Sunday Evening News No 333



2023-07-03 - 2023-07-09

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EU-Commission – Proposal for the regulation of plants obtained by certain new genomic techniques

European Commission - Press release: European Green Deal: more sustainable use of plant and soil natural Resources.

https://ec.europa.eu/commission/presscorner/detail/en/ip_23_3565

Commission: New techniques in biotechnology

https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

Proposal:

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_proposal.pdf

ANNEXES to the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 https://food.ec.europa.eu/system/files/2023-07/gmo biotech ngt proposal annex.pdf

Commission: New genomic techniques can help cut pesticides use or shield from celiac disease

https://knowledge4policy.ec.europa.eu/news/new-genomic-techniques-can-help-cut-pesticides-use-shield-celiac-disease_en

Sanchez Fernandez, B., Barro, F., Smulders, M.J., Gilissen, L.J. and Rodriguez Cerezo, E., **Socioeconomic impact of low-gluten celiac-safe wheat developed by gene editing**, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/280847, JRC131711.

Advances in biotechnology over the last decades have led to the development of new genomic techniques (NGTs). In 2021, the "Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16" was published as requested by the Council of the European Union (Council Decision (EU) 2019/1904). The study defined NGTs as techniques which are able to alter the genetic material of an organism and which have been developed after the adoption of the current EU legislation on genetically modified organisms (EU Directive 2001/18/EC). In addition last year, the Joint Research Centre of the European Commission published two reports on the technological state-of-the-art and on current and future market applications of NGTs (Broothaerts et al., 2021; C. Parisi & Rodriguez-Cerezo, 2021).

This report presents the case study of a product developed with a NGT - CRISPR/Cas targeted mutations – namely the low-gluten celiac-safe wheat. Here, a detailed description of the gene-edited low-gluten celiac-safe wheat products currently under development in the EU is provided. Furthermore, we illustrate the potential contribution this product would make to ensure food security, nutrition and public health if it were approved for cultivation and marketing in the EU. This report is drafted to support the impact assessment accompanying the Commission proposal on Legislation for plants produced by certain new genomic techniques. https://publications.jrc.ec.europa.eu/repository/handle/JRC131711

Schneider, K., Barreiro Hurle, J., Kessel, G., Schouten, H., Vossen, J., Strassemeyer, J. and Rodriguez Cerezo, E., **Economic and environmental impacts of disease resistant crops developed with cisgenesis,** Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/715646, JRC131721.

In the recent Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 regarding the Status of New Genomic Techniques (NGTs) under Union Law, the European Commission defines NGTs as techniques which are able to alter the genetic material of an organism, developed after the publication of the EU Directive 2001/18/EC (European Commission, 2021). Last year, the Joint Research Centre of the European Commission published two reports on the technological stateof-the-art and on current and future market applications of NGTs (Broothaerts et al., 2021; C. Parisi & Rodriguez-Cerezo, 2021). Here, we present two case studies on crops with improved biotic resistances which were developed with a NGT. Namely, cisgenic potatoes with resistance to Phytophthora infestans and cisgenic apples with resistance to Venturia inaequalis. We will discuss the potential advantages of cisgenesis in tackling challenges breeders

currently face in the development of varieties with improved biotic resistances, and assess potential impacts that these varieties could have for the European agri-food system. https://publications.jrc.ec.europa.eu/repository/handle/JRC131721

Press Releases - Media / Presse- und Medienberichte

Bachmair A.: **Zwei verbreitete Missverständnisse über Gentechnik bei Pflanzen** <u>https://www.derstandard.de/story/300000177842/zwei-verbreitete-missverstaendnisse-ueber-gentechnik-bei-pflanzen</u>

Aigner F.: Gentechnik: Am Thema vorbeigestritten

https://futurezone.at/meinung/wissenschaft-florian-aigner-gentechnik-landwirtschaft-eu-crispr-pflanzenverbot/402512416

Ludwig W.: "Wir müssen auf die Wissenschaft hören"

https://www.stuttgarter-zeitung.de/inhalt.interview-zur-gentechnik-wir-muessen-auf-die-wissenschafthoeren.732703a5-f826-41b0-a1ec-01d4c5b0c5d2.html

