of seed stocks;
- the proportion of imported rice containing viable grains;
- whether and where spillages of imported rice have occurred in the past.

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<sup>1</sup> Summary Notification Format (SNIF), Notification C/GB/03/M5/3, submitted on 22 August 2003, paragraph 29

<sup>2</sup> Federation of European Rice Millers <http://www.ferm-eu.org/index1.html>

## Initial assessment incomplete

The initial assessment of Bayer's application under EU Directive 2001/18/EC to import GM rice was undertaken by the UK competent authorities. The UK authorities only assessed the environmental risk as a result of potential seed spill for the UK, where spilled seed would not survive because of the climate. Rice is also not grown in the UK. Yet despite only considering UK conditions, the UK authorities gave the green light for this GMO for the whole of Europe. Even members of the UK's advisory panel commented, *"there was a concern over measures to deal with accidental spillage, which could be an issue for southern European countries."*<sup>3</sup>

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As rice is cultivated in Bulgaria, France, Greece, Hungary, Italy, Portugal, Romania and Spain, possible spillage and out-crossing of genetically modified rice is a matter of serious concern, the effects of which have not been assessed under the relevant conditions. Greenpeace and Friends of the Earth consider that the UK authorities acted inappropriately by giving a positive opinion on this GM rice without fully considering the impacts on other European countries.

## Health risks for humans and animals

There are serious concerns about the safety of LLRICE62 rice for human and animal consumption. The feeding studies conducted by Bayer raise more questions than they answer:

A feeding trial on poultry showed no differences between GM and non-GM fed birds, but the UK authorities noted the study had *"limited capacity"* to identify adverse effects. It is unclear whether glufosinate (the herbicide that is normally sprayed on LLRICE62 rice) treated rice was used in this study. This is essential because glufosinate tolerant crops using the pat or bar gene produce a new metabolite in the plant after glufosinate is applied.<sup>4</sup> This could influence the nutritional value of the feed.

A second feeding study over 100 days using pigs found that animals fed the GM rice treated with the herbicide glufosinate gained more weight than animals fed untreated GM rice and non GM rice. This effect does not appear to have been investigated further.

Last but not least, the French food safety authority AFSSA has already commented that the mice feeding study regarding the toxicity of LLRICE62 rice *"cannot be considered as acceptable within the framework of a food safety evaluation."*<sup>5</sup>

## Negative impact in the developing world

Rice is the most important staple food crop in the world, eaten daily by approximately 2.5 billion people. GM-rice is currently not grown on a commercial scale anywhere in the world. But if the EU were to approve LLRICE62 for marketing in the EU, Bayer could then push for the cultivation of GM rice elsewhere in the world. Bayer itself comments that, *"Bayer Cropscience has not released LLRICE62 [in other countries,*

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<sup>3</sup> Advisory Committee on Releases to the Environment, advice on a notification for marketing of herbicide tolerant GM rice, 25 November 2003.

<sup>4</sup> OECD (2002) Series on harmonisation of regulatory oversight in biotechnology, No 25. Module II: Phosphinothricin. ENV/JM/MONO(2004)14

<sup>5</sup> Advice 2004-SA-0109 by the French food safety authority AFSSA, 21 April 2004, <http://www.afssa.fr/Ftp/Afssa/24246-24247.pdf>

GPI, FoE], pending authorizations in key export destinations (EU).<sup>6</sup> Therefore, when assessing LLRICE62 EU countries should take into consideration not only the risks to health and environment within the EU, but consider also the consequences of the EU's decision for the rest of the world.

