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Comparative Law in Germany: Yesterday's Hobby or Tomorrow's Science?

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In this issue all the published scientific works have been accepted after double blind peer review.

Agri-Food Biotechnologies Regulation: a comparative perspective

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Abstract

Technological change impacts the agri-food sector and generates new competitive pressure. As well as the digital technologies that are introducing new business models and revolutionizing the traditional food chain, with new consumers' protection tools, emerging genetic engineering techniques (e.g. gene editing) - which the present article is focused on – are thoroughly impacting food nature and production modality. This new step of scientific progress is also blurring the line between issues traditionally ascribed to the different fields of environment law and safety law. Biotechnology is, in fact, one of the strategic keys enabling technologies to support a new green and sustainable economy (i.e. bioeconomy) responding to the need for new food production technology, more efficient resource use, and responsible value chains, in a context in which sustainable food system is promoted by the *European Green Deal* and the *Farm to Fork* strategies.

Analyzing the current European debate on the appropriateness of stringent GMO legislation to new DNA alterations (such as gene editing) and discussing upcoming changes, such as for instance the perspective of overcoming the “safe enough” narrative (EGE, 2021), and the proposal stemming from the EU Commission's Study on the status of new genomic techniques (April 29, 2021), the article aims at finding out how the European Union manages to balance economic interests with consumers' fundamental rights protection to maintain the appropriate functionality of the internal market fostering innovation. The comparative study between the two main regulatory models, historically characterizing different food cultures and

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contexts will be analyzed in parallel with a keen eye to the most recent debate about the EU need to empower new innovative technologies for sustainability will lead us to express some critical remarks toward the factors that prevent the development of an adequate regulatory environment for agri-food biotechnologies.

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Keywords

European Law – Regulatory models – Safety – Consumers protection – Environment – Health Protection – Biotechnologies.

1. Introduction

The almost forty years long European debate about genetically modified organisms (from now on: GMO) authorization and suitable regulatory policy¹, is considered a pivotal experience to study the impact of scientific uncertainty on culture, policy and law. Furthermore, it represents the result of the swinging faith and skepticism in agri-food biotechnologies both in public perception and stakeholders' assessment.

Instead of coming to an end, the debate recently intensified and characterized the EU again: in the past few years, a innovative technique for genome editing, CRISPR-Cas, with wider potential and easier applicability, has rapidly advanced

¹ Between 1985 and 2010, the EU invested about € 250 million to assess the safety of GMOs. It also collected and made public the available data in two publications. The first one, the European legislation on GMOs, dates back to the 1990s (Council Directive (EC) on the deliberate release into the environment of genetically modified organisms, [1990] OJ L 117, pp. 15-27). The third whereas of this Directive stated that: "the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment: in reality, living organisms containing genes of different species, whether they are understood in the scientific sense (as organisms resulting from transgenesis), or in the legal sense introduced in the EC Directive No. 18/2001, have occupied the scene since the '70s. Legal, scientific and commonly understood by society do not coincide. For more information see: E. Sirsi, 'In tema di etichettatura dei prodotti geneticamente modificati', in F. Maggino et al. (eds), *I Georgofili. Atti della Accademia dei Georgofili* (Edizioni Polistampa, 2015); F. Albújar, Van der Meulen, 'The Legal GMO Concept Reassessment of the GMO definition in the light of new breeding techniques (NBTs)' (2017) *European Institute for Food Law Working Paper Series* 03. For a definition of GMO see ECJ case C-442/09, *Bablok* [2011] ECR I-7419, para 62. Opposing countries include Italy, Austria and Hungary, as well as numerous NGOs. In the European market there is an implicit "feeling" of aversion to GMOs linked to their presumed potential danger, although minimal traces, not exceeding 0.9%, are tolerated. This means that when the presence of GMOs in food products is accidental, or derives from contamination not otherwise avoidable, and does not exceed that threshold, the food will not be subject to the labelling requirements specifically provided for by Regulation n. 1830/2003 EC, by virtue of art. 12, paragraph 2, of the same. Food containing GMOs that exceeds this threshold, on the other hand, will have to meet the requirements of this regulation, which has a supplementary nature compared to reg. n. 1169/2011 EU. Consumers are concerned about the maintenance of biodiversity; the possible change in ecological balances; the limitations on the development of a competitive market; and the possible allergenicity or antibiotic resistance of food derived from or containing GMOs. States in favour, on the other hand, identify a means of improving plant species (e.g., increased resistance to insect virus pesticides), adaptability to climates, increased productivity in agriculture, reduced impact on the environment, and response to food security issues. R. Defez, *Il caso ogm. Il dibattito sugli organismi geneticamente modificati* (Carocci, 2016).

plant biology research and the development of applications for plant breeding. As the paper will explain, the issue heated up in 2018 after the European Court of Justice (ECJ) ruled that organisms obtained by new plant breeding techniques (from now on: NBTs) should, in principle, fall under the GMO Directive.

