Essays

Genetically modified organisms and sustainable development: regulatory approaches, access to resources and traceability

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GENETICALLY MODIFIED ORGANISMS AND SUSTAINABLE DEVELOPMENT: REGULATORY APPROACHES, ACCESS TO RESOURCES AND TRACEABILITY

ABSTRACT: The regulation of GMOs lies within the framework of a multiplicity of principles and interests at stake ranging from food security to the fight against hunger and malnutrition, to healthy food, sustainable development, biodiversity and food sovereignty. From a comparative perspective, a circulation of legal models, in particular the European one based on the precautionary principle, is inserted in the context of the existing legal pluralism. However, this phenomenon raises questions, on the one hand, with respect to the dynamics of international trade with more permissive legal systems such as the United States, on the other, with regard to the limited effectiveness of the application of this model in some systems such as the Chinese one. As regards the recognition of intellectual property rights, the case of foods obtained from CRISPR shows the difference in regulatory approaches also with respect to patentability on both sides of the Atlantic. Lasty, with regard to ensuring the transparency and traceability of GMO products, the new option of "techno-regulation" is emerging through technologies based on distributed registers such as the blockchain.

KEYWORDS: OGM; sustainable development; CRISPR; biotechnology; patentability

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1. Introduction. Genetically modified organisms and sustainable development

The most advanced genetic engineering[1] goes far beyond the possibility of modifying natural genomes[2] to insert characters of greater resistance, longevity or adaptability to the environment, giving rise to genetically modified organisms, so-called GMOs[3].

Genetically modified crops and foods, in particular, prefigure interesting prospects for social and economic evolution, with a view to providing a solution to the problems of hunger and malnutrition.

However, such biotechnological innovations pose relevant issues, especially from the point of view of sustainable development[4] and comparative law. This is particularly relevant for developing countries, with regard to the impact of GMOs on the biodiversity of the ecosystem and on the survival of local production and small farmers[5].

In light of the rapid evolution of the sector, therefore, scholars are called to deal with issues of considerable importance, regarding access to basic inputs such as seeds and the limits to their use, the diffusion of technologies and biotechnological products, food safety, transparency and consumer information, *etc.*[6].

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[1] Expression used to indicate the modifications artificially introduced into the genetic information of a cell by inserting other genetic information into it. In this regard, see: INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY, *entry "gene manipulation"*, 2017, which defines the genetic manipulation such as the use of in vitro techniques to produce DNA molecules containing new combinations of genes or altered sequences, and the insertion of these into vectors that can be used for their incorporation into host organisms or cells in which they are capable to continue the propagation of the modified genes; L. YOUNT, *Biotechnology and Genetic Engineering*, New York, 2008 (3rd edition); D.S.T. NICHOLL, *An Introduction to Genetic Engineering*, Cambridge, 2008 (3rd edition); J.D. WATSON, *Recombinant DNA: Genes and Genomes: A Short Course*, San Francisco, 2007; S. SMILEY, *Genetic Modification: Study Guide (Exploring the Issues)*, Cambridge, 2005.

[2] The genome is the totality of the DNA of a biological organism; see: INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY, *entry "genome"*, cit.

[3] The World Health Organization defines genetically modified foods as those derived from organisms whose DNA has been modified in a way that does not occur naturally (WHO, *Food, Genetically Modified*, http://www.who.int/topics/food_genetically_modified/en).

[4] The 2030 Agenda for Sustainable Development, adopted by the United Nations in 2015, provides a shared blueprint for peace and prosperity for people and the planet. At its heart are 17 Sustainable Development Goals, which are an urgent call for action by all developed and developing countries in a global partnership. They recognize that ending poverty and other deprivations must go hand-in-hand with strategies that improve health and education, reduce inequality, and spur economic growth; all while tackling climate change and working to preserve our oceans and forests. Regarding the relation between the 2030 UN Agenda and issues related to genetic modification, see among others: G. RAGONE, *The GMO authorization procedure in EU: inclusivity, access to justice and participation in decision-making*, in *Diritto Pubblico Europeo Rassegna Online*, 2, 2019, 206 ff, http://www.serena.unina.it/index.php/dperonline/article/view/6532. On the relation between the Sustainable Development Goals and the European Union regulation, see e.g.: A. RENDA, *How can Sustainable Development Goals be 'mainstreamed' in the EU's Better Regulation Agenda?*, Ceps Policy Insights, 12, 2017, 1 ff, https://bit.ly/2NcQA35.

[5] See, among others: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, in *TLI Think!*, Paper 83/2017, 2 ff, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3049616.

[6] In this regard, see among others: F. CAPRA, U. MATTEI, *The Ecology of Law. Toward a Legal System in Tune with Nature and Community*, Oakland, 2015; A. STAZI, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, Cheltenham, 2015; R. BIN, N. LUCCHI, S. LORENZON (eds.), *Biotech Innovations and*

In this scenario, the main issues, made more complex by the transnational dimension that characterizes agricultural markets and GMO products, are to establish a) forms and limits of the freedom of access and commercial exploitation of crops or genetically modified products, and b) effective rules for the protection of the healthiness of food and the guarantee of transparency for consumers[7].

2. Opportunities, risks and regulatory options

According to the most recent data, in the world there are 815 million people suffering from chronic hunger and 52 million children suffering from acute malnutrition[8].

A decade after the devastating global food crisis of 2007-2008, which triggered food riots in several countries and clearly demonstrated the fragility and interconnection of today's global food production, food[9] insecurity continues to increase[10]. There are several factors that contribute to this, including armed conflicts, globalization and financialization of the food system, climate change, *etc.*[11].

In this context, the increasingly pressing question of how to feed the world fairly and sustainably has sparked lively debate and profound contestation[12]. In view of its increasingly evidently transnational dimensions, the concept of "food safety" emerged as the basis of the various food-related programs that have been introduced by various international organizations[13].

Fundamental Rights, Berlin, 2012; C. CASONATO (ed.), *Life, Technology and Law*, Padua, 2007; C.M. ROMEO CASABONA, *Los genes y sus leyes. El derecho ante el genome human*, Bilbao-Granada, 2002.

[7] See, among others: NATIONAL RESEARCH COUNCIL, *Global Challenges and Directions for Agricultural Biotechnology: Workshop Report*, Washington, https://www.ncbi.nlm.nih.gov/pubmed/25032331; R. PRASAD, *The Fertility Tourists*, in *The Guardian*, 30 July 2008, https://www.theguardian.com/lifeandstyle/2008/jul/30/familyandrelationships.healthandwellbeing. At present, in fact, mankind is facing the great challenges of an ever-growing world population and the growing threats associated with climate change. The world is expected to reach 9.8 billion people in 2050 and 11.2 billion people in 2100; see: UNITED NATIONS – DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS, *World Population Projected to Reach 9.8 Billion in 2050, and 11.2 billion in 2100*, UN Reports, 2017, https://bit.ly/2UYjM2c; PHYS, *UN warns of 'perfect storm' of hunger, climate change*, 2018, https://phys.org/news/2018-10-storm-hunger-climate.html.

[8] See, especially: FAO, *What We Do*, 2018, http://www.fao.org/about/what-we-do/en.

[9] In this regard, see: A. SHAH, *Global Food Crisis 2008*, in *Global Issues*, August 2008, https://bit.ly/30Y3JW0.

[10] See: FAO et al., *The State of Food Security and Nutrition in the World 2018: Building Resilience for Peace and Food Security*,. https://bit.ly/2AUzx3h.

[11] Indeed, climate change is rapidly becoming a problem of serious concern due to its global and complex nature and its devastating impact on food production, affecting the most vulnerable populations with the greatest severity.

[12] Thus: P.C. ZUMBANSEN, E. WEBSTER, *Introduction: Transnational Food (In) Security*, in *Transnational Legal Theory*, 9, 3-4, 2019, 175 ff (TLI Think! Paper 6/2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3247625.

[13] See, among others: UNITED NATIONS, *Transforming Our World: The 2030 Agenda for Sustainable Development*, A/RES/70/1, 2015, https://bit.ly/2Blm7NM; WORLD FOOD SUMMIT, *Rome Declaration and Plan of Action*, 1996; in doctrine: A. ORFORD, *Food Security, Free Trade, and the Battle for the State*, in *Journal of International Law and International Relations*, 11, 2, 2015, 1 ff; L. JAROSZ, *Comparing Food Security and Food Sovereignty Discourses, Dialogues in Human Geography*, 4, 2, 2014, 168 ff; R. RAYFUSE, N. WEISFELT (eds.), *The Challenge of Food Security: International Policy and Regulatory Frameworks*, Cheltenham, 2012; B. KARAPINAR, C. HÄBERLI (eds.), *Food Crises and the WTO*, Cambridge, 2010.

These efforts, for better or for worse, contributed to the spread of the notion that a market-based liberal approach to food security had to be based on the assumption that food insecurity exists because food production and distribution do not meet the needs of the world population[14].

Therefore, currently the dominant view seems to be that it is necessary to develop greater and better food production, and in particular access to food[15], through the use of existing technologies, liberalized trade and global finance[16].

This approach has been questioned by the emergence of the "food sovereignty" discourse, which is generally associated with social movements including in particular La Via Campesina[17], and collaborates with international institutions in order to promote broader considerations than the traditional interpretation of food security.

In particular, biodiversity, intergenerational equity, resistance and dismantling of the industrial domain of food production and trade, rights to decision-making regarding land use and food production, and notions of equality and development of the rights of the peasants, are increasingly taking hold in the debate on the matter[18].

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[14] See: P.C. Zumbansen, E. Webster, *Introduction: Transnational Food (In) Security*, cit., 1; C. Pearson, *A fresh look at the roots of food insecurity*, in R. Rayfuse, N. Weisfelt (eds.), *The Challenge of Food Security: International Policy and Regulatory Frameworks*, cit., 19 ff.

