

Ten crucial elements in the environmental risk assessment of genetically engineered plants

Christoph Then, September 2010

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Testbiotech e. V.
Institute for Independent
Impact Assessment in
Biotechnology

Introduction:

The decision to cultivate genetically engineered crops must be met on political level. It cannot be reduced to a purely scientific risk assessment and must take into account the various interests of consumers and farmers. At the same time, it must be recognized that risk assessment plays an important role in current decision making within the EU. There is a valid need to adopt a sound and reasonable system for environmental risk assessment (as well as for food and feed) based on reliable mandatory and empirical investigations that explore the technical qualities and potential risks of genetically engineered plants.

Testbiotech has published two reports on the risk assessment of genetically engineered crops in the EU (Then&Pothof, 2009; Then, 2010). These reports were prepared with support of the GEKKO foundation (Germany) and the Green Party of the European Parliament. The following paragraphs summarize some of the most crucial elements - they represent solely Testbiotech's position.

Testbiotech does not claim that these criteria are comprehensive. However, they do show some basic shortcomings in current and planned risk assessment practice (EFSA 2006 REF current guidelines and EFSA 2010 Ref draft new guidelines). The following ten points have been identified as crucial for the risk assessment of genetically engineered plants:

- generate a broad range of non biased data and drop the concept of substantial equivalence
- develop a coherent step by step procedure that includes a set of mandatory investigations before and during experimental field trials
- make it compulsory for applicants to reveal all existing studies and data
- include all levels of the food web, do not rely on a tiered approach, make it compulsory for applicants to present data from different receiving environments
- take into account accumulated, combinatorial and delayed effects
- treat stacked events as new products that need independent assessment
- request feeding studies over the lifetime of certain animal species including the following generations
- develop an integrated approach for risk analysis including criteria for ethical, socio economic issues
- define some cut off criteria for the rejection of market applications such as invasiveness and persistence
- establish comprehensive monitoring

The following explanations and background information clarify the relevance of these issues.

1. Generate a broad range of non biased data and drop the concept of substantial equivalence

As a starting point for risk assessment, substantial equivalence is a too narrow and biased approach for generating and interpreting relevant data. It oversimplifies and can give rise to misleading conclusions. Therefore, this concept should be replaced.

Genetically engineered plants should be regarded as technically derived products with no true comparator: In genetic engineering, invasive methods introduce DNA beyond the borders of species. Methods are not based on the mechanisms of natural gene regulation and heredity. Genetic engineering technology is unique in that newly introduced gene constructs have a specific potential to escape and /or disturb gene regulation in recipient organisms. Thus, the comparison of genetically engineered plants with their isogenic counterparts is an important tool but must be done without any presupposition or hypothesis regarding similarity or equivalence.

Empirical data generated over a broad range of relevant issues should be the starting point for the risk assessment of genetically engineered plants. Genetic stability and the interactivity between genome and environment under defined conditions and throughout the life cycle of a plant are crucial issues. Measurement of gene activity, the transcriptom, the metabolom should be used to develop hypotheses for further investigations. A stress test (or “crash test”) covering a broad range of defined environmental conditions should be introduced to obtain more information on the potential reactions of the plants to ongoing climate change and other environmental stressors. Some data on the effects from the genetic background of certain varieties need to be included.

If the plant produces specific compounds such as insecticides, the specific range of its content within all kinds of plant material must be determined under various conditions. Methods for measurements need to be validated and published and an event-specific detection method must be published and made available.

2. Develop a coherent step by step procedure that includes a set of mandatory investigations before and during experimental field trials

In many cases, the field trials conducted do not aim to investigate relevant environmental risks. Their main purpose is to generate agronomic data. What needed is a mandatory list of defined data that have to be generated step by step before any environmental release takes place, or before cultivation on larger scale can be allowed. This issue deserves stronger cooperation with national authorities since they are the ones to decide on first experimental releases. It is imperative to define a minimum set of necessary data to be generated before and during experimental field trials and to make full use of these data in a transparent manner before cultivation on a large scale follows.

3. Make it compulsory for applicants to reveal all existing studies and data

It should be compulsory for applicants to reveal any data already available from studies that have been carried out on an event. Applicants must also provide an informative list of all studies performed or commissioned by them on an event including all data collected. This will put risk assessors in the position to decide independently which studies and results are relevant for risk assessment.

4. Include all levels of the food web, do not only rely on a tiered approach, make it compulsory for applicants to present data from different receiving environments

In exploring the risks for non target organisms risk assessment should follow a concept to 'expect the unexpected' rather than a concept such as a linear decision making tree or a 'tiered approach'. All levels of the food web should be taken into account, such as prey, predators, parasites, organisms below and above the ground, terrestrial as well as aquatic, including the whole range of organisms from micro-organism to vertebrates. Indirect and delayed effects that emerge from specific processes within the ecosystem are likely to be overlooked if risk assessment is based on hypotheses that are derived at an early stage of risk assessment. The recipient environment with its specific fauna and flora has to be taken into account as well as existing regional agricultural practices and potential additional stressors such as the use of pesticides.

