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Institute for Independent Impact Assessment in Biotechnology

Legal analysis: Release of genetically engineered organisms and the precautionary principle

A Testbiotech briefing on a legal dossier written by Professor Dr. Ludwig Krämer, October 2013

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Summary

Testbiotech commissioned Professor Dr. Ludwig, a former official in the EU Commission, to draw up the legal dossier “Genetically Modified Living Organisms and the Precautionary Principle” (Krämer, 2013). The conclusions from the dossier are of major relevance for (1) the environmental risk assessment of genetically engineered organisms and a planned new implementation regulation in the EU, (2) the possibilities for EU Member States to adopt national legislation and (3) for the discussions around the planned Transatlantic Trade & Investment Partnership (TTIP). The dossier identifies a considerable number of uncertainties in the risk assessment of genetically modified organisms. It discusses the application of the precautionary principle and legal implications of the evidence. Some relevant conclusions are:

- The precautionary principle is the decisive instrument for dealing with the many uncertainties in risk assessment and facilitating a broad range of regulatory approaches. However, there are major deficiencies in current practice, and the EU frequently fails to prioritise the precautionary principle.
- Based on the precautionary principle, the EU could take policy decisions to prohibit the release of genetically engineered organisms into the environment (in part or in full) without coming into conflict with international trade laws.
- Currently, there are no coherent regulations governing the release of genetically engineered organisms that cannot be retrieved from the environment. Nevertheless, the legal dossier clearly identifies an EU obligation for EU authorities to prevent such releases on a case by case basis.
- EU Member States clearly have options to make decisions related to the release of genetically engineered organism at a national level. According to the dossier, current EU regulations on genetically engineered organisms are not based on the correct article of the *Treaty on the Functioning of the European Union* (TFEU) which would be Article 192. This article would allow Member States to adopt their own legislation to protect the environment. Member States could stop authorisations for cultivation or adopt their own legislation if they challenge the current basis of EU legislation and insist on their rights as foreseen in Article 192, TFEU.

Testbiotech recommends

– strengthening the precautionary principle in particular to prohibit any release of genetically engineered organism that cannot be controlled in its spatio-temporal distribution;

– defending and extending the precautionary principle in ongoing negotiations regarding the new free trade agreement with the US (TTIP);

– transferring the legal basis for regulations on genetically engineered plants to Article 192, TFEU.

1. Introduction

Testbiotech asked Professor Dr. Ludwig Krämer to draw up a legal dossier on the possibilities for the EU and its Member States to restrict or prohibit releases of genetically engineered plants if they cannot be removed from the environment. Ludwig Krämer worked as an official for the EU Commission until 2004. He has been head of the unit on Environmental Governance in DG Environment since 2001 and was involved in establishing the current EU regulations.

The background to this project is an increasing number of publications about the uncontrolled spread of genetically engineered plants in the environment, and the escape of transgenes into populations of wild relatives (see for example the case of genetically engineered oilseed rape, Bauer-Panskus & Then, 2013).

The dossier gives an overview of the current legal framework and regulatory practice in the EU, and to some extent in the US and on an international level, taking into account the Convention on Biological Diversity (CBD). It contains a detailed insight into the current practice of risk assessment performed by EFSA exemplified by several case studies involving genetically engineered plants such drought tolerant maize, genetically engineered oil seed rape and transgenic salmon.

Beyond the specific questions raised by Testbiotech, the conclusions of the legal dossier (Krämer, 2013) are of general relevance to the discussion on the environmental risk assessment of genetically engineered organisms in the EU. It is further relevant to possible changes that EU Member States might want to make to their own national legislation and to discussions on the planned new Free Trade Agreement between EU and US (Transatlantic Trade & Investment Partnership, TTIP). It is evident that there are still major uncertainties in the risk assessment of genetically engineered plants, and that therefore the precautionary principle needs to be strengthened.