[15] See: FAO, *The State of Food Insecurity in the World 2001*, https://bit.ly/37IOWQr; J. Drèze, A. Sen, *Hunger and Public Action*, Oxford, 1989; A. Sen, *A Poverty and Famines: An Essay on Entitlement and Deprivation*, Oxford, 1981.

[16] In this sense, see: The World Bank, *Food Security*, 2018, https://www.worldbank.org/en/topics/food-security; United Nations – Conference for Trade and Development, *Trade and Environment Review 2013: Wake Up Before It Is Too Late*, https://unctad.org/en/publicationslibrary/ditcted2012d3_en.pdf; in doctrine: M.E. Margulis, *The World Trade Organization between law and politics: negotiating a solution for public stockholding for food security purposes*, in *Transnational Legal Theory*, 9, 3-4, 2019, 1 ff; A. Anyshchenko, *The Interaction Between Science, Policy and Law in the Field of Food Security: Can Biotechnology Contribute to Sustainable Agriculture?*, 2019, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3325406; E. Brodwin, *A controversial technology could save us from starvation – if we let it,* in *Business Insider*, April 2018, https://www.businessinsider.com/crispr-genetic-modification-agriculture-food-2018-4; K. Burnett, S. Murphy, *What place for international trade in food sovereignty ?*, in *The Journal of Peasant Studies*, 41, 6, 2014, 1065 ff; L. Jarosz, *Comparing Food Security and Food Sovereignty Discourses, Dialogues in Human Geography*, 4, 2, 2014, 168 ff; in a critical sense, see: J. Clapp, *Hunger and the global economy: strong linkages, weak action*, in *Journal of International Affairs*, 67, 2, 2014, 1 ff; J. Clapp, S. Murphy, *The G20 and Food Security: a Mismatch in Global Governance?*, in *Global Policy*, 4, 2, 2013, 129 ff.

[17] See: M. Edelman, S.M. Borras, *Political Dynamics of Transnational Agrarian Movements*, Nova Scotia, 2016; J. Brem-Wilson, *La Vía Campesina and the UN Committee on World Food Security: Affected publics and institutional dynamics in the nascent transnational public sphere*, in *Review of International Studies*, 43, 2, 2016, 302 ff; J. Wilson, *Global Food Security Governance: Civil Society Engagement in the Reformed Committee on World Food Security*, London, 2015; A.A. Desmarais, M.G. Riviera-Ferre, B. Gasco, *Building Alliances for Food Sovereignty: La Vía Campesina, NGOs, and Social Movements*, in D.H. Constance, M.C. Renard, M.G. Riviera-Ferre (eds.), *Research in Rural Sociology and Development*, 21, 2014, 92 ff; H. Wittman, *Food Sovereignty: A New Rights Framework for Food and Nature?,* in *Environment and Society: Advances in Research*, 2, 2011, 87 ff; H. Wittman, A.A. Desmarais, N. Wiebe, *The Origins & Potential of Food Sovereignty*, in Iidd. (eds), *Food Sovereignty: Reconnecting Food, Nature and Community*, Oakland, 2010, 1 ff.

[18] In this perspective, see: *Draft United Nations declaration on the rights of peasants and other people working in rural areas*, A/HRC/WG.5/15/3, 2018, available online at: https://www.ohchr.org/Documents/HRBodies/HRCouncil/WGPleasants/Session5/A_HRC_WG.15_5_3-_English.pdf; The Committee on World Food Security, *About*, 2017, http://www.fao.org/cfs/home/about/en; United Nations – Human Rights Office of the High

The movement for food sovereignty aims to bring together the people most affected by food insecurity in order to form and mobilize transnational networks that articulate new rights to food, biodiversity and food production through the struggles of farmers, peasants and indigenous peoples. This is achieved, for example, by identifying the negative effects of biofuels and monocultures for food production and the environment, and opposing the agri-food interests that dominate the global food supply chain[19]. These speeches have been crucial in drawing attention to the causes of food insecurity and possible solutions, albeit in widely divergent and contrasting ways.

On the other hand, several scholars recognize a movement within the literature far from the dichotomous understanding of food safety and food sovereignty and aim at a more nuanced understanding of the relationship between the two, which moves beyond the rigid tracks to examine more effectively the extent to which these two approaches collide, converge and configure each other[20].

In the light of the legal process[21], in fact, in recent years we have witnessed the evolution of a food governance system, which consists of a series of State and non-State actors, international organizations, supranational bodies and political and legal mechanisms. The institutional complexity of those agreements has led to the emergence of a multiplicity of regulatory models, geared towards, but not limited to, the emergence of complex global supply chains. Such phenomena have been described as

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COMMISSIONER FOR HUMAN RIGHTS, *The Right to Adequate Food*, Human Rights Fact Sheet No. 24, 2010, https://www.ohchr.org/documents/publications/factsheet34en.pdf; B. MONJANE, *The right to adequate food is the right to dignity and life*, in *La Via Campesina*, 2018, https://viacampesina.org/en/the-right-to-adequatefood-is-the-right-to-dignity-and-life. In doctrine: P. CLAEYS, *Human rights and the food sovereignty movement: reclaiming control*, London, 2015; R. PATEL, *Food Sovereignty*, in *The Journal of Peasant Studies*, 36, 3, 2009, 663 ff. The Nyéléni Declaration of 2007, signed by more than 500 representatives from over 80 countries, states that: «[f]ood sovereignty is the right of peoples to healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and their right to define their own food and agriculture systems» (https://nyeleni.org/IMG/pdf/DeclNyeleni-en.pdf; in doctrine, see: L. JAROSZ, *Comparing Food Security and Food Sovereignty Discourses,* cit., 170).

[19] In this regard, see: FIAN INTERNATIONAL, *Beyond Food Security, Towards Food Sovereignty*, 2016, https://www.fian.org/en/news/article/beyond_food_security_towards_food_sovereignty; LA VIA CAMPESINA, *Food Sovereignty*, 2003, https://viacampesina.org/en/food-sovereignty; in doctrine, see: P.C. ZUMBANSEN, E. WEBSTER, *Introduction: Transnational Food (In) Security*, cit., p. 6 f.; L. JAROSZ, *Comparing Food Security and Food Sovereignty Discourses,* cit., 168 ff.

[20] In this sense, see: C.M. SCHIAVONI, *The Contested Terrain of Food Sovereignty Construction: Toward a Historical, Relational and Interactive Approach*, in *The Journal of Peasant Studies*, 44, 1, 2016, 1 ff; J. CLAPP, *Food security and food sovereignty: Getting past the binary*, in *Dialogues in Human Geography*, 9, 2, 2014, 206 ff; B. AGARWAL, *Food sovereignty, food security and democratic choice: critical contradictions, difficult conciliations*, in *The Journal of Peasant Studies*, 41, 6, 2014, 1247 ff.

[21] With regard to the relevance of the analysis of the process of formation and application of the rules in comparative analysis, one may refer to: H.M. HART JR., A.M. SACKS, *The Legal Process. Basic Problems in the Making and Application of Law*, edited by WN ESKRIDGE JR., PP FRICKEY, New York, 1994; H.M. HART JR., H. WECHSLER, *The Federal Courts and the Federal System*, edited by RH FALLON JR. ET AL., New York, 2009, 6th ed.; E. RUBIN, *The New Legal Process, the Synthesis of Discourse, and the Microanalysis of Institutions*, in *Harvard Law Review*, 109, 1996, 1393 ff. For the application and relevance with respect to biotechnology, see also: A. STAZI, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., 263 ff.

a transition from the national government level to the international and from public to private governance[22].

At international level, this path has led in particular to the adoption of the Treaty on Plant Genetic Resources[23] and the Nagoya Protocol[24], both aimed at mitigating the tensions related to access to genetic resources and the fair sharing of the benefits deriving from their use, as well as most recently of the United Nations Declaration on the rights of farmers and other people working in rural areas[25].

The Treaty, adopted by FAO in 2001, is aimed at recognizing the contribution of farmers to the conservation of crops that feed the planet, establishing a global system that allows farmers and researchers to access plant genetic material easily and free of charge, and to ensure that the benefits of plant improvement or the use of biotechnology are shared with the countries of origin of the material.

The Protocol, adopted by the Conference of the Parties to the Convention on Biological Biodiversity in 2010, pursues the objective of equitable sharing of the benefits that derive from the use of genetic resources, including adequate access to genetic resources and the appropriate transfer of relevant technologies, taking into consideration all the rights regarding those resources and technologies and appropriate funds, and thus contributing to the conservation of biological diversity and the sustainable use of its components.

These instruments, however, do not appear so far to have fully produced the predetermined results, not only because of the non-accession of countries such as China and Russia and the United States and Japan respectively, but especially because they only provide a public law framework that defines a basic enforcement structure to ensure that access is subject to prior informed consent and that agreed contractual conditions are defined. On the other hand, the application of benefit-sharing commitments in contracts is left to suppliers and users, relying on private law mechanisms that are affected by the existing contractual imbalances[26].

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[22] In this regard, see: P.C. ZUMBANSEN, E. WEBSTER, *Introduction: Transnational Food (In) Security*, cit., 7 f.; T. HAVINGA, D. CASEY, F. VAN WAARDEN, *Changing Regulatory Arrangements in Food Governance, The Changing Landscape of Food Governance*, Chelthenam, 2015, 3.

[23] *International Treaty on Plant Genetic Resources and Agriculture*, adopted in Rome on 3 November 2001 by the thirty-first meeting of the FAO Conference (and signed by the European Union and most of its Member States).

[24] *Nagoya Protocol to the Convention on Biological Diversity on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization*, adopted by the Conference of the Parties to the Convention on Biological Diversity during its 10th meeting on 29 October 2010 in Nagoya, Japan (and signed by the European Union and most of its Member States on 23 June 2011).

