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Impact Assessment in
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“Patents, case studies and chimeric proteins:
what is key for future regulation of NGT plants?”

Christoph Then, 19 January 2024

(1) NGTs in the maze: Equivalence to conventional breeding

The rapporteur of the EP proposes that only those NGT plants should be subjected to mandatory risk assessment which produce new, altered or chimeric proteins.

“1. A NGT plant is considered equivalent to conventional plants if the following conditions referred to in points 1 and 1a are met:

(1) The number of the following genetic modifications, which can be combined with each other, does not exceed 3 per any specific protein-coding sequence (mutations in introns and regulatory sequences are excluded from this limit): (...)

(1 a) The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in species from the gene pool for breeding purposes or does not interrupt an endogenous gene; (...)”

Proposal of EP rapporteur 17 January 2024

NGTs in the maze: Equivalence to conventional breeding

New genetic engineering is typically used to switch off specific plant genes. As result, NGT plants can exhibit characteristics and risks that go far beyond the results of breeding and the characteristics of the natural species. 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 new, altered or chimeric proteins. Therefore, according to the rapporteur's proposal, in none of the aforementioned cases, mandatory risk assessment would be required.

NGTs in the maze: data gaps

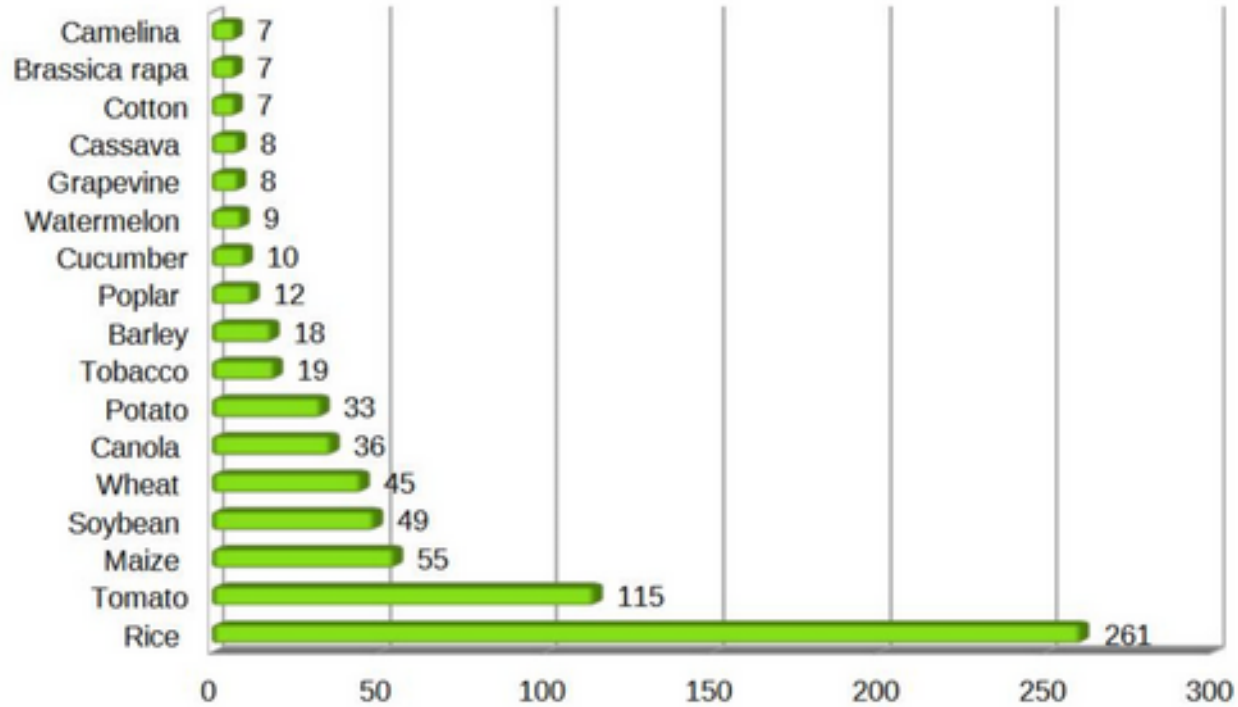
There is a huge data gap between the EFSA opinions and the data provided in various databases. This data gap is largely impacting the EU Commission proposal on the future regulation of NGT plants.