2. Main Results

2. 1 On legal framework and regulatory practice

The precautionary principle is applied in the EU as well as in the US and under the Convention on Biodiversity (CBD) in the context of the deliberate release of genetically engineered organisms:

For example

- in the US, there are specific regulations that prohibit the cultivation of genetically engineered cotton in certain regions to prevent transgene escape to wild populations
- genetically engineered salmon in North America can only be kept in tanks in order to prevent uncontrolled spread into Atlantic ecosystems
- the CBD foresees measures to be taken against invasive species

- the precautionary principle in EU regulations is of general relevance to risk assessment and risk management. For example, EU risk regulation requests the risk assessors to assume that unlikely events will occur, thus requiring a worst- case scenario assessment.

However, there are several gaps and differences in current regulations.

- There are by and large, no coherent regulations preventing the release of genetically engineered organisms which cannot be retrieved from the environment.
- The precautionary principle is decisive in dealing with the many uncertainties and offers a broad range of regulatory approaches. However, in current practice, the precautionary principle is not given the necessary weight.
- For example, current European Food Safety Authority, EFSA, practice hardly takes note of the worst-case scenarios.

2. 2 Uncertainties in the risk assessment of genetically engineered plants and the precautionary principle

The dossier identifies a considerable number of scientific, technical and factual uncertainties linked to the release of genetically modified organisms into the environment. Amongst others, the dossier refers to the outcome of an EU project, the 2009 BEETLE study. This study analysed more than 700 scientific publications from all over the world on genetically engineered plants and their potential effects on environment and biodiversity. Around 100 to 167 contributions were made to the online surveys from environmental experts representing a wide range of knowledge with special focus on the EU. The study identified many “great” or “important” uncertainties mostly related to long-term and cumulative effects. Some examples:

- Increased fitness of the genetically engineered plants
- Hybridisation between genetically engineered plants and wild species relatives and its persistence
- Altered fecundity causing increasing seed (gene) flow
- Development of resistance in pests
- Effects on non-target organisms (NTO)
- Effects on NTO due to accumulation of toxic compounds
- Effects on rhizosphere microbiota
- Effects on symbiotic NTO Changes on soil functions

- Effects on biological control
- Altered use of agrochemicals
- Indirect changes in susceptibility of crops against plant pathogens
- Adverse effects on agro-biodiversity
- Indirect changes in fertiliser use
- Potential changes in landscape structure
- Increased mineral nutrient erosion and fertilizer leaching
- Altered chemical attributes of soil fractions
- Effects of stacked events
- Regional aspects

In the light of this evidence and current knowledge, the dossier comes to the conclusion that risk assessment in particular will always include substantial uncertainties about the long-term effects of releasing genetically engineered organisms.

2.3 When is it possible or even necessary to prohibit releases?

Regulatory practice in the EU accepts a certain degree of uncertainty and risk without spelling out which level of risk is deemed to be acceptable. Risk assessment is done on a case by case basis. In theory, releases of genetically engineered organisms might be allowed even if they cannot be withdrawn from the environment. However, so far no commercial cultivation of crop species such as oilseed rape, which is known for its potential to spread beyond the fields, has been allowed. Furthermore, existing regulations make it very unlikely that in future such an authorisation will be given. As the dossier states:

> “the existence of genetically modified plants or animals in the natural environment constitutes a *serious* risk. The spread of GMOs into the environment is not a local event, but is capable of having a wide geographical dispersion. Such organisms will have long-term effects on the environment, as they will persist in it and lead a life of their own. The duration of the risk is thus, theoretically unlimited. And the release into the environment, once it is achieved, is *irreversible*: the GMOs cannot be retrieved or taken back.” (168)

According to the dossier,

> “there appears to exist a relatively large consensus among lawyers and scientists that the spread of genetically modified plants and animals into

> the environment constitutes a serious and irreversible risk for the environment.” (169)

Two cases exemplify the possibility or even necessity of taking precautionary measures: Genetically engineered (or modified) salmon (a) and genetically engineered (or modified) oilseed rape (b).

