CRISPR patents are a threat to conventional breeding

NO PATENTS ON SEEDS!

Dr. Christoph Then
info@no-patents-on-seeds.de
www.no-patents-on-seeds.org

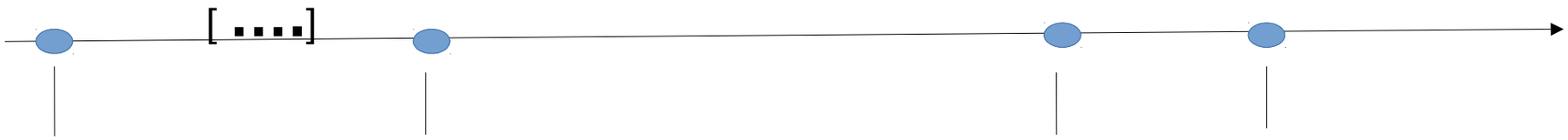
Overview:

- Differences between regulated and non-regulated organismen in EU GMO legislation
- Distinction between invention and essentially biological processes in patent law

- Patent law defintion of essentially biological processes
- Confusion between technical inventions and essentially biological processes
- Scope of CRISPR-patents

- Demand

Historical overview: conventional plant breeding and genetic engineering



Since ~ 9.000 B.C.:
Selective breeding

Since ~ 1920:
Non-targeted mutagenesis using chemical and physical mutagenes to speed up mutations which may occur naturally

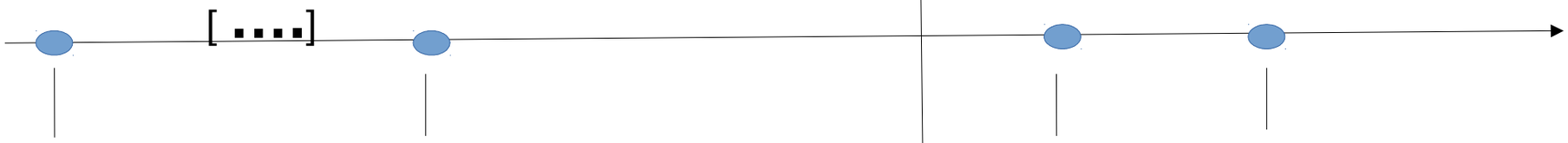
Since ~ 1980:
Transgenic plants

Since ~ 2000:
New GE (‚genome editing‘) using biotechnological mutagenes to create new genotypes and traits which typically are unlikely to occur naturally

GMO Regulation: conventional plant breeding and genetic engineering

conventional breeding
and non-regulated GMO

genetic engineering
and regulated GMO



Since ~ 9.000 B.C.:
Selective breeding

Since ~ 1920:
Non-targeted mutagenesis using chemical and physical mutagenes to speed up mutations which may occur naturally

