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What is a ‘conventional GMO’?

EU Commission’s new terminology is in conflict with EU GMO Regulation

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This backgrounder considers the term ‘conventional GMO’ and elucidates its meaning as defined by the EU Commission in its 2021 report on the status of new genomic techniques (New GE). It is shown that, the term ‘conventional GMO’, in the sense of a ‘transgenic organism’, as used and defined by the EU Commission, is set to cause fundamental legal and scientific problems: it confuses and contradicts the categories of genetic engineering and conventional breeding that are essential for GMO Regulation in the EU. Furthermore, Testbiotech warns that the use of this term is likely to undermine the Court of Justice ruling in Case C-528/16. This backgrounder further provides some insight into how the term ‘conventional GMO’ was introduced into the current debate on New GE. There is evidence that the definition of ‘conventional GMO’ as used by the EU Commission, lacks sufficient reference, explanation or justification and its use must be revised.

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Introduction and summary

In 2021, the EU Commission published its report on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 (EU Commission, 2021). The report was based on a consultation process in which many stakeholders, NGOs and EU Member States participated. In the report, the EU Commission uses and defines the term ‘conventional GMO’, thereby equating it to ‘transgenic organisms’. This may have serious regulatory implications.

In its C-528/16 ruling, the EU Court of Justice defined ‘conventional’ as techniques with a history of safe use. In this context, the legal and scientific framework established in EU Directive 2001/18/EC, the Commission Implementing Regulation (EU) 503/2013, the Court ruling and by

EFSA, only allows the term ‘conventional GMO’ to be used for plants derived from processes that do not involve genetic engineering. Thus, for example, random mutagenesis might be used to produce a ‘conventional GMO’, while transgenic plants cannot be considered to be ‘conventional’. Consequently, while, e.g. randomly mutated plants are defined as ‘GMOs’ under the EU Directive, these plants are exempt from the regulatory requirements such as mandatory risk assessment.

In this context, the well-established legal meaning of ‘conventional’ is the application of traditional breeding methods based on usage of genetic diversity and natural biological mechanisms. The resulting characteristics could also occur naturally and are generally considered safe. Genetic engineering techniques, on the other hand, are associated with specific, inherent risks and can result in genetic changes which are unlikely to occur in nature. Accordingly, ‘conventional GMOs’ are exempt from EU regulation, while transgenic organisms or organisms derived from New GE are definitely within the scope of the regulation and cannot be defined as ‘conventional’.

Testbiotech is concerned that the new terminology introduced by the EU Commission might be interpreted in a way that exempts genetically engineered organisms from EU GMO regulation and mandatory approval processes. However, it is difficult to draw any final conclusions since the report makes no reference as to why such a definition was introduced and what implications it may have. Neither does the report provide an explanation. In response, Testbiotech, was interested to find out how the term was introduced into the report during the consultation period and has sought to assess regulatory implications.

It appears that the term was first introduced by some researchers with no explicit intention to influence GMO regulation. However, during the consultation process for the Commission report, some stakeholders, such as EuropaBio, used the term ‘conventional GMO’ with a specific, regulatory meaning, thus insinuating that genetic engineering techniques have no specific or inherent risks. That said, neither the EU scientific services, the European Food Safety Authority (EFSA), the Joint Research Center (JRC) nor the vast majority of experts participating in the consultation, used this terminology. Nevertheless, the term ‘conventional GMO’ was integrated in the report - with exactly that meaning, i.e. ‘transgenic’, as proposed by industry.

As a result, the term ‘conventional GMO’ as used by the EU Commission in its report is not referenced at all, and there is no sufficient explanation or justification as to why it was introduced. Consequently, the EU Commission’s definition is likely to cause far reaching confusion in regard to legal definitions and biological categories, which are essential for GMO regulation, risk assessment and the Court ruling.

The proper response of the EU Commission to the findings presented in this backgrounder should be to review its report and either reconsider the used terminology or clarify why and how it was introduced as well as what effects it may have on GMO regulation.

In this review of the report, the EU Commission should also carefully avoid giving the impression that scientific findings which show intended and unintended effects or risks associated with ‘old’ and ‘new’ GE processes, are being denied or set aside without due diligence. The Commission report as it is falsely assumes there are no inherent risks in the processes of New GE; this strongly contradicts many relevant publications and findings (for overview see Testbiotech, 2021a). Therefore, it is not sufficient to only consider the intended characteristics of the newly developed organisms, it should also include unintended genetic changes resulting from the multistep processes of New GE applications as well as their inherent risks.

