Is the Covid-19 Pandemic a Game Changer in GMO Regulation?

La pandémie Covid-19 va-elle changer la donne dans la réglementation des OGM ?

Stellt die Covid-19-Pandemie einen Wendepunkt in der GVO-Verordnung dar?



Justus Wesseler and Kai Purnhagen

New developments in biology have stimulated a wide range of technological changes in the bioeconomy. They have proven potential to contribute to solving many of the global challenges currently faced during the Covid-19 pandemic. In this article we focus on two key challenges: the contribution of biotechnologies to the creation of a vaccine; and to addressing food shortages induced by the Covid-19 pandemic.

La pandémie de Covid-19 pourrait agir comme un déclencheur fort nécessaire du changement.

The regulatory framework at EU level concerning GMOs has been described as rather hostile towards allowing EU citizens to benefit from modern biotechnology (Purnhagen et al., 2018). The existence of a special regulatory framework for GMOs is widely supported in the EU, reflecting state-of-the-art regulation in a number of Member States (Eriksson et al., 2019). The current EU framework, however, has been criticised by many stakeholders as too costly, cumbersome and unpredictable in terms of outcomes (Purnhagen and Wesseler, 2019); it

can be ill-suited to managing risks while, at the same time, not stifling innovation (Purnhagen, 2019).

The Covid-19 pandemic has the potential to act as a much-needed trigger for change. The European Parliament and Council agreed in Recital 17 of Regulation 2020/1043 that the approval procedure for GMOs (which aims at health and environmental protection) is ill-suited to improving public health in the case of vaccination approval in the context of the Covid-19 pandemic (Recital 17). This Regulation can be viewed in the context where many vaccines under development against the coronavirus are based on methods which would fall under the EU GMO testing regime; including methods concerning regulation of the release of a genetically modified organism into the environment and its placing on the market in the EU (Directive 2001/18).

Within agri-food systems there are threats of similar magnitude to those associated with Covid-19; for example, in the area of sustainable development, where biotechnology control solutions have similar potential. However, causal links to these solutions are not so easy to establish and benefits may not be immediately



Field trial of a Black Sigatoka resistant banana from 2007 in Uganda; the field trial had to be fenced by law. ${\rm \odot}$ Justus Wesseler

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Covid-19: A Game Changer in GMO Regulation?



Hemp field in Eastern Germany: one of the promising crops for the bioeconomy. © Justus Wesseler.

evident. Nonetheless, this does not diminish the potential of GMOs, particularly via gene-editing, to solve these problems; and especially in the Covid-19 crisis. Several studies have shown that the crisis reduces the purchasing power of many households and increases their vulnerability towards food shortages (for a summary, see Jones, 2020). In some regions, increases in food prices have further exacerbated problems of vulnerable groups, spreading hunger once again, in contrast to eradicating it - one of the Sustainable Development Goals (Editorial, Nature Plants, 2020).

The Covid-19 crisis is also draining government budgets due to reduced economic growth at a time when additional expenditures are needed for the health sector (Blumenthal *et al.*, 2020). Public sector funding for research and development is reduced, as illustrated in the current EU budget allocation. The Covid-19 pandemic has therefore accelerated the urgency of realising the potential benefits of plant breeding technologies in food production.

New crops that are resistant to pests and diseases, and herbicides have had a positive impact on agricultural productivity. The technologies have contributed to increased yields and lowered insecticide and herbicide

use; and via this effect have reduced the amount of toxic compounds released into the environment, as well as greenhouse gas emissions (Klümper and Oaim, 2014). Additional indirect benefits include improvements in health and safety of farmers due to reduced exposure to pesticides (Huang et al., 2005), micronutrient enriched staple crops, and reduced pressure on nature reserves via land use savings (Barrows et al., 2014). In the current political climate pest management solutions based on the use of pesticides and inorganic fertilisers are not preferred. However, new breeding technologies that allow the development of better disease and pest resistant crops that use fertiliser more efficiently can fill this gap; thus contributing to sustainable intensification, fulfilling several of the sustainable development goals.

There are, however, potential solutions to address nutritional shortages that do not require large research investments. Micronutrient enriched staple crops such as Vitamin A enriched rice have the potential to substitute for Vitamin A supplements; and for reduced Vitamin A supply from vegetables as a result of reduced purchasing power limiting healthy food choices. This is just one example of a micronutrient enriched staple crop, but there are many more such as those developed under the Harvest Plus initiative. Many are developed using modern biotechnologies, which fall within the ambit of GMO regulation at the EU level.

The statements in the recitals of Regulation 2020/1043 to justify the streamlining of GMO approval procedures, with a view to having vaccines to end the Covid-19 pandemic, are in contrast to the decision making for agricultural crops. In the EU there is virtually no cultivation of genetically modified crops. Only one agricultural crop, an insect resistant maize, has approval for cultivation. The EU, however, has approved a number of GMO crops for import and processing. In addition, many everyday products containing GM techniques are legally excluded from authorisation. Recently, new plant breeding technologies have entered the market. These are even more precise and faster than most of those already on the market (Nationale Akademie der Wissenschaften Leopoldina. Deutsche Forschungsgemeinschaft und Union der deutschen Akademien der Wissenschaften, 2019). According to many scholars, a June 2018 decision of the Court of Justice of the European Union is to be interpreted as subjecting these newly developed crops to the specific EU regulations on GMOs. This process includes a lengthy, costly and unpredictable approval process.

Die Covid-19-Pandemie hat das Potenzial, als dringend benötigter Auslöser für Veränderungen zu wirken.