There have only been few attempts to assess the data of specific cases (Kawall, 2021a and b; Koller & Cieslak 2023a; Eckerstorfer & Heissenberger, 2023; ANSES, 2023). These studies demonstrate that NGT plants can overcome the boundaries of the known characteristics of a plant species, even if no additional genes are inserted and with very small genetic changes are made and without the need to produce new (or chimeric) proteins.

NGTs in the maze: latest from EFSA

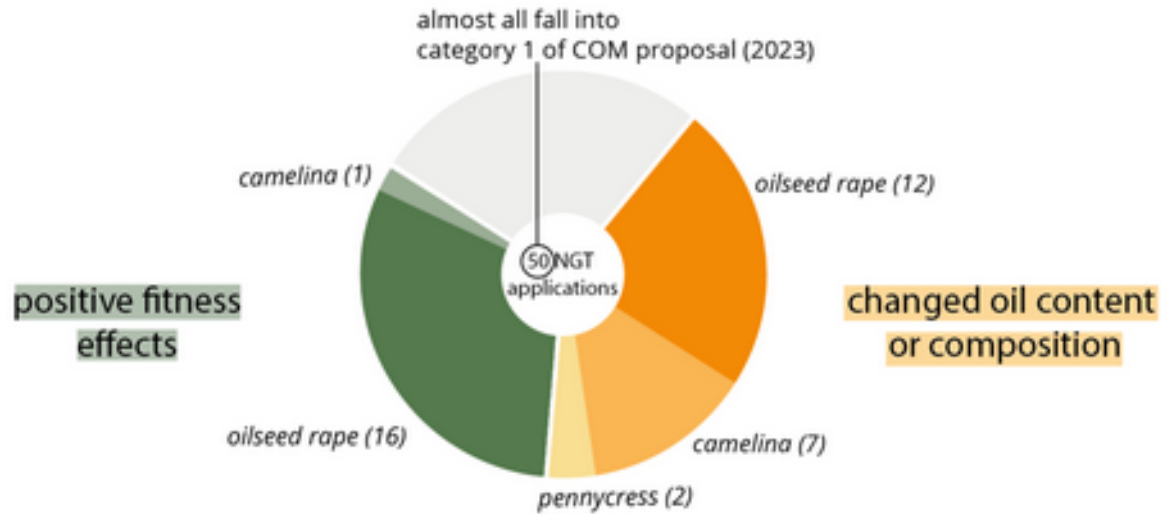
The Panel had a discussion on the challenges plants obtained through NGTs poses to the risk assessment. The six criteria identified by EFSA (2022) were applied to several hypothetical case studies. The Panel discussed the relevance of the information as by the current data requirements for GM plants for the identified NGT case studies. The Panel identified the need to further discuss the implication on RA the NGT plants might have.

https://www.efsa.europa.eu/sites/default/files/2023-12/Minutes_3.pdf



Number of published potential NGT applications in plants, taken from the EU-SAGE database at the end of 2023 (original data:<http://www.eu-sage.eu/genome-search>)

