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Genetically Modified Crops, Agricultural Sustainability and National Opt-Outs – Enclosure as the Loophole?

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Abstract

EU Member States are faced with a quandary – after decades of demanding powers to choose whether to cultivate genetically modified (GM) crops or not, the EU has returned some limited but significant powers to them for the time since the area was regulated. A 2015 EU Directive permits Member States to ‘opt-out’ from GM cultivation, provided that they fulfil relevant criteria. Member States need to decide urgently and carefully whether and how to restrict GM crops, as the permeable nature of the environment facilitates the spread of GMOs once cultivated. A potential and significant consideration is agricultural sustainability (agri-sustainability). In principle GM crops could promote agri-sustainability, including through increasing agricultural biodiversity (agrobiodiversity) as they facilitate introducing new traits or species into an ecosystem. However, the nature of their modifications allows for the applicability of patenting law, which enables the legal ‘enclosure’ of the crops’ genetic make-up. This impacts negatively upon the long-term availability of plant genetic resources and agrobiodiversity, primarily as farmers and other breeders operate in a context where accidental cultivation of patented material can still attract liability. This article argues that legal enclosure could justify imposing restrictions on GM cultivation, in order to conserve agrobiodiversity as an exhaustible natural resource essential to agri-sustainability. To improve the likelihood of restrictions being upheld legally at both the EU and WTO level, such justifications must be distinguished clearly from any broader environmental concerns. This is as both the EU and WTO impose stringent restrictions where environmental objectives are raised.

Keywords: Agricultural sustainability; enclosure; genetically modified crops; opt-outs; exhaustible natural resources.

1. Introduction

This article investigates whether the impact of ‘legal enclosure’ of plant genetic resources on agri-sustainability can justify the imposition of restrictions on genetically modified (GM) crops at both the EU and WTO level. It does so in the context of a new EU ‘opt-out’ clause for Member States, which creates the possibility of objectively justifying restrictions on GM cultivation.

Agri-sustainability is not merely an ideal but a fundamental requirement if global food needs are to be met for current and future generations. Within the EU, the need for agri-sustainability can be found reflected in core Common Agricultural Policy reform documents,¹ the EU 2020 strategy² and the establishment of an European

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Innovation Partnership on ‘Agricultural Productivity and Sustainability’. It is linked inherently to objectives of food security and food sovereignty, with ‘sustainable intensification’ as the central tenet. Yet, we continue to see serious environmental degradation, biodiversity loss, crop disasters, famine and other key indicators that agri-sustainability is not common practice. Further, increased stressors will arise with climate change, as the environmental and climatic conditions change more rapidly than plants can adapt, which emphasizes the urgency of addressing agri-sustainability.

The issue of genetically modified (GM) crops arises within this context. As with plants that have been developed through more traditional breeding, these plants have the potential to impact significantly upon agri-sustainability and the related issues of food security and sovereignty – whether positively or negatively. However, the nature of their modifications (direct modification of the genome, including across species) brings with it further important scientific and legal considerations, including the potential for ‘enclosure’ of plant genetic material. Enclosure involves the corrralling of apparently public or common goods in order to transform them into private goods. Enclosure of genetic material is relevant not merely to debates regarding the rights of subsistence farmers/peasants, accumulation by corporations or indeed the theoretical elements of enclosure of a public good to create a private good. It also has knock-on effects on agri-sustainability and issues such as food security and food sovereignty, especially through impacting upon agricultural biodiversity (agrobiodiversity). This is as farmers and other breeders are restricted in their use of plant genetic resources in the short-term, with further long-term impacts on the existence of plant genetic resources also – most obviously, if farmers and breeders have a smaller pool from which to grow or breed crops, then this reduces the opportunity for genetic diversity to develop. However, there is also the risk of being held liable for accidental cultivation of patented traits. As the release of plant material cannot easily be undone and existing property rights are not lightly restricted, careful consideration of the desirability of such an occurrence is required in the first

9 See Section 3.
instance. Should enclosure of plant genetic material be facilitated to the extent currently possible?

Consideration of this issue in the EU context is increasingly relevant due to significant on-going changes within the EU GM cultivation regime. The overall EU GM cultivation regime is regulated by Directive 2001/18,\textsuperscript{10} which provides for a maximum harmonisation approach that facilitates EU level authorisation of the cultivation of new GM crops based on a risk assessment. Once authorised, in line with the free movement of goods within the EU, Member State may not hinder the circulation and cultivation of these crops except in accordance with EU law.\textsuperscript{11} However, in March 2015, Directive 2015/412/EU\textsuperscript{12} was adopted as a result of significant internal and external pressures.\textsuperscript{13} In an exceptional act of partial de-harmonisation, the Directive restores some unilateral powers to Member States to restrict the cultivation of individual GM crops (to ‘opt-out’) if they so wish. During the transitional period (April-October 2015) and future (re)authorisation periods, Member States can request a voluntary geographic restriction by the notifiers. However, any other restrictions must be objectively justified, as outlined in Section 4 below.\textsuperscript{14} In doing so, the Member States must still comply with EU law and they must also bear in mind obligations under international law.\textsuperscript{15} Consequently, Member States and regions are currently considering very carefully who should be responsible for Directive 2015/412,\textsuperscript{16} whether to implement it and, if so, how – with no quick-fix solution.

Indeed, whilst 19 of the 28 Member States availed of the opt-out clause during the transitional period between April and October 2015,\textsuperscript{17} the varying reasoning behind the decisions to avail or not of the clause highlights the challenge for its implementation.\textsuperscript{18} For some, this was merely a stopgap measure to provide time to


\textsuperscript{15} The WTO is of particular significance to the EU, as highlighted by the Biotech Dispute European Communities — Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R, [2006] 3 DSR 847 (EC Biotech); and Randour, Janssens and Delreux, op. cit. supra note13.

\textsuperscript{16} In particular, for some States such as Germany, Italy, Belgium and the UK, their federal make-up leads to a complicated internal multi-level division of powers that are relevant to the clause.

\textsuperscript{17} See http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en.htm.

\textsuperscript{18} In order to gain insight into the reasoning of such decisions, as well as into the potential future implementation of the clause, the author undertook empirical research with representatives of both the Member States and the Regions between May 2015 and July 2016. This encompassed: (a) oral and email interviews with representatives from 8 of the 19 Member States who availed of the opt-out clause (for some or all of the State), as well as with 1 representative from a Member State that declined to avail of the clause; (b) written communications with representatives of 3 Member States that did not
evaluate the situation further – at least two Member States had no specific objections to GM crops but wanted time to consider whether to facilitate GM crops or not and also wanted to avoid providing a precedent for allowing future GM crops.19 Other Member States and regions had a range of reasons for availing of the clause, including a ‘green image’, distrust of GM technology, public opinion, environmental concerns and concerns over the challenge to prevent the presence of GMOs in non-GM crops (admixture). 20 However, many of these Member States and regions remained uncertain as to how they would implement the Directive in the future and whether their concerns could translate into legal justifications upon which to found their restrictions. Even amongst those States who did not avail of the opt-out clause on this occasion were those who were still debating how to transpose and potentially implement the legislation, having not ruled out its application in the future. It is worth noting that the challenge for Member States to identify a relevant objective justification is increased as reliance on purely economic concerns is excluded and reliance on environmental concerns is heavily restricted due to the level of harmonisation of environmental protection. It is for this reason, along with the significance of agri-sustainability in its own right, that the focus herein is upon agri-sustainability rather than environmental sustainability.

