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Testbiotech input to the “public consultation on plants produced by certain new genomic techniques”

EU Commission consultation, May 2022 to July 2022

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Introduction & summary

The EU Commission has opened a public consultation on the future regulation of New GE (new genomic techniques).[1] Testbiotech has concerns that the questions put forward by the Commission are biased towards the expected outcome: to deregulate many (most?) genetically engineered plants by (partially or wholly) exempting them from the mandatory approval process. This is apparent from the way in which many of the questions are formulated. Apparently, the the aim of future legislation is to accelerate the introduction of the plants onto the market. Loaded questions are being used to support EU Commission arguments in favour of deregulation, and are preempting the outcome of the consultation.

In a nutshell, the Commission seems to assume that it would be sufficient to only assess the intended traits of the resulting plants or products derived from new genomic techniques. It Commission appears that new categories for genetically engineered plants shall be introduced, i.e. the so-called ‘risk profiles’. This means that genetically engineered plants whose intended characteristics are seemingly similar to conventionally-bred plants may no longer need to undergo risk assessment.

In doing so, the Commission is ignoring the risks associated with unintended genetic changes. There are, in fact many scientific publications providing evidence that, for example, CRISPR/Cas applications are associated with unintended effects and specific risks. A mandatory approval process and risk assessment are therefore vital to assess the risks in each case.

1 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

However, instead of clarifying the risks, the EU Commission is mostly directing the attention of the public to the potential benefits of the genetically engineered plants. Most of the questions are directed at the latter. The problem: the supposed benefits have neither been independently nor systematically assessed. In addition, the issue of seed patents, which is crucial for the economic impact of New GE, has deliberately been excluded from the consultation process.

Testbiotech has made a substantial contribution to the scientific debate on the risks of NGT organisms from the perspective of the precautionary principle. In addition to several reports and backgrounders summarizing the current levels of scientific knowledge (Testbiotech, 2019a/b; Testbiotech, 2020a-d; Testbiotech, 2021a-e; Testbiotech, 2022; Testbiotech & CBAN, 2022), Testbiotech has been involved in several peer-reviewed publications about risks of NGTs (as authors or project holders) which were received with great interest by the scientific community (Kawall, 2019; Kawall, 2021 a/b; Kawall et al., 2020; Then et al., 2020).

Against this backdrop, Testbiotech is demanding a detailed case-by-case risk assessment within the current EU regulatory framework. In addition, a new, complementary regulatory framework is needed to introduce a prospective technology assessment (TA) into EU regulation. Typically, a prospective technology assessment is performed before or in parallel to the introduction of new technologies. TA can be used to systematically assess the impact of technologies on the environment and health, and can include socio-economic, social or ethical issues (see, for example, Liebert & Schmidt, 2015; Böschen et al., 2021; GAO, 2021).

In general, if genetically engineered organisms are released into the environment, their potentially negative impacts need to be minimized. At the same time, their potentially negative impacts might be dependent on the scale of their release, e.g. the number of organisms, different traits and species. These effects might easily escape the risk assessment of the distinct organisms. In analogy to other regulation aiming to protect the environment, this implies that ways must be found to effectively reduce releases to the absolute minimum. In this context, reliable instruments and criteria are needed to distinguish traits with ‘real benefits’ from those which are just ‘empty promises’. Prospective technology assessment (TA) may help to define criteria for minimizing potential adverse effects and identify applications with a credible expectation of real benefits.

Therefore, in addition to the mandatory case-by-case risk assessment, a regulatory framework for a prospective technology assessment should be a priority for political decision-makers. The regulatory framework should take the systemic risks of NGT into account, as these extend beyond the individual applications, e.g. the unintended interactions of several NGT organisms within a shared environment. It also should include robust criteria to assess the potential benefits of NGTs for production systems and the environment. TA would thus represent a second level of scrutiny (additional to individual risk assessment) to evaluate whether these technologies are really needed and suitable to solve the problems at hand.

Testbiotech hopes the EU has learnt some lessons from the last few decades: political decision-making was not able to take measures early enough to protect nature and the environment from being damaged by climate crises, environmental pollution and a decrease in biodiversity. When it comes to the protection of the ‘nature of life’, we should be giving very high priority to the precautionary principle to avoid the next ‘man-made disaster’.

