Hans-Georg Dederer · David Hamburger
Editors

Regulation of Genome Editing in Plant Biotechnology

A Comparative Analysis of Regulatory Frameworks of Selected Countries and the EU

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Preface

The publication of a contributed volume is an undertaking that, by its very nature, is not possible without the fruitful collaboration of various parties.

That said, our gratitude goes first and foremost to our esteemed country rapporteurs Margaret Rosso Grossman, Tetsuya Ishii, Martin Lema, Karinne Ludlow, Ansgar Münichsdorfer, Stuart Smyth, Brigitte Voigt and Agustina Whelan. Without their commitment and dedication to the project, we and our readers would not have the opportunity to learn from, and be captivated by the accumulation of, their vast knowledge that is abundantly visible in their country reports.

The country rapporteurs presented their reports at a workshop in Munich on 22nd and 23rd of March 2018 which was attended by academics, regulators, practitioners and stakeholders both from Germany and abroad. The stimulating and intriguing discussions during the workshop undoubtedly left their mark on the final versions of the country reports.

Besides, it was the generous support from the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) which has created the financial underpinnings for this project to thrive. This contributed volume is published as part of the research project "Genome editing in plant biotechnology – a science-based legal analysis of regulatory problems" which is in its entirety funded by the BMBF (project no. 01GP1615). While this research project is mainly concerned with the regulation of genome edited plants in the European Union, this edited volume constitutes the project's contribution to the comparative law aspect of this field of study.

The funding by the BMBF was complemented by outstanding administrative support through the German Aerospace Center (Deutsches Zentrum für Luft- und Raumfahrt e.V., DLR) throughout the entire duration of the research programme.

In order for a book project to finally see the light of day, it is in the end the backing from a publisher that is indispensable. In that regard, we were fortunate to have received from early on the trust of such a renowned and experienced publishing house as Springer. As a result, we have been accompanied with the highest level of expertise and know-how during all stages of our research endeavour.

Finally, special thanks are due to the student assistants Sabrina Brzezinski, Clemens Dienstbier, Sebastian Graup and Katharina Schreiber, who provided with their exceptional work effort invaluable support in the completion of the final manuscript.

Since the country reports are for the most part based on the presentations made at the workshop in March 2018, changes after this date could only be partially taken into account.

Passau, Germany — Hans-Georg Dederer
Passau, Germany — David Hamburger
May 2019

Contents

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Chapter 1
Introduction: Regulation of Plants Derived from Genome Editing—What Lessons To Be Learned from Other Countries?

Hans-Georg Dederer and David Hamburger

Abstract The advent of genome editing in plant breeding and the resulting blurring of the boundaries between natural and artificially induced genetic modifications present regulators worldwide with new challenges. In such a time of regulatory uncertainty, or dispute over how to regulate genome edited plants, legislators are well advised to seek external guidance on how this issue could be addressed appropriately. Since genome edited organisms pose similar challenges to regulatory systems around the world, it seems sensible to study the practices of other jurisdictions in order to draw lessons for one's own regulatory efforts. To be able to choose from a diverse selection of regulatory approaches, countries with differing attitudes towards genetically modified plants were chosen as research objects. Broadly speaking the studied jurisdictions can be divided into those which embrace the cultivation of GMOs (Argentina, Canada and the USA), those which are reluctant adopters of GMOs (Australia and Europe) and a de facto absolute abstainer from GM crop cultivation (Japan). Based on a comparative analysis of the regulatory frameworks and an identification of possible best practices, the conclusion is made that a consistent regulatory regime should be product-based, i.e. the risk regulation should be triggered by a plant's traits. From a procedural point of view, an obligatory upstream procedure should be used for channelling the respective plant into the relevant regulatory framework. This process can be further catalysed by a voluntary early consultation procedure. Within such a framework the one-door-one-key principle should apply, which means that all relevant authorizations are granted upon a single application.

1.1 Introduction

The advent of so called new breeding techniques (NBTs) and the resulting blurring of the boundaries between natural and artificially induced genetic modifications present regulators worldwide with new challenges.

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The rapidly adopted and constantly improving genome editing technology, in particular the CRISPR-Cas technology, makes it possible to develop new genetically modified plant varieties that are indistinguishable from conventionally bred plants or naturally occurring mutants.[1] This development calls into question the established regulatory differentiation between genetically modified organisms (GMOs) and non-GMOs.[2]

Depending on the applicable domestic regulation, it may be unclear to what extent plants derived from new breeding techniques are subject to the relevant legal provisions. As a consequence, national legal frameworks for the regulation of GMOs are faced with the challenge that their scope of application has to be redefined or at least clarified with respect to genome edited organisms (GEOs). Even if the regulatory status of GEOs has, at least in significant part, been determined either by a governmental authority or by a court,[3] there may be doubts among regulators, or debates among politicians, seed developers, farmers, environmentalists and other actors of civil society, concerning the appropriateness of the applicable rules.