The spread of the techniques for artificial modification of the genome through targeted alterations of DNA and RNA are competing with traditional phenotype use of living organisms. All in all, these new genetic engineering techniques not only are modifying existing organisms, but they can also create new cells and new organisms².

Regardless of the different point of view, it is undeniable that the use of agri-food biotechnologies affects a multiplicity of sectors and socio-economic interests³ and fuels many doubts about unknown long-term effects of consuming biotech foods on humans, including nutritional differences and new diseases developed in the human gut and allergic reactions raise uncertainty. These fears, however, are not, in most cases, supported by scientific data⁴.

The identification of the regulatory model for biotechnology becomes, therefore, a complex and multidimensional objective⁵, such that any public decision implies choices of a discretionary nature⁶: this is because governance is a crucial issue and it is thus strategic to unfold its multiple facets both on environment and safety sides. A primary factor is the state of the existing and emerging legislative and regulatory strategies across the various purposes and domains (humans, non-human animals,

² N. De Sadeleer, 'Marketing and Cultivation of GMOs in the EU. An Uncertain Balance between Centrifugal and Centripetal Forces', (2015) 6 *Eur. J. Risk Reg.* 532.

³ For the same reason in 2006, the World Trade Organization (WTO) had condemned the EU to remove an alleged moratorium against GMOs from Canada, the United States and Argentina for lack of sufficient scientific information. EC - *Measures Affecting the Approval and Marketing of Products* (29 September 2006) WT/DS/291, 292, 293, *Reports of the Panel*, Geneva.

⁴ D. Bressanini, B. Mautino, *Contro natura. Dagli OGM al «bio», falsi allarmi e verità nascoste del cibo che portiamo in tavola* (Rizzoli, 2016).

⁵ See D. Bevilacqua, 'La regolazione pubblica degli OGM tra tecnica e precauzione', (2016) 2 *Riv. crit. dir. priv.* 275.

⁶ See *ibid* [278]; F. Cittadino, 'Libera circolazione degli OGM: più spazio per la tutela dell'ambiente alla luce della direttiva (UE) 2015/412?', (2016) 1 *Riv. giur. amb.* 219.

plants, microorganisms, gene drives); a pertinent component is the historical dimension and legacy of legislative approaches (with questions of path dependency, institutional mimesis, transnational epistemic communities, and learning forms), which also demand to be addressed there.

It is possible to trace several evolutionary steps in the agri-food biotechnology policy: at first the debate was focused on the opposing positions for and against GMOs; at a second time, the attention was aimed at investigating the real extent of scientific uncertainty about the effects of new agri-food products on human health and/or the environment when, to date, there is still scientific evidence about the actual danger of the use of genetic engineering in the agri-food field. Finally, the promotion of a holistic approach aimed at weighing also other non-measurable components, including ethical ones⁷. In practical terms, following the recent Ege Opinion n. 32⁸, disputing the ‘safe enough’ narrative implies questioning the inclination of scientific and technological developments to shape governance and indeed ethics. This also extends to coordination matters, diversity, inequalities and power relations. As a matter of fact, ‘safety’ or ‘trustworthiness’ do not pertain merely to technologies yet also extend to institutions and forms of governance in societies – including matters of oversight as well as of democracy and rule of law.

In this perspective, comparative research has already presented findings to show to what extent public perceptions and food culture are crucial elements for determining the acceptance of a model of food governance in a domain where “technological risks”⁹, unlike simple risks (e.g. car accidents), cannot be calculated according to traditional technocratic models, namely as a statistically foreseeable

⁷ Among the many see G.E. Seralini, E. Clair, R. Mesnage, S. Gress, N. Defarge; M. Malatestab, D. Hennequin, J. Spiroux de Vendomois, ‘Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize’, (2012) 50(11) *Food and Chemical Toxicology* 4221.

⁸ European Group on Ethics in Science and New Technologies Opinion on Ethics of Genome Editing, Opinion n. 32, March 2021, available at: https://ec.europa.eu/info/sites/default/files/research_and_innovation/ege/ege_ethics_of_genome_editing-opinion_publication.pdf.

⁹ M. Weimer, L. Marin, ‘The Role of Law in Managing the Tension between Risk and Innovation: Introduction to the Special Issue on Regulating New and Emerging Technologies’ (2016) 7(3) *European Journal of Risk Regulation* 469.

function of probability.¹⁰ Within this thread the perspective implemented in this paper is inserted.