> (a) “Genetically modified salmon has wild relatives. When such a salmon is released into the environment, it may reproduce with wild relatives and thus become non-retrievable. Specific conditions for the release could limit this risk, for example the condition to only release sterile animals, and/or the condition to release salmons only in specific water tanks which are unconnected to open waters. Such conditions considerably reduce the risk of a spread of genetically modified salmon in the environment - though they do not altogether eliminate the risk, because of the possibility of human errors, unforeseen events, deliberate sabotage or other factors. This means that the competent authorities within the EU will have to weigh this residual risk and decide, whether they could authorize the release into the environment of genetically modified salmon. In this author's opinion, the residual risk remains too high, so that a release of genetically modified salmon could not be allowed under either Directive 2001/18 or Regulation 1828/2003.” (191)
>
> (b) “Genetically modified oilseed rape species have the capacity to survive, pollinate and spread into the environment. Examples of such events, stemming from the transport of oilseed rape, not from its cultivation, were found within the European Union. Little is known, whether these populations are able to permanently survive and spread in the environment, though a survival during eight years was described. Therefore, a cultivation of genetically modified oilseed rape is likely to considerably increase this risk of this species spreading in the environment and no longer to be "safe" for humans and the environment. An authorization to cultivate oilseed rape within the European Union would thus not be compatible with Directive 2001/18 or Regulation 1829/2003, or, in other words: any decision to allow the cultivation of oilseed rape in the EU would be, in this author's opinion, incompatible with the precautionary principle.” (192)

Despite these high hurdles, in the EU there is no general legal obligation to stop releases of genetically engineered organisms if they cannot be retrieved from the environment. According to the dossier, the competent authorities have to weigh the risks in each specific case and decide, whether it is acceptable or not. Nevertheless, the dossier identifies a clear obligation for EU authorities to prevent such releases even on a case by case basis:

> “Where there is, in a concrete case, a likelihood that genetically modified plants or animals cannot be retrieved, the legal obligation to ensure that

any release must be "safe" requires the refusal to authorize such releases." (250)

2.4 Possibilities for the EU to restrict or prohibit the release of genetically engineered organisms

According to the dossier, existing EU regulations provide a wide range of options to make general decisions on whether to restrict or prohibit the release of genetically engineered organisms without interfering with EU or international regulations. As the dossier explains:

> "For example, the EU could decide
>
> - the prohibition of allowing the placing on the market of genetically modified animals;
> - the prohibition of allowing the placing on the market of genetically modified animals other than domesticated animals;
> - the prohibition of any cultivation of genetically modified plants in the EU;
> - the prohibition of the cultivation of those genetically modified plants which have wild relatives in Europe, thus, at present in particular oilseed rape and sugar beet;
> - the prohibition of placing on the market of genetically modified plants which have wild relatives in Europe;
> - the prohibition of cultivating genetically modified plants in "Natura 2000" areas, as well as in a buffer zone around them;
> - the prohibition of cultivating genetically modified plants in other sensitive natural zones;
> - the prohibition of cultivating genetically modified plants in agriculturally sensitive zones." (210)

The dossier establishes that this extensive scope for political decision-making is due to the many gaps in knowledge about the actual effects that might be expected from releasing genetically engineered organisms into the environment:

> "As there are numerous uncertainties as to the effects of a release of GMOs into the environment, existing EU law already allows at present that EU institutions altogether prohibit any release of GMOs into the environment, because it is not ensured, at present, that such releases are "safe for the environment It is also possible to take measures which reach less far, as for example a general prohibition to cultivate genetically modified plants within the EU, a prohibition to release genetically modified animals into the environment, or the restriction of the cultivation of genetically modified

plants in certain sensitive areas. All these decisions are of a political nature. Science and law do not interfere in this." (245)

"Should the EU take a policy decision to prohibit the release of GMOs into the environment (in part or in full), such a decision appears to be compatible with international trade law, as international trade law explicitly provides that each State (or regional organization as the EU) has the right to determine itself the degree of risk which it is ready to accept from products such as GMOs." (248)

2.5 Possibilities for EU Member States to restrict or prohibit the release of genetically engineered organisms

The dossier also sheds light on current debates on an initiative of the European Commission to give Member States more legal possibilities to restrict or prohibit the cultivation of genetically engineered plants on their territory. The dossier comes to the conclusion that the initiative started by the Commission cannot solve the *environmental* problems raised by the release of genetically engineered plants.