We see therefore that the EU Member States are faced with new powers to restrict GM cultivation for the first time since the EU regulated the area – powers that are significant, uncertain and challenging. However, it is also important to note that the European Commission’s hope was that the powers would appease Member States sufficiently in order to facilitate the EU level authorisation of future GM crops that receive a positive risk assessment during the authorisation process. 21 Therefore, Member States may be faced repeatedly with the choice of whether to avail of the opt-out clause or not.

In light of concerns over food security and the urgency for EU Member States to determine how they will treat GM crops, this article considers the challenges that GM crops pose for agri-sustainability. Specifically, it argues that legal enclosure could have a profound negative impact upon agri-sustainability, which can justify EU Member States in imposing restrictions upon GM cultivation at both the EU and WTO levels. However, the States will need to maintain a clear focus on agri-sustainability rather than the closely related issue of environmental sustainability, as the EU and WTO legal frameworks impose further conditions where broader environmental concerns are raised.

avail of the clause; (c) oral and email interviews with representatives of 4 individual regions, one of whom is a representative of the GM-Free Regions Network; and (d) written questionnaires completed by representatives of regions in the GM-Free Regions Network (insufficient number to provide statistically significant date, but with some valuable qualitative material). There was some overlap within these, as 2 of the Member State representatives interviewed (a) were also simultaneously representatives of the regions (c). Representatives were those at the national or regional level with expertise and responsibilities in the area, e.g. Ministers, COREPER Ambassadors, and senior departmental members.

19 Empirical data gathered, ibid.
20 Empirical data gathered, ibid.
21 Randour, Janssens and Defreux, op. cit. supra note13.
In making these arguments, this article builds upon existing literature on legal enclosure\(^ {22}\) of plant genetic resources,\(^ {23}\) in order to consider both the attachment of the patent to the crop’s progeny and the multiple impacts upon agri-sustainability. Further, it builds upon initial forays by authors such as Weimer and Lee on the new EU opt-out clause,\(^ {24}\) by investigating in-depth the potential of agri-sustainability and its links with the concept of ‘exhaustible natural resources’ at the WTO level to justify national restrictions of GM crops. A significant issue at any stage, the context of the new opt-outs heightens the urgency of such an analysis for the Member States and broader society.

2. Agri-sustainability and genetic diversity

So what then does agri-sustainability involve? It essentially is the long game for agricultural production, which attempts to reconcile\(^ {25}\) the potentially competing goals of agricultural intensification\(^ {26}\) to meet increasing demands for global food production\(^ {27}\) with that of sustainability.\(^ {28}\) It recognises the need to adapt agricultural production to produce more food in an environmentally friendly and sustainable manner.\(^ {29}\) It includes consideration of how agriculture operates within an ecosystem\(^ {30}\) and very careful management of resources, e.g. water\(^ {31}\) and soil biodiversity.\(^ {32}\)

Of particular significance to us is the need for biodiversity\(^ {33}\) and, within that, genetic diversity.\(^ {34}\) This is fundamental to agri-sustainability,\(^ {35}\) and thereby food security and

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\(^{23}\) See references, supra note 7.


\(^{25}\) Brussaard et al, “Reconciling biodiversity conservation and food security: scientific challenges for a new agriculture”, 2:1 Current Opinion in Environmental Sustainability (2010), 34-42.


\(^{27}\) UN Food and Agriculture Organisation, How to feed the world in 2050, Rome, 12-13 October, 2009.


\(^{29}\) Royal Society, op. cit. supra note4.


\(^{32}\) Brussaard, de Ruiter and Brown, “Soil Biodiversity for Agricultural Sustainability”, 121:3 Agriculture, Ecosystems and Environment (2007), 233-244.


\(^{34}\) E.g. Article 2 of the Convention on Biological Diversity; and Moffet and Bregha, “The Role of Law in the Promotion of Sustainable Development” 6 J Envtl L & Prac (1996), 1, 5.

\(^{35}\) E.g. Frison, Cherfas and Hodgkin, “Agricultural Biodiversity is Essential for a Sustainable Improvement in Food and Nutrition Security” 3 Sustainability (2011), 238-253.
sovereignty. It helps reduce the potential for the collapse of entire agricultural systems for instance in the case of disease, drought or pest; genetic diversity may mean that some crop varieties are grown that provide lower yields or are not as popular with producers or consumers for some reason, but it also leads to risk diversification. Furthermore, it enables the development of further advantageous traits, which may then be protected and cultivated further, as reflected in the successful breeding of high yielding and nutritious crops throughout history and the gathering of plant genetic resources from other biospheres with extensive diversity (‘biopiracy’ and ‘bioprospecting’). In some instances, these resources may as of yet be entirely untapped or their specific significance unknown and therefore we may not actively be trying to protect them. Hence, Article 8 of the Convention on Biological Diversity imposes upon Contracting Parties the obligation to ‘[r]egulate or manage biological resources important for the conservation of biological diversity… with a view to ensuring their conservation and sustainable use.’

At first sight genetic diversity is assured, since plants by their very nature involve living organisms that propagate and lead to the dispersal of their genetic material. Indeed, genetic diversity can be enabled through a wide range of mechanisms, including natural mechanisms such as wind pollination, bee pollination or dispersal of genetic material by birds and animals. Daily agricultural practices, i.e. ‘on-farm’ activities can also play a significant role in developing genetic diversity and promoting agri-sustainability. For instance, this can be via seed-saving and exchange between farmers leading to the gradual alteration of the plants’ genetic make-up, or indeed the introduction of entirely new crops or varieties into a different locale. Further, intentional breeding or genetic modification can lead to the development of new varieties or traits, based on a varied genetic make-up. Consequently, the development and maintenance of genetic diversity appears to be promoted by both nature and humankind.

