

New report: strict regulation of new genomic techniques is scientifically necessary

Environmental impacts of CRISPR/Cas and its challenges for risk assessment

17 March 2020 / In a new report, Testbiotech provides an overview of the latest research developments in environmental risk assessment and new methods of genetic engineering (also known as 'genome editing' or 'new genomic techniques'). The authors come to the conclusion there are imperative scientific reasons for all organisms derived from these new techniques to undergo mandatory risk assessment before they can be released or marketed. Therefore, regulation requirements foreseen by current GMO law in the EU must be mandatory whether or not additional DNA sequences are inserted. In addition, a broad range of ethical and social issues must be taken into account by the regulatory decision-makers.

The report focuses on possible impacts that new methods of genetic engineering (genome editing) can have on the environment. It is primarily concerned with CRISPR/Cas nucleases classified as 'site directed nucleases' SDN-1 and SDN -2. These applications are not meant to introduce additional gene sequences. Nevertheless, the pattern of intended and unintended changes and the resulting new combinations of genetic information arising from genome editing will, in most cases, be different in comparison to those derived from conventional breeding. These differences co-occur with biological characteristics and risks that need to be fully investigated before any conclusions on the safety of the new organisms can be drawn.

The authors identified the following aspects as particularly important for regulatory decision-making:

- New patterns of genetic change and resulting genetic combinations are, in many cases, likely to result from the application of SDN-1 and SDN-2.
- The applications of 'old' methods of genetic engineering (such as biolistic methods or *Agrobacterium tumefaciens*) used in most cases to introduce the CRISPR/Cas component into the plant cells can cause a broad range of unintended effects.
- CRISPR/Cas technology itself can cause many specific unintended effects; these would be dependent on the individual process, the surrounding experimental parameters, the chosen target location on the genome and the specific organism. Therefore, each specific case must be investigated. Often this challenge in risk assessment goes far beyond what is discussed as 'off-target effects'.

The report uses selected examples to provide a greater understanding of regulatory challenges resulting from SDN-1 and SDN-2 applications. The examples are grouped into five categories:

- Changes in the composition of plants that may impact the food web;
- Changes in the composition of plants that may impact plant communication and the interaction with the environment;
- Changes in the biological characteristics of the GE organisms meant to enhance fitness;
- Problems with risk assessment of organisms with the potential to persist and propagate in the environment;
- Examples with ethical implications, including animal health and welfare, nature protection and rights of future generations.

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Further information: [The report](#) [2]

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