The starting point of the consultation

The Commission, in its introduction for the consultation, claims that "t*he European Food Safety Authority (EFSA) has concluded that plants obtained by targeted mutagenesis and cisgenesis can have the same risk profile as plants produced with conventional breeding*". This statement is misleading. It should be born in mind that EFSA never provided a full and comprehensive overview of risks caused by the intended and unintended effects of NGT plants in its (partially outdated) previous reports (such as EFSA, 2012a/b and EFSA, 2020). For example, the most recent EFSA opinion (2020) explicitly states that no comprehensive literature research was conducted on this issue. In addition, several publications highlighting specific risks (for overview see, for example, Kawall et al., 2020; Kawall, 2021a; Kawall, 2021b; Eckerstorfer et al., 2021; Testbiotech & CBAN, 2022) were not referenced in these opinions. EFSA has so far only elaborated on questions relating to whether current guidelines and regulations on risks associated with transgenic plants could also be applied to plants derived from NGT.

This creates the impression that plants obtained with NGT generally have the same 'risk profile' as plants produced with conventional breeding, and this is not only a false claim, also it lacks sufficient basis in the work of EFSA. It may very well be that some specific plants derived from NGT may carry similar risks compared to plants derived from conventional breeding. However, such conclusions can only be made after in-depth risk assessment, including specific cases and not precluded by what the EU Commission calls 'risk profiles'. In short, these 'risk profiles' as introduced by the EU Commission, only consider the intended characteristics of the final product, and mostly leave aside unintended effects caused by the process of NGTs.

It is hugely concerning that the EU Commission has not avoided issuing such statements as those quoted above, as these are likely to cause greater confusion and misunderstandings, and may ultimately influence the outcome of the consultation.

a) Questions about the regulation and risks of NGTs

The first question asks whether current regulation is considered to be adequate ("*With regard to the problems above, what is your view of the existing provisions of the GMO legislation for plants produced by targeted mutagenesis and cisgenesis?*") and what the consequences may be for specific sectors if the current regulation is not changed as envisaged by the Commission ("*If plants obtained by targeted mutagenesis and cisgenesis continue to be regulated under the current GMO framework, do you expect short, medium or long term consequences for you/your activity/sector?*"). Question 3 is directed to current standards in risk assessment ("*Currently, plants produced by targeted mutagenesis and cisgenesis are risk assessed as any other GMOs. What is your view on their risk assessment?"*). Only question 4 leaves some limited opportunity for comments.

The EU Commission appears to be ignoring specific risks associated with NGT processes for political reasons. Consequently, future GMO regulation might be based upon flawed assumptions, and thus unfounded in reality. In general, one cannot ignore that the processes used to generate NGT plants are complex and have both intended and unintended effects. Many of these effects are unlikely to emerge from methods of conventional breeding (including random mutagenesis) (see for example Kawall, 2019; Kawall, 2021 a/b). Therefore, the idea that introducing 'risk profiles' would allow any conclusions to be drawn on the safety of NGT plants without detailed risk assessment, must be rejected. Rather, all plants derived from NGT processes (including cisgenesis) should both now and in the future undergo a mandatory approval process and detailed risk assessment, taking the precautionary principle into account.

Testbiotech is concerned that in many cases the answers to the questions will be strongly influenced by the assumptions made by the EU Commission. Already in its introduction, the Commission ignores the specific risks associated with the processes of NGT (for overview see Testbiotech & CBAN, 2022). Consequently, future GMO regulation might be based on flawed assumptions, and thus suffer from what appears to be the Commission's loss of reality.

Furthermore, the Commission seems to be indicating that current regulation cannot be adapted or further developed, and cannot therefore be applied to NGTs. However, it should be acknowledged that the existing regulatory framework provides the scope (see ECJ decision, Case C-528/16) and substantial flexibility needed to adapt the guidelines to the risk assessment of various NGT applications. Even though the methodologies currently applied in risk assessment would need some adaptation, further consideration and development, this is not something that would cause major problems.

In addition, the wording of question 2 seems to indicate a strong bias towards the perspective of stakeholders with an interest in introducing NGT plants. There may, however, also be many negative consequences for specific sectors or the general public if the current regulation were to be fragmented or discontinued. Generally speaking, there is a risk that future generations may well pay the price for insufficient GMO regulation. Ecosystems and our livelihoods could be seriously threatened.

b) Questions about sustainability

As a starting point, the Commission raises the expectation "*that plants obtained by NGTs have the potential to contribute to the objectives of the European Green Deal and in particular to the Farm to Fork and Biodiversity Strategies and the United Nations' SDGs for a more resilient and sustainable agri-food system. Examples of potential benefits include plants more resistant to pests, diseases and the effects of climate change (e.g. notably increasing severity and frequency of extreme heatwaves, droughts and rainstorms) or environmental conditions in general, or requiring less natural resources and fertilisers. NGTs could also improve the nutrient content of plants for healthier diets, or reduce the content of harmful substances such as toxins and allergens.*" However, it is not made clear that actually none of these expectations were ever subjected to objective, transparent or reliable scrutiny. Instead, it creates the impression that the potential of NGT plants to solve these problems and provide the expected benefits can simply be taken for granted.