Consequently, to balance new techniques' implementation of global environmental sustainability with safety exigence, European Institutions are already involved in analyzing in depth how law and regulation can successfully adapt to biotech progress integrating both legal and non-legal tools¹¹.

This article starts from the analyzes of the different regulatory models and specific mechanisms applied in different geopolitical contexts to agri-food biotechnologies with attention to their legal culture. For this purpose, from a methodological point of view, the analysis aims to engage with real-world issues and takes a practical perspective, following the path of contemporary comparative legal scholarship¹². Moreover, even if the examined subject impacts on two distinct fields

¹⁰ M. Graziadei, 'Modernisation and Risk Regulation in the Italian Food Sector', in M. Dyson M. (ed.), *Regulating Risk through Private law* (Intersentia, 2018) 347; M. Weimer, L. Marin, 'The Role of Law in Managing the Tension between Risk and Innovation: Introduction to the Special Issue on Regulating New and Emerging Technologies' (2016) 7(3) *European Journal of Risk Regulation* 469.

¹¹ As a matter of fact, for long time, questions concerning the socio-economic, ethical and wider ecological impacts on the technology-including have been excluded as bona fide questions within a strictly risk-based regulatory framework, see S. Jasanoff, 'Commentary: Between risk and precaution – reassessing the future of GM crops' (2000) 3(3) *Journal of Risk Research* 277. Attempts to address uncertainty by reducing the distance between understanding the true degree of risk (scientific fact) and adopting legal measures taken on the basis of assessments that are not strictly scientific can already be found in more recent legislation: for example, with the introduction of dir. no. 350/2018 EU (Commission Directive (EU) 350/2018 amending dir. No. 18/2001 EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms [2018] O.J L67/30), in the part relating to the environmental risk assessment of GMOs "in order to adapt to technical progress and to take into account the experience gained in the environmental risk assessment of genetically modified plants."

¹² U. Kischel, *Comparative Law* (Oxford University Press, 2019); M. Siems, 'New Directions in Comparative Law' in M. Reimann, R. Zimmermann (eds.), *The Oxford Handbook of Comparative Law* (Oxford University Press, 2nd edition, 2019); H. Spamann, 'Empirical Comparative Law' (2015) 11 *Annual Review of Law and Social Science* 131; D. Nelken, 'Comparative Legal Research and Legal Culture: Facts, Approaches, and Values' (2016) 12(1) *Annual Review of Law and Social Science* 45-62 ; A. Riles, 'Comparative Law and Socio-Legal Studies' in M. Reimann, R. Zimmermann, *The Oxford Handbook of Comparative Law* (Oxford University Press, II ed., 2019) 773.

- environment law and consumers' protection law - the paper will individualize some issues in common share, and it prospects a more unified approach¹³.

Findings will lead to express some critical remarks regarding, particularly, the European model. It will also focus on factors that prevent the development of an appropriate regulatory environment in this critical area.

Finally, the comparison will offer some food for thought toward the “suitable ingredients” of a successful regulatory model promoting biotech foods respectful of traditions and vice-versa. These will be some preliminary key attitudes for designing an effective and socially desirable biotech regulation, coherent to balance the EU innovation goal and cultural food policy.

The paper is articulated in three parts: it starts from the reconstruction of the landscape of agri-food biotechnologies (§ 2), shedding light on the variety and diversity of them in light of EU case law (§ 3); the second part is dedicated to the exploration of the main regulatory mechanisms, namely, precautionary principle and substantial equivalence principle underlying the different models (§§ 4-5); the third part, instead, analyzes the different regulations in force in different countries to reflect on the European model, included in the broader framework of objectives expressed by the EU Green Deal¹⁴ and the Farm to Fork strategy¹⁵. This part will

¹³ This remark is in line with the path traced by recent literature: see P. Macnaghten, M.G.L. Habets, 'Breaking the impasse. Towards a forward-looking governance framework for gene-editing with plants' (2020) 2 *Plant People Planet* 353. The article offers a comprehensive view of perspectives and counter-perspectives on the environment and food security effects of technological manipulations.

¹⁴ Commission Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on the European Green Deal [2019], (COM(2019) 640 final).

¹⁵ Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system [2020] (COM/2020/381 final). In brief, the European Green Deal sets out how to make Europe the first climate-neutral continent by 2050. It maps a new, sustainable and inclusive growth strategy to boost the economy, improve people's health and quality of life, care for nature, and leave no one behind. The Farm to Fork Strategy is at the heart of the Green Deal. It addresses comprehensively the challenges of sustainable food systems and recognizes the inextricable links between healthy people, healthy societies and a healthy planet. The strategy is also central to the Commission's agenda to achieve the United Nations' Sustainable Development Goals (SDGs). All citizens and operators across value chains, in the EU

identify contradictory aspects that prevent the predisposition of a coherent and adequate regulation (§§ 6-7). The final purpose will be to investigate which ones are implied in the European current model and would potentially constrain the development of an adequate regulatory regime, letting Europe in stand by position.