In such a time of regulatory uncertainty, or dispute over how to regulate GEOs adequately, legislators are well advised to seek external guidance on how this issue could be addressed appropriately. Such orientation can be provided *inter alia* by scientific gain of knowledge, public opinion, economic considerations, political necessities or ethical convictions. However, since GEOs pose similar challenges to regulatory systems around the world, it seems sensible to study the practices of other jurisdictions in order to draw lessons for one's own regulatory efforts. This way, a legislative endeavor can adopt advantages of different regulatory approaches as well as regulatory solutions already found in other legal frameworks while at the same time avoiding the repetition of their mistakes.

Just as there is a plethora of different jurisdictions, there is also a wide variety of regulatory approaches towards GMOs. In order to be able to filter out and make use of the best practices a specific regulatory regime has to offer, it is imperative that the objectives of the foreign regulatory system are identified as well. Legal provisions regarding GMOs can pursue different purposes like ensuring safety, promoting research and development, or facilitating the adoption of GMOs. Regulatory means are, in turn, aligned with regulatory objectives, *i.e.* they are intended, and hence specifically designed, to achieve a particular regulatory purpose. To ensure the compatibility of an identified foreign best practice with the domestic regulatory approach it is, therefore, decisive to ensure that the respective foreign regulatory measure, or mechanism, fits into the domestic overall regulatory structure and its object and purpose.

[1] Cf. Sprink et al. (2016), p. 1497; Voigt and Klima (2017), p. 321; Schenkel and Leggewie (2015), p. 265.

[2] Cf. Sprink et al. (2016), pp. 1494–1495; Globus and Qimron (2018), pp. 1293–1294.

[3] As is the case in the European Union (EU) with regard to the Court of Justice of the European Union's judgment of 25 July 2018 (CJEU, C-528/16, *Confédération paysanne et al.*). Cf. European Court of Justice (2018).

In order to be able to choose from a diverse selection of regulatory approaches with different objectives, countries with differing attitudes towards genetically modified plants were chosen as research objects. Very broadly speaking, the studied jurisdictions can be divided into three groups regarding their attitude towards GM crop cultivation: those which embrace and support the cultivation of GMOs (Argentina, Canada and the USA), those which are reluctant adopters of GMOs with regions that opted-out of GMO cultivation (Australia and Europe) and *de facto* absolute abstainers from GM crop cultivation (Japan).[4]

Consequently, the selection of these countries promises the identification of a wide variety of regulatory tools, which can be used to achieve a similarly manifold range of objectives.

1.2 Specific Characteristics of the Regulatory Approaches

A first step in determining transferable regulatory tools is the identification of the regulatory regimes' specific characteristics. This is crucial because the features that distinguish regulatory systems from each other facilitate the detection of a best practice by means of comparison.

1.2.1 Argentina

Argentina has been the first country in the world to adopt, in 2015, a new regulation[5] specifically addressed to NBTs including genome editing. However, this is not a substantive regulation (*i.e.* not laying down rules on, *e.g.*, risk assessment, authorization or labelling), but a regulation of a procedural nature only.

The decree lays down the process that is used to determine whether a plant derived from an NBT constitutes a GMO as defined by the Argentine regulatory system. The outlined administrative procedure, therefore, precedes the application of the regulatory framework for GMOs that will follow if the plant in question is found to constitute a GMO. Such an upstream procedure has the advantage that the original GMO regime can remain unchanged, while this newly established procedure ensures that it remains applicable whenever a new breeding technique emerges. Importantly, this novel procedure is not tied to specific technologies, *i.e.* it is technology-neutral.

At the same time, the upstream procedure serves the purpose of consulting with plant breeders. Plant breeders can ask the competent authority for an assessment

[4]For a detailed illustration of those countries' varying attitude towards GM cultivation see Chap. 8, Sect. 8.2.1.

[5]Ministerio de Agricultura, Ganadería y Pesca (2015). For detailed information on the content and working of this decree see Chap. 2, Sect. 2.3.2.

of an individual plant variety and they are entitled to an answer, whether the crop is considered to be a GMO or a non-GMO, within 60 days. A special feature of this procedure is the possibility to ask for a preliminary classification of a plant variety while it is still at the design stage. This early consultation procedure provides a developer with the opportunity to receive a regulatory classification of the envisaged product at an early point of his research and development efforts. As soon as the new plant variety has been developed, molecular biology studies on the relevant genetic alteration must be submitted to the authorities. If the final plant variety corresponds to the earlier product that was the subject of the early consultation procedure, the preliminary assessment regarding its regulatory status retains its validity.

If the plant, or plant variety, does not fit into the category of GMOs, it is subject to those rules which are applicable to 'conventional' plants, or plant varieties respectively. Interestingly, however, if the competent authority in charge of the (early) consultation procedure identifies (possible) risks arising from such a NBT-derived plant or plant variety, it may issue safety-related recommendations to the plant breeder. In addition, the authority has to notify the agency, which is in charge of plant variety registration, of such (possible) risks. The registration may be rejected, in the end, if commercialization of the variety poses unacceptable sanitary or phytosanitary risks. Thus, there is no, or at least no significant, regulatory gap between regulation of GM varieties and non-GM varieties as regards risks.