This incorrect impression is taken further in the wording of the following questions: Question 5 asks whether the assumed benefits should be included in future regulation ("*Should the potential contribution to sustainability of the modified trait of a product be taken into account in new legislation on plants produced by targeted mutagenesis or cisgenesis?*"). Question 6 asks which characteristics may be considered to be beneficial in this context ("*In your view, which of the following traits are most relevant for contributing to sustainability*?" followed by suggestions such as resistance to stress). Question 7 suggests that incentives should be introduced to support sustainable applications ("*In your view, which of the following would be the best incentives to encourage the development of plant products of targeted mutagenesis or cisgenesis with traits contributing to sustainability?*"). Question 8 introduces the idea of labelling specific NGT products as 'sustainable' ("*Do you think information about the sustainability contribution of a modified trait of a plant produced by targeted mutagenesis or cisgenesis should be made available to the consumer?*"). Only question 9 allows limited opportunity for further comments.

Testbiotech is once again concerned that the answers to these questions will be widely influenced by the assumptions and expectations raised by the EU Commission. It is creating the false impression that the hypothetical benefits of NGT plants are given fact. However, as yet there is no established regulatory system to provide sufficiently clear and transparent standards or criteria needed to make evidence-based decisions on sustainability and potential benefits. Therefore, no incentives can be issued and labelling cannot be used to inform consumers. There is a high risk that, given the current situation, misinformation and market distraction will result from the planned initiative of the EU Commission. In this context, the experience gained from the first generation transgenic crops should be taken into account; these were at the time not subject to adequate technology assessment. Despite many of the expected benefits never actually materializing, none of the products, such as herbicide resistant plants, were sanctioned or removed from the market.

Other experience gained from GE organisms can be used to exemplify the problem: for example, in 2014, EFSA published its opinion on the risk assessment of transgenic soybean MON87769, which was supposed to have a positive effect on health by increasing the concentration of Omega-3 fatty acids in food products (EFSA, 2014). EFSA did not assess the claims made by Monsanto about the benefits to health and was not able to assess any long-term effects from the consumption of these food products. Nevertheless, the Commission allowed the import of the soybeans for food production. It is very likely that now there will be many more applications filed for approval of products derived from NGT plants with claimed health effects. For example, Japan approved the first 'CRISPR tomatoes' for use in food production in 2021. The tomatoes supposedly have a much higher concentration of a plant compound (GABA) compared to conventionally-bred tomatoes (Nonaka et al., 2017). GABA (γ-Aminobutyric acid) can diminish the transmission of specific signals in the central nervous system which may, amongst others, cause lower blood pressure. However (to our best knowledge), no detailed assessment was performed by the Japanese authorities to assess the intended benefits nor any unintended effects caused by the consumption of these tomatoes. Similarly to the above-mentioned case, plants which, according to the EU Commission, are expected to "*improve the nutrient content of plants for healthier diets",* would need a detailed assessment in each and every case if the applicants make claims of sustainability.

In addition to the mandatory case-by-case risk assessment, the priority for political decision-makers should be a complementary regulatory framework for prospective technology assessment. It should take into account the systemic NGT risks which reach beyond the distinct applications, such as those emanating from unintended interactions of several NGT organisms within a shared environment. It should also include robust criteria to assess potential benefits of NGTs for production systems and the environment. In this way, TA would represent a second level of scrutiny (additional to case-specific risk assessment) to evaluate whether these technologies are really needed and suitable to solve the problems at hand. While TA cannot replace the risk assessment of the specific organisms (events), it can nevertheless help political decision-making in seeking a balance between potential benefits and the need to reduce the overall risk of adverse effects on biodiversity and human health. However, in the context of NGTs, the methodology for comprehensive TA still needs to be developed.

