GREENPEACE
background briefing

Pioneer maize corn 1507 as approved by EFSA: proof of the EFSA's total failure

Introduction
On 4 March 2005 the European Food Safety Authority (EFSA) gave a green light for the marketing and cultivation of the GM (genetically modified) maize (corn) 1507 by Pioneer Hi-Bred (DuPont) with a insecticidal toxin (Cry1F) derived from bacteria *Bacillus thuringiensis* (*Bt*) and a herbicide tolerance to glufosinate (Liberty) (C/ES/01/01).

It is the first time EFSA has given its approval not only for the import and processing of a GM product, but also for the commercial release and cultivation of a GMO (genetically modified organism). This case sets a precedent for other applications concerning cultivation and related questions such as risk assessment, monitoring and coexistence.

Since there is no EU regulation on monitoring the effects of GMOs and no "coexistence" legislation, nor liability regime, aimed at protecting non-GM farming from contamination, the commercialisation of GM crops seems to be premature.

The details of risk assessment on 1507 maize shows that this crop, in particular, should not be allowed to be marketed. It also shows that the EFSA is completely failing in its task to protect the environment and consumers. If this EFSA report is accepted by the Commission and Member States, it will have severe negative impacts on the standards of European GMO regulation. The confidence and trust of European citizens in the current EU regulations will be eroded further.

The EFSA GMO panel and their reports have been widely criticised by environmental groups (see reference). Some members of the GMO panel seem to confuse their EFSA responsibilities with industry interests. So far, the EFSA has failed to develop either a comprehensive approach to assess GMOs or to set the necessary scientific standards to investigate the risks of GMOs as required by EU legislation. The report on GM maize 1507 shows the total failure of EFSA to assess missing or insufficient data, significant findings, or define the necessary obligations to monitor the impact of the GM crop on the environment. This raises serious doubts about the competency – and objectivity – of the EFSA GMO Panel.

In this precedent-setting case, the EFSA fails to follow up significant findings that show unwanted, unintended and even risky effects. Therefore, Greenpeace urges EU member states and the European Commission to

(1) re-organise EFSA procedures thoroughly in order to make sure that experts are independent and perform their work with the necessary scrutiny and responsibility. The GMO panel should also be open to experts proposed by consumer or environmental groups.

(2) completely reject the report of EFSA on 1507 maize corn because:
- there is lack of scientific scrutiny and even pure ignorance in the way EFSA performing its assessment
- significant findings demonstrate that Pioneer's maize corn 1507 cannot be considered safe and needs to be thoroughly investigated
- basic and crucial data necessary for any risk assessment are missing in the current application.

Conclusion on the risk assessment of Pioneer's maize 1507 as performed by EFSA
1. The EFSA states several times that there are statistically significant differences between 1507 maize and control groups. However, in all cases these differences are just brushed aside, without sufficient scientific reasons:

- Indications for toxicity in feeding studies were disregarded because significant differences appeared in one sex only (a decrease of white blood cell count in female rats). This ignores the fact that different sexes can indeed have different tolerances for toxic compounds in feed and food.

2. The EFSA is aware of the fact that crucial data for risk assessment are missing but does not ask for further investigations:

- The impact on non-target organisms is mainly studied with other Bt toxins than the one produced by 1507 maize corn (Cry1F), but the EFSA considers such data sufficient.
- Data on the Bt concentration in root tissue and possible exudation from roots is completely lacking, even though data for other tissues are provided.
- Field trials were undertaken in three countries on different continents for one year at each location, but nowhere for two or more consecutive years. Therefore no long-term effects and/or accumulation of the Bt toxin e.g. in the soil could be studied. The EFSA points out that long-term effects might become relevant if 1507 maize is grown without crop rotation, but does not consider it relevant to study this, or even to monitor.
- 1507 maize is also tolerant to a herbicide, but no data were made available about the environmental effects of the combination of the two inherited traits, nor are any data available concerning the use of sprayed crops for food and feed.

3. The EFSA has to be aware of the fact that the 1507 maize is a mess from a technical point of view, but it does not urge any further clarifications:

- There are seven unintended fragments of DNA incorporated into the plant, likely to give rise to unwanted components in the plants. The necessary investigations on whether these components are produced are incomplete. In fact, they are only done for one part of the plant (the kernel) which is known to produce different components than the rest of the plant, and doesn't even produce one of the intended new proteins.
- The genetic modification included the insertion of DNA from chloroplasts from outside the nucleus into the plant chromosomes. This proves that these plants were produced with crude methods that possibly, and indeed are likely to disturb the whole metabolism of the plant.
- The original DNA sequence of the insertion site is not provided. So, as even the EFSA, points out, deletion of DNA cannot be ruled out. However, the EFSA does not find it necessary to request such information from Pioneer Hi-Bred.

4. Specific risks of these Bt-plants are ignored by the EFSA:

- The concentration of the Bt toxin in the pollen is much higher then in other tissues (3 to 20 times higher then in the whole plant). From the experience with Bt176 maize, high Bt levels in pollen are known to be a risk for non-target moths and butterflies. There is no further study of why Bt production in pollen is so high or whether these levels in 1507 maize cause adverse effects for European butterflies.

- No data are provided on Bt amounts in the roots, nor about accumulation of Bt toxins in the soil. The degradation of the Bt toxin is only studied for isolated Bt proteins, and described with a half life of about 3 days. However, it is known from other plants that the residence time is variable depending on soil type and climate. Bt toxins can get into the soil from the roots and plant debris, and can stay active for more then 200 days (Zwahlen et al., 2003). The EFSA does not find it necessary to conduct studies with real plants under real conditions.

5. The plan for monitoring the plants does not fulfil EU legal requirements:

According to decision of the Council 2002/811/EC, the monitoring of GMOs should cover potential effects and risks to both human health and the environment, and seek to identify and record any indirect, delayed and/or cumulative adverse effects. Regional conditions have to be taken into account, such as specific climatic conditions. As the Council of Ministers of Environment on 10 March 2005 clearly demonstrated, member states are not satisfied with current application of monitoring rules in the case of MON810. The true content of the monitoring plan of Pioneer´s 1507 is no better than that of MON810. It is now up to the Member States to take the necessary initiatives and to prevent the authorisation of 1507.

- Despite a long list of known risks posed by the growing of Bt plants, only the emergence of resistance against the Bt toxin amongst the pest insects is, to some extent, considered in the current monitoring plan.
- Effects on non-target organisms are mentioned, but no systematic approach for monitoring these is delivered by Pioneer.
- Effects on soils, biodiversity and possible effects on human or animal health are not even mentioned.
- No regional climatic conditions are taken into account, nor any regional species that would be relevant for non-target effects.
- General impacts on non-target population of insects (endangered species, other pest insects, parasites or even useful insects) are not considered.

According to a recent review (Lövei & Arpaia, 2005), most of the peer-reviewed articles on the effect of Bt crops on non-target predators and parasitoids are not sufficient to investigate their real impact in the field. However, these studies are used as arguments by Pioneer Hi-Bred and the EFSA to say that 1507 maize would be safe to grow. Thus, Pioneer's application for growing maize 1507 has to be rejected.

References

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