However, the promotion of genetic diversity is not as certain as it might appear. Whilst development of new plant genetic resources continues, much of the existing diversity is disappearing. In particular, one of the challenges posed by our society is

the industrialisation of agriculture and the push towards monoculture approaches.\textsuperscript{43} This is due to a range of factors, including environmental stresses, control of seed banks and supplies by large corporations,\textsuperscript{44} the reduced role of on-farm development and the desire to cultivate ‘improved’ crops or only the most competitive varieties available. Indeed, whilst genetic diversity as a whole may not have undergone a substantial reduction, bearing in mind the creation of gene banks,\textsuperscript{45} genetic diversity within individual crops grown in individual countries has decreased dramatically and there is far greater reliance upon released varieties.\textsuperscript{46} For instance, a Rural Advancement Fund International study on diversity in the United States discovered that there has been a loss of 86.2\% and 87.7\% of apple and pear varieties between 1804 and 1904.\textsuperscript{47} On the vegetable front, the study concluded that there has been a loss of at least 80\% for 72 of 75 vegetable varieties in the United States between 1903 and 1983.\textsuperscript{48} However, erosion extends beyond the United States and other developed countries. An FAO Report in 2010 stated in relation to wheat cultivation globally that ‘[t]he instances of absence of genetic erosion or lack of vulnerability are rare.’\textsuperscript{49} Even allowing for potential errors in calculating erosion, this is a worrying situation for society.

Consequently, if we are to analyse GM crops in light of agri-sustainability, then we must necessarily consider their impact upon biodiversity and specifically upon genetic diversity – this is not merely their impact upon the existence of diversity in principle but the presence in situ and ‘access to a wide range of genetic diversity’\textsuperscript{50} (emphasis added) currently and in the future that are essential to agri-sustainability. Whilst intentional breeding and modification play an important role in the development of new varieties and traits, the role of on-farm practices and development should not be underestimated or ignored. ‘Breeder concentration’ and the reduction of seed-saving

\textsuperscript{45} FAO Second Report on the ‘State of the world’s plant genetic resources for food and agriculture’ Rome, 26 October 2010, 17.
\textsuperscript{48} Fowler and Mooney, \textit{ibid}, 63-7.
\textsuperscript{49} FAO op. cit. \textit{supra} note 45, 312.
\textsuperscript{50} Visser and Louwaars, ‘The contribution of plant genetic resources to food security’ in Rayfuse and Weisfelt (eds.), \textit{The Challenge of Food Security}, (Edward Elgar, 2012), 114.
and exchange can pose serious threats to agrobiodiversity and thereby agri-sustainability.\footnote{51}

3. \textbf{Relationship of GM Crops with Agri-sustainability}

There is as yet no clear evidence as to whether GM crops and biotechnology impact positively or negatively upon agrobiodiversity and agri-sustainability.\footnote{52} The crucial thing from the perspective of agri-sustainability is not to reject options, including GM crops, from ideological bases,\footnote{53} but instead to consider the very practical impact upon sustainability due for instance to the nature of the crops, the surrounding practices and the legal rules that apply.

GM crops involve the amendment of the genome within the crop based on scientific research, typically in order to develop a new advantageous trait. This can even involve introducing materials from other species. Thereby they automatically would increase the potential for diversity, similarly to traditional forms of breeding and seed-exchange. Furthermore, the modification could enable crops to be grown in different locations, e.g. to be drought-resistant.\footnote{54} Alternatively the modification could be such as to reduce the need for intensification, e.g. through increasing the yield or nutritional quality of the crop,\footnote{55} or to reduce the need for chemicals, e.g. through making a crop pest or disease resistant.\footnote{56} Consequently, GM crops have the potential to impact positively upon agri-sustainability through a range of mechanisms.\footnote{57}

However, GM crops also have the potential to pose threats to the environment and agri-sustainability, e.g. through the possibility for outcrossing of these advantageous traits to wild relatives leading to ‘superweeds’, encouraging heavy-handed spraying of pesticides where for instance the crops are ‘Roundup Ready’, or encouraging further intensification and monocultures in order to gain a temporary advantage.\footnote{58} The area is further complicated by the surrounding scientific uncertainty and hence the precautionary principle is applied.\footnote{59}

\footnote{51} Heinemann \textit{et al}, \op.cit. supra note46, 71-4 and 78-82.
\footnote{53} Pretty \textit{et al}, “Resource-Conserving Agriculture Increases Yields in Developing Countries”, 40:4 Environmental Science and Technology (2006), 1114.
\footnote{57} Hauptli \textit{et al}, \op.cit. supra note30.
Consequently, individual GM crops can impact both positively and negatively upon agricultural production and the environment, and thereby agri-sustainability. However, it is the use of and control over GM crops as a whole that currently poses the greatest threat to agrobiodiversity and thereby agri-sustainability. This is through the potential for those developing GM crops to ‘enclose’ plant genetic material and thereby transform something that might be considered a public good into a private good, facilitating the exclusion of others. Whilst other plant genetic resources will continue to exist and develop independently, enclosure can spread via a range of mechanisms and typically will attach to crops with advantageous (and competitive) traits.

**Imprinting enclosure on seeds**

Seed companies and plant breeders are understandably protective of varieties and advantageous characteristics that they have developed through the considerable investment of resources. Bearing in mind the context of our market economy and the goal of wealth maximisation for companies, it is also hardly surprising that the companies attempt to control the supply and demand of plants, seeds and plant genetic material. Two specific mechanisms that companies avail of in order to protect their investments and gain control are biological confinement (bioconfinement) mechanisms and techno-legal mechanisms – enabling varying enclosure of plant genetic material.

Bioconfinement mechanisms involve adapting the plant’s genome in order to restrict the spread of genetic material and therefore would impact negatively on biodiversity. Existing practices include hybridisation where any progeny do not replicate the advantageous traits of the original generation, thereby encouraging repeat purchases of the seeds/plants. A more modern and absolute form of bioconfinement is that of ‘Genetic Use Restriction Technologies’ (GURT). GURT, also known as ‘traitor’ and ‘terminator technologies’, involves the adaptation of the genome to restrict the manifestation or dispersal of an organism’s traits, including through plant sterility. Unlike with legal mechanisms, if GURT is effective then the control is absolute and for instance breeders would be unable to avail of the genetic material to develop new plants. If it is partially ineffective, then sterility could spread to non-target organisms via outcrossing. In either situation, the actual genetic diversity present would be reduced. However, such is the controversy surrounding GURT that an international de facto moratorium on the use of terminator seeds has been in place since 2000.
The companies are not left powerless however, as the law provides them with ample tools. Common legal mechanisms in this area include contracts and technology user agreements between the supplier and the farmer. These can encompass obligations to purchase other products from the supplier, not to save or exchange seeds, and so forth, thereby increasing the control over the farmer and indirectly the market. However, the main legal mechanisms of relevance to us are sourced in intellectual property (IP) law and specifically patents.

Intellectual property rights (IPRs) permit the holder to exclude others from use of their IP in accordance with the relevant law and vary considerably depending on the IP tool in question. The aim is twofold and based in the recognition of the value of the products and the role of the individual/company in developing this product. Therefore IPRs aim to protect the investments of the individual/company who provided the resources (time, effort and money), thereby encouraging further beneficial activities including research and innovation. The fear is that without such protection, society would stagnate – IPRs provide an incentive to innovate.

