Van: 10.2.e
Aan: 10.2.e
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Onderwerp: Kamerbrief over precisielandbouw, nieuwe veredelingstechnieken en innovatie
Datum: maandag 11 mei 2020 12:33:40
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Beste 10.2.e
Hoop dat het jou en jouw dierbaren gelukt is om de COVID pandemie in goede gezondheid te doorstaan.
Vorige maand spraken we elkaar over de Kamerbrief m.b.t. precisielandbouw, nieuwe veredelingstechnieken en innovatie die minister Schouten bij het AO Landbouw, Klimaat & Voedsel (in reactie op een verzoek van 10.2.e) de Kamer **vóór 1 mei a.s.** had toegezegd.
Vooralsnog heb ik deze brief nog niet zien passeren.
COVID en enkele andere politiek zware landbouwdossiers hebben wellicht voor vertraging gezorgd. Zou je mij een globale indicatie kunnen geven wanneer jij verwacht dat de “NBT brief” daadwerkelijk naar de Tweede Kamer wordt gezonden?
Met vriendelijke groet,

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Van: 10.2.e
Aan: 10.2.e
Cc: 10.2.e
Onderwerp: RE: Kamerbrief over precisielandbouw, nieuwe veredelingstechnieken en innovatie
Datum: maandag 18 mei 2020 10:44:11
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Beste 10.2.e,
Hier alles OK, qua werken niet ideaal (thuis en tel / video confs) maar we moeten het er maar even mee doen.
Dank voor bericht. Erg benieuwd of de NBTs / gene editing deze week door de COM nog (stevig) zullen worden meegenomen in haar finale F2F-document.
Met vriendelijke groet,
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Van: 10.2.e
Verzonden: maandag 18 mei 2020 10:29
Aan: 10.2.e
CC: 10.2.e
Onderwerp: RE: Kamerbrief over precisielandbouw, nieuwe veredelingstechnieken en innovatie

Beste 10.2.e
Dank voor je bericht. Ik hoop dat alles goed met jou en je familie en vrienden gaat.
Als het goed is zal de Kamerbrief deze week worden verzonden. Het NBT onderdeel zal niet veel nieuws bevatten, eerder een vermelding van de tot nu toe genomen stappen en resultaten van het EU traject.
Gr,

10.2.e
Senior beleidsmedewerker biotechnologie
EU-coördinator PAV
……
Directie Plantaardige Agroketens en Voedselkwaliteit
Ministerie van Landbouw, Natuur en Voedselkwaliteit
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Aanwezig ma t/m vrijdag

Van: 10.2.e
Verzonden: maandag 11 mei 2020 12:34
Aan: 10.2.e @minlnv.nl>
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Onderwerp: Kamerbrief over precisielandbouw, nieuwe veredelingstechnieken en innovatie

Beste 10.2.e
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Statement

On the EC study on New Genomic Techniques (NGTs)

Brussels, 27.5.2020

Summary

The European Plant Science Organisation (EPSO) welcomes the ongoing European Commission (EC) study on new genomic techniques (NGTs). These are defined as techniques capable of changing the genetic material of an organism, which have emerged or have been developed since 2001. In this statement, EPSO refers specifically to genome editing leading via mutagenesis (point mutations or other modifications existing in nature) in plants and products obtained thereby.

EPSO members remarked that the implementation of **GMO legislation with regard to NGTs** did not cause any major technical obstacles, but represents a major administrative and financial burden, leads to increasing space constraints in GMO facilities, drastically reduces the number of field experiments, causes problems with the status of incoming germplasm, and has a negative impact on funding and on bringing products to the market.

Despite these constraints, fundamental and applied **research on NGTs** and **NGT products** is still blooming in Europe and concerns over 50 plant species. Although the ECJ ruling of 2018 led to widespread demotivation and reduced funding, efforts continue to increase the range of species and of genotypes in which NGTs can be applied, to further enrich the binding and/or cutting features of Cas9-like enzymes, and to generate the knowledge needed to improve traits by NGTs. A research gap exists in the comparison of NGTs to older techniques with a history of safe use.

NGTs and **NGT products** present numerous **benefits and opportunities** since they are a tool of choice to address major challenges to agriculture in Europe and worldwide, such as the overuse of pesticides and inputs, climate change, crop monocultures, and the desire for improved food and feed. NGTs can contribute to meeting and managing these challenges by enhancing genetic progress towards more diverse, better adapted, and yet high-yielding plant varieties.

EPSO did not note any specific **concerns on NGTs** or **NGT products** but identified obvious **challenges**. The detection of NGTs in foreign germplasm and products is not feasible, SMEs are not able to play a notable role due to the high cost of licence fees and of regulatory approval, and patents on NGTs and NGT traits raise questions on access to NGT technology and its coexistence with plant variety rights. **Safety concerns** should not differ from those relevant to plants obtained using methods with a history of safe use, because NGT mutations could also arise in nature or during conventional breeding programs. Off-target events can easily be reduced to a level similar to that of

spontaneous mutations occurring during natural plant reproduction in conventional breeding.

The real question on **ethical aspects** is not whether NGTs or NGT products as such are acceptable, but whether the use we make of them supports commonly accepted values and avoids harm to humans and the environment. It would be ethically problematic to reject NGTs having beneficial traits, provided they are not considered to pose a higher risk to humans or the environment than similar varieties developed by conventional methods.

With regard to **consumers' right for information** and **freedom of choice**, EPSO is opposed to obligatory labelling because it implies that NGT products as such are harmful or problematic, could not be enforced, and would lead to both labelling and non-labelling of identical products. Voluntary labelling has the advantage of giving voice to different types of values, maintaining information levels equal to all actors, and taking into account various lifestyle choices.

NGTs and NGT-products have a role to play in the European **Farm-to-Fork** strategy by ensuring sustainable food production and the shift to healthy, sustainable diets, for example through disease resistant crops, reducing pesticide use, and allergen-free food that promotes human health. They can also contribute to implement the European **Biodiversity** strategy by improving the performance and nutritional content of underutilised fruit, vegetable and cereal crops and thereby substantially increase diversity of cultivated crops.

Context

Upon request by the Council of the European Union, the European Commission (DG Health and Food Safety) is presently carrying out a study on new genomic techniques (NGTs), which will have to be delivered by 30 April 2021. This study regarding the status of NGTs (= techniques capable to change the genetic material of an organism and that have emerged or have been developed since 2001) under Union law will be crucial for the future of genome editing in Europe. It will have to (i) draw a picture of the status of NGTs after the Court of Justice's judgment in case C-528/16 and (ii) come up with a proposal, if appropriate in view of the outcomes of the study[1]. One of many possible outcomes would be a proposal to alleviate the present legislation on certain genome editing techniques.

In the framework of this study, the European Commission carried out targeted consultations with Member States and EU-level stakeholders (including EPSO) to gather information on different aspects of NGTs. The EPSO contribution[2] to the 7 themes has been submitted on 13 May 2020 and is summarized hereafter. In this statement, the terms NGTs and NGT-products are limited to plants and derived food and feed products obtained by genome editing leading to mutagenesis (point mutations or other modifications existing in nature) for agri-food and industrial applications and for research, unless otherwise specified.

1-Implementation and enforcement of the GMO legislation with regard to NGTs

Public European research is very active in the NGT field to (i) enhance the efficiency and specificity of NGTs and broaden their field of application, (ii) use NGT-plants in fundamental research to decipher biological processes and (iii) develop NGT-crops with improved agricultural performance or product quality.

Due to the longstanding experience with GMO legislation, its application to NGT-plants produced by European researchers did not present major technical obstacles. However, its implementation has several drawbacks that hinder full exploitation of NGTs. They include (i) the application of GMO regulation represents an extraordinary administrative

and financial burden, (ii) the massive use of NGTs leads to increasing space constraints in facilities fulfilling GMO requirements, (iii) there is a strong reluctance to perform field trials despite a strong scientific interest to confirm results obtained in confinement under agricultural conditions, (iv) researchers used to work freely with EMS or transposon-induced mutants lack experience with GMO legislation and are bridled in their ambition and (v) in some countries the application of GMO legislation to NGT-plants had a negative impact on funding of public research in the NGT field.

With regard to incoming NGT-plants or NGT-products, GMO legislation can readily be applied if the genome modifications are known, which is the case, for example, in international scientific collaborations. However, in the absence of prior knowledge on the potential genome alterations their detection and identification does not seem to be feasible by PCR-based detection methods[3]. Often suggested as the ultimate tool, whole genome DNA sequencing actually allows under certain conditions the near-exhaustive detection of unknown DNA modifications in a plant genome. However, the detection of a sequence alteration does not permit the identification of the process that generated it and to decide whether GMO legislation needs to be applied or not[4]. Indeed, identical DNA alteration may be obtained by NGTs or by conventional breeding or random mutagenesis techniques, which are exempted from GMO legislation.

GMO legislation has a strong negative impact on the number of field trials involving NGT-plants carried out in Europe. The number of 5 past or present trials and 3 foreseen projects is approximately 50-fold lower than the number of research projects in confined environments. There is also a more than 10-fold difference between Europe and the rest of the world, China and the USA carrying out the vast majority of field trials[5]. This is fundamentally different from research with mutants obtained by techniques with a safe history of use, which are frequently analysed under field conditions, or research in conventional breeding, which is essentially carried out under field conditions.

2-Research on NGTs/NGT-products

Among NGTs, genome editing techniques leading to mutagenesis (point mutations or other modifications existing in nature) are the almost exclusive focus of research efforts. Since its development in the last 10-15 years, genome editing spread very quickly in all fields of plant research and is nowadays a routinely used tool in 45 plant genera belonging to 24 botanical families for plant researchers worldwide[6]. (Shan et al., 2020). In particular, CRISPR/Cas9 based applications in plant science grew exponentially since their discovery in 2012, representing 78% of the 1328 studies reported in 555 publications reviewed in 2019[7]. Among the 51 genome-edited plant species, more studies were devoted to the model species rice (35.0%), Arabidopsis (16.4%) and tobacco (8.1%) than to crops such as tomato (6.3%), maize (5.8%), wheat (4.7%) or soybean (4.0%). This reflects both the intense daily use of genome editing in fundamental research and a growing effort in applied research.

European research is still competitive with 15% of the published studies[7] and a recent survey in France documented active research on 38 species of microalgae and higher plants. Two European research programs have been funded by EU H2020 grants to apply genome editing to chicory (CHIC, 7.3 M€) and tobacco (NEWCOTIANA, 7.2 M€) for health benefits and industrial uses. In addition, there have been several major national funding initiatives providing support for research not only on models and major crops but also on minor crops with local or regional importance such as olive, apple, cherry, strawberry, basil, eggplant, artichoke or rose. The goals of the applied research programs concern (i) agronomic value characteristics such as biomass, architecture, flowering time or fruit shape, (ii) disease resistance to fungi, bacteria and viruses, (iii) resilience to abiotic stresses such as drought, high/low temperature or heavy metals and (iv) food and feed quality, for example balanced oil composition, low allergen content or enhanced vitamin content.

The 2018 ECJ ruling had a major negative impact on this flourishing research. A substantial number of European public researchers reported overall demotivation and a

direct or indirect effect on the funding of research involving NGTs or NGT-products. An example for direct effects are 5 international consortia that were declared ineligible for the SusCrop ERA-Net Cofund Action under H2020 because of planned confined NGT work. European researchers now tend to avoid participation in big collaborative applied projects that would require the intentional release of NGT-plants for proof of concept in the field. Indirect funding restrictions are caused by demotivation of industrial partners who are not interested to invest in projects without the later possibility to use the product in the EU. Even fundamental research is concerned, since research grant applications are not only judged for their scientific excellence but also their socio-economic impact, which certain reviewers now consider as not credible. Altogether, in particular applied research using NGTs is clearly handicapped in the EU compared to other countries in Asia and South- and North-America that handle NGTs more flexibly.

A number of needs and gaps were identified regarding NGT-related research. An urgent need is to increase the efficiency of transformation and regeneration to increase the range of species and of genotypes within species in which NGTs can be applied[8,9]. In addition, the number and type of addressable target sequences in a given genome needs to be enhanced, for example by further enrichment of the family of Cas9-like enzymes that possess different binding and/or cutting features (i.e. different PAM sequences)[10]. Most importantly, there is a continued need to generate the upfront knowledge necessary to improve traits by NGTs. There is also a large need to improve research/society interactions, so that research can take on board society's expectations and fears, both from technical and ethical point of views. In addition to these research needs, an identified research gap is the comparison of NGTs to older techniques with a history of safe use (e.g. chemical mutagenesis, in vitro propagation, conventional breeding) with regard to large deletions, inversions and other genome modifications. Such a comparison would undoubtedly help to put an end to current suppositions and to assess the safety of NGTs on a scientific basis.

3-Potential benefits and opportunities of NGTs/NGT-products:

NGTs are a lever to address challenges to agriculture in Europe and worldwide, such as the overuse of pesticides and inputs, climate change, crop monocultures or the desire for improved human food. NGTs can contribute to meeting and managing these challenges by enhancing genetic progress towards more diverse, better adapted and yet high yielding plant varieties[7,11,12].

To reduce pesticide use, novel disease resistance traits can be introduced into crop varieties by inactivation of susceptibility genes, activation of silent resistance genes by promoter editing or copying active alleles. To mitigate climate change impact, NGTs allow to adapt the length of the life cycle by mutations in flowering genes or to improve stress tolerance to drought, high temperature, cold, salinity, flooding by acting on transport or hormone genes[13]. To contribute to global food security, higher yields can be achieved by knocking out genes with negative effects on grain number, size, weight, panicle size or tiller number[14]. To increase cultured biodiversity the domestication of forgotten crops or wild relatives can be accelerated by the simultaneous modification of known domestication genes[15,16]. In addition to such contributions to a sustainable and yet productive agriculture, NGTs can be used to satisfy consumers' demands by alleviating health problems through knockout of allergen genes or increased contents in vitamins or other health promoting compounds[17,18]. Finally, NGT can ease the transition to a bio-sourced industry, for example by modifying starch products, and reduce pollution, for example by modifying lignocellulosic material[19].

One major advantage of NGTs in comparison to other genetic tools is to obtain a desired plant variety in a much shorter time frame. This concerns the introgression of resilience traits from wild relatives just like the breeding for elite traits in wild species with high nutritional potential, and is particularly important in breeding of perennials with generation times of several years, such as forest and fruit trees or grapevine. In addition, the replacement of recurrent backcrosses or breeding cycles by NGTs makes the

process more precise since they assure that the modifications at a genetic locus are not subject to dragging linkage to unfavorable genes. A second advantage is even more specific to NGTs, which permit to markedly improve vegetative propagated varieties, which are less or not amenable to conventional breeding, since the desired traits are linked to specific clones and generally lost during sexual crosses. Finally, NGTs allow to enlarge the available gene pool beyond the species of interest by copying interesting alleles from other plant species. For example, nucleotide changes providing viral disease resistance in pepper have been successfully copied into the same gene of Arabidopsis, cucumber and tomato[20].

4-Potential challenges and concerns on NGTs/NGT-products:

EPSO feels that NGTs/NGT-products do not raise any specific concerns, since NGTs produce the same result (plant) as conventional breeding or mutation-induced breeding. If there are concerns, they should be similar to the ones for conventional breeding methods with a history of safe use and similar rules should be applied.

A first challenge concerns traceability and detection. As pointed out above, it is not feasible to detect trace amounts of unknown genome modifications and, more importantly, it is impossible to prove that the variation is synthetic and generated by NGTs and not induced/selected in natural variation. This will clearly become a challenge in the next decade for our breeding activities if NGTs are implemented without publicly available description of the modifications in some countries and not others. As we expect quite a large number of NGT-traits without the necessity to trace them back (according to the regulation in countries like China, the US or South and Latin America) the enforcement of the EU regulation will be a big challenge.

A second challenge concerns SMEs, despite the fact that the development of NGTs has been marked by a strong involvement of SMEs, which are also very present in the development of NGT-products. This potential is threatened by the cost of licence fees to access the technology and the cost of regulatory approval in the countries where NGT-products fall under GMO legislation. Whereas a look at the history of licensing patents on earlier foundational technologies such as recombinant DNA, small interfering RNA and PCR suggests that there is room for hope of reasonable arrangements on the licence issue, the cost of regulatory approval and stewardship presents an almost insurmountable financial effort for SMEs/small scale operators. Obligatory labelling of NGT-products would be an additional burden for efficient marketing. Although SMEs have been shown to quickly surpass multinational companies in the number of applications for NGT development in Argentina, where NGTs and NGT-products are exempted from GMO legislation[21], the scenario in Europe is likely to be the opposite. Present GMO legislation of NGT-products therefore deprives such consumers and bio-industries from the benefits of NGT-products.

A last challenge to a large and rapid application of NGTs are patents. Firstly, NGTs are patented and access to the technology at reasonable conditions is a challenge for EPSO members, as soon as they go beyond basic research and wish to provide services or to translate academic research into new plant varieties. The patent situation is further complicated by the arrival of new variants of genome editing technology not covered by the current licence package proposed for CRISPR/Cas9 applications in agriculture. In any case, EPSO considers that the general benefits for society resulting from NGT-use need to be considered by patent holders in licence negotiations. Secondly, traits present in NGT-plants can also be patented in Europe. Although mechanisms exist to deal with the coexistence of patent and plant variety rights, they may be difficult to handle at a large scale and the infringement difficult to prove. Systematic patenting, especially in minor crops, would likely be counterproductive to rapid and widespread use of the benefits of NGT-products. In conclusion, most EPSO members prefer a simple protection by plant variety rights as for natural mutants and conventional products, but remain open to parsimonious patenting of NGT-traits, keeping in mind the widespread use of patenting in other parts of the world.

5-Safety of NGTs/NGT-products:

When NGTs are used to introduce mutations that could also arise in nature or during conventional breeding programs, safety concerns should not differ from those which apply to plants obtained using methods that have a history of safe use[22,23].

While it is clear that any new trait can have some associated risk, any trait depends on the presence of specific sequences, or on epigenetic changes. Thus, if the range of variation obtained by a specific NGT is the same as the one potentially obtainable using traditional techniques, that specific NGT is not expected to lead to the introduction of phenotypes associated with additional risks.

Off-target effects are frequently cited as an argument to question the safety of NGTs/NGT-products. Intended off-target events can easily be avoided by state-of-the art design of genome editing tools if the genome sequence to be modified is available, either by excluding such sites from the design or by checking for absence of modifications at the expected off-target sites. With regard to unintended off-target effects, there is consensus among plant scientists that there is no evidence for bona fide off-target mutations even in the case of continued expression of Cas9 or Cpf1[24].Thus, off-target events can be drastically reduced to a level similar to that of spontaneous mutations occurring during natural plant reproduction in conventional breeding.

6-Ethical aspects of NGTs/NGT-products:

Questions related to food production have a profound ethical basis related to the right to food as an essential component to the right to life and dignity. The goals of food security, food safety and sustainability are first priorities and guiding principles to which any technology in agriculture must adhere[25]. NGTs, as any other technology, may be useful to achieve "Zero hunger" and other Sustainable Development Goals of the Unites Nations. In this sense the ethical question of a proportionate risk assessment may be balanced by the risk of refusing to apply promising new developments.

The Danish Council on Ethics replies to the question of whether it is ethical to withhold the benefits of a technology from the European farmer, consumer and citizen, that it would be ethically problematic to reject NGTs with beneficial traits provided they are not assessed as posing a higher risk to humans or the environment than similar varieties developed by conventional methods[26].

With regard to ethical concerns raised about GM crops and extended to NGTs, EPSO considers that (i) there is no specific potential harm to human health since NGT-plants are indistinguishable from mutants obtained by methods considered to have a safe history of use and are produced by methods that are less invasive than classical transgenesis shown to have no negative impact on mammalian health[27,28], (ii) there is no intrinsic potential damage to the environment, since NGT-plants are indistinguishable from "natural" mutants and therefore should not be subject to specific evaluations beyond the UPOV certification of conventional varieties, (iii) there is no technical reason that would prevent NGT-crops to be cultured in traditional or non-conventional farming systems[29], (iv) there is no technical barrier hindering the democratisation of NGTs and high potential to avoid excessive corporate dominance, as demonstrated by the predominant implication of SMEs and public actors in Argentina over the last 4 years[21] and (v) there is a sharp contrast between the alleged unnaturalness of NGT-crops and scientific data showing that major genome rearrangements are part of an ongoing evolutionary process[30], that not only sequence polymorphisms but also structural differences (large deletions, insertions and inversions) exist naturally between crop varieties of the same species[31], and that horizontal gene transfer between species concerns "natural" crop varieties[32].

Ethics generally relate more to the application of a technology rather than to its nature[33]. The real question is not whether genome editing as such is acceptable, but whether the use we make of it supports commonly admitted values and avoids harm to humans and the environment. Another important consideration is that many of the plant varieties

obtained by NGTs are not different from identical products obtained by techniques with a history of safe use. Whereas there are ideological arguments to reject them due to their origin, there is no factual basis allowing specific regulations to discriminate between them.

7-Consumers' right for information/freedom of choice:

Consumers need to be informed in order to be able to exercise their freedom of choice and labelling is one of the possibilities to provide this information. According to our members, labelling of NGT-products should not be obligatory as it is presently the case for GMO products, but voluntary labelling may be envisaged, both in a negative (NGT-free) and positive fashion (benefits of NGT-products). A major pitfall of labelling is the technical inability to discriminate NGT-products from conventional products, which is indispensable for the enforcement of any labelling rules.

EPSO is opposed to obligatory labelling because (i) it may give the wrongful impression that public authorities consider NGT-products as such to be harmful or problematic (ii) it is dependent on traceability, which is not feasible for NGT-products if the modifier construct is not present in the final product, (iii) it is delicate in the present international context where consumers would have difficulties to understand that food made with NGT-products is labelled as GM if the products were harvested in Europe and not at all labelled if the products were imported from many other countries and (iv) it refuses equal treatment since similar or even identical products that have been obtained with technologies with a history of safe use can be marketed without labelling.

Voluntary labelling has the advantage to give voice to different types of values, to maintain information levels equal to all actors and to take into account various lifestyle choices. It allows to mention not only the possibility to exit (for example NGT free) but also to underpin proven benefits (for example produced without pesticides). In fact, in order to offer a true choice to consumers, the information content of a potential NGT label has to exceed the fact of the mere use of the technology in the production process[34].

Conclusion

NGTs are one of the building stones needed to assure the success of the ambition announced by the European Commission in the European Green Deal and which will mobilize research and foster innovation. Two examples are pest-resistant NGT-plants allowing to achieve the zero pollution ambition for a toxic-free environment and allergen-free or bio-fortified NGT-products realising the "From Farm-to-Fork" concept for a fair, healthy and environmentally-friendly food system.

NGTs and NGT products can help implement the “European Biodiversity strategy for 2030” by improving underutilised fruit and vegetable crops and cereals, which are often nutritious but need breeding to improve their economic performance and possibly further improve their nutritional content. Such underutilised crops often did not benefit from critical-mass breeding efforts in the past, due to their poor market share compared to the time and effort needed to improve them with classical technologies. NGTs, under improved legislation, could be used to improve underutilised crops and thereby substantially increase the diversity of cultivated crops as a whole, a main target of the biodiversity strategy. Finally, the application of NGTs to neglected species will help to explore biodiversity by revealing metabolic pathways of a large variety of bioactive secondary metabolites, which are often no longer present in main crops.

This statement summarises EPSO’s submission to the EC study on NGTs. The submission was developed by the EPSO Agricultural Technology Working Group led by 10.2.e *with input from and approved by the EPSO Representatives and Board.*

References

[1] EC study on new genomic techniques (NGTs) (https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en)

[2] EPSO contribution to the stakeholder consultation on new genomic techniques to contribute to a Commission study requested by the Council, 15.5.2020.
- ID: 9c35adb8-621d-4e6c-a6e7-652c4c6ae06c.pdf https://bit.ly/2M0SDHe
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Useful links

Court of Justice of the EU: Judgment in Case C-528/16, 25.7.2018. English Press Release; Ruling in English:
https://epsoweb.org
EPSO Working Group on Agricultural Technologies:
Statements drafted by this group and approved by the EPSO representatives are for instance:

- EPSO updated statement on Crop Genetic Improvement Technologies, 12.01.2017
- EPSO: Opinion on the SAM Explanatory Note on New Techniques in Agricultural Biotechnology, 15.9.2017
- EPSO: First reaction on the Advocate General's Opinion regarding mutagenesis and the Genetically Modified Organisms Directive, 18.1.2018
- EPSO: Statement on the Court of Justice of the EU ruling regarding mutagenesis and the GMO Directive, 19.2.2019
- EPSO: EPSO welcomes Commissioner Andriukaitis statement and call for action 'New plant breeding techniques need new regulatory framework', 29.3.2019
- EPSO: Synthetic Biology should not be confused with the application of new breeding techniques, updated statement, 30.8.2017
- EPSO: Comment on the report of the Ad Hoc Technical Expert Group on Synthetic Biology, 8.3.2018, original report of the AHTEG and all submitted comments.

EPSO communications: https://epsoweb.org/news/
EPSO member institutes and universities: https://epsoweb.org/about-epso/epso-members/
EPSO representatives: https://epsoweb.org/about-epso/representatives/

About EPSO

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European Plant Science Organisation
https://epsoweb.org

Statement

Farm to Fork Strategy by the European Commission

Brussels, 2.6.2020

EPSO welcomes the EC Farm to Fork Strategy and offers to collaborate with the European Commission, the Member States and stakeholders to implement it.

EPSO appreciates that the strategy links Food and Nutritional Security, environmental sustainability and human health. EPSO urges to apply this approach across the strategy as a whole.

Concepts like diverse crops for diverse diets and human and resilient production, as well as combined approaches on crop improvement, crop management and crop processing, will enable interdisciplinary approaches with co-benefits in Europe and beyond.

EC rightly defines the goals and should lead the process to achieve these – based on open and transparent approaches raging from research to innovation, public procurement to legislation.

We provide further insight on how these concepts can benefit the implementation of the strategy and how plant scientists can contribute to this in the Annex.