2. Law and the variety of innovative agri-food biotechnologies: a matter of classification

As a matter of fact, varietal improvement techniques are numerous and a «failure to distinguish between biotechnology and biotechnology has to often lead to the impoverishment of the debate»¹⁶.

Although in the European regulatory framework it is necessary to navigate between positive and negative definitions of the various biotechnological techniques, traditionally an organism is deemed to be genetically modified where its genetic endowment is altered in a way that cannot be achieved naturally either by multiplication or recombination¹⁷. More precisely, the EU Directive 2001/18 defines a GMO as “*genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*” (art. 2 n. 2 of the Directive)¹⁸.

and elsewhere, should benefit from a just transition, especially in the aftermath of the COVID-19 pandemic and the economic downturn. A shift to a sustainable food system can bring environmental, health and social benefits, offer economic gains and ensure that the recovery from the crisis puts us onto a sustainable path.

¹⁶ J. Kloppenburg, ‘Impeding dispossession, enabling repression: biological open source and the recovery of seed sovereignty’ (2010) 10(3) *Journal Agrarian Change* 381. It has to be noted that in 2017 the Scientific Advise Mechanism (SAM) published the explanatory note title “New Techniques in Agricultural Biotechnology”, 2/2017, where it recognized the heterogeneity among NGTs and the fact that this was reflected in the variety of NGT products.

¹⁷ See in particular Article 2(2) of the *Convention on Biological Diversity*; Article 5(5)(2) of the German Federal Law of 21 March 2003 on Non-Human Gene Technology; and Article L 531-1(2) of the French Environmental Code.

¹⁸ When the pollen stemming from a variety of genetically modified corn loses its capacity of reproduction and is devoid of any capacity to transfer genetic material, it does not constitute a GMO within the meaning of secondary law anymore. See Case C-442/09 *Bablok* [2011] ECR I-7419, para. 62.

Even though this definition is now known to all, it is useful to recall it in order to point out that itself and its extension have become crucial in relation to the evolution of technologies of genetic modification that has led, gradually, to introduce the differentiation between traditional or conventional biotechnology and new biotechnology.

To use the terminology recently adopted in the EGE's Opinion n. 32, the term conventional GMOs will be used to refer to plant GMOs obtained by recombinant DNA technology and characterized by the presence of introduced DNA sequences from the same or other species in the final organism.

We first identified the definition of GMO as it has become a new battleground with the advent of the *new breeding techniques*¹⁹. Genome editing is a group of new directed mutagenesis techniques that facilitate addition, removal, or alteration of DNA sequences at a specific location in the genome.

The identification of DNA alterations from genome editing that are not unique remains, therefore, extremely difficult, as the altered sequences may mimic naturally occurring sequence variants, or they may not be distinguishable from those alterations obtained with conventional mutagenesis.

Like all techniques, also those of mutagenesis have evolved over time: before the adoption of the GMO Directive (dir. n. 18/2001 CE) only traditional methods of mutagenesis applied *in vivo* on whole plants were used. With more recent progress, these techniques have also been used to obtain GMOs.

The main difficulty has been – and still with reference to NBTs – to outline the area of genetically modified organisms, for which Europe has deemed necessary an ad hoc regulation.

The origins of the concerns lies in the controversial nature of the object of the analysis: food or seeds resulting from the application of modern biotechnology. The long European debate on the safety of GMOs, which has occupied the scene since the 1970s, is a paradigmatic example of the way in which scientific information on

¹⁹ On the subject, most recently E. Sirsi, *Note sulla definizione giuridica di OGM e sulle cd New Breeding Techniques*, report given at the Senate 9th Committee (Agriculture and Food Production) Hearing on 7/13/2016, available at: www.senato.it.

safety filter – into the choices made by legislators to shape innovation: on many occasions, scientific uncertainty concerning the dynamics of GMO propagation in the environment, or impacting on allergenicity or biodiversity depletion has led, on the one hand, consumers to identify in the products of progress risks never attested by scientific data; and on the other hand, European legislators to make extensive use of precautionary logic. In the knowledge that not all stages of uncertainty lead to reification of risk, and not all legitimize recourse to the precautionary principle, a more integrated analysis of scientific and legal data could reveal that some products that lead to alarm are in fact not dangerous²⁰.

This appears to be a controversial point even with respect to proposals developed at the international level to standardize the concept of GMOs, biotechnology and new biotechnologies (art. 12 del *Codex alimentarius*; Cartagena Protocol, *etc*).