1.2.2 Australia

What specifically distinguishes the Australian regulatory framework for GMOs from the other examined approaches is the existence of a bi-national authority, the Food Standards Australia New Zealand (FSANZ).[6] FSANZ is responsible for the assessment and market approval of GM food prior to the commercial release into Australia and New Zealand. FSANZ does not make such an assessment separately for Australia and New Zealand, but issues a single market approval for both countries. Therefore, exactly the same rules and procedures are applied to both jurisdictions.

The existence of a common, in fact supranational, approval authority is especially interesting when taking into account that no cultivation of GMOs takes place in New Zealand while Australian farmers cultivate GMOs. Although Australia and New Zealand have a completely different approach towards the cultivation of GMOs, both countries were able to find common ground with regard to the consumption of GM food.

Besides the regulatory framework for GM foods implemented by FSANZ, there is a separate solely Australian regulatory framework for GMOs which applies to

[6]The situation seems at a first glance similar to the European approach. However, since the EU has the competence to shape the legal framework for marketing of GMO based on its own volition, the European situation is in this concrete instance more comparable to that of a federal state—even though the EU is not a state entity in legal terms.

"dealings" with GMOs such as GMO cultivation. Although both regulatory regimes are ultimately triggered by the use of "gene technology", the two frameworks define the decisive term "gene technology" differently. Due to those differing legal definitions, the Australian regulatory status of GEOs currently depends on whether they are used for, e.g., cultivation or food production which means, in the end, that GEOs may be covered, e.g., by the general GMO framework but not by the GM food framework.

1.2.3 Canada

What stands out in the case of Canada is the use of a solely product-based regulatory approach when it comes to the approval of GMOs for cultivation. Here, the decisive trigger for a stricter approval process is not the use of gene technology or any other, traditional or modern, breeding technique but the existence of a novel trait in a new plant variety. Such a variety with a novel trait is defined as "a plant containing a trait not present in plants of the same species already existing as stable, cultivated populations in Canada, or is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada".[7] Consequently, exactly the same rules apply to genome edited plants, crops derived from "classic" genetic engineering and conventionally bred varieties.

Such a purely product-based approach concerning the cultivation approval of new plant varieties is unique among the examined countries. To avoid confusion—and a common misconception—it should be stated, though, that it is only the approval process for cultivation, which is solely product-based. When it comes to GM food, a process-based component comes into play. However, that does not imply that all GM foods are reviewed simply because of the use of modern biotechnological techniques of genetic modification. Rather GM foods must also display a feature of novelty. GM foods are not considered to be sufficiently novel (so as to require administrative review) if there is a history of safe use abroad or if no "major change" concerning the food's composition has occurred.

1.2.4 European Union

Among the examined regulatory frameworks, the European regime is currently the only one that allows an ex ante determination of the regulatory classification of GEOs with regard to cultivation as well as concerning the marketing of food derived from genome edited plant varieties, even without knowing the specific product characteristics.

[7] Directive 94-08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, Sec. 1.

The Court of Justice of the European Court of Justice (CJEU) ruled that mutagenesis induced by genome editing leads to organisms which are fully covered by the current European GMO regulatory framework.[8] It can be safely derived from the Court's reasoning that directed mutagenesis through genome editing covers both SDN and ODM techniques. The CJEU did not make a determination on genome editing techniques that are not mutagenesis techniques. However, its interpretation of the European GMO definition allows for conclusions about other forms of genome editing as well. Since the Court ruled—at least implicitly, and insofar in line with the wording of the GMO definition—that the classification as GMO depends on whether the breeding technique used was natural,[9] it seems safe to assume that the use of all techniques of genome editing results in GMOs within the meaning of the European regulatory framework.[10]

Consequently, the European regulatory regime is characterized by two distinctive features: (1) the legal status of all forms of genome edited plant varieties and products derived from them can be considered to be settled, and (2) the legal framework is based on a process-emphasizing approach requiring minimal artificially induced genomic changes (such as point mutations) only to suffice to lead to a GMO.

Even though the restrictive interpretation of the European GMO framework by the ECJ has been widely criticized,[11] it cannot be denied that it provides a high degree of legal certainty.

1.2.5 Japan

Having a closer look at the Japanese approach, it is especially the overall regulatory outcome that stands out. While Japan has no ban for GMOs in place and even a comparable high number of GM varieties are approved for cultivation, no actual cultivation takes place.[12]

This peculiar situation can be partly explained by non-regulation-related factors. Japanese companies give a comparable high amount of attention to consumer's satisfaction and are, therefore, very sensitive with regard to voiced concerns or preferences. Due to the prevailing negative attitude towards GMOs within the Japanese society, local farmers and manufactures are reluctant to use GMOs (at least in food production). Moreover, it is argued that the traits of currently existing GM crop varieties are less compatible with Japanese farm sizes and agricultural habits. However, an adoption of GM crops is also hampered by local

[8]European Court of Justice (2018).

[9]European Court of Justice (2018), para. 29.

[10]Cf. Chap. 5, Sect. 5.3.2. The same view is held by Seitz (2018), p. 763.