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Useful links

	EPSO www.epsoweb.org
[R1 NS]	EPSO: Contributions from plant science towards Nutritional Security and human health, Draft Statement, 11.5.2020
[R2 HE]	EPSO Statement on the Horizon Europe Strategic Plan, 18.2.2020
[R3 Diverse crops]	EPSO Submission to the EC consultation on EU research and innovation missions (FP9), 30.3.2018, incl. 1001 Crops – diverse crops for diverse diets and human health and sustainable production.
[R4 NGT]	EPSO Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020
[R5 Feed]	Plant ETP and ATF: Policy Brief Research and Innovation towards a more sustainable and circular European agriculture: Exploring synergies between livestock and crop sectors, 18.5.2020
[R6]	EPSO submission on orientation towards strategic programming, 20.12.2019 (17.11.2019 Contribution ID 666b7610-ddca-4262-b4be-dc125b7ec2cf) to the EC
[R7 GE]	EPSO Genome editing – improving legislation and starting flagships to better address climate, environmental, food and health challenges, 4.11.2019
[R8 MiBi]	EPSO Implementing a Plants and Mircobiomes Strategy in Europe – Recommendations,18.10.2019

[R9 F2F] EC: Farm to Fork Strategy, 20.5.2020
[R10 Biodiv] EC: Biodiversity Strategy for 2030, 20.5.2020
[R11 Green Deal] EC: A European Green Deal, 11.12.2019

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Annex: EPSO suggestions for the implementation of the EC Farm to Fork Strategy

The Farm to Fork (F2F) Strategy – hereafter you find an extract of the content *to which EPSO makes ►suggestions for the implementation and offers to get involved, referring to previous publications [R1-7 listed above]:*

1. Need for action

- F2F at heart of European Green Deal and central to EC agenda to achieve the UN's SDGs
- Just transition: shift to sustainable food systems + environmental, health and social benefits, economy gains, recovery from COVID-19 crisis onto sustainability path.
- F2F strategy = new comprehensive approach to how Europeans value food sustainability:
  - Opportunity to improve lifestyles, health and the environment; societies want food that is fresh, less processed and sustainably sourced; shorter supply chains
  - European food is already the global standard for safe, plentiful, nutritious, high quality food; it should become the global standard for sustainability
    - *EPSO: ►Further increase nutritional quality of food AND environmental sustainability AND human health [R1 NS, R2 HE, R3 Diverse crops, R4 NGT]*
  - Food production has a profound impact on biodiversity…climate change and environmental degradation. Need to reduce dependency on pesticides and antimicrobials, excess fertilisation, increase organic farming, improve animal welfare, reverse biodiversity loss
    - *EPSO: welcome ►Encourage contributions not only from organic farming, but from the plant R&I sector at large [R1 NS; R3 Diverse crops; R4 NGT]; Add need to improve Food and Nutritional Security (FNS) under biodiversity as well to encourage underutilised crops which already have a good nutritional quality and can be further improved in this respect [R1 NS; R3 Diverse crops; R4 NGT].*
- European diets are not in line with national dietary recommendations (& food environment not healthy option as easy option); if they were in line with dietary recommendations, the env. footprint of food systems would be significantly reduced
    - *EPSO: ►Most welcome addressing FNS and environmental sustainability as co-benefits [R1 NS, R2 HE], ►e.g. with as diverse crops for diverse diets and human health and resilient production [R3 diverse crops]*

2. Building the food chain that works for consumers, producers, climate and the environment

EU goals for EU food system: ↓ environmental and climate footprint, ↑resilience, global transition, new opportunities:

- Ensure food chain has a neutral or positive environmental impact
  - *EPSO: most welcome ►see concept diverse crops [R3] addressing FNS and environmental sustainability and human health*

- Ensure food security, nutrition and public health – everyone has access to sufficient, nutritious, sustainable food
    - *EPSO: most welcome ►see concept diverse crops [R3] addressing FNS and environmental sustainability and human health*
- Ensure most sustainable food also becomes the most affordable
    - *EPSO: most welcome ► add nutritional quality (FNS) ►see concept diverse crops [R3] addressing FNS and environmental sustainability and human health, see use of New Genomic Techniques [R4 NGT]*
- ♦EC legislative proposal for a 'framework for a sustainable food system, before end 2023
    - *EPSO: ► Offer to contribute*

2.1. Ensuring sustainable food production

- The use of chemical pesticides: ♦EC will revise the 'Sustainable use of Pesticides' Directive, enhance provisions on Integrated Pest management (IPM), promote greater use of safe alternative ways protecting harvests from pests and diseases. (♦EC will develop with MSs an 'integrated nutrient action plan' for the livestock sector)
    - *EPSO: ► Include improving crops in IPM (in addition to crop management) [R3 HE; R4 NGT]*
- The excess of nutrients (especially N, P): to reduce nutrient losses by at least 50% without reducing soil fertility, this will reduce use of fertilisers by at least 20% by 2030. By applying balanced fertilisation, sustainable nutrient management, managing N and P better throughout their lifecycle
    - *EPSO: ►Include improving crops (in addition to crop management) [R3 HE; R4 NGT]*
- Reduce EU's GHG emissions: 10.3 % come from agriculture, nearly 70% of those from the animal sector. Incl.: Facilitate sustainable feed additives; Fostering EU-grown plant proteins, alternative feed materials & by-products from bio-economy
    - *EPSO: welcome ►Include improving crops for protein production [R1 NS, R5 feed]*
- Reduce antimicrobial resistance (AMR): reduce antimicrobials for farmed animals and in aquaculture by 50% by 2030. Promote one health.
    - *EPSO: welcome; ►Include improving crops for healthy feed and for secondary metabolites with antimicrobial functions [R1 NS, R4 feed]*
- Improving plant health: reduce dependency on pesticides. ♦EC carries out study on request of the MSs on potential of NGTs to improve sustainability along the food supply chain. Rely on seed security and diversity: ensure farmers access to a range of quality seeds for plant varieties adapted to climate change, incl. easier market access for traditional and locally-adapted varieties
    - *EPSO: welcome; ►Do not restrict to organic farming, include classical and NBTs [R2 HE, R1 NS, R3 Diverse crops; R4 NGT]*
- New CAP: MSs submit draft Strategic Plans. New 'eco-schemes' funding to boost sustainability practices such as precision agriculture, agro-ecology (incl. org farm), carbon farming and agro-forestry. EC will ring-fence minimum budget for this. Ensure as well Biodiversity Strategy for 2030 addressed.
    - *EPSO: welcome ►Focus on goal and leave path open (incl. integrated approach of crop improvement + crop management + crop processing) [R2 HE]*

2.2. Ensuring food security

- ♦EC will develop contingency plan for ensuring food supply and food security to be put in place in times of crisis
    - *EPSO: ►Offer to contribute*

2.3. Stimulating sustainable food processing, wholesale, retail, hospitality and food service practices

- ♦EC will develop with relevant SHs an EU Code of conduct for responsible business and marketing practice. Reformulating food products for healthy, sustainable diets; lower environmental footprint and energy consumption, affordable prices, less packaging…

- *EPSO: ►Offer to contribute, including e.g. diverse crops [R3], crop improvement with management and processing [R2 HE]*

- ♦EC prepares initiative to improve the corporate governance framework, facilitate shift to healthier diets incl. by setting up nutrient profiles restricting the promotion of high fat / sugars / salty foods.
  - *EPSO: ►Offer to contribute (Nutritional Security WG)*
- ♦EC supports circular business models
  - *EPSO: welcome ► Suggest combine crop improvement with management and processing [R2 HE]*

2.4. Promoting sustainable food consumption and facilitating the shift to healthy, sustainable diets

- Food consumption patterns currently unsustainable from health & env. point of view (too high energy, red meat, sugars, salt, fats; too low whole-grain cereals, fruit and vegetables). Reverse rise of overweight and obesity rates by 2030. Moving to a more plant-based diets with less and processed meat and with more fruits and vegetables will reduce risks of life-threatening diseases and env. impact of the food system. … EU's beating cancer plan includes promotion of healthy diets for cancer prevention.
  - *EPSO: most welcome ►contributions from the Nutritional Security WG [R1 NS; R4 NGT]*
- Empower consumers: ♦EC supports harmonising green claims to create a sustainability labelling framework that covers the nutritional, climate, env. and social aspects of food products.
  - *EPSO: most welcome – see [R2 HE, R1 NS; R4 NGT]*
- Availability and price: ♦EC support setting minimum mandatory criteria for sustainable food procurement.
  - *EPSO: welcome ► Offer to contribute: Focus on the goal, not the path (not restrict to organic farming), rather continue from 1st paragraph 2.4. before (+NS ..), include NGT [R4]*
- Tax incentives: to choose sustainable and healthy diets. VAT rates proposed (support organic fruit and vegetables)
  - *EPSO: = ► above, include other sustainable production contributors*

3. Enabling the transition

3.1. Research, innovation, technology and investments

- H20: new call for proposals for Green Deal priorities in 2020 for ∑ 1 Bill €
- HE: - *for all: EPSO ►Offers to get involved*
  - Proposed 10 Bill € for the food …. cluster. Incl. e.g. microbiome, food from oceans, urban food systems, alternative proteins (plant / microbial / marine / insect proteins; meat substitutes)
  - Soil health and food mission
  - Agro-ecology living labs partnership
  - Safe and sustainable food systems partnership: co-benefits for nutrition, food quality, climate, circularity, communities
  - EIP-AGRI
  - Eur. Regional Development Fund (ERDF)

3.2. Advisory services, data and knowledge-sharing, and skills

- ♦EC will promote effective Agricultural Knowledge and Innovation Systems (AKIS) involving all food chain actors
  - *EPSO: ►Offer to contribute*
- ♦EC will convert current NW into Farm Sustainability Data Network, collecting data from F2F, Biodiversity strategies and other sustainability indicators
  - *EPSO: ►link to EPSO data Task Force*

4. Promoting the global transition

- ♦EC will develop Green Alliances on sustainable food systems – based on SDGs, international cooperation, trade policy
- ♦EC will ensure ambitious sustainability chapter in all bilateral trade agreements
  - *EPSO: welcome, ►extend to FNS as well*
- ♦EU trade policy to obtain ambitious commitments from third countries in e.g. animal welfare, pesticide use, fight antimicrobial resistance; boost cooperation to improve nutrition and to alleviate food insecurity by strengthening resilience of food systems and reducing food waste
  - *EPSO: welcome, ►Suggest e.g. Diverse crops for diverse diets and human health and resilient production [R3]*
- ♦EU will focus its international cooperation on food research and innovation with ref. to climate, agro-ecology, sustainable landscape management and land governance, biodiversity conservation and sustainable use, nutrition and healthy diets ..
  - *EPSO: welcome, ►Suggest e.g. Diverse crops for diverse diets and human health and resilient production = FNS and environmental sustainability and human health [R1 NS, R3 Diverse crops, R4 NGT]*
- ♦EC will present 2021 legislative proposal on EU's contribution to reduce global deforestation and forest degradation
  - *EPSO: ►Offer contribution from Tree biology and biotechnology WG*
- Safer plant protection products
- International standard setting bodies ..: e.g. Conference of Parties to the UN Convention on Biological Diversity, the Nutrition for Growth Summit, the UN Food Systems Summit 2021
- Food information to consumers: promote higher uptake of sustainability standards
  - *EPSO: ►Offer contribution – e.g. add FNS standards*

5. Conclusions

- Aim of F2F = make the EU food system a global standard for sustainability (healthy, equitable and env.-friendly food)
  - *EPSO: ►extend to sustainability AND FNS standards*
- Implement in coherence with Biodiversity strategy 2030, new CEAP, Zero Pollution …

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Statement

European Commission First Draft Implementation Strategy for Horizon Europe

Brussels, 3.6.2020

EPSO welcomes the EC First Draft Implementation Strategy for Horizon Europe and offers to collaborate with the European Commission, the Member States, and stakeholders to finalise and implement it.

EPSO congratulates the EC for defining expected **impacts** (goals), but not the path to get there, inspiring innovative comprehensive solutions.
EPSO fully supports including the UN SDGs in the Key Impact Factors, encouraging co-benefits and also a comprehensive approach to address several SDGs in parallel – e.g. Food and Nutritional Security, environmental sustainability, and human health.
Regarding the level of TRLs in collaborative research, EPSO urges closing the R&I cycle by giving stronger support to basic research in there, thus becoming equivalent to applied research, demonstration and innovation actions.

EPSO appreciates increasing **transparency and simplification**, particularly a more concrete, simplified approach regarding the budgetary responsibility to truly encourage and enable interdisciplinary projects across intervention areas and clusters to address the UN SDGs and achieve co-benefits. Examples EPSO suggests are concepts like 'diverse crops for diverse diets and human health and resilient production', as well as 'combined approaches on crop improvement, crop management and crop processing'.
As challenges and science are global, EPSO welcomes further improving international cooperation.

Fostering **synergies with other EU spending programmes**, particularly allowing accumulation of funds from different programmes in one project is most appreciated by scientists and can help to widen participation.

Finally, EPSO encourages the EC to **ease access and outreach**, as outreach and stakeholder engagement are key to public appreciation and support of the R&I efforts we undertake. EPSO is happy to discuss our experience with stakeholder engagement, arts & science, and the Fascination of Plants Day with the EC to truly enable scientists to better engage with the public throughout the R&I process.

We provide further insight on how these concepts can benefit the implementation of the strategy and on how plant scientists can contribute to this in the Annex.

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Useful links Most comprehensive are R3 and R10

EPSO www.epsoweb.org

[R1 HE] EPSO Statement on the Horizon Europe Strategic Plan, 18.2.2020

[R2 FP9] EPSO position on FP9, 19.9.2017

[R3 FoPD] EPSO: The Fascination of Plants Day Success Stories 2019, 10.12.2019

[R4 F2F] EPSO: Statement on the Farm to Fork Strategy by the European Commission, 2.6.2020

[R5 NS] EPSO: Contributions from plant science towards Nutritional Security and human health, Draft Statement, 11.5.2020

[R6 Diverse crops] EPSO Submission to the EC consultation on EU research and innovation missions (FP9), 30.3.2018, incl. 1001 Crops – diverse crops for diverse diets and human health and sustainable production.

[R7 NGT] EPSO Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020

[R8 Feed] Plant ETP and ATF: Policy Brief Research and Innovation towards a more sustainable and circular European agriculture: Exploring synergies between livestock and crop sectors, 18.5.2020

[R9] EPSO submission on orientation towards strategic programming, 20.12.2019 (17.11.2019 Contribution ID 666b7610-ddca-4262-b4be-dc125b7ec2cf) to the EC

[R10 GE] EPSO Genome editing – improving legislation and starting flagships to better address climate, environmental, food and health challenges, 4.11.2019

[R11 MiBi] EPSO Implementing a Plants and Mircobiomes Strategy in Europe – Recommendations,18.10.2019

[R12 F2F] EC: Farm to Fork Strategy, 20.5.2020

[R13 Biodiv] EC: Biodiversity Strategy for 2030, 20.5.2020

[R14 Impl HE] EC: First Draft Implementation Strategy, 30.4.2020

[R15 Green Deal] EC: A European Green Deal, 11.12.2019

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Annex: EPSO suggestions for the implementation of the EC Draft Implementation Strategy for Horizon Europe

Draft Implementation Strategy – hereafter you find an extract of the content *to which EPSO makes ►suggestions for the implementation and offers to get involved, referring to previous publications [R1-11 listed above]:*

The Implementation Strategy

Objective Maximising impacts:

- Clearer specify expected impacts:
  - New: targeted impacts at call or group of topics level, BUT topics will be open to a range of different pathways to achieve those impacts
    - *EPSO: welcome ►Define goals, but not the path to get there [R2 FP9; R1 HE]*
  - Expected outcomes continue per topic
- Monitoring and reporting:
  - Key Impact Pathways (KIP) to better measure scientific, societal and economic impacts of projects (incl. their contributions in meeting SDGs)
    - *EPSO: welcome SDGs in KIP ►Encourage co-benefits / comprehensive approach to address several SDGs in parallel [R1 HE]*
  - Level of TRLs in collaborative research

- *EPSO: urges to ►Close the R&I cycle by giving stronger support to basic research in there, equivalent to applied, demo and innovation actions [R1 HE]*

Objective Ensuring greater transparency and further simplifications

- Shorter proposals (↓page limit),
- Two- stage calls simplified: shorter pre-proposals – possibly only on excellence √; Pilot anonymous pre-proposal
  - *EPSO: Not sure how well this will work ►Test carefully*
- Improve interaction between experts and applicants → *EPSO: most welcome!* e.g.
  - interviews like ERC, EIC and hearings under FP7
  - Or right to react (rebuttal)
  - ↑level of detail in feedback given to applicants
- Simpler Model Grant Agreement (MGA) → *EPSO: most welcome!*
  - Simplified costs: Single formula for calculating personnel cost; Lump sum-based projects
- Rationalise and simplify control regime → *EPSO: most welcome!*
  - System and Process Audits (SPAs) – test of controls and transactions …. positive SPA may reduce audit burden of beneficiaries …
- Executive Agencies to implement budget and legacy so that RTD continues focusing on policy making
  - *EPSO: welcome, but ►improve feedback to RTD on ongoing / ended projects*
- General governance of HE
  - Concerted, simplified flexible approach of the budgetary responsibilities
    - *EPSO: welcome to ►truly encourage and enable interdisciplinary projects across intervention areas and clusters to address SDGs, co-benefits*
- International cooperation further improve
  - *EPSO: most welcome! Science is global*

Objective Fostering synergies with other EU spending programmes

- Allow accumulation of funds from different programmes in a single project, or with alternative funding when HE cannot cover all high-quality proposals
  - EPSO: *most welcome! ►Support widening participation*

Objective Easing access through digital transformation and outreach

- Outreach and stakeholder engagement will be a continuous process…all interested parties provide their input and feedback
  - *EPSO: most welcome ►Happy to discuss (Stakeholder groups, art & science [R1 HE]; ►Provide better resources (e.g. FoPD) [R3 FoPD]*
- National Contact Points (NCPs): .. special support to NCPs in widening countries
  - EPSO: *most welcome ►Widen participation [ISE statement on HE in preparation]*

EPSO 3rd informal science – policy meeting on genome editing in Brussels, 3.11.2020

List of participants - confirmed in bold – by 30.6.2020 **Chatham House Rules**

Participating countries:

Belgium
10.2.e , Federal Ministry of Environment – possibly other meeting, then send deputy
10.2.e **, VIB**

Estonia
10.2.e , Ministry of Environment – interested, finally confirm later on
10.2.e **, Tallinn University of Technology**

Finland
10.2.e **, Ministry of Agriculture and Forestry**
10.2.e **, LUKE & EPSO President**

France
10.2.e **, Ministry for Agriculture and Food**
10.2.e **, INRA**

Germany
10.2.e **, Ministry for Education and Research**, 726 Bioeconomy
10.2.e **, Ministry for Education and Research,** 611 Ethics & Law in Life Sciences
10.2.e , Ministry of Food and Agriculture, 222 – New Technologies – apologies
10.2.e **, Ministry of Food and Agriculture,** 222 – New Technologies
10.2.e , Ministry of Food and Agriculture, 222 – New Technologies – apologies
10.2.e **, JKI**

Italy
t.b.a., Ministry for Environment
10.2.e **, CNR**

The Netherlands
10.2.e , Ministry for Agriculture
10.2.e **, WUR**

Norway
10.2.e , Ministry of Climate and Environment
10.2.e **, NO Agricultural Cooperatives**
10.2.e **, NO University of Life Sciences**

Spain
10.2.e **, Ministry for Agriculture**
10.2.e **, CSIC**

Sweden
10.2.e **, Min. of Enterprise and Innovation**
10.2.e **, Min. of Enterprise and Innovation**
10.2.e **, SLU**

Europe
10.2.e **, European Parliament, chair AGRI Committee**
10.2.e **, EPSO**
10.2.e **, EMBO**

Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: 10.2.e ontweek de vraag over NBTs
Datum: woensdag 1 juli 2020 15:30:08
Bijlagen: image001.gif

Ik heb morgen interdepartementaal overleg. Daar kan ik vragen of we het stuk misschien willen gaan inzetten (van uit de stakeholders); in ieder geval dat er geen tegengas is. Kan geen kwaad en dan scheelt het weer om de hele beraadsgroep af te gaan

Van: 10.2.e
Verzonden: woensdag 1 juli 2020 14:45
Aan: 10.2.e
Onderwerp: RE: 10.2.e ontweek de vraag over NBTs

Hij draait er nog wel omheen, maar de vraag was uitstekend!
(van onze onderzoeksman)
Met vriendelijke groet,

10.2.e
Directeur
Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e @minlnv.nl>
Verzonden: woensdag 1 juli 2020 14:36
Aan: 10.2.e @plantum.nl>
Onderwerp: RE: 10.2.e ontweek de vraag over NBTs

Lijkt mij niet onhandig – hou mij dan ook op de hoogte graag

Van: 10.2.e @plantum.nl>
Verzonden: woensdag 1 juli 2020 14:36
Aan: 10.2.e @minlnv.nl>
Onderwerp: RE: 10.2.e ontweek de vraag over NBTs

Ja – duidelijk . . . .
Wat dacht je ervan als ik mijn analyse over ethiek vanuit het platform modernisering biotechbeleid netjes maakt en naar hem toestuur?
Met vriendelijke groet,

10.2.e
Directeur
Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01

website www.plantum.nl

Van: 10.2.e @minlnv.nl>
Verzonden: woensdag 1 juli 2020 14:30
Aan: 10.2.e @plantum.nl>
Onderwerp: 10.2.e ontweek de vraag over NBTs

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen.
De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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The State accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.

Van: 10.2.e
Aan: 10.2.e
Onderwerp: Re: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; Interest in webinar on NO consumer survey? + participant list
Datum: vrijdag 3 juli 2020 10:28:10

Dank!

Van: 10.2.e
Datum: vrijdag 3 juli 2020 om 10:04
Aan: 10.2.e
Onderwerp: RE: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; Interest in webinar on NO consumer survey? + participant list

Ha 10.2.e,
Moet lukken om erbij te zijn. Ik stuur nog wel een mail naar 10.2.e.
Gr,
10.2.e

Van: 10.2.e
Verzonden: donderdag 2 juli 2020 22:35
Aan: 10.2.e
Onderwerp: FW: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; Interest in webinar on NO consumer survey? + participant list
Urgentie: Hoog

Hi 10.2.e,
Zie bijgaand, was jij van plan om aan te sluiten?
Hoor graag,
Groet,
10.2.e

Van: 10.2.e @epsomail.org>
Datum: dinsdag 30 juni 2020 om 08:50
Aan: 10.2.e @wur.nl>
Onderwerp: FW: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; Interest in webinar on NO consumer survey? + participant list

Dear 10.2.e,
Can you pls remind 10.2.e to kindly confirm his participation to us? Again under Chatham House Rules.
I attach the updated participant list, only for participants.
Best
10.2.e

From: 10.2.e
Sent: 04 June 2020 16:58
To: 10.2.e @mapa.es) 10.2.e @mapa.es>; 10.2.e 10.2.e @agriculture.gouv.fr>; 10.2.e @regeringskansliet.se) 10.2.e @regeringskansliet.se>; 10.2.e @kld.dep.no>; 10.2.e @regeringskansliet.se>; 10.2.e 10.2.e @bmbf.bund.de>;10.2.e @fz-juelich. de 10.2.e @fz-juelich.de) 10.2.e @fz-juelich.de>;10.2.e @bmbf.bund.de>; 10.2.e 10.2.e @bmbf.bund.de) <10.2.e @bmbf.bund.de>; 10.2.e 10.2.e @bmel.bund.de>; 10.2.e @bmel.bund.de)

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10.2.e @environment.belgium.be>;10.2.e @envir.ee)
10.2.e @envir.ee>; 10.2.e .Razumas@smm.lt)
10.2.e @smm.lt>
Cc: 10.2.e @helsinki.fi) 10.2.e @helsinki.fi>; 10.2.e
10.2.e @ibba.cnr.it) 10.2.e@ibba.cnr.it>;10.2.e @cnb.csic.es)
10.2.e@cnb.csic.es>; 10.2.e @taltech.ee)
10.2.e @taltech.ee>; 10.2.e - Wageningen
10.2.e @wur.nl) <10.2.e @wur.nl>; 10.2.e '
10.2.e @lammc.lt>; 10.2.e @embo.org)
10.2.e @embo.org>; 10.2.e @nmbu.no) <10.2.e
@nmbu.no>; 10.2.e @ens-lyon.fr) 10.2.e @ens-lyon.fr>; 10.2.e @vib.be) 10.2.e @vib.be>; 10.2.e
10.2.e @landbruk.no) <10.2.e @landbruk.no>; 10.2.e
10.2.e @plen.ku.dk>;10.2.e @slu.se) 10.2.e @slu.se>; 10.2.e
10.2.e @julius-kuehn.de) 10.2.e @julius-kuehn.de>

Subject: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; Interest in webinar on NO consumer survey? + participant list

Importance: High

Dear colleagues from national ministries,

Dear 10.2.e ,

Thanks to your replies, we are happy to **confirm our 3rd informal science and policy meeting will take place in Brussels @ Kowi on 3 November 2020.**

The room is large enough to adhere to social distancing. In case of new restrictions, we would hold the meeting online.

Pls find attached the participant list [Chatham House Rules – INTERNAL USE ONLY] – 9 countries and the European level are already confirmed (in bold).

This time we will welcome in addition 10.2.e , MEP, chair of the AGRI Committee of the European Parliament.

10.2.e : pls kindly confirm your participation as well.

As we agreed, the 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.

We will now invite colleagues from DK, IT, LT, PT who apologised last time. You are welcome to send us more suggestions too.

EPSO activities: we submitted in the meantime to the EC NGT survey (see below), the EFSA NGT consultation and to the JRC study on NGTs.

Pls find attached recent EPSO statements including references to NGTs:

- EPSO: Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020 (incl. links to original submission files)
- EPSO: Statement on the Farm to Fork Strategy by the European Commission, 2.6.2020 (incl. contributions from NGTs, include in R&I incentives)
- EPSO: Statement on the First Draft Implementation Strategy for Horizon Europe by the EC, 3.6.2020 (define the goals, but not the path to get there..)

10.2.e **kindly offered holding a webinar with you** on the final outcome of her study among Norwegian

consumers – **pls express your interest** to set a date:

- I am interested in the consumer survey webinar: yes / no
- I would prefer this in: end June, early July, September

We very much look forward to your replies and to continue the discussion
Stay safe!
10.2.e
****
10.2.e
Executive Director
European Plant Science Organisation, EPSO
Rue de l'Industrie 4, 1000 Brussels, Belgium
10.2.e epsomail.org ; T/F: +10.2.e
www.epsoweb.org ; EU Transparency Register Number 38511867304-09
****

From: 10.2.e **Sent:** 18.5.2020 **To:** Participants
Subject: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU, 2 or 3 or 6.11.2020 - Your availability by 22.5.2020 pls

Dear colleagues from national ministries,
We already received the availability from our colleagues from Germany and France and would like to remind the others to **kindly reply their availability pls as well by 22 May so we can confirm the date to everybody next week:**
Meet in Brussels in the European quarter at KoWi **on 2 or 3 or 6.11.2020**
I am interested to join the 3rd meeting and would be available:

- Mo, 2 Nov 2020: yes / possible / no
- Tu, 3 Nov 2020: yes / possible / no
- Fr, 6 Nov 2020: yes / possible / no

In case of new restrictions due to the corona pandemic, we would hold the meeting online.
We very much look forward to your replies and to continue the discussion
Stay safe!
10.2.e

From: 10.2.e **Sent:** 24.4.2020 **To:** Participants
Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020 - Report - reply pls by 8.5.2020

Dear colleagues from national ministries,
Thank you for a very open and constructive meeting!
Please find attached

- The Report – you may use publicly
- The Presentations – Chatham House Rule - you may use internally to discuss with your colleagues
- The Handout and the participant list – Chatham House Rule – only for participants.

