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Free trade for 'high-risk biotech'?

Future of genetically engineered organisms, new synthetic genome technologies and the planned free trade agreement TTIP – a critical assessment

Dr. Christoph Then, Testbiotech
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Summary

This is a report on future developments in agro-biotechnology and genetic engineering. It focuses on the kinds of genetically engineered organisms for which market authorisation has been applied in the EU and those that are in the pipeline and might soon be on the market. Special attention has been given to new genome technologies. Furthermore, it includes a discussion of the potential influence of the planned free trade agreement (Transatlantic Trade and Investment Partnership, TTIP) on the authorisation of new genetically engineered organisms for use in agriculture and food production.

The majority of currently pending market applications are for genetically engineered plants with herbicide resistance and insecticidal toxicity. These same traits also appear in so-called stacked events, which are a combination of several genetically engineered plants in one event. The stacks of the highest order (so far) are plants that are resistant to up to four herbicides and at the same time produce half a dozen insecticidal toxins. Stacking such genes ultimately means pyramiding risks and uncertainties.

Some of the genetically engineered trees and animals that might be used in agriculture or forestry in the near future show a high potential for spreading uncontrollably in the environment. These risks are particularly relevant for planned field trials of genetically engineered olive flies and forest trees such as poplar.

In recent years, several new genome technologies have been developed that allow a radical transformation of the genome. These new technologies are summarised in this report as 'synthetic genome technologies'. They are already applied in practice without this being widely known. Not only are these new technologies associated with new risks but also with ethical problems concerning genetic identity and the integrity of living beings.

In the near future, it is to be expected that industry will want to market a larger number of risky new products for use in agriculture and food production in the EU. At the same, the new free trade agreement (TTIP) between EU and USA might facilitate placing such products on the market. This report presents some of the arguments used by the proponents of this policy who want to pave the way for the marketing of these products.

As the report shows, current developments are moving away from the traditional systems of breeding and agriculture and expanding into technologies that are complex, failure-prone and associated with a great number of uncertainties regarding risks. If society wants to allow the use of some of these technologies and applications there is no alternative but to strengthen the precautionary principle in parallel. This is the only way to deal with the many uncertainties and factual limits of knowledge in a rational way.

The report recommends

- strengthening the precautionary principle;
- extending ethical debates on the protection of genetic identity and integrity of living beings;
- a change in agricultural policy to include more comprehensive protection of the environment and enhancement of biodiversity

The implementation of these recommendations should have priority above further releases and market authorisations.

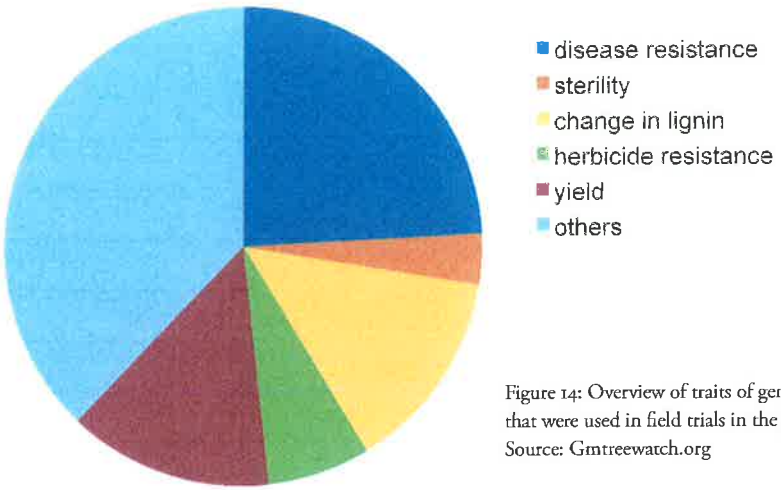

Figure 14: Overview of traits of genetically engineered trees that were used in field trials in the EU.
Source: Gmtreewatch.org

The risks of genetically engineered trees are generally different from those of genetically engineered crop plants:

- Trees do not grow in fields. They grow in complex and vulnerable ecosystems such as forest and pasture landscapes. There is a particular risk of uncontrolled spread of the transgenes within these ecosystems.
- The long lifecycle and genetic variability facilitate genetic instabilities and unexpected effects.
- Because trees live for a long time they can also have an impact on soil, the food web and forest ecosystems over long periods.
- Trees have an extreme potential to proliferate in the environment. Some tree species produce enormous amounts of pollen and seed which can be transported over many kilometres. Several species can also propagate via shoots and broken or cut twigs.