In the wide spectrum of the plurality of sources intervened to regulate GMO food²¹, the circumstance that the techniques of genetic modification have been employed with reference to the most important *commodities* justifies, in fact, the interest also of the centers of standardization of international importance, and explain the debate that has surrounded the stipulation of some International Treaties²². The most significant normative context at the international level to evaluate the legitimacy, with reference to the rule of world trade, of national regulations is still represented by the SPS (*Sanitary and PhytoSanitary*) and TBT (*Technical Barriers to Trade*) Agreements within the WTO and by the rules of the *Codex alimentarius*.

²⁰ In any case, it is worth remembering that the technique of risk assessment, management and communication (Risk Analysis), developed since the 1970s, is today governed by a body of scientific rules and regulations drawn up by Codex Alimentarius and WHO which, over time, has become increasingly organic and adherent to scientific developments. This was remembered by V. Sberveglieri, A. Pulvirenti, P. Giudici, 'Della valutazione quantitativa ai modelli di previsione dei rischi ignoti' in L. Foffani, A. Doval Pais, D. Castronuovo, *La sicurezza agroalimentare nella prospettiva europea* (Giuffrè, 2014) 4.

²¹ See also E. Sirsi, 'Le regole degli OGM nello spazio globale: un'agenda per i governanti del futuro' (2010) 3 *Riv. dir. agr.* 469.

²² E. Sirsi, *In tema di etichettatura dei prodotti geneticamente modificati* (n. 1) 644.

Consequently, institutional debates on the topic have become commonplace in recent years. In 2017, for example, the Italian Committee for Biosafety, Biotechnology and Life Sciences started a reflection on NBTs in order to foresee possible scenarios and suggest appropriate institutional choices²³. The classification that distinguishes *Conventional Breeding Techniques* (CBT), *Established Techniques of Genetic Modification* (ETGM) from *New Breeding Techniques* (NBT) was adopted. NBTs, in turn, encompass a wide variety of other techniques that are either a refinement of CBTs, or are used in combination with ETGM. The most promising NBTs are those that allow the correction or revision of the genome (so-called *genome editing*) to obtain precise modifications of the DNA sequence, which can vary from point mutations (modification of one or a few nucleotides) to the insertion of genes from scratch. The genome editing process was already possible for several years in an inefficient way. It has been recently greatly improved and has literally exploded in the last five years with the exploitation of RNA-dependent nucleases, typical of the bacterial system CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) and similar systems²⁴.

As already mentioned, genetic modifications induced in organisms through genome editing, although often derived from genetic engineering techniques, are in many cases indistinguishable from those obtained by conventional methods of mutagenesis, or resulting from spontaneous mutations and therefore do not involve greater risks to health and the environment and often involve also undesired mutations (so-called "off target") increasingly documented by the scientific literature.

²³ National Committee for Biosafety, Biotechnology and Life Sciences, *New breeding techniques (NBT): 1- The position of the main Italian stakeholders* (n. 1) 17.7.2017, available at: http://presidenza.governo.it/biotecnologie/documenti/new_breeding_techniques_NBT.pdf

²⁴ It is useful to remember that today the most discussed applications of the CRISPR technique are in the field of human research, aimed at modifying the human genome. It is recent the news of the birth of two Chinese twins born with DNA modified through this technique to produce a mutation on the CCR5 gene and make them more resistant to HIV. See D. Cyranoski, 'Baby gene edits could affect a range of traits. Gene targeted for its role in HIV is linked to increased severity of other infectious diseases — and has implications for learning in mice' (2018) 12.12.2018 *Nature*, available at: <https://www.nature.com/articles/d41586-018-07713-2>.

As we will see later, in the light of recent European documents, the vision of the Bioethics Committee appears to have been revised, since it hoped that each plant variety produced through NBT would be regulated on the basis of the character or characters modified or introduced and in relation to the possible increased risk to health and the environment compared to the risk commonly associated with the plant from which it originates, since «the impact on human health and the environment depends on the genetic makeup of the plant and not on the process by which this genetic makeup was obtained»²⁵.

As it is well known, the questions of definition are not valuable in themselves, but because the main regulatory coordinates applicable depend on them. As detailed below, in Europe, the ad hoc regulation of the production and marketing of food and seed containing GMOs originated in the 1990s²⁶, and consists of stringent legislation to ensure the safety of food and feed for health and the environment; consumers' choice between GMO and conventionally-produced food; and the functioning of the internal market, once authorized. Once classified as such, the authorization of GMOs (which took place at the European level) can be subject to possible restrictions: each Member State can deny the circulation of GMOs within its territory on the basis of requirements other than environmental and health ones without, therefore, having to base its choices on the evaluation of information emerging from risk assessment processes. In general, this legislative choice seems to be informed by the broader and transversal vision introduced with the Europe 2020 strategy, according to which European policies are called to respond to the three parameters of ethical acceptability, sustainability and social desirability²⁷.

