



**Friends of
the Earth
Europe**

November 2004

**Comments from Friends of the Earth Europe regarding the
application for marketing consent by Mycogen Seeds
/DowAgrosciences for the import and processing of Bt cotton line
281-24-236/3006-210-23 (C/NL/04/01).**

Friends of the Earth is writing to object to the proposal to allow the import and industrial processing of cottonseeds of this Bt cotton line, which contains genes for two different forms of the Bt toxin and a gene conferring resistance to the herbicide glufosinate ammonium.

1. Approval is premature

This application does not cover use in feed or food, which means that a full food and feed safety assessment has not been conducted. Because the application is for import, an environmental risk assessment has not been conducted either. Friends of the Earth considers that, as a result, the GMO should not be approved. Without full assessment, there can be no guarantee of the safety of GM cotton line 281-24-236/3006-210-23 if contamination of human food or animal feed occurs, nor for the environment if seeds are accidentally released (eg during transport) or if the GM seeds contaminate conventional cotton seed supplies.

The assessment report notes that around 350,000 ha of cotton are grown in the EU, and Greece is the seventh largest producer of cotton in the world¹. In addition, mills which process cotton seed for industrial oils also process cottonseed for oils for use in foods and feeds and may also process other oilseeds for use in human food and animal feed. The majority of cottonseed processing is for feed use and so there is a realistic possibility of contamination of feed supplies. Measures for ensuring that contamination does not occur during processing are not even mentioned in the summary notification; in fact the applicant states that "*no specific conditions of use and handling are required for 281-24-236/3006-210-23 cotton. Imported 281-24-236/3006-210-23 cotton products will be used, stored and handled as any other commercial cotton products.*" But the size of this industry means that the potential for accidental release or contamination of food and feed supplies cannot be dismissed.

¹ http://www.nationmaster.com/graph-T/agr_cot_pro

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A full safety assessment is required to ensure proper protection of human and animal health in the EU. For example, there is good evidence to suggest that the Bt toxins expressed in this GM cotton – Cry1F and Cry1ac – could be potential allergens:

- A 1999 study partly sponsored by the US Environmental Protection Agency found evidence to suggest that the Bt protein Cry1Ac can elicit antibody (IgE) responses consistent with allergic reactions in farm-workers²
- a series of studies have demonstrated that Cry1Ac protoxin and toxin are potent immunogens that elicit both mucosal and systemic immune responses and that Cry1Ac protoxin is a potent systemic and mucosal adjuvant and binds to surface proteins in the mouse small intestine³.

The assessment report by the Netherlands authority suggests that a condition of approval be a requirement for monitoring for “unforeseen adverse effects on human health by handling and processing the cotton seeds.” However, as a full human health safety assessment has yet to be conducted this would effectively be an experiment upon the workers involved in these activities. This not only raises the question of whether it is acceptable to approve a GMO when full safety for human health has not been established, but also the question of whether it would be acceptable to expose workers to this GMO under such circumstances and where liability would lie if health effects were to occur.

2. Implications for developing countries must be considered

An approval of this GMO for import and industrial processing would create the impression that the EU had given this GMO a safety clearance, when in fact a full feed and food safety assessment has not been conducted. Several developing countries, including India and Pakistan, are large producers of cotton and are coming under significant pressure to allow rapid adoption of GM technology. The Cartagena Protocol On Biosafety 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”. Therefore there is an added responsibility upon EU member states to examine the wider consequences of their actions. The decisions made by the European Union with respect to this GM cotton will be extremely influential in countries with limited resources to undertake their own regulatory assessment. Thus the EU should wait until a full food, feed and environmental risk assessment has been conducted before making any decisions about this GMO.

2 Bernstein, et al (1999). I.L., Bernstein, J.A., Miller, M., Tierzieva, S., Bernstein, D.I., Lummus, Z., Selgrade, M.K., Doerfler, D.L. and V.L. Seligy. “Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides,” *Environmental Health Perspectives*, 107(7): pp. 575-582.

3 Vazquez et al (1999a). “Intragastric and intraperitoneal administration of Cry1Ac protoxin from *Bacillus thuringiensis* induces systemic and mucosal antibody responses in mice,” *Life Sciences*, Vol. 64, No. 21, pp. 1897-1912.

Vazquez et al (1999b). “*Bacillus thuringiensis* Cry1Ac protoxin is a potent systemic and mucosal adjuvant,” *Scandinavian Journal of Immunology* 49, pp. 578-584.

Vazquez et al (2000a). “Characterization of the mucosal and systemic immune response induced by Cry1Ac protein from *Bacillus thuringiensis* HD 73 in mice,” *Brazilian Journal of Medical and Biological Research* 33: pp. 147-155.

Vazquez et al (2000b). “Cry1Ac protoxin from *Bacillus thuringiensis* sp. kurstaki HD73 binds to surface proteins in the mouse small intestine,” *Biochemical and Biophysical Research Communications* 271, pp. 54-58.