Poplar trees are the most commonly used trees in forest bio-tech and a good example of the potential for uncontrolled spread into the environment. The trees each produce around 25-50 million seeds per year. According to Rathmacher et al. (2010), there is proof of seeds being transferred over distances of up to two kilometres and pollen over eight kilometres. Dispersal is further fostered by rivers, which can transport seeds, twigs and roots over many kilometres. In addition, poplars can mix with other poplar species and render hybrids as well as propagate through cuttings. After a poplar tree is cut down new shoots come up from the roots over several years. In particular, there is no way to control the spatio-temporal dimension in the commercial cultivation of genetically engineered poplar trees in, for example, China where more than a million trees have been grown over the last ten or more years. If adverse effects do become noticeable in ecological systems or if transgenes escape into wild populations of poplar trees, there is hardly any effective action that can be taken to prevent permanent damage (see Then & Hamberger, 2010).

The Chinese example does not appear to be deterring other interested parties Especially ArborGen is pushing for the commercialisation of genetically engineered eucalyptus trees in the US (Barker, 2013). Further, there are plans to release genetically engineered poplar trees with an altered wood composition in Belgium over a period of several years[11].

11 http://www.bio-council.be/docs/BAC_2013_0580_CONS_rev0410.pdf

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The most troubling message in the EASAC report is that genetic engineering in plants should no longer be perceived as a risky technology and current regulations should be overhauled to that effect. The precautionary principle, in particular should no longer be the basis for risk analysis in the EU in its present form and current practice. EASAC experts argue that enough experience with genetically engineered plants has been gathered to agree that there would be no specific risks associated with their use in agriculture and food production:

> *"Even if stringent application of the precautionary principle had been justifiable in the early days of GM crop research and development when there were more uncertainties about impact, it is difficult to defend the merits of retaining a rigid, cautious, technology-specific regulation today when there is much less uncertainty."*

The precautionary principle as applied in the EU presupposes that market authorisation can be refused if there are substantial uncertainties regarding safety. This means that uncertainties and gaps in knowledge are very relevant for risk assessment[32]. This approach has evolved over more than a decade of discussions in the EU and it is a basic provision of EU regulations such as 178/2002 and Directive 2001/18. Contrary to existing EU regulations, the EASAC experts propose to reject market authorisations only in cases where there is already evidence of adverse effects. This would mean that measures might be taken too late. Further they are of the opinion that it would not be necessary to subject all genetically engineered organisms to risk assessment, but only specific products which are already known to have potential hazards. The effect would be a similar lack of regulatory oversight as shown by Ledford (2013). Further the authors claim evidence of benefits for agriculture:

> *"(...) in common with other sectors, the aim should be to regulate the trait and/or the product but not the technology in agriculture. The regulatory framework should be evidence-based. There is no validated evidence that GM crops have greater adverse impact on health and the environment than any other technology used in plant breeding. There is compelling evidence that GM crops can contribute to sustainable development goals with benefits to farmers, consumers, the environment and the economy. Action is needed to unify and harmonise the regulatory and innovation-enabling roles of the EU policymaking institutions and to ensure that regulation of the outputs of all the crop genetic improvement technologies has a firm foundation in sound science."*

However, it should be kept in mind that the so called "compelling evidence" of the benefits of the technology is just as controversial as the safety of the products (see Then 2013). If the opinion of EASAC´s experts is adopted in new regulations this would mean:

- replacing the precautionary principle with a system that will only accept evidence of adverse effects as a trigger for regulatory measures;
- abolishing regulations for centralised registration and risk assessment covering all genetically engineered organisms;
- abolishing comprehensive and mandatory labelling of genetically engineered organisms and products thereof and leading to less transparency and less choice for farmers and consumers.

32 As for example pointed out in EU Regulation 178/2002, which is also the founding regulation for EFSA.