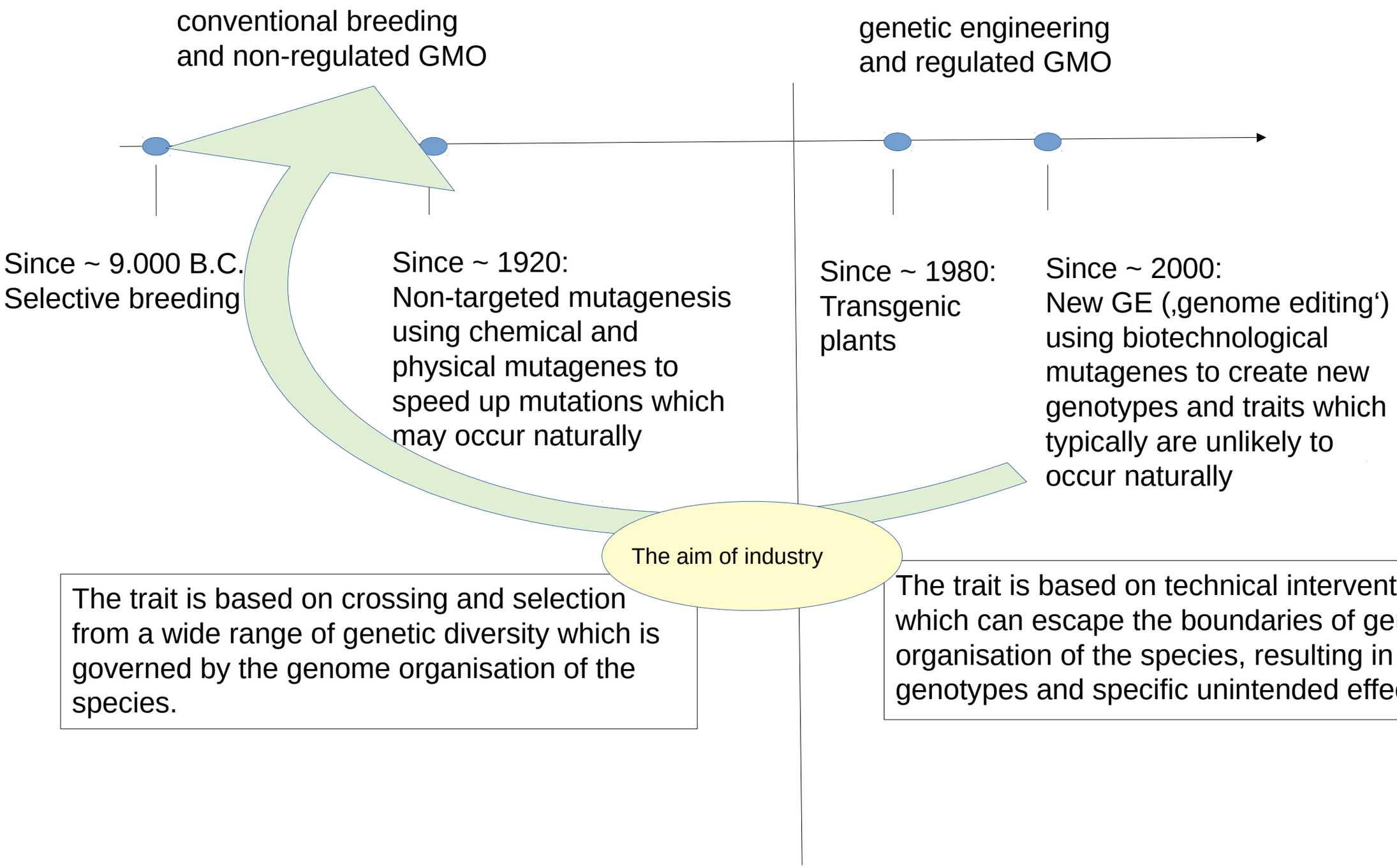
Since ~ 1980:
Transgenic plants

Since ~ 2000:
New GE (‚genome editing‘) using biotechnological mutagenes to create new genotypes and traits which typically are unlikely to occur naturally