Testbiotech emphasizes that if, in particular, any incentives are discussed, these would require clear, transparent, reliable and enforceable assessments, standards and criteria, which allow evidence-based decisions to be made on sustainability and potential benefits predicated on a comprehensive technology assessment. The criteria should take into account alternatives which are based on conventional breeding, agroecology or other sectors within the food production systems. In future, the regulator should aim to prevent releases of any NGT plants based on non-justified claims and

empty promises. Otherwise not only market distraction and disruption will ensue from the planned initiatives of the EU Commission, but also damage to health and the environment.

c) Detection and labelling of NGT products

Questions 10 to 12 discuss if and how NGT plants can be detected and identified, and which information can be provided to consumers and producers along the food chain. Question 13 provides a limited opportunity for further comments.

Current EU regulation includes an obligation for the applicants to provide a detection method that is specific to the product, i.e. it can both detect and differentiate it from other products. However, the Commission is concerned that, while analytical methods might be able to detect the product, these methods might not be sufficient to differentiate them from similar conventionally-bred plants.

However, it is not likely that these issues will cause major regulatory problems: the application of site-directed nucleases (SDNs), such as CRISPR/Cas or TALENs, will in most cases lead to typical patterns of genetic change - and these patterns can be used for identification and traceability. Only a few plant genes are found as single genes. Unlike random mutagenesis, NGTs are able to knock out genes present as multiple copies in the plants. Thus, whenever a crop is found in which multiple copies of the same gene have been knocked out, it will almost certainly be an NGT product. Consequently, plants changed through NGT can usually be very clearly distinguished from other plants. For most NGT products, a clear signature can be found in the DNA, for instance, where the exact same nucleotide stretch is erased. If that signature is revealed by the developer, then PCR technology can in most cases be used to detect and monitor genome-edited products. The typical patterns of genetic change as well as specific alterations of single DNA sequences will allow the identification and traceability of NGT organisms in most cases (Duensing et al., 2018). Therefore, it is essential to ensure that the companies provide the necessary data during the mandatory approval process. Typically, methods of detection and differentiation would be possible if the relevant data are provided. In addition to PCR, whole genome sequencing, metabolomics and information from international registers as well as documentation transmitted through the operator chain, may all be combined to detect and identify the NGT plants (BfN, 2022).

d) Other aspects

Questions 14 creates the impression that a change in EU regulation is needed for "*improving legal clarity in the legislation, putting in place mechanisms that facilitate easy adaptation to scientific progress*" and "*a risk assessment that takes into account the characteristics and risk profile of a final product*".

This questions is biased and misleading. It creates the impression that the Commission needs to take urgent action to facilitate the market introduction of NGT plants. However, an EU Court of Justice ruling in 2018 (Case C-528/16) already provided legal clarity. Furthermore, there are many mechanisms in place to support innovation, research and development in the EU. In addition, the characteristics of the end products are already taken into account in current regulations.

Question 15 asks which measures are most relevant for co-existence with the existing agricultural practices (e.g. conventional, organic).

Testbiotech agrees these are important issues: In general, measures safeguarding coexistence should be strengthened at EU level, e.g. labeling, traceability, seed purity and protection against contamination as well as the protection of GE-free agriculture and food production. Detection methods are key in this context, and therefore the mandatory approval process for NGT plants should be applied to ensure the companies do indeed provide the relevant data and the certified reference materials. In addition, other effective measures need to be established, e.g. to monitor contamination along the food production chain, distances between the fields, public registers, the implementation of the "polluter pays" principle and clear liability.

Question 16 asks if regulatory measures should be included in any new legislation to facilitate access to NGT or plant genetic resources. At the same time, the Commission states that the consultation does include intellectual property rules such as biotechnology patents.

It seems as if the EU Commission is trying to avoid any discussion on patents currently being granted on seeds, plants and harvest. However, any impact assessment on the market introduction of NGT plants would be incomplete unless it considers the significant role of patents. Current EPO practice in granting patents not only covers the new technologies, but also impacts access to the biological resources needed by all breeders. Therefore, if breeders are pushed into using NGT applications, the current situation at the EPO means that the unresolved problems with patents will cause even more consolidation concentration in the seed markets, thus leaving just a few companies with the power to control the seed markets and food production systems. The whole question appears to be not only heavily biased but also driven by the perspective of stakeholders (patent applicants) interested in marketing their products. No account is taken of the needs and concerns of those SMEs which may need support to maintain their traditional methods of breeding. Consequently, the complex problems behind this question strongly support the need for a complementary, comprehensive and prospective technology assessment.