5. Take into account accumulated, combinatorial and delayed effects

So far, risk assessment does not sufficiently consider the cumulative and long term effects from combined cultivation of several traits of genetically engineered plants. Empirical studies are needed to investigate the combinatorial effects between these traits, Furthermore, existing agricultural practices and potential other stressors have to be included. For example, combinatorial effects between insecticidal proteins (produced by the genetically engineered plants) and other factors such as agrochemicals must be investigated systematically, also taking into account several levels of the food web. In addition, the long term accumulation of insecticidal proteins or complementary herbicides must be considered when different genetically engineered crops with a similar trait are cultivated in the same field in rotation. In experimental investigations, proteins as produced by the plant must be used rather than simply using similar proteins as produced by bacteria. In assessing traits with herbicide tolerance, the residues and metabolites and its potential interactivities have to be taken into account.

6. Treat stacked events as new products that need independent assessment

Stacked events must be considered as new applications. Their risk assessment cannot be reduced to a risk assessment of their individual compounds. Emerging combinatorial (even non-linear) effects can only be assessed by empirical investigations using all the plant material that incorporates the relevant combination of gene constructs.

7. Request feeding studies over the lifetime of certain animal species including the following generations

This is a complicated issue that needs to be discussed in the light of animal welfare. So far there is no sound scientific system for surveillance of health effects in human or animals (livestock or wild species) after the genetically plants have entered the market. Thus, there is a need to obtain more information on potential (subchronic or chronic) health effects before any market authorisation is given.

Since genetically engineered plants are supposed not only to be used in food and feed, but can also be fed to wild life animals such as birds and mammals, mandatory feeding studies over the lifetime of relevant animals, including their offspring, are necessary. Detailed analyses of the fate of the gene construct and its passage into animal tissue need to be included.

Feeding studies must be performed in a way that avoids harming the animals. Several generations and different species in arthropods should be tested before vertebrates are included. Any test should be included within the framework of an integrated concept of risk analysis to reduce the use of animals as far as possible (see below). If the risk manager comes to the conclusion that animal

feeding studies cannot be justified for the marketing of certain crops then the products should not enter the market.

8. Develop an integrated approach for risk analysis including criteria for ethical, socio economic issues

An integrated concept is needed to deal with ethical and socioeconomic issues in an adequate manner. These issues should be included at early stage and accompany the whole process of risk analysis. Experts who can identify relevant ethical, social or socioeconomic issues should accompany the work of the GMO panel at EFSA.

If for example, contaminations of other crops cannot be controlled or managed effectively this fact can become crucial for the final decision on a market application. In this case, the company should be given a clear signal at an early stage of the risk analysis process that their market application is very likely to be rejected in the end, no matter what the outcome of risk assessment might be. This integrated approach will help to reduce costs for the companies as well as help to avoid environmental releases and animal feeding studies that are not necessary. This issue deserves close cooperation between the risk assessor and the risk manager.

9. Define some general cut off criteria for rejection of market applications such as invasiveness and persistence

Companies as well as authorities can take responsibility for genetically engineered plants only as long as those released into the environment can be recalled at any time if necessary. There is a very basic need to have an option to control the abundance of relevant genetic material in terms of time and regional distribution. This option should be seen as an absolutely indispensable precondition of any release or commercial cultivation of the plants. So far, the lack of this basic prerequisite is not defined as a clear criterion for rejection of market applications. In general, genetically engineered crops that show a potential for invasiveness and persistence should be excluded from any release into the environment to prevent unintended effects during long term evolutionary processes that cannot be predicted or controlled. Within the ecosystems in Europe, for example, rapeseed and genetically engineered poplar show a high potential for invasiveness and persistence. In these cases, a general concept of prevention is necessary.

There is a need for further criteria for rejection of market applications: Also if certain crops do not suit sustainable agricultural practises (or other socioeconomic criteria), they should not enter the market. For example, if it is known that the use of herbicides will be increased or new pests triggered then genetically engineered plants do not comply with the long term goal of sustainable agriculture within the European Union and should be excluded from its market.

10. Establish comprehensive monitoring

Risk assessment cannot end there. In particular, combinatorial, cumulative and delayed effects may emerge during commercial use of GM plants. These effects can hardly be observed through existing networks and farmers filling in questionnaires. Therefore, a scientifically sound monitoring plan must be developed.

In this context it is an important condition that any material released for commercial use (and its isogenic counterparts) must be freely available for independent scientific research and must not be restricted by consensus or contract with the intellectual property holder, as is the current practice.

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Contact:

Testbiotech e.V.
Institute for Independent Impact Assessment in Biotechnology
Frohschammerstr. 14,
80807 München
info@testbiotech.org
www.testbiotech.org