As we agreed at the end of our 2nd meeting, the 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.
Actions:

- **All participants (this always includes those that apologised to due to overlapping activities) kindly provide to us by 8 May their availability to meet in Brussels** in the European quarter (likely at KoWi) **between 19.10. and 6.11.2020** and **Ministry / funders participants kindly indicate if they wish to present** ongoing, approved or possible future opportunities regarding flagship projects:
  - I am interested to join the 3rd meeting: yes / no
  - Availability between 19.10. and 6.11.2020:
    - I am available all dates yes / no*

- *I am NOT available on these dates: list
- I would be interested to present ongoing, approved or possible future opportunities regarding flagship projects: yes (keyword) / no

Based on your availability, we will let you know mid-May 1-3 dates to pencil in for the 3rd meeting. Monitoring the corona developments we will let you know by 4th September if the meeting can already take place and on which of the reserved dates.

- All participants are welcome to send us news items for a quarterly update regarding genome editing legislation and efforts to improve the legislation from among the participants.
- Ministry participants kindly suggest to EPSO which additional ministry colleagues to invite (providing name, ministry, email). Should this not be possible under GDPR, please recommend such colleagues to contact EPSO expressing their interest to join the next such informal meeting.

We very much look forward to your replies and to continue the discussion
Stay safe!
10.2.e

From: 10.2.e **Sent:** 09.04.2020 **To:** Participants
Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Norwegian consumers' attitudes toward gene editing

Dear colleagues from national ministries,
Thank you for a very interesting meeting and apologies for the delay in sending the report, you will receive it later in April.
As we are all busy with the EU survey on NGTs, you may find the report useful towards which 10.2.e presented first outcome at our meeting:
The Norwegian Biotechnology Advisory Board (2020). Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture. www.bioteknologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf
With best wishes and have a nice Easter
10.2.e

Van: 10.2.e
Aan: 10.2.e
Onderwerp: Beknopte agenda voor telefonisch overleg morgen
Datum: dinsdag 7 juli 2020 22:28:09
Bijlagen: image005.jpg
image006.jpg
20GMO206_French decree mutagenesis_Notification_FEDIOL arguments_FINAL_29June20.pdf

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Dag 10.2.e,
Om de 30 minuten die wij morgen hebben voor ons telefonisch overleg zo efficiënt mogelijk te gebruiken, heb ik alvast een aantal punten onder elkaar gezet. Wellicht schiet mij morgenochtend nog een aanvullend item te binnen. Mocht je onderwerpen missen dan hoor ik dat uiteraard graag.

- Ontwikkelingen in Frankrijk:
  a. Franse decreet mutagenese en reacties hierop (privaat/publiek);
  b. politiek (reshuffle Cabinet en zeer prominente positie voor Minister Barbara Pompili);
- Tweede Kamer: BNC-fiche F2F (SO LV-Raad 13 juli, AO LKV 29 sept - 1 okt, AO Biotechnologie 6-8 oktober);
- Oplevering studie die door de Raad aan de EC is verzocht (vooralsnog uiterlijk 30 april 2021); Vertraging naar zomer 2021?
- Nadere initiatieven vanuit NL, vooruitlopend op deze studie?
- Ontwikkelingen in andere Lidstaten, w.o. Duitsland en Italië;
- Programma Duits EU-voorzitterschap;
- (Geen) vergaderingen PCVD/GMO tot dusver in 2020, verdere vertraging toelatingen.

Met vriendelijke groet,

10.2.e
10.2.e
10.2.e

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+31 (0)62 10.2.e (mobile)
10.2.e
www.mvo.nl
EU Transparency register 086387026863-41

MVO – The Netherlands Oils and Fats Industry
Louis Braillelaan 80, 2719 EK Zoetermeer, The Netherlands

FEDIOL
The EU Oil & Proteinmeal Industry

29 June 2020
20GMO206

From: EU vegetable oil and proteinmeal association (FEDIOL)
To: European Commission, TRIS website
Date: 29June 2020
Subject: FEDIOL stakeholder contribution to the notification by France of three draft legal acts related to the status of certain plant varieties obtained via in vitro mutagenesis (notifications 2020/0280/F, 2020/0281/F and 2020/0282/F)

FEDIOL, the EU vegetable oil and protein meal industry association, represents the interests of the European oilseed crushers, vegetable oil refiners and bottlers. FEDIOL members are 10 national associations and associated company members in 7 other EU countries. With about 180 facilities in Europe, the sector provides 20,000 direct employments. Its members process approximately 55 million tonnes of basic products a year, both of EU origin and imported from third country markets. The sector processes notably rapeseed, sunflower seed, soybeans and linseed into oils and meals for food, feed, technical and energy uses essentially on the European market.

On May 6th 2020, France has notified to the European Commission ("**the Commission**") three draft technical regulations relating to genetically modified organisms ("**GMOs**"), in accordance with the procedure laid down in Directive (EU) 2015/1535.

These notifications include:

- a draft decree *amending the list of techniques for obtaining GMOs traditionally used without any noted drawbacks with regard to public health or the environment* (**notification 2020/280/F**);

- a draft order *laying down the list of varieties mentioned in Article 2 of Decree [xx]* (**notification 2020/281/F**);

- a draft order *amending the Official Catalogue of Species and Varieties of Cultivated Crops in France (rape seeds and other crucifer seeds)* (**notification 2020/282/F**).

These notifications from the French State are supposed to implement several rulings from the Court of Justice of the European Union ("**CJEU**") and the French Council of State ("**CE**"), France's highest administrative Court, but in fact they go further and we consider they put Internal Market at risk.

By a ruling of 3 October 2016, the CE referred 4 questions to the CJEU for a preliminary ruling, aimed in particular at clarifying the scope of Directive 2001/18/EC. In a ruling dated 25 July 2018 (in case C-528/16), the CJUE clarified that Article 3(1) of Directive 2001/18/EC, read in conjunction with point 1 of Annex I B to that directive:

- "*cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted*";
- "*must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive*".

168, avenue de Tervuren (bte 12) ● B 1150 Bruxelles ● Tel (32) 10.2.e ● Fax (32) 10.2.e ● Email : fediol@fediol.be ● http://www.fediol.be

Following the CJEU's preliminary ruling, the CE delivered a decision on 7 February 2020 (No. 388649), whereby it notably enjoined:

- the Prime Minister to fix by decree, taken after the opinion of the *High Council of Biotechnology*, the restrictive list of mutagenic techniques or methods conventionally used in a number of applications and which have a long safety record;
- the competent authorities to identify, within the common catalogue of varieties of agricultural plant species, those varieties that would have been registered without having carried out the evaluation to which they should have been submitted having regard to the technique used to obtain them.

The draft decree notified under **2020/280/F** provides its own interpretation of the techniques of mutagenesis exempt from the scope of the regulations on GMOs. It foresees the exemption of "*random mutagenesis, with the exception of in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents*".

The draft Decree also provides for transitional measures for plant crops obtained via *in vitro* random mutagenesis, as defined above, which have already been sown or planted on the date of application of the above orders.

The draft order notified under **2020/281/F** identifies the varieties originating from *in vitro* random mutagenesis consisting in subjecting plant cells cultivated *in vitro* to chemical or physical mutagenic agents. As a consequence, it lists those varieties *(i)* whose registration in the French Official Catalogue of Species and Varieties of Cultivated Crops has been revoked and *(ii)* **those which France considers as supposed to satisfy the conditions for revocation of registration in the EU catalogue**.

As indicated on the TRIS database, the varieties listed "*are the herbicide-tolerant varieties of rapeseed, marketed under the name Clearfield rapeseed, whose method of production described in the bibliography corresponds to this technique*".

The draft order notified under **2020/282/F** lists the varieties originating from *in vitro* random mutagenesis that are deleted from the French Official Catalogue of Species and Varieties of Cultivated Crops, as being the result of *in vitro* random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents.

As indicated on the TRIS database, once these texts will be published, "*it will be **prohibited in France to cultivate or sell the varieties** resulting from in vitro random mutagenesis, consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents, due to them not having been evaluated and authorised under the regulations on GMOs*".

FEDIOL welcomes the possibility to comment on these notifications.

FEDIOL is very concerned by the notified French draft decree and orders aimed at specifying the mutagenesis techniques which are exempt from the scope of the French legislation on GMOs transposing Directive 2001/18/EC (making plant organisms resulting from in vitro random mutagenesis falling within the scope of this GMO legislation), and at laying down the list of varieties resulting from in vitro random mutagenesis which will be prohibited from being placed on the market and cultivated in France (due to them not having been evaluated and authorised under the GM legislation).

FEDIOL concerns relate to the approach taken by France and what the proposed draft decree and orders may achieve if implemented:

- GMOs are today regulated at EU level through different pieces of legislation. FEDIOL position has always been that any new legislation on GMOs should remain harmonized within the EU. Should there be a solid scientific reason for distinguishing

in vivo and in vitro mutagenesis (the substantiation of which is not clear in the French proposal), FEDIOL believes that this should therefore be handled by the European Union and not by individual Member States.

It **should also be in compliance with the CJEU** ruling which did not make any such distinction between *in vivo* and *in vitro* mutagenesis techniques. As indicated, the CJUE only distinguished between "*techniques conventionally used in a number of applications and which have a long safety record*" and "*new techniques/methods of mutagenesis, which have appeared or have been mostly developed since Directive 2001/18 was adopted*".

This has been clearly highlighted by the European Commission in its letter of 20 May 2020 requesting EFSA for a scientific opinion on *in vitro* random mutagenesis techniques (ARES(2020)2651289): "*The CJEU in its reasoning referred to the "application of conventional methods of random mutagenesis"* ***without distinguishing further between in vivo and in vitro random mutagenesis*** *and distinguished them from "new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted""* (emphasis added).

That letter from the Commission further indicates that EFSA has made "***no distinction between the application of the techniques in vitro or in vivo***" (emphasis added) and that "***Member States have never made a distinction between in vitro and in vivo either when implementing the seed legislation, the plant propagating material legislation or the GMO legislation***".

It is the French CE which decided on its own and without any clear legal or scientific justification that "*both the so-called "directed" or "genome editing" techniques or methods and the in vitro random mutagenesis techniques subjecting plant cells to chemical or physical mutagens* […] *appeared after the date of adoption of Directive 2001/18/EC or have mainly developed since that date*" and should therefore "*be regarded as being subject to the obligations imposed on genetically modified organisms by that Directive*".

The conclusions of the *Rapporteur public* further clarify the reasons why the CE pretends that such in *vitro techniques* should be included in the scope of the GMOs regulations: "*the earliest in vitro reconstitution methods were experimented in the late 1960s and in connection with random mutagenesis in the early 1980s. However, for field crops, [the Minister] only mentions the obtaining of varieties of bananas of interesting size and earliness in 1993 and the marketing of the Clearfield® rapeseed in France from 1995. In order to apply the criteria of the ECJ, only field use seems relevant to us and if you follow us* […], ***the six to eight years up to 2001 are not enough to characterize a tradition***" (emphasis added).

Such a ruling, as transposed into the draft decree and orders, is highly questionable and may not be shared by other Members States, all the more that no other Member States has ever made such a distinction between *in vitro* or *in vivo* techniques while implementing the GMO legislation, as indicated above.

By going beyond the CJEU ruling, France should be considered in breach of its duty of sincere cooperation (article 4(3) TUE). Also, by not asking for new preliminary reference to CJEU before imposing prohibitions to *in vitro* established practices, the French CE was in breach of its duty to do so as Court of last resort (Article 267 TFUE) and to Article 4(3) TUE accordingly.

Leaving it to a Member State, namely France via its Conseil d'Etat and the notified drafts to clarify the distinction drawn by the CJEU as regards the list of techniques/methods which should be considered as conventional or new (and

therefore excluded or included in the scope of Directive 2001/18/EC) will create both national discrepancies in the functioning of the Internal Market, and breaches the uniform application of EU law, "*which is a fundamental requirement of the Community legal order*"[1].
The decree and orders will also breach Article 34 of the TFEU by impeding the sales of varieties lawfully produced and marketed in other Member States, which is the "*most extreme form of restriction*"[2].

In addition, the decree and orders will also raise international trade issues as they will significantly impede rapeseed exports from Canada, Ukraine and Australia and could be understood as designed in a discriminatory manner

- FEDIOL assumption is that imports of rapeseed derived from the list of varieties listed in the proposed order, and any derived products (like meals or vegetable oils), will be considered as non-authorized GMOs/GM products in France. Considering that:
    1. varieties listed in the French proposal are cultivated in many geographical origins (EU and non-EU) from which FEDIOL member companies source their materials,
    2. in the third countries from which rapeseeds are imported (to France[3] and to the EU), these varieties are not segregated or traced and would be expected to be contained within in-coming rapeseed consignments for processing that are not declared as GMOs.
    3. grains (i.e. oilseeds for crushing) considered as non-GMOs according to the EU legislation are bulk commodities (meaning that many different lots of grains, from different geographical origins, may be mixed together before being crushed and refined),
    4. it is today not possible for FEDIOL member companies to know whether in vitro mutagenesis has been used to produce the grains (i.e. oilseeds) they use[4],
    5. it is today impossible to detect and control whether grains (and the products derived thereof) have been obtained via in vitro mutagenesis,

  the French proposal will therefore lead to the disruption of the internal market by preventing FEDIOL member companies to import their products, notably those lawfully produced and marketed in other Member States, to France[5].

  In this respect that the Council Decision (EU) 2019/1904 of 8 November 2019 itself states that "*The ruling* [of the CJEU] *brought legal clarity as to the status of new mutagenesis techniques,* ***but also raised practical questions which have consequences for the national competent authorities, the Union's industry, in particular in the plant breeding sector, research and beyond. Those questions concern, inter alia, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, from products resulting from natural mutation, and how to ensure, in such a situation, the equal treatment between imported products and products produced within the Union***".

[1] Judgement of the Court of 6 December 2005, ABNA e.a., case C-453/03, paragraph 104.
[2] Judgment of the Court of 14 December 1979, Regina v Maurice Donald Henn and John Frederick Ernest Darby, case 34/79, paragraph 12.
[3] In 2018, France imported 718 000 tonnes of rapeseed from outside EU notably from Ukraine, Canada and Australia where Clearfield rapeseed varieties are cultivated. Clearfield varieties are understood to represent around 16% and 5% of the total oilseed rape production market area in Ukraine (source: BASF) and Canada (source: Canola Council of Canada).
[4] No information is available in the Common Catalogue of varieties of agricultural crops.
[5] In 2018, France imported 157 000 tonnes of crude rapeseed oil and 402 000 tonnes of rapeseed meal, from EU and non-EU countries, in which the listed varieties are authorized and being grown.

The Council has therefore considered that "*a study is necessary to clarify the situation*" and requested "*the Commission to submit, by 30 April 2021, a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law*", as well as to "*submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study*".

In such a context, by regulating what should be regarded as new mutagenesis techniques/methods ahead and outside of any European consultation, the French draft decree and orders appear premature, which further impedes the uniform application of EU law and breaches internal market principles, as it raises a situation of total legal uncertainty.

- As notified, the proposed decree is also formulated in a way too opened for interpretation, thus leading to legal uncertainty for FEDIOL member companies.
    - The Directive 2018/18/EC (transposed in the French Code of the Environment) establishes the procedural requirements for R&D trials involving environmental release of GMOs, and for the commercialisation of GMOs. However, GMOs destined for food or feed are subject to EU specific legal provisions, defined in Regulation (EC) No 1829/2003. The French Decree is creating uncertainty about the status of these products, in particular when processed, because introducing a different definition of GMOs than the one referred to in Regulation (EC) No 1829/2003 that is the definition in the Directive.
    - What would be the transitory period for a processed product produced in another Member State than France, like a vegetable oil (having a long shelf life) that would be obtained from grains belonging to the varieties listed in the French proposal but cultivated elsewhere than in France. As from which date such product (would processed products well be falling under the scope of the decree) would be considered as a (non-authorized) GM product in France?
    - Should all products derived from the listed varieties be withdrawn from the market after the implementation of the decree (knowing that such action would be impossible in practice considering the absence of traceability of these varieties)?
    - How can the French authorities be certain of the use of these varieties in processed products if no analytical tools are available?

  Such type of unclarity undermines a proper understanding of the decree and its application, which constitutes a further breach of Article 34 of the TFEU.

  The CJEU has indeed ruled that a national regulation constituted an unjustified obstacle to the free movement of goods when it created an "*ambiguous factual situation by maintaining, for economic operators, a state of uncertainty as regards the possibilities for marketing* [in a Member State products] *which are lawfully manufactured and/or marketed in other Member States*"[6].

FEDIOL is therefore very concerned about the barrier to trade created by the French proposal which is also neither based on strong scientific evidence, nor justified by a clear public interest as it should be (protection of health? problems with herbicide tolerant varieties? problems with plant varieties obtained via in vitro mutagenesis?) nor hardly enforceable in practice without causing disruption of the Internal Market.

[6] Judgment of the Court of 28 January 2010, Commission v./ France, case C-333/08, paragraph 112.

For this reason, FEDIOL urges the Commission to take action and disapprove the French legislative proposal by issuing a detailed opinion.

FEDIOL stands ready to provide further information to any request from the European Commission.

Van: 10.2.e
Aan: 10.2.e
Onderwerp: Wir müssen auf Experten hören – und mehr Gentechnik wagen!: 10.2.e Bundesministerin für Ernährung und Landwirtschaft
Datum: donderdag 16 juli 2020 10:13:56

Beste 10.2.e

Misschien ten overvloede maar eindelijk weer een politiek signaal van onze Oosterburen. Opinie Minister 10.2.e in Tagesspiegel.

Groet,

10.2.e

https://www.tagesspiegel.de/politik/nicht-nur-bei-corona-auch-in-der-agrarwirtschaft-wir-muessen-auf-experten-hoeren-und-mehr-gentechnik-wagen/26000058.html

Van: 10.2.e
Aan: 10.2.e
Onderwerp: Kennismaken en twee vragen
Datum: donderdag 27 augustus 2020 07:57:44

Beste 10.2.e ,
Wij hebben elkaar volgens mij een keer ontmoet in Brussel toen je voor 10.2.e werkte (ging over hormoonverstoring).
Ik vroeg mij af of je binnenkort tijd hebt om bij te praten. Ik begreep dat je nu bij LNV veredeling in je portefeuille hebt.
Ik heb voor nu twee concrete vragen waar wij meer informatie over zoeken.

1. Wij begrepen dat NL opmerkingen heeft gemaakt bij de concept Franse regels voor mutagenese (TRIS proces). De vraag is of NL die opmerkingen met ons kan delen.
2. Op 15 September a.s. is er een SCOPAFF GMFF. Dat is positief gezien de vele bijeenkomsten die niet doorgingen. Wat ons opviel op de concept agenda die wij onder ogen kregen is dat er twee producten van ons niet opstaan. Wij vinden dit enerzijds opmerkelijke gezien deze producten eerder een EFSA opinie kregen dan een ander product op de agenda, en anderzijds zorgelijk gezien de lange vertraging in de procedure. Specifiek gaat het SIP2Xtend en Mega mais. Wij zijn benieuwd waarom deze producten niet op de agenda voor de 15de staan. Agendering van deze producten is voor ons belangrijk in verband met de teelt van deze producten in Noord- en Zuid-Amerika. Een deel van de oogst daar wordt naar Europa geëxporteerd.

Ik hoop dat je er voor voelt om telefonisch bij te praten. Ik was graag naar Den Haag gekomen maar ik neem aan dat jullie ook bezoekbeperkingen kennen.
Ik hoor graag van je.
Vriendelijke groet,

10.2.e
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foods

MDPI

Article

A Real-Time Quantitative PCR Method Specific for Detection and Quantification of the First Commercialized Genome-Edited Plant

10.2.e [1], 10.2.e [2], 10.2.e [2], 10.2.e [3], 10.2.e [2] and 10.2.e [1,*]

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Abstract: Discussion regarding the regulatory status of genome-edited crops has focused on precision of editing and on doubts regarding the feasibility of analytical monitoring compliant with existing GMO regulations. Effective detection methods are important, both for regulatory enforcement and traceability in case of biosafety, environmental or socio-economic impacts. Here, we approach the analysis question for the first time in the laboratory and report the successful development of a quantitative PCR detection method for the first commercialized genome-edited crop, a canola with a single base pair edit conferring herbicide tolerance. The method is highly sensitive and specific (quantification limit, 0.05%), compatible with the standards of practice, equipment and expertise typical in GMO laboratories, and readily integrable into their analytical workflows, including use of the matrix approach. The method, validated by an independent laboratory, meets all legal requirements for GMO analytical methods in jurisdictions such as the EU, is consistent with ISO17025 accreditation standards and has been placed in the public domain. Having developed a qPCR method for the most challenging class of genome edits, single-nucleotide variants, this research suggests that qPCR-based method development may be applicable to virtually any genome-edited organism. This advance resolves doubts regarding the feasibility of extending the regulatory approach currently employed for recombinant DNA-based GMOs to genome-edited organisms.

Keywords: GMO detection; GMO quantitation; genome-edited crops; real-time quantitative PCR; regulatory enforcement; biosafety; traceability

1. Introduction

In recent years, biotechnologists have begun to employ genome editing methods such as ODM (oligonucleotide-directed mutagenesis), CRISPR/Cas (clustered regularly interspaced short palindromic repeats/CRISPR associated protein), TALEN (transcription activator-like effector nuclease) and ZFN (zinc finger nuclease) to modify the characteristics of organisms important in production of food and feed. At present, two genome-edited plants have been commercialized in North America, a herbicide-tolerant canola variety [1] and a soy bean variety with modified oil composition [2].

The regulatory landscape regarding genome-edited crops is currently not well defined globally. Despite the commercialization of the above two genome-edited crops and recent policy changes by the US Department of Agriculture, the US has not formalized a comprehensive position on the regulation of genome editing methods. A handful of other countries have established laws or regulations

regarding genome-edited plants [3]. The European Court of Justice has ruled [4] that crops modified by directed mutagenesis fall within the scope of Directive 2001/18/EC on the release of GMOs into the environment [5]. In practice, this means that genome-edited crops are regulated according to that Directive [5]. Preceding and following this decision, there has been sustained discussion with wide-ranging perspectives regarding the regulation of these methods among EU [6–8] and member state [9–12] government representatives, within the Convention on Biodiversity [13,14], and among representatives of the biotechnology industry [15,16] and the academic community [3,17–23].

Although the precision of genome editing and range of off-target and other unintended effects, especially in comparison with random mutagenesis, have been one focus of the discussion regarding regulatory status of genome-edited organisms [3,19,22–25], a second, prominent focus has been feasibility of developing methods for detecting genome-edited organisms [3,7,10,25–29]. One of the arguments put forward to justify regulating genome-edited crops differently from recombinant DNA-based GMOs is that Directive 2001/18/EC requires analysis-based surveillance of GMOs, while, it is claimed, there are many technical and regulatory challenges that make development of GMO regulation-compliant analytical identification and quantitation methods for genome-edited organisms difficult or even impossible [7,10,25,26,28,29]. However, these claims are controversial [3,27].

To date, discussions regarding detection and quantification of genome-edited organisms have remained mostly on the theoretical level [28]. To provide an empirical basis for the discussion, we have begun to explore these questions in the laboratory and have successfully developed a real-time quantitative PCR (qPCR) method for identification and quantitation of the first genome-edited crop commercialized, an herbicide-tolerant canola. This method is fully compliant with regulations for monitoring of GMOs in the EU and similar jurisdictions. A single base pair edit in the canola *AHAS1C* gene has rendered the resulting gene-product tolerant to sulfonylurea and imidazolinone herbicides [30]. We deemed this product a worthy test of the question of whether methods could be developed for identification and quantitation of genome-edited crops, since this product embodies many of the more challenging features that genome-edited crops may present, such as the fact that: (1) the edit consists of a single base pair modification and, (2) while the edit has been carried out on one member of a multigene family (*AHAS1C*), (3) a second member of the family (*AHAS3A*) carries the same single base pair modification generated via chemical mutagenesis. Thus, it was necessary to design a method capable of distinguishing between these two.

Using standard qPCR methodology, in conjunction with the use of locked nucleic acids (LNAs) in primer design, we were able to develop a high-sensitivity quantitative detection method for the single-nucleotide genome edit described above. This approach is likely to apply to other single-nucleotide edits and, since the scientific community has two decades of experience successfully using standard qPCR methods to quantitatively detect indels and gene insertions, this is an approach to method development that may be applicable to all classes of genome-edited crop for which at least minimal construct information is available. This is an important conclusion, because it establishes a clear path forward for analysis-based regulation of genome-edited organisms that is fully compliant with current GMO regulations in jurisdictions such as the EU [5,31,32] and fully consistent with existing practices, workflows, and expertise available in contemporary GMO analytical laboratories. This paper describes the development and independent validation of this method, which has been placed in the public domain, available for use by all laboratories.

2. Materials and Methods

2.1. Canola Germplasm

Seed samples of 20 wild-type canola varieties were obtained through the U.S. National Plant Germplasm System (North Central Regional Plant Introduction Station, Ames, IA, USA). The specific varieties are listed in Table S1 in Supplementary Materials. They include varieties bred for production in Bangladesh, Canada, China, Denmark, France, Germany, Japan, the Netherlands, New Zealand,

Poland, Russia, South Korea, Sweden, and the United States. Commercial seed from three Clearfield sulfonylurea and imidazolinone herbicide-tolerant canola varieties, developed via chemical mutagenesis, were used, 5545 CL (Brett-Young Seeds Ltd., Winnipeg, MB, Canada), CS2200 CL (Canterra Seeds LTD., Winnipeg, MB, Canada), and 2022 CL (Viterra Inc., Calgary, AB, Canada). Certified seed from three SU (sulfonylurea and imidazolinone herbicide-tolerant) canola varieties, C1511, C5507, and 40K (Cibus US LLC/Falco Brand, San Diego, CA, USA) all developed by oligonucleotide directed mutagenesis [1,30] were used.