[11]See for example Lappin (2018), Neslen (2018), Callaway (2018), Stokstad (2018) and Science Media Centre (2018).

[12]See Chap. 8, Fig. 8.5.

administrative provisions. Local governments impose burdensome application requirements, require coexistence measures that are difficult to adhere to or charge application fees that render the cultivation of GM crops economically less feasible.[13] This makes abundantly clear that not just the legal provisions should be taken into account when assessing a regulatory regime for GMOs but also the social, political, and economic environment.

Concerning the regulatory regime, the decisive trigger for its application, and for the classification of an organisms as GMO, is the presence of foreign "nucleic acids" (which includes both RNA and DNA) within an organism. In this regard, referring to "nucleic acids" as "products", the regulatory approach might be called "product-based". Nucleic acids are not foreign if they are present in organisms of the same species or in organisms of other species which exchange nucleic acids with the species of the genetically altered organism. Under this framework, the classification of GEOs as GMOs or non-GMOs depends decisively on whether guide RNA used for purposes of SDN techniques is a foreign "nucleic acid" and whether the guide RNA is stably integrated into the genome or for other reasons continuously present in the organism. In case of ODM, on the other hand, the classification of the resultant organisms depends on whether oligonucleotide sequence is a foreign DNA sequence.

1.2.6 United States

The US approach differs from others by the use of unique, but selective triggers for the regulation of GMOs. Accordingly, at least in theory, GMOs could escape the regulatory regime completely, if they do not meet any of the criteria which trigger GMO regulation.

With regard to the cultivation of plants, it is the existence of a plant pest, or plant pest risk respectively, or a plant incorporated protectant that subjects the plant to regulatory requirements. When it comes to the marketing of food, it is decisive for the applicability of the regulatory framework whether the food contains residues from plant incorporated protectants or a food additive or whether the food is adulterated or misbranded.

Another distinctive feature of the US regulatory regime is that it resorts to a purely product-based trigger with regard to regulation of food under an informal consultation procedure. At least among the examined countries, this is a unique feature of the United States regulatory framework.

Concerning the regulatory status of GEOs under the current regulatory framework, there is a remarkable degree of legal uncertainty. This is due to the "product-based" approach according to which only the presence of certain "products", or "products" with certain characteristics, (e.g. plant pests, noxious weeds, food additives, plants with pesticidal properties, pesticidal residues in foods, adulterated foods

[13]Cf. for this paragraph Sato (2015), 6, 15–16.

etc.) triggers existing regulations. Accordingly, GEOs escape the regulatory framework if they are not covered by one of the categories of regulated "products". However, this deficiency is mitigated, albeit to a limited extent only, by voluntary consultation procedures according to which developers of GEOs may request for a determination of the regulatory status of the respective organism.

1.3 Identification of Best Practices

"Best practices" is a rather frequently used term in science, management and politics. However, as it is typical for vogue expressions, they lose their clear-cut substantive meaning with the increasing frequency of their use and progressively deteriorate into mere buzzwords. To avoid confusion how the term is used subsequently, it is therefore necessary to define the underlying understanding of "best practices".

In general, from an abstract-methodological point of view, "best practices" are processes, methods or concepts that achieve the envisaged outcome more (1) efficiently, (2) effectively and (3) comprehensively than other practices (*i.e.* processes, methods or concepts).[14] A practice is most efficient if it is applied in such a way that the results achieved and the resources used are in the best possible cost-benefit ratio. Effectiveness describes the degree to which a practice is able to realize its objectives. The higher the efficacy and the level of attainment, the more efficient a measure is. A practice is comprehensive when it is able to take into account all concerns designated as its direct or indirect objectives. To qualify as a best practice, these three elements must be brought to bear in a manner that ensures that every single one of them is able to unfold its maximal potential.

Beyond that general concept, individual best practices can range from empirically well-established or scientifically evidence-based best practices over promising best practices to just emerging and not yet solidified best practices.[15] The subsequently

[14]There does not exist a uniform definition of "best practices" which is agreed upon. For different definitions see for example Bretschneider et al. (2005), p. 309; Bendixsen and de Guchteneire (2003), pp. 678–679.

[15]"Emerging best practices" describes a process or method for which there is only a low degree of scientific evidence to qualify as a best practice. In the case of a "promising best practice" the existing quantitative and qualitative data is elevated to a moderate level. An "evidence-based best practice" is supported by a convincing and strong set of scientific evidence regarding its general effectiveness and efficiency. For a more detailed illustration of different best practice categories and sources of best practice evidence see Spencer et al. (2013); Bhatta (2002), p. 102; Moore and Browne (2017), p. 385; Canadian Homelessness Research Network (2013), p. 7; Myers et al. (2006), p. 374.