Gerster L. und Heinemann P.: Die ewige Angst vor dem Monstermais <u>https://www.faz.net/aktuell/politik/inland/welternaehrung-warum-die-gruenen-gegen-gentechnik-sind-19018753-p3.html</u>

BMBF: Stark-Watzinger: Die Neuen Züchtungstechniken sind der Schlüssel für die großen Herausforderungen der Menschheit

https://www.bmbf.de/bmbf/shareddocs/kurzmeldungen/de/2023/07/230705-nzt.html

Wirtschaftsministerium Rheinland-Pfalz: Schmitt begrüßt Vorschlag der EU-Kommission zu Gentechnik

https://mwvlw.rlp.de/presse/detail/schmitt-begruesst-vorschlag-der-eu-kommission-zu-gentechnik

BMUV: Bundesumweltministerin Steffi Lemke zu den Plänen der EU-Kommission zur Neuen Gentechnik

https://www.bmuv.de/meldung/bundesumweltministerin-steffi-lemke-zu-den-plaenen-der-eukommission-zur-neuen-gentechnik

BMEL: Özdemir zu Gentechnik: Koexistenz und Patentfreiheit müssen gewährleistet sein https://www.bmel.de/SharedDocs/Pressemitteilungen/DE/2023/095-gentechnik.html

vzbv: Gentechnik: Gesetzesvorschlag zu neuen Gentechnik-Pflanzen inakzeptabel https://www.vzbv.de/pressemitteilungen/gentechnik-gesetzesvorschlag-zu-neuen-gentechnikpflanzen-inakzeptabel

VLOG: Gentechnik-Pläne: "EU-Kommission schickt sich an, nachhaltige Unternehmenswerte zu vernichten"

https://www.ohnegentechnik.org/artikel/gentechnik-entwurf-eu-kom

AFBV-WGG press release: AFBV and WGG welcome EU proposals for the regulation of NGTs as a step in the right direction

https://www.wgg-ev.de/info/genome-editing/afbv-wgg-presse-release-on-proposal-for-ngt-plants/

Stokstad E.: European Commission proposes loosening rules for gene-edited plants <u>https://www.science.org/content/article/european-commission-proposes-loosening-rules-gene-edited-plants?utm_source=sfmc&utm_medium=email&utm_campaign=WeeklyLatestNews&utm_content=alert&et_ri d=17035139&et_cid=4805948</u>

Haerlin B.: **New Genetic Engineering – Small Cause, Big Effect** https://www.arc2020.eu/new-genetic-engineering-small-cause-big-effect/

IFOAM Organics Europe: NGT proposal a step backward for biosafety, freedom of choice and consumers' inform

https://www.bioecoactual.com/en/2023/07/06/ngt-proposal-a-step-backward-for-biosafety-freedom-of-choiceand-consumers-information/

GM Watch: The EU's dangerous climbdown over Frankenfoods

https://gmwatch.org/en/

Only some selected press releases or media reports are listed here. The daily up-date of the press releases and media reports are here: June week 27 (in particular to the commission proposal)

Publications – Publikationen

Jones N. (2023): The new proteins coming to your plates Protein made in labs and factories could increasingly form a part of our diets. Contenders include insect powder and proteins spat out by bacteria. https://www.nature.com/articles/d41586-023-02096-5

Guo, Y., Zhao, G., Gao, X. et al. (2023): CRISPR/Cas9 gene editing technology: a precise and efficient tool for crop guality improvement. Planta 258, 36

https://doi.org/10.1007/s00425-023-04187-z

Main conclusion: This review provides a direction for crop guality improvement and ideas for further research on the application of CRISPR/Cas9 gene editing technology for crop improvement.