Established meaning of the term ‘conventional’ in the context of GMO regulation

In its ruling C-528/16, the Court of Justice refers to Directive 2001/18/EC particularly emphasises the wording of Recital 17: “*This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.*”

In its ruling, the Court uses the term ‘conventional’ only to refer to methods, such as random mutagenesis and processes of crossing and selection, which existed before GE technology was established (see Annex I B of Directive 2001/18/EC). It was for this reason that the Court decided these techniques are considered to have a long history of safe use. Organisms, derived from such processes may be categorised as ‘conventional GMOs’: they are derived from traditional random processes and exempt from regulation. However, as the Court argues, techniques without a history of safe use (transgenic plants, New GE) are not ‘conventional’ in this sense and therefore subject to EU GMO regulation and mandatory approval processes.

In the context of EU GMO regulation, the term ‘conventional’ is used in two closely related meanings:

- On the one hand, the term conventional is used to mean traditional, which refers to its history of safe use.

- On the other hand, conventional, in the context of breeding, is used for processes which make use of a high level of genetic diversity (which can be increased by random mutagenesis) and are based on biological mechanisms, such as crossing and selection. It is assumed that the resulting (intended and unintended) genetic changes can also occur in nature, and do not therefore pose generic risks.

It is not only the Court ruling which relied on these established meanings, they are also crucial for comparative EFSA risk assessment of GE plants: in risk assessment, transgenic plants are compared to ‘conventional counterparts’ derived from processes, such as crossing and selection, and which are, therefore, the base line to demonstrate safety (see Implementing Regulation 503/2013). In addition, EFSA (2012), defines ‘conventional plant breeding’ as methods used by plant breeders for the improvement of commercial varieties, which are not covered by the legal definitions of GMO regulation. In this context, EFSA (2012) published a fairly long list to interpret the exemptions defined in Annex I B of the Directive 2001/18/EC (“*sexual crosses, bridge crosses, embryo rescue, somatic hybridisation, translocation breeding and mutation breeding*”), which, nevertheless, correlates to the established legal and scientific framework.

Within EU GMO regulation, transgenic plants are not conventional

Industry and affiliated experts have long sought to blur the differences between conventional breeding (in the legal and biological sense) and organisms derived from genetic engineering, to show that plants derived from genetic engineering should not be regulated (or at least partially deregulated). This strategy has been used for decades, ever since the industry managed to introduce the term ‘substantially equivalent’ into international GMO regulation (Millstone et al., 1999). However, this terminology was abandoned in EU GMO regulation because of its misleading connotations.

The new EU Commission report shows that precisely this strategy may finally be having some success: the EU Commission, in its report, mostly highlights findings which give the impression that the techniques used in New GE, do not have any specific, inherent risks when compared to conventional breeding. Therefore, the Commission has mostly ignored existing scientific evidence (for overview see Testbiotech, 2021a).

Moreover, the EU Commission has not only introduced and used the term 'conventional GMOs' – it has also included it in the glossary, and thus given it a meaning in a regulatory sense: the term '*conventional GMOs*' is defined as "*GMOs resulting from established genomic techniques. Conventional GMOs that have been authorised to date in the EU are transgenic.*"

The way in which this term is used by the EU Commission confuses the regulatory categories of conventional breeding and transgenic plants, both of which were explicitly kept separate in the Court ruling. In essence, this definition can be understood as (at least some) 'transgenic plants are conventional'. In another, even more confusing meaning, it could also be understood as 'only transgenic plants are regulated'.

Whatever the case, this definition of 'conventional GMO' contradicts Ruling C-528/16 and is in conflict with established EU GMO regulation. The Court ruling, the wording of Directive 2001/18/EC and the Implementing Regulation 503/2013 as well as the EFSA reports, all show that transgenic plants cannot simply be considered to be 'conventional' in EU GMO regulation. Table 2 compares the terminology used by the EU Commission with the legal and biological definitions established by the EU Court of Justice and in EU Directive 2001/18.

Table 2: What is a 'conventional GMO'? Comparison of the terminology as used by the EU Commission with the legal and biological definitions established by the EU Court of Justice and the EU Directive 2001/18

EU Institution	Directive 2001/18/EC	Court ruling	EFSA (2012)	Commission (2021)
Quotes	*Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:* *(1) mutagenesis,* *(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.* (Annex I B)	*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.* (Answer to first Question)	*Within the context of this document, conventional plant breeding is defined as methods used by plant breeders for the improvement of commercial varieties and where the resulting plants/varieties are not covered by the legal definitions of genetic modification (Directive 2001/18/EC). Breeding for the improvement of commercial plant varieties involves selection of plants carrying the desired traits acting upon existing variation and/or newly created variation.* (page 13/14)	"*GMOs resulting from established genomic techniques. Conventional GMOs that have been authorised to date in the EU are transgenic.*" (Glossary)
Definition of 'conventional GMO'	obtained by random mutagenesis, crossings or specific cell fusions.	obtained by random mutagenesis or crossing.	obtained by methods in accordance with Directive 2001/18/EC, Annex I B ("*sexual crosses, bridge crosses, embryo rescue, somatic hybridisation, translocation breeding and mutation breeding*".)	transgenic

Deliberately orchestrated confusion

Research shows that the confusion crept into the Commission report in several stages. In conducting this research, Testbiotech was made aware that expressions such as ‘conventional genetic engineering’ are used in several contexts. However, most of them do not seem to have any link to regulatory issues, and therefore have no legal implications for EU GMO legislation: for example, one early reference to the wording ‘conventional genetic engineering’ emerged in 2013.[1] Another early source for ‘conventional genetic engineering’ can be found in a paper by Butler et al. (2015) on CRISPR/Cas applications in potatoes. However, there does not appear to be any intention to link this wording to regulatory issues in the EU.