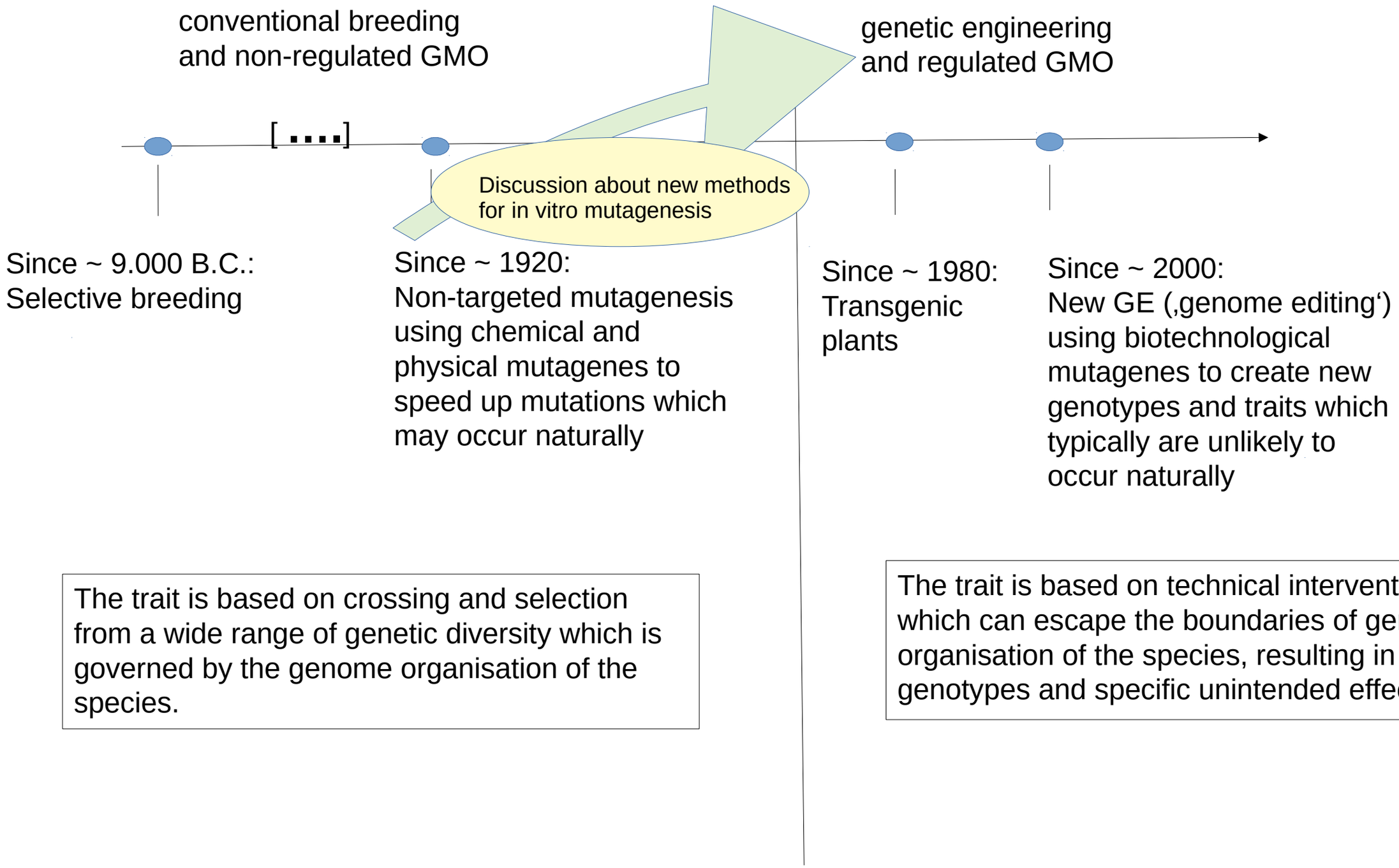
The trait is based on crossing and selection from a wide range of genetic diversity which is governed by the genome organisation of the species.

The trait is based on technical intervention which can escape the boundaries of genome organisation of the species.

GMO Regulation: the dispute (1)



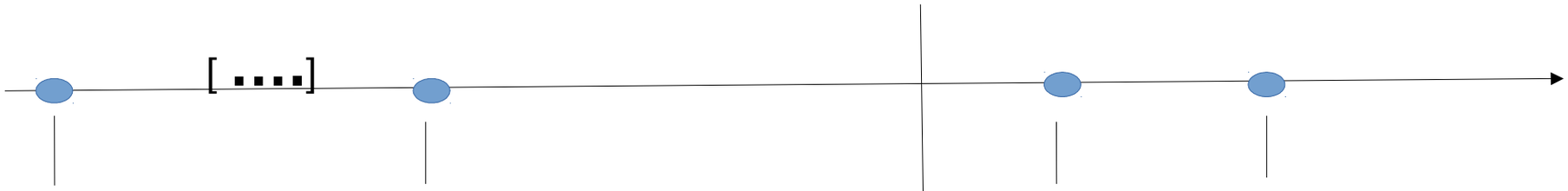
GMO Regulation: the dispute (2)