In general, the possibilities for single EU Member States to draw up and enforce regulations on a national basis are limited. However, according to the dossier, a Member State could successfully challenge the legal basis of current authorisations for the cultivation of genetically engineered crops. According to the author, the EU regulations on the release of genetically engineered organisms should be based on the environmental provisions in Article 192 (and Article 193) TFEU which gives the Member States a chance to draw up their own national legislation for the protection of the environment. Currently, the basis for EU authorisations are set out in the provisions of Article 114 TFEU on the internal market, agriculture (at present Article 43 TFEU), and public health (at present Article 168 TFEU):

"The choice of the legal basis of EU legislation depends, according to the consistent jurisprudence of the Court of Justice, on the objective and content of the legislation (centre of gravity) and is subject to judicial control. Both pieces of EU GMO-legislation have as their primary objective the protection of human health and the environment, objectives which are both capable of being achieved by the provisions of Article 192 TFEU. The extensive provisions on the release of GMOs into the environment, the environmental risk assessment, the intervention of the European Food Safety Authority EFSA, the possibility to consult the EU Committee on Ethics, and the genesis of Directive 2001/18 which was adopted after a considerable dispute within the EU on the issues related to the release of GMOs into the environment, all show that the concern about the effects of GMO on human health and on the environment were the main objectives of the EU GMO-legislation; these objectives also found their expression in the different provisions of the two pieces of legislation. For this reason, Article 192 TFEU would have been the most appropriate legal basis." (227)

The dossier considers current regulations on genetically engineered organisms to be not in line with general EU legal framework since the issue concerns living organisms and not products. That is why Article 36, TFEU comes into play, which allows national legislation to protect plants and animals:

> “It is submitted that these legal bases are not correct. Genetically modified organisms are *organisms*, in other words living beings. Under EU law, living beings are not the same as products. This follows from Article 36 TFEU which allows Member States to take measures which restrict or eliminate the free circulation of products, in order to protect the health and life of animals and plants; such a right does not exist to protect products.” (226)

This interpretation of EU legal framework opens a wide range of possibilities for EU Member States:

> “it is a fundamental decision of the EU Treaties that measures which directly affect the environment, should not be the subject of harmonizing legislation, but that EU legislation should respect the diversity of the environment within the EU – including the different approaches which EU Member States might be prepared to have in this regard. (…) How EU Member States are prepared to protect – and even over-protect – their environment, is their decision. And the insertion of genetically modified living organisms is such a significant and important interference with the environment that Member States must be able to declare the EU level of environmental protection not to be sufficient and adopt more stringent provisions in this regard.” (228)

Thus, it is possible for EU Member States to adopt national legislation to stop the release of genetically engineered organisms on their territory:

> “if a Member State were determined to challenge the legal basis of the existing EU GMO-legislation, it would have the possibility to adopt national legislation which altogether prohibits or which restricts the release of GMOs into the environment – as if Article 192 TFEU were applicable. Should the Commission then take action against that Member State under Article 258 TFEU, the Member State could raise, in the case before the EU Court of Justice, all arguments in fact and in law which plead in favour of the legal basis of Article 192 TFEU.” (230)

The EU Member States could also take targeted legal action to stop the release of genetically engineered organisms on their territory which already have EU authorisation :