²⁵ Comitato nazionale per la Biosicurezza, Biotecnologie e Scienze della Vita, *Le new breeding techniques (NBT)* (n. 1) 7.

²⁶ The first directives are: Council directive no. 90/219/EEC on the contained use of genetically modified micro-organisms [1990] OJ L 117, p. 1-14, and Council directive no. 220/90 EEC on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117, p. 15-27.

²⁷ These are the guiding principles of the process that underpins the so-called *Responsible Research and Innovation*. R. Von Schomberg, 'A vision of responsible innovation', in R. Owen, J. Heintz, J. Bessant, J. Wiley (eds.), *Responsible Innovation* (Wiley, 2013). In any case, member states would be required to justify the compatibility of their *opt-out* measures with EU law and the principles of proportionality and non-discrimination between domestic and non-domestic products.

In any case, once authorized, a GMO, or a product resulting from other biotechnological processes that the legislator decides to equate with it, is subject to a regulatory framework is stratified and complex²⁸. In short, the regulation differs in consideration of the techno-scientific process applied to obtain the product: genetic engineering, on the one hand, and all other technologies (organic chemistry and biology; nanotechnology; synthetic biology etc.) on the other. To the food derived from the first one are dedicated Reg. 1829/2003 EC and 1830/2003 EC (now under revision, following the Commission's Political Guidelines Communication of 15.7.2014²⁹, to extend to GMO food the approach adopted by EU dir. n. 412/2015 on seeds). The second category, on the other hand, is covered by Reg. 2283/2015 of the European Parliament and of the Council of 25.11.2015 on novel foods, or novel foods, which replaces the previous Reg. 258/97³⁰. GMO cultivations, on the other hand, are the focus of Dir. 18/2001 EC considered "horizontal" legislation due to the fact that the requirements applicable to marketing apply to all GMOs outside of those covered by the sectoral framework³¹.

²⁸ A first reconstruction is offered by M. Ferrari, U. Izzo, *Diritto alimentare comparato* (Il Mulino, 2012) 167. For a summary of food legislation in European Union law and international treaties, see F. Casucci, P. Saccomanno, 'Il diritto agroalimentare' in GA. Benacchio, F. Casucci (eds), *Temie istituti di diritto privato dell'Unione europea* (Giappichelli, 2017) 69.

²⁹ Commission Communication (EU) 1286/2014 on Guidelines on the application of Regulation of the European Parliament and of the Council on key information documents for packaged retail and insurance-based investment products [2017] OJ C 218, p. 11-14.

³⁰ *Novel foods* is an expression referring to any food or ingredient that was not consumed to a significant degree within the European Union until May 15, 1997. In the list of *Novel foods* we find all those products or ingredients made from microorganisms, fungi and algae, plants, animals or parts thereof (including insects), foods with new or modified molecular structure or resulting from a new production process or made from engineered nanomaterials, and finally vitamins, minerals and other substances not used before the entry into force of the new regulation (GMO foods are excluded when and to the extent that they are used as food enzymes, food additives and flavorings and extraction solvents). With the entry into force of the new European Parliament Regulation (EU) 2015/2283 of the European Parliament and of the Council No 1169/2011 on novel foods, amending Regulation of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2018] OJ L 327/2015. It fully repeals the old regulation, a special Union List of authorized novel foods has been established; 90 new foods have been approved within our market; and a more streamlined and faster approval process, reducing the waiting time from when you send your request to when you get an approval response.

³¹ N. De Sadeleer (n. 2) 221.

Depending on the framework, of course, different procedures for approval, authorization, labeling, traceability and marketing of food are derived.

The EU policy on GMOs is inclusive as it copes with the development of GMOs, the progressive release into the environment, the general cultivation and seed production, marketing, labelling, enforcement and the entire agro-food chain, from bottom up to the final consumption by humans and animals.

In 2011, upon request of DG SANTE, the Joint Research Center reviewed the state-of-the-art of some of the emerging new plant breeding technologies, their level of development and adoption by the breeding sector and the prospects for a future commercialization of plants created by these techniques. Additionally, with support of several experts, the challenges for the detection of organisms developed through these techniques were evaluated.

But the most disputed phase of the debates regarding the regulatory framework of NBTs arose following the interpretative ruling of the European Court of Justice C-528/16 of July 25, 2018 to which we refer in the next paragraph for a more extensive discussion.

3. European trajectories in the regulation of the agri-food biotechnologies after the CJEU C- 528/16 judgement

Crucial intervention in the regulation of emerging biotechnologies took place when the Court of Justice of the European Union ruled on the interpretative question regarding the classification of organisms obtained through the new techniques of mutagenesis: it ruled that organisms obtained by new mutagenesis techniques in contrast to conventional mutagenesis techniques "that have conventionally been used in a number of applications and have a long safety record", are not exempted from the GMO legislation³².