Patent law: essentially biological breeding and technical invention

‘essentially biological processes‘

‘technical inventions‘



Since ~ 9.000 B.C.:
Selective breeding

Since ~ 1920:
Non-targeted mutagenesis using chemical and physical mutagenes to speed up mutations which may occur naturally

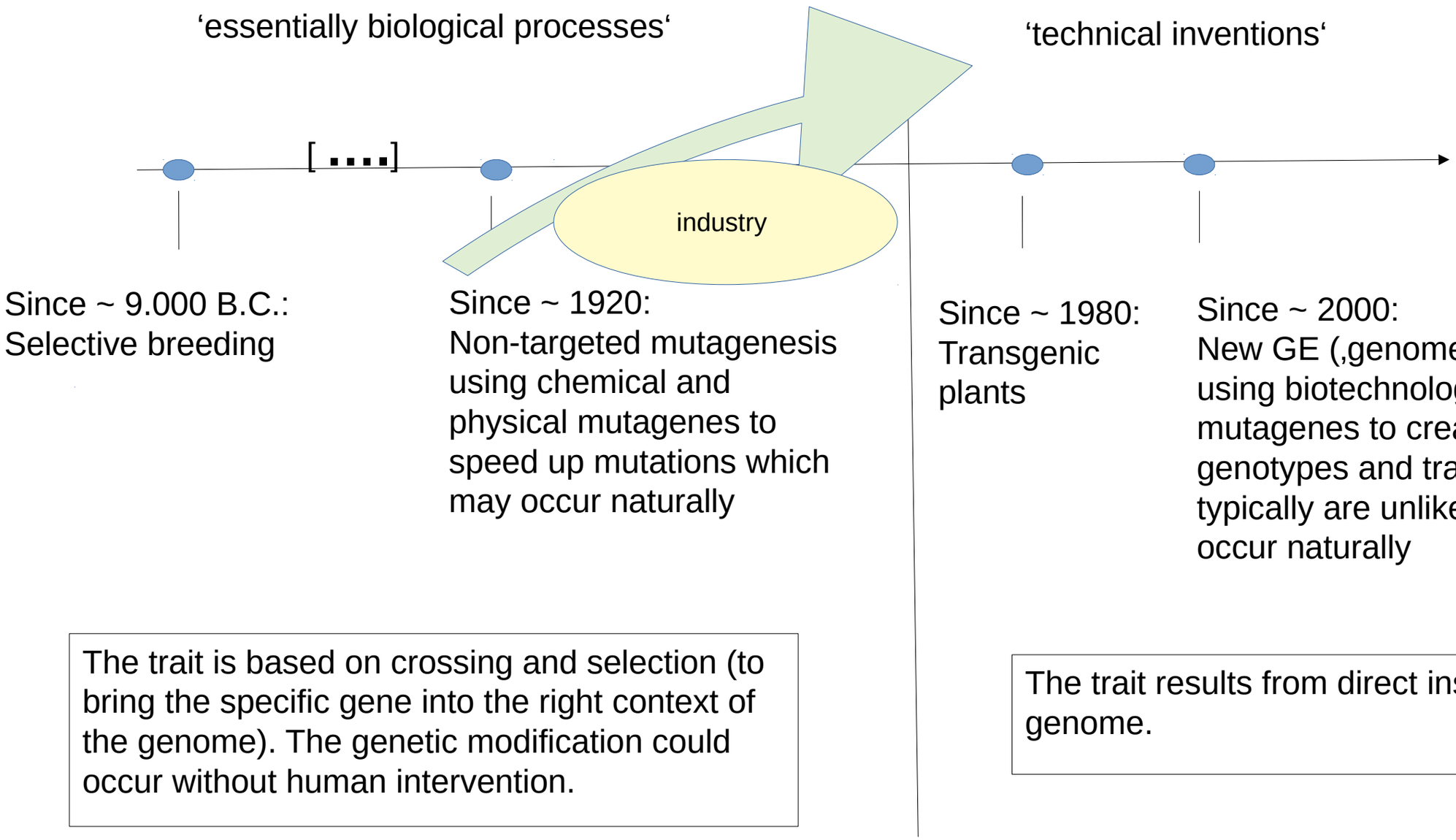
Since ~ 1980:
Transgenic plants

Since ~ 2000:
New GE (‚genome editing‘) using biotechnological mutagenes to create new genotypes and traits which typically are unlikely to occur naturally