[25] *United Nations Declaration on the Rights of Peasants and other People Working in Rural Areas*, A/C.3/73/L.30, October 2018, based on the approach according to which the sustainable development of rights must be of an ascending type, guided and articulated by the people concerned. UNDROP came after a seventeen-year process involving a large network of civil society actors around the world, including the transnational agrarian movement La Via Campesina (LA VIA CAMPESINA, *UN General Assembly adopts Peasant Rights declaration! Now focus is on its implementation*, 2018, https://viacampesina.org/en/finally-un-general-assembly-adopts-peasant-rights-declaration-now-focus-is-on-its-implementation). In doctrine, see: P.C. ZUMBANSEN, E. WEBSTER, *Introduction: Transnational Food (In) Security*, cit., 15; P. CLAEYS, *Human rights and the food sovereignty movement: reclaiming control*, cit.

[26] In this regard, see among others: J.H. REICHMAN, *Why the Nagoya Protocol to the Convention on Biological Diversity Matters to Science and Industry Everywhere*, in C. CORREA, X. SEUBA (eds), *Intellectual Property, Technology Transfer and Investment: Understanding the Interfaces and Development Impact*, Berlin, 2018, 295 ff.; H. GROSSE RUSE-KHAN, *The Private International Law of Access and Benefit-Sharing Contracts*, ivi, 315 ff.; D.F. ROBINSON

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Furthermore, the development of synthetic biology poses new challenges with respect to the framework set in such instruments, since the content of information and knowledge of the genetic material could be increasingly extracted, processed and exchanged in its own way, separate from the physical exchange of the plant genetic material[27].

In this scenario, the issue of the so-called GMOs – that is, as mentioned, organisms whose genetic material has been modified in an unnatural way[28] – is particularly relevant. The purpose of genetically modified organisms is to introduce new genetic traits to improve their usefulness and value[29]. The most common GMOs on the market today are genetically modified crops. One of the main reasons for the development of such crops is to improve their yield, through the introduction of genetic traits that allow greater resistance to plant diseases or tolerance to herbicides[30].

Although the marketing of genetically modified crops has grown exponentially over the years, it is still controversial whether the presence of these GMOs is completely safe and whether they should continue to grow[31]. On the one hand, these crops contribute to food safety, sustainability and climate change issues[32]. On the other hand, as noted by the World Health Organization, they give rise to the risks of the involuntary introduction of allergens into food, the transfer of antibiotic-resistant genes, and the migration of genes from genetically modified plants into conventional crops or related natural species[33].

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et al., *New Challenges for the Nagoya Protocol: Diverging Implementation Regimes for Access and Benefit-Sharing*, ivi, 377 ff.; D. Beldiman, *Commercialization of genetic resources: leveraging ex situ genetic resources to shape downstream IP protection*, in J. Rosén (ed.), *Intellectual Property at the Crossroads of Trade*, Cheltenham, 2012, 111 ff.; G. Ghidini, *Equitable sharing of benefits from biodiversity-based innovation: Some reflections under the shadow of a neem tree*, in K.E. Maskus, J.H. Reichman (eds.), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*, Cambridge, 2005, 695 ff.

[27] In this regard, see: E. Welch et al., *Potential Implications of New Synthetic Biology and Genomic Research Trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture*, in *Emory Legal Studies Research Paper*, 2017, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3173781; M.A. Bagley, *Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology*, in *Virginia Public Law and Legal Theory Research Paper*, 11, 2016, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2725986.

[28] See: K. Gostek, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, in *Michigan State International Law Review*, 24, 2016, 761 ff.; S. Shrestha, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 3 ff.; D.M. Strauss, *The international regulation of genetically modified organisms: importing caution into the US food supply*, in *Food and Drug Law Journal*, 61, 2, 2006, 167 ff.

[29] Thus: T. Phillips, *Genetically modified organisms (GMOs): Transgenic crops and recombinant DNA technology*, in *Nature Education*, 1, 1, 2008, 213 ff.

[30] In this regard, see again: WHO, *Food*, cit.

[31] See, among others: K. Gostek, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit., 763 ff.

[32] In this sense, it is reported that between 1996 and 2012, for example, the production and use of genetically modified crops compared to conventional crops allowed the saving of 497 million kg of active ingredients of pesticides and the reduction of CO2 emissions of 26.7 billion kg in 2012 alone, helping to alleviate poverty for about 16.5 million smallholder farmers; see: International Service for the Acquisition of Agri-Biotech Applications, *ISAAA Brief 46-2013: Top Ten Facts*, http://www.isaaa.org/resources/publications/briefs/46/topfacts/default.asp.

[33] WHO, *Frequently Asked Questions on Genetically Modified Foods*, http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modifiedfood/en.

The development of biotechnologies that allow intervention on crops and food and its economic and legal consequences, therefore, has given rise to a particularly heated debate, which sees on the one hand the supporters of their development in the name of the objective of food security necessary to meet the growing need for food, on the other hand those who repudiate the use of the same to protect the biodiversity, sovereignty, healthiness or integrity of food as appropriate[34].
From a legal point of view, these different visions have prompted legislators from all countries to confront the need to provide regulation to the phenomenon[35].

3. Food healthiness and labeling in comparative law

A first set of critical issues emerging from the debate on the development of GMOs, and in particular the use of transgenic plants and genetically modified foods, is linked to the fear that the effects of the changes introduced with DNA recombination have not been adequately assessed[36].
In this sense, the first question discussed by scholars concerns the promise that GMOs will allow an improvement in production. First of all, the use of genetically modified seeds does not appear to increase crop yield potential. Rather, these seeds help prevent crop losses from pests, thereby allowing crops to reach their yield potential.
Therefore, the profitability of genetically modified seeds largely depends on the value of the yield losses mitigated and the costs associated with pesticides and seeds[37]. The idea that the introduction of new, more nutritious foods will be able to reduce the problem of world food needs is still debated, especially compared to a constantly growing population[38].
Another issue concerns the argument that the use of genetically modified organisms has increased the presence of allergens in new products. With respect to this risk, many scholars emphasize the need to provide the consumer with adequate information tools, in particular through product labeling[39].

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[34] See, among others: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 3 ff.; K. KARIYAWASAM, *Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture*, in *Pacific Rim Law & Policy Journal*, 19, 3, 2010, 459 ff.; A. ANYSHCHENKO, *The Interaction Between Science, Policy and Law in the Field of Food Security: Can Biotechnology Contribute to Sustainable Agriculture?*, cit.

[35] See, for example: K. GOSTEK, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit., 761 ff.

[36] This, as mentioned above and highlighted below, regarding both the impact on the environment and biodiversity, and the risk to human health deriving from the introduction of new allergenic or toxic properties transmitted by genetically modified organisms.

[37] See: J. FERNANDEZ-CORNEJO et al., *Genetically Engineered Crops in the United States*, USDA Report No. 162, 2014, https://www.ers.usda.gov/webdocs/publications/45179/43668_err162.pdf?v=41690, 12 ff.

[38] See, among others: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 3 ff.; A. ANYSHCHENKO, *The Interaction Between Science, Policy and Law in the Field of Food Security: Can Biotechnology Contribute to Sustainable Agriculture?*, cit.; S.S. HUCHHANAVAR, *The Precautionary Principle in the International Environmental Law: Conflicting Dimensions in Economic Perspectives*, 2018, https://ssrn.com/abstract=2766819.

[39] On the subject, see: D.M. STRAUSS, *Genetically Modified Organisms in Food: Ethical Tensions and the Labeling Initiative*, in H.M. JAMES JR. (ed.), *Ethical Tensions from New Technology: The Case of Agricultural Biotechnology*, CABI Publishing Biotechnology Series, 2018, 83 ff.; X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, in *Food and Drug Law Journal*, 71, 1, 2016, 30 ff. On the genetic flow of

Another aspect is related to the hypotheses that, on the one hand, the genetic modifications made on GMOs could make certain organisms resistant to current antibiotics, on the other, the new antibiotics used as a result could make the organisms themselves immune from the bacteriological point of view, but at the same time dangerous for individuals who will come into contact with them[40].

Genetic engineering often uses genes for antibiotic resistance such as so-called "selectable markers". Early in the process, these markers help identify cells that have taken on foreign genes. Even if they have no further use, the aforementioned genes continue to be expressed in plant tissues and therefore in food. Consuming these foods could reduce the effectiveness of antibiotics in fighting disease. Additionally, resistance genes could be transferred to human or animal pathogens, making them resistant to antibiotics. If the transfer were to occur, it could further aggravate the health problem of antibiotic-resistant organisms[41].

In recent years, debates have arisen around the world on the risks associated with the cultivation and consumption of genetically modified food. The different positions on the topic have led to different regulatory frameworks in various countries, with respect to which unsuccessful attempts have been made to summarize internationally, which have so far been of little effectiveness[42].

The United States is the world's largest producer of genetically modified crops. Conversely, over the years many countries, especially within the European Union such as Switzerland, France, Austria and Italy, have banned the cultivation of genetically modified crops within their borders[43].

These different regulations regarding the testing and approval procedures for GMO foods or the incompatible regulations on labeling and identification requirements, give rise to global commercial problems, including between the United States and the European Union[44].

new allergens caused by the use of GMOs, see: G.N. MANDEL, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, in *William and Mary Law Review*, 45, 5, 2004, 2167 ff.

[40] In this regard, see: R. BRATSPIES, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, in *NYU Environmental Law Journal*, 10, 2002, 297 ff.

[41] In this sense, see: T.B. MEPHAM, *The role of food ethics in food policy*, in *Proceedings of the Nutrition Society*, 59, 4, 2000, 609 ff. With regard to the most recent developments and questions posed by human genomics, see also: A. STAZI, *Human genomics and surrogate motherhood: legal pluralism and the circulation of models*, in *Comparative Law Review*, 9, 2, 2018, 75 ff.