This state-of-the-art does not fit well with the reality that biotechnological innovations generated by the private sector are becoming increasingly important. Reducing regulatory compliance costs can provide the stimulus needed for these developments. We already observe

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The efficient conversion of biomass at farm level depends on biotechnology. $\ensuremath{\textcircled{}}$ Shutterstock.

that the private sector is sensitive to the regulatory environment it faces by choosing breeding techniques that are less heavily regulated. However, this comes at a cost: more time is needed to bring a solution to the market and hence fewer possible solutions become available. Thus, if the regulatory framework does not change there is a risk that the Union will be unable to realise the potential benefits of modern biotechnology. The recitals of Regulation 2020/1043 endorse this view from the perspective of the European Parliament and the Commission.

The Covid-19 pandemic has the potential to act as a much-needed trigger for change.

The Covid-19 pandemic may thus provide the final push for a longneeded change in the regulatory environment of GMO regulation in the EU. A new generation of scholars and citizens may take a fresh look at the evidence and get inspired by the opportunities new developments in biotechnology have to offer for addressing the societal challenges ahead of us.

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Summary

Is the Covid-19 Pandemic a Game Changer in GMO Regulation?

My The Covid-19 pandemic has the **T** potential to act as a muchneeded trigger for changes to the European Union regulations around genetically modified organisms (GMOs). There are two main reasons for this potential development. Firstly, the majority of vaccines under development would fall under Directive 2001/18 on the release of GMOs into the environment. The European Parliament and Council agreed that, in Recital 17 of Regulation 2020/1043, the current approval procedure for GMOs is not well-suited to improving public health. This was driven in particular by the need for vaccine approval in the context of the Covid-19 pandemic; and a more appropriate approval procedure would be applied. Secondly, several studies have shown that the Covid-19 crisis reduces the purchasing power of households and increases their vulnerability in the case of food shortages; and consequent increases in food prices further exacerbate the nutritional problems of vulnerable groups. Modern plant breeding has the potential to provide less expensive solutions to support vulnerable groups. As the Covid-19 crisis drains government budgets, views around GMOs in the EU may change in the light of positive experiences from the approval of Covid-19 vaccines.



La pandémie de Covid-19 pourrait agir comme un déclencheur fort nécessaire pour changer la réglementation de l'Union européenne concernant les organismes génétiquement modifiés (OGM). Il y a deux raisons principales à cela. Premièrement, la majorité des vaccins en cours de développement relèveraient de la directive 2001/18 relative à la dissémination d'OGM dans l'environnement. Le Parlement européen et le Conseil sont convenus qu'au considérant 17 du règlement 2020/1043, la procédure d'approbation actuelle des OGM n'est pas bien adaptée pour améliorer la santé publique. Cela ressort en particulier de la nécessité d'approuver les vaccins dans le contexte de la pandémie de Covid-19; et une procédure d'approbation plus appropriée serait appliquée. Deuxièmement, plusieurs études ont montré que la crise du Covid-19 réduit le pouvoir d'achat des ménages et accroît leur vulnérabilité en cas de pénurie alimentaire; et les augmentations des prix alimentaires qui en résultent aggravent encore les problèmes nutritionnels des groupes vulnérables. La sélection végétale moderne est capable de fournir des solutions moins coûteuses pour soutenir les groupes vulnérables. Alors que la crise de la Covid-19 épuise les budgets publics, les avis sur les OGM dans l'Union européenne peuvent changer à la lumière des expériences positives découlant de l'approbation des vaccins anti-Covid-19.

Stellt die Covid-19-Pandemie einen Wendepunkt in der GVO-Verordnung dar?

Die Covid-19-Pandemie hat das Potenzial, als dringend benötigter Auslöser für Änderungen in den Richtlinien der Europäischen Union für genetisch veränderte Organismen (GVO) zu wirken. Für diese mögliche Entwicklung gibt es zwei Hauptgründe. Zum einen würde die Mehrheit der in der Entwicklung befindlichen Impfstoffe unter die Richtlinie 2001/18 über die "Freisetzung von GVO in die Umwelt" fallen. Das Europäische Parlament und der Rat waren sich im Hinblick auf Erwägungsgrund 17 der Verordnung 2020/1043 einig, dass das derzeitige Zulassungsverfahren für GVO nicht gut geeignet ist, um die Gesundheit der Bevölkerung zu verbessern. Diese Diskussion wurde insbesondere durch die Notwendigkeit einer Impfstoffzulassung im Zusammenhang mit der Covid-19-Pandemie vorangetrieben. Dabei sollte ein geeigneteres Zulassungsverfahren zur Anwendung kommen. Zum anderen haben mehrere Studien gezeigt, dass die Covid-19-Krise die Kaufkraft der Haushalte verringert und ihre Krisenanfälligkeit im Falle einer Nahrungsmittelknappheit erhöht. Der mit einer solchen Verknappung verbundene Anstieg der Lebensmittelpreise verschärft die Ernährungsprobleme von benachteiligten Bevölkerungsgruppen noch weiter. Die moderne Pflanzenzüchtung bietet die Möglichkeit, kostengünstigere Lösungen für die Unterstützung dieser Bevölkerungsgruppen bereitzustellen. Da die Covid-19-Krise die öffentlichen Haushalte stark belastet, könnten sich angesichts der positiven Erfahrungen mit der Zulassung von Covid-19-Impfstoffen die Meinungen innerhalb der EU zum Thema GVO ändern.