2.2. Sanger Sequencing

Sanger sequencing of a segment of the *AHAS1C* gene that included two single-nucleotide variants (SNVs) unique to *AHAS1C* and the genome edit at position 1676, which is common to both *AHAS1C* and *AHAS3A*, was used to characterize the three SU canola varieties and the three Clearfield varieties described in Section 2.1. For Sanger sequencing, 10 ng of canola genomic DNA was amplified with *AHAS1C* gene-specific primers in a volume of 50 microliters, using 5 units of HotFirepol (Solis BioDyne, Tartu, Estonia). The forward primer was CTATTGCTGCAGTTTCCCAAC, spanning base pairs 284 to 263 upstream of the start codon of the *AHAS1C* gene; this primer is selective for the *AHAS1C* gene versus the *AHAS3A* gene. The reverse primer was GGTCCCCGAGATAAGTGTGAGCTCTG, spanning base pairs 1706 to 1726 of the *AHAS1C* gene. PCR profile: 1 × 95 °C for 15 min, 40 × (95 °C for 30 s, 65 °C for 30 s, 72 °C for 60 s), 1 × 72 °C for 10 min. The expected PCR product, 2007 bp long, was purified from the agarose gel using Zymoclean Gel DNA Recovery kit (ZymoResearch, Irvine, CA, USA). A total of 100 ng of PCR product was subjected to Sanger sequencing at Retrogen (San Diego, CA, USA) using the primer CTCCGCAGTACGCGATTCAGA, which spans base pairs 1343 through 1363 of the *AHAS1C* gene. The length of the read was 384 nucleotides. All primers were designed based on the *AHAS1C* sequence, Genbank accession number Z11524.1. All primers were synthesized at IDT (Cedar Rapids, IA, USA).

2.3. DNA Extraction

Genomic DNA was extracted from ground seeds using the DNeasy Plant Mini Kit (Qiagen, Hilden, Germany, cat. no. 69104). The extracted DNA was further purified from degraded DNA or other contaminants by passing through an Illustra MicroSpin G-50 column (cat. no. 27533001). The concentrations and quality of the extracted DNA solutions were evaluated by measuring UV absorbance (ND-1000, NanoDrop Technologies, Wilmington, DE, USA). All genomic DNA solutions were adjusted to concentrations of 30 and 10 ng/μL for real-time PCR analyses. DNA solutions were stored at −20 °C until used.

2.4. Oligonucleotide Primers and Probes

DNA primers and TaqMan® probes were synthesized by Integrated DNA Technologies, Inc. (Coralville, IA, USA), except for the locked nucleic acid (LNA)-containing primer, which was obtained from QIAGEN Genomic Services (Frederick, MD, USA). The probes were labeled with 6-carbocyfluorescein (FAM) at the 5′ end and BHQ-1 at the 3′ end.

2.5. Real-Time Quantitative PCR

Real-time quantitative PCR assays were performed using an Applied Biosystems 7500 Fast qPCR system (Thermo Fisher Scientific) in a final volume of 25 μL containing 300 ng of a DNA template, 12.5 μL Master Mix (Kapa Probe Fast), 0.4 μL of each primer (100 μM), and 0.2 μL probe (100 μM) (SU canola method) and 0.2 μL of each primer (100 μM), and 0.1 μL probe (100 μM) (*CruA* method). The step-cycle program was 10 min at 95 °C, followed by 45 cycles of 30 s at 95 °C, and 1 min at 60 °C.

2.6. Independent Method Validation

The SU canola-specific qPCR method was subjected to formal validation by the Laboratory for GMO Analysis (LGA) of the Umweltbundesamt GmbH (Environment Agency Austria), which is accredited according to ISO 17025:2017 for GMO analysis and is a member of the European Network of GMO Laboratories (ENGL). The validation was conducted with regard to LOD/POD and robustness according to the "Guidelines for the single-laboratory validation of qualitative real-time PCR methods" of the German Federal Office of Consumer Protection and Food Safety [Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)] [33] as well as the ENGL guidance document, "Verification of analytical methods for GMO testing when implementing interlaboratory validated methods-Version 2" [34].

The methods used by LGA in the validation were as described in the Methods section of this paper except for a few minor differences: (1) LGA used a denaturation time of 15 s and we (HRI/SomaGenics) used 30 s. This difference would only become significant if the amplicon size were 2 kb or greater. (2) We used Kapa Probe Fast qPCR master mix, while LGA used Kapa Probe Force qPCR master mix. The polymerase used in the latter master mix is considered more resistant to inhibitory contaminants that might be present in the DNA preparation. However, this difference in master mixes is not significant since both laboratories used very stringent DNA purification procedures that differed only in that LGA used Illustra MicroSpin S300 columns (cat no. 27533001) as a cleanup step while we used Illustra MicroSpin G-50 columns. (3) For the *CruA* probe, LGA used TAMRA as quencher, while we used BHQ-1. These two quenchers perform quite similarly. These minor differences would not be expected to influence the performance of the method, which is confirmed by the consistency of results obtained by the two laboratories.

2.7. Intellectual Property

Consistent with the commitment to open source the detection method described in this article, we have prepared a statement regarding the associated intellectual property, which can be found as File S1. Statement Regarding Associated Intellectual Property of this paper.

3. Results

3.1. Development of a qPCR Method Specific for SU Canola

According to the literature, the canola *AHAS* gene family consists of five genes. *AHAS1C* and *AHAS3A* encode catalytic subunits of the functional acetohydroxy acid synthase. *AHAS4A* and *AHAS5C* are probably inactive, appearing to have interrupted coding sequences. *AHAS2A* appears to have a separate function and differs in sequence from *AHAS1C* and *AHAS3A* in the coding region, the signal peptide region and in upstream DNA sequences [35]. Whereas *AHAS1C* and *AHAS3A* are constitutively expressed, *AHAS2A* is expressed in specialized ovule tissues [36]. *AHAS1C* and *AHAS5C* reside on the C genome, while the other three genes reside on the A genome of *Brassica napus* [35].

The 1300 to 1700 bp regions of the *AHAS1C* and *AHAS3A* genes are diagramed in Figure 1. The G-to-T SNV at 1676/1667 confers both sulfonylurea and imidazolinone herbicide tolerance. This SNV is shared by *AHAS1C SU* and *AHAS3A*, while the two SNVs at 1363/1354 and 1381/1372 are shared by *AHAS1C* SU and *AHAS1C* wild type (WT).

Canola event BnALS-57 was generated by oligonucleotide directed G-to-T mutagenesis at base pair 1676 of the *AHAS1C* gene. Variety 5715 was created by crossing canola BnALS-57 with the commercial Clearfield canola variety SP Cougar CL [30,37,38], in which a G-to-T mutation at position 1667 of the *AHAS3A* gene was created by chemical mutagenesis, conferring herbicide tolerance on the *AHAS3A* gene product. The result was a canola variety in which both the *AHAS3A* and *AHAS1C* genes carried mutations conferring tolerance to both sulfonylurea and imidazolinone herbicides, *AHAS3A* (via chemical mutagenesis) and *AHAS1C* (via ODM). Based on the fact that variety 5715 was the only Cibus ODM variety authorized/deregulated at the time varieties C1511, C5507 and 40K were commercialized, it can be concluded that these varieties were derived from variety 5715.

genes carried mutations conferring tolerance to both sulfonylurea and imidazolinone herbicides, *AHAS3A* (via chemical mutagenesis) and *AHAS1C* (via ODM). Based on the fact that variety 5715 was the only Cibus ODM variety authorized/deregulated at the time varieties C1511, C5507 and 40K were commercialized, it can be concluded that these varieties were derived from variety 5715.

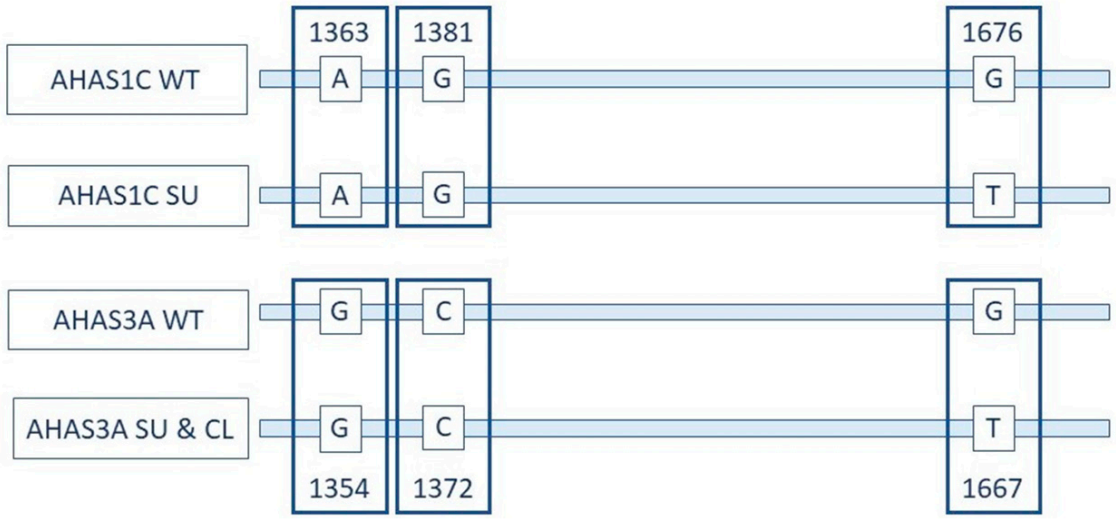

Figure 1. Relationship between *AHAS1C* and *AHAS3A* and positions of a key mutation. Representation of coding strands of the *AHAS1C* gene and *AHAS3A* gene in wild-type (WT), genome edited for sulfonylurea and imidazolinone tolerance (SU) and Clearfield (CL) canola varieties. These regions of the *AHAS1C* and *AHAS3A* genes are identical except for the bases indicated. Differences in numbering of the two genes is due to differences in sequences upstream of the region depicted. The two SNVs at 1363/1354 and at 1381/1372 differentiate *AHAS1C* from *AHAS3A*. The SNV at 1676/1667 differentiates *AHAS1C SU*, *AHAS3A SU* and *AHAS3A CL* from *AHAS1C WT* and *AHAS3A WT*. See papers cited in this section for details on structure of the *AHAS* gene family.

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We verified that the configuration depicted in Figure 1 was present in SU canola varieties 40K, C1511 and C5507 by sequencing the *AHAS1C* region from 1340 to 1700 by the Sanger method. The results of the Sanger sequencing were consistent with the SNVs at 1363/1354 and 1381/1372 differentiating *AHAS1C* from *AHAS3A* and the SNV at 1676/1667 differentiating SU canola varieties from CL canola varieties. The results of the Sanger sequencing were also consistent with the ability of the primers designed on the basis of the *AHAS1C* gene sequence (GenBank Accession Z11524.1) to discriminate between SU canola and Clearfield canola varieties. As shown in Figure 2, the nucleotide at position 1676 in Clearfield canola variety 5545 CL was T, which is the wild type according to the sequence of *Brassica napus* in GenBank (accession Z11524.1). In contrast, the nucleotide at position 1676 in SU canola variety 40K was C, which is the SNV that confers tolerance to sulfonylurea and imidazolinone herbicides [30,37,38]. Interestingly, both 5545 CL and 40K were found to be heterozygous at position 1676 in C1511 and C5507. Although there is no confirmation of SNV that confers tolerance to sulfonylurea herbicides in varieties C1511 and C5507, this suggests that these two varieties are heterozygous, with 40K being homozygous at position 1676. We noted that all three varieties, 40K, C1511 and C5507, possess the characteristics expected for SU canola, and that Clearfield canola variety 5545 CL possesses the characteristics expected for CL canola, with 5545 CL being homozygous at position 1676. We concluded that all these varieties, 40K, C1511 and C5507 (Table S2, Supplementary Materials), were derived from variety 5715 CL. Similar Sanger sequencing results were found for the two other Clearfield varieties, CS2200 CL and 2022 CL.

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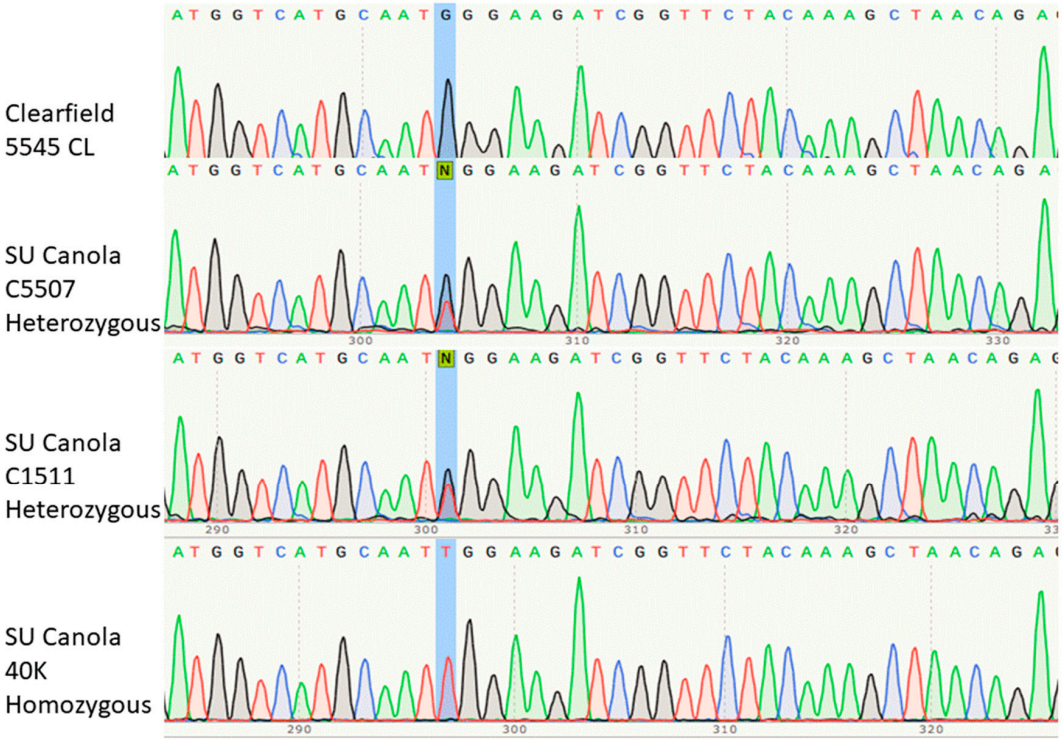

Figure 2. Portion of the Sanger sequencing of the segment of the *AHAS1C* gene spanning the site of genome editing, at position 1676, highlighted in blue. This base is homozygous G (wild type) in Clearfield canola variety 5545 CL, homozygous T (mutant) in SU canola variety 40K and G/T heterozygous in SU canola varieties C5507 and C1511. The region sequenced extended from *AHAS1C*-specific SNVs at positions 1363 and 1381 to beyond position 1704, verifying the location of the genome edit at position 1676. The location of the primer used for sequencing is indicated in Figure 3.

Figure 2. Portion of the Sanger sequencing of the segment of the *AHAS1C* gene spanning the site of genome editing, at position 1676, highlighted in blue. This base is homozygous G (wild type) in Clearfield canola variety 5545 CL, homozygous T (mutant) in SU canola variety 40K and G/T heterozygous in SU canola varieties C5507 and C1511. The region sequenced extended from *AHAS1C*-specific SNVs at positions 1363 and 1381 to beyond position 1704, verifying the location of the genome edit at position 1676. The location of the primer used for sequencing is indicated in Figure 3.

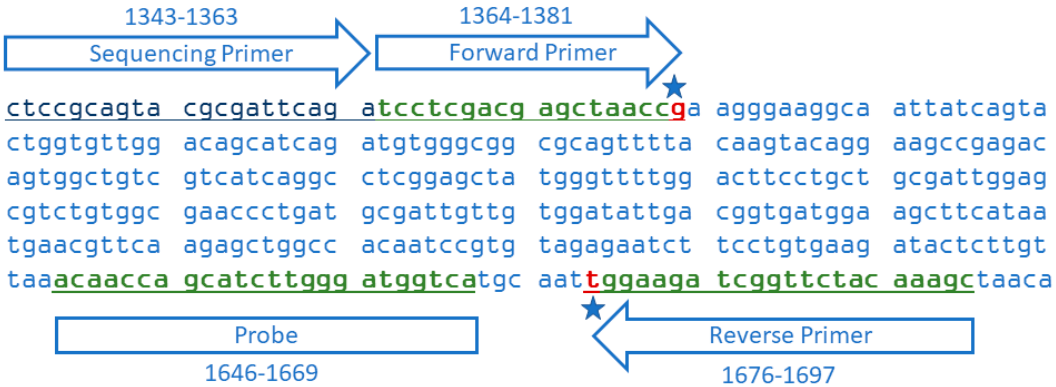

Figure 3. Sequence of part of exon 2 of the SU canola *AHAS1C* gene showing alignments of the primers and probe for the 334 bp amplicon. The forward primer and probe correspond to the target sequence while the reverse primer is complementary to the target sequence. The star by the forward primer indicates the G that is characteristic of the *AHAS1C* gene, distinguishing it from the *AHAS3A* gene which has a C at that site. The star on the reverse primer indicates the single SNV that confers herbicide tolerance on *AHAS1C* SU and *AHAS3A* SU and CL. The sequencing primer is the oligonucleotide use as primer for the Sanger sequencing presented in Figure 2.

Figure 3. Sequence of part of exon 2 of the SU canola *AHAS1C* gene showing alignments of the primers and probe for the 334 bp amplicon. The forward primer and probe correspond to the target sequence while the reverse primer is complementary to the target sequence. The star by the forward primer indicates the G that is characteristic of the *AHAS1C* gene, distinguishing it from the *AHAS3A* gene which has a C at that site. The star on the reverse primer indicates the single SNV that confers herbicide tolerance on *AHAS1C* SU and *AHAS3A* SU and CL. The sequencing primer is the oligonucleotide use as primer for the Sanger sequencing presented in Figure 2.

Table 1. Sequences of primers and probes used. +A denotes the locked nucleic acid (LNA) version of A; FAM, 6-carboxyfluorescein; BHQ, Black Hole Quencher 1.

Name	Primer Sequence (5′ to 3′)	Position	Amplicon Length	Reference
SU Canola-Specific Primers and Probe				
SU-Forward Primer	TCC TCG ACG AGC TAA CCG	1364–1381	334	This Study
SU-Reverse Primer	GCT TTG TAG AAC CGA TCT TCC +A	1676–1697		

To uniquely distinguish *AHAS1C* SU from *AHAS3A* SU and *AHAS3A* CL, we developed a forward primer that targeted the *AHAS1C* SNV at 1381, and a reverse primer that targeted the *AHAS1C* SNV at 1676, as is illustrated in Figure 3. PCR amplification using these primers generated a 334 base pair amplicon specific for *AHAS1C* SU. The sequence of these primers and the corresponding probe are

delineated in Table 1, along with sequences of primers and probe for a taxon-specific endogenous reference gene, which generates a 101 bp amplicon of the cruciferin A gene (*CruA*) [39].

Table 1. Sequences of primers and probes used. +A denotes the locked nucleic acid (LNA) version of A; FAM, 6-carboxyfluorescein; -BHQ, Black Hole Quencher-1.

Name	Primer Sequence (5′ to 3′)	Position	Amplicon Length	Reference
	SU Canola-Specific Primers and Probe			
SU-Forward Primer	TCC TCG ACG AGC TAA CCG	1364–1381	334	This Study
SU-Reverse Primer	GCT TTG TAG AAC CGA TCT TCC +A	1676–1697		
SU-Probe	FAM-ACA ACC AGC ATC TTG GGA TGG TCA-BHQ	1646–1669		
	Endogenous Reference Primers and Probe			
CruA-Forward Primer	GGC CAG GGT TTC CGT GAT	1408–1425	101	[39]
CruA-Reverse Primer	CCG TCG TTG TAG AAC CAT TGG	1488–1508		
CruA-Probe	FAM- AGT CCT TAT GTG CTC CAC TTT CTG GTG CA-BHQ	1427–1455		

3.2. Specificity of the SU Canola-Specific qPCR Method

We evaluated the specificity of these primer sets using DNA isolated from Clearfield canola varieties that carry the G-to-T mutation at position 1667 in the *AHAS3A* gene, but not in the *AHAS1C* gene and from SU canola DNA, which carries the G-to-T mutation at position 1667 in the *AHAS*3A gene and at position 1676 in the *AHAS*1C gene. As shown in Table 2 and Figure 4, while the *CruA* PCR system amplified both Clearfield and SU canola DNA, the SU canola-specific PCR system amplified only the DNA from SU canola. There was no amplification of the water/no-template control. As expected, since C5507 and C1511 appear to be heterozygous based on Sanger sequencing, while 40K appears to be homozygous (see Figure 2), the Ct for 40K with the SU canola primer-probe set was roughly 1 Ct lower than that of C1511 and C5507. See Table S3 Supplementary Materials for original data.

Table 2. Real-time qPCR amplification of SU canola and Clearfield canola DNA with PCR systems specific for the canola endogenous reference gene *CruA* and for the *AHAS1C-SU* gene of SU canola. DNA isolated from three SU canola varieties, C1511, C5507, and 40K, and three Clearfield canola varieties, 5545 CL, CS220 CL, and 2022 CL, were tested with primers specific for the *AHAS1C-SU* gene or for the *CruA* gene, with 200 ng input DNA per reaction. PCR conditions are as described in Methods. For all conditions except water control, $n = 3$. ND indicates that no amplification was detected; NA indicates "Not Applicable" because no amplification was observed.

PCR Specificity	***AHAS1C-SU***		***CruA***	
Canola Variety	**Mean Ct**	**Ct% CV**	**Mean Ct**	**Ct% CV**
5545 CL	ND	NA	20.81	0.16%
CS2200 CL	ND	NA	21.24	0.48%
2022 CL	ND	NA	21.02	0.16%
C5507	23.71	0.15%	20.93	0.09%
C1511	23.40	0.08%	20.87	0.10%
40K	22.37	0.41%	20.55	0.29%
Water	ND	NA	ND	NA

C5507	23.71	0.15%	20.93	0.09%
C1511	23.40	0.08%	20.87	0.10%
40K	22.37	0.41%	20.55	0.29%
Water	ND	NA	ND	NA

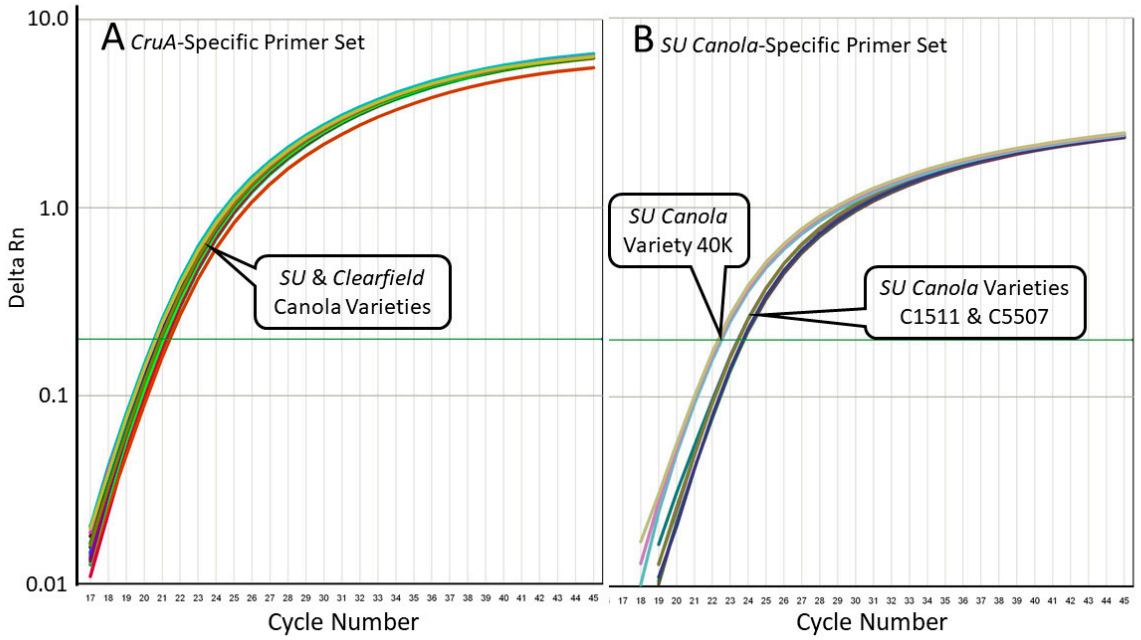

Figure 4. Quantitative PCR amplification curves for the results shown in Table 2, with primers specific for the *CruA* gene (**Panel A**) or with primers specific for the SU canola *AHAS1C-SU* gene (**Panel B**). In Panel B, amplification occurred only with the SU canola varieties 40K, C1511, and C5507, while in Panel A, amplification also occurred with the Clearfield canola varieties.

To confirm the specificities of the *AHAS1C-SU* PCR system for SU canola, we tested its ability to amplify *AHAS1C* sequences from 20 different wild-type canola varieties. Whereas the primer set targeting the *CruA* canola reference gene amplified DNA from all 20 wild-type varieties as well as DNA from the three SU canola varieties and a Clearfield canola variety (Figure 4, Panel A), the SU canola-specific primer set failed to amplify DNA from any of the 20 varieties of wild-type canola or from the Clearfield variety but did amplify all three of the SU canola DNA positive controls (Figure 4, Panel B). Weak background amplification was observed in a few reactions of three of the wild-type varieties, but this was not consistent among replicates. Of the 63 replicates run with wild-type or Clearfield canola, only 4 or 5 showed amplification, and this occurred only at very high cycle numbers, 41 or greater, in contrast to a Ct of 25.5 for an equivalent concentration of SU canola DNA. See Table S4 in Supplementary Materials for original data, which shows lack of consistency among replicates. Weak background was also seen for the no DNA control for the *CruA* but not the *AHAS*1c SU primer set. For *Cru*A, the difference in Ct between the no DNA sample and samples containing 300 ng DNA was 14.9, which clearly differentiates background from real signals.

The 20 wild-type varieties tested are representative of canola varieties in production globally, including varieties from Bangladesh, Canada, China, Denmark, France, Germany, Japan, The Netherlands, New Zealand, Poland, Russia, South Korea, Sweden, and the United States. See Supplementary Data Table S1 for accession numbers and origins of all varieties used. From the results presented in Tables 2 and 3 and Figures 4 and 5, we conclude that the SU canola-specific qPCR method is highly selective for SU canola and does not detect the wild-type or Clearfield canola varieties tested.

Table 3. Real-time qPCR amplification of DNA from SU canola event 40K, Clearfield canola variety 5545 CL and 20 varieties of wild-type canola with PCR systems specific for the *CruA* endogenous canola reference gene and the *AHAS1C-SU* SNV present in SU canola. PCR conditions are as described in Methods, with 300 ng input DNA per reaction for each variety except that the concentrations of DNA in the reactions labeled 40K-10, 40K-1 and 40K-0.1 were 300, 30 and 3 ng DNA of 40K DNA, respectively, with total DNA adjusted to 300 ng with DNA from canola variety 5454 CL for reactions 40K-1 and 40K-01. For all wild-type varieties, $n = 4$. ND indicates that no amplification was detected; NA indicates "Not Applicable" because no amplification was observed.