Abstract: Various important crops, such as wheat, rice, soybean and tomato, are among the main sources of food and energy for humans. Breeders have long attempted to improve crop yield and quality through traditional breeding methods such as crossbreeding. However, crop breeding progress has been slow due to the limitations of traditional breeding methods. In recent years, clustered regularly spaced short palindromic repeat (CRISPR)/Cas9 gene editing technology has been continuously developed. And with the refinement of crop genome data, CRISPR/Cas9 technology has enabled significant breakthroughs in editing specific genes of crops due to its accuracy and efficiency. Precise editing of certain key genes in crops by means of CRISPR/Cas9 technology has improved crop quality and yield and has become a popular strategy for many breeders to focus on and adopt. In this paper, the present status and achievements of CRISPR/Cas9 gene technology as applied to the improvement of quality in several crops are reviewed. In addition, the shortcomings, challenges and development prospects of CRISPR/Cas9 gene editing technology are discussed. https://link.springer.com/article/10.1007/s00425-023-04187-z

Campa M., Miranda S., Licciardello C., Lashbrooke J.G. et al.: (2023): Application of new breeding techniques in fruit trees. Plant Physiology, kiad374,

https://doi.org/10.1093/plphys/kiad374

Climate change and rapid adaption of invasive pathogens pose a constant pressure on fruit industry to develop improved varieties. Aiming to accelerate the development of better adapted cultivars, new breeding techniques have emerged as a promising alternative to meet the demand of a growing global population. Accelerated breeding, cisgenesis and CRISPR/Cas genome editing hold significant potential for crop trait improvement, which have proven to be useful in several plant species. This review focuses on the successful application of these technologies in fruit trees to confer pathogen resistance, tolerance to abiotic stress, and to improve quality traits. In addition, we review the optimization and diversification of CRISPR/Cas genome editing tools applied to fruit trees, such as multiplexing, CRISPR/Cas-mediated base editing and site-specific recombination systems. Advances in protoplast regeneration and delivery techniques, including the use of nanoparticles and viral-derived replicons, are described for the obtention of exogenous DNA-free fruit tree species. Regulatory landscape and broader social acceptability for cisgenesis and CRISPR/Cas genome editing are also discussed. Altogether, this review provides an overview of the versatility of applications for fruit crop improvement, as well as current challenges that deserve attention for further optimization and potential implementation of new breeding techniques.

https://academic.oup.com/plphys/advance-article/doi/10.1093/plphys/kiad374/7216940?login=false

Farhad Md, Kumar U., Tomar V., Bhati B.K. et al. (2023): Heat stress in wheat: a global challenge to feed billions in the current era of the changing climate. Front. Sustain. Food Syst. - Volume 7 - 2023 | https://doi.org/10.3389/fsufs.2023.1203721

Crop failure is largely caused by various climate hazards, and among them, heat stress is the primary factor hindering crop production. The significant global loss of crop yield is primarily due to heat-related damage during the reproductive phase. Terminal heat stress has been well documented in wheat, causing morphophysiological alterations, biochemical disruptions, and reduction of genetic potential. The formation of shoots and roots, the effect on the double ridge stage, and early biomass in the vegetative stage are also impacted by heat stress. The final negative outcomes of heat stress include reduced grain number and weight, slower grain filling rate, reduced grain quality, and shorter grain filling duration. Plants have developed mechanisms to adapt to heat stress through modifications in their morphological or growth responses, physiological and biochemical pathways, and changes in enzyme reactions. Numerous heat tolerance genes have been identified in wheat, but the more extensive study is needed to increase heat tolerance in crops to satisfy the food demands of the world's growing population. The global food policy needs to prioritize and promote additional joint research and the development of heat-tolerant wheat breeding to ensure the world's food security.

https://www.frontiersin.org/articles/10.3389/fsufs.2023.1203721/full

Liu Xiao-Jing, Xing Bao, Wang Meng-Yu, Li Xiao-Man, Wang Xu-Jing & Wang Zhi-Xing (2023 : Transcriptional and proteomic analysis, GM Crops & Food, 14:1, 1-16, |

10.1080/21645698.2023.2229927

Unintended effects of gene edit crops may pose safety issues. Omics is a useful tool for researchers to evaluate these unexpected effects. Transcriptome and proteomics analyses were performed for two gene editors, CRISPR-Cas9 and adenine base editor (ABE) gene edit rice, as well as corresponding wild-type plants (Nipponbare). Transcriptome revealed 520 and 566 rice differentially expressed genes (DEGs) in the Cas9/Nip and ABE/Nip comparisons, respectively. Kyoto Encyclopedia of Genes and Genomes (KEGG) pathway enrichment analysis showed that most DEGs participated in metabolism of terpenoids and polyketones, plant–pathogen interactions, and plant signal transduction. It mainly belongs to environmental adaptation. Proteomics revealed 298 and 54 rice differentially expressed proteins (DEPs) in the Cas9/Nip and ABE/Nip comparisons, respectively. KEGG pathway enrichment analysis showed that most DEPs participated in the biosynthesis of secondary metabolite and metabolic pathways.