[42] See: M. BUIATTI, P. CHRISTOU, G. PASTORE, *The application of GMOs in agriculture and in food production for a better nutrition: two different scientific points of view*, in *Genes & Nutrition*, 8, 3, 2013, 255 ff. With regard to sources and bodies operating on the subject at international level, which go beyond the scope of this contribution, please refer to: K. GOSTEK, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit.,776 ff.; D.M. STRAUSS, *Genetically Modified Organisms in Food: Ethical Tensions and the Labeling Initiative*, cit., 85 ff.

[43] See again: K. GOSTEK, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit., 761 ff.

[44] In this regard, see: WTO, *DS291: European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm. On 13 May 2003, the United States requested consultations with the European Union regarding measures taken by the EU and its Member States affecting imports of agricultural and food imports from the United States. The United States asserted that the moratorium applied by the EU and some of its Member States since October 1998 on the approval of biotech products has restricted imports and marketing of agricultural and food products from the United States. In doctrine, see: Y. DEVOS et al., *Coexistence of genetically modified (GM) and*

From a comparative perspective, two macro-models can be distinguished, one based on the precautionary principle with respect to the use and consumption of GMOs, adopted in Europe, China, Japan and Africa, and another in which a general policy prevails, as primarily in the United States.
Another corollary traditionally considered for the distinction between these models is given by the awareness and relative concern of the consumer with respect to the consumption of these products. In this sense, Europe, China and Japan can be included in a first group[45], where the consumer has been interested for years in any risk profiles deriving from the consumption of these products. On the other hand, in the United States only since few years this type of considerations appears to have come to the attention of consumers[46].
Regulation of genetically modified crops started with similar approaches in both the United States and Europe, but the two models soon diverged. Between the sixties and eighties of the last century the regulation was considered more rigid in the United States than in Europe, but in the mid-eighties the European regulations on health, safety, and environmental risks became, and still are, more restrictive than overseas ones[47].

no-GM crops in the European Union. A review, in *Agronomy for Sustainable Development Journal*, 29, 1, 2009, 11 ff.; I.M. DEMENINA, G*enetically Modified Foods in the International Arena: Trade Conflicts, Labeling Controversy, and the Importance of Informed Consumer Choice*, in *Brigham Young University International Law & Management Review*, 2, 2, 2006, 311 ff.

[45] Regarding the labeling of GMO products, the regulatory approaches in China and Japan appear more similar to the European one and to the related precautionary principle, rather than to the US one with the relative liberal approach. See: X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, cit., 41 ff. On the other hand, if China and Japan require producers of genetically modified organisms to have similar transparency and traceability with respect to Europe, Chinese legislation, in some respects, appears to be stricter than European legislation. For example, consider that in the Chinese regulations the expected tolerance relating to the accidental presence in GMO-free products is 0%, while this threshold in Europe is 0.9%. These more stringent requirements, if on the one hand reflect the commitment of the Chinese legislator to achieve the best legislation for the labeling of genetically modified foods, on the other hand are, according to some scholars, an "empty promise", too strict rules for some aspects unattainable when compared with European ones. Furthermore, EU legislation defines the specific details of the labeling and traceability requirements and covers a wide range of products ranging from food to feed, while those required by Chinese legislation are still too vague and limited. Thus: Y. ZHUANG, W. YU, *Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European Union*, in *Vermont Journal of Environmental Law*, 14, 3, 2013, 465 ff.

[46] Therefore, part of the doctrine believes that the United States should reform its food labeling policy in order to increase trust and transparency within its market and with respect to international trade, given the large number of countries which have a more rigorous approach. See: D.M. STRAUSS, *Genetically Modified Organisms in Food: Ethical Tensions and the Labeling Initiative*, cit., 85 ff.; ID., *The international regulation of genetically modified organisms: importing caution into the US food supply*, cit., 191 ff.

[47] See: D. LYNCH, D. VOGEL, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, Council on Foreign Relations, 2001, http://www.cfr.org/agricultural-policy/regulation-gmoseurope-united-states-case-study-contemporary-european-regulatory-politics/p8688; R.E. LÖFSTEDT, D. VOGEL, *The Changing Character of Regulation: A Comparison of Europe and the United States*, in *Risk Analysis,* 21, 3, 2001, 399 ff.

ISSN 2284-4503

3.1. The regulation in the United States

The United States has gone from a highly politicized regulatory system in the framework of public distrust in government and skepticism about new science technologies to a more sectoral and product-oriented regulatory system in support of technological and scientific innovation. Conversely, Europe has gone from a light and cooperative regulatory model to a more horizontal and process-oriented one, based on a greater and deeper public intervention[48].

In the United States, after the first GMO patent was recognized in 1980 and in Diamond v. Chakrabarty case[49] the Supreme Court stated that genetically modified life forms could be patented[50], in 1982 the Food and Drug Administration approved the first genetically modified drug: biosynthetic human insulin produced by bacteria created through rDNA technology[51].

In 1989, the National Research Council published a GMO safety report in which it concluded that the product of genetic modification and selection should be the main target for making decisions, and not the process by which the products were obtained[52].

From there, in 1992 the FDA published a statement in which it clarified its interpretation of the Federal Food, Drug and Cosmetic Act[53] with respect to the use of biotechnology, arguing that genetically modified foods should not be subject to special rules just because food is genetically modified[54]. In addition, the FDA claimed that special labeling was not required for such foods, unless there was a "material" change from the natural ones[55]. Two years later, the first genetically modified product, known as the FLAVR SAVR tomato, was approved by the FDA and marketed[56].

[48] See: K. Gostek, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit., 765 ff.; J. Scholderer, *The GM Foods Debate in Europe: History, Regulatory Solutions, and Consumer Response Research*, in *Journal of Public Affairs*, 5, 3, 2005, 263 ff.

[49] *Diamond v. Chakrabarty*, 447 US 303, 303 (1980).

[50] For a reconstruction of the path of patentability from microorganisms to biotechnological innovations relating to the human being, one may refer to: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., 136 ff.

[51] In this regard, see: S. White Junod, *Celebrating a Milestone: FDA's Approval of First Genetically-Engineered Product*, FDA History Corner, 2007, https://www.fda.gov/media/110447/download.

[52] See: National Research Council, *Field Testing Genetically Modified Organisms: Framework for Decisions*, 1989, http://www.nap.edu/catalog/1431/field-testing-genetically-modified-organismsframework-for-decisions, especially 14.

[53] *Federal Food, Drug, and Cosmetic Act*, Public Law 75-717, 21 USC ch. 9 § 301 et seq., 25 June 1938.

[54] Thus: *Statement of Policy: Foods Derived From New Plant Varieties*, 57 Fed. Reg. 22984-01, 29 May 1992; in doctrine, see: N.A. Belson, *US Regulation of Agricultural Biotechnology: An Overview*, in *AgBioForum*, 3, 4, 2000, 268 ff.

[55] With regard to the debate on GMO labeling in the US, especially on the alleged incompatibility of this obligation with the First Amendment which protects free speech also in the form of commercial speech, see: G.A. Kimbrell, A.L. Paulsen, *The Constitutionality of State-Mandated Labeling for Genetically Engineered Foods: A Definitive Defense, in Vermont Law Review*, 39, 2, 2014, 341 ff.; J.H. Adler, *Compelled Commercial Speech and the Consumer "Right to Know"*, in *Arizona Law Review*, 58, 2, 2016, 421 ff.

[56] In this regard, see: G. Bruening, J.M. Lyons, *The Case of the FLAVR SAVR Tomato*, in *California Agriculture*, 54, 4, 2000, 6 ff.

In November 2015, the FDA published guidelines[57] in which it reiterated that special labeling was not required for foods derived from genetically modified plants. Therefore, in the United States the labeling of products with GMO labels or non-GMO labels has been voluntary and left to the manufacturer[58]. In addition to the interventions of the aforementioned regulatory bodies, however, there have recently been changes in the labeling of GMOs by both federal and state regulatory bodies, including the presentation of legislative proposals aimed at introducing the labeling obligation for genetically modified crops, including the one adopted in Vermont in 2014[59].

In 2016, the adoption of the National Bioengineered Food Disclosure Standard Law[60] banned individual States from adopting - and Vermont implementing - their own GMO labeling legislation. Although the labeling for "bioengineered" foods was provided to be mandatory, it was left to the producers to choose the method of affixing the packaging via "text, symbol or electronic or digital connection"[61].

According to specific rules, small food producers have been given the choice to comply by entering a phone number that provides access to additional information and a website with an indication of the genetically modified ingredients[62].

In December 2018, the provisions of the law led the United States Department of Agriculture to establish the mandatory national standard for the spread of foods that are or could be bioengineered[63]. The standard defines such foods as those that contain detectable genetic material that has been modified

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[57] FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, 2015, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059098.htm.

[58] Although several voices in the US doctrine have highlighted how economic analysis also supports transparency and disclosure of this information. According to this reconstruction, the GMO market for both the consumer and the farmer is currently unable to obtain a rational, efficient and socially optimal result due to asymmetric information. Without adequate information, consumers cannot make rational decisions regarding the purchase and consumption of GMOs, farmers do not have the tools to negotiate with producers of genetically modified and organic seeds, and cannot effectively allocate resources to protect the collected from contamination from genetic drift. On this point, see: D.M. STRAUSS, *Genetically Modified Organisms in Food: Ethical Tensions and the Labeling Initiative*, cit., 86, who also notes that it must be recognized that many consumers make food choices based not only on safety reasons but also on considerations related to tastes and preferences, health, religion, ethics and the environment; L. BRUSSEL, *Engineering a Solution to Market Failure: A Disclosure Regime for Genetically Modified Organisms*, in *Cumberland Law Review*, 34, 2003, 427 ff.

[59] Act 120, 5/8/2014. See, among others: *Genetically Engineered Food Right-to-Know Act*, HR 913, 114th Cong. (1st Sess. 2015); Center for Food Safety, State Labeling Initiatives, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labelinginitiatives#.

