



**Friends of  
the Earth  
Europe**

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## GENETICALLY MODIFIED SWEET CORN

### 10 reasons not to approve Bt11 Sweet Corn

The European Commission wants EU Member States to approve a controversial genetically modified (GMO) sweet corn. However serious questions remain over its safety and also the process the Commission is using. This briefing gives 10 good reasons why member states should not approve Syngenta's Bt11 sweet corn.

#### **1. Question marks over the genetic modification**

Research by the Belgium authorities questions the quality of the work done by Syngenta to identify whether the genes had been inserted as expected. They found that there were "uncertainties concerning the molecular data", unexpected DNA fragments present which need investigating and that Bt11 might be contaminated by an earlier GMO (Bt176).<sup>i</sup>

#### **2. French authorities concerned about safety**

The French government's food safety authority (AFSSA) re-examined the dossier for Bt11 sweet corn in November 2003. It concluded that, on the basis of the information supplied by Syngenta, "unforeseen effects cannot be discounted" and stated that further safety tests needed to be conducted before making conclusions on its safety for human consumption.<sup>ii</sup>

#### **3. New report attacks the safety research**

A new report by the Austrian Government gives a damning verdict for the Bt11 application.<sup>iii</sup> The researchers had access to the whole dossier and accompanying documentation. They concluded:

- there was no toxicological testing with the whole plant
- there were no tests on the long terms effects of eating the novel protein
- the test for allergic reactions are insufficient and that many assumptions argued by Syngenta are false
- the safety of Bt 11 is based on theoretical argument rather than evidence.

This report seriously questions the quality of the work carried out by the EU's old Scientific Committee on Foods (SCF) who gave a positive opinion to Bt11.

#### **4. Growing concerns over allergies from Bt toxins**

Recently published evidence indicates that Bt toxins may have allergenic properties. In addition, scientists working for the US Food and Drug Administration concluded that the similarity between the amino acids of the Bt toxin and of a common egg yolk allergen "might be sufficient to warrant additional evaluation". None were done. Furthermore, the allergy testing used would not meet the standards developed by the FAO/WHO. The EU's SCF opinion fails to even mention allergies from the Bt toxin.

#### **5. The EU's scientific opinion raises unanswered questions**

Although the SCF gave a positive verdict, the opinion they gave raised more questions than answers with many arguments based on pure assumptions. SCF concluded that it was "of the opinion that despite the large number of studies, the company (Syngenta) did not commission systematic information on the composition of the genetically modified or control plants". In fact, the SCF states that the evidence provided by Syngenta "provide only limited evidence for safety". In the absence of adequate data from the applicant, the SCF appears instead to have relied on:

- no “visible adverse effects” observed when livestock were fed Bt 11 for “a few weeks”
- a study conducted on Bt tomatoes
- an unpublished, two-week study on mice.

## 6. Fails to meet new food safety criteria

New EU food law requires that foods that are placed on the market are not injurious to health. Article 14(4) of EC Regulation 178/2002 explicitly states that not only the short- or long-term effects must be taken into account, but also effects on subsequent generations, cumulative toxic effects and also the effects on health sensitive consumers. Proceeding with the approval of Bt11 sweet maize under the Novel Foods procedures bypasses this level of scrutiny and precaution.

## 7. No transparency

Improving openness and transparency in the approval process is a key step to building public trust in the decisions and recommendations made. The Novel Foods Regulations allow the public no access to the dossiers submitted by the biotech industry. Proceeding with applications under these regulations allows decisions to be made in virtual secrecy.

## 8. Ignores new regulations.

Bt11 maize is being pushed through the old Novel Food Regulations even though new laws improving the approval process became applicable this week. The new regulations also require a post-approval safety-monitoring plan.

## 9. Feed authorisation

The new Food and Feed Regulations bring in for the first time an approval process for GM animal feeds. It requires that GM animal feeds do not have adverse effects on animal health or the environment. No such consideration is required under the Novel Foods Regulation. New research has discovered the Bt toxin in the digestive system of pigs fed Bt11 corn that raises new safety questions<sup>iv</sup>. The SCF notes that for Bt11 “processing by-products are used as animal feedstuffs”. Under the old rules the safety of Bt11 for use as an animal feed will not have to be assessed.

## 10. Dangerous precedent

The quality of this application and the supporting safety research is clearly of a poor and insufficient standard. If this sweet corn is approved using this evidence then a dangerous precedent will be set for future approvals. The public demands the highest quality of research into the safety of their food.

## Real testing. Real Transparency

Friends of the Earth believe that Bt11 should be rejected until proper testing is carried out. This should use the whole plant, include chronic toxicological tests and use allergy tests that meet the FAO/WHO guidelines. The process should be transparent and open and take into consideration diverging scientific views on its safety.

<sup>i</sup> [http://www.biosafety.be/TP/MGC\\_reports/Report\\_Bt11.pdf](http://www.biosafety.be/TP/MGC_reports/Report_Bt11.pdf)

<sup>ii</sup> OPINION of the French Food Safety Agency (AFSSA - AGENCE FRANCAISE DE SECURITE SANITAIRE DES ALIMENTS) concerning the marketing authorisation application for Bt11 sweet maize under EC Regulation 258/97 on Novel Foods and Novel Food Ingredients 28 November 2003

<sup>iii</sup> Gaugitsch H, Spök A, Hofer H, Lehner P, Kienzl-Plochberger K, Valenta R (2003), Toxikologie und Allergologie von GVO-Produkten. Roten Reihe des Bundesministeriums für Gesundheit und Frauen - Sektion IV, Band /03

<sup>iv</sup> Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11, J. Anim. Sci. 2003. 81:2546–2551

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