Consequently, although controversial due to claiming ownership over living material and excluding others from benefiting from what could be considered a public good or part of the ‘common heritage of mankind’, international law provides for legal protection over living organisms, e.g. Article 16 of the Convention on Biological Diversity, the International Union for the Protection of New Varieties of Plants (UPOV) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). The challenge then becomes to determine where the balance should lie between competing ownership claims. Whilst State and local community claims are relevant, frequently the focus is upon the initial breeder, any secondary breeders and farmers. In contrast with the International Treaty on Plant Genetic Resources for Food and Agriculture (Seeds Treaty), this balance tends to weigh in favour of the initial breeder, whose IPRs are being protected, although some flexibility does exist to alter that balance.

In particular, TRIPS recognises the possibility of ownership claims over innovations in plants in the form of patents. Patents generally involve very strong controls that attach to inventions and exclude other parties from using these inventions other than with the consent of the patent holder for the duration of the patent. Applied to plants,
this includes (commercial or non-commercial) planting, saving, exchanging and re-planting seeds of patented plants/plants containing the patented trait, as exemplified by cases such as *Bowman v Monsanto* and *Schmeiser v Monsanto*. A patent holder can charge a fee for such use, impose other conditions or refuse use – if an individual infringes the patent, they can be made pay damages (including all profits accrued through use of the product) or even hand over/destroy the relevant product. Therefore, where a patent is available, it can provide seed companies with extensive powers. However, TRIPS provides the Contracting Parties with considerable flexibility in their approach to patenting over living organisms and therefore much will depend on the approach taken nationally in implementing TRIPS.

For instance, the United States of America permit both plant patents (asexually propagated plants) and utility patents (sexually propagated plants). In contrast the EU’s approach is seemingly less favourable to the patent holder: whilst the EU Biotech Directive and European Patent Convention permit patents that focus on the genetic modification itself within the seed or plant, it excludes plant varieties. Nonetheless, the EU regime still provides considerable powers to the patent holder and can endanger agrobiodiversity through its impact on other breeders and farmers.

Firstly, in contrast with plant variety protection (PVP) where secondary breeders automatically have the right under EU law to develop further varieties without any fee applying, secondary breeders are faced with further costs where they wish to avail of patented organisms and for less reward. Secondary breeders may apply for a contractual licence or avail of Article 12 of the Biotech Directive to demand a compulsory licence in order develop new strains where criteria are met. However, as part of this, secondary breeders must pay a suitable royalty and agree to a cross-licence for the patent holder. Essentially, it can become increasingly costly to engage in breeding, to the point that only large corporate entities may have the necessary resources to do so and still protect their interests.

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*73 Bowman v Monsanto, Supreme Court of the United States, No. 11-796, 13 May 2013, [http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf](http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf).*

*74 Monsanto Canada Inc v Schmeiser, [2004] 1 SCR 902.*

*75 E.g. Article 30 of TRIPS.*


*78 Article 52 of the Convention on the Grant of European Patents (European Patent Convention).*


*80 Article 4.1 of the Biotech Directive; and Article 53(b) of the European Patent Convention.*

*81 This is a form of intellectual property right that applies to plant varieties, i.e. groups of plants ‘within a single botanical taxon of the lowest known rank’ that share the same characteristics ‘from a given genotype or combination of genotypes’ (uniform), are distinct from other groups and are stable: Article 5(2), Council Regulation (EC) No2100/94 on Community plant variety rights, [1994] OJ L227/1.*

*82 Article 15, Regulation 2100/94 ibid.*

*83 E.g. Blakeney, op. cit. supra note42, 15.*
Secondly, farmers who purchase the patented seeds/plants are also restricted in their actions. The *de facto* position under TRIPS and the EU Biotech Directive is that farmers may not impinge upon patent rights. Nonetheless, under Article 11 of the Biotech Directive a limited exemption does exist for farmers to save patented seed for their own use. Via Article 14 of the EU Regulation on Plant Variety Rights, small farmers of specific crops may save seed freely for their own use and other farmers may save seed upon paying an ‘equitable’ fee that is lower than the commercial rate. However, whether under TRIPS or under the EU Biotech Directive, no farmers may exchange patented seeds/plants with others.

The accumulation of these factors has the potential to have a significant impact upon diversity. From a positive perspective, patent holders and potential future patent holders are strongly protected and may be encouraged to engage in further research, leading to further genetic diversity. Similarly, some on-farm diversity may develop, due to seed-saving and licenced breeding. However, access to the diversity is limited to those who are willing to purchase the patented seeds/crops in the first instance. Further, the financial benefits for others to save or breed patented seeds decrease with the need to pay fees and also royalties in the latter case. The exclusion of seed-exchange also decreases the attractiveness of even seed-saving and reduces the dispersal of genetic material. Consequently, overall the on-farm diversity and especially the access to genetic diversity is likely to decrease.

However, a third factor exacerbates the impact of patenting on agri-sustainability. Third party farmers may end up cultivating the original patented crops or the progeny containing the patented traits, without intentionally purchasing and sowing patented seeds. Once released into the environment, the spread of the protected genetic material is highly likely to occur beyond the initial seed/plant and indeed beyond the intended area – especially without the availability of effective bioconfinement mechanisms. It is difficult, if not impossible, and costly to undertake to avoid admixture or to remove plants that demonstrate a patented trait – a trait that may also only manifest after considerable time and investment of resources. Yet the patent still applies equally to relevant crops grown by third party farmers.

Within the EU, the focus of the patent on the genetically modified trait within the plant enables the patent protection to attach to the plant’s progeny also that retain the patented trait, even where the progeny are not identical or even substantially similar. Whilst such inherited IPRs may make little difference to a farmer who has purchased the original seed or plant (as already affected by the relevant legislation and technology use agreements), this can have profound impacts upon other farmers and the diversity of seed supply. As intention is irrelevant to whether there is patent infringement or not, a third party farmer can save and exchange seed in good faith but may then find out that they are liable and any infringement may lead to being sued for

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86 Article 8 of the EU Biotech Directive. A comparable approach is taken in both the United States (*Bowman*) and Canada (*Schmeiser*).
damages or the uprooting of crops. Further, even in the EU where the Biotech Directive provides for slightly greater flexibility regarding patents over seeds, the exemptions available to farmers who purchased the initial patented seeds/plants do not appear to cover third parties. Unadjusted, patenting in the context of admixture can be especially severe on third party farmers.

The danger is that farmers face substantial economic risks if they undertake normal farming practices and thereby breach a patent, even unknowingly. They might therefore alter their behaviour and no longer save or exchange seed, even though their own current crops are not patented. Thus, where patents and PVP apply in the United States, practices of seed-saving and exchange are prohibited and have predominately died out. These same farmers might even go so far as to purchase the patented seeds, as they still face the costs of repeat purchases but without the benefit of the ‘improved’ crops – furthering a monoculture approach. The result is profound for agri-sustainability: not only is access to the existing diversity controlled, but the opportunities for further development of diversity on-farm are reduced.

