SCIENTIFIC OPINION

Statement on a scientific publication on vertical gene flow in rice and its potential ecological consequences by Lu & Yang (2009) [1]

EFSA Panel on Genetically Modified Organisms[2,3]

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ABSTRACT

Following a request from the European Commission, the Panel on Genetically Modified Organisms was asked to review the published scientific paper of Lu & Yang (2009) and to indicate whether this paper contains new information that would alter the previous EFSA GMO Panel environmental safety conclusions on the genetically modified rice event LLRice62. This scientific paper reviews vertical gene flow between cultivated GM rice and cross-compatible wild/weedy rice relatives and the potential ecological consequences thereof. In 2007, the EFSA GMO Panel issued a scientific opinion on the risk assessment evaluation of application EFSA/GMO/UK/2004/04 for the market authorisation of LLRice62 for food/feed uses, import and processing in the EU. In light of the new scientific paper provided by the European Commission and, having considered relevant scientific publications on vertical gene flow in rice, the EFSA GMO Panel concludes that, in terms of risk to the environment, no new scientific evidence has been provided that invalidates the previous environmental risk assessment evaluation of LLRice62 for its intended uses, which exclude cultivation.

KEY WORDS

Rice, vertical gene flow, potential ecological consequences, wild/weedy relatives, grain spillage, environmental safety

1 On request from the European Commission on a scientific publication by Lu & Yang (2009) on vertical gene flow in rice, Question No EFSA-Q-2009-00781, adopted on 22 October 2009.

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SUMMARY

Following a request from the European Commission, the Panel on Genetically Modified Organisms was asked to review the published scientific paper of Lu & Yang (2009) and to indicate whether this paper contains new information that would alter the previous EFSA GMO Panel environmental safety conclusions on the genetically modified (GM) rice event LLRice62. This scientific paper reviews vertical gene flow between cultivated GM rice and cross-compatible wild/weedy rice relatives and the potential ecological consequences thereof.

In 2007, the EFSA GMO Panel issued a scientific opinion on the risk assessment evaluation of application EFSA/GMO/UK/2004/04 for the market authorisation of LLRice62 for food/feed uses, import and processing in the EU.

In light of the new scientific paper provided by the European Commission and, having considered relevant scientific publications on vertical gene flow in rice, the EFSA GMO Panel concludes that, in terms of risk to the environment, no new scientific evidence has been provided that invalidates the previous environmental risk assessment evaluation of LLRice62 for its intended uses, which exclude cultivation.

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BACKGROUND

On 6 August 2009, the European Commission (Directorate-General for Health and Consumers) requested the Scientific Panel on Genetically Modified Organisms of EFSA (EFSA GMO Panel) to review the recently published scientific paper of Lu & Yang (2009) and to indicate whether this paper contains new information that would alter the EFSA GMO Panel environmental safety conclusions on the genetically modified (GM) rice event LLRice62 (EFSA, 2007).

The scientific paper to be considered reviews the processes of vertical gene flow between cultivated GM rice and its cross-compatible wild/weedy relatives, as well as its potential ecological consequences; considers hybridisation frequencies between these plants; and addresses transgene expression, inheritance and fitness changes in wild/weedy relatives.

On 30 October 2007, the EFSA GMO Panel issued a scientific opinion on the application EFSA-GMO-UK-2004-04 for the market authorisation of LLRICE62 for food/feed uses, import and processing in the EU (EFSA, 2007). In its 2007 scientific opinion, the EFSA GMO Panel concluded that "*there is 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*".

Hence, the EFSA GMO Panel advised that "*appropriate management systems should be in place to prevent seeds of LLRICE62 entering cultivation*" and concluded that "*the monitoring plan provided by the applicant is in line with the intended uses of LLRICE62"*.

Upon request of the European Commission, the EFSA GMO Panel scrutinized the scientific publication by Lu & Yang (2009) in the context of its previous environmental risk assessment evaluation of LLRice62. In giving its view on the scientific paper at stake, the EFSA GMO Panel also considered other relevant scientific publications on vertical gene flow in rice.

TERMS OF REFERENCE

The EFSA GMO Panel was requested, under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to review the scientific publication by Lu & Yang (2009) on vertical gene flow in rice and to indicate whether this paper contains new scientific elements that could lead the EFSA GMO Panel to reconsider the outcome of its previous scientific opinion on LLRice62 issued in 2007.

EVALUATION

On 6 August 2009, the European Commission (Directorate-General for Health and Consumers) requested the Scientific Panel on Genetically Modified Organisms of EFSA (EFSA GMO Panel) to review the recently published scientific paper of Lu & Yang (2009) and to indicate whether this paper contains new information that would alter the EFSA GMO Panel environmental safety conclusions on LLRice62 (see EFSA, 2007). This scientific paper states that pollen-mediated gene flow is the major pathway for transgene escape from genetically modified (GM) rice to certain of its cross-compatible wild/weedy relatives and that transgenes may persist and spread into wild populations. This scientific paper also reviews the potential ecological consequences of vertical gene flow between cultivated GM rice and its cross-compatible wild/weedy relatives; considers hybridisation frequencies between these plants; and addresses transgene expression, inheritance and fitness changes in wild/weedy relatives.

