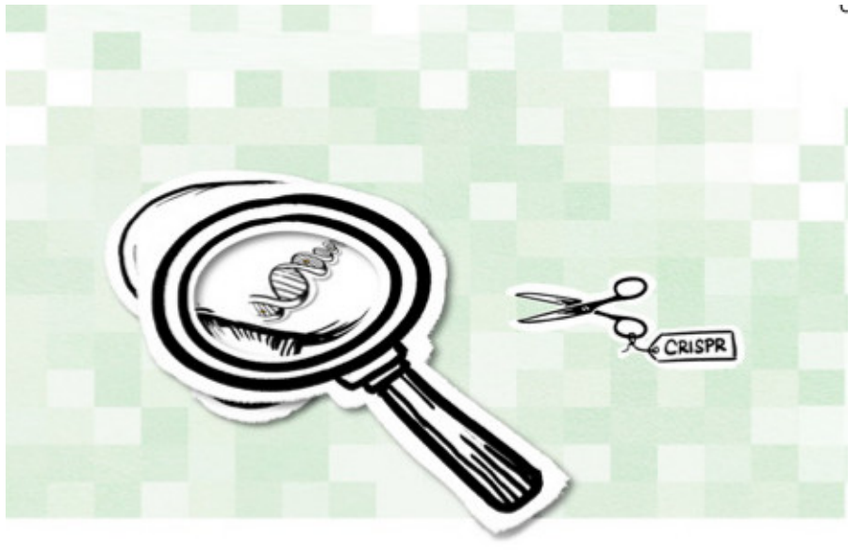
TEST BIOTECH



Frequently asked questions on the regulation of ‘New GE’

(1) What are the differences between New GE and conventional breeding?

(2) Are there specific risks associated with New GE?

(3) How should the risks of New GE organisms be assessed within the approval process?

(4) Can New GE organisms be identified and traced?

(1) What are the differences between New GE and conventional breeding?

(1) Differences between New GE and breeding

Conventional breeding

- increases in genetic diversity needed for further crossing and selection (genetic diversity is not unintended);
- uses unspecific physico-chemical mutagenes;
- restricted by ‚flexible barriers in the genome' which impact the rate and the distribution of mutations (repair mechanism, protected genomic regions, etc.).

New GE

- Inserts new traits directly by change of targeted sites;
- uses specific biotechnological mutagenes (nucleases)
- resulting genotypes and phenotypes can exceed the range of characteristics developed through previous (conventional) breeding methods;
- can overcome the flexible barriers in the genome;
- mostly, in plants, is combined with ‚Old GE'.

(2) Are there specific risks associated with New GE?

(2) Risks associated with intended effects

CRISPR/Cas applications very often result in complex patterns of genetic change (genotypes) and profound intended changes in the biological characteristics (phenotypes).

These profound changes …

…are possible even without insertion of additional DNA sequences.

…often go beyond what is possible through natural variation and conventional breeding methods.

…neccessarily go along with specific risks for environment and health.

(2) Risks associated with unintended effects

A wide range of specific unintended effects have been observed when New GE is applied.

Causes are...

...the multi-step process of the genetic intervention, which in many cases also implies the use of Old GE methods.

...the lack of precision of the CRISPR/Cas gene scissors.

These unintended effects can be significantly different to those caused by conventional breeding.

(2) Specific risks: summary

The patterns of intended and unintended changes will typically be different in comparison to those derived from conventional breeding.

These pattern of genetic changes necessarily go along with specific risks.

Detailed examination of an organism’s genotype and phenotype, starting with the process that was used to generate the organism, is needed to decide whether the organism is safe.

(2) Examples for potential impact on the environment

There is a broad range of risks for ecosystems, agriculture and food production. Some examples:

- **Wild species & food webs:** Changes in plant composition can impact wild animals such as mammals, birds or insects and their food webs.

- **Food & feed safety** can also be affected by changes in plant composition.

- **Plants' interaction and communication with the environment** can be affected by changes in plant composition. These risks can affect e.g. insects (such as pollinators and beneficial species), symbiotic organisms (such as associated micro-organisms) or plant 'enemies' (such as pest insects) and stress reactions (climate change).

- **Uncontrolled spread in the environment:** New GE organisms can cause 'next generation effects' with adverse impacts which are not predictable from the characteristics of the original event.