An example for a widely adopted and well-regarded best practice in the realm of GMO regulation are the international frameworks for risk assessment. Cf. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2226 U.N.T.S. 208, 39 ILM 1027, UN Doc. UNEP/CBD/ExCOP/1/3 42; UNEP International Technical Guidelines for Safety in Biotechnology; OECD Safety Considerations for Biotechnology 1992. See also the OECD Consensus Documents on Safety Assessment of Transgenic Organisms.

discussed concepts lack yet the scientific evidence to qualify already as best practices. Since regulation of GEOs has started only recently and is still heavily debated in most jurisdictions, there is—at least with regard to genome edited plants—insufficient available data and evidence to support such a conclusion. However, there are, in our opinion, certain indications which allow the assumption of emerging or promising best practices of how to regulate GEOs adequately.

After having outlined the terminology, it remains to be clarified how best practices can be identified. Best practice research is described as "the selective observation of a set of exemplars across different contexts in order to derive more generalizable principles and theories of management".[16] In a more instructive manner this process could be described as looking "for [solutions tried in other jurisdictions] that appear to have worked pretty well, [trying] to understand exactly how and why they might have worked, and evaluat[ing] their applicability to [one's] own situation".[17]

In order to perform such an inductive evaluation drawing on different practices, i.e., in our case, on different regulatory approaches and concepts, the objectives of the looked-for best practices must be clearly defined beforehand. With regard to the regulation of genome edited crops many different regulatory interests and factors are at play.[18] This raises the question for what objectives and purposes best practices should aim for. Due to the manifold and in part contradictory regulatory objectives, a generally valid assumption cannot be made. Therefore, the further examination will have a limited scope by concentrating on possible best practices that (1) take into account the science-based risk potential of genome edited crops, (2) facilitate a transparent, even-handed and appropriate approval process or other administrative oversight mechanism, (3) comply with international law obligations and (4) are not more restrictive than necessary.

Applying this methodology to the regulation of genome edited crops and products derived from them as they are discussed in the subsequent country reports, certain approaches and concepts can be identified as emerging best practices that could over time evolve into evidence-based, or empirically-established, best practices.

1.3.1 Voluntary Early Consultation Procedure

A voluntary early consultation procedure presents a plant breeder with the opportunity to ask the competent administrative authority for an early decision on the regulatory classification of a prospective new plant variety, i.e. whether it would constitute a GMO pursuant to the respective legal framework.

[16]Overman and Boyd (1994), p. 69.

[17]Bardach and Patashnik (2016), p. 125.

[18]For an overview see Hamburger (2018).

Such an early consultation on the regulatory classification of a genome edited plant or plant variety, which is in its design phase, enables the developer to decide on the breeding technique to be applied in the coming breeding process. Should the originally envisaged breeding technique lead to the classification of the plant or plant variety as a GMO, the developer might change to another breeding method to ensure the desired non-GMO status.

An early consultation procedure does not only improve legal certainty, but also reduces the economic risks which are associated with a costly GMO approval procedure. At the same time, this facilitates research and development since a developer can assess relatively early, whether a designed plant or plant variety is likely to be profitable.

While such a procedure ensures transparency, legal certainty and a timely administrative decision, it is also in line with safety interests. Due to the early involvement of the authorities, they can discourage the developer from pursuing the breeding of high-risk varieties or steer them into the direction of less risk-prone genetic alterations. That way, risks can be mitigated before they even materialize.

Decisive for the effectiveness of such an early consultation procedure is, on the one hand, a specified and rather short timeframe within which the competent authority has to arrive at a decision. Otherwise, a non-transparent and lengthy process would make such a procedure less attractive. On the other hand, it is important that the preliminary classification remains its validity if the marketable final plant or plant variety is congruent with the one that has been discussed during the early consultation process. This way it can be ensured that legal certainty continues beyond the early research and development phase.

An early consultation procedure can, however, not mitigate the problem that non-GMOs might remain unregulated even if the competent authority has identified potential risks of the novel plant or plant variety on health or the environment. This holds particularly true if the trigger of the regulatory framework for GMOs is the process, *i.e.* the breeding technique. In this case, the early consultation procedure would not be able to channel the plant or plant variety into the GMO framework. If no other risk assessment and risk management mechanisms are in place, the non-GM novel plant or plant variety could enter the market unregulated.

1.3.2 Single Point or Multiple Point of Entry

While the legal frameworks of Argentina, Japan and the EU use a single trigger for cultivation and marketing (i.e. a particular GMO definition), Australia, Canada and the USA use multiple triggers.[19]

[19]See Chap. 8, Table 8.5.

Different triggers within the same jurisdiction can lead to a situation where a plant variety is able to escape the strict GMO rules with regard to cultivation, but the distribution of its products are at the same time subject to them—or vice versa. This is especially apparent if GMO definitions trigger two different regulatory frameworks, e.g. for cultivation on the one side and foods on the other side, but these two definitions differ significantly from one another. In any case, jurisdictions applying multiple triggers for different regimes have a clear tendency to be fragmented and complex and may result in uncoordinated administrative procedures imposing undue burdens and most likely higher costs on the developer.