PCR Specificity	***AHAS1C-SU***		***CruA***	
Canola Variety	**Mean Ct**	**Ct% CV**	**Mean Ct**	**Ct% CV**
40K-10	25.36	0.08%	19.88	0.20%
40K-1	28.19	2.09%	20.10	0.72%
40K-0.1	33.43	1.44%	20.22	0.12%
5545 CL	ND	NA	20.88	0.46%
Variety 1	ND	NA	21.25	0.20%
Variety 2	ND	NA	19.64	0.75%
Variety 3	ND	NA	20.15	0.35%
Variety 4	ND	NA	19.45	0.11%
Variety 5	ND	NA	19.37	0.52%
Variety 6	ND	NA	18.74	0.49%
Variety 7	ND	NA	19.27	0.19%
Variety 8	ND	NA	19.19	0.48%
Variety 9	ND	NA	19.22	0.55%
Variety 10	ND	NA	19.67	0.73%
Variety 11	ND	NA	19.56	0.78%
Variety 12	ND	NA	19.12	0.38%
Variety 13	ND	NA	19.45	0.19%
Variety 14	ND	NA	19.08	0.49%
Variety 15	ND	NA	19.62	0.28%
Variety 16	ND	NA	20.47	1.12%
Variety 17	ND	NA	21.23	0.20%
Variety 18	ND	NA	19.06	0.50%
Variety 19	ND	NA	23.65	0.26%
Variety 20	ND	NA	18.29	0.39%
No DNA	ND	NA	34.36	2.48%

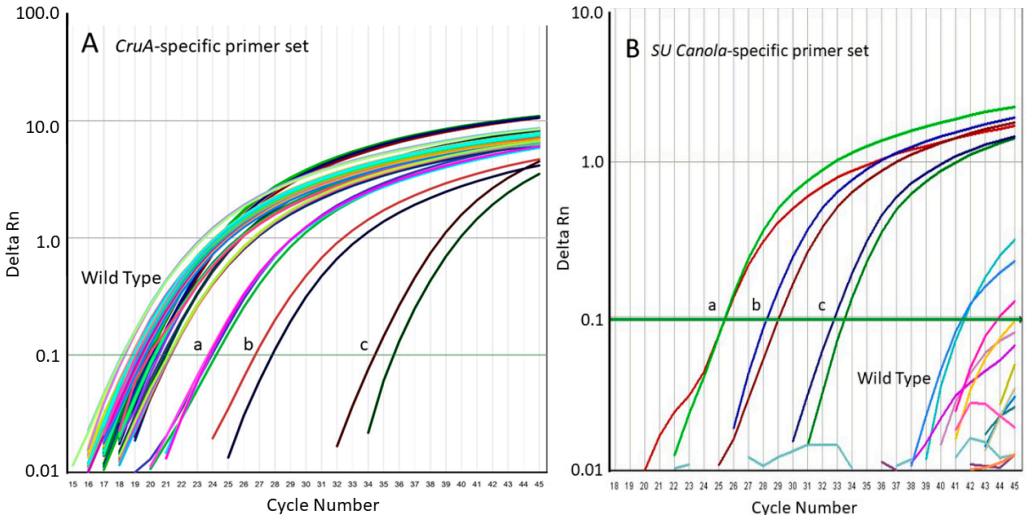

Figure 5. Quantitative PCR amplification curves for the results shown in Table 3. **Panel A**, amplification using the qPCR method specific for the canola endogenous reference gene (*CruA*); **Panel B**, amplification using the qPCR method specific for the *AHAS1C-SU* SNV of SU canola. Positive controls are DNA from SU canola event 40K at 300 (a), 30 (b), and 3 (c) ng 40K DNA per reaction.

Figure 5. Quantitative PCR amplification curves for the results shown in Table 3. **Panel A**, amplification using the qPCR method specific for the canola endogenous reference gene (*CruA*); **Panel B**, amplification using the qPCR method specific for the *AHAS1C-SU* SNV of SU canola. Positive controls are DNA from SU canola event 40K at 300 (a), 30 (b), and 3 (c) ng 40K DNA per reaction.

3.3. Precision, Trueness, Limit of Quantitation and Limit of Detection of the SU Canola Method

To determine the precision, trueness, limit of quantitation and limit of detection of the SU canola method, we combined decreasing proportions of DNA from SU canola event 40K with DNA from Clearfield canola variety 5545 CL. The units of relative concentration of SU canola DNA in 300 ng total DNA per reaction are weight SU canola DNA/weight total DNA (SU canola plus canola variety 5545 CL) percent. The results for proportions of SU canola DNA of 10%, 1.0%, 0.5%, 0.1%. 0.05% 0.01% and 0.0% are shown in Tables 4 and Figure 6. Total DNA was maintained constant at 300 ng/reaction

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Table 4. Real-time quantitative PCR analysis of SU canola DNA, variety 40K, mixed at five concentrations with Clearfield canola variety 5545 CL. Total DNA was 300 ng/reaction and n = 12. PCR conditions, as described in Methods using the SU canola-specific primers and probe. % CV indicates % Coefficient of Variation.

Declared SU Canola DNA Conc.	Average Measured SU Canola DNA Conc.	Std Dev of DNA Conc.	% CV of DNA Conc.	Percent Trueness of Measured DNA Conc.	Average Ct	Std Dev of Ct	% CV of Ct
10.00%	8.631%	0.758	8.8	13.69%	25.6490	0.1545	0.60
1.00%	1.011%	0.050	5.0	1.10%	29.0010	0.0762	0.26
0.10%	0.103%	0.012	11.1	3.38%	32.5780	0.1798	0.55
0.05%	0.045%	0.006	16.8	6.93%	33.8381	0.2587	0.76
0.01%	0.004%	0.003	69.0	56.68%	37.8368	0.9926	2.62

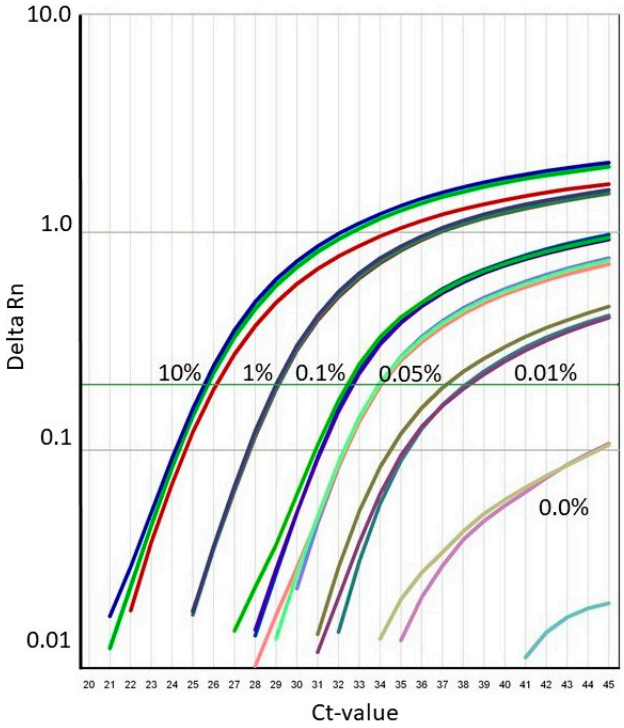

Figure 6. Typical amplification curves for the results shown in Table 3 of SU canola DNA variety 40K mixed at five concentrations with Clearfield canola DNA variety 5545 CL.

Figure 6. Typical amplification curves for the results shown in Table 3 of SU canola DNA variety 40K mixed at five concentrations with Clearfield canola DNA variety 5545 CL.

3.4. Independent Validation of the SU Canola-Specific qPCR Method

Independent validation of the SU canola-specific qPCR method was conducted by the Laboratory for GMO Analysis (LGA) of the Umweltbundesamt GmbH (Environment Agency Austria). Their results are summarized below. The full report is provided in Supplementary Materials, Item 6.

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The LGA determined the absolute limit of detection by two distinct methods, concluding that the LOD was 5 to 10 genomic copies with a level of confidence of 95%, which is in line with the ENGL acceptance criteria of <25 copies with a level of confidence of 95% [40]. This is consistent with the relative LOD determined during method development.

Specificity of the SU canola-specific qPCR method was assessed by the LGA by performing tests with DNA from eight wild-type canola varieties, three Clearfield varieties, six GM canola varieties, and DNA from corn, soy, rice, potato, and cotton. The SU canola-specific primer set failed to amplify all of these, while consistently amplifying the two SU canola varieties.

As part of the validation, LGA verified that the method met robustness criteria for six key factors, including PCR equipment, PCR master mix, annealing temperature, volume variation, primer concentration, and probe concentration.

The validation also verified quantitative performance from 0.10% to 5.00% SU canola DNA, and PCR efficiency and linearity were also verified over the full range of quantitation. In parallel, trueness and precision were assessed at 0.10%, 1.00% and 5.00% SU canola DNA. Both were well within the ENGL acceptance criteria of 25% across the entire dynamic range of the assay [40].

The lowest concentration of analyte tested by the LGA as part of their validation was 0.1%. Therefore, according to their validation study, the LOQ is at or below 0.10%. As part of the formal validation, the absolute Limit of Quantitation was found to be 40 genomic copies or lower, which is consistent with the relative LOQ determined during method development.

In summary, the validation carried out by the Laboratory for GMO Analysis of the Umweltbundesamt GmbH established that the SU canola-specific qPCR method meets all criteria for GMO testing methods established by the ENGL and by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit *Guidelines for the single-laboratory validation of qualitative real-time PCR methods* [33–36,40].

4. Discussion

We present in this paper the first experimental evidence addressing the feasibility of developing GMO regulation-compliant analytical methods for identification and quantitation of genome-edited plant material.

The recent report by ENGL [28] as well as a number of other articles (for instance [7,10,25,29]) have raised doubts regarding whether it is possible to create accurate and sensitive PCR methods for detection and quantitation of genome-edited plant materials that meet requirements for testing methods set out in the GMO regulations of the EU and similar jurisdictions. Our work provides a definitive answer to this question, demonstrating that highly sensitive and specific PCR methods that meet GMO regulatory requirements can be developed to detect and quantify edited organisms even when the genome edit consists of only a single base pair alteration, and even in cases of multicopy gene targets. This can be achieved even in complex allotetraploid genomes such as that of canola.

Based on the success with this challenging case of genomic editing, we are optimistic that standard qPCR, augmented with strategies such as the use of LNAs in primer design, will prove capable of delivering quantitative detection methods that meet GMO regulatory standards for all classes of genome-edited organisms, including single-nucleotide edits, as well as the indels and larger inserts for which qPCR methods are well established and in use for quantitative detection of GMOs created using recombinant DNA methods. Factors such as genome size and the possibly constrained sequence context of a given SNV (challenges such as the SNV being imbedded in an AT-rich, repetitive or primer–dimer-forming region) can also influence the sensitivity and specificity of the tests that can be developed for a given genome-edited event. However, a number of strategies are available for optimizing performance of the primer-probe set for a given SNV. In the present case, it was incorporation

of an LNA residue into the reverse primer that led to a significant increase in specificity of the *AHAS1C SU* primer-probe system. Other strategies may be successful in other situations. Adjusting primer position by just a few bases can increase specificity by as much as 7 or 8 Ct, and targeting GC-rich regions as primer sites, incorporating mis-matches into primer sequence and use of minor groove binding for probes are additional strategies that have yielded practical success.

Such methods are compatible with the basic standards of practice, equipment and molecular biological expertise found in most regulatory and commercial GMO laboratories, and could be readily integrated into the analytical routine and infrastructure of these laboratories. They also meet the current ENGL requirements [40] for GMO detection and quantitation methods.

Because of the complexity of the canola *AHAS* gene family, the method that we developed for specific detection of SU canola relied on the presence of two SNVs, one at the site of genome editing, and a second that distinguished the *AHAS1C* gene from the *AHAS3A* gene. However, in most cases, targeting a single SNV at a defined location in the genome of the genome-edited organism will be sufficient to achieve definitive detection and quantitation of the genome-edited event. This was not the case for SU canola because it carried an *AHAS3C* gene with the same G-to-T alteration (brought about by chemical mutagenesis is) that was effected by genome editing in the *AHAS1C* gene of SU canola. There may be other infrequent exceptions in which a combination of markers may be needed, depending on the specifics of the gene of interest and its genomic context. In each case, it will be necessary to identify gene and genomic features that are distinctive for the genome-edited event of interest and design the test around those features. It is ideal for a method to focus on one SNV, if possible, since this makes it possible to minimize amplicon length. In the case of SU canola, the amplicon length turned out to be 334 bases, which carries the disadvantage that, for samples in which the DNA has been partially degraded by food processing, sensitivity will be reduced as amplicon length increases [41].

In the case of deletion or insertion of nucleotides via genome editing techniques, developing definitive qPCR detection methods will be even more straightforward than for single base pair edits. For instance, in the case of the Calyxt high-oleic soy, the TALEN nuclease effected deletions of approximately 4 to 63 base pairs at defined positions within soy fatty acid desaturase genes. Because the length of deletions cannot be precisely controlled using the TALEN method, the exact sequence at the deletion site is randomly determined and therefore unique since the probability of generating, by any mechanism, an identical deletion of exactly the same length is extremely low. Thus, a primer that spans the deletion point will uniquely differentiate that event.

At present, the model that most laboratories employ in GMO surveillance is called the matrix approach, where a series of sequence features common to many GMOs, such as the CaMV P-35S promoter and the T-nos terminator are targeted, along with event-specific targets for GMOs that do not carry common sequences [42,43]. The result is a minimal set of PCR targets that, together, are capable of efficiently detecting a broad range of authorized GMOs and known-unauthorized GMOs. To incorporate genome-edited GMOs into this scheme is straightforward: the sequence target or targets for each genome-edited GMO are incorporated into the screening matrix along with target sequences for other GMOs that do not carry common sequences. The number of genetically modified crops lacking common sequences has been increasing in recent years, and genome-edited crops will add to this number. Thus, screening will require an increasing number of primer-probe sets in the future. This could become economically unsustainable, if the field continues to rely on real-time qPCR. However, the use of next-generation sequencing technology's capacity to carry out massively parallel multiplexed quantitative amplicon sequencing provides a viable alternative, although it will require significant development effort. This approach has already been applied qualitatively in GMO screening [44]. Fields such as microbiological ecology have already applied this approach quantitatively [45].

Discussions regarding the ability to develop methods for detection and quantitation of genome-edited crops often focus on the challenge of definitively demonstrating whether a particular

genome modification is the result of genome editing or, for instance, chemical mutagenesis. However, a close reading of Directive 2001/18/EC [5] and Commission Implementing Regulation (EU) No 503/2013 [31] indicates the capacity for such discrimination is not necessary to meet the requirements for marketplace surveillance of GMOs, established in European Union law:

> "The method(s) shall be specific to the transformation event (hereafter referred to as 'event-specific') and thus shall only be functional with the genetically modified organism or genetically modified based product considered and shall not be functional if applied to other transformation events already authorized; otherwise the method cannot be applied for unequivocal detection/ identification/quantification."—Section 3.1.C.1. of Annex III to Regulation (EU) No 503/2013

This passage from the EU Commission's implementing regulation clearly does not require that GMO analytical methods must be able to ascertain the process by which a particular GMO was created. It only requires the analytical method to be able to distinguish the modified event from other authorized events in the marketplace. Language similar to that quoted above from Regulation (EU) No 503/2013 is also found in the ENGL document, Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing [40]. Based on these authoritative sources, it is clear that methods such as the one reported in this paper for SU canola meet the event specificity requirements for GMO analytical methods under EU regulations.

We based development of the detection and quantitation method for SU canola on information available in the public domain, referenced earlier in this paper. More broadly such information would include GMO-related patents, documents related to governmental regulatory approvals, communications to investors and market information relevant to commercialization. This information is accessible to any interested party so that it can be systematically monitored and used for development of test methods. It is unlikely that a commercial product could enter the global food system without sufficient information being released into the public domain to adequately inform the method development process. In certain jurisdictions, such as the EU, information related to detection methods is available through another route, as well; GMO regulatory law requires commercial entities, seeking market authorization for genetically modified food products, to provide a product-specific detection and quantitation method. They are also required to make available reference material. Since the European Court of Justice has already established that genome-edited products fall within the scope of the EU GMO regulation [4], methods for detection and quantitation of genome-edited products must be made available by the developer as part of the market authorization process for every genome-edited product.

A final issue raised in discussions regarding methods for detection and quantitation of genome-edited crops is challenges related to detection of unauthorized genome-edited crops. In the past, commodities have been screened for unauthorized GMOs using tests that detect common sequence elements, such as the CaMV P-35S promoter and the T-nos terminator that have been used in the construction of many GMOs. It has been argued that genome-edited products are challenging because they do not carry these common sequences and therefore unauthorized genome-edited crops could not be detected using these broad screening methods [28]. It should be pointed out that this is not a limitation exclusive to genome-edited products. As discussed at length in a report from ENGL [28] and elsewhere [42,43], it is not difficult, using even recombinant DNA methods, to develop GMOs that are free from common sequence elements. Consequently, many such GMOs have been commercialized, and it is quite possible that there are unapproved GMOs in the marketplace, even now, that have not been detected because they do not carry any common sequences. Thus, unauthorized genome-edited products represent just one new class of unauthorized genetically modified products, among others, that cannot be detected by using the existing screening strategy. Screening for unauthorized GMOs is not, and never has been, an exhaustive process, and the presence of genome-edited products in

the commercial food system does not create a new set of circumstances that demands fundamental changes in the regulatory regime for GMOs.

Although our work demonstrates that it may be possible to develop event-specific, GMO regulation-compliant detection methods for virtually any gene-edited organism based on information disclosed by the developer or gathered from the public domain, screening methods capable of detecting whole classes of gene-edited products, such as CRISPR or TALEN, would also be a useful addition to the screening matrix. CRISPR and TALEN modified organisms are often transgenic due to the incorporation into the host genome of the genetic apparatus that synthesizes the sequence- specific nuclease involved. Demorest et al. [46], as an example, reported that 80% of the TALEN events that they generated were transgenic. Screening methods for CRISPR or TALEN could, for instance, rely on retained transgenic fragments unintentionally left in the final plants' genomes. There are attempts to select events that do not carry these sequences [47] or to use strategies that do not require such expression vectors [48], but there is quite limited empirical evidence at this time demonstrating the success and generalizability of these efforts. We expect that research in coming years will lead to screening methods for at least some, if not all, categories of genome-edited products.

5. Conclusions

We have developed a sensitive, GMO regulation-compliant method for detecting the first genome-edited crop to be commercialized and suggest that it may represent a general approach for detecting genome-edited organisms. This effort was intended to address the concern voiced by several [7,10,25,26,28,29] that it may not be possible to develop quantitative detection methods for genome-edited plant materials that meet GMO regulatory requirements in jurisdictions such as the EU. In particular, they questioned the feasibility of developing quantitative methods that target single-nucleotide edits and that are sufficiently sensitive and specific to meet the requirements of EU law and regulations. The research presented here provides a clear answer to these concerns, showing that straightforward qPCR methods can be developed for single-nucleotide edits (SNVs). This, in conjunction with the fact that the scientific community has been using qPCR to quantitatively detect indels and inserted genes for two decades, indicates that it may be possible to develop qPCR methods for virtually any genome edit.

Our approach does not rely on specialized point mutation detection procedures, but employs straightforward real-time qPCR methods that are compatible with the basic standards of practice, equipment and molecular biological expertise found in most regulatory and commercial GMO testing laboratories. The resulting methods can readily integrate into the analytical routine of the typical regulatory or commercial GMO testing laboratory, including the matrix approach. The SU canola assay has been independently validated and fully meets the requirements for GMO testing methods laid down in European Union law and regulations and has been placed in the public domain, accessible to all laboratories.

This work establishes the basis for developing a test-based strategy for monitoring genome-edited plant products that integrates seamlessly into the same strategy that is used today in the EU and most other countries to monitor and regulate GMOs developed through recombinant DNA methods. Such an approach will deliver the transparency that consumers are increasingly demanding for the food that they provide to their families, and will, if necessary, provide the post-market traceability needed in case of unintended biosafety, environmental or socio-economic impacts.

Supplementary Materials: The following are available online at http://www.mdpi.com/2304-8158/9/9/1245/s1, Table S1. List of Wild Type Canola Varieties, Table S2. Complete sequences from Sanger sequencing of four canola varieties, Table S3. PCR amplification of SU canola and Clearfield canola DNA with *CruA* and SU canola specific primer sets, Table S4. Quantitative PCR amplification of DNA from SU canola, event 40K, Clearfield canola variety 5545 CL and 20 varieties of wild type canola with *CruA* and SU canola-specific primer sets, Table S5a,b. Determination of Limit of Quantitation, Limit of Detection, Trueness and Precision for Quantitative PCR System Specific for *AHAS1C SU* and S6 AEA Validation Report, File S1—Statement Regarding Associated Intellectual Property.

Author Contributions: Conceptualization, J.F. and S.J.H.; methodology, P.C., J.F., H.I., S.A.K., and B.H.J.; validation, P.C. and H.I.; investigation, P.C. and H.I.; resources, J.F.; writing—original draft preparation, J.F.; writing—review and editing, B.J., P.C., S.J.H., S.A.K., and J.F.; visualization, J.F.; supervision, J.F. and B.J.; funding acquisition, S.J.H.; project administration, S.J.H., J.F., and B.J. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest: J.F. was the founder of an international GMO testing company. Since 2013, he has had no financial or other connection with that company or any other company involved in GMO testing. P.C. was Senior Scientist at a GMO testing company but currently has no financial or other affiliation with that or other companies in the GMO testing space. The other authors declare no conflicts of interest.

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Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: bijpraten
Datum: woensdag 9 september 2020 11:07:08
Bijlagen: image001.gif

Zullen we mikken op 16u? Half uurtje is prima volgens mij

Van: 10.2.e
Verzonden: dinsdag 8 september 2020 15:39
Aan: 10.2.e
Onderwerp: RE: bijpraten

Prima – donderdag alleen tussen half 3 en 5 wat mij betreft
Vrijdag heb ik wat meer opties – voor 10:00; tussen 12 en half 2 en na 3.30
Met vriendelijke groet,

10.2.e
Directeur
Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e @minlnv.nl]
Verzonden: dinsdag 8 september 2020 14:03
Aan: 10.2.e @plantum.nl>
Onderwerp: bijpraten
Urgentie: Hoog

Ha 10.2.e ,
Alles goed? Fijne vakantie gehad? Heb je toevallig tijd om binnenkort bij te praten, bijvoorbeeld donderdag? Paar ontwikkelingen die momenteel weer spelen.
Gr,
10.2.e

European Plant Science Organisation
www.epsoweb.org

Statement

Detecting a point mutation does not clarify its origin

Brussels, 9.9.2020

Does a point mutation look different when it is made by one process or another? No! One cannot tell from the mutation itself whether it was spontaneous or triggered by genome editing, and additional information on the history of the genetic material is needed as a precondition to evaluate from which breeding process it originates. Spontaneous or edited, point mutations are the same for all intents and purposes.

EPSO fully agrees that known gene edits including single nucleotide changes can be detected by PCR**.** EPSO declared this in its input to the present EC study on NGTs (New Genomic Techniques) and connected statements. The Greenpeace-funded work by the Chhalliyil et al (2020) publication merely confirms this well-established fact.
However, the published method has two main limitations: It does not present a means to establish that genome editing is the cause of the detected mutation, since it just displays a sequence modification without identification of the modification process. This has been seen from the beginning as the major challenge, since edited plants produced in countries with more open regulation are not declared as such. In addition, the method is not applicable to unknown gene modifications, since edited plants, contrary to classical GMOs (Genetically Modified Organisms), do not share common elements, and a method detecting a specific sequence variation cannot detect different variations in other plants and sequences. The detection of a single nucleotide change does not provide any proof by itself that this change was provoked by genome editing rather than natural mutation**.**

On 7 September 2020, Chhalliyil et al. published the paper 'A real-time quantitative PCR (Polymerase Chain Reaction) method specific for detection and quantification of the first commercialised genome-edited plant'. This is based on the detection of SNPs (Single Nucleotide Polymorphism) in two respective genes conferring a resistance to sulfonylurea and imidazolinone herbicides. One gene is thought to be modified by genome editing (ODM), the other by chemical mutagenesis. The authors developed a method to specifically detect these SNPs in the relevant sequences.

Chhalliyil et al. 2020 claimed that "certified seed from three SU (sulfonylurea and imidazolinone herbicide-tolerant) canola varieties, C1511, C5507, and 40K (Cibus US LLC/Falco Brand, San Diego, CA, USA) all developed by oligonucleotide directed mutagenesis [1,30] were used." and furthermore that "based on the fact that variety 5715 was the only Cibus ODM variety authorized/deregulated at the time varieties C1511, C5507 and 40K were commercialized, it can be concluded that these varieties were derived from variety 5715."

However, it is not clear that the mutation was in fact a product of genome editing (ODM): Health Canada (reference 30 in Chhalliyil et al. 2020) explained: "***The petitioner hypothesized that the single nucleotide mutation was the result of a spontaneous somaclonal variation*** that

occurred during the tissue culture process, and ***not due to the specific oligonucleotide used in the* RTDS *protocol***". Moreover, Cibus describes: "MEET FALCO™, BROUGHT TO YOU BY CIBUS™ Falco™ sulfonylurea-tolerant (SU Canola™) canola is a first generation Cibus trait ***developed through traditional plant breeding methods***. 32K, 68K and *40K SU Canola*™ hybrids offer high yields and excellent weed control and will soon be joined by a number of other innovative hybrids as our product pipeline continues to grow."

So Chhalliyil et al. (2020) describe a method to detect a SNP by qPCR, not a method to determine the origin of this mutation. The link to genome editing is not established by the method, but simply circumstantial: based on their inconsistent historic (pedigree) information on how the SNP was generated. They cannot judge by their method whether "natural" or "engineered". In fact, the paper by Chhalliyil et al. 2020 underlines how important a priori information is, and that it is impossible to judge just from a short sequence whether it has been modified by genome editing or natural mutation. They actually demonstrate that the pure method is insufficient to judge compliance and scrutinize law enforcement.

Thus the conclusion in the EPSO statement "On the EC study on New Genomic Techniques (NGTs) *Brussels, 27.5.2020* is confirmed: "With regard to incoming NGT-plants or NGT-products, GMO legislation can readily be applied if the genome modifications are known, which is the case, for example, in international scientific collaborations. However, in the absence of prior knowledge on the potential genome alterations their detection and identification does not seem to be feasible by PCR-based detection methods. Often suggested as the ultimate tool, whole genome DNA sequencing actually allows under certain conditions the near-exhaustive detection of unknown DNA modifications in a plant genome. However, the detection of a sequence alteration does not permit the identification of the process that generated it and to decide whether GMO legislation needs to be applied or not. Indeed, identical DNA alteration may be obtained by NGTs or by conventional breeding or random mutagenesis techniques, which are exempted from GMO legislation."