According to integrated transcriptomes and proteomics analysis, the results showed that no newly generated genes were identified as new transcripts of these differentially expressed genes, and gene edit tools had little effect on rice transcription levels and no new proteins were generated in the gene-edited rice. https://www.tandfonline.com/doi/full/10.1080/21645698.2023.2229927

Suh, SM., Kim, HJ., Shin, MK. et al. (2023): **Multiplex PCR detection method of genetically modified canola event (MON94100, LBFLFK, and NS-B50027-4) combined with capillary electrophoresis**. Food Sci Biotechnol | https://doi.org/10.1007/s10068-023-01377-z

Genetically modified organisms (GMOs) have been continuously developed for their convenience and productivity. In the past three years, three new GM canola events (MON94100, LBFLFK, and NS-B50027-4) have been developed. To efficiently control these GM canola events, the detection methods were needed. Therefore, the multiplex PCR method combined with capillary electrophoresis was developed for three GM canola events. Ten GM canola, eighteen GM soybean, thirty-two GM maize, and ten non-GM crops were used to evaluate the specificity of the method. The detection limit of the multiplex PCR assay was determined to be 0.005 ng in the DNA mixture and 0.1% in the spiked sample. The aim of this study was to establish multiplex PCR coupled with capillary electrophoresis for the newly produced three GM canola events. The developed method is expected to contribute to monitor the commercially available GM canola events. https://link.springer.com/article/10.1007/s10068-023-01377-z

Kusmec A, Attigala L, Dai X, Srinivasan S, Yeh C-T", Schnable PS (2023): A genetic tradeoff for tolerance to moderate and severe heat stress in US hybrid maize. PLoS Genet 19 (7): e1010799. https://doi.org/10.1371/journal.pgen.1010799

Global climate change is increasing both average temperatures and the frequencies of extreme high temperatures. Past studies have documented a strong negative effect of exposures to temperatures >30°C on hybrid maize yields. However, these studies could not disentangle genetic adaptation via artificial selection from changes in agronomic practices. Because most of the earliest maize hybrids are no longer available, side-by-side comparisons with modern hybrids under current field conditions are generally impossible. Here, we report on the collection and curation of 81 years of public yield trial records covering 4,730 maize hybrids, which enabled us to model genetic variation for temperature responses among maize hybrids. We show that selection may have indirectly and inconsistently contributed to the genetic adaptation of maize to moderate heat stress over this time period while preserving genetic variance for continued adaptation. However, our results reveal the existence of a genetic tradeoff for tolerance to moderate and severe heat stress, leading to a decrease in tolerance to severe heat stress over the same time period. Both trends are particularly conspicuous since the mid-1970s. Such a tradeoff poses challenges to the continued adaptation of maize to warming climates due to a projected increase in the frequency of extreme heat events. Nevertheless, given recent advances in phenomics, enviromics, and physiological modeling, our results offer a degree of optimism for the capacity of plant breeders to adapt maize to warming climates, assuming appropriate levels of R&D investment. https://journals.plos.org/plosgenetics/article?id=10.1371/journal.pgen.1010799

Jacobs, D.F., Dumroese, R.K., Brennan, A.N. et al. (2023): **Reintroduction of at-risk forest tree species using biotechnology depends on regulatory policy, informed by science and with public support.** New Forests 54, 587–604 | https://doi.org/10.1007/s11056-023-09980-y