In the United States -where Bayer already has permission to cultivate LLRICE62- an authorisation for marketing of LLRICE62 in the EU would almost certainly be used as an argument to encourage rice farmers to convert from GM-free to GM farming. Experiences have shown that the US has failed repeatedly to segregate GM crops from non-GM crops. So far the US has not even agreed to label and provide identification of GMOs present in its commodity exports. So if GM rice is commercially grown in the US, it is very probable that wide-scale contamination of all US rice will occur. Contamination of exports could lead to unknown releases of GM rice in the centres of rice diversity, such as China, Thailand and India. In those countries, GM rice could outcross with wild and native rice varieties. This is of particular concern because it could lead to the extinction of traditional rice varieties in the centres of agricultural biodiversity. The importance of protecting these centres of diversity and treating them as precious world resources cannot be overstated. For example, rice resistant to two of Asia's four main rice diseases originated from a single sample of rice that came from central India.<sup>7</sup>

The Cartagena Protocol to the Convention On Biological Diversity notes that there are *"limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms"*. The decision by the European Union with respect to Bayer's GM rice will therefore be extremely influential in countries with limited resources to conduct their own regulatory review. If the EU does not handle Bayer's application for GM LLRICE62 with the greatest caution, India, Thailand and China and other centres of diversity for rice could end up jeopardising their principal food source. The EU has a moral obligation to undertake the most thorough and exhaustive analysis of the safety of this new GM crop, in order to be sure that it is safe for consumption, the environment where it is grown and that it will not cause genetic contamination. Given the moral dimension of this application, we urge the EU and its member states to assess GM rice also from an ethical perspective, as intended by article 29 of Directive 2001/18 and outlined in preamble 9 which states that *"Member States may take into considerations ethical aspects when GMOs are deliberately released or placed on the market as or in products."*

## Regulatory processes

On 22 August 2003, Bayer submitted an application for the approval of LLRICE62 rice under Directive 2001/18/EC (notification number C/GB/03/M5/3). The scope of this application is for *"the import of raw commodities"* and *"the import of processed food/feed products"* containing rice grain derived from rice LLRICE62 and does *"not include cultivation in the EU"*<sup>8</sup>

One year later -on 26 August 2004- Bayer submitted another application for LLRICE62 rice, this time under EU Regulation 1829/2003 (EFSA/GMO/UK/2004/04)

<sup>6</sup> Bayer Crop Science: 1829/2003 LLRICE62 -Part II-. EFSA/GMO/UK/2004/04, page 24

<sup>7</sup> World Recourses Institute: <http://www.wri.org/wri/biodiv/agrigege.html>

<sup>8</sup> Assessment report of the UK competent authority in accordance with Directive 2001/18/EC. Notification C/GB/03/M5/3 from Bayer Cropscience LTD for consent to market LLrice62, 7 January 2004, page 3.

The scope of this second application is the same as the scope of the first one: import and processing, use as food/food ingredient and feed/feed ingredient.<sup>9</sup>

Currently both applications are being assessed by the European Food Safety Authority (EFSA). It is unclear when EFSA will deliver its opinions. Greenpeace and Friends of the Earth believe that –as a minimum- EFSA should take the above issues into account.

## Conclusion

Before any consent is given, the European Union must thoroughly investigate all safety aspects with regard to the release and import of this GM product. In particular the EU must:

- Investigate the impacts of an accidental release into rice-producing areas within the EU and introduce legally-binding measures that protect such areas.
- Demand a higher quality application from Bayer that includes appropriate long-term safety testing to ascertain the effects on human and animal health.
- Use article 29 of Directive 2001/18 to investigate the safety, social and ethical issues relating to the impact on developing countries of an EU approval of GM rice.

## Further reading:

- Greenpeace comments to Bayer's application under Directive 2001/18 for marketing authorisation for the herbicide tolerant GM rice LLRICE 62 (C/GB/03/M5/3). Submitted: 26 February 2004 (available from Greenpeace International)
- Comments by Friends of the Earth Europe and Gene Campaign (India) regarding "Notification for placing on the market according to Article 13 of Directive 2001/18/EC Glufosinate-tolerant rice transformation event LLRICE62 from Bayer Crop Science Ltd (C/GB/03/M5/3)" Submitted on 24 February 2004 (available from Friends of the Earth Europe)

Amsterdam, Brussels, 12 September 2005

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<sup>9</sup> Bayer Crop Science: 1829/2003 LLRICE Part II. EFSA/GMO/UK/2004/04. Date of reception 26 August 2004.