This statement was developed by 10.2.e *(EPSO President) and* 10.2.e *(EPSO Agricultural Technology Working Group co-chair) and approved by the EPSO Board, based on previous statements approved by the Agricultural Technology Working Group and the EPSO Representatives.*

Contacts
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Useful links

- Chhalliyil et al. (2020) A real-time quantitative PCR method specific for detection and quantification of the first commercialised genome-edited plant. Foods 9:1245 [doi: 10.3390/foods9091245].
- EFSA draft scientific opinion on the safety assessments of plants developed using Site-Directed Nucleases type 3, SDN-3 https://www.efsa.europa.eu/sites/default/files/consultation/consultation/Scientific_opinion_SDN1_2_ODM_for_PC.pdf
- EC study on new genomic techniques (NGTs) https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en
- Court of Justice of the EU: Judgment in Case C-528/16, 25.7.2018.English Press Release; Ruling in English:

https://epsoweb.org
EPSO Working Group on Agricultural Technologies:
Statements drafted by this group and approved by the EPSO representatives are for instance:

- EPSO statement on the EFSA draft opinion on directed mutagenesis, 25.6.2020
- EPSO: Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020
- EPSO: Statement on the Court of Justice of the EU ruling regarding mutagenesis and the GMO Directive, 19.2.2019
- EPSO: EPSO welcomes Commissioner Andriukaitis statement and call for action 'New plant breeding techniques need new regulatory framework', 29.3.2019

EPSO communications: https://epsoweb.org/news/

EPSO member institutes and universities: https://epsoweb.org/about-epso/epso-members/
EPSO representatives: https://epsoweb.org/about-epso/representatives/

About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 31 countries, mainly from Europe, and 2.600 individual Personal Members, representing over 26 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science including science advice to policy, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science. https://epsoweb.org | EU Transparency Register Number 38511867304-09

Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: EPSO statement: Point mutation detection does not clarify its origin - pls disseminate
Datum: donderdag 10 september 2020 13:07:28
Bijlagen: image001.jpg

Ha 10.2.e,
Veel dank! Had ook al hele nuttige stukken van o.a. 10.2.e en 10.2.e gekregen. Moeten goed kijken hoe we dit aanpakken want er zullen ongetwijfeld (TK) vragen over binnenkomen.
Gr,
10.2.e

Van: 10.2.e
Verzonden: woensdag 9 september 2020 21:36
Aan: 10.2.e
Onderwerp: FW: EPSO statement: Point mutation detection does not clarify its origin - pls disseminate
Urgentie: Hoog

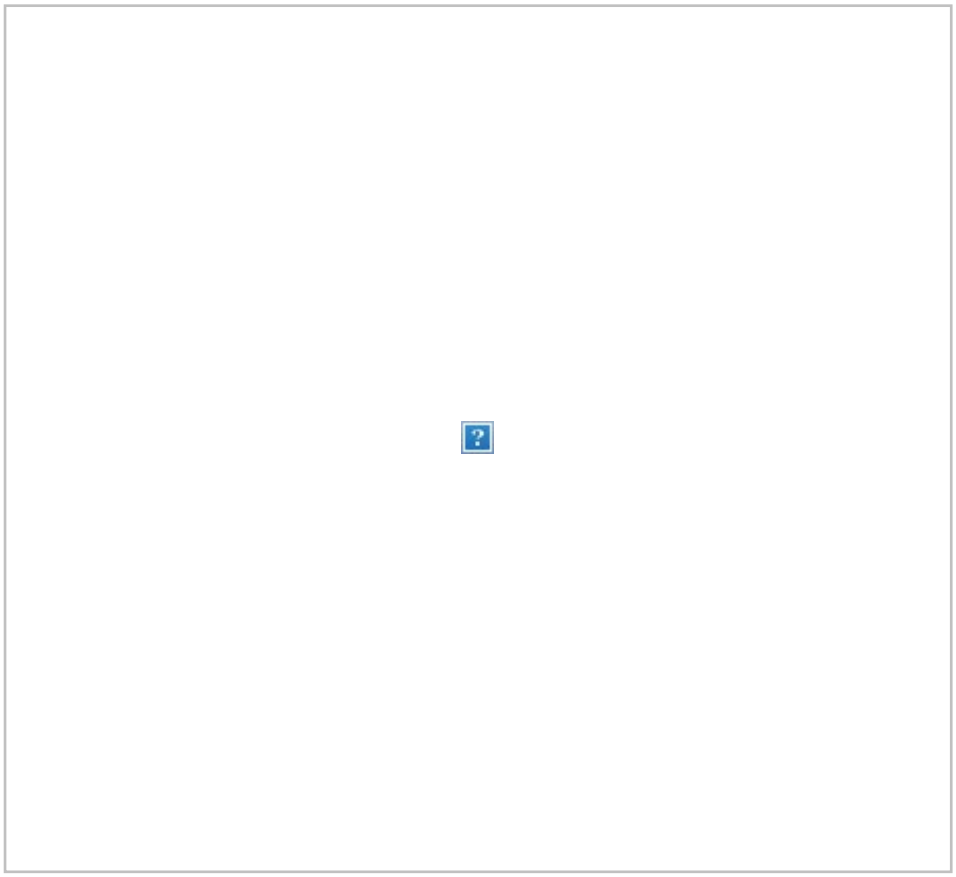
Hi 10.2.e,
Wellicht had je de consternatie rond de publiciteit van Greenpeace over de mogelijkheden om gene-editing te kunnen detecteren in planten al meegekregen. Bijgaand, ter info, het EPSO-statement wat is uitgebracht vandaag, wellicht handig voor je om te weten,
Groet,
10.2.e

Van: 10.2.e @epsomail.org>
Datum: woensdag 9 september 2020 om 17:37
Aan: 10.2.e @epsomail.org>
CC: 10.2.e @helsinki.fi)" <10.2.e @helsinki.fi>, 10.2.e @ens-lyon.fr)" 10.2.e @ens-lyon.fr>, 10.2.e @julius-kuehn.de)" 10.2.e @julius-kuehn.de>
Onderwerp: EPSO statement: Point mutation detection does not clarify its origin - pls disseminate

Dear EPSO Representatives, Supporting Scientists and AgT WG members (all in bcc),
Pls find attached the EPSO statement 'Point mutation detection does not clarify its origin', 9.9.2020, we just published online and via twitter.
Pls re-tweet and disseminate widely among your colleagues from academia as well from relevant ministries and funding agencies.
I will do so at EU level.
Background:

- This responds to a journalist request to comment the Greenpeace brief (7.9.2020) 'First open source detection test for a gene-edited GM crop'. www.greenpeace.org/eu-unit/issues/nature-food/4102/first-open-source-detection-test-for-a-gene-edited-gm-crop-2/ . Alan will answer the request tomorrow.
- Attached (7.9.2020): Chhalliyil et al. (2020) A real-time quantitative PCR method specific for detection and quantification of the first commercialised genome-edited plant. Foods 9:1245 [doi: 10.3390/foods9091245].
- Euroactive interviews (8.9.2020): www.euractiv.com/section/agriculture-food/news/first-detection-test-developed-for-gene-edited-crop-campaign-groups-claim/

Thanks to 10.2.e who developed our statement, approved by our Board.
With best wishes
10.2.e



****
10.2.e
Executive Director
European Plant Science Organisation, EPSO
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****

Van: 10.2.e
Aan: 10.2.e @mapa.es); 10.2.e ;10.2.e @regeringskansliet.se); 10.2.e ;10.2.e @fz-juelich.de); 10.2.e @bmbf.bund.de); 10.2.e @bmel.bund.de); 10.2.e @mmm.fi); 10.2.e @fz-juelich.de); 10.2.e @bmbf.bund.de); 10.2.e @envir.ee); @smm.lt)
Cc: 10.2.e @helsinki.fi); 10.2.e @ibba.cnr.it); 10.2.e @cnb.csic.es); 10.2.e @taltech.ee); 10.2.e @wur.nl); 10.2.e @embo.org); 10.2.e @nmbu.no); 10.2.e @ens-lyon.fr); 10.2.e @vib.be); 10.2.e @landbruk.no); 10.2.e @slu.se); 10.2.e @julius-kuehn.de)
Onderwerp: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; + participant list; Travel restrictions?
Datum: vrijdag 11 september 2020 16:23:05
Bijlagen: 20_07_03_EPSO_Genome editing - 3rd informal meeting_Participants.docx

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Dear colleagues from national ministries,

Dear 10.2.e ,

Pls find attached the updated participant list [Chatham House Rules – INTERNAL USE ONLY] – 9 countries and the European level are already confirmed (in bold).

This time we will welcome in addition 10.2.e , MEP, chair of the AGRI Committee of the European Parliament.

@10.2.e : pls kindly confirm your participation as well.

We will hold our 3rd informal science and policy meeting on 3 November 2020.

Pls let us know if you have travel restrictions – in this case we would hold the meeting online.

The 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.

EPSO activities: upon several journalist requests, we published this week (attached):

- EPSO statement 'Point mutation detection does not clarify its origin', 9.9.2020

We very much look forward to your replies and to continue the discussion

Take care!

10.2.e
****
10.2.e
Executive Director
European Plant Science Organisation, EPSO
Rue de l'Industrie 4, 1000 Brussels, Belgium
10.2.e "epsomail.org ; T/F: +10.2.e
www.epsoweb.org ; EU Transparency Register Number 38511867304-09
****

From: 10.2.e **Sent:** 04 June 2020 **To:** Participants

Subject: EPSO: Genome editing - 3rd Informal science - policy meeting in BRU: 3.11.2020 confirmed; Interest in webinar on NO consumer survey? + participant list

Dear colleagues from national ministries,

Dear 10.2.e ,

Thanks to your replies, we are happy to **confirm our 3rd informal science and policy meeting will take place in Brussels @ Kowi on 3 November 2020.**

The room is large enough to adhere to social distancing. In case of new restrictions, we would hold the meeting online.

Pls find attached the participant list [Chatham House Rules – INTERNAL USE ONLY] – 9 countries and the European level are already confirmed (in bold).

This time we will welcome in addition 10.2.e , MEP, chair of the AGRI Committee of the European Parliament.

EPSO 3rd informal science – policy meeting on genome editing in Brussels, 3.11.2020

List of participants - confirmed in bold – by 3.7.2020

Participating countries:

Belgium
10.2.e , Federal Ministry of Environment – possibly other meeting, then send deputy
10.2.e **, VIB**

Estonia
10.2.e , Ministry of Environment – interested, finally confirm later on
10.2.e **, Tallinn University of Technology**

Finland
10.2.e **, Ministry of Agriculture and Forestry**
10.2.e **, LUKE & EPSO President**

France
10.2.e **, Ministry for Agriculture and Food**
10.2.e **, INRA**

Germany
10.2.e **, Ministry for Education and Research**, 726 Bioeconomy
10.2.e **, Ministry for Education and Research,** 611 Ethics & Law in Life Sciences
10.2.e , Ministry of Food and Agriculture, 222 – New Technologies – apologies
10.2.e **, Ministry of Food and Agriculture,** 222 – New Technologies
10.2.e , Ministry of Food and Agriculture, 222 – New Technologies – apologies
10.2.e **, JKI**

Italy
t.b.a., Ministry for Environment
10.2.e **, CNR**

The Netherlands
10.2.e **, Ministry for Agriculture**
10.2.e **, WUR**

Norway
10.2.e , Ministry of Climate and Environment
10.2.e **, NO Agricultural Cooperatives**
10.2.e **, NO University of Life Sciences**

Spain
10.2.e **, Ministry for Agriculture**
10.2.e **, CSIC**

Sweden
10.2.e **, Min. of Enterprise and Innovation**
10.2.e **, Min. of Enterprise and Innovation**
10.2.e **, SLU**

Europe
10.2.e **, European Parliament, chair AGRI Committee**
10.2.e **, EPSO**
10.2.e **, EMBO**

@10.2.e : pls kindly confirm your participation as well.

As we agreed, the 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.

We will now invite colleagues from DK, IT, LT, PT who apologised last time. You are welcome to send us more suggestions too.

EPSO activities: we submitted in the meantime to the EC NGT survey (see below), the EFSA NGT consultation and to the JRC study on NGTs.

Pls find attached recent EPSO statements including references to NGTs:

- EPSO: Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020 (incl. links to original submission files)
- EPSO: Statement on the Farm to Fork Strategy by the European Commission, 2.6.2020 (incl. contributions from NGTs, include in R&I incentives)
- EPSO: Statement on the First Draft Implementation Strategy for Horizon Europe by the EC, 3.6.2020 (define the goals, but not the path to get there..)

Sigrid kindly offered holding a webinar with you on the final outcome of her study among Norwegian consumers – **pls express your interest** to set a date:

- I am interested in the consumer survey webinar: yes / no
- I would prefer this in: end June, early July, September

We very much look forward to your replies and to continue the discussion

Stay safe!

10.2.e

From: 10.2.e **Sent:** 24.4.2020 **To:** Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020 - Report - reply pls by 8.5.2020

Dear colleagues from national ministries,

Thank you for a very open and constructive meeting!

Please find attached

- The Report – you may use publicly
- The Presentations – Chatham House Rule - you may use internally to discuss with your colleagues
- The Handout and the participant list – Chatham House Rule – only for participants.

As we agreed at the end of our 2nd meeting, the 3rd meeting will shortly look into updates regarding improving the legislation and mainly focus on flagship projects towards genome edited products with consumer benefits for the European market by 1) Discussing if more countries want to follow the Norwegian consumer survey, 2) present ongoing / approved calls, projects, and 3) discuss opportunities for future calls / programmes / projects at national and multinational levels.

Actions:

- **All participants (this always includes those that apologised to due to overlapping activities) kindly provide to us by 8 May their availability to meet in Brussels** in the European quarter (likely at KoWi) **between 19.10. and 6.11.2020** and **Ministry / funders participants kindly indicate if they wish to present** ongoing, approved or possible future opportunities regarding flagship projects:
  - I am interested to join the 3rd meeting: yes / no
  - Availability between 19.10. and 6.11.2020:
    - I am available all dates yes / no*
    - *I am NOT available on these dates: list
  - I would be interested to present ongoing, approved or possible future opportunities regarding flagship projects: yes (keyword) / no

  Based on your availability, we will let you know mid-May 1-3 dates to pencil in for the 3rd meeting. Monitoring the corona developments we will let you know by 4th September if the meeting can already take place and on which of the reserved dates.
- All participants are welcome to send us news items for a quarterly update regarding genome editing legislation and efforts to improve the legislation from among the participants.

- Ministry participants kindly suggest to EPSO which additional ministry colleagues to invite (providing name, ministry, email). Should this not be possible under GDPR, please recommend such colleagues to contact EPSO expressing their interest to join the next such informal meeting.

We very much look forward to your replies and to continue the discussion

Stay safe!

10.2.e

From: 10.2.e **Sent:** 09.04.2020 **To:** Participants

Subject: EPSO: Genome editing - 2nd Informal science - policy meeting in BRU, 24.1.2020; Norwegian consumers' attitudes toward gene editing

Dear colleagues from national ministries,

Thank you for a very interesting meeting and apologies for the delay in sending the report, you will receive it later in April.

As we are all busy with the EU survey on NGTs, you may find the report useful towards which 10.2.e presented first outcome at our meeting:

The Norwegian Biotechnology Advisory Board (2020). Norwegian consumers' attitudes toward gene editing in Norwegian agriculture and aquaculture. www.bioteknologiradet.no/filarkiv/2020/04/Report-consumer-attitudes-to-gene-editing-agri-and-aqua-FINAL.pdf

With best wishes and have a nice Easter

10.2.e

Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: Vraag nav WFSR workshops over aanpassing GGO-regelgeving
Datum: dinsdag 15 september 2020 14:10:25
Bijlagen: image001.png

Hallo 10.2.e,

Om ca 17:30 uur bellen is prima.

Groet,
10.2.e

10.2.e
Program manager

Holland BIO

10.2.e @hollandbio.nl | www.hollandbio.nl | twitter.com/hollandbio
T: + 31 (0)70 10.2.e | M: + 31 (0)6 10.2.e

Bezoekadres: Laan van Nieuw Oost-Indië 131-133, 2593 BM Den Haag
Postadres: : Laan van Nieuw Oost-Indië 131E, 2593 BM Den Haag

Van: 10.2.e @minlnv.nl>
Verzonden: dinsdag 15 september 2020 13:57
Aan: 10.2.e @hollandbio.nl>
Onderwerp: RE: Vraag nav WFSR workshops over aanpassing GGO-regelgeving

Ha 10.2.e,

Zullen we aan het einde van de dag even bellen? 17.30u bijvoorbeeld?

Gr,

10.2.e

Van: 10.2.e @hollandbio.nl>
Verzonden: dinsdag 15 september 2020 12:06
Aan: 10.2.e @minlnv.nl>
Onderwerp: Vraag nav WFSR workshops over aanpassing GGO-regelgeving

Beste 10.2.e,

Via Wageningen Food Safety Research hebben we het verzoek gekregen om een uitnodiging voor expert workshops in oktober over de aanpassing van de Europese GGO- regelgeving (mogelijke scenario's, waaronder 'process naar product-based') onder onze leden uit te zetten. Natuurlijk doen wij dat graag. Het zou ons helpen als we weten hoe we deze workshops en beleidsondersteunende traject dat WFSR voor jullie uitvoert in verhouding staan met de andere trajecten binnen jullie departement op dit gebied. Kun je me daar wat meer info over geven? Dat kan per mail, maar bellen is ook prima. Ik ben bereikbaar op mijn mobiele nummer (06-10.2.e .

Ik hoor graag van je.

Met vriendelijke groet,

10.2.e
Program manager

10.2.e @hollandbio.nl | www.hollandbio.nl | twitter.com/hollandbio
T: + 31 (0)70 10.2.e | M: + 31 (0)6 10.2.e

Bezoekadres: Laan van Nieuw Oost-Indië 131-133, 2593 BM Den Haag
Postadres: : Laan van Nieuw Oost-Indië 131E, 2593 BM Den Haag

Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: workshop GGO-wetgeving Wageningen
Datum: woensdag 16 september 2020 09:50:01
Bijlagen: image001.gif

Was een beetje een primaire reactie van mij ☺ – we zijn inderdaad al een paar jaar op verschillende manieren in gesprek. Product based is (technisch-) wetenschappelijk gezien best logisch, maar de praktische implicaties zouden wel eens juist meer complexiteiten geven (was het Rathenau dat zo'n rapport uitgebracht heeft?).
Anyway – we gaan zeker meedoen met deze workshop
Met vriendelijke groet,

10.2.e
Directeur
Plantum

Beschrijving: Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e [mailto:10.2.e @minlnv.nl]
Verzonden: woensdag 16 september 2020 09:26
Aan: 10.2.e
Onderwerp: RE: workshop GGO-wetgeving Wageningen
Ha 10.2.e,
Het is een project dat al een aantal jaar loopt als onderdeel van onze kennisbasis en beleidsondersteunend onderzoek. Bedoeling is volgens mijn dat ze verschillende scenarios verkennen aan de hand van huidige ontwikkelingen. Ze zijn af en toe erg enthousiast maar de BOs zijn nuttig om bij te blijven met de wetenschap/kennis.
Enfin, we zullen zien wat voor informatie ze op halen.
Gr,
10.2.e

Van: 10.2.e @plantum.nl>
Verzonden: woensdag 16 september 2020 08:37
Aan: 10.2.e @minlnv.nl>
Onderwerp: workshop GGO-wetgeving Wageningen
Ha 10.2.e,
Weet jij waar dit ineens vandaan komt? De risico-lieden van de WUR zijn al een tijd bezig met product-based benaderingen en lijken het weer als de nieuwe waarheid aan de man te willen brengen terwijl het in Canada (enige product-based systeem bij mijn weten) helemaal niet zo soepeltjes loopt . . ..
Met vriendelijke groet,

10.2.e
Directeur

Plantum

Beschrijving: Plantum

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website www.plantum.nl

Van: 10.2.e @wur.nl]
Verzonden: maandag 14 september 2020 14:47
Aan: 10.2.e @plantum.nl>
CC: 10.2.e @wur.nl>
Onderwerp: RE: Vraag m.b.t. mogelijke bijdrage Plantum aan onze activiteiten m.b.t. proces- versus product-gebaseerde regelgeving voor plantenbiotechnologie

Beste 10.2.e,
Dank voor jouw email en excuses voor de late terugkoppeling over de uitnodigingen voor de expert workshop voor het beleidsondersteunend project voor LNV aan het voorbereiden zijn. In de bijlage tref je een PDF aan met de uitnodigingen voor de online workshop voor experts uit de plantveredelingssector op donderdag 8 oktober 2020
Hieronder volgt tevens een uitnodigende tekst (*). Zoals gezegd zouden we Plantum erkentelijk zijn als deze uitnodigingen onder de desbetreffende leden verspreid kunnen worden aangezien ook de visie vanuit de sector essentieel is als feedback voor onze opdrachtgever over o.a. de noodzaak, haalbaarheid en wenselijkheid van mogelijke scenario's voor toekomstige regelgeving (m.n. ook naar aanleiding van de discussie over de wetgeving rond gene editing).
Voor eventuele discussie hierover zijn 10.2.e (projectleidster) en ikzelf beschikbaar, bijvoorbeeld vanmiddag vanaf 16:00 en morgen (behalve tussen 10:30 en 11:30). Laat maar even weten of en wanneer jouw voorkeur is hiervoor.
Per separate email zal ik een voorstel doen voor een datum voor een interview.
Alvast dank voor jouw medewerking.
Met vriendelijke groet,
10.2.e

*) begeleidende tekst:
Wij schrijven u dit bericht gezien uw expertise, ervaring en bekendheid op het gebied van de plantenveredeling en biotechnologie en de daarmee gerelateerde werkvelden zoals veiligheid, regelgeving, beleid, duurzaamheid, innovatie, en maatschappelijk-economische impact.
De ontwikkelingen in biotechnologie, met name op het gebied van gene editing, gaan razendsnel. Dreigt Europa echter achterop te raken zolang deze nieuwe technieken onder de strenge regelgeving voor genetisch gemodificeerde organismen vallen? Hoe zou een toekomstbestendige regelgeving er volgens u uitzien?
Om deze en andere vragen te beantwoorden willen we u graag uitnodigen voor de online workshop: "Towards new legislation for modern biotechnology in the EU: Opportunity or burden for the Dutch plant breeding sector?" op donderdag 8 Oktober 2020 van 13:00 tot 15:30 uur.
In deze workshop geven we informatie over GGO regelgeving en mogelijke aanpassingen en willen we met u discussiëren over de kansen en mogelijkheden van een aanpassing in regelgeving voor Nederland. Zie bijlage voor meer informatie. (Let op, de workshop is in het Engels!)
De workshop vormt onderdeel van een langer lopend beleidsondersteunend project dat Wageningen Food Safety Research uitvoert voor het ministerie van Landbouw, Natuurbeheer en Voedselkwaliteit
U kunt u aanmelden per retournerende email aan 10.2.e @wur.nl met "accept" in de onderwerpregel.

We hopen u online te kunnen begroeten op 8 oktober.
Met vriendelijke groet,
10.2.e (projectleidster), 10.2.e
Wageningen Food Safety Research

From: 10.2.e @plantum.nl>
Sent: dinsdag 8 september 2020 15:03
To: 10.2.e @wur.nl>
Subject: RE: Vraag m.b.t. mogelijke bijdrage Plantum aan onze activiteiten m.b.t. proces-versus product-gebaseerde regelgeving voor plantenbiotechnologie

Ha 10.2.e

Ad 1) prima – dat zijn heel wat vragen in de bijlage – laten we maar een afspraak prikken; ik graag mee

Ad 2) kunnen we altijd verspreiden naar alle leden – maar specifiek naar de leden van onze hoofdcommissie Veredelingsmethoden

Met vriendelijke groet,

10.2.e
Directeur
Plantum

Beschrijving: Plantum

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telephone +31 10.2.e reg . no. Rotterdam 24319599
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website www.plantum.nl

Van: 10.2.e @wur.nl]
Verzonden: dinsdag 8 september 2020 14:33
Aan: 10.2.e @plantum.nl>
Onderwerp: Vraag m.b.t. mogelijke bijdrage Plantum aan onze activiteiten m.b.t. proces-versus product-gebaseerde regelgeving voor plantenbiotechnologie

Beste 10.2.e

Nogmaals dank voor jouw suggesties. Graag wilde ik je nog de volgende twee vragen voorleggen over een mogelijke bijdrage van Plantum (als deelnemer van activiteiten/stakeholder):

1) Interview: Ben je zelf mogelijk beschikbaar voor een interview over de mogelijke implicaties van een transitie van proces- naar product-gebaseerde regelgeving voor plantenbiotechnologie? Zoals je je misschien weet te herinneren is dit onderdeel van onderzoek voor ons beleidsondersteunend project voor LNV. Een Word document in de bijlage geeft een indruk van de soort vragen die we zouden willen stellen. Deelnemers worden uiteraard geanonymiseerd en kunnen feedback geven op de interviewverslagen. Als dit inderdaad mogelijke
2) Workshop uitnodigingen verspreiden: Is het mogelijk om de aankondiging voor een workshop (8 oktober a.s.) onder PLantum leden te laten verspreiden? Voor hetzelfde project organiseren we namelijk ook workshops met kleinere groepen experts (o.g.v. plant, dier, of micro-organismen; 3 parallelle workshops) deze herfst om de resultaten van de eerder interviews (anonieme samenvattingen) te delen en te vragen wat er nog toegevoegd kan worden en waar de mogelijkheden en uitdagingen liggen voor de toekomst. Dit wordt een online evenement van ca. 2.5 uur.

Alvast dank voor jouw antwoord.

Groet,

10.2.e

10.2.e @wur.nl
tel. kantoor +31-10.2.e / receptie +31-(10.2.e
mobiel tel. 06-10.2.e

From: 10.2.e @plantum.nl>
Sent: woensdag 22 april 2020 15:01
To: 10.2.e @wur.nl>
Subject: RE: misschien interesseert je dit - ik ben benieuwd wat je ervan denkt

Beste 10.2.e

Dank je wel voor deze suggesties! 10.2.e is een echte veteraan op dit gebied, weet ik me te herinneren van allerlei projecten en meetings met zijn betrokkenheid als “stakeholder”. Zelf had ik de volgende namen bedacht: 10.2.e (ENZA), 10.2.e (HZPC), en 10.2.e (Euroseeds).

10.2.e is algemeen directeur van ENZA (en voorzitter van Plantum) en zit zelf niet zo in deze materie. Ik denk dat 10.2.e hier wel meer bij betrokken is, hij is net als ik van vóór de moleculaire biologie in zijn veredelingsstudie en hij heeft zich meer op de economie gericht, maar vooral omdat zij ook actief zijn in Canada. 10.2.e is technisch heel onderlegd maar heeft weinig ervaring (denk ik) met de bedrijfsmatige aspecten van GGO-aanvragen. Laat me maar weten wie je kiest.