(3) How should the risks of New GE organisms be assessed within the approval process?

(3) Risk assessment

- **‘Product-based’ risk assessment cannot guarantee safety.** To assess safety, all steps of the technical process and their specifities need to be considered (‘process-based’ risk assessment).

- **Adequate methods** have to be applied to assess the complex biological changes intentionally and unintentionally caused by the New GE techniques.

- **‘Comparative approach’ may not be sufficient.**
- In many cases it will be difficult or impossible to find adequate organisms with a history of safe use to compare them with the New GE organisms (‘comparative approach’).

(3) Risk assessment

- **‘Omics’ data** are necessary to assess changes in the genome, the transcriptome (RNAs), the proteome (production of proteins) and the metabolome (several levels of metabolic functions).

- **Whole Genome Sequencing** needs to be applied to assess the whole pattern of intended and unintended genetic changes and their effects.

- **Comparative data** must be requested to provide evidence in case it is assumed that the results of ‘genome editing’ cannot be distinguished from those of conventional breeding.

(4) Can New GE organisms be identified and traced?

(4) Identification of New GE organisms

In most cases, the typical patterns of genetic changes as well as specific alterations of single DNA sequences will allow the identification and traceability of New GE organisms.

However, it has to be ensured that the companies provide the necessary data as requested for the mandatory approval process.

Summary

- Detailed process-based risk assessment has to be mandatory for all new GE organisms.
- This is also necessary if no additional DNA sequences were inserted.

Without adequate regulation of New GE…

... large numbers of organisms can be expected to be released in an uncontrolled way within a short period of time.

Without adequate regulation of new GE...

…severe damage to biological diversity, ecosystems and agriculture is not unlikely.
…risks to food production may be introduced and accumulate unnoticed.
...access to data needed for risk assessment by independent experts would not be available.
…no measures can be taken against the uncontrolled spread of the organisms in the environment;
…no data are available to track and trace the New GE organisms and products derived thereof.
…GE-free agriculture and food production can no longer be protected.

A wider perspective

- *Indeed, we are already supplanting the deaf, dumb, and blind system that has shaped genetic material on our planet for eons and replacing it with a conscious, intentional system of human-directed evolution.*

- Jennifer Doudna, ‘A Crack in Creation‘

- *Nature and landscape, because of their own value and as basis for live and health of humans also in responsibility for future generations […] have to be protected in a way that (1) biodiversity […] (3) diversity, character and beauty as well as the recreational value of nature and landscape is protected in perpetuity [...].*

- German law for nature protection, Article 1

Thanks for your attention!

Further reading & references:

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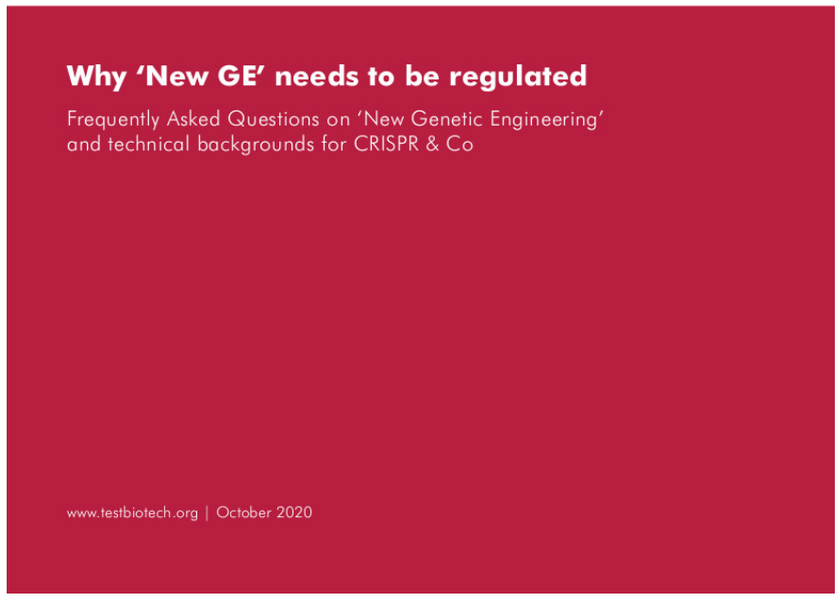
Institute for Independent
Impact Assessment in
Biotechnology



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