Current NGT applications in *Brassicaceae*



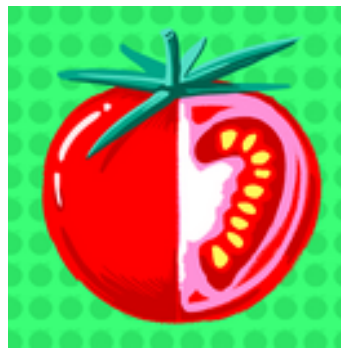
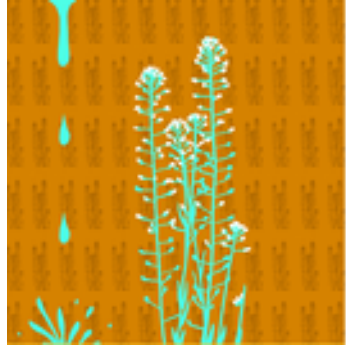
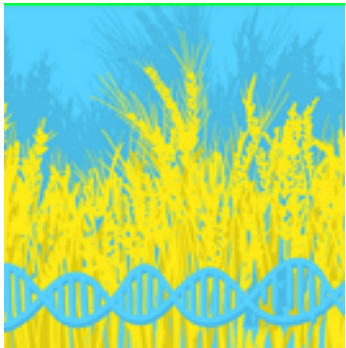
An initial overview of NGT applications in *Brassicaceae* used for oil production revealed differences and similarities to conventionally-bred plants (Koller & Cieslak, 2023).

As shown, more in-depth risk assessment is needed to prove or disprove similarity.

As yet, no further overview has been published for other plant species, such as rice, tomato, maize, soybean and wheat.

Case by case risk assessment is needed

Genomic data from NGT plants and molecular risk assessment (in-door risk assessment) will certainly be needed on a case-by-case basis to prove or disprove similarity or 'equivalence' to conventionally-bred plants, and to decide which further data will be needed to ensure both human health and environmental safety.



See short-cut examples of 'non-equivalent' camelina, tomato, wheat and others at:
www.testbiotech.org/en/limits-to-biotech

(2) NGTs in the maze: patents

The rapporteur of the EP proposes to prohibit patents on NGT plants. No patents shall be granted on:

“(c) NGT plants, plant material, parts thereof genetic information and process features they contain, as defined in Regulation (EU) .../... and the genetic information they contain; (...)“

Proposal of EP rapporteur 17 January 2024

NGTs in the maze: patents

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. Also all national patent laws of the EU member states have to be in line with the text of the EPC.

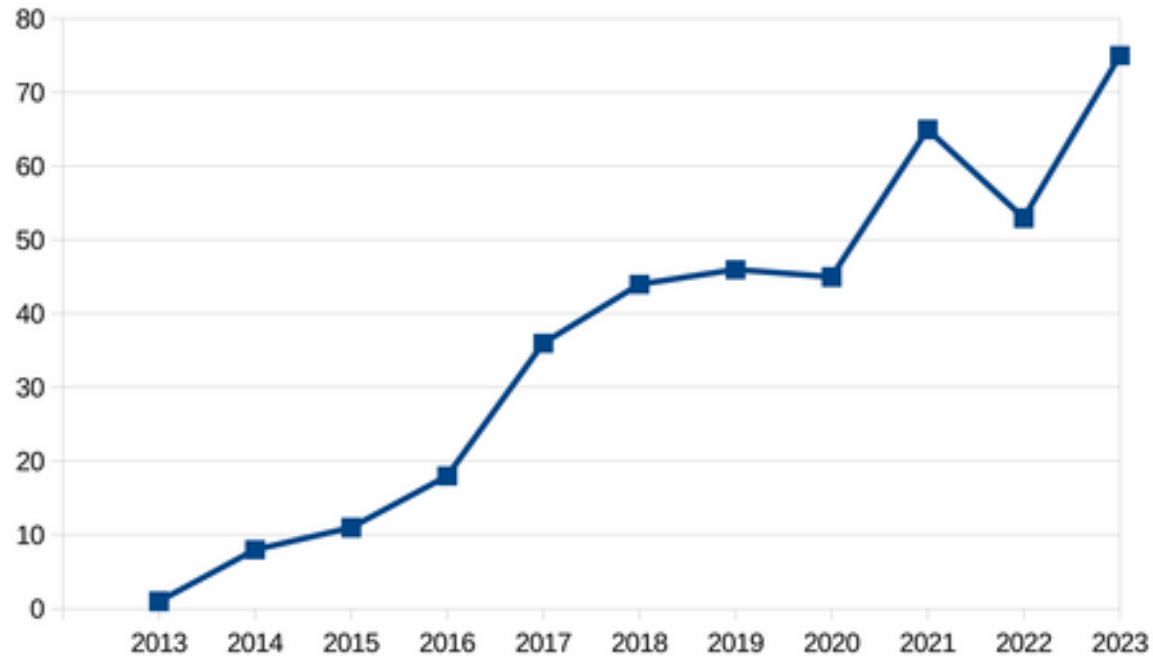
No matter, what is changed in the EU patent directive 98/44, as long as it contradicts the EPC, it will have zero effect for the decisions taken by the EPO (European Patent Office), national patent offices or national patent courts.

