TESTBIOTECH Background 17 - 1 - 2024

New genetic engineering (NGT): EU Parliament in the maze

The amendments proposed by the European Parliament’s rapporteur are absurd

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

Summary:
There is increasing confusion in the EU Parliament about the future regulation of plants derived from new genetic engineering (NGT). The rapporteur Jessica Polfjärd’s (EPP) most recent proposed amendments lack sufficient scientific basis and would turn mandatory risk assessment of NGT plants into a rare exception. In addition, the non-realistic hope is encouraged that NGT plants could be exempted from patent protection.

In current documents, the rapporteur proposes that only those NGT plants that produce new ('chimeric') proteins should be subjected to mandatory risk assessment. The problem: New genetic engineering is typically used to switch off specific plant genes. As a result, NGT plants can exhibit characteristics and risks that go far beyond the results of breeding and the characteristics of natural species. However, it is by no means necessary for NGT plants to form 'chimeric' proteins to exhibit such traits.

There are numerous examples of drastic changes in NGT plants, such as blood pressure-lowering (GABA) tomatoes, camelina for agrofuel, newly domesticated tomatoes and early-flowering poplars. In none of these cases, however, the plants are intended to produce 'chimeric' proteins. In order to examine the risks of these plants, their intended and unintended genetic changes would have to be examined. However, according to the rapporteur's proposal, in none of the aforementioned cases, this would be mandatory in future.

Testbiotech also analysed the rapporteur's proposals to prevent patents on NGT plants and comes to the conclusion that these proposals would be largely ineffective. In addition, the proposal of the rapporteur fails to limit patents to the respective technical processes. Without adequate legal provisions, CRISPR patents could even be extended to conventional breeding.

Introduction

The draft compromise amendments as proposed by rapporteur Polfjärd introduce major confusion in the debate on future regulation of NGT plants, with detrimental consequences for safety, health and the environment as well as the future of agriculture and plant breeding in general. It can be seen as an attempt to exempt all NGT plants from risk assessment (as long as they are not transgenic) and would allow patent holders to take control of conventionally-bred plants:

- The amendments ignore basics in biology, such as the function of regulatory gene sequences. This would result in a situation where nearly all NGT plants are exempted from mandatory risk assessment (as long as they are not transgenic). The proposed amendments would drastically enlarge the already large array of genetic changes in comparison to the

Commission proposal, while still equating such NGT plants to conventionally bred plants. This would be unacceptable in regard to health and environmental safety.

- The proposals made to change the EU patent directive 98/44 are likely to have zero effect on European Patent Office (EPO) decisions on NGT plants. On the other hand, urgently needed clarifications to prevent conventional plant breeding from being controlled or blocked by patent holders are not provided. Consequently, patents could be used to block access to biodiversity needed by all breeders.

Testbiotech looked into the current amendments and learned that the wording of the amendments had been adopted from experts who had been invited as speakers to the European Parliament. Testbiotech also has access to two of these presentations that completely ignore the risks of NGT plants as mentioned above. In contrast, authorities from various member states such as France, Austria and Germany, as well as independent scientific expert groups, have come to the conclusion that NGT plants such as GABA tomatoes must be thoroughly examined for their risks, on a case-by-case basis.[1]

If accepted, this proposal would not enable safe use of NGT plants for food and feed, grown as agricultural crops or released into the environment for other purposes. In regard to patents, it would end the freedom to operate for conventional breeders and have no positive effects for small and medium breeders in Europe that want to use NGTs.

DNA sequences coding for chimeric proteins as category of Annex 1

In current documents, the rapporteur proposes that only those NGT plants that produce new ('chimeric') proteins should be subjected to mandatory risk assessment. In consequence, the mandatory risk assessment of NGT plants would become a rare exception.

1. It is important for risk assessment to investigate if chimeric proteins (no matter if intended or unintended) are produced by NGT plants. For example, by knocking out specific plant genes, such new proteins can unintentionally be caused by frame shift mutations (see for example knock-out of ‘gluten associated’ genes[2]). In this context, chimeric proteins are defined as being created through the joining of two or more genes or parts of genes that originally coded for separate proteins.

2. However, if chimeric proteins are established as main criteria for category 1, only a minor part of relevant intended and unintended genetic changes and associated risks would be taken into account:

(a) The DNA sequences that code for proteins only represent a part of the targeted gene sequence, as it consists of non-coding sequences (introns) and coding-sequences (exons). However, non-coding areas of a gene may have important regulatory functions, but according to the amendment, this would be ignored. In result, this criterion would allow for much more genetic changes (number of nucleotides) than envisaged in the original Commission proposal.

(b) In many NGT plants currently under development, the intended biological effects are caused by knock-out of plant genes that are involved in gene regulation (see examples[3] like GABA tomato, de-novo domesticated tomato, agrofuel camelina, prematurely flowering poplar). However, according to the rapporteur's proposal, in none of the mentioned cases, mandatory risk assessment would be required in future.

---

1 https://www.testbiotech.org/node/3181

2 https://www.testbiotech.org/en/limits-to-biotech/genetically-engineered-wheat

3 https://www.testbiotech.org/en/limits-to-biotech

What is crucial for future regulation: Based on these amendments, NGT plants may have much more than 20 changes on different sites in the genome (as proposed by the Commission), but nevertheless would not have to undergo risk assessment and could be equated to conventionally bred plants.

Summary:
The proposed amendments would drastically enlarge the group of NGT plants that would escape risk assessment. The number of changes in nucleotides as well as the overall number of genetic changes in the genome would be largely increased for NGT plants that are equated to conventionally-bred plants. At the same time, the proposal ignores the biological effects that can be caused by changes in regulatory gene sequences. All in all, the proposed amendments are unacceptable in regard to safety for health and the environment.

Patentability of NGT plants
The proposal made by Polfjärd also gives the impression that NGT plants could be exempted from patent protection. However, Testbiotech comes to the conclusion that these proposals would be largely ineffective:

1. The proposed amendments ignore that the EU cannot change the EPC (European Patent Convention), which is the basis for the national patent law of 39 countries as well as for the decision making of the EPO (European Patent Office). All national patent laws of the EU member states have to be in line with the text of the EPC. Thus, no matter, what is changed in the EU patent directive 98/44, as long as it contradicts the EPC, it will have zero effect on the decisions taken by the EPO, national patent offices or national patent courts.

2. There is no doubt that exempting technical inventions such as CRISPR/Cas processes (and products derived thereof) from patentability would be in contradiction to the EPC. On the other hand, a change of the EPC would require the unanimous vote of 39 contracting states of the EPC.

3. The EU can prohibit patents on non-technical processes (essentially biological processes) by clarifying the interpretation of the EPC. Thereby, the EU could exclude all processes in conventional breeding that make use of non-targeted, random processes. For such a clarification of interpretation of patent law (which is in line with EPC), only a simple majority of the 39 contracting states would suffice. If no such clarification is made, patents will increasingly block access to biological resources needed by all (also conventional) breeders.

Summary:
The proposal made in regard to a change of the EU patent directive is likely to have zero effect on the decisions made by the European Patent Office (EPO). On the other hand, it does not introduce the necessary clarifications to at least prevent conventional breeding from being blocked or controlled by patent holders. Currently, in Europe, more than 1000 conventionally bred varieties are already being impacted by patents granted by the EPO. If this development is not stopped, it will end the freedom to operate for conventional plant breeders, with serious repercussions for the biodiversity of cultivated crops and their adaption to climate change.[4]

[4] https://www.no-patents-on-seeds.org/sites/default/files/news/2023_Report_NPoS_final_version.pdf