³² For a more detailed analysis of the CJEU decision see G. Guerra, 'Sul rapporto sicurezza - innovazione nel diritto agroalimentare europeo: tra «elefanti nella stanza» e «tigri di carta»' (2019) 2(II) *Nuova giur. civ. comm.* 394.

In summary, the Court had been said of the matter following an appeal by the French *Conseil d'État*³³, brought by the transalpine agricultural union (the Confédération paysanne) and eight other plaintiff associations against national legislation (Article D 531-1 French Environment Code) exempting organisms obtained by mutagenesis (rapeseed varieties) from the obligations imposed by the European directive on GMOs.

According to the remarks of the French referring court, these techniques would entail risks similar to those associated with transgenesis and would allow an acceleration of modifications of the genetic heritage incomparable to modifications occurring naturally or by chance: this would lead to a multiplication of the probability of damage resulting from unintentional modifications of the genome and inherent to the properties of the obtained plant.

The Court's interpretation is based on a careful reconstruction of the systematic structure of the directive itself, which, however, only confirms, once again, the practical incidence of the assessment of the technological process (some mutagenesis techniques examined involve the use of chemical or physical mutagenic agents; others involve the use of genetic engineering) despite the conclusions of the Advocate General leaning towards the adoption of a product-based framework³⁴.

The same judges clarify that Annexes I A, part 2, and I B of Dir. n. 18/2001 EC indicate which techniques are not considered to be genetic modification, and it is relevant to note that these annexes are excluded from the revision for adaptation to technical progress, as they are not among the essential elements ex art. 27 Dir. n. 18/2001 EC. In other words, the notion of GMO has never been revised, despite the requests of biotech companies and the work of the European group which was established *ad hoc*.

The definition of GMOs under Article 2(2) of the Directive includes both techniques whose use involves a genetic modification and techniques which do not. In letter a) of the same provision it is established that a genetic modification is

³³ The French Conseil d'Etat referred the question of interpretation to the Court of Justice for a preliminary ruling in the following case. Conseil d'État, 3ème-8ème *chambres réunies*, 3.10.2016, n. 388649, published on *recueil Lebon*.

³⁴ Opinion of the Advocate General (Michal Bobek) delivered on 18.1.2018.

obtained at least through the use of the techniques listed in Annex I A, part 1, which does not expressly cover those of mutagenesis.

Notwithstanding, the possible inclusion of NBTs in Annex I A, part 1, is not to be overruled, as the list is not exhaustive. In summary, we can infer that the combined provisions of art. 2, paragraph 2, letter b), Dir. No 18/2001 EC and Annex IA, Part 2, mutagenesis is not included among the techniques that do not involve genetic modification. On the contrary, it is expressly mentioned among the techniques involving genetic mutation, in the list of the Annex dedicated to the organisms to be excluded from the scope of the Directive (Annex IB and art. 3.1).

In order to unravel the knot, the Court proposed a re-reading of the provisions in light of the context and purpose of the legislation: the general formulation of mutagenesis does not provide sufficient guidance as to the specific types and methods of mutagenesis that the legislature intended to exclude from the application of the directive. And it is precisely in view of the context that the Court makes one of the central findings³⁵: the Directive does not cover organisms obtained through certain genetic modification techniques used "conventionally" in various applications with a "long tradition of safety." In many countries, for example, maize produced by conventional techniques of mutagenesis does not fall within the scope of the legislation on GMOs. The latter, therefore, applies in principle only to mutagenesis techniques involving modification of genetic material according to methods developed after the adoption of the directive, whose risks could be similar to those resulting from the production and dissemination of GMOs through transgenesis³⁶.

However, although characterized by a long tradition of safety, even conventional mutagenesis techniques could be subject, by virtue of the decentralization of choices in the field, to the same obligations provided for GMOs, since States are free to adopt measures to subject them to the obligations provided for GMOs, in compliance with European rules protecting the free movement of goods (ex articles 34 to 36 TFEU).

³⁵ See paragraph 31 of the Court of Justice. Case C-535/15, *Pinckernelle* [2017] available at www.curia.europa.eu.

³⁶ Thus, noted in paragraph 48 of the judgment under review.

The interpretative solution of the Court has provoked various reactions. The accredited scientific literature has from the outset expressed many doubts, since the judges, thus establishing, subject the "results" of the NBT to onerous pre-market evaluation tests in the absence of scientific evidence to outline the hypotheses of dangers, identifying, instead, as the only danger that of concretely preventing Europe from being able to easily disseminate technologies that contribute decisively to the problem of food security and positive impact on the environment³⁷.