There is no doubt that the proposal of the rapporteur is actually in contradiction to the EPC.

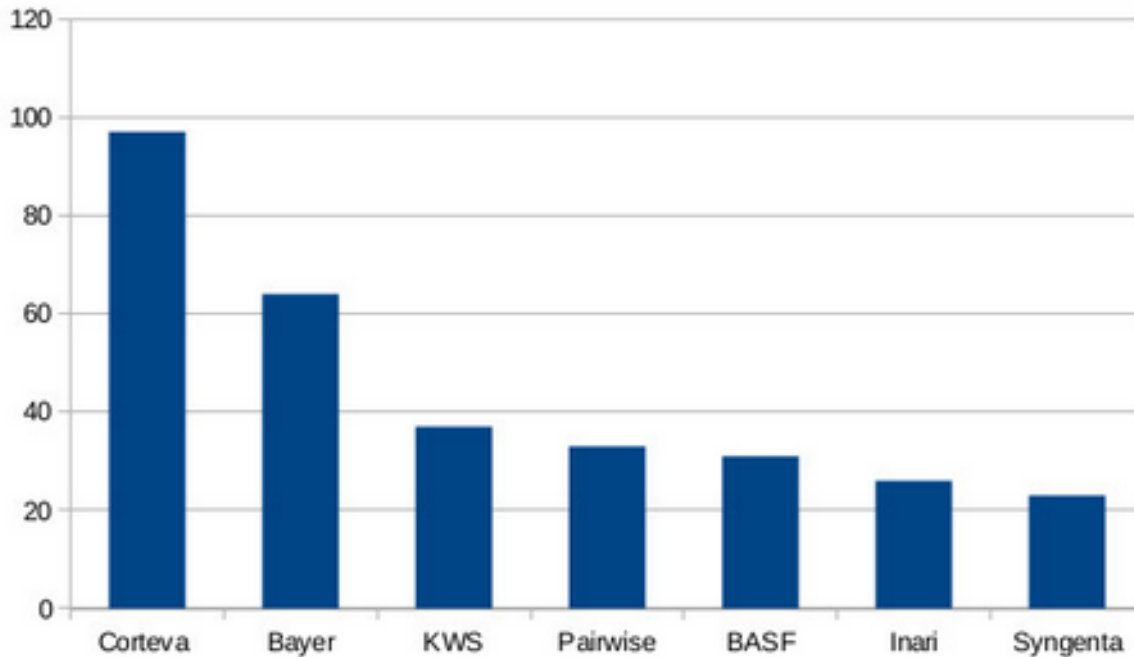
NGTs in the maze: patents

In many cases, the scope of NGT patents is not limited to genetically engineered plants. They often include claims on the respective genetic modifications, even if they are the result of random mutations. This is a way for companies to control access to biodiversity without the involvement of genetic engineering.

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.



