

Statement on the potential allergenicity of the Bt toxin, Cry1Ac

We, the undersigned, note with concern the recent discoveries of contamination of rice¹ and rice products, including baby food², with an experimental genetically engineered (GE) rice. The GE rice contains a gene for the Cry1Ac protein, or possibly for a fusion Cry1Ab/Cry1Ac protein with similar immunogenic properties to Cry1Ac³.

Cry1Ac has not been approved for human consumption in any food crop and there is concern over its potential allergenicity. Research⁴ into the gene for Cry1Ac has found that

1. Cry1Ac protoxin is a potent immunogen.
2. The protoxin is immunogenic by both the intraperitoneal (injected) and intragastric (ingested) route.
3. The immune response to the protoxin is both systemic and mucosal.
4. Cry1Ac protoxin binds to surface proteins in the mouse small intestine, and this could induce mid or long-term effects on mammalian health.

Therefore, we urge the developers and regulatory authorities of this GE rice to proceed with caution with the use of the gene for the Cry1Ac in any part of the genetic construct within the GE rice. It is possible that humans, in particular sub-populations such as infants and small children could be exposed to immunogenically-significant amounts of Cry proteins contained in foods.

A thorough evaluation of its food safety prior to any import, consumption, approval or further development of this GE rice would be necessary as rice is a staple food crop. Studies following the steps recommended by the FAO/WHO expert consultation⁵ to evaluate allergenicity should be conducted by independent scientists, and their results published in peer-reviewed journals to allow evaluation of food safety. In addition, further studies into the potential allergenicity of Cry1Ac and other Bt proteins should be undertaken as a matter of the utmost urgency.

Signed

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¹ Zi, X. (2005) GM rice forges ahead in China amid concerns over illegal planting. *Nature Biotechnology* 23: 637.

² <http://www.greenpeace.org/china/en/press/releases/20060314-heinz-rice-cereal>

³ Tu, J., Zhang, G., Datta, K., Xu, C., He, Y. Zhang, O., Khush, G. & Datta, S.K. (2000) Field performance of transgenic elite commercial hybrid rice expressing *Bacillus thuringiensis* δ -endotoxin. *Nature Biotechnology* 18: 1101-1104.

⁴ Moreno-Fierros, L. García, N. Gutiérrez, R. López-Revilla, R. & Vázquez-Padrón, R.I. (2000) Intranasal, rectal and intraperitoneal immunization with protoxin Cry1Ac from *Bacillus thuringiensis* induces compartmentalized serum, intestinal, vaginal and pulmonary immune responses in Balb/c mice. *Microbes Infect* 2: 885-90;

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⁵ FAO/WHO 2001. Evaluation of allergenicity of genetically modified foods. Report of a joint FAO/WHO expert consultation on allergenicity of foods derived from biotechnology, 22 – 25 January 2001. Rome, Italy.