**Overall GM challenges for Agri-sustainability**

Consequently, the primary challenge for agri-sustainability posed by GM crops as a whole is situated in the legal constructs, rather than in their make-up. Although IPRs can encourage and facilitate research by protecting its economic viability, which can clearly increase seed diversity and supply, the capture of IP law undermines genetic diversity. The difficulty arises from a generic patenting system that does not take into account the nature of living organisms in the environment, traditional farming practices, the challenges for both traditional and modern breeding, and the urgent need for agrobiodiversity. Seed-saving and exchange, research by secondary breeders and actual access to the genetic diversity are simultaneously hindered. Considering the availability of alternatives to patenting, e.g. through sui generis systems, open source supplies, promoting on-farm diversity/breeding and public research, it is questionable whether the application of patenting as it currently operates is justified.

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87 Patent holders may decide not to enforce such a right, as Monsanto promised in America where the infringement was unintentional and under 1%: Organic Seed Growers and Trade Association et al. v Monsanto, Supreme Court of the United States, No.13-303, 13 January 2014, http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/12-1298.Opinion.6-6-2013.1.PDF. Nonetheless, this does not provide protection where farmers are aware of the possibility of admixture or where it goes above 1%.

88 Lee and Burrell, op. cit. supra note7, 524-5.

89 Lee and Burrell, op. cit. supra note7, 519-523. It is of course arguable that all farmers should have to pay a nominal fee to companies for any financial benefit that they accrue relative to what they might otherwise have obtained.

90 Heinemann et al, op. cit. supra note46, 82.


93 Article 27(3) TRIPS.


95 Heinemann et al, op. cit. supra note46, 84.

96 Heinemann et al, op. cit. supra note46, 84-5.

97 Heinemann et al, op. cit. supra note46, 74 et seq.
However, this is the approach that exists at the EU level and, in light of the on-going controversy and debates surrounding GM crops, it is unlikely that any significant legislative changes will be developed in the near future due to the level of political agreement required amongst the Member States to amend the EU regime.\textsuperscript{98} Indeed, the recent European Patent Office decisions strengthen the EU’s patenting regime over living organisms.\textsuperscript{99} The question thereby arises as to whether States are able to respond unilaterally to these challenges in order to protect agri-sustainability.\textsuperscript{100} Specifically, in light of the limited scope of the existing mechanisms, can the new Directive 2015/412 facilitate such action by the EU Member States? In this respect, the very potential for enclosure of the plants’ genetic material via patenting may be its own downfall, as pushing the balance too far in favour of the large seed companies and private ownership.


The EU GM regime is highly harmonised, with limited flexibility for Member States to make unilateral policy decisions. The general stance towards GM crops (authorise if safe) is pre-determined at the EU level and the authorisation process itself is typically undertaken and concluded at the EU level. Member States are predominately left to implement and enforce the regime, rather than with core policy-making powers,\textsuperscript{101} and must not create obstacles to the free movement of authorised crops except in accordance with EU law. However, three limited mechanisms exist that might enable Member States to restrict or prohibit GM crops where necessary to protect and promote agri-sustainability, with the key one being that of Article 26b of Directive 2001/18 as inserted by Directive 2015/412. It is worth noting briefly that, prior to April 2015, the two main mechanisms enabling unilateral Member State action were safeguard clauses and the coexistence clause.

Safeguard clauses enable Member States to act swiftly, unilaterally and provisionally in order to protect against environmental or health risks. The main relevant safeguard clauses are found within Article 23 of Directive 2001/18, Article 34 of Regulation 1829/2003\textsuperscript{102} and Article 114(5) TFEU. If interpreted broadly, these could easily facilitate restrictions related to agri-sustainability, as genetic diversity in agriculture also promotes a range of habitats for wildlife, broader biodiversity and environmental sustainability. However, these are narrow in scope and have been interpreted and controlled restrictively by the Commission and the European Court of Justice,\textsuperscript{103} to the point that they are of limited application and of little help regarding the issue of agri-sustainability. Crucially, all three would require new scientific evidence of a risk to the environment posed by the GM crop, rather than for instance a reassessment of

\textsuperscript{98} Lee and Burrell, op. cit. supra note7, 525. For instance, the introduction of Article 26b was first proposed officially by the European Commission in 2010, went through intensive negotiations and took until 2015 to come to fruition.

\textsuperscript{99} See the “Tomato II” and “Broccoli II” decisions, op. cit. supra note79.

\textsuperscript{100} It should be noted that unilateral national action could impact on the level of EU agreement also, by paving the way for other Member States to follow.

\textsuperscript{101} Lee, “The Ambiguity of Multi-Level Governance and (De-)Harmonisation in EU Environmental Law”, 15 CYELS (2012), 357; and Dobbs, op. cit. supra note14.

\textsuperscript{102} Regulation 1829/2003/EC on genetically modified food and feed, O.J. 2003, L 268/1.

\textsuperscript{103} E.g. Joined Cases C-58/10 to C-68/10 Monsanto SAS and Others v Ministre de l’Agriculture et de la Peche, [2011] ECR I-7763; Weimer, op. cit. supra note24; and Dobbs op. cit. supra note14, 15-17.
existing evidence despite the applicability of the precautionary principle. This is due to the level of harmonisation of the area, with the CJEU recently stating that in light of the EU legislation’s objective of ‘avoiding artificial disparities in the treatment of a serious risk, the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the European Union Courts.’ Whilst discussing sister legislation to Directive 2001/18, the same logic would be greatly applicable.

The coexistence clause (Article 26a of Directive 2001/18) enables Member States to develop ex ante or ex post measures to protect farmers that would be affected detrimentally by admixture of GM and non-GM crops occurring. Such measures are important, but they are of limited use to States in this context due to their inherent focus on managing admixture and favouring of one agri-type over the other. They could encompass measures to minimise the chances of admixture, thereby preventing the spread of patenting controls. Alternatively the measures could aim to impose the financial and legal responsibility of any admixture on GM farmers and potentially even on the seed companies. However, either scenario is not wholly favourable to the development of genetic diversity. Where ex ante measures aim to prevent admixture of neighbouring crops via outcrossing, this undermines the development of on-farm diversity. Where admixture occurs but ex post measures are present, this still does not prevent seed companies enforcing their IPRs and demanding the uprooting of any crops containing patented genes. Further, in light of the insulation that seed companies grant themselves through their user agreements, the financial risks and costs will lie on whichever farmer is responsible for preventing admixture and they may find the costs too burdensome and decide not to cultivate their crops at all. The other main challenge is that the measures are tied to the economic impact upon farmers and it is doubtful that an outright prohibition based on Article 26a would be justifiable beyond the EU.

This brings us to the new possibilities for unilateral action by Member States based on Article 26b of Directive 2001/18. Article 26b provides Member States with two options, enabling them to demand a geographical restriction (via the Commission) from the notifier of the request for authorisation of the GM crop during the (re-)authorisation process and/or unilaterally impose such a geographical restriction at any time. For the first time since the EU commenced regulating GM cultivation, Member States have a real possibility of ‘opting-out’. However, the basis for any restrictions must be carefully considered and supported.