The EFSA GMO Panel has concluded its environmental risk assessment evaluation of application EFSA/GMO/UK/2004/04 for the market authorisation of LLRice62 for import and processing as follows: "*The imported GM rice is likely to include a proportion of viable grains which will be transported through rice growing areas of Europe to processing plants. Accidental release into the environment is possible and viable 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 concludes 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 advises that appropriate management systems should be in place to restrict seeds of LLRICE62 entering cultivation as the latter requires specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003. These should include management measures to prevent LLRICE62 spillage into EU rice growing areas and subsequent establishment of GM plants and outcrossing. The efficacy of these measures should be reported as part of the general surveillance activities*".

In its environmental risk assessment evaluation, the EFSA GMO Panel considered that viable brown/paddy rice grains would be included in imported rice commodities. Moreover, in countries of origin, the scientific literature shows that vertical gene flow between cultivated, wild and weedy (such as red) rice is inevitable where these plants occur in the same vicinity (Oard et al., 2000; Song et al., 2003, 2009; Messeguer et al., 2004; Zhang et al., 2003, 2004, 2006; Gealy, 2005; Wang et al., 2006; Shivrain et al., 2007, 2008, 2009; Sanchez Olguin, 2009; Xia et al., 2009). This literature is directly relevant to vertical gene flow in GM herbicide tolerant (HT) rice as recently reviewed by Lu & Yang (2009). Therefore, the EFSA GMO Panel considered that rice imported into the EU could contain GMHT weedy rice and wild hybrids between them and the cultivated GMHT rice (EFSA, 2007).

While most viable rice grains are being imported by boat and processed in or near the ports of entry in the EU, it also became apparent that some of the imported grains are transported inland to processing facilities located in rice growing areas in the EU. To reach these processing facilities transporters pass close to rice fields. Conventional rice is transported in different ways; some of it in open trucks and some in closed containers, or in bags and sacks. Grain spillage of rice from some of these modes of transport is a distinct possibility. If grain spillage of LLRice62 was to occur in these rice growing areas, then viable GMHT grains could be introduced into fields cultivating rice.

In the additional information requested to the applicant by the EFSA GMO Panel, the applicant responded that some imported rice would be transported in closed containers to prevent grain spillage, but commented that "*the Italian port of Savona handles bulk cargoes of paddy rice. From Savona the rice is transported to the Piedmont mills centered on Vercelli, an average distance of approximately 150-200 kilometers that includes the Piedmont rice growing region. In this region the rice is cultivated continuously on the same land, without rotation crops by specialist producers*".

The consequence of LLRice62 entering EU rice growing areas via grain spillage during transportation through these rice growing areas was considered by the EFSA GMO Panel. If GMHT rice plants derived from spilled viable grains grow in rice fields and remain uncontrolled, they could establish and grow, depending upon the adaptability of the introduced rice to these regions. So far, there is no indication that the HT trait would confer agronomic and fitness advantages to escaped GMHT rice plants in rice fields, unless the herbicides for which tolerance is obtained would be applied. With the exception of the occasional use of glufosinate-ammonium-based herbicides as dessicant or pre-emergent/post-harvest weed control, these herbicides are not currently used in EU cultivated rice or crops rotated with rice. However, glufosinate-ammonium-based herbicides are sometimes used to control weeds growing on banks and ditches close to rice fields as well as in some dryland orchard crops in some EU countries. If GMHT rice is introduced accidentally into these areas and treated with glufosinate-ammonium-based herbicides, then escaped GMHT plants will have a fitness advantage. Paddy rice is adapted to growing in flooded fields, and so establishment in dryland is unlikely. However some weedy rice and wild hybrids may have the ability to establish populations in certain dryland habitats and would have an increased likelihood that GMHT plants would establish if treated with glufosinate-ammonium-based herbicides.

If viable GMHT rice grains are spilled into rice early in the growing season and left uncontrolled, they could grow alongside local rice, and flower. Likewise, weedy rice and wild hybrids growing in dryland areas where glufosinate-ammonium-based herbicides are applied might flower. If flowering coincides with that of local rice varieties, then cross-pollination can occur between these plants, though frequencies are generally low (as reviewed by Gealy, 2005; Lu & Yang, 2009). Cultivated rice is characterised by high rates of self-pollination and very little cross-pollination between adjacent plants or fields (typically less than 1.0%) (Messeguer et al., 2001; Zhang et al., 2003; Rong et al., 2005, 2007; Wang et al., 2006; Kanya et al., 2009). Moreover, these cross-pollination frequencies decrease rapidly with increasing distance of a few meters between plants (Messeguer et al., 2004; Jia et al., 2007; Yuan et al., 2007). Cross-pollination would result in some GM seeds in addition to the set seed on the GM plants.