However, taking into account that Japan and the EU make use of a single point of entry regime, while the USA and Canada use different triggers, it becomes clear that a single point of entry is not in itself an indicator for a more permissive or flexible regulatory framework. This is the case, because a single-point of entry can be used to cover as wide a spectrum of GM varieties and uses as possible. This may be done in order to apply the same burdensome risk assessment and risk management tools to all covered new plants or plant varieties, independent of different risk levels. However, it may also be an unintended consequence since a single trigger does not allow for a higher degree in specificity.

Consequently, a multiple point of entry regime can make up for its disadvantages by its more specific, even-handed and less restrictive nature. That way only those plant varieties can be targeted which the regulator deems necessary with respect to a certain use (e.g. environmental release, food or feed).

If a single or a multiple point of entry approach qualifies as best practice, depends, therefore, on the concrete design in the individual case.

1.3.3 One-Door-One-Key Principle

The one-door-one-key principle describes a regulatory approach that requires only a single application to obtain both the approval for cultivation and the authorization of marketing for consumption as or in food and feed.

As a result, only one approval procedure has to be completed and the synergy effects usually save time and therefore financial resources. A further advantage of having both approvals at the same time is that the liability risk for unintentional presence of GM material, which is authorized for cultivation but not for consumption (or vice versa), can be minimized.[20] Furthermore, this approach creates legal certainty not just for the developer but also for the farmer who can be sure from the beginning that the harvest of the GM crops can be sold on the domestic market.

If, however, the procedure is designed in such a way that an approval is only issued when there are no objections to both cultivation and consumption, the risk

[20]Purnhagen and Wesseler (2016), p. 151.

that neither one is approved is elevated ("all or nothing approach").[21] Therefore, the one-door-one key principle should be implemented so that if only one envisaged usage cannot be approved the other one will still receive approval. Otherwise, it could be more attractive for developers to file two separate applications.

The one-door-one-key principle as described above is reflected, e.g., in the EU's GMO framework.[22] A more complete, but probably also more complex, variant of the one-door-one-key principle would be that the single application relates not only to the authorization of cultivation and consumption as or in food and feed but also, e.g., to plant variety registration.

1.3.4 Mandatory Upstream Procedure

For regulatory frameworks that make use of the dichotomy GMO and non-GMO, it is a common hurdle to establish a clear demarcation line between GMOs and non-GMOs with regard to NBTs. This issue can be tackled by designing the general regulatory scheme as a two-tiered one, which means that the application of the regulatory framework (e.g. for GMOs) is preceded by a classification procedure. Accordingly, the design of a new plant or plant variety is, at first, subject to a procedure that clarifies whether it is legally classified as a GMO. Depending on its outcome, e.g. if the plant or plant variety is classified as a GMO, the new plant or plant variety would be subject to the substantive and procedural requirements of the regulatory framework applicable to GMOs.

An upstream procedure to determine whether a new plant or plant variety falls within the scope of the GM regime has the advantage that the current regulatory framework can stay in place without any amendments. Since a change of an already existing legal regime is often a burdensome and lengthy political process, an upstream procedure is a comparably efficient way to ensure legal certainty regarding the classification of genome edited plants.

Furthermore, the well-established dichotomy of GMOs and non-GMOs can be maintained. Without recourse to an upstream procedure, it could become necessary to introduce a third category into the current framework to ensure its compatibility with genome edited crop varieties.

Another advantage of an obligatory upstream procedure is that the competent authorities are enabled to review all novel plants or plant varieties without exception no matter whether they will be classified later on as GMOs or non-GMOs. This way the frequently existing regulatory gap[23] caused by a tight regulation of GMOs on the one side and the lack of oversight with regard to non-GMOs one the other side can be

[21] Purnhagen and Wesseler (2016), p. 151.

[22] For a detailed illustration of that principle's application in the EU see van der Meulen and Yusuf (2014).

[23] For more on this issue see Voigt and Klima (2017), p. 335.

mitigated to a certain extent. However, an upstream procedure is only assisting in closing this regulatory gap if a risk assessment and risk management mechanisms for non-GMOs is in place.

1.3.5 Product-Based Approach

Compared to a process-based regime, a product-based approach, which takes into account only the traits of a new plant variety and does not consider the breeding technique used, has the advantage that it is more science-based. It is scientifically sound to assume that a risk potential is not inherent in genetic modification techniques as such but only linked to the traits of the resulting organisms in question.[24]

At the same time, therefore, it seems to be easier to ensure compatibility with international legal obligations stipulated, e.g., by WTO law or free trade agreements, since a product-based approach is more likely to avoid unjustifiable discrimination or unnecessary trade restrictions than a regulatory approach based on certain breeding techniques. This is because what may cause risks to human health and the environment are not breeding techniques as such but rather the resultant traits of the genetically altered organisms. Accordingly, it may be considered inconsistent to subject, e.g., herbicide tolerant plants or plant varieties to differently burdensome authorization procedures depending on the breeding technique used to provoke herbicide tolerance.

Additionally, a product-based approach has the advantage that it is not necessary to consider whether the criticized[25] dichotomy of GMO and non-GMO has to be supplemented by a third category.