The first option under Article 26b appears the easy option for Member States, as all that is required of the Member States is a simple request. However, it is a weak instrument, as this request must be communicated via the Commission within a

106 E.g. supra note67.
108 If the notifier does not refuse the demand, then the (re-)authorisation application will automatically be adjusted to reflect the restriction.
relatively brief time period and success depends upon the notifiers’ consent. The notifiers acceded to all relevant requests by 19 of the 28 Member States during the transitional period, but notifiers may refuse such requests in the future. Consequently, although the first option is something simple and useful for Member States wishing to restrict GM cultivation, they will still need to consider whether they wish to avail of the second option and, if so, how. Further, a developed framework or policy for implementing the second option could also strengthen any requests under the first option – if States have clearly expressed that they will use the second option and have well-formulated grounds for doing so, why would notifiers fight the inevitable?

The second option poses a greater challenge for Member States initially – any unilateral measures must aim to fulfil a legitimate objective in a proportionate and non-discriminatory manner. Article 26b(3) only outlines six independent objectives alongside a supporting seventh objective of public policy, but significantly this is a non-exhaustive list. Consequently, flexibility exists if Member States can demonstrate the relevance of a legitimate objective generally and in particular for that Member State. However, the question remains as to whether the provision is sufficiently flexible to encompass measures targeted at protecting and promoting agri-sustainability.

Focussing on those objectives already listed within Article 26b(3), two require brief mention as potentially viable mechanisms. The first is prevention of admixture, which clearly aims to supplement Article 26a coexistence measures noted above. It is similarly of import, but does not fully support agri-sustainability. The second is public morality and provides a possibility for some unilateral action. However, the State must demonstrate that the measures are actually necessary due to public mores, which has proven challenging in the past – what evidence can establish this as fact? Further, national policy may be inconsistent and undermine any claims of necessity, e.g. if the State does not always seek to prohibit all GM crops or if they treat similar crops differently, e.g. upgraded crops or indeed other crops subject to patents.

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110 It in principle would also be open to the notifiers and Member States to engage in negotiations, e.g. for notifiers to agree to a limited geographical restriction in return for a vote in favour of authorisation. This raises important questions over whether such negotiations are appropriate, e.g. Greenpeace, ‘EU Parliament to adopt new GM crop national opt-out law’, 12 January 2015, available at: http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2015/GMOs%20briefing%2012012015%20%20FINAL.pdf; and Achterberg, “How to establish GMO cultivation bans”, Greenpeace presentation at GMO-Free Europe Conference 2015, Berlin, 7th May 2015, slides available at: http://www.gmo-free-regions.org/fileadmin/files/gmo-free-europe/How_to_establish_GMO_cultivation_bans_by_Franziska_Achterberg.pdf. However, the process does not automatically facilitate this and indications suggest that the Member States will not engage in such negotiations. Of all the Member States and regional representatives spoken to in undertaking this research (n18), one indicated the possibility of negotiating with the notifiers but concluded that it was not something that would happen in practice.
112 On a practical note, to establish the sincerity and relevance of their arguments, Member States will need to be consistent at both EU and WTO levels – which limits the range of justifications available.
115 Dobbs, op. cit. supra note107, 355.
in this context. This could become more challenging in the future if an EU proposal to permit restrictions on GM food and feed\textsuperscript{116} is adopted and the Member State in question does not avail of it – whilst distinct policies can legitimately exist, as related to another form of GMO, it would indicate an apparently arbitrary approach that would need to be satisfactorily explained.\textsuperscript{117}

However, the main focus here is on the possibility of availing of a combination of listed Article 26b(3) grounds relating to agricultural and environmental policy objectives, alongside land use and socio-economic impacts. These grounds are closely intertwined with the issues of agri-sustainability and agrobiodiversity. Further, the list in Article 26b(3) is non-exhaustive. Consequently, Article 26b(3) would seem to encompass these issues readily enough. This is also supported by the EU’s recognition of the significance of agri-sustainability and agrobiodiversity, as noted above.\textsuperscript{118} However, the provision may still raise further challenges, as it expressly limits the potential for States to rely on environmental policy objectives.

As mentioned, the EU GM regime is highly harmonised and environmental issues are meant to be raised and dealt with during the authorisation process, including through attaching authorisation conditions. Although it is arguable that there should be greater powers at the national and regional levels regarding environmental and health risks,\textsuperscript{119} this is currently not the case. Whilst Article 26b(3) provides some flexibility in this regard, any measures relating to ‘environmental policy objectives’ must not conflict with the environmental risk assessment carried out in accordance with the EU legislation. Considering that the environmental risk assessment is a fundamental step in the EU authorisation of any GM crops, this might appear like a significant stumbling block.

However, the key point to make is that the focus of such measures is on agri-sustainability and agrobiodiversity, rather than on environmental risks or concerns directly. The concerns in question relate to agriculture and broader societal issues of food security, food sovereignty and agri-sustainability. Whilst these link in to environmental considerations, they are not subsumed by them and remain distinct. Thereby, even if environmental policy objectives are effectively excluded, this does not prevent a Member State relying upon the remaining listed objectives (and other relevant objectives) to promote agri-sustainability and agrobiodiversity. Provided that the Member States can demonstrate that the issue is important to their own State and that the measures are necessary to attain their legitimate objectives, without acting in an arbitrary or discriminatory manner, it would appear that they could take such measures in compliance with EU law.

\textsuperscript{116} Proposal for a Regulation of the European Parliament and the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory COM/2015/0177 final - 2015/0093 (COD). This can be seen as the logical next step following on from Directive 2015/412, since these are also GM and also are a controversial and political topic. However, different issues and objectives arise that will make its progression uncertain and varied.


\textsuperscript{118} Supra note1-3.

\textsuperscript{119} Lee, op cit. supra note111, 230-1, 234 and 236; and Dobbs, op. cit. supra note14, Section 4.1.
Whilst it could be argued that strict coexistence measures preventing admixture under either Article 26a or 26b would suffice and therefore be more proportionate than an outright prohibition, and such logic might follow for protecting the economic interests of non-GM farmers initially, this does not work from the perspective of agri-sustainability. The prohibition of such crops contrasts with admixture controls in two key ways. It not only encourages those who have chosen to cultivate patented seeds to choose from other seeds with lesser legal protection, breaking the patent cycle, but also enables other third parties to grow crops and save seeds as they can cross-pollinate from their neighbours’ crops without concern over legal obligations being imposed upon them unilaterally. Consequently, it would seem feasible that the Member States could avail of Article 26b to prohibit unilaterally the cultivation of GM crops within their territories on the basis that they contain plant material subject to patents. However, EU law is not the end of the story and Member States will have to consider other commitments and specifically WTO law.