The trait is based on crossing and selection (to bring the specific gene into the right context of the genome). The genetic modification could occur without human intervention.

The trait results from direct insertion into the genome.

Patent law: the dispute



Take home message (1)

There are different legal frameworks and different questions that need to be answered in GMO regulation compared to patent law.

Even if plants derived from in vitro mutagenesis would be submitted to regulatory processes in the EU, they still would ‘essentially biological’ in the meaning of patent law.

Even if organisms derived from New GE would escape current mandatory EU GMO regulations, they still would be ‘technical inventions’ in patent law.

Essentially biological processes and the profound differences between conventional breeding and genetic engineering

The broccoli & tomato I decisions (G2/07 and G1/08) provide a distinction between conventional breeding and genetic engineering:

"*genetic engineering techniques applied to plants (…) differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant.*"

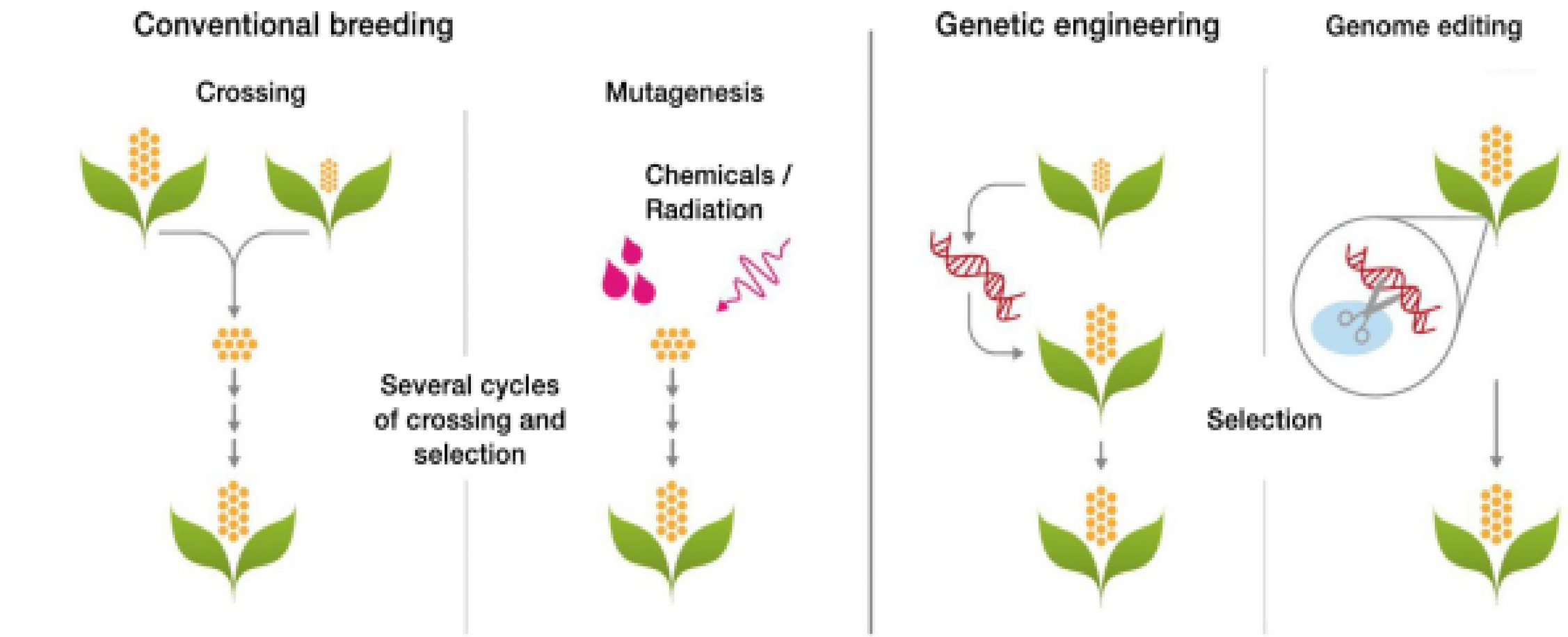
Only processes that contain a step of a technical nature, which "*by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced*" are not excluded from patentability under Article 53(b) EPC. (Headnote 3)