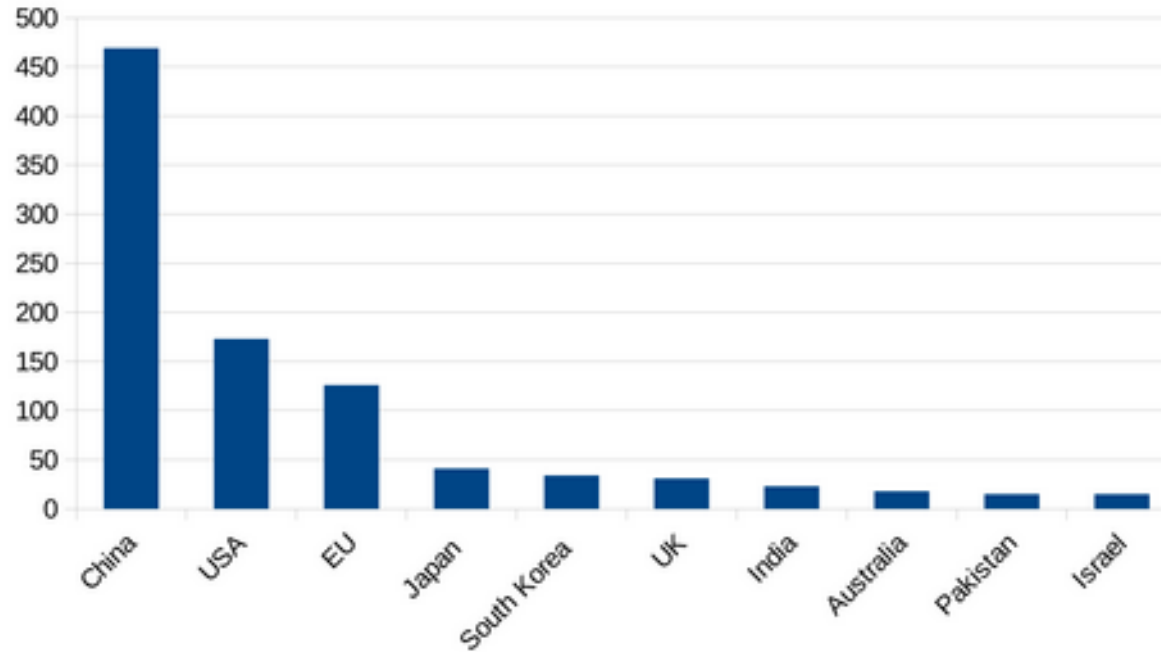
Number of international patent applications filed for genetically engineered plants (WIPO/PCT) per year which include the term 'CRISPR' in the claims. Note: This research includes only patent applications filed in English language.
(<https://patentscope.wipo.int/search/en/search.jsf>, search within IPC C12N15/82)



Number of international patent applications (WIPO /WO) for the usage of nucleases (CRISPR/Cas, TALEN, zinc finger- or meganucleases) in the food plant sector, categorised by companies, up until the end of 2022.

Note: This research includes only English language patent applications.

(<https://patentscope.wipo.int/search/en/search.jsf>, search within IPC C12N15/82)



Number of published studies for NGT applications in plants categorised by country / regions.
Note: several countries / regions can be involved in one publication
(original data: <http://www.eu-sage.eu/genome-search>).

EU should limit the scope of patents to technical inventions

The EU requested the exclusion of conventionally-bred plants from patentability as early as 2017. The problem is not yet solved: This initiative actually resulted in the EPO correcting its interpretation of the patent law. However, at the same time, a further loophole was established which still allows patents to be granted on genetic variants derived from random processes.

Austria shows the way forward: The national law does not permit patents if they are "based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic modifications occurring in nature."

Thanks for your attention!

Selected sources (with further references):

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

<https://www.testbiotech.org/node/3182>

10 questions and answers: What do we really know about NGT plants?

<https://www.testbiotech.org/node/3181>

How to ensure a science-based and up-to-date regulation of NGT plants

<https://www.testbiotech.org/node/3175>