[60] Public Law No: 114-216, 7/29/2016, also critically called DARK ("*Denying Americans the Right to Know*") Act.

[61] For example, via QR code which can be accessed with a smartphone) (Section 293 (b) (2) (D)).

[62] The law was criticized for not specifically requiring manufacturers to publish a label or a warning about GMO-containing food. In this regard, see: D.M. STRAUSS, *Genetically Modified Organisms in Food: Ethical Tensions and the Labeling Initiative*, cit., 89 ff.; C. BEGLEY, *'So close, yet so far': The United States follows the lead of the European Union in mandating GMO labeling. But did it go far enough?*, in *Fordham International Law Journal*, 40, 2017, 625 ff.; H. NAT, *Will consumers be in the 'dark' about labels on genetically engineered and modified foods?*, in *Journal of Food Law & Policy*, 12, 2016, 199 ff.

[63] *National Bioengineered Food Disclosure Standard*, adopted on 21 December 2018 and effective on 19 February 2019.

ISSN 2284-4503

through laboratory techniques and cannot be created through traditional breeding or found in nature[64]. The mandatory compliance date has been set at the beginning of 2022[65].

3.2. The framework in the European Union

In the European Union, regulatory intervention dates back to the nineties of the last century through the adoption of directives 90/219/EEC and 90/220/EEC[66]. The first intervention was aimed at regulating the techniques of genetic modification of microorganisms, viruses and bacteria made in the laboratory, and was replaced by Directive 2009/41/EC[67]. The second represented the first intervention at European level on the release into the environment of genetically modified organisms, based on the so-called precautionary principle, which requires taking protective action before there is scientific proof of a risk[68].

The EC Regulation n. 258/97[69] established an approval procedure to ensure that genetically modified foods were not dangerous, misleading or nutritionally disadvantageous for the consumer. In addition, the Regulation established specific labeling requirements for genetically modified foods.

[64] The USDA has developed a list of genetically modified foods to identify crops or foods that are available in bioengineered form worldwide and for which regulated entities are required to keep records. The registers will inform the regulated entities whether a communication to consumers should be made regarding the bioengineering of these foods (according to the various options already provided for by the 2016 law).

[65] Specifically, the expected implementation date is 1 January 2020, with the exception of small food producers, for which January 1, 2021 is indicated. Finally, the mandatory compliance date is set for 1 January 2022. Also in this case, several criticisms have been recorded, focusing in particular on the use of the concept of "bioengineered" organisms rather than the widespread concept of "genetically modified", and on the symbol indicated by the USDA which would seem rather relative to natural and sustainable products. In this regard, see: A. BENDIX, *A new rule requires GMO products to be labeled by 2022, and some food companies are rejoicing*, in *Business Insider*, December 2018, https://www.businessinsider.com/gmo-products-must-be-labeled-by-2022-usda-2018-12?IR=T; A. GERMANOS, *"A Disaster": Critics Blast New GMO Labeling Rule From Trump's USDA*, in *EcoWatch*, December 2018, https://www.ecowatch.com/gmo-labeling-usda-2624267518.html.

[66] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms, and Council Directive 90/220 / EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, both in OJ L 117, 8.5.1990. In doctrine, see: K. GOSTEK, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit., 772; I.M. SHELDON, *Regulation of Biotechnology: Will We Ever 'Freely' Trade GMOs?*, in *European Review of Agricultural Economics*, 29, 1, 2002, 155 ff.; D. LYNCH, D. VOGEL, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, cit.

[67] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms (Recast), in OJ L 125, 21.5.2009.

[68] In this regard, see: European Commission, *Communication from the Commission on the precautionary principle*, COM (2000) 1 final, 2 February 2000; in doctrine, for critical issues, see: J.N. HATHCOCK, *The Precautionary Principle – An Impossible Burden of Proof for New Products*, in *AgBioForum*, 3, 4, 2000, 255 ff.; A. ANYSHCHENKO, *The Precautionary Principle Through the Viewscreen of Cost-Benefit Analysis*, 2019, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3326413.

[69] Regulation (EC) n. 258/97 of the European Parliament and of the Council of 27 January 1997 on novel products and novel food ingredients, in OJ L 43, 14.2.1997.

Then, in 2003, the European Union created an updated legal framework on GMOs, based on the precautionary principle enshrined in Articles 130 (2) and 174 of the EC Treaty[70].

Directive 90/220/EEC was repealed by Directive 2001/18/EC[71], which dictated rules regarding both the deliberate release of GMOs for any purpose other than placing on the market, and the marketing of GMOs and products containing GMOs. The Directive provided a procedure which required in particular an environmental risk assessment, consent to release, a monitoring plan and information to the public, as well as a proposal for labeling and a proposal for packaging with respect to marketing[72].

Subsequently, regulation no. 1829/2003/CE[73] dictated rules on food and feed «containing, consisting of or produced from GMOs» which are placed on the European Union market[74], providing that they are subject to an approval limited to a maximum of ten years but renewable. The Regulation also established standards for the labeling of GMO food or feed on the market, requiring mandatory labeling without prejudice to a tolerance threshold of 0.9% for the accidental or technically unavoidable presence of GMOs, and regardless of the detectability of DNA or protein resulting from the genetic modification in the final product (as previously foreseen)[75].

The assessment of the safety of GMOs in line with the above directives and regulations - among others - was left to the European Food Safety Authority, established with EC regulation no. 178/2002[76].

[70] Regarding the EU framework, see: D. PLAN, G. VAN DEN EEDE, *The EU Legislation on GMOs: An Overview*, JRC Scientific & Technical Reports, Luxembourg, 2010, https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eu-legislation-gmos-overview.

[71] Directive 2001/18 / EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220 / EEC, in OJ L 106, 17.4.2001.

[72] In doctrine, see among others: G. STEIER, *A Window of Opportunity for GMO Regulation: Achieving Food Integrity Through Cap-and-Trade Models from Climate Policy for GMO Regulation*, in *Pace Environmental Law Review*, 34, 2, 2017, 310 ff.; I.M. SHELDON, *Regulation of Biotechnology: Will We Ever 'Freely' Trade GMOs?*, cit., 159.

[73] Regulation (EC) n. 1829/2003 of the European Parliament and of the Council of 22 September 2003 relating to genetically modified food and feed, in OJ L 268, 18.10.2003.

[74] Therefore, following its enactment, the scope of Directive 2001/18/EC is limited to the release of GMOs into the environment for non-commercial purposes, that is, for testing purposes.

[75] See: D. PLAN, G. VAN DEN EEDE, *The EU Legislation on GMOs: An Overview*, cit., 8. Regulation no. 1830/2003/CE, then, establishes that genetically modified foods must also comply with the requirements regarding traceability, defined as the ability to trace GMOs and products obtained from them at all stages of placing on the market through the production chain and distribution, with the possibility of carrying out quality checks and possibly withdrawing products from the market; Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, in OJ L 268, 18.10.2003. For specific application implications, see the Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006, in OJ L 157, 8.6.2013.

[76] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in OJ L 31, 1.2.2002.

In 2015, then, the Directive 2015/412/EU[77], by amending Directive 2001/18/EC, recognized the possibility for Member States to limit or prohibit the cultivation of genetically modified organisms on their territory despite these having been authorized at European level[78].

3.3. The governance in China

Turning our attention to the Asian scenario, we must recall in particular the regulations in force in China, the first importer of genetically modified crops worldwide. Despite the great opportunities for the needs and the agri-food economy deriving from GMOs, the Chinese model is based on the full consideration of the multiple risks deriving from the use of the same for crops, for food safety and finally for the security of the entire ecosystem[79], in the same way as foreseen by the European precautionary approach.

In addition to the fundamental Environmental Protection Law on the protection of the environment and biological safety[80], the legal framework is based on a series of regulatory acts relating to the agri-food safety of genetically modified products, in particular from the Regulations on Agro-GMO Biosafety Management of 2001 to the Licensing Measures on Livestock Genetic Materials Production of 2010. This set of regulations imposes basic rules regarding the approval and classification of products, labeling and production license[81].

Then there is the discipline relating to further safety and transparency profiles, from the Management Measures on Biological Genetic Engineering Safety of 1993 which require laboratories to adopt risk management measures and operate in safety, to the Management Measures on Food Labeling of 2007

[77] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, in OJ L 68, 13.3.2015.

[78] The aforementioned Directive added to the text of Directive 2001/18/EC the art. 26-*ter*, which in point 3 states that: «[a] Member State may adopt measures that limit or prohibit the cultivation of a GMO or a group of GMOs defined on the basis of the crop, or part of it, piecewise, once authorized pursuant to Part C of this Directive or of Regulation (EC) no. 1829/2003, provided that these measures are in accordance with Union law, motivated and respectful of the principles of proportionality and non-discrimination and, moreover, that they are based on imperative factors such as those related to: a) environmental policy objectives; b) urban and territorial planning; c) land use; d) socio-economic impacts; e) the need to avoid the presence of GMOs in other products, without prejudice to Article 26a; f) agricultural policy objectives; g) public order». The provision was aimed at resolving the conflict between subsidiary bodies of the Member States, which claimed the right to decide what to grow and what to ban in their territories, and the needs related to the maintenance and efficiency of the European single market. See: M. WEIMER, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology*, Oxford, 2019, 191 ff.; R. MAMPUYS, L.M. POORT, *Controversy first: factors limiting the success of Directive (EU) 2015/412 for national decision-making on the cultivation of GM crops*, in *Law, Innovation and Technology*, 11, 2, 2019, 175 ff.

[79] See in this sense: Y. ZHUANG, W. YU, *Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European Union*, cit., 466 ff.; W. YU, C. WANG, *Agro-GMO Biosafety Legislation in China: Current Situation, Challenges, and Solutions*, in *Vermont Journal of Environmental Law*, 13, 4, 2012, 866 ff.

