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Herrn

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20.8.2002

**Betr.: Maissilage aus Bt-Mais *event* 176**  
**hier: Untersuchungsergebnisse Grünmaisverfütterung**  
**Verwaltungsvorschrift GenTG**

**Bezug: Ihre elektronischen Nachrichten vom 05. und 07. August 2002**

Ihr Zeichen

Unser Zeichen

6788-02-0006

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Sehr geehrter Herr Glöckner,

aus den Unterlagen zum Antrag auf Genehmigung des Inverkehrbringens des gentechnisch veränderten Maises, der auf das Transformationsereignis Bt-176 zurückgeht (Bt-Mais *event* 176), **liegen uns keine Ergebnisse zu Fütterungsversuchen mit Grünmais vor.** Für die Prüfung, ob die Voraussetzungen für die Erteilung einer Genehmigung des Inverkehrbringens dieses gentechnisch veränderten Maises hinreichend erfüllt sind, **waren diese Informationen entbehrlich.**

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Für den Vollzug des Gentechnikgesetzes sind das Robert Koch-Institut als Bundeseinrichtung sowie die Bundesländer mit unterschiedlichen Aufgabenbereichen verantwortlich. Für den Teil, der in der Verantwortung des Robert Koch-Instituts liegt, gibt es keine spezifisch gentechnikrechtliche Verwaltungsvorschrift. Ob in den einzelnen Bundesländern Verwaltungsvorschriften zur Erfüllung der Aufgaben der Länder nach dem GenTG erlassen worden sind, entzieht sich unserer Kenntnis. Zur Klärung dieser Frage können Sie sich an die zuständigen Landesbehörden wenden, in Hessen wäre das das Regierungspräsidium Gießen.

Die Texte des Gentechnikgesetzes und der dazugehörigen Verordnungen sind im Internet z. B. unter

<http://www.rki.de/GENTEC/GESETZ/GESETZ.HTM> sowie unter

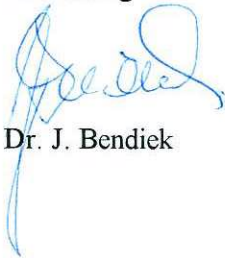
<http://www.bba.de/gentech/report34.htm> abgelegt.



Eine Kopie dieses Schreibens senden wir an Syngenta Agro GmbH, Maintal,  
zur Information.

Wir hoffen, Ihnen mit diesen Ausführungen geholfen zu haben und verbleiben  
mit freundlichen Grüßen

im Auftrag

A handwritten signature in blue ink, appearing to read 'J. Bendick', with a long vertical flourish extending downwards from the end of the signature.

Dr. J. Bendick

Dossier C/F/96.05.10, updated

Update of an application for placing on the market a genetically modified plant  
according to Part C of the Directive 2001/18/EC

## **Insect Tolerant Maize**

(Referred to as Bt11 maize)

Application submitted by:

**Syngenta Seeds SAS**

on behalf of:

**Syngenta Seeds AG**  
CH-4002 Basle, Switzerland

And all affiliated companies

To:

**Commission du Génie Biomoléculaire**

Ministère de l'Agriculture et de la Pêche,  
Direction Générale de l'Alimentation, France

May 2002  
(Updated version)

**CONFIDENTIAL BUSINESS INFORMATION**

## CONFIDENTIAL BUSINESS INFORMATION

The following information is claimed "Confidential Business Information", on the basis of contractual obligation relating to the transformation method and the disclosure of the collaboration.

Complement to question 28 "method used for the genetic modification" and to Appendix 2 "Product characterization"

The transformation was performed using a protoplast transformation/regeneration system, similar to that described by Negratiu *et al.* (1987). This was done under contract for Novartis Seeds AG by Dr. Gunter Donn, Hoechst AG, Frankfurt, Germany. Plant material from Hoechst AG HE89 corn line (Moroncz *et al.* 1990) was initially transformed.

### References:

1. Mórocz S., Donn G., Németh J. & Dudits D. 1990. An improved system to obtain fertile regenerants via maize protoplasts isolated from a highly embryogenic suspension culture. *Theor. Appl. Genet.* 80: 721-726.
2. Negratiu I., Shillito R., Potrykus I., Biasini G. & Sala G. 1987. Hybrid genes in the analysis of transformation conditions. *Plant Molec. Biol.* 8: 363-373.

## CONFIDENTIAL BUSINESS INFORMATION

## FINAL REPORT

## TITLE:

Evaluation of Transgenic Event 176-Derived and Bt11-Derived  
"Bt" Corn (Maize) in the Diet of Lactating Dairy Cows

Starting Date  
of Experiment: 13 September 1996

Completion Date  
of Experiment: 2 October 1996

Reported by:

Marjorie A. Faust, PhD

Date

Study Director

Associate Professor of Animal Science

Address: Department of Animal Science  
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Site Location: University Dairy Farm  
Iowa State University  
2600 Mortensen Road  
Ames, Iowa 50011 USA

Sponsor: Novartis Seeds, Inc.  
Seeds Biotechnology Research Unit  
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## CONFIDENTIAL BUSINESS INFORMATION

## Abstract

A 14 day study was conducted to determine whether milk produced by lactating dairy cows contained CryIA(b) or PAT proteins when cows are fed fresh whole-plant corn from Novartis Seeds' transgenic *Bt* hybrids. Twelve high producing Holstein dairy cows were selected from the Iowa State University dairy herd in Ames, Iowa, USA, and were assigned to receive one of 3 study diets; study diets contained chopped whole-plant corn from commercial Novartis Seeds hybrids representing 1) an Event 176-derived transgenic hybrid, 2) a *Bt11*-derived transgenic hybrid, or 3) a non-transgenic control hybrid. Daily composite milk samples from each cow and four additional composite milk samples to which purified CryIA(b) and PAT proteins were added intentionally were evaluated by the Seeds Biotechnology Research Unit of Novartis Seeds, Research Triangle Park, NC, USA for the presence of CryIA(b) and PAT proteins. A second set of composite milk samples was evaluated by Dairy Lab Services in Dubuque, Iowa, USA for milk components. The CryIA(b) protein was detected in samples of diet that were prepared using fresh chopped whole-plant corn from the two transgenic hybrids, but no CryIA(b) protein was detected in samples of the control study diet. No CryIA(b) or PAT proteins were detected in standard samples of milk collected from cows fed study diets; however, transgenic proteins were detected in all 55 samples to which CryIA(b) and PAT proteins were added intentionally. On average, groups of cows that were fed study diets consumed more than 43 kg of feed (as fed) daily per cow and produced more than 38 kg of milk daily per cow. Milk yield, feed intake, composition of milk, and udder health were similar for all study diet groups. In general, cows remained healthy and in good body condition throughout the study. Findings from this study indicate clearly that CryIA(b) and PAT proteins cannot be detected in milk from cows that are consuming diets prepared using Novartis Seeds' transgenic corn hybrids that produce these proteins. Moreover, we detected no adverse effects of these transgenic proteins for dairy cows that consumed green plant material from Novartis Seeds' transgenic *Bt* corn hybrids.