Interestingly, the term ‘conventional GMOs’ was also used in the sense of transgenic in a European Network of GMO Laboratories report (ENGL, 2019). In this case, this term was chosen to explain the differences in detection methods needed for old and new GE. However, the report (ENGL, 2019) is not directed at specific regulatory changes since it states: “*In the European Union the authorisation system for the introduction of GMOs in the agro-food chain is governed by stringent legislation to ensure: (…) consumers’ choice between GM, organic and conventionally-produced food (…).*” In this statement, the meaning of ‘conventional’ clearly means ‘not genetically engineered’ (or non-transgenic). Nevertheless, the terminology used in the report should be revised.

During the consultation process for the EU Commission report (2021), the term ‘conventional GMO’ was coined to have a specific regulatory meaning. Apparently, the term is now meant to imply that there are no generic risks associated with the techniques used in genetic engineering. Reference was made to two specific sources. Therefore, these sources are of importance for the history and the interpretation of the term as used in the EU Commission report:

(1) One reference made during the consultation cited an article written by Detlef Weigel (Weigel, 2019). As a director at the Max Planck Institute for Developmental Biology[2], he is known to consult with industry (such as Bayer)[3]. He is also behind several patent applications[4], acts as a Member of the Advisory Board at VIB[5] and is also busy with EU SAGE activities, which are coordinated by VIB[6]. VIB (Vlaams Institute for Biotechnology) is a public research institution with a long history of industry involvement and lobbying for GMOs. The institute even has companies such as Bayer CropScience on its board of directors.[7] VIB and EU SAGE were recently exposed as actively lobbying for the deregulation of New GE (CEO, 2021). In his above mentioned text, Weigel (2019) introduced the terms ‘*conventional GMO’* and ‘*conventional transgenic plants’* into the debate on GMO regulation and New GE.

(2) Weigel also contributed to the joint report of the National Academy of Sciences, Leopoldina, the German Research Foundation (DFG) and the Union of German Academies of Sciences (Leopoldina, 2019). In this report, the term ‘*conventional genetic engineering*’ is again used. This term is accompanied by false claims that, so far, no risks inherent to the technology used in transgenic plants have been detected (see Table 1). The report puts the term ‘conventional GMO’ in the context of regulatory aspects (and the need for risk assessment) and was used as a second (and

1 https://www.technologyreview.com/2013/12/17/112585/why-we-will-need-genetically-modified-foods/
2 https://www.mpg.de/151769/entwicklungsbiologie
3 https://www.nature.com/articles/ng.3484
4 https://worldwide.espacenet.com/searchResults?ST=singleline&locale=en_EP&submitted=true&DB=&query=detlef+weigel
5 https://vib.be/about/institutional-advisory-board
6 https://www.eu-sage.eu/contact
7 https://vib.be/about/board-directors

maybe most important) reference by stakeholders during the consultation process and also advocates this terminology.

(3) By referring to Weigel (2019) and Leopoldina (2019), a handful of stakeholders, such as EuropaBio[8], EPSO[9] and EU SAGE[10], introduced terms such as '*conventional GMOs*' into the consultation process for the EU Commission report. In doing so, EuropaBio even uses wording very similar to that of Leopoldina (2019) to insinuate there would be no specific risks going along with such plants (see Table 2). These false claims completely ignore all relevant findings identifying inherently severe risks associated with transgenic plants (for overview see Testbiotech, 2021a and 2021b). It is likely these claims were made to convince the legislator that transgenic plants are generally safe (as are conventional plants) and no longer need to be regulated.

Table 2: Comparison of selected quotes taken from an academic source and the EuropaBio statement.

Leopoldina (2019)	EuropaBio (2020)[11]
Likewise, even after almost 30 years of worldwide utilisation of transgenic crops produced using conventional genetic engineering in agriculture, no risks inherent to the technology could be detected for humans, nature or the environment.	On the other hand, conventional genetic modification which produces transgenic organisms, incorporating genetic material from other species, has been practiced very widely for about three decades. It is very strictly regulated, with mandatory risk assessments, yet no actual safety issues have ever arisen from GMOs placed on the market.