G2/07 and G1/08 are referring to decision T356/93:

"*the insertion of the relevant DNA sequence into the genome of the plant, could not occur without human intervention.*"

(emphasis added)

Essentially biological processes and the profound differences between conventional breeding and genetic engineering



adopted from Genomxpress Scholae Nr 5, funded by the German Ministry for Education and Research (BMBF), www.no-patents-on-seeds.org/en/publications/report2021

Essentially biological processes and the profound differences between conventional breeding and genetic engineering

The EPA document CA/56/17 is confusing the differences between conventional methods and genetic engineering.

The President of the EPO, in preparing the decision on Rule 28(2) in 2017, published a preparatory document (CA/56/17): "*Mutagenesis as such is considered to be a technical process which results in a modification of the genome of the plant or animal. This applies to 'traditional' methods like irradiation or chemical mutagenesis, but even more so to molecular methods like Zinc Finger Nucleases, CRISPR, TALEN, ODM (oligonucleotide directed mutagenesis), etc. which require man-made molecules for targeted mutagenesis.*"

(!) Note: modification of genome does not mean to directly insert a new trait. It does not necessarily require human intervention.

(emphasis added)

Essentially biological processes and the profound differences between conventional breeding and genetic engineering

In consequence, there is major confusion in the Guidelines for Examination of the EPO: *"Thus transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not. Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical processes."*

But also:

"*Genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant are patentable (see T 356/93).*"

(!) Note: UV induced mutations occur in the fields, without any human intervention. In general, all mutations derived from random process also may occur in nature (without human intervention), contrary to those that result from genetic engineering.

Essentially biological processes and the scope of patents

If a patent is granted on plants or animals with specific traits, absolute product protection can also cover plants or animals derived from conventional breeding with the patented characteristics.

(1) example patent application Nunhems (BASF) WO2020239495 on tomatoes with improved tolerance to phytophthora (plants are derived from random mutations, no GE). The methods listed in the claim 17 are: "*(…) chemical mutagenesis, radiation mutagenesis, tissue culture or targeted genome editing techniques such as CRRIPR based techniques (…).*"

(2) example patent application (Center for Aquaculture Technologies, US) WO2020033940 fishes with sterile offspring (fish are derived from CRISPR/Cas), in the claims only the term mutation is used: "*breeding (…) a female [male] mutated fish (...)*".

(3) example granted patents for Carlsberg and Heineken (EP 2 373 154 B1) on barley and beer (plants are derived from random mutations, no GE): *"(…) barley plant, or part thereof, carries a mutation in the gene (….)*".

Essentially biological processes and the scope of patents

If a patent is granted on plants or animals with specific traits, absolute product protection can also cover plants or animals derived from conventional breeding with the patented characteristics. This is especially true for plants with all kind of random mutations.