5. Compliance with WTO Law

As highlighted by the Biotech Dispute, WTO law is of great significance to the EU and indirectly therefore to the Member States. Non-EU Contracting Parties can challenge measures by the EU and its Member States, encompassing both Article 26b and the national measures permitted by it, before the WTO dispute bodies. Furthermore, interested third parties similarly may be able to challenge these measures in other fora via agreements such as the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union. Even if the challenge relates to Article 26b and the EU Commission’s approach to enforcing it, this could have a knock-on effect upon the Member States’ use of the provision. Consequently, it is a sensible position for the Member States (and others thinking of acting similarly) to ensure that their measures comply with WTO law if feasible.

However, Member States may be able to avail of Article 26b whilst avoiding WTO law entirely. WTO law is aimed at State action, where the State action imposes an obligation or detrimental effect upon a third party. Although the first option under Article 26b does involve a ‘demand’ by the Member States, the notifiers may refuse any requested geographical restriction without obvious legal consequence. Consequently, if notifiers agree to self-impose geographical limitations, as was done for the transitional measures in 2015, this should technically avoid WTO law.

Problems for the Member States arise where the notifiers do not simply agree to the demand and there is no guarantee that they will do so each and every time in the future – especially if the Member States overall do not take a stance more favourable to them regarding EU authorisations or national safeguard measures. Three resulting scenarios where there is ‘sufficient governmental involvement’ could trigger WTO law: firstly, if the notifiers do not respond to the request, as this automatically leads to a geographical restriction of the authorisation application; secondly, if Member

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120 Supra note15.
122 Dobbs, op. cit. supra note14, 264.
States were to negotiate with the notifiers regarding the scope of the restrictions under the first option; and thirdly, if Member States move to the second option and impose unilateral restrictions/prohibitions. In each of these, significant governmental involvement would be triggering the restriction. Whilst representatives of several Member States and regions have indicated that they will not enter negotiations with the notifiers, 
notifiers may not respond and Member States currently are attempting to formulate clear plans for implementing the second option as noted above. Consequently, it is of fundamental importance for the Member States and the EU as a whole to consider in what circumstances restrictions or prohibitions in part(s) or the entirety of a State may be justified.

Where States impose a *de jure* or *de facto* prohibition of patentable crops or crops subject to similar IP protection, and therefore currently GM crops, this will be deemed a quantitative restriction which is prohibited under Article XI of the General Agreement on Trade Tariffs (GATT). Such quantitative restrictions can only be justified where the measures correspond to an exhaustive list of relatively narrow objectives in Article XX of GATT and comply with the chapeau requirements. Of greatest relevance to the issue of agri-sustainability and patenting of GM crops is Article XX(g) on exhaustible natural resources (ENRs).

Article XX(g) permits quantitative restrictions where they relate to the conservation of ENRs. The first challenge is to establish that plant genetic material and diversity is an ENR and thereby falls within the scope of Article XX(g). This appears a simple task in light of the discussion of agri-sustainability and genetic diversity loss, but much depends on the provision’s interpretation.

The concept of ENRs within Article XX(g) has gone through a number of transformations since it was initially introduced. However, there remains no clear definition or set of parameters delineating what may fall within or outside the scope of this concept. The Dispute Panel has even stated that it considers it unnecessary to establish the ‘precise meaning or scope’ of ENRs. Consequently, a case-by-case approach applies and will continue for the foreseeable future. Nonetheless, some guidance is available.

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124 *Supra* note110.
125 General Agreement on Tariffs and Trade, 1867 UNTS 187.
126 Technically, States could argue that their measures are justified under Article XX(a) on public morality (Dobbs, op. cit. *supra* note107, 360.), but this will pose similar challenges as at the EU level and specifically the issue must be relevant to that State’s mores. Alternatively, States could attempt to rely upon Article XX(b) on the environment if consistent with the arguments proffered at the EU level. Whilst this could be tied in to the arguments on agri-sustainability, via consideration of biodiversity and the ecosystem more generally, this would entail further complications as it would lead to the application of the Phyto-Sanitary (SPS) Agreement, 1867 UNTS 493, and the need for a risk assessment: Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures – A Commentary* (CUP, 2013) 610-4.
A narrow interpretation was clearly feasible, e.g. through focussing upon the resources’ economic value, but a broader approach was taken to encompass ecological value also. Significantly, it was also arguable that ENRs were limited to non-renewable resources, such as oil, in light of the use of the term ‘exhaustible’ and the drafters’ original intentions, as was contended in US – Gasoline, and also in US – Shrimp. In US – Gasoline, the Panel side-stepped the issue by considering that clean air had a value and could be depleted and that any measures designed to prevent or minimise the depletion of clean air related to the conservation of natural resources and fell within the scope of Article XX(g).

In US – Shrimp, the Appellate Body concluded that ENRs were not limited to non-renewable resources as the concept was not static but evolutionary. It could thereby embrace both living and non-living organisms. In order to determine whether something fell within the scope, the Body considered that it was necessary to read the provision in light of the ‘contemporary concerns… about the protection and conservation of the environment’, including sustainable development. Thereby, the WTO Agreement’s preamble could act as an interpretative tool, by adding ‘colour, texture and shading’, as could other international documents such as CITES.

Part of the reasoning for the evolutionary approach and flexible interpretation of ENRs is the ever-changing situation regarding the environment and organisms – something whose existence is not threatened today may be endangered tomorrow and vice versa. Just because something is ‘renewable’ does not mean it is impervious to exhaustion, as confirmed by ‘modern biological sciences’. Although criticism exists regarding the expansive interpretation, it helps counter any potential preference towards free trade when balancing it with global environmental concerns.

135 WT/DS58/AB/R, [128].
136 [6.37].
137 [130].
138 [130].
139 [129].
140 [152-3].
141 [153] and [155].
143 US – Shrimp, [128].
The WTO’s evolutionary approach and indications that renewable, living organisms, including turtles, fish stocks and dolphins, can be ENRs, provides significant flexibility. It seems feasible that plant material and genetic diversity could similarly fall within the scope of Article XX(g). Indeed, Bentley has argued that non-GM varieties could be considered as ENRs. However, is plant material and specifically plant genetic diversity truly ‘exhaustible’?

In US – Shrimp, the presence of turtles in the list of endangered species in CITES was noted as a significant factor. Yet, plant genetic diversity is clearly still capable of depletion and can become endangered. As noted above, significant genetic diversity loss has already occurred and is likely to continue unless conservation measures are taken. Hence, it has been argued that land produce (amongst other things) are ‘[l]imited and exhaustible natural resources’ which ‘should be considered as a patrimony or capital and not as goods’. Irrespective of whether plant genetic material and diversity is labelled officially as ‘endangered’ or ‘exhaustible’, it is clear that this significant resource is being threatened by both our practices and legal systems, and therefore should fall within the scope of Article XX(g). Indeed, the Appellate Body in US – Shrimp had already effectively concluded that the turtles were exhaustible and merely availed of CITES to support their position, i.e. their endangered status under CITES was not the decisive factor in and of itself.