Introduced pests (insects and pathogens) have rapidly increased the numbers of at-risk native forest tree species worldwide. Some keystone species have been functionally extirpated, resulting in severe commercial and ecological losses. When efforts to exclude or mitigate pests have failed, researchers have sometimes applied biotechnology tools to incorporate pest resistance in at-risk species to enable their reintroduction. Often erroneously equated solely with genetic engineering, biotechnology also includes traditional and genome informed breeding—and may provide a holistic approach toward applying genomic-based information and interventions to increase tree species' pest resistance. Traditional tree breeding is responsible for successes to date, but new technologies offer hope to increase the efficiency of such efforts. Remarkable recent progress has been made, and for some at-risk species, novel biotechnological advances put reintroduction within reach. The high costs of reintroduction of at-risk species at necessary scale, however, will initially limit the pursuit to a few species. Successful deployment of pest resistant material may require improved species-specific knowledge and should integrate into and leverage existing reforestation systems, but these operations are sometimes rare where pest threats are greatest. While use of some biotechnologies, such as traditional tree breeding, are commonplace, others such as genetic engineering are controversial and highly regulated, yet may be the only viable means of achieving reintroduction of some at-risk species. Efforts to modify policy toward allowing the use of appropriate biotechnology, especially genetic engineering, have lagged. Provided that risk-benefits are favorable, policy is likely to follow with public opinion; in some countries, society is now increasingly open to using available biotechnologies. Continued engagement using the most recent advances in social science to build public trust, combined with a science-based collaboration among land managers and regulators, will generate the collective momentum needed to motivate policymakers to act rapidly given the speed at which forest health threats unfold and the large areas they affect. https://link.springer.com/article/10.1007/s11056-023-09980-y

Special for Germany: ZKBS - members /ZKBS - Mitglieder

https://www.zkbs-online.de/ZKBS/SharedDocs/00 Fachmeldungen/2023/2023 07 04 Fa ZKBS 249.html

Developments in OECD Delegations on:

- Biosafety Issues, June 2022 April 2023: https://lnkd.in/eKRKQ8N8
- Novel Food & Feed Safety issues, June 2022 April 2023: https://lnkd.in/e6uu66Qr

Biotech-Update, June 2023: Newsletter presenting the OECD activities on biotechnology and life-science, Who is doing What? https://lnkd.in/eqTbfYrv

EFSA

Glyphosat: keine kritischen Problembereiche, aber Datenlücken festgestellt https://www.efsa.europa.eu/de/news/glyphosate-no-critical-areas-concern-data-gaps-identified

Allergencity:

Mills, ENC, Nitride, C, Pilolli, R, French, C, Javed et al. (2023): **Detection and quantification of allergens in foods and minimum eliciting doses in food-allergic individuals (ThRAII).** EFSA supporting publication 2023: 20 (7):EN-8059. 56 pp. doi:<u>10.2903/sp.efsa.2023.EN-8059</u> <u>https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2023.EN-8059</u>

Doytchinova I, Dimitrov I and Atanasova M. (2023): **PreDQ – a software tool for peptide binding prediction to HLA-DQ2 and HLA-DQ8.** EFSA supporting publication:EN-8108. 19 pp. doi:10.2903/sp.efsa.2023.EN-8108. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2013.EN-8108

Enzymes:

CEP Panel (2023): Scientific Opinion on the safety evaluation of the food enzyme triacylglycerol lipase from the genetically modified *Saccharomyces cerevisiae* strain LALL-LI. EFSA Journal 21 (7):8091, 13 pp. <u>https://doi.org/10.2903/j.efsa.2023.8091</u> <u>https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8091</u>

CEP Panel (2023): Scientific Opinion on the safety evaluation of the food enzyme glucan-1,4α-maltohydrolase from the genetically modified *Bacillus subtilis* strain AR-453. *EFSA Journal* 2023; 21(7):8089, 14 pp. <u>https://doi.org/10.2903/j.efsa.2023.8089</u> <u>https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8089</u>

 Wie immer wird für Hinweise und der Zusendung von Publikationen und sonstigen Informationen gedankt. pdf-Dateien können meist direkt aus den links heruntergeladen werden.
As always, I thank you all for hints and for publications. Most of the pdf files can be downloaded directly from the links.
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