(4) In addition, several Member States, mostly arbitrarily, also made reference to terms such as '*conventional GMOs*' in their input to the Commission's consultation. These countries include Germany (which, for example, might have been influenced by its own academic institutions) as well as Estonia, Hungary, Lithuania and Sweden. Other countries, e.g. Austria, Belgium, the Czech Republic and Norway also used similar terms but put these in quotation marks. By carefully highlighting the term, these Member States and also Norway, [show that they] are aware of problems that may be caused if it were to be adopted as official regulatory language. Therefore, their statements delivered during the consultation process do not encourage the terminology as defined in the Commission report.

At the same time, the huge majority of statements[12] delivered during the consultation for the EU Commission (2021) report, clearly distinguish between conventional breeding and genetic engineering. In this context, the meaning of 'conventional breeding' is clearly restricted to random processes used in combination with crossing and selection, in accord with the Court ruling. Furthermore, in their reports published as Annexes to the EU Commission report, both EFSA (2021) and JRC (2021) avoid mixing up these categories.

In its report, the EU Commission nevertheless embraced the definition of the term 'conventional GMO' proposed by stakeholders with well-documented vested interests. Given the potential for far reaching implications and the de facto contradictions to the established EU legal and scientific framework, this wording should be corrected.

8 https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_stake-cons_stake-reply-23.pdf
9 https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_stake-cons_stake-reply-60.pdf
10 https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_stake-cons_stake-reply-69.pdf
11 https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_mod-bio_stake-cons_stake-reply-23.pdf
12 https://ec.europa.eu/food/plant/gmo/modern_biotech/stakeholder-consultation_en

Conclusions and recommendations

The term ‘conventional GMO’, in the sense of a ‘transgenic organism’, as used and defined by the EU Commission, is set to cause fundamental legal and scientific problems: it confuses and contradicts the categories of genetic engineering and conventional breeding that are essential for GMO Regulation in the EU.

In addition, the term ‘conventional GMOs’ as used by the EU Commission in its report is not sufficiently referenced, and has no explanation or justification. As a result, the EU Commission’s definition of this term is likely to cause significant regulatory uncertainty and confusion, and is therefore a matter of serious concern.

Consequently, the EU Commission should review its report and clarify how and why the term was introduced, including what effects it may have on GMO regulation if transgenic organisms are considered to be conventional.

In its review of the report, the EU Commission should carefully avoid the impression that many scientific findings providing evidence of the inherent risks of New GE technology are neither denied nor set aside without due diligence.

References

Butler, N.M., Atkins, P.A., Voytas, D.F., Douches, D.S. (2015) Generation and inheritance of targeted mutations in potato (Solanum tuberosum L.) using the CRISPR/Cas system. PLoS ONE 10(12): e0144591. https://doi.org/10.1371/journal.pone.0144591

CEO (2021) Derailing EU rules on new GMOs - CRISPR-Files expose lobbying tactics to deregulate new GMOs. Corporate Europe Obervatory, https://corporateeurope.org/en/2021/03/derailing-eu-rules-new-gmos

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

EFSA (2021) Overview of EFSA and European national authorities’ scientific opinions on the risk assessment of plants developed through New Genomic Techniques. EFSA Journal, 19(4): 6314. https://doi.org/10.2903/j.efsa.2021.6314

ENGL (2019) Detection of food and feed plant products obtained by new mutagenesis techniques. European Network of GMO Laboratories, https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

EU Commission (2021) Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16. https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en

JRC (2021) New genomic techniques - State-of-the-art review. Publications Office of the European Union, https://op.europa.eu/en/publication-detail/-/publication/5a661f2b-a180-11eb-b85c-01aa75ed71a1/language-en

Leopoldina (2019) Towards a scientifically justified, differentiated regulation of genome edited plants in the EU. https://www.leopoldina.org/en/publications/detailview/publication/wege-zu-einer-wissenschaftlich-begruendeten-differenzierten-regulierung-genomeditierter-pflanzen-in/

Millstone, E., Brunner, E., Mayer, S. (1999) Beyond ‘substantial equivalence’. Nature, 401(6753): 525-526. https://doi.org/10.1038/44006

Testbiotech (2021a) Deregulation of New GE: Reasonable? Proportional? Testbiotech Background, www.testbiotech.org/node/2746

Testbiotech (2021b) Risk assessment of GE plants in the EU: Taking a look at the ‘dark side of the moon’. Testbiotech Background, www.testbiotech.org/content/risk-assessment-ge-plants-eu-taking-look-dark-side-moon

Weigel (2019) Genome editing in plants. In: Discussion paper focusing on the scientific relevance of genome editing and on the ethical, legal and societal issues potentially involved. Ethics Council of the Max Planck Society, www.mpg.de/14007808/mpg-discussion-paper-genome-editing