

## European Food Safety Authority (EFSA)

### Scientific Opinions, Publications & Reports

#### Mandates related to the environmental risk assessment of GM plants

Each GM plant grown in the European Union has to undergo an extensive environmental risk assessment to anticipate and, if possible, to identify any adverse effect it may have on the environment. The information provided by an applicant must also include data covering several seasons of field growing trials so that any possible adverse effects on the environment can be detected. So far only one type of GM plant, the GM Maize MON 810 which is resistant against the European corn borer, is cultivated in some countries of the EU.




In addition, each GM application has to be accompanied by an environmental monitoring plan demonstrating how the applicant will monitor the GMO product with annual and longer term reporting on any possible and unexpected adverse environmental impact. This monitoring plan will also provide important information for the 10-year renewal assessment for a GMO application. Once an authorisation is given by the European Union for a GMO, it must be reassessed again after a 10-year period in order to maintain its authorisation on the market.

In parallel to the evaluation process for GM applications, EFSA has continued to update its scientific approach to environmental risk assessment. EFSA organised for example a [Scientific colloquium on Environmental Risk Assessment](#) in June 2007 with leading experts in the field from Europe and beyond. The Colloquium considered various approaches to environmental risk assessment in the light of current scientific thinking on issues, such as long-term effects and adverse impact on non-target organisms such as insects. EFSA has also developed further work on [Post Market Environmental Monitoring](#) which, after a public consultation, resulted in the publication of a specific guidance document.

Based on this work and feedback received at a [meeting with Member States on GMO risk assessment approaches](#) in November 2007, EFSA's GMO Panel will continue to develop its approach to environmental risk assessment through a self-task activity on so-called "Non-target Organisms". This will consist of further developing guidance for assessing potential adverse effects that the GM plants might have on non-target organisms, such as insects (e.g. butterflies, beetles), not targeted by the specific insect-resistant trait expressed by the GM plant. Many GMOs are developed to be resistant to certain pests which are referred to as "target organisms". Non-target organisms would be those plants or animals which are affected unintentionally by a GMO resulting in an undesired effect on plants or animals in the environment.

At the same time, EFSA has also discussed and accepted a complementary mandate from DG Environment of the European Commission. Under this mandate, EFSA will further update the current GMO Panel's Guidance Document and will also cover some of the issues discussed during EFSA's colloquium on environmental risk assessment. More specifically, the mandate will cover issues, such as potential long-term environmental effects and the development of criteria for setting up field trials to assess environmental impact. EFSA "self-tasking" Working Group on statistics and experimental design will assist in this. EFSA's GMO Panel will complete this work over the next 24 months.

#### General mandate: update of EFSA guidance on environmental assessment of GMOs


-  [Initial request from European Commission](#)
-  [Mandate: EFSA reply to European Commission on revised ToR](#)
-  [Acknowledgement of ToR by European Commission](#)

#### Self-task mandate on non-target organisms

 [Request from GMO Panel for a self-task mandate](#)

 [EFSA letter of acceptance for self-task mandate](#)

 [Mandate on non-target organisms](#)

 [Working Group members](#)

Publication date: 02/04/2008