Voor wat betreft jouw stuk: zeker interessant en voorziet in een informatiebehoefte! Een paar observaties van mijn zijde van theoretische scenarios:

- Veredelingsdoel (fenotype) is op celniveau gerelateerd aan verhoogde productie van toxine / allergen, bijvoorbeeld toxines (glycoalkaloiden, quinozilidine etc.) voor bescherming tegen insectenvraat en allergen (pathogenesis-related protein) tegen stress.
- Beta-caroteen productie in rijstkorrels: voorbeeld van latente metabole route: ooit in de evolutie uitgeschakeld door inactivatie intermediaire stap: re-activatie door transgenese/mutatie van genen betrokken bij ontbrekende stap (bekend van o.a. Gouden Rijst). Zou dit ook voor toxines kunnen opgaan?

Ad 1) natuurlijk levert natuurlijke selectie mechanismen op die de plant beschermen tegen (of ontwijken van) predatoren. Mede daarom is het zo apart dat menselijke selectie die druk volledig onder controle heeft gebracht – of waar dat niet kon, zoals cyaniden in Cassave, hebben we geleerd hoe ermee om te gaan na de oogst. Het grappige is dat sommige van die stoffen – glycosinolaten in kool – juist weer wel gewild zijn als gezondheidsbevorderaars . . . .

Ad 2) ik wist niet dat die provitamine A route van nature in rijst zit. Voor de ‘golden rice’ hebben ze nogal wat genen van buiten (narcis oa) moeten halen om het weer aan de gang te krijgen. Vind jij dat er een fundamenteel verschil zit wat betreft veiligheid of een bestaande, maar ‘vergeten’ route nieuw leven ingeblazen wordt of dat er een hele nieuwe route wordt gecreeert?

Groet, 10.2.e

From: 10.2.e @plantum.nl>
Sent: woensdag 22 april 2020 13:53
To: 10.2.e @wur.nl>
Subject: RE: misschien interesseert je dit - ik ben benieuwd wat je ervan denkt

Oeps – ik was vergeten dat je dat gevraagd had.

Ik denk dat interessante lieden vanuit de veredelingssector (3 geledingen) zouden kunnen zijn:

- 10.2.e Avebe - 10.2.e @AVEBE.COM (bekend vanuit de COGEM misschien - landbouw)
- 10.2.e @rijkzwaan.nl (voorzitter van onze commissie veredelingsmethoden - groenten

-10.2.e @royalvanzanten.com - sierteelt

Als je er meer wilt – laat maar weten

PS – had ik jou mijn bijdrage aan het liber amicorum voor Food Law hoogleraar 10.2.e gestuurd. Vanuit verwondering over het feit dat er (bijna) nooit wat mis gaat kom ik tot vergelijkbare conclusies.

Naast de tijd die het kost om een nieuw ras te maken, verwonder ik mij nog meer, omdat er tijdens het veredelingsproces en daarna tijdens de jaren van instandhouding en zaadproductie volop mutaties optreden. Dat aspect nemen de schrijvers van dit stuk niet mee, volgens mij.

PS2 ik ben nog steeds wel geinteresseerd hoe je in het EUginius verhaal een volledig beeld zou kunnen krijgen van gene edits. Nu, verwacht ik, worden ze nog grotendeels gepatenteerd, maar dayt gaat er snel af als de technieken veel gebruikt gaan worden, dus wat voor idetifyers zouden er dan zijn?

Met vriendelijke groet,

10.2.e
Directeur
Plantum

Beschrijving: Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e @wur.nl>
Verzonden: woensdag 22 april 2020 13:34
Aan: 10.2.e @plantum.nl>
Onderwerp: RE: misschien interesseert je dit - ik ben benieuwd wat je ervan denkt

Beste 10.2.e,

Dank je wel, dat is zeker interessant & relevant! Opvallend dat de lange periode van introgressie en veldtesten onder verschillende milieucondities (en het verwijderen van off-types) als een soort argument voor veiligheid wordt aangehaald. Dat deden de Europese rechters ook in hun oordeel in 2018, als een additionele reden waarom de moderne methoden (met kortere cycli) niet de zelfde geschiedenis van veilige toepassing zouden hebben!

A propos, is het misschien nog steeds mogelijk suggesties voor interviewees voor ons project m.b.t. “product- versus process-based” te sturen? Alvast dank!

Groet, 10.2.e

From: 10.2.e @plantum.nl>
Sent: woensdag 22 april 2020 13:18
To: 10.2.e @wur.nl>
Subject: misschien interesseert je dit - ik ben benieuwd wat je ervan denkt

Ik zag deze langs komen – misschien interessant voor je

Groet,

10.2.e

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u

Van:	10.2.e
Aan:	10.2.e
Cc:	10.2.e @julius-kuehn.de); 10.2.e @slu.se); 10.2.e 10.2.e @helsinki.fi)
Onderwerp:	EPSO: Genome editing - 3rd Informal science - policy meeting ONLINE: 3.11.2020; Draft agenda; Participant list; Your updates with slides or orally?
Datum:	maandag 21 september 2020 17:26:59
Bijlagen:	20_09_21_EPSO_Genome editing - 3rd informal meeting_Invitation and agenda.pdf 20_09_21_EPSO_Genome editing - 3rd informal meeting_Participants.docx
Prioriteit:	Hoog

Dear colleagues from national ministries, the EP and EPSO scientists (all in bcc),

To easier adhere to the **Chatham House Rules**, we take three measures:

- **All participants are in bcc – please read and reply to these emails!**
- **Only confirmed participants from the attached list will get access to the call**. Those not in bold yet, pls confirm your online participation to Karin by 30.9.2020
- **Slides** will only be presented during the meeting and not sent to the participants.

Following your replies, we will hold our **3rd informal science and policy meeting ONLINE on 3 November from 11 am – 4pm.**

Pls find attached the invitation / draft agenda and updated participant list [Chatham House Rules – INTERNAL USE ONLY].

10 countries and the European level are already confirmed (in bold).

Action for you:

- **Ministry / EP colleagues**: please let us know if you will send us slides (only for the meeting, not to circulate) or only speak about the update from your country regarding
  - Regulation: Submission to the EC and progress since January
  - Flagships: Present approved calls; Discuss opportunities for future calls / programmes / projects at national and multinational levels.
- **Science colleagues**: please let us know if you will send us slides or only speak about the update from your country regarding
  - Flagships: Present ongoing calls and / or projects
- **Participants not in bold yet**, pls confirm your online participation to 10.2.e by 30.9.2020.

We very much look forward to a fruitful discussion

10.2.e
****
10.2.e
Executive Director
European Plant Science Organisation, EPSO
Rue de l'Industrie 4, 1000 Brussels, Belgium
10.2.e epsomail.org ; T/F: +10.2.e
www.epsoweb.org ; EU Transparency Register Number 38511867304-09
****

European Plant Science Organisation
https://epsoweb.org

Invitation and agenda

Genome editing
Improving legislation and start flagships to better address climate, environmental, food and health challenges

3rd Informal meeting online 3.11.2020
11 am – 4 pm
Zoom

Brussels, 21.9.2020

The European Plant Science Organisation (EPSO) invites policy makers to join EPSO members in a 3rd informal meeting exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide**.**

Draft agenda: **11 am – 3 pm on 3.11.2020**

11:00 All log in to be granted access

11:10 Welcome [10.2.e] and tour de table

11:30 Legislation – how could it be improved? [chaired by 10.2.e]

- EPSO activities since January 2020 [10.2.e
- Feedback from national ministries on their submission to the EC and additional activities since January 2020 [ministry colleagues]
- View from a Member of the European Parliament 10.2.e
- Discuss next steps until / beyond April 2021 (for which EC study is expected)

12:30 Break

13:00 Flagships towards GE products with consumer benefits on the market in Europe **[chaired by 10.2.e]**

- Summary from the 2nd informal meeting 10.2.e
- Discuss if more countries want to follow the Norwegian consumer survey (e.g. SE) [10.2.e, t.b.a.]
- Present ongoing / approved calls, projects, [all: pls let 10.2.e know who can present something]
- Discuss opportunities for future calls / programmes / projects at national and multinational levels.' [all: pls let 10.2.e know who can present something]
  - e.g. 10.2.e / DE
  - Consider study on flagship(s) including socio-economic and environmental benefits 10.2.e

14:30 Conclusions, next steps 10.2.e

14:55 Closing 10.2.e

The meeting will be an open-minded, informal discussion under **Chatham House Rules** between plant scientists (1 / country) and policy makers (1-3 / country) from countries which already indicated to support an innovative approach for agriculture and plant breeding in Europe. The meeting shall build on the 1st and 2nd one. We will continue to broaden the discussion and invite more representatives from countries interested in the issue.

EPSO offers to collaborate with policy makers to develop an appropriate future-ready regulation to enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the environmental impact of agriculture. Notwithstanding the technical option retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.

Those still pending (not in bold in attached participant list), please kindly **confirm your participation best by 9 October to** 10.2.e **@epsomail.org** .

10.2.e

10.2.e *, EPSO Chairs WG Agricultural Technologies;* 10.2.e *, EPSO President;* 10.2.e *, EPSO Board;* 10.2.e *, EPSO Executive Director.*

Attachments:
- List of participants – only for meeting participants (Chatham House Rules)

Contacts:
10.2.e , JKI / DE, T: +10.2.e 10.2.e @Julius-kuehn.de
10.2.e , SLU Uppsala, T: +10.2.e 10.2.e @slu.se
10.2.e , LUKE / FI, T: +10.2.e 10.2.e @Helsinki.fi
10.2.e , WUR / NL, T: +10.2.e 10.2.e @wur.nl
10.2.e , EPSO, T: +10.2.e ; 10.2.e @epsomail.org

About EPSO
EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 32 countries, mainly from Europe, and 2.600 individuals Personal Members, representing over 26 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science including science advice to policy, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science. https://epsoweb.org | EU Transparency Register Number 38511867304-09

EPSO 3rd informal science – policy meeting on genome editing, online, 3.11.2020

List of participants - confirmed in bold – by 21.9.2020

Participating countries:

Belgium
10.2.e , Federal Ministry of Environment – possibly other meeting, then send deputy
10.2.e **, VIB**

Estonia
10.2.e , Ministry of Environment
10.2.e **, Tallinn University of Technology**

Finland
10.2.e **, Ministry of Agriculture and Forestry**
10.2.e **, LUKE & EPSO President**

France
10.2.e **, Ministry for Agriculture and Food**
10.2.e **, INRA**

Germany
10.2.e **, Ministry for Education and Research**, 726 Bioeconomy
10.2.e **, Ministry for Education and Research,** 611 Ethics & Law in Life Sciences
10.2.e **, Ministry of Food and Agriculture**, 222 – New Technologies
10.2.e **, Ministry of Food and Agriculture,** 222 – New Technologies
10.2.e **, JKI**

Italy
t.b.a., Ministry for Environment
10.2.e **, CNR**

The Netherlands
10.2.e , Ministry for Agriculture
10.2.e **, WUR**

Norway
10.2.e , Ministry of Climate and Environment
10.2.e **, NO Agricultural Cooperatives**
10.2.e **, NO University of Life Sciences**

Spain
10.2.e **, Ministry for Agriculture**
10.2.e **, CSIC**

Sweden
10.2.e **, Min. of Enterprise and Innovation**
10.2.e **, Min. of Enterprise and Innovation**
10.2.e **, SLU**

Europe
10.2.e **European Parliament, chair AGRI Committee**
10.2.e **, EPSO**
10.2.e **, EMBO**

Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: dialoog tbv EU traject
Datum: dinsdag 22 september 2020 14:50:23
Bijlagen: image001.gif

Ik heb 10.2.e gisteren twee documenten gestuurd: B1 (inclusief kleine aanpassingen vanuit de vorige bespreking) en B2 in ben samen met 10.2.e tot februari bezig geweest om het stuk helemaal om te gooien om het meer aan ethiek-theorie op te hangen (voornamelijk cut and past – reorganiseren, niet veel nieuwe tekst), maar toen is dat door Corona helemaal in de vergetelheid geraakt, dus dat stuk moet duidelijk nog een flinke redactieslag krijgen als er nog interesse voor is.
Met vriendelijke groet,

10.2.e
Directeur
Plantum

Beschrijving: Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e [mailto 10.2.e @minlnv.nl]
Verzonden: dinsdag 22 september 2020 13:12
Aan: 10.2.e
Onderwerp: RE: dialoog tbv EU traject
We willen nu ook als overheid de trekkersrol oppakken. Wel hebben we gemerkt dat we iets meer flexibel willen zijn in het format maar willen het wel serieus doen. Vandaar dit voorstel
Geldt dus ook voor B3 (dat zal vervallen) – wij zien dat nu dat wij die rol moeten oppakken. Vandaar dus deze doorstart

Van: 10.2.e @plantum.nl>
Verzonden: maandag 21 september 2020 16:29
Aan: 10.2.e @minlnv.nl>
Onderwerp: RE: dialoog tbv EU traject
Het tweede stuk (over discussies in EU), daar zijn wij nationaal al een heel tijdje mee bezig in het moderniseringstraject – soms uit elkaar in groen, rood, wit; soms thematisch . . . . alleen nog niet de 4 scenario's – misschien had dat 'mijn' thema B3 moeten zijn. Ik heb net met 10.2.e afgesproken nog één keer naar de rapporten B1 en B2 te kijken – en misschien (kijk of ik nog een avondje over heb) zelfs een aftrapje te geven voor B3 hoewel ik nog steeds vind dat beleidsopties meer iets van de ambtenaren is.
Met vriendelijke groet,

10.2.e
Directeur
Plantum

Beschrijving: Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e @minlnv.nl>
Verzonden: donderdag 17 september 2020 16:16
Aan: 10.2.e @plantum.nl>
Onderwerp: FW: dialoog tbv EU traject

Ook even informeel naar jou. Laat maar weten wat je er van vindt!

Van: 10.2.e - BSK 10.2.e @minienw.nl>
Verzonden: donderdag 17 september 2020 16:13
Aan: 10.2.e @hollandbio.nl>; 10.2.e 10.2.e @hollandbio.nl>
CC: 10.2.e @minlnv.nl>
Onderwerp: dialoog tbv EU traject

Hallo 10.2.e ,

We hebben elkaar al een aantal keren gesproken over thema D. Nu met de beraadsgroep in aantocht hebben 10.2.e en ik nog gesproken over hoe input op te halen voor het EU traject. We denken aan een apart traject hiervoor, zie de bijgevoegde notitie.

We zijn benieuwd hoe jullie er tegenaan kijken. Misschien kunnen we komende week hier even over overleggen via webex? Een half uurtje op bijvoorbeeld dinsdagmiddag of op woensdagochtend of woensdagmiddag vanaf 3 uur? Is dat in te plannen voor jullie?

Groeten,

10.2.e
10.2.e
.....
Directie Omgevingsveiligheid en Milieurisico's
DG Milieu en Internationaal
Ministerie van Infrastructuur en Waterstaat
Rijnstraat 8 | 2515 XP | Den Haag
Postbus 20951 | 2500 EX | Den Haag
.....
M 06 10.2.e
E 10.2.e @minienw.nl
.....
ma-di-wo-do aanwezig

Van: 10.2.e
Aan: 10.2.e ;10.2.e
Cc: 10.2.e
Onderwerp: RE: kader (nieuw)
Datum: woensdag 23 september 2020 18:44:37
Bijlagen: image001.gif
afweginskader7.docx

10.2.e , Toch een versie 7 met vooral aanpassingen aan de laatste hoofdstukken (zo heb ik de verantwoordelijkheden van de ketenpartijen onder de morele zaken van de deugdenethiek gebracht).
10.2.e, k denk niet dat het slim is om het naar de hele groep rond te sturen – wordt verwarrend denk ik. We vertellen wel dat het werk weer opgepakt is na een Corona-pauze ☺
Met vriendelijke groet,

10.2.e
Directeur
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fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e
Verzonden: woensdag 23 september 2020 16:00
Aan: 10.2.e
CC: 10.2.e
Onderwerp: Re: kader (nieuw)
Dag 10.2.e,
Dank voor je mail. Ik heb de afgelopen maanden wel enkele malen gedacht aan ons project. Maar dor allerlei publicatie drukte niet aan toegekomen erover contact op te nemen.
Helemaal eens met je voorstel richting beraadsgroep a.s. maandag. Ik hoop ook mee te doen.
Laten we daarna weer contact opnemen om het verdere proces te bespreken.
Vr groet,
10.2.e

Van: 10.2.e
Aan: 10.2.e
Onderwerp: 10.2.e : Commission yet to decide position on gene-edited crop
Datum: vrijdag 25 september 2020 15:38:50

Dag 10.2.e,

Mogelijk heb je onderstaande info (Politico report van zojuist) al direct ontvangen.

Groeten,

10.2.e

Top EU official: Commission yet to decide position on gene-edited crops

-- By 10.2.e
9/25/20, 3:21 PM CET | View in your browser

The European Commission has not yet decided whether gene-edited crops and food should be regulated less strictly than genetically modified organisms, a top EU civil servant said today.

"The decision is absolutely not taken as to what we are going to do," said 10.2.e 10.2.e head of biotechnology at the Commission's health and food safety department, during POLITICO's Agriculture and Food summit.

10.2.e said the Commission is analyzing responses from stakeholders as part of a study the Commission is carrying out on the pros and cons of new gene-editing techniques. That study was requested by EU governments and the Commission will finalize it next year.

"We haven't decided that the potential is wonderful and that something must be absolutely done to liberalize these products. Not at all. Absolutely no decision has been taken, we want to analyse this in a very open manner," the EU official said.

10.2.e
10.2.e

+31 (0)79 10.2.e (office)
+31 (0)6 10.2.e (mobile)
10.2.e
www.mvo.nl
EU Transparency register 086387026863-41

MVO – The Netherlands Oils and Fats Industry
Louis Braillelaan 80, 2719 EK Zoetermeer, The Netherlands

Van: 10.2.e
Aan: 10.2.e@rijkzwaan.nl
Cc: 10.2.e
Onderwerp: Re: Virtueel werkbezoek Rijk Zwaan - thema "Biotech"
Datum: vrijdag 2 oktober 2020 16:12:03
Bijlagen: ATT00001.jpg
ATT00002.gif
ATT00003.jpg
ATT00004.gif
aangepast programma meeting minister Van Nieuwenhuizen 5 okt 2020.docx
overzicht deelnemers bezoek Minister I&W aan Riik Zwaan.docx

Geachte deelnemers,

Van sommigen van u ontving ik een reactie dat de bestanden te groot zijn en om die reden niet ontvangen waren.
Hierbij nog een poging. Bijgevoegd het programma voor a.s. maandag, evenals een overzicht van de deelnemers.

Via de link kunt u de bedrijfsbrochure en CSR-brochure van Rijk Zwaan downloaden.
https://rijkzwaan.sharefile.eu/d-se3d6aec420a4c928

Excuses voor het ongemak.

Met vriendelijke groeten / Kind regards,

10.2.e | Specialist Communication & Public Affairs | Communication & Public Affairs
Direct +31 10.2.e | Mobile +31 6 10.2.e | 10.2.e@rijkzwaan.nl

Rijk Zwaan Zaadteelt en Zaadhandel B.V.
Burgemeester Crezéelaan 40 | PO Box 40 | 2678 ZG De Lier | The Netherlands
T +31 10.2.e | F +31 10.2.e
info@rijkzwaan.com | www.rijkzwaan.com
Chamber of commerce Haaglanden 27214459 0000

From 10.2.e /DL/RijkZwaan
To: 10.2.e@rijkzwaan.nl
Cc: 10.2.e /DL/RijkZwaan@RijkZwaan
Date: 02-10-2020 14:54
Subject: Virtueel werkbezoek Rijk Zwaan - thema 'Biotech'

Geachte deelnemers,

A.s. maandag brengt de minister van I&W, mevr. 10.2.e , een virtueel werkbezoek aan Rijk Zwaan in het kader van het thema 'biotechnologie'.
Als het goed is, heeft u zojuist een mail ontvangen met daarin de uitnodiging en de link om in te kunnen bellen in Webex Meetings.

Bijgevoegd treft u voor de volledigheid een overzicht met alle deelnemers, evenals het programma. Eveneens bijgevoegd ter kennisneming de bedrijfsbrochure van Rijk Zwaan, en een boekje met daarin onze activiteiten op het gebied van MVO.

[attachment "aangepast programma meeting minister 10.2.e 5 okt 2020.docx" deleted by 10.2.e /DL/RijkZwaan] [attachment "overzicht deelnemers bezoek Minister I&W aan Rijk Zwaan.docx" deleted by 10.2.e /DL/RijkZwaan] [attachment "RZ company folder-NL.pdf" deleted by 10.2.e /DL/RijkZwaan] [attachment "20190108_csr_brochure_rijk_zwaan_eng.pdf" deleted by 10.2.e /DL/RijkZwaan]

Graag ontmoeten we u digitaal op maandag 5 oktober, om 13.30 uur.

Mocht u vragen hebben m.b.t. het programma of de Webex-uitnodiging, dan kunt u contact met mij opnemen.

Voor nu een goed weekend.

Met vriendelijke groeten / Kind regards,

10.2.e | Specialist Communication & Public Affairs | Communication & Public Affairs
Direct +31 10.2.e | Mobile +31 6 10.2.e | 10.2.e@rijkzwaan.nl

Rijk Zwaan Zaadteelt en Zaadhandel B.V.
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Chamber of commerce Haaglanden 27214459 0000

Van: 10.2.e
Aan: 10.2.e
Cc: 10.2.e
Onderwerp: RE: FYI - paper about economic impact
Datum: woensdag 7 oktober 2020 09:06:53
Bijlagen: image001.gif

Zeer nuttig, dank!

Van: 10.2.e
Verzonden: woensdag 7 oktober 2020 09:02
Aan: 10.2.e
CC: 10.2.e
Onderwerp: FYI - paper about economic impact

Twee recente studies over effecten (op andere landen) van EU-beleid (en – 10.2.e - ondersteunend aan Consequentialisme-hoofdstukje van onze paper):
https://onlinelibrary.wiley.com/doi/full/10.1002/aepp.13084?mc_cid=27cb0a0fbf&mc_eid=e6d7ff95bf
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7521901/
Met vriendelijke groet,

10.2.e
Directeur
Plantum

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fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Online Workshop "Towards new legislation for modern biotechnology in the EU: Opportunity or burden for the Dutch plant breeding sector?"

Thursday 8 October, 13:00

Because of gene editing techniques, particularly with CRISPR-Cas9, biotechnology develops faster than ever before. Also within agriculture and food production, there are many possible applications for these novel techniques, for example for yield improvement or sustainability purposes.

Novel genetically modified plant varieties developed using new breeding techniques, such as gene editing with CRISPR-Cas, have been characterized as genetically modified organisms (GMOs) by the European Court of Justice. This means that the stringent GMO legislation is applicable to products made with these novel techniques. As a consequence, biotechnological innovation in Europe may be hindered, and so is the current enforcement of GMO legislation, as gene-edited products may not always be distinguished from conventional bred products at DNA level. The European commission has initiated an assessment of the possibilities of revising the current legislation, which will lead to a proposal in the spring of 2021. The Netherlands will contribute to this and is developing a vision and strategy for the revision of the legislation.

This projects aims to give technical, scientifically sound input on GMOs and gene editing, regarding:

1. Most recent technological developments and possibilities
2. Traceability of GMOs, including gene edited organisms
3. Food safety of GMOs, including gene edited organisms
4. The impact of a possible transition from the current GMO legislation towards a revised, product-based, legislation on traceability and food safety.

In this workshop we will:

- provide information on GMO legislation with regards to gene edited organisms
- summarize the results of a series interviews with experts
- verify where there is consensus among scientists (among the participants), and where there are diverging views on the points mentioned above
- explore if there are knowledge gaps with regards to the traceability, hazards and risks of new GM techniques
- present different regulatory scenarios and evaluate them with the participants. Is this an opportunity or a burden for the Dutch sector?

Program:

13:00-13:10	Welcome & Introduction
13:10-0:30	Interactive presentation on risks of various techniques, GMO legislation, and enforcement issues
13:30-13:40	Plenary explanation on legislative scenario's
13:40-15:00	Discussions in smaller groups of the different scenario's
15:00-15:30	Plenary discussion of outcomes & closure

This online workshop is part of a policy supporting project, financed by the Dutch ministry of Agriculture, Nature, and Food Quality, that is carried out by Wageningen Food Safety Research

For whom?

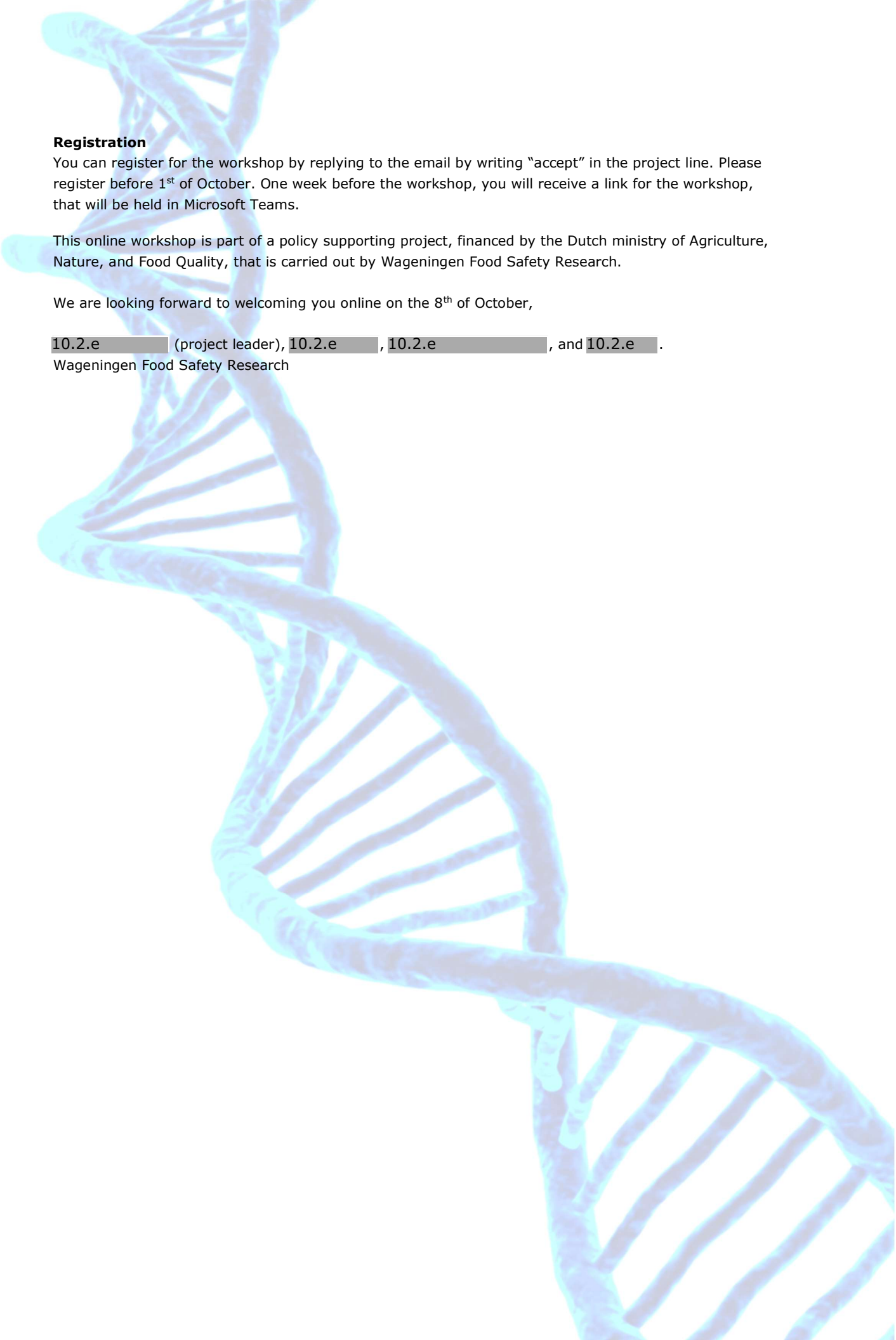
This workshop is for scientists from academia and industry who work on or deal (indirectly) with gene editing or GMOs for crop breeding. Particularly PhDs, postdocs, and senior researchers are encouraged to participate. The workshop will be given in English.