This leads to a further benefit of a product-based regulatory regime: There is no regulatory gap between GMOs and non-GMOs. Since process-based GMO frameworks make a clear-cut differentiation between GMOs and non-GMOs not based on their actual risk potential but solely based on the breeding method used, the same risks arising from a particular trait may be treated differently in individual cases. Consequently, new plants or plant varieties are subject to either the strict GMO regulation or the far more permissive non-GMO regulation—but nothing in between. Even if a non-GMO plant variety poses a high risk potential, no stricter rules apply than for other conventionally bred crops. This results in a gap with regard to the risk assessment and the approval requirements between GMOs and non-GMOs including conventionally bred plants. A product-based approach, however, allows the approval requirements to be defined individually based on the specific product in question.

[24]Dederer (1998), pp. 32–49.

[25]Herring (2008), p. 459; Herring and Paarlberg (2016), p. 398.

Accordingly, a product-based approach is preferable only if it allows for a thoroughly tiered risk regulation. If all plants or plant varieties with novel traits are subjected to equally strict risk governance, this may lead to undesirable economic consequences in the case that, e.g., only the global players have the means and resources to cope with the onerous regulatory framework.

1.4 Conclusions

A comparison of the different national regimes' special features showed that there are indicators for emerging and promising best practices regarding the regulation of genome edited plant varieties.

However, it remains to be seen to what extent legislators are willing to adopt best practices. Since national legislators usually voice strong belief in the superiority of their own legal approach, a widespread dissemination of best practices must be viewed with scepticism. However, this view is often based not only on personal convictions but also on purely practical and political considerations. On the one hand, it is difficult for a legislator to acknowledge the inferiority of one's own concept. On the other hand, there is a strong incentive to promote its own regulatory regime, because the more countries that follow a similar approach, the easier it will be to trade products between these countries. Therefore, especially export-oriented countries have an interest to export not just their agricultural products but also their own regulatory approach to other countries to prevent trade barriers before they even arise.

This interest in establishing one's own approach as standard, however, can also promote the spread of best practices. Against this background, different national regulatory regimes are in a competitive relationship with each other. Therefore, it stands to reason that the regulatory approach will prevail, which suits the interest of the majority of parties best—i.e. which constitutes a best practice. Consequently, legislators, who are interested in disseminating their regulatory approach, are inclined to either adopt best practices or to make sure that the own approach constitutes a promising best practice.

With regard to the future, it can therefore be presumed that legislators might be more drawn towards best practices in an effort to prevail in this realm of regulatory competition and to shape an emerging international framework. If these or other best practices become widely accepted, the agricultural sector might move more closely towards a global regulatory standard.

In sum, based on the comparative analysis of the regulatory frameworks in Argentina, Australia, Canada, the EU, Japan and the US and the identification of possible best practices, our impression is that the purpose of a regulatory framework should be primarily aimed at preventing or, at least, minimizing risks to health and the environment. Such risks arise from plants and their traits. Of course, any such traits are gene-based. Accordingly, any genetic alteration may produce traits which cause the plant posing a risk to human health and the environment. However, it does

not logically follow that it is techniques of genetic alteration, *i.e.* breeding techniques, as such which are inherently risk-prone. In fact, "classic" GMOs, especially GM crops, have been cultivated and consumed as feed or in foods on a global scale without any hint to risks to human health and the environment. This is in line with the continuous results of safety research aimed especially at the identification of GMO specific health and environmental risks. Hence, novel combinations of genetic material as such, even if brought about by transgenesis, should no longer be considered as a relevant trigger for risk assessment and risk management and, therefore, not for risk regulation related to genetically altered plants.

A consistent regulatory approach, therefore, should be product-based, *i.e.* the risk regulation should be triggered by a plant's traits. The regulatory problem then is to define those traits which deserve a closer look by administrative authorities. We think that the product-based trigger should be the "novelty" of the trait. Hence, "novelty" would be the single point of entry into the regulatory framework. "Novelty", in turn, should be defined in terms of "familiarity". That means that, independent of the breeding technique, only plants with "unfamiliar" traits should be considered "novel" and, therefore, subjected to the regulatory framework. We are fully aware, of course, that the term "familiarity" is vague and needs further specification. Factors to be considered within the concept of "familiarity" could be the long history of the trait in the crop plant species, the long history of safe use and consumption of plants with the respective trait, the substantial equivalence of the composition of the plant etc.

From a procedural point of view, an obligatory upstream procedure should be the initial step channelling the respective plant into the relevant regulatory framework. This process can be further catalysed from the outset by a voluntary early consultation procedure. Within that framework the one-door-one-key principle should apply, which means, *e.g.*, that all relevant authorizations (*e.g.* for cultivation as wells use as or in food and feed) including variety registration are granted upon a single application.

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Chapter 2
Regulation of Genome Editing in Plant Biotechnology: Argentina

Agustina I. Whelan and Martin A. Lema

Abstract Argentina is a world leader in regards to regulation and adoption of GM crops. As a consequence, the regulatory aspects of gene editing applied to agriculture were considered proactively, and a simple but sound pioneer regulation was developed.