> “Should the ensuing dispute between the company that wants to place the GMO on the market and the prohibiting Member State be brought before a national court of justice, that court would be entitled and under certain conditions be obliged to submit to the EU Court of Justice the question for a preliminary ruling, whether the present legal bases for the two pieces of legislation are the correct ones (Article 267 TFEU). The Member State in

question would then have the opportunity to raise all the arguments which plead in favour of an application of Articles 192 and 193 TFEU.” (250)

3. Testbiotech conclusions and recommendations

The legal dossier drawn up by Ludwig Krämer offers valuable insight into the current practice of regulation in the field of genetically engineered organisms in the EU and on international level. On the basis of this dossier, Testbiotech is of the opinion that the role of the precautionary principle in the risk assessment and risk management of genetically engineered organisms should be strengthened in the EU to achieve a more coherent approach:

Genetically engineered organisms can still be released or authorised on the basis of the precautionary principle even if there are still some uncertainties about actual risks for human health and / or the environment. After authorisation, they nevertheless still need to be monitored, and if evidence of adverse effects emerges, the products must be removed from the market. EU Directive 2001/18 foresees emergency measures in the event that new information on severe risks becomes available (Art 23):

> „The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.“

Further, market authorisation must be reassessed after 10 years (Art. 15,4 of Directive 2001/18). Market authorisation can be terminated if there is new information on adverse impacts. Genetically engineered organisms must be removed from the market once they no longer have authorisation. (Art . 4 (5) of Dir. 2001/18).

The release of genetically engineered organisms which cannot be controlled in spatio-temporal dispersal is in deep conflict with these provisions. The precautionary principle as established in Directive 2001/18, can only be implemented if efficient measures can be taken to remove the genetically engineered organism from the environment if this is urgently required. Therefore, spatio-temporal control is a prerequisite for implementing precaution. If a genetically engineered organism cannot be retrieved from the environment, the precautionary principle is meaningless. Consequently, spatio-temporal control is an obligatory precondition for any release of genetically engineered organisms.

As the dossier explains, the existing regulations in the EU do not provide sufficient legal clarity in this respect. For example, it is not clear, how to deal with genetically engineered organisms which are not fully characterised regarding their potential to persist and / or invade the environment or which are known to proliferate in an uncontrolled manner as soon as they escape beyond safety barriers as, for example, discussed in the case of genetically engineered salmon.

From the Ludwig Kramer dossier, it is also evident that existing legislation in the US and under the Convention of Biological Diversity (CBD) is not sufficient to prevent the release of genetically engineered organisms that cannot be retrieved.

On the basis of the documented cases and current gaps in knowledge regarding dispersal, interactions with the environment and long-term ecological behaviour of genetically engineered plants, we recommend strengthening the precautionary principle and prohibiting releases of genetically engineered organisms if

a) they can persist and invade the environment if they unintentionally escape their containment.

b) there are major doubts about whether they can be withdrawn from the environment within a reasonable period of time if this is urgently required.

c) it is already known that they will persist or show invasive behaviour after release into the environment.

Further, we strongly recommend defending and extending the precautionary principle in ongoing negotiations regarding the new free trade agreement with the US (TTIP), and adopting higher standards for the risk assessment of genetically engineered plants.

The EU and its Member States should transfer the basis of its legislation on genetically engineered to Article 192, TFEU in order to escape the current deadlock in negotiations on the initiative of the European Commission to give Member States the possibility to restrict or prohibit the cultivation of genetically engineered organisms. This would allow Member States to take appropriate measures to protect the environment, and thereby restrict or prohibit the release of genetically engineered organisms on their territory.

This last point is also of some relevance for current negotiations between EU Commission and Member States how to apply the new competences of the EU Commission foreseen under Article 290, TFEU, to change Directive 2001/18 and Regulation 1829/2003. Article 290 delegates to the Commission the power to adopt amendments to current legislation without involving EU Parliament and EU Member States. Some experts are warning that this might encourage the EU Commission to lower current regulatory standards to comfort the negotiations regarding TTIP. In the light of this legal dossier such an attempt has to be rejected as undermining safety for human health and the environment.

References

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