Question 17 is heavily biased towards the perspective of stakeholders interested in marketing their products. This creates the impression that regulatory measures are being included in new legislation in order to facilitate the uptake of these technologies by small and medium-sized enterprises.

Testbiotech does not share this view. Whatever the case, the idea of facilitating access could only be discussed after a comprehensive technology assessment. We should be aware that NGT cannot be regarded as a transformation technology in the same was as renewable energy which is necessary to shut down energy production from fossil fuels. There is no basis for proposing that NGT should widely replace traditional breeding. Currently, it is not possible to predict the extent, the purpose, in which circumstances or for what outcomes NGT could be applied in plant production. There are some interesting examples for proof of concept and a lot of (often questionable) promises, but no criteria on how to identify real needs, 'true' benefits or potentially disruptive effects on the economy and/or ecology. Therefore, without comprehensive TA, this question is misleading. In this context, it is important to emphasize that risk assessment (of the single events) and TA (the systemic effects of food production systems) are organised in separated regulations and should not be confused with each other.

Question 18 provides a limited amount of opportunity to raise any additional points or provide further information and evidence. In this context, Testbiotech again wants to emphasize the general need for a prospective technology assessment, which is a topic that is not addressed at all in the EU Commission consultation:

Due to the intended or unintended effects arising from NGT processes, the release of NGT organisms may not be ‘neutral’ to the functioning of ecosystems. Therefore, if NGT plants or other NGT organisms are released into the environment, their potentially negative impact needs to be minimized. However, the potentially negative impact might be dependent on the scale of the release, e.g. the number of NGT organisms, the different traits and species. Political decision-making should, therefore, not only consider the risks associated with single NGT organisms (events), but should also take systemic risks into account. In this context, reliable instruments and criteria are needed to distinguish traits with ‘real benefits’ from those which are just ‘empty promises’. There should also be further consideration of the possible adverse effects on socio-economic systems, such as food production and the breeding of plants and animals. Future scenarios developed within prospective technology assessment may help to define criteria for minimizing potential adverse effects and identify applications with a plausible expectation of real benefits. In addition to mandatory risk assessment, complementary prospective technology assessment should be made a priority for the political decision-makers – it should take the intended and unintended effects and potential interactions into account and include the development of robust criteria to assess potential benefits.

References

BfN, Bundesamt für Naturschutz (2022) Analyse von Nachweismethoden für genomeditierte und klassische GV-Pflanzen. BfN Schriften 622, https://www.bfn.de/publikationen/bfn-schriften/bfn-schriften-622-analyse-von-nachweismethoden-fuer-genomeditierte-und

Böschen, S., Grunwald, A., Krings, B.-J., Rösch, C. (2021) Technikfolgenabschätzung: Handbuch für Wissenschaft und Praxis. Nomos Verlagsgesellschaft mbH & Co. KG, Baden-Baden, https://doi.org/10.5771/9783748901990

Duensing, N., Sprink, T., Parrott, W.A., Fedorova, M., Lema, M.A., Wolt, J.D., Bartsch, D. (2018) Novel features and considerations for ERA and regulation of crops produced by genome editing. Front Bioeng Biotechnol, 6: 79. https://doi.org/10.3389/fbioe.2018.00079

Eckerstorfer, M.F., Grabowski, M., Lener, M., Engelhard, M., Simon, S., Dolezel, M., Heissenberger, A., Lüthi, C. (2021) Biosafety of genome editing applications in plant breeding: considerations for a focused case-specific risk assessment in the EU. BioTech, 10(3): 10. https://doi.org/10.3390/biotech10030010

EFSA (2012a) Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA J, 10(2): 2561. https://doi.org/10.2903/j.efsa.2012.2561

EFSA (2012b) Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA J, 10(10): 2943. https://doi.org/10.2903/j.efsa.2012.2943

EFSA (2014) Scientific Opinion on application (EFSA-GMO-UK-2009-76) for the placing on the market of soybean MON 87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA J, 12(5): 3644. https://doi.org/10.2903/j.efsa.2014.3644

EFSA (2020) Applicability of the EFSA Opinion on site directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis. EFSA J, 18(11): 6299. https://doi.org/10.2903/j.efsa.2020.6299

GAO, United States Government Accountability Office (2021) Technology Assessment Design Handbook. GAO-21-347G, https://www.gao.gov/products/gao-21-347g

Kawall, K. (2019) New possibilities on the horizon: genome editing makes the whole genome accessible for changes. Front Plant Sci, 10: 525. https://doi.org/10.3389/fpls.2019.00525