[80] *Environmental Protection Law of the People's Republic of China*, 26 December 1989, available online at: http://www.china.org.cn/english/government/207462.htm.

[81] To these are added the technical standards for the biosafety of genetically modified agri-food products, established especially between 2003 and 2009 by the Chinese Ministry of Agriculture.

ISSN 2284-4503

which establish the obligation of labeling, aimed at ensuring the traceability of genetically modified organisms and their relative presence within the products purchased by the consumer[82].

As regards the institutions responsible for the matter, in China there are also several institutions aimed at controlling the production and distribution of GMOs. The main one is represented by the Ministry of Agriculture, assisted in its control work by other institutions including agencies responsible for risk assessments on the biosecurity of genetically modified agri-food products, others responsible for controlling the labeling process, and others to which the control of the licenses issued by the Ministry of Agriculture for the production and export of GMO products to other countries is required[83].

On the other hand, criticisms have emerged regarding the inadequacy of the Chinese legislation with reference to food safety. In particular, the absence of clear and effective rules capable of regulating the phenomenon, the fragmentary nature of a legal framework dictated by multiple institutions and the relative administrative skills regarding the control of imported and exported products, and the ineffectiveness of enforcement by the bodies responsible for supervising genetically modified organisms in China[84].

Even the legislation governing the issue of labeling is considered to be unclear and complex to apply, thus causing many problems in the internal market and in foreign trade. The problem is of particular importance, also at an international level, considering that China is one of the world's largest exporters of cotton, corn and soybeans, from which many products are obtained[85]. In the Chinese market, in fact, despite the presence of legislation similar to the European one regarding the traceability of genetically modified products, the labeling obligation does not appear to be given sufficient execution[86].

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[82] So, in China as in Europe, there is a mandatory regulation regarding the process by which GMOs are obtained. Vice versa, in Japan, Indonesia, Taiwan, South Korea, Russia, Saudi Arabia, and so far the United States, the regulation concerns only the final product and not the process by which it was obtained. See: G.P. GRUÈRE, S. RAO, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, in *AgBioForum*, 10, 1, 2007, 51 ff.

[83] For more details, see: W. YU, C. WANG, *Agro-GMO Biosafety Legislation in China: Current Situation, Challenges, and Solutions*, cit., 869 ff.

[84] In this sense, see among others: X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, cit., 30 ff.; W. YU, C. WANG, *Agro-GMO Biosafety Legislation in China: Current Situation, Challenges, and Solutions*, cit., 873 ff.

[85] On this point, see: X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, cit., 33; Regarding the related risk of genetic flow of new allergens caused by the use of GMOs, see: G.N. MANDEL, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, cit., 2171.

[86] It should also be noted that the problem of labeling actually involves many countries on the Asian and international scene. Scholars, in fact, in addition to highlighting the difference between the countries that have provided themselves with mere guidelines on voluntary labeling, such as Hong Kong, Canada, South Africa and so far the United States, from those that have provided for mandatory labeling for products GMOs, such as the EU, China, Japan, Australia, Brazil and in the United States perspective, have highlighted that a fair implementation of the rules has occurred only in China, Japan, South Korea, Taiwan, Russia, Saudi Arabia, unlike Vietnam, Thailand, Indonesia, Ukraine, Sri Lanka, *etc.* where, on the other hand, the implementation of the labeling laws may not be considered efficient and implemented in the same way as the European one. See: G.P. GRUÈRE, S. RAO, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, cit., 52-54.

ISSN 2284-4503

In this regard, scholars have identified various reasons: the first relating to the considerable rigidity of the legislation, given that it establishes a tolerance threshold considered excessive, such as not to allow even the incidental presence of GMOs in food[87]; a second relating to the ambiguous language that characterizes the regulation and makes its application complex; finally, another relating to the fact that the same does not guarantee the traceability of the products in all its phases up to their distribution on the market[88].

4. Food sovereignty and patentability. The case of foods obtained from CRISPR

Ever since the advent of genetically modified organisms on world markets, the prospects for the economic exploitation of genetic engineering products and their large-scale use have given rise to a real race to grab the genetic resources of the planet, through the protection deriving from intellectual property rights over genetic information, both the result of artificial synthesis processes and relative to forms of animal or plant life[89].

An important argument used in favor of the spread of GMOs regards the feeding of the developing world and the reduction of hunger. However, concerns are raised about the multiplication of patents and the biotechnological scenario increasingly controlled by the private sector. Patents allow large multinational companies substantial control over plant genes. If farmers – already struggling in the current economy due to globalization, increased competition and climate change – find themselves having to buy patented seeds each year, this could affect their income and food security[90].

A further risk of centralized control of the seed market in the hands of a few large patent holders that manage seed rights is that the biodiversity standard is replaced by global uniformity[91].

Traditionally, farmers spared the seeds that the plants produced and used them for the following season. Today, farmers have to return every year to buy seeds from biotechnology companies. They can no longer keep the seeds and keep them for the next sowing season as this would violate patents. This

[87] In China, the permitted incidental threshold of GMOs in GMO-free products is even 0%, while in other Asian countries such as Japan and Taiwan it is 5%, and still in Russia, similarly to the European Union, it is 0,9%.

[88] In this regard, see: X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, cit., 37 ff.; Y. ZHUANG, W. YU, *Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European Union*, cit., 468 ff.; *contra*: G.P. GRUÈRE, S. RAO, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, cit., 53.

[89] In this way, biotech companies have obtained, through the instrument of the patent, the recognition of the patent rights on the organisms studied and on the genetic sequences used in the biotechnological applications intended for marketing. On the subject, see among others: G. GHIDINI, *Rethinking Intellectual Property, Balancing Conflicts of Interests in the Constitutional Paradigm*, Cheltenham, 2018, 69 ff.; A. STAZI, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., 237 ff.; J. RIFKIN, *The biotech century. Harnessing the Gene and Remaking the World*, New York, 1999, 37 ff.

[90] See, in addition to the references previously reported: A. STEINBACH, *Technology, Patents, and Plants: Are the Next Generation of GMOs Patentable?*, 2018, https://ssrn.com/abstract=3266049; J. KAISER, *Biotechnology – A Solution to Hunger?*, in *UN Chronicle*, 2009, https://unchronicle.un.org/article/biotechnology-solution-hunger.

[91] See: GRAIN AND THE ALLIANCE FOR FOOD SOVEREIGNTY IN AFRICA, *The real seeds producers: Small-scale farmers save, use, share and enhance the seed diversity of the crops that feed Africa*, in *GRAIN*, 2018, https://www.grain.org/article/entries/6035-the-real-seeds-producers-small-scale-farmers-save-use-share-andenhance-the-seed-diversity-of-the-crops-%20that-feeds-africa.

jeopardizes small farmers and innovation, as they will have to return year after year to buy seeds from the patent owner[92].

In addition, fears have emerged that large biotechnology companies such as Monsanto or AstraZeneca will market the "terminator gene", a genetically engineered technology designed to inhibit plants' ability to germinate a second time causing seed sterilization. The privatization of genetic resources therefore appears to jeopardize not only agricultural research in developing countries, but ultimately the livelihood of a majority of small farmers in Africa, Asia and Latin America and even in the United States, who rely on saving seeds year after year to control costs and keep agricultural operations profitable[93].

In addition, long-term studies in the United States have shown that in just sixteen years the problem of pest and plant resistance has led farmers to use more toxic chemicals, further reducing their revenues and damaging the environment. Therefore, the small farmers are those who suffer the most, as their financial situation is either of extreme poverty or of previous indebtedness[94].

In recent years, still in the United States, intellectual property rights rules have been used by multinational corporations to report farmers in order to protect their patent rights related to genetically modified seeds[95]. In 2013, a leading case reached the United States Supreme Court, which denied farmers the right to sue in a lawsuit against Monsanto[96]. Lastly, in 2019, the Indian Supreme Court set aside an order of the division bench of the Delhi High Court that revoked a patent granted to Monsanto by the Indian Patent Office on genetically modified Bacillus thuringiensis cotton, so-called Bt Cotton[97].

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[92] With related increase in costs and dependence on the company itself. See: A. STEINBACH, *Technology, Patents, and Plants: Are the Next Generation of GMOs Patentable?*, cit., 3.

[93] See: S. CHRISMAN, *Animal Welfare, Farming, Food Policy, Rural Environment and Agriculture Project*, in *Civil Eats*, 2018, https://civileats.com/2018/09/10/is-the-second-farm-crisis-upon-us/. For example, in a South African case study, Monsanto initially provided the seeds for free, but later its use of terminator technology to cause seed sterility required farmers to buy back additional seeds or pesticides in later stages of genetically modified agriculture; see: T. KAPHENGST, L. SMITH, *The impact of biotechnology on developing countries*, European Parliament Policy Department, Brussels, 2013, 5 ff.; G. CONWAY, *Genetically modified crops: risks and promise*, in *Conservation Ecology*, 4, 1, 2000, 2 ff.

[94] See: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 4; T. KAPHENGST, L. SMITH, *The impact of biotechnology on developing countries*, cit., 9 ff.

[95] In this regard, see: CENTER FOR FOOD SAFETY, *Seed Giants v. US Farmers*, 2013, https://www.centerforfoodsafety.org/reports/1770/seed-giants-vs-us-farmers; P. HARRIS, *Monsanto sued small famers to protect seed patents, report says*, in *The Guardian*, February 2013, https://www.theguardian.com/environment/2013/feb/12/monsanto-sues-farmers-seed-patents. This, according to various reconstructions, also regardless of whether the seeds had been contaminated by genetically modified seeds; but for a different view see: L. KATIRAEE, *Dissecting claims about Monsanto suing farmers for accidentally planting patented seeds*, in *Genetic Literacy Project*, 2018, https://geneticliteracyproject.org/2018/06/01/dissecting-claims-about-monsanto-suing-farmers-for-accidentally-planting-patented-seeds.