Provided that plant genetic material and/or the diversity thereof is an ENR, the States must then demonstrate that the measures relate to the conservation of these resources. Unlike with other headings under Article XX there is no requirement of being ‘necessary’. This leads to a more flexible criterion, potentially ‘because any measure that limits the depletion of a natural resource is justified per se.’ Provided that the measures are ‘reasonably related’ to conservation of ENRs and such a relationship is a ‘close and real one’, this will suffice. Furthermore, in contrast with Article XI:2(a), the focus is conservation and not just limited to where there are critical shortages. Thus, seemingly any measures that aim directly or indirectly at conserving natural resources fall within the provision’s scope.

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147 Ghori op. cit. supra note128, 23-4.

148 Bentley, “A re-assessment of Article XX, paragraphs (b) and (g) of GATT 1994 in the light of growing consumer and environmental concern about biotechnology”, 24:1 Fordham International Law Journal (2000), 107.

149 Bentley ibid, 126-7.

150 US – Shrimp, [132]; and Stuart op. cit. supra note142, 401-3.


152 US – Shrimp, [125].


155 Bentley op. cit. supra note148, at 112.


158 [7.250].
However, the measures must still comply with Article XX’s chapeau,\textsuperscript{159} which seeks to protect other States’ rights and helps avoid misuse or abuse of the justifications.\textsuperscript{160} The chapeau requires that any measures must not be ‘applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries’ or ‘a disguised restriction on international trade’.\textsuperscript{161} Consequently, if countries with the same conditions are treated differently, if there is no real possibility for monitoring and evaluating the appropriateness of the application of the measures to individual countries or if the measures are rigid and inflexible irrespective of the circumstances, then this may amount to unjustifiable discrimination.\textsuperscript{162} Similarly, a lack of adequate due process, e.g. a lack of transparency and procedural fairness in the administration of the measure, may amount to arbitrary discrimination.\textsuperscript{163}

This chapeau has teeth and is not merely a symbolic consideration. Thus, the initial American measures in \textit{US – Shrimp} were found to be discriminatory under the chapeau and not justified, even though the measures fell within the expansive interpretation of Article XX(g). The USA subsequently adjusted their regime and their later measures were challenged and upheld as compliant with the chapeau.\textsuperscript{164}

Bentley has considered that, whilst non-GM crops may be an ENR, the cultivation of new GM crops is much like the introduction of any other new plant into the environment – there is no justification for special treatment.\textsuperscript{165} However, the argument here is not focussing upon the genetic modification \textit{per se}, but the subsequent legal consequences in particular. It is to justify measures restricting the cultivation of crops subject to patenting or other similar IP protection. Provided that States applied an equivalent approach to crops subject to similar protection, then such measures would not be obviously arbitrarily discriminatory.

However, the successful application of Article XX does not negate the application of other international law. The obvious other sources are TRIPS and UPOV, which are at the heart of enclosure. Whilst a thorough investigation of compliance with these agreements is beyond the scope of this article, it is worth noting that Article 27(3) of TRIPS does not actually require patents for plants. It permits States to exclude patenting for plants and ‘essentially biological processes’, other than microorganisms and ‘non-biological and microbiological processes’. Protection for plant \textit{varieties} is required, but this can be via an effective \textit{sui generis} system. Consequently, a \textit{sui generis} system with low-level protection for breeders/inventors as undertaken in India and the Philippines,\textsuperscript{166} alongside patenting for microorganisms (not incorporated within a plant) and the relevant processes would seem to suffice from the perspective

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\textsuperscript{159} van den Bossche, op. cit. \textit{supra} note127, at 614-623. The chapeau is the over-arching, introductory paragraph that applies to the entire Article.
\textsuperscript{160} \textit{US – Shrimp}, [157] and [159].
\textsuperscript{161} Telesetsky, op. cit. \textit{supra} note146, at 645-7.
\textsuperscript{162} \textit{US – Shrimp}, [150] and [165].
\textsuperscript{163} \textit{US – Shrimp}, [164].
\textsuperscript{165} Bentley, op. cit. \textit{supra} note148, at 126-7.
\end{flushleft}
of international obligations. Where these are present, a prohibition on plant patents and on patents on microorganisms within plants would seem to comply with Article 27(3) TRIPS.

6. Conclusion

GM crops are not inherently ‘evil’ or threatening to agri-sustainability. They have the potential to provide significant advantages regarding agri-sustainability, e.g. through facilitating cultivation in otherwise inhospitable locations, through reducing the need for pesticides and through increasing genetic diversity. However, they do simultaneously pose our society with numerous challenges and dilemmas, not least because of the potential for enclosure.

Whilst patented crops are only subject to limited cultivation in the EU currently, the patenting system and the experiences in the United States hint at the potential consequences for agri-sustainability if they take hold. Through IP law, corporations are able to effect the legal enclosure of seeds, making seed-saving, seed exchange and secondary breeding more challenging. Legal enclosure thereby can impact negatively on the practical, day-to-day biodiversity – which is already affected by changing farming practices and the rise of monocultures. Thus, the spread of patented seeds threatens agri-sustainability, as well as food security and sovereignty, even whilst potentially improving individual crop yields or quality.

Enclosure’s impact on agri-sustainability therefore both demands and justifies legal action to control the use of GM crops – not because they are GM per se, but because of the associated attributes. The potential threats to agriculture and society necessitate a contestation of legal enclosure of seeds as a whole and not merely over individual ownership claims. This might be through considering the development of specific sui generis systems, open source systems or even publicly funded resources. However, Member States are limited in their ability to make significant changes to the European or global approach to IPRs regarding plants in the immediate future and, whilst the WTO facilitates a spectrum of approaches by Contracting Parties in implementing TRIPS and UPOV, its default is nonetheless a neoliberal approach with the balance in favour of the IPR holder. Similarly, whilst the EU has adopted some limited protection for farmers and other breeders, indicating an element of paternalism, it nonetheless retains the neoliberal theme. Member States can however take some limited action within their own territories.

Article 26b of Directive 2001/18 provides the Member States with a mechanism to counteract this threat to agri-sustainability, through focussing on grounds such as those relating to agricultural policy objectives. They could prohibit the cultivation of GM and other crops subject to patenting or other similarly restrictive IPRs on the basis of protecting agri-sustainability. Furthermore, such measures could simultaneously be justified under Article XX(g) by focussing on the nature of genetic material and specifically genetic diversity as an ENR. There is no guarantee that these justifications will be accepted at the EU or WTO levels, but there are strong arguments to support such an approach.

167 This is of particular interest considering the EU’s somewhat more precautionary, paternalistic approach to risk regulation in relation to authorisation of GM crops.
A final reflection seems warranted. Restricting GM cultivation is not a panacea for ensuring agri-sustainability – indeed, if society can re-take control and adapt the way in which GM crops are governed, they may play a positive role instead. However, GM crops highlight the broader significance of protecting agri-sustainability, developing resilience and attempting to counter monocultures at all levels. A more holistic and purposive approach is required, which considers whether we need to undertake a fundamental overhaul of our governance of food production to ensure sustainability and how this might be achieved.