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Options to Reform the European Union Legislation on GMOs: Post-authorization and Beyond

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We discuss options to reform the EU genetically modified organism (GMO) regulatory framework, make risk assessment and decision-making more consistent with scientific principles, and lay the groundwork for international coherence. In this third of three articles, we focus on labeling and coexistence as well as discuss the political reality and potential ways forward.

In a series of three articles, we propose various details that may be reformed within the legislative framework for GMOs in the EU. In the previous two articles, we focused on the scope and definitions as well as the process to assess and manage risk [1,2]. In this final article, we address certain post-authorization procedures (Figure 1) and discuss the implications and the political reality concerning reforms for GMOs in general and the products of gene editing in particular.

Reforming Post-authorization Requirements

Labeling

According to Regulation (EC) No 1830/2003, labeling of GM food and feed products should 'ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner' [Art. 4, cf. Art. 21, Regulation (EC) No 1829/2003]. Products under the GMO Regulation are subject to mandatory labeling. We propose that, given that the current GMO definition remains unchanged, the labeling requirements for GMOs should be reconsidered in the light of difficulties in establishing traceability and molecular identification of many gene-edited products [3]. Foods and products developed with gene editing should be exempt from labeling requirements as long as they do not contain foreign DNA. This labeling exemption would be equivalent to the one for products developed with conventional mutagenesis. It should be taken into account that consumers have an interest both in adequate information and in access to a variety of affordable products, which in most countries can be realized only via enabling an effective trade system that allows the import of foreign products.

Coexistence

The lack of established means for the identification of organisms with minor targeted mutations will create problems in the application of current coexistence frameworks. In practice, these frameworks can make it increasingly difficult to introduce useful new plant varieties, such as pest-resistant varieties that reduce the need for pesticides. Coexistence policies, while framed by EU recommendations, are designed by Member States. Coexistence policies may act as an indirect cultivation ban, enabling Member States to set up conditions that make it virtually impossible for farmers to cultivate authorized GM crops [4]. On the one hand, GMOs positively assessed for cultivation by EFSA are considered safe for humans and the environment. On the other hand, EU law also acknowledges that consumers have a right to know which foods they consume, not only with respect to health and safety but also taking into account their social and ethical considerations. Additional production standards are required by EU law and the market, such as for GMO-free or organic certified food products. As these regulations refer to the general rules on GMOs in the EU, the determination of GMO-free and organic products would be based on production methods as well, if our proposal were to be adopted. As a consequence, these products would be regulated similar to the certification rules for organic products in the USA [5]. When Member States would have more freedom to define their own risk management measures, a possibility may emerge to adjust cultivation distance rules (down to 0) and possibly also thresholds for the adventitious presence of authorized GMOs. If this were not the case, the market for GMO-free and organic products may be endangered in the EU. In the literature, this has been discussed in relation to the possibility of producing certified GMO-free and organic products in Germany [6].

The Way Forward

The reform options proposed here aim at an improved EU regulatory framework for the products of molecular breeding technologies (transgenesis, targeted mutagenesis, and other related gene technologies) that: (i) is more predictable from an innovation perspective; (ii) does not discriminate certain techniques and their derived products without a valid reason; (iii) is adaptable to scientific progress and accumulated experience; and (iv) acknowledges the potential benefits and possible shortcomings of molecular breeding technologies, while at the same time ensuring the safety of the products of modern breeding in a socially responsible manner. As both research on and trade in GMOs and their derived products feature mainly at an international level, these respective amendments should be monitored and ultimately brought in line with initiatives to create a