[96] *Organic Seed Growers and Trade Association v Monsanto Company* [2013] 134 Supreme Court 901. This has been found to be a disturbing precedent for smallholder farmers in developing countries, as companies often use their governments to put pressure on host countries to strengthen their patent protection; see: P. NEWELL, *Biotechnology and the politics of regulation*, Institute of Development Studies Working Paper 146, 2002, 20, https://www.ids.ac.uk/files/Wp146.pdf.

[97] Supreme Court of India, *Monsanto Technology LLC & Ors v Nuziveedu Seeds Ltd & Ors*, 8 January 2019. For a critical appraisal, see: V. CHAWLA, *Indian Supreme Court on patentability of genetically modified life forms - a missed opportunity?*, in *Journal of Intellectual Property Law & Practice*, 14, 5, 2019, 343 ff.

ISSN 2284-4503

Therefore, GMOs appear likely to lead to higher costs and lower revenues for small farmers, threatening their subsistence, regardless of whether they adopt genetically modified crops or not[98].

Finally, it has been pointed out that biotechnology companies and the governments of developed countries tend to press developing countries to strengthen their intellectual property rights, a phenomenon which, as mentioned, reduces farmers' income substantially, because consequently they can not continue their traditional saving, sale and exchange of seeds practices[99].

Thus, businesses in developing countries find a sort of laboratory in which to test controversial biotechnology in the West, due to the economic vulnerability and lack of political capacity of those countries to reject foreign investments[100].

The first generation of genetically modified crops caused several concerns among the public and scientists. With this in mind, recently scientists have discovered a new gene modification technology that appears cheaper, more effective and less controversial than the first generation of GMOs[101], called "Clustered Regularly Interspaced Short Palindromic Repeats" (CRISPR)[102], which is emerging as a powerful tool capable of changing the DNA of plants and beyond[103].

CRISPR techniques are actually inspired by a natural process and resemble natural mutations of plants. These technologies allow scientists to add, modify or remove genetic or altered material at particular locations in the genome[104].

The most recent development is the so-called CRISPR-Cas9 (protein 9 associated with CRISPR)[105]. Researchers create a small fragment of RNA with a DNA sequence that attaches to a specific target DNA

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[98] In this regard, see: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 5.

[99] See: G. CONWAY, *Genetically modified crops: risks and promise*, cit., 8. In this perspective, for example, it has been found that the Indian government had been pushed to create a "single" approval process, in order to speed up the process for companies, leaving insufficient time for risk assessment; see: P. NEWELL, *Biotechnology and the politics of regulation*, Institute of Development Studies Working Paper 146, 2002, 19, https://www.ids.ac.uk/files/Wp146.pdf; S. HUMPHREY, *Theater of the Rule of Law. Transnational Legal Intervention in Theory and Practice*, Cambridge, 2010, 184.

[100] So, again: S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 4; P. NEWELL, *Biotechnology and the politics of regulation*, cit., 19 f.

[101] See: M. CROSSEY, *What is CRISPR gene editing, and how does it work?*, in *The Conversation*, January, 2018, https://theconversation.com/what-is-crispr-gene-editing-and-how-does-it-work-84591; D. FREEMAN, *The Truth About Genetically Modified Food*, in *Scientific American*, September 2013, https://www.scientificamerican.com/article/the-truth-about-genetically-modified-food.

[102] That is, short palindrome repeats grouped and separated at regular intervals.

[103] In this regard, see: A. VIDYASAGAR, *What Is CRISPR?*, in *Live Science*, April 2018, https://www.livescience.com/58790-crispr-explained.html.

[104] See.: A. RICRONCH, P. CLAIRAND, W. HARWOOD, *Use of CRISPR systems in plant genome editing: toward new opportunities in agriculture*, in *Emerging Topics in Life Science*, 1, 2, 2017, 169 ff.

[105] See: F. ZHANG, Y. WEN, X. GUO, *CRISPR/Cas9 for genome editing: progress, implications and challenges*, in *Human Molecular Genetics*, 23, 2014, R1, R40 ff.; A. VIDYASAGAR, *What Is CRISPR?*, cit. CRISPR-Cas9 has been adapted from a natural genome modification system in bacteria. The bacteria capture DNA fragments from invading viruses and use them to create DNA segments known as CRISPR arrays. The CRISPR arrays allow bacteria to "remember" viruses, so if the viruses attack again, the bacteria produce RNA from the CRISPR arrays to target the DNA of the virus. The bacteria then use Cas9 or a similar enzyme to cut the DNA and intervene on it to kill the virus.

sequence in a genome. RNA is used to recognize the targeted DNA sequence, and researchers use the Cas9 enzyme to cut DNA in the target position. Once the DNA is cut, the researchers use the DNA of the cell's repairing apparatus to add or remove parts of genetic material, or to make changes to the DNA by replacing an existing segment with a customized DNA sequence[106].

CRISPR GMOs are considered highly efficient in producing the desired results. In studies on rice and mustard plants, for example, CRISPR-Cas9 allowed transgenic offspring to preserve most of the modified traits, with percentages of up to 89% for mustard plants and 92% for rice[107].

As regards the patentability of CRISPR techniques and products, to the "gold rush" to which the development of these biotechnologies is giving rise[108], corresponds a difference in approaches to patentability on both sides of the Atlantic. In this regard, of particular importance is the case of the Broad Institute, which, established by MIT and Harvard University in 2004 to use genomics to improve human health, successfully obtained a patent from the United States Patent Office for its use in eukaryotes. However, the European Patent Office has revoked the first of several patents obtained by the Broad Institute, recognizing a clear lack of novelty[109].

The Broad Institute patent has been opposed by many for a number of reasons, including the lack of new results due to the presence of numerous previous patent publications. On the other hand, given the enormous potential of CRISPR / Cas9, it was noted how logical it would be to ensure that these biotechnologies remain accessible in Europe and worldwide for the development of highly effective agro-food innovations or therapies against devastating diseases[110].

Conversely, in the United States, in September 2018 the Court of Appeal for the Federal Circuit confirmed a previous decision by the Patent Office that granted the patent on CRISPR/Cas9 to the Broad

[106] In this regard, see: NATIONAL INSTITUTE OF HEALTH, *What are genome editing and CRISPR-Cas9?*, National Institute of Health - Genetics Home Reference, 2018, https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting.

[107] See: K. BELHAJ et al., *Plant genome editing made easy: targeted mutagenesis in model and crop plants using the CRISPR/Cas system*, in *Plant Methods*, 9, 1, 2013, 39 ff.

[108] For a framework of the complex regulatory issues in which the related patents and licenses are being developed, see: P. ENRIQUEZ, *CRISPR GMOs*, in *North Carolina Journal of Law & Technology*, 18, 4, 2017, 432 ff.; T. CYNOBER, *CRISPR: One Patent to Rule Them All*, in *Labiotech*, February 2019, https://labiotech.eu/features/crispr-patent-dispute-licensing; O. FEENEY et al., *Patenting foundational technologies: Lessons from CRISPR and other core biotechnologies*, in *American Journal of Bioethics*, 18, 12, 2018, 36 ff.; J.S. SHERKOW, *Inventive steps: the CRISPR patent dispute and scientific progress*, in *EMBO Reports*, 18, 2017, 1047 ff. Regarding the public acceptance and valuation of CRISPR-produced food, see: A.M. SHEW et al., *CRISPR versus GMOs: Public acceptance and valuation*, in *Global Food Security*, 19, 2018, 71 ff.

[109] This news was evidently received with satisfaction by the ERS Genomics company, co-founded by one of the inventors of CRISPR/Cas9 Emmanuelle Charpentier to provide access to the intellectual property of the technology. The exclusive worldwide patent of the ERS differs from that of the Broad Institute in that it covers the use of CRISPR/Cas9 to modify the genome of an organism, but not for therapeutic use in humans.

[110] For example, the companies CRISPR Therapeutics and Vertex Pharmaceuticals are exploring the possibilities of using the CRISPR/Cas9 technology for the treatment of beta-thalassemia blood disease, obtaining interesting results from the first trials. See: B. LIPSCHULTZ, *Crispr Gene Editing Shows More Promise in Blood Disease Update*, in *Bloomberg News Wire*, 12 June 2020, https://www.bnnbloomberg.ca/crispr-gene-editing-shows-more-promise-in-blood-disease-update-1.1449393. In the meantime, the technique has been used in the laboratory to enhance the T-cell cancer elimination ability and identify new targets for the treatment of acute myeloid leukemia. See: A. DALE, *The European Patent Office Revokes the Broad Institute's CRISPR Patents*, in *Labiotech*, January 2018, https://labiotech.eu/policy-legal-finance/crispr-patents-revoked-ers-genomics.

ISSN 2284-4503

Institute. Although many patents have already been filed describing various aspects of the modification of the CRISPR-Cas9 gene, the Court of Appeal found that the Broad Institute's patent applications are particularly important as they cover a very wide range of potential CRISPR-Cas9 products[111].

On the other hand, also in the United States, given the strong similarity with the natural mutations of plants, it has been observed that recent Supreme Court decisions appear to indicate that in the near future the patentability of CRISPR techniques and products could be questioned[112].

According to critics, in fact, the patenting of CRISPR techniques and their licensing to other researchers cannot be admitted since the CRISPR process borrows processes from a natural event. Similarly, plants produced through this mutagenesis and their offspring cannot be patentable because the plants created do not include any new or different DNA from identical species existing in nature[113].

The control and monetization of patent rights held by large companies evidently increases the start-up and management costs for small farmers, giving rise to economic barriers to agricultural development and competition[114].