Table 3: Some examples of patent applications covering New GE as well as conventional breeding

Patent number	Company	Content
WO 2014110552	Recombinetics	Hornless cattle for natural and synthetic genetic applications
WO2017040695	Recombinetics	Selection of genetic variants in cattle such as polled, climate adaption and fertility and related usages
WO2017044744	Monsanto	Mildew resistance in maize
WO2017106731	Monsanto	Northern leaf blight resistance
WO2018031874	Monsanto	Resistance to 'late wilt' in maize
WO2014006159	Bayer	Changed oil composition in soybean
WO2015000914	Bayer	Changes in flowering times
WO2016176476	Bayer	Changed oil composition in oilseed rape

Patent application on new GE plants

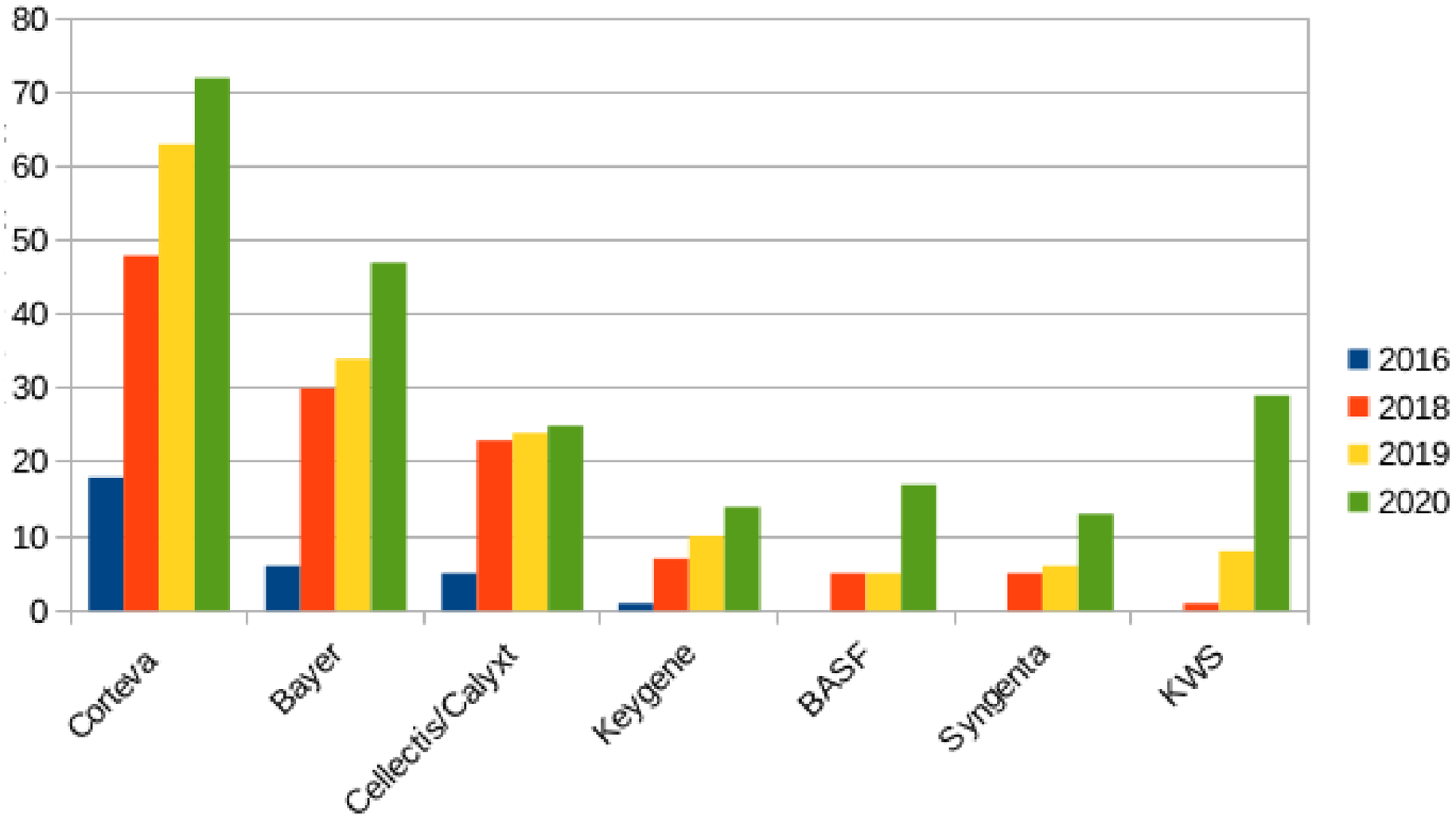


Figure 3: Number of international patent applications (WIPO /WO) on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) in the food plant sector up until the end of 2020[12] (number of patent applications accumulated[13]).

www.testbiotech.org/node/2772

Take home message (2)

Blurring the differences between genetic engineering and ‘essentially biological processes’ allows to extent the scope of patents to conventionally bred plants and animals.