Initial levels of cross-pollination between escaped viable GMHT rice and cultivated or weedy rice will be related to levels of grain spillage into rice fields and subsequent establishment of GMHT rice populations in and immediately adjacent to rice fields. Only 50% of the pollen contains the transgene as LLRice62 is a heterozygous hybrid formed between GM and non-GM parent lines. Thus cross-pollination will result in the formation of GMHT progeny in 50% of the crosses. Since no information is available on the nature, growth characteristics and adaptability to EU agricultural and climatic conditions of the escaped rice varieties, no conclusion can be made on the competitiveness of escaped plants with local rice varieties or weedy rice. It is important to bear in mind that the acquisition of the HT trait will not increase the fitness or invasiveness of escaped GMHT or weedy rice, and GMHT wild hybrids, except in the presence of glufosinate-ammonium-based herbicides, which is occasionally used in rice growing areas. Therefore, the worst-case scenario was assumed whereby LLRice62 would be no different in its growth characteristics from the local rice.

Some seed from escaped GMHT plants would also shed or be spilled at harvest and could result in GMHT volunteer plants growing in subsequent seasons. In addition, GMHT hybrid weedy rice could shed seed to form a seed bank of GMHT weedy rice. Because rice is often repeatedly grown in the same field or in short rotations in the EU, a gradual build up of GMHT plants and seeds is possible, especially if the introduced genetic material is adapted to the local environment. In addition, if imported GMHT rice is repeatedly introduced into an area, then a more rapid increase in the escaped GMHT population and GM hybrids with the local rice could occur. However GMHT rice plants can be controlled in other crops by the application of currently used herbicides with alternative modes of action for controlling graminaceous plants (OECD, 1999; Gealy, 2005).

The level of GM grains in the harvested local crop would be difficult to predict without knowledge of the fitness of the paddy rice varieties, as well as their simultaneous occurrence and flowering

synchrony with local rice varieties. A worst-case scenario would be that these plants are adapted and have similar developmental characteristics and cross-compatibility with local rice. In this case, significant levels of harvest admixtures might result after a few years due to a gradual build up of the initial introduced GMHT rice. This build up would be further enhanced by uncontrolled spillage resulting in repeated introductions into rice fields. Therefore, the consequence might be (1) the unintended cultivation of unapproved GM plants; (2) the environmental release of GM cultivated and weedy rice; and (3) the subsequent vertical gene flow from the LLRice62 transgene to locally cultivated rice varieties (e.g., Lu & Snow, 2005).

Considering all these factors, the EFSA GMO Panel concluded from its environmental risk assessment evaluation of 2007 that, if spillage occurred from transporters, spilled grains could enter rice fields and some surrounding areas, and might establish and set seed. These escaped GMHT plants could, through cross-pollination, spread the transgene to local rice, though at low frequencies.

CONCLUSIONS AND RECOMMENDATIONS

In line with its previously published scientific opinion, the EFSA GMO Panel reiterates that appropriate management measures should be in place to restrict viable LLRice62 grains being spilled into EU rice growing areas. In addition, operators should report any grain spillage of GMHT rice in areas adjacent to cultivated land used for rice production, and report on the efficacy of measures to remove or destroy any subsequent escaped GMHT plants. The EFSA GMO Panel notes that the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of LLRice62.

In light of the new scientific paper provided by the European Commission and, having considered relevant scientific publications on vertical gene flow in rice, the EFSA GMO Panel concludes that, in terms of risk to the environment, no new scientific evidence has been provided that invalidates the previous environmental risk assessment evaluation of LLRice62 for its intended uses, which exclude cultivation.

DOCUMENTATION PROVIDED TO EFSA

1. Letter, dated 6 August 2009, from the Deputy Director-General of the European Commission/Directorate-General for Health and Consumers Paola Testori-Coggi to Catherine Geslain-Lanéelle, Executive Director EFSA (ref SANCO/E1/SP/mb (2009) D/510432) requesting for a review of a scientific publication on vertical gene flow between cultivated genetically modified rice and its wild/weedy relatives in the context of the environmental assessment of LLRice62, and comprising the following scientific publication:
   Lu BR, Yang C, 2009. Gene flow from genetically modified rice to its wild relatives: Assessing potential ecological consequences. Biotechnology Advances, DOI:10.1016/j.biotechadv.2009.05.018.
2. Acknowledgment letter, dated 16 September 2009, from EFSA to the Director-General of the European Commission/Directorate-General for Health and Consumers.

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