In this sense, given the recent interventions of the Supreme Court aimed at limiting the scope of DNA patents, scholars have argued that the Court itself should rule against the patentability of CRISPR, or there should be legislative reforms in this sense. This, according to the opinion that the more the law creates artificial legal barriers to access to natural products and incentives for the industrialization of agriculture, the more the opportunities for better local products will be penalized and people will suffer from hunger, malnutrition, food scarcity and price injustice[115].

[111] See United States Court of Appeals of the Federal Circuit, Regents of Univ. Of California v. Broad Inst., Inc. 2018 903 F.3d 1286. For a comment, see: H.Ledford, *Pivotal CRISPR patent battle won by Broad Institute*, in *Nature*, September 2018, https://www.nature.com/articles/d41586-018-06656-y.

[112] See the decisions: *Association for Molecular Pathology v. Myriad Genetics*, Inc., 569 US 576 (2013); *Alice Corp. v. CLS Bank International*, 573 US 208, 134 S. Ct. 2347 (2014). In doctrine: A. Steinbach, *Technology, Patents, and Plants: Are the Next Generation of GMOs Patentable?*, cit., 18 ff.; R. Rader B. Christoff, *Patent Law in a Nutshell*, St Paul, 2018 (3rd edition), 71 ff.; J. Straus, *Intellectual property rights and bioeconomy*, in *Journal of Intellectual Property Law & Practice*, 12, 7, 2017, 576 ff.; A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., 154 ff.; J. Conley, *Myriad, Finally: Supreme Court Surprises by not Surprising*, in *The Privacy Report*, June 2013, 1 ff, https://theprivacyreport.com/2013/06/18/myriad-finally-supreme-court-surprises-by-not-surprising.

[113] In this perspective, see: A. Steinbach, *Technology, Patents, and Plants: Are the Next Generation of GMOs Patentable?*, cit., 17 ff.

[114] In this regard, see among others: C. Jewell, *Who benefits from IP rights in agricultural innovation?*, in *WIPO Magazine*, April 2015, https://www.wipo.int/wipo_magazine/en/2015/04/article_0003.html; G. Ghidini, *Equitable sharing of benefits from biodiversity-based innovation: Some reflections under the shadow of a neem tree*, cit., 695 ff.

[115] Thus: A. Steinbach, *Technology, Patents, and Plants: Are the Next Generation of GMOs Patentable?*, cit., 26 f. Regarding the relevance of recent US and EU case law developments with respect to a possible common Western approach on the limits of patentability, one may refer to: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., 293 ff.

5. Final considerations. Regulatory approaches, access to resources and traceability of products

The analysis carried out has highlighted how the GMO regulation is placed within the framework of a multiplicity of principles and interests at stake, ranging from food safety to contrast hunger and malnutrition, healthy food, sustainable development, biodiversity and food sovereignty.

From a comparative perspective, in the context of the legal pluralism[116] a circulation of models, in particular the European one based on the precautionary principle, characterizes the legal pluralism existing on the subject[117]. This phenomenon raises questions, on the one hand, with respect to the dynamics of international trade with more permissive regulations such as the United States[118], on the other, regarding the limited effectiveness of the application of this model in some regulations such as the Chinese one[119].

As regards the profile of the recognition of intellectual property rights, the case of foods obtained from CRISPR shows the difference in approaches also with respect to patentability on both sides of the Atlantic, which is likely to give rise to competition between regulations which could have further

[116] On which, see among others: L. NIGLIA (ed.), *Pluralism and European Private Law*, Oxford, 2013; W.W. BURKE-WHITE, *International Legal Pluralism*, in *Michigan Journal of International Law*, 25, 2004, 963 ff.

[117] In this regard, see: W. YU, C. WANG, *Agro-GMO Biosafety Legislation in China: Current Situation, Challenges, and Solutions*, cit., 883 ff.; N. KRISCH, *Pluralism in Global Risk Regulation: The Dispute over GMOs and Trade*, in *LSE Law, Society and Economy Working Papers*, 17, 2009, 1 ff, https://bit.ly/2NhkO53; D.M. STRAUSS, *The international regulation of genetically modified organisms: importing caution into the US food supply*, cit., 191 ff. On the circulation of models, see among others: J. FEDTKE, *Legal Transplants*, in J.M. SMITS (ed.), *Elgar Encyclopedia of Comparative Law*, 2012 (2nd ed.), Cheltenham, 550 ff.; C. LEI, *Legal Transplants: China and Hong Kong*, in P.G. MONATERI (ed.), *Methods of Comparative Law*, Cheltenham, 2012, 192 ff.; M. GRAZIADEI, *Legal Transplants and the Frontiers of Legal Knowledge*, in *Theoretical Inquiries in Law*, 10, 2, 2009, 72 ff.; V.V. PALMER, *Mixed Legal Systems… and the Myth of Pure Law*, in *Louisiana Law Review*, 67, 4, 2007, 1205 ff.

[118] Therefore leading the US doctrine to wonder about the opportunity for the United States to introduce a regulation on GMOs closer to the European one, in particular with regards to mandatory labeling, which allows to recover the losses suffered so far in agricultural exports. See: K. GOSTEK, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, cit., 785 ff.; R. BRATSPIES, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, cit., 350 ff.

[119] See: X. ZHU, M.T. ROBERTS, K. WU, *Genetically modified food labeling in China: in pursuit of a rational path*, cit., 30 ff.; W. YU, C. WANG, *Agro-GMO Biosafety Legislation in China: Current Situation, Challenges, and Solutions*, cit., 873 ff.

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consequences relevant to international trade[120] and to sustainable development, biodiversity and food sovereignty[121].

Lastly, regarding the guarantee of transparency and traceability of GMO products, an increasingly central feature in the various legal systems, following the increase in consumer attention to the potential risks deriving from them[122] as well as developments also in more permissive regulations such as the US one with the recent labeling provisions[123], the new option of a "techno-regulation"[124] through technologies based on distributed ledgers such as the blockchain.

This kind of technologies, in fact, if the issues relating to the introduction costs and the responsibility of the controls were solved, could provide an effective tool to ensure the effective traceability and transparency of the characteristics of the products of the agro-food chain, thus also contributing to the protection of sustainable agriculture and local producers[125].

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[120] In other words, the pursuit of countries or transnational organizations aimed at providing more favorable regulations to private entities operating in their own jurisdictions, as well as directing cross-border flows of resources in their favor – so-called "race to the top" – possibly also through real barriers to entry in the protectionist sense. In this regard, see: P. DRAHOS, *The TRIPS Review and the CBD: A Dress Rehearsal?*, in P. DRAHOS, M. BLAKENEY (eds), *IP in Biodiversity and Agriculture: Regulating the Biosphere*, London, 53 ff. See also: H.N. BUTLER, L.E. RIBSTEIN, *Legal Process and the Discovery of Better Policies for Fostering Innovation and Growth*, in THE KAUFFMAN TASK FORCE ON LAW, INNOVATION AND GROWTH, *Rules for Growth: Promoting Innovation and Growth Through Legal Reform*, Kansas City, 2011, 463 ff., who highlight the risk that the competition facilitated by *ex ante* choice of law may turn into a "race to the bottom" towards more permissive rules and responsive only to partisan interests.

[121] In this regard, see among others: F. CAPRA, U. MATTEI, *The Ecology of Law. Toward a Legal System in Tune with Nature and Community*, cit., 6 ff., according to whom Western jurisprudence, together with science, has contributed significantly to the materialistic and extractive mentality: hence, the need for a change of perspective from economic efficiency to ecological sustainability; S. SHRESTHA, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., 16; T. NARDIN, *Justice and authority in the global order*, in *Review of International Studies*, 37, 5, 2011, 2059 ff.

[122] On this point, see: S. WUNDERLICH, K.A. GATTO, *Consumer Perception of Genetically Modified Organisms and Sources of Information*, in *Advances in Nutrition*, 6, 6, 2015, 842 ff.; Y. ZHUANG, W. YU, *Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European Union*, cit., 477 f.

[123] Although also in this case subject to criticism in terms of effectiveness; see: A. BENDIX, *A new rule requires GMO products to be labeled by 2022, and some food companies are rejoicing*, cit.; A. GERMANOS, *"A Disaster": Critics Blast New GMO Labeling Rule From Trump's USDA*, cit.

[124] For an overview of the functions and limits of techno-regulation as an aid tool for the law, see among others: R.E. LEENES, *Framing Techno-Regulation: An Exploration of State and Non-State Regulation by Technology*, in *Legisprudence*, 5, 2, 2011, 143 ff., available online at: https://bit.ly/2Yigadz; as well as the key authors on the theme referred to therein, including primarily: L. LESSIG, *Code and Other Laws of Cyberspace*, New York, 1999; J.R. REIDENBERG, *Lex Informatica: The Formulation of Information Policy Rules Through Technology*, in *Texas Law Review*, 76, 3, 1998, 553 ff.

[125] Regarding the opportunities related to the application of the blockchain to agriculture, in terms of traceability, health and sustainability, see: H. KIM, M. LASKOWSKI, Agriculture on the Blockchain, in D. TAPSCOTT (ed.), *Supply Chain Revolution: How Blockchain Technology Is Transforming the Global Flow of Assets*, Toronto, 2018, 67 ff.; D. FRIEDMANN, *Protecting the Integrity of Consumer Information and the Supply Chain of Wine in China*, forthcoming in F. DIAS SIMÕES (ed), *Consumer Protection in China: Current Challenges and Future Prospects*, Leiden, 2020, https://bit.ly/3fFLxEI; N. POPPER, S. LOHR, *Blockchain: A Better Way to Track Pork Chops, Bonds, Bad Peanut Butter?*, in *The New York Times*, 4 March 2017, https://nyti.ms/3dnhxM5. For further information on the peculiarities of the blockchain, together with a reading oriented towards regulation through technology, see: P. DE FILIPPI, A. WRIGHT, *Blockchain and the Law. The Rule of Code*, Cambridge-London, 2018.

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