By using tools like the gene scissors CRISPR/Cas, also results from conventional breeding can be imitated.

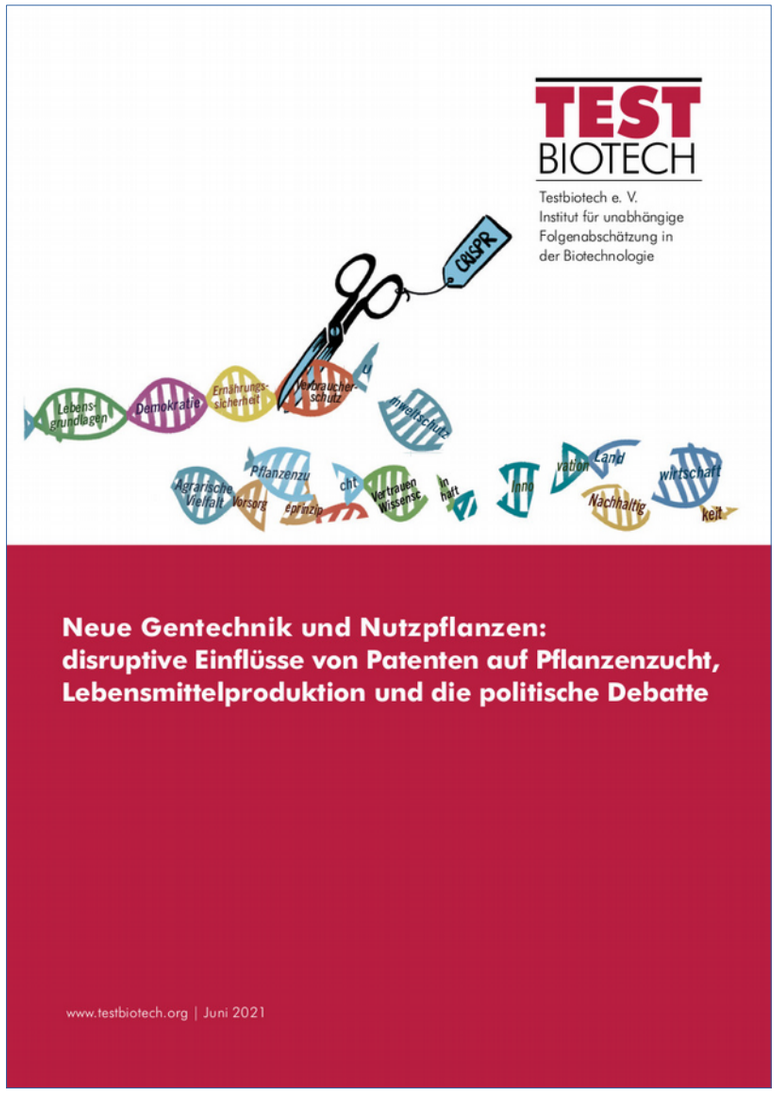
If these patents are granted they also can concern plants (or animals) from conventional breeding. This is especially true for plants with all kind of random mutations.

Thereby, the existing legal prohibitions (Art. 53 (b), Rule 28 (2) of the EPC) are under threat to become meaningless.

Demand

To render the existing prohibitions effective, it is necessary to restrict the scope of patents on inventions which concern plants or animals to the processes of genetic engineering (including New GE).

Recommended reading



www.testbiotech.org/node/2772



www.no-patents-on-seeds.org/en/background/publications