Registration
You can register for the workshop by replying to the email by writing "accept" in the project line. Please register before 1st of October. One week before the workshop, you will receive a link for the workshop, that will be held in Microsoft Teams.

This online workshop is part of a policy supporting project, financed by the Dutch ministry of Agriculture, Nature, and Food Quality, that is carried out by Wageningen Food Safety Research.

We are looking forward to welcoming you online on the 8th of October,

10.2.e (project leader), 10.2.e , 10.2.e , and 10.2.e .
Wageningen Food Safety Research



Comitology Reform Proposal:
From product authorisations when safe to authorisations when popular?

Briefing Note, 26 October 2020

Executive Summary
The Commission's comitology reform proposal **would make product authorization procedures even more complicated than today**. The European Parliament's (EP) lead committee (legal affairs) adopted a version on 1 October 2020, which would make the **authorisation of new products de facto impossible in certain sectors**. EP plenary may vote in late 2020 (not confirmed). Council position on the recently adopted draft is to be investigated/confirmed (not very supportive of the Commission's proposal in the past)

Background: Comitology refers to a set of procedures through which EU countries control how the Commission implements EU law. Comitology procedures inter alia apply to pre market product authorisations, and typically involve the Commission consulting a committee of experts from the Member States (Standing Committee) on draft implementing acts authorising products. If the Member States do no reach a qualified majority in favour or against, the Commission refers to the **Appeal Committee**. In case of no opinion even in the Appeal Committee (**which happens regularly for GM products**, sometimes for crop protection, and occasionally for other types of products), the Commission approves the product supported by the EFSA's scientific opinion.

What the Commission proposed
The Commission proposal contains the following three main changes:

- **Change of voting rules:** At the Appeal Committee, abstaining Member States would be seen as "non-participating". This would in some cases threaten the approval of safe but 'politically sensitive' products, especially after Brexit.
- **Additional votes and delays:** Introduction of up to two additional rounds of voting.
- **Other proposed changes**: Quorum of participating Member States; publication of Member States votes.
  While we support the proposed increase in transparency, the COM proposal will result in even lengthier processes due to more -unnecessary- votes.

What the EP legal affairs committee proposed to add

- **Products to be approved only when they have overwhelming political support disregarding the scientific assessment on safety?**
  The legal affairs committee added one important additional change to the existing comitology regulation: it foresees that the Commission would not be allowed to authorise a product, even if it is fully asseses as safe by EFSA, unless there is a qualified majority of Member States in support. **This change would revert the current logic 'approve when safe' to 'approve when popular'** (Otherwise, the committee made only minor changes).

Present comitology system vs. new system according to legal affairs committee:
The **present comitology regulation** provides for a rather science-based system: It essentially foresees that products should be authorised when safe. Vetoing the approval of a safe product requires the qualified majority of Member States (55% of the Member States representing 65% of the EU's population). The **new system** as proposed by the EP legal affairs committee essentially foresees that the political opinions are more important than the extensive scientific evidence assessing safety of products. According to the committee, products should only be authorised when they have a political support by a qualified majority of Member States (55% of the Member States representing 65% of the EU's population). This, in turn, means that **a minority of Member States could block the approval of safe products**.

The new provision adopted by the legal affairs committee would significantly decrease the role of science in the EU's product approval systems and further weaken the role of European agencies such as EFSA. In the short term, it concretely threatens to make **approvals of GM products and of some crop protection products impossible**. More generally and in the longer term, the approval of any product could be much more easily vetoed, even if the product is deemed safe by the risk assessor.

Impacted business sectors

Many industry associations from the food and feed chain and beyond showed their concern. The Comitology reform draft voted in the Legal Affairs committee will impact the whole value chain associated with biotechnology products, including farmers and the livestock industry, input industries, grain trade, animal feed industry and the vegetable oil as well as proteinmeal industry.

Position & additional Info

- EuropaBio position paper 2020, with links to related documents.
- While we support more transparency in the comitology system (inter alia through publication of the Member State votes), the other changes proposed by the Commission would not bring additional value in our view, but merely make the processes for product authorisations even lengthier. **The proposal by the legal affairs committee would revert the current logic 'approve when safe' to 'approve when popular'.**
- For additional information and documentation, please see the Legislative Observatory.

Van: 10.2.e
Aan: 10.2.e
Cc: 10.2.e
Onderwerp: RE: Vraag bij - SO Biotechnologie en Tuinbouw
Datum: dinsdag 3 november 2020 09:51:51

Ha 10.2.e,
Nog veel dank voor de info. SO stukken zijn naar de Kamer gestuurd. Vooral veel proces in de antwoorden.
@10.2.e : Welkom! Zullen we binnenkort een kennismaking inplannen? 10.2.e , welkom om aan te haken natuurlijk .
Gr,

10.2.e
Senior beleidsmedewerker biotechnologie
EU-coördinator PAV
.....
Directie Plantaardige Agroketens en Voedselkwaliteit
Ministerie van Landbouw, Natuur en Voedselkwaliteit
Bezuidenhoutseweg 73 | 2594 AC | Den Haag
Postbus 20401 | 2500 EK | Den Haag
.....
T 06 10.2.e | 070-10.2.e
E 10.2.e @minlnv.nl
www.rijksoverheid.nl/lnv
.....
Aanwezig ma t/m vrijdag

Van: 10.2.e
Verzonden: donderdag 8 oktober 2020 11:55
Aan: 10.2.e
CC: 10.2.e
Onderwerp: Vraag bij - SO Biotechnologie en Tuinbouw

Ha 10.2.e
10.2.e gaf aan dat de volgende vraag gesteld is (door D'66) – even voor de duidelijkheid – die was niet door ons ingegeven ☺

- Kan de minister inzicht geven in de vraag welke hoeveelheid van de groenten en fruit die in de supermarkten verkrijgbaar zijn tot stand zijn gekomen door technieken die ertoe leiden dat deze producten officieel gezien worden als ggo, maar uitgezonderd zijn van de GGO-regelgeving?

Als je wat info wilt, laat maar weten.
Het gaat hier dus vooral over (random) mutatieveredeling (en celfusie tussen verwante soorten – zie annex 1). Zaak is in elk geval dat er geen registratie van is, dus dat de minister dat niet kan kwantificeren. Registratie was niet mogelijk en niet nodig. Niet nodig omdat deze technieken al tientallen jaren gebruikt waren toen de wetgeving ingevoerd werd en niet nodig omdat er (dus) geen zorgen waren rond veiligheid voor mens en milieu – waar de wetgeving op gebaseerd was. Daarnaast omdat mutagenese ook in de natuur voorkomt.
De mutanten vallen dus juridisch onder de EU definitie van GGO (heeft het Hof in de CRISPR-uitspraak bevestigd) maar in de praktijk dus niet. De parallel is natuurlijk dat gerichte mutaties biologisch gezien niet wezenlijk anders zijn dan ongerichte mutagenese, wat de basis is van het beleid om dat toe te voegen aan annex 1 (waar D'66 overigens voorstander van is, volgens mij). Gerst is een voorbeeld van een gewas waar in de jaren '50 belangrijke eigenschappen (ziekteresistentie en brouwkwaliteit) via mutagenese ingebracht zijn en we kunnen er gevoeglijk vanuit gaan dat alle huidige gerstrassen (al ons bier !) wel één van die gemuteerde ouders in de stamboom heeft. Daarnaast wordt mutatieveredeling ook nu nog veel gebruikt in een heleboel voedsel – en sierteeltgewassen (volgens mij alle Chrysanten – moet ik nog checken, maar het was altijd zo dat een veredelaar ene nieuwe chrysant kweekte via kruising –bloemvorm,

houdbaarheid – en dat dan via mutaties alle kleurtjes ‘gemaakt’ kunnen worden van dat nieuwe type). Als je meer voorbeelden wilt, wil ik nog wel wat verder snuffelen in de literatuur.
Misschien is deze vraag dus een mooi opstapje naar het uitleggen van het staande beleid?
Overigens – we zijn wat aan het schuiven met het takenpakket binnen Plantum. 10.2.e van Vegchel neemt het dossier Veredelingsmethoden van 10.2.e over. 10.2.e blijft uiteraard relevant via haar contacten bij de politiek. 10.2.e is niet zo heel lang afgestudeerd in plantenbiotechnologie in Wageningen, dus zij zal met de technische details beter kunnen dealen dan wie ook (inclusief een oude veredelaar als ik ☺)
10.2.e

Van: 10.2.e
Aan: 10.2.e
Onderwerp: RE: Proposal for Commitology Reform: CALL FOR ACTION
Datum: dinsdag 3 november 2020 10:35:09
Bijlagen: image002.gif
image003.jpg

Als jij er nog even naar kunt kijken met onze vrienden in Brussel – graag . . .
Met vriendelijke groet,

10.2.e
Directeur
Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599
fax +31 10.2.e VAT NL809984738B01
website www.plantum.nl

Van: 10.2.e [mailto:10.2.e @minlnv.nl]
Verzonden: dinsdag 3 november 2020 10:02
Aan: 10.2.e
Onderwerp: RE: Proposal for Commitology Reform: CALL FOR ACTION
Ha 10.2.e,
Dank hiervoor, was er niet van op de hoogte.
Lijkt vooral een lopende inter-institutionele zaak te zijn. COM is klaar met de boeman te zijn – lees Juncker 2015 voorstel – omdat de lidstaten keer op keer er niet lijken uit te komen. Dit is dus vooral pushback richting de lidstaten. Ja, het kan betekenen dat keuzes politiek gaan worden (aan de lidstaten aan wat voor goedkeuringsbeleid ze volgen), maar dat maakt het ook een mijnenveld voor stakeholder bemoeienis volgens mij. In NL baseren we de posities op wetenschappelijke adviezen, in anderen lidstaten misschien niet. Misschien een lichtpuntje, het weren van GGO producten voor "socio-economische" redenen lijkt dan niet meer nodig gezien de noodzaak voor politieke keuzes er niet meer zou zijn door het in de EU toelating al te regelen. Dus achteraf wellicht meer integratie en marktharmonisatie.
Voor zo ver ik het kan zien moet het überhaupt nog door het EP. Ik denk wel dat AM7 het zou moeten halen. Dan moet het nog door trialoog. Daar acht ik de kans niet erg groot. Ik ga even kijken met de PV hoe/wat.
Gr,
10.2.e

Van: 10.2.e @plantum.nl>
Verzonden: maandag 2 november 2020 13:36
Aan: 10.2.e @minlnv.nl>
Onderwerp: Proposal for Commitology Reform: CALL FOR ACTION
10.2.e,
De bijgaande 'alert' gaat rond. Het gaat mijn pet een beetje te boven.
Heb jij in de gaten wat hier aan de hand is en waarom – en wat de voordelen/risico's zouden zijn????
Met vriendelijke groet,

10.2.e
Directeur
Plantum

address Vossenburchkade 68, 2805 PC Gouda
telephone +31 10.2.e reg . no. Rotterdam 24319599

Beschrijving: Plantum

fax +31 10.2.e VAT NL809984738B01

website www.plantum.nl

Van: 10.2.e
Aan: 10.2.e
Onderwerp: Re: bijpraten binnenkort
Datum: donderdag 12 november 2020 14:55:42

Beste 10.2.e,

Woensdag as is prima. Mogelijkheden zijn van mijn kant, 10.00 uur, 14.00 uur of vanaf 16.30 uur.

Met vriendelijke groet,

10.2.e

> Op 12 nov. 2020 om 14:32 heeft 10.2.e het volgende geschreven:
>
> Beste 10.2.e
> Zullen we woensdag afspreken? Ik heb die dag weinig afspraken en ben nog flexibel.
> Gr,
> 10.2.e
>
> **Van:** 10.2.e
> **Verzonden:** donderdag 12 november 2020 09:42
> **Aan:** 10.2.e
> **Onderwerp:** Re: bijpraten binnenkort
> Beste 10.2.e
> Dank voor je mail. Hier alles gezond met mij, familie en vrienden. Hoop dat jij en de mensen om je heen deze vervelende fase ook gezond hebben doorstaan.
> Morgen zit ik wat krap in mijn agenda maar komende week voldoende mogelijkheden. Dinsdag en woensdag (17 of 18 november) zijn de dagen waarop het overleg mij het best zou uitkomen.
> Met vriendelijke groet,
> 10.2.e
>
> > Op 12 nov. 2020 om 09:20 heeft 10.2.e 10.2.e @minlnv.nl> het volgende geschreven:
> >
> > Beste 10.2.e
> > Hoe gaat het? Ik hoop dat alles goed gaat met jou, je familie en vrienden.
> > Heb je misschien morgen of volgende week tijd om bij te praten? Het is weer een tijdje geleden.
> > Gr,
> > 10.2.e
> > Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u
> > niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden,
> > wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen.

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen.
De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message.
The State accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.

Van: 10.2.e
Aan: 10.2.e
Onderwerp: Aandachtspunten voor overleg vandaag 16:30 uur
Datum: woensdag 18 november 2020 16:00:18
Bijlagen: image001.jpg
image002.jpg

Hi 10.2.e
Indien mogelijk zou ik de volgende zaken zo beknopt willen doorlopen. Wellicht heb jij hier ook nog zaken aan toe te voegen.
Met vriendelijke groet,
10.2.e

- Raadsbesluit m.b.t. EC studie over new genomic techniques vóór eind april 2021;
- Voortgang in de genomic editing expert group.
- EU-markttoelating GGO's: in de periode januari-augustus 2020 geen SCoPAFF meetings dus "standstill";
- Nog meer onduidelijkheid over stemprocedures en uitslag stemmingen in SCoPAFF en AC;
- EC-aankondiging in september 2020 dat het aanvragen voor markttoelating GGO in behandeling zal blijven nemen, "*pending a different approach based on sustainability considerations*"(?).
- Wijziging comitology-procedure met mogelijke consequenties EU markttoelating GGO's;
- Chinese importbelemmeringen ten aanzien van plantaardige oliën in relatie tot GGO (na verstrijken 31/10/2020 datum uit questionnaire);
- Tweede Kamer: (V)SO Biotechnologie en plenaire behandeling Landbouwbegroting.

10.2.e
10.2.e

+31 (0)79 10.2.e (office)
+31 (0)62 10.2.e (mobile)
10.2.e
www.mvo.nl
EU Transparency register 086387026863-41

MVO – The Netherlands Oils and Fats Industry
Louis Braillelaan 80, 2719 EK Zoetermeer, The Netherlands

Van: 10.2.e
Aan: 10.2.e
Onderwerp: GMO / NBT issues
Datum: woensdag 18 november 2020 17:29:15
Bijlagen: image002.jpg
image004.jpg
DG SANTE reply to EuropaBio on GM authorisations 20200911.pdf
MVO_GM-Soybean-table-280920 (006) tbv 10.2.e .pdf

Hi 10.2.e,
Dank voor het uitgebreide overleg van zojuist.
In bijgaande PDF de brief van DG Santé 10.2.e aan EuropaBio met de interessante en tegelijkertijd zorgwekkende zin „*it will continue processing the applications for GM food and feed under existing rules pending a different approach based on sustainability considerations*". Deze brief is niet bedoeld voor verdere verspreiding.
Misschien al bij jou bekend, maar via volgende link de inmiddels openbare brief van 11 MEPs (10.2.e, Häusling c.s.) aan 10.2.e over meer transparantie m.b.t. Joint Working Group on 'new genomic techniques' https://martin-haeusling.eu/images/201112_Letter_to_DG_SANTE_access_to_docs.pdf
Tijdens ons overleg gaf ik aan dat - vanwege de COVID-restricties - de stemmingen in de SCoPAFF en AC ook anders verlopen. Volgens mij krijgen LS een beperkt aantal dagen om kenbaar te maken of zij de toelating van een bepaalde applicatie al dan niet steunen (meer info zou welkom zijn). Na een standstill periode van 9 maanden, zijn de SCoPAFF-vergaderingen in september weer hervat.
De events die onze bijzondere aandacht hebben, zijn in bijgaand overzicht geel gemarkeerd.
Tenslotte zag ik net dat het EFSA panel op 25-26 november a.s. ook de "Scientific opinion on in vitro random mutagenesis techniques" op de agenda heeft staan.
Met vriendelijke groet,

10.2.e
10.2.e
10.2.e

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EU Transparency register 086387026863-41

MVO – The Netherlands Oils and Fats Industry
Louis Braillelaan 80, 2719 EK Zoetermeer, The Netherlands

GM soybean traits: market approval in the EU/China (import) and main cultivating countries (cultivation)

Unique identifier	Event/Species	Applicant	Traits	EU (import and processing) Approved	China (import and processing) Approved	U.S. (cultivation) Approved	Canada (cultivation) Approved	Brazil (cultivation) Approved	Argentina (cultivation) Approved
MON-Ø4Ø32-6	MON Ø4Ø32 (Roundup Ready)	Monsanto	HT (glyphosate)	✔	✔	✔	✔	✔	✔
MON-89788-1	MON 89788 (RR2Yield)	Monsanto	HT (glyphosate)	✔	✔	✔	✔	✔	✔
ACS-GMØØ5-3	A27Ø4-12 (Liberty Link)	Bayer CropScience	HT (glufosinate- ammonium)	✔	✔	✔	✔	✔	✔
ACS-GMØØ6-4	A5547-127 (Liberty Link)	Bayer BioScience	HT (glufosinate- ammonium)	✔	✔	✔	✔	✔	✔
DP-356Ø43-5	356043 (Optimum GAT)	Pioneer Hi-Bred [9]	HT (glyphosate and acetolactate synthase- inhibiting herbicides)	✔	✔	✔	✔		
MON-877Ø1-2	MON 877Ø1 (Genuity)	Monsanto	IR (lepidopteran)	✔	✔	✔	✔	✔	✔
MON-877Ø1-2 x MON-89788-1	MON 877Ø1 x (Genuity) MON 89788 (RR2Yield)	Monsanto	IR (lepidopteran) HT (glyphosate)	✔	✔ [1]	✔ [1]	✔ [1]	✔	✔
DP-3Ø5423-1	305423 (Plenish)	Pioneer Hi-Bred [9]	FA (high-oleic)	✔	✔	✔	✔	✔	✔
MON-877Ø5-6	MON 877Ø5 (Vistive gold)	Monsanto	FA (high-oleic) HT (glyphosate)	✔	✔	✔	✔		
BPS-CV127-9	BPS-CV127-9	BASF Plant Science and Embrapa	HT (imidazolinone)	✔	✔	✔	✔	✔	✔
MON-877Ø8-9	MON 877Ø8	Monsanto	HT (dicamba)	✔	✔	✔	✔	✔	
MON-87769-7	MON 87769	Monsanto	FA (sda / omega 3)	✔	✔	✔	✔		
MON-877Ø5-6 x MON-89788-1	MON 877Ø5 (Vistive Gold) x MON 89788 (RR2Yield)	Monsanto	FA (high oleic) HT (glyphosate)	✔	✔ [1]	✔ [1]	✔ [1]		
MST-FGØ72-2	FG72	Bayer CropScience	HT (glyphosate and HPPD inhibitor herbicides)	✔	✔	✔	✔	✔	✔
MON-877Ø8-9 x MON-89788-1	MON 877Ø8 x MON 89788 (RR2Yield)	Monsanto	HT (dicamba and glyhosate)	✔	✔ [1]	✔ [1]	✔ [1]	✔	[2]
DP-3Ø5423-1 x MON-Ø4Ø32-6	305423 (Plenish) x MON Ø4Ø32 (Roundup Ready)	Pioneer Hi-Bred [9]	HT (glyphosate) FA (high-oleic)	✔	✔ [1]	✔ [1]	✔ [1]	✔	✔
MON-87769-7 x MON-89788-1	MON 87769 x MON 89788 (RR2Yield)	Monsanto	FA (sda / omega 3) HT (glyphosate)	EFSA opinion published on 8 October 2015 [7]	✔ [1]	✔ [1]	✔ [1]		
DAS-68416-4	DAS-68416-4 (Enlist)	Dow AgroSciences [9]	HT (2,4-D and glufosinate)	✔	Withdrawn	✔	✔	✔	
MON-87712-4	MON 87712	Monsanto	IY			✔	✔		
DAS-444Ø6-6	DAS-444Ø6-6 (Enlist E3)	Dow AgroSciences [9]	HT (2,4-D, glyphosate and glufosinate)	✔	✔	✔	✔	✔	✔
SYN-ØØØH2-5	SYHTØH2	Syngenta and Bayer CropScience	HT (glyphosate and HPPD)	Awaiting vote in Appeal Committee [7]	✔	✔	✔		✔
DAS-68416-4 x MON-89788-1	DAS-68416-4 (Enlist) x MON 89788 (RR2Yield)	Dow AgroSciences [9]	HT (2,4-D, glufosinate and glyphosate)	Withdrawn		✔ [1]	✔ [1]		

Unique identifier	Event/Species	Applicant	Traits	EU (import and processing) Approved	China (import and processing) Approved	U.S. (cultivation) Approved	Canada (cultivation) Approved	Brazil (cultivation) Approved	Argentina (cultivation) Approved
MST-FGØ72-2 x ACS-GMØØ6-4	FG72 x A5547-127	Bayer CropScience	HT (glyphosate and HPPD inhibitor herbicides / (glufosinate- ammonium)	✔	✔ 1)	✔ 1)	✔ 1)	✔	✔
DAS-81419-2	DAS-81419-2 (Conkesta)	Dow AgroSciences 9)	IR (lepidopteran)	EFSA opinion published on 5 December 2016 7)	✔	✔	✔	✔	✔
MON-87751-7	MON 87751	Monsanto	IR	✔	✔	✔	✔	✔	
MON-877Ø5-6 x MON-877Ø8-9 x MON-89788-1	MON 877Ø5 (Vistive Gold) x MON 877Ø8 x MON 89788 (RR2Yield)	Monsanto	FA (high oleic) HT (glyphosate and dicamba)	EFSA opinion published on 18 May 2020 7)	✔ 1)	✔ 1)	✔ 1)		
IND-ØØ41Ø-5	IND410 (HB4)	Verdeca LLC / Indear SA	IY			✔		✔	✔ 5)
IND-ØØ41Ø-5 x MON-Ø4Ø32-6	IND410 (HB4) x MON Ø4Ø32 (Roundup Ready)	Verdeca LLC / Indear SA	IY HT (glyphosate)			✔ 1)		✔	✔ 5)
MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1	MON 87751 x MON 877Ø1 x MON 877Ø8 x MON 89788 (RR2Yield)	Monsanto	IR IR (lepidopteran) HT (dicamba) HT (glyphosate)	Vote in Standing Committee on 7 October 2020 7)	✔ 1)	✔ 1)	✔ 1)	✔	
MON-87751-7 x MON-877Ø1-2 x MON-89788-1	MON 87751 x MON 877Ø1 x MON 89788 (RR2Yield)	Monsanto	IR IR (lepidopteran) HT (glyphosate)	Withdrawn	✔ 1)	✔ 1)	✔ 1)		
DAS-81419-2 x DAS-444Ø6-6	DAS-81419-2 (Conkesta) x DAS-444Ø6-6 (Enlist E3)	DowAgroSciences 9)	HT (2,4-D glyphosate and glufosinate-ammonium) IR (lepidopteran)	In EFSA pipeline 6) 7)	✔ 1)	✔ 1)	✔	✔	✔
MON-877Ø8-9x MON-89788-1x ACS-GMØØ6-4	MON 877Ø8 x MON 89788 (RR2Yield) x A5547-127	Monsanto	HT (dicamba, glyphosate and glufosinate ammonium)	✔	✔ 1)	✔ 1)	✔ 1)		
DP-3Ø5423-1 x MON-877Ø8-9 x MON-89788-1	305423 (Plenish) x MON 877Ø8 x MON 89788 (RR2Yield)	Pioneer Hi-Bred 9)	FA (high-oleic) HT (dicamba) HT (glyphosate)	Withdrawn	✔ 1)	✔ 1)	✔ 1)		
BCS-GM151-6	GMB 151	BASF	IR (cyst nematode) HT (HPPD inhibitor herbicides)	In EFSA pipeline 3)		Pending	Pending		
DBN-Ø9ØØ4-6	DBN9004	Perseus BVBA / Beyong DaBeiNong / Indear SA	HT (glyphosate and glufosinate-ammonium)	In EFSA pipeline 4)	✔				✔
SHZD32-01	SHZD32-01	Shanghai Jiao Tong University	HT (glyphosate)		Pending				

1) In the US, Canada and China there is no (separate) approval required for "stacked events", at least when all the individual events that are part of such a stack have been approved.
2) Argentina, approved for processing (not cultivation)
3) EFSA status: additional data request
4) EFSA status: under consideration
5) This approval is only applicable after the import approval of this event by China
6) EFSA status: in progress
7) De facto threshold for adventitious presence (max 0.1%) of minute traces of this GMO in feed (not food)
8) Waiting for full dossier
9) Pioneer Hi-Bred and Dow AgroSciences are member of the Corteva AgriScience group

HT = Herbicide Tolerant
FA = Fatty Acid composition (change in)
IR = Insect and/or Virus Resistant
IY = Increased Yield