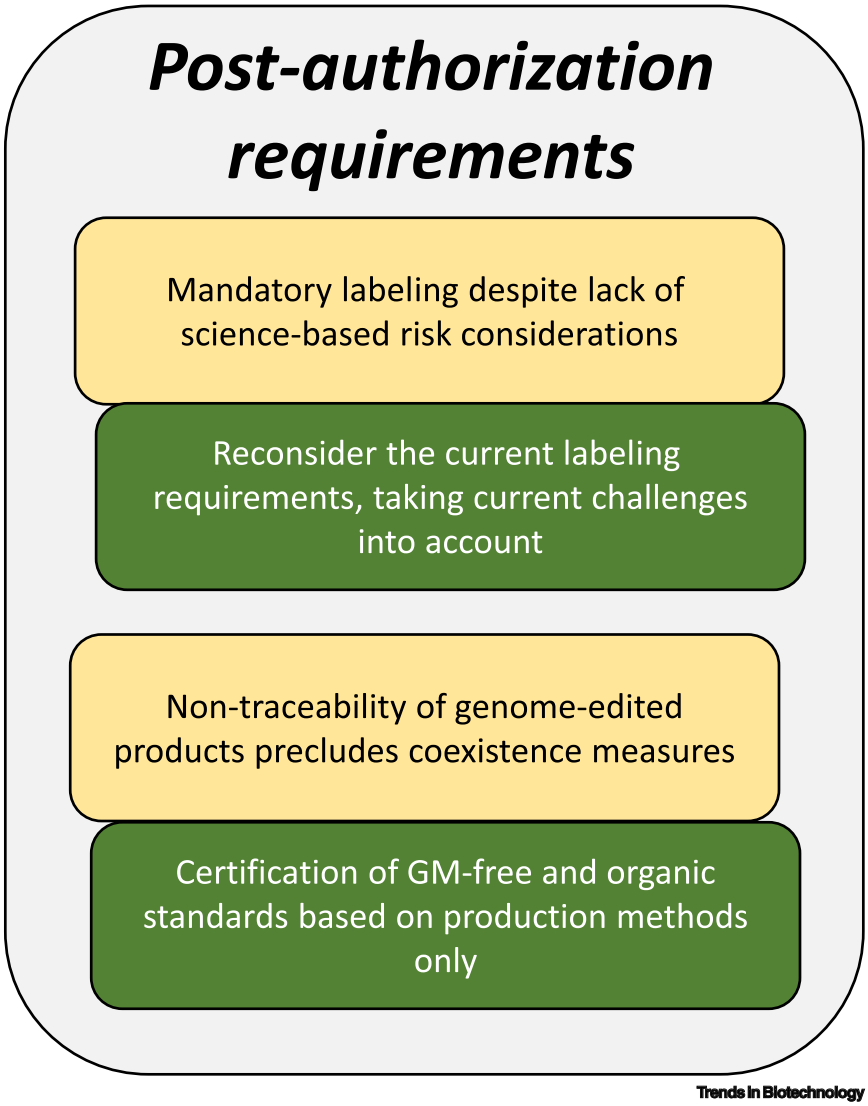

Figure 1. Reform Options of the Legislative Framework for Genetically Modified Organisms in the EU, Concerning Certain Post-authorization Requirements. In yellow boxes are identified problematic issues with the regulatory framework; in green boxes are suggested potential solutions.

transnational level playing field. This should not disrespect, however, the different needs and business structures of agriculture across the world. Hence, regulation of these varieties and their derived products at a national level needs to remain possible to some extent.

Any reform process has to be initiated by the EC or EU citizens. According to the Directive (EU) 2015/412 (the 'opt-out directive') the EC should not later than April 2019 have reported to the European Parliament and to the Council on the use of this opt-out directive, 'accompanied by any legislative proposals the Commission considers appropriate'. While no further details were specified, now the Council of the EU has requested the EC to conduct a study on the status of novel gene technologies and the problems of legal compliance that the CJEU ruling in C-528/16 brought on new mutagenesis techniques and 'to submit a proposal, if appropriate in view of the outcome of the study' [Council Decision (EU) 2019/1904, https://eur-lex.europa.eu/eli/dec/2019/1904/oj].

We have discussed a number of aspects that may be addressed by the EC in this and other contexts. We suggest that the EC actively explores what reform options are feasible at this point, seeking advice from the academic community and striving for solutions that can provide the basis for international coherence.

Any serious attempt to reform the EU legislation or its application in this area will have to take the differing political realities and policy preferences in the Member States into account. Currently, chances appear to be slim of a reform of the legislation concerning traditional, transgenic GMOs. When EU Directive 2015/412 was introduced in EU law, 17 Member States, among them Germany, Poland, France, and Italy, and two regions immediately asked for territorial restrictions of cultivation of MON810. The resistance to GMOs is prevalent across the political spectrum. By contrast, the chances of reform seem to be much better for the products of targeted mutagenesis. A major reason for this is that the small, targeted interventions obtainable with these new mutagenesis techniques are in practice impossible to distinguish from natural mutations or from mutations obtained with the older, nontargeted techniques that have always been exempted from the legislation on the basis of a long history of safe use. This makes the application of the current legislation impossible to control or enforce, in particular regarding international trade with gene-edited products.

Several initiatives have been taken that indicate political viability for regulatory reform concerning the new technologies. In May 2019, The Netherlands, supported by Estonia, called for the EU to address the legal uncertainties that follow from the

CJEU's ruling in Case C-528/16 and, by extension, adopt a 'unified approach' to new plant breeding techniques (https://data.consilium.europa.eu/doc/document/ST-8134-2019-INIT/en/pdf). This call has since then been supported by 12 more EU Member States, including Belgium, France, Finland, Germany, Greece, Italy, Spain, and Sweden (https://www.euractiv.com/section/agriculture-food/news/14-eu-countries-call-for-unified-approach-to-gene-editing-in-plants/), eventually leading to the Council Decision 2019/1904 of 8 November 2019 that requests the EC to perform a study that, if necessary, should be accompanied by a reform proposal. This assignment opens a window of opportunity to provide the EC with adequate information on the scientific consensus in pertinent issues and to submit proposals for modifications in the legislation and/or its application that can solve the problems identified in the Council Decision 2019/1904, by the Joint Research Centre, by the Scientific Advice Mechanism to the EC, and elsewhere.

Any such deliberations ought to be conducted bearing in mind that the GMO regulatory system does not operate in a void, but has consequences. It provides regulators in the EU with information about new technologies. It is furthermore intended to enable more scientifically robust and socially acceptable policies. However, if the regulatory system introduces hurdles that are so high that they hinder innovation in promising technologies, society may lose important tools to solve pressing problems such as achieving more sustainable and economically viable agriculture. In particular, it may impede the introduction of efficient means to reduce pesticide use [7–10], crops with an improved nutritional profile and with fewer health concerns [11–13], and crops that provide environmentally sustainable industrial raw materials [14,15]. It may have profound negative impacts on small and medium-sized breeding companies and publicly funded breeding programs in the EU [16,17] and is very likely to marginalize EU-based researchers ([18,19]; https://issuu.com/biocom/docs/ebm2018_winter). Reforming the EU GMO regulations to facilitate safe and benign use of the technologies is therefore something that has to be addressed thoroughly, adequately, and with scientific rigor by the EC to strengthen our capacity to tackle the societal challenges.

Author Contributions

D.E. took the initiative and prepared the first draft manuscript. All other coauthors contributed with a section each to the manuscript and shared in the finalizing of the manuscript.

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