At present, the Argentine regulatory system is fully able to establish if a gene-edited crop should be classified (and handled) either as a GM crop or a conventional new variety. To this end, the concept of "novel combination of genetic material" derived from the Cartagena Protocol is of paramount importance.

After some pilot cases that have been handled under the new regulation, applicants appreciate the ease, speed and predictability of this regulation. Moreover, it has been considered by other countries in developing their own regulations, thus acting also as a harmonization factor for the safe and effective insertion of these technologies in the global market.

The information and views are those of the authors as individuals and experts in the field, and do not necessarily represent those of the organizations where they work.

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2.1 Introduction

Argentina belongs to a group of six countries which were the first in the world to simultaneously allow genetically modified (GM) crops to be marketed. This happened in 1996, and particularly in Argentina it began with the introduction of herbicide (glyphosate) tolerant soy. Ever since then, Argentina has increased its production of GM crops, and it is currently the third largest grower of biotech crops in the world, after the United States and Brazil. During the 2015–2016 season the country produced 13% of the world's total biotech crop harvest; this included soybeans (18.7 million planted hectares), corn (4.74 million hectares) and cotton (400,000 hectares).[1] Regarding the degree of adoption of GM varieties, in the case of soy and cotton GM seeds make up 99% of total trade with these crops; in the case of maize it is slightly lower, at 94%.[2]

From a world trade perspective, Argentina is currently the main world exporter of soya oil and meal, and the third exporter of soy grains; it is also the second main exporter of corn grain, according to INDEC[3] and COMTRADE.[4]

In total, Argentina has issued 48 commercial authorizations for GM crops (which in some cases include more than one event or stacked events),[5] and it displays the highest number of events approved in recent years.[6]

There are some studies available that estimate the productive, social and economic impacts derived from the introduction of GM crops.[7] One of them, which spans the first 20 years of commercialization, has estimated that the gross benefit derived exclusively from the introduction of genetic engineering (i.e. the difference between the actual economic figures and the estimated incomes of a modelled scenario without GM crops) was close to US$127 billion. This GDP surplus, according to the authors, might account for the creation of two million jobs during that period.[8]

The introduction of GM crops has contributed with the sustainability of agriculture in two ways. On one hand, through a reduction in the use of chemical insecticides, in the case of insect-resistant "BT" crops. On the other side, through the synergy between herbicide-resistant crops and no-till farming practices where the latter enables better conservation of soils, through reduced erosion and reduced oxidation of organic matter. Intensification of no-till, greatly facilitated by the use of GM crops, also reduces the emission of greenhouse gases from exposed (plough) soil organic matter and from fuel consumption of agricultural machinery, as well as

[1] ISAAA (2016).
[2] ASA (2018).
[3] INDEC (2018).
[4] COMTRADE (2018).
[5] MINAGRO (2018).
[6] ISAAA (2016).
[7] Barfoot and Brookes (2014).
[8] Trigo (2016).

improved carbon sequestration. Additionally, these practices also facilitate having multiple cropping in one season (e.g. second crop soybeans after wheat in the same growing season).[9]

In the last couple of years, Argentina has also allowed the market release of GM varieties with innovative traits (including cases of added value), and in different crops. This includes, for instance, high-oleic and drought-resistant soy, virus-resistant potato and safflower expressing bovine chymosin for the cheese-making industry.[10] However, these are very recent and (for commercial reasons) slow-paced innovations whose presence in the market is still negligible.

In regards to Gene Editing Techniques (GETs), although the regulators of a few other countries took earlier decisions on the regulatory standing of specific products, Argentina was the first in the world to incorporate specific provisions on its regulatory framework for dealing with products derived from New Breeding Techniques (NBTs) based on innovative biotechnology approaches. This was the outcome of a 3-year science-based policymaking work, which reviewed national and international legislation, the state of the art and parallel discussions overseas.[11]

2.2 The Regulatory Framework for Genetically Modified Organisms (GMOs): An Overview

2.2.1 Overview, Applicable Laws and Regulations

The Argentine GMO regulatory framework has been described *in extenso* elsewhere.[12] It is one of the pioneers in the world and the second-oldest in Latin America after the Mexican regulatory system. It has been active uninterruptedly since 1991, when the National Commission on Agricultural Biotechnology (CONABIA) was created.

Since its inception, applicable laws and implementing regulations have been updated frequently. At present, the activities involving GM crops are regulated in Argentina under several laws including the National Law 20.247 on Seeds and Phytogenetic creations,[13] the National Law 27.233 on Animal and Plant Health,[14] the National Law 22.520 on the Ministries of the Executive Branch (the latter, in turn, combined with its implementation Decrees 1940/2008 13/2015 and 32/2016).[15]

[9]Penna and Lema (2003).

[10]Bustamante (2018).

[11]Whelan and Lema (2015).

[12]Burachik (2012) and Burachik and Traynor (2002).

[13]INFOLEG (1973).

[14]INFOLEG (2015).

[15]INFOLEG (1992). Noteworthy, there is also a National Law 20.270 on the Promotion of the Development and Production of Modern Biotechnology—see INFOLEG (2007). However, it does