Kawall, K. (2021a) Genome-edited Camelina sativa with a unique fatty acid content and its potential impact on ecosystems. Environ Sci Eur, 33(1): 1-12. https://doi.org/10.1186/s12302-021-00482-2

Kawall, K. (2021b) The generic risks and the potential of SDN-1 applications in crop plants. Plants, 10(11): 2259. https://doi.org/10.3390/plants10112259

Kawall, K., Cotter, J., Then, C. (2020) Broadening the EU GMO risk assessment in the EU for genome editing technologies in agriculture. Environ Sci Eur, 32(1): 1-24. https://doi.org/10.1186/s12302-020-00361-2

Liebert, W., & Schmidt, J.C. (2015). Demands and challenges of a prospective technology assessment. In: J. Hahn, L. Hebáková, T. Michalek, C. Scherz, & S. Seitz (Eds.) The Next Horizon of Technology Assessment (pp. 331–340). Technology Centre ASCR. http://www.risk.boku.ac.at/download/pub/2015/Demands_and_Challenges_ProTA.pdf

Nonaka, S., Arai, C., Takayama, M., Matsukura, C., Ezura, H. (2017) Efficient increase of ɣ-aminobutyric acid (GABA) content in tomato fruits by targeted mutagenesis. Sci Rep, 7: 7057. https://doi.org/10.1038/s41598-017-06400-y

Then, C., Kawall, K., Valenzuela, N. (2020) Spatio-temporal controllability and environmental risk assessment of genetically engineered gene drive organisms from the perspective of EU GMO Regulation. Integr Environ Assess Manag, 16(5): 555-568. https://doi.org/10.1002/ieam.4278

Testbiotech (2019a) Am I Regulated? The US example: why new methods of genetically engineering crop plants need to be regulated, https://www.testbiotech.org/node/2345

Testbiotech (2019b) Differences between conventional breeding and genetic engineering: An assessment of the statement made by the Group of Chief Scientific Advisors' (SAM). Testbiotech Background 04 - 12 - 2019, www.testbiotech.org/node/2452

Testbiotech (2020a) Overview of genome editing applications using SDN-1 and SDN-2 in regard to EU regulatory issues / New methods of genetic engineering (genome editing) and their potential impact on nature protection and the environment, www.testbiotech.org/node/2569

Testbiotech (2020b) Genetic engineering endangers the protection of species - Why the spread of genetically engineered organisms into natural populations has to be prevented, www.testbiotech.org/node/2605

Testbiotech (2020c) Why ‘New GE’ needs to be regulated Frequently Asked Questions on ‘New Genetic Engineering’ and technical backgrounds for CRISPR & Co, www.testbiotech.org/node/2659

Testbiotech (2020d) Comment on EFSA’ s draft on Synthetic Biology developments in micro-organisms, environmental risk assessment aspects (ERA), Testbiotech Background 4 - 6 - 2020, www.testbiotech.org/node/2612

Testbiotech (2021a) New GE and food plants: The disruptive impact of patents on breeders, food production and society, www.testbiotech.org/node/2772

Testbiotech (2021b) Testbiotech comment on the IUCN report “Genetic frontiers for conservation, an assessment of synthetic biology and biodiversity conservation”, www.testbiotech.org/node/2802

Testbiotech (2021c) What Members of the European Parliament should consider when discussing new genetic engineering (New GE) with STOA. Testbiotech Background 12 - 4 – 2021, www.testbiotech.org/node/2732

Testbiotech (2021d) Deregulation of New GE: Reasonable? Proportional? Critical assessment of possible changes in EU GMO law to deregulate plants derived from new genomic techniques (genome editing), Testbiotech Background 18 - 5 - 2021, www.testbiotech.org/node/2746

Testbiotech (2021e) Testbiotech analysis of the EU Commission’s Inception Impact Assessment on “Legislation for plants produced by certain new genomic techniques”, published 24 September 2021, Testbiotech Background 12 - 10 - 2021, www.testbiotech.org/node/2817

Testbiotech (2022) Testbiotech comment on EFSA’s draft updated opinion on plants developed through cisgenesis and intragenesis, Testbiotech Background 27 - 06 - 2022, www.testbiotech.org/node/2934

Testbiotech & CBAN (Canadian Biotechnology Action Network) (2022) Unintended effects caused by techniques of new genetic engineering create a new quality of hazards and risks, www.testbiotech.org/node/2901