The consequences of the Luxembourg decision are different. The "frozen" interpretation of the Court of Justice, according to which, by invoking the precautionary principle, only those safe (conventional) techniques that were regularly used at the time of the adoption of the GMO directive, fall under the exemption of mutagenesis, leaving unaffected the possibility of prohibiting them on the basis of the operation of the opt-out clause, does not contribute to a solution.

After all, the operational solution - conducted on the basis of traditions, and many other elements related to social change and national cultures - may, in other words, lead to interpret the declaratory rule in a dissociated way from what science indicates about the real degree of uncertainty that characterizes the level of risk to health and the environment inherent in biotechnology.

The decentralization of the choices regarding the authorization of products derived from genetic engineering could, consequently, lead to submit to the onerous procedures of evaluation and authorization provided for GMOs even those techniques of varietal improvement, considered safe by the scientific literature.

³⁷ In Europe, the EPSO documents are fundamental guidelines: the *European Plant Science Organisation* bringing together 28.000 European Scientists (available at: <http://www.epsoweb.org/file/2038>); and EASAC documents (available at: http://www.easac.eu/fileadmin/PDF_s/reports_statements/Easac_14_NBT.pdf). See also the European Plant Science Organization (EPSO) document On the ECJ Ruling regarding mutagenesis and the Genetically Modified Organisms Directive, Brussels, 26.7.2018 (available at www.epsoweb.org). With this document the EPSO had already expressed the scientific evidence about the advantages and strengths of NPBTs in the paper *Crop Genetic Improvement Technologies*, Brussels, 26.2.2015 (with updates of 18.12.2015 and 12.1.2017), available on the same website. Opinions from many other scientific organizations follow the same direction. For a reconstruction, please refer to the paper of the *National Committee for Biosafety, Biotechnology and Life Sciences, The New Breeding Techniques* (NBT) (n. 1).

What should be carefully considered here are the developments of the debate in the post-judgment phase.

In October 2018, the Joint Research Centre was entrusted with the mandate on behalf of the EU Commission (DG Sante) to work out the implications of this ruling in order to identify such organisms. The document addresses issues concerning the new analytical challenges for the detection, identification and quantification of genome-edited food and feed products of plant origin³⁸, considering the compliance with the GM food and feed legislation, including the prerequisites for method validation as part of the GMO authorization procedures, and to the Official Controls Regulation provisions on the routine testing of food and feed by the enforcement laboratories.

Furthermore, in November 2019, the Council of the European Union requested the Commission in Decision 2019/1904³⁹ to submit, by April 30, 2021, "a study in light of the judgment of the Court of Justice in Case C-528/16 concerning the status of new genomic techniques in Union law." First, based on this study, it is important to emphasize the distinction based on time limits the importance NGTs are defined as techniques that can modify the genetic material of an organism and that have emerged or have been developed since 2001, when the current GMO legislation was adopted.

³⁸ European Network of GMO Laboratories (JRC - EU Commission), Detection of food and feed plant products obtained by new mutagenesis techniques, Report endorsed by the ENGL Steering Committee [March, 2019].

³⁹ Council Decision (EU) 2019/1904 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study [2019]. The expected study would have dealt with: (a) a state-of-play on the implementation and enforcement of the GMO legislation, as regards NGTs, based on 1) contributions from targeted consultations of the Member States and stakeholders (to consult the consultation procedure see: https://ec.europa.eu/food/plant/gmo/modern_biotech/stakeholder-consultation_en); 2) work of the European Union Reference Laboratory, together with the European Network of GMO Laboratories, on the detection of products obtained by new mutagenesis techniques (<https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf>); (b) information on the status and use of NGTs in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications. Moreover, an overview on the risk assessment of plants developed through new genomic techniques, prepared by the European Food Safety Authority (EFSA, <https://www.efsa.europa.eu/en>), based on its own previous and ongoing work and on work carried out at national level.

Finally, the response came last April, 29, when the EU Commission published the staff working document's about the *Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16* (from now on: the Study)⁴⁰. In sum, the study confirms that organisms obtained through new genomic techniques are subject to the GMO legislation. However developments in biotechnology, combined with a lack of definitions or the ones that resulted unclear are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty⁴¹. Consequently, the current regulatory system involves implementation and enforcement challenges in the EU for NGT and also underlined the need for flexibility and proportionality in the related risk assessment.

What is also relevant it is the fact that the study recognized the synergic role of the analysis of the ethical and societal implications of gene editing that is being developed by the European Group on Ethics in Science and New Technologies⁴². This is due to the fact that based on the findings of the Study most of the ethical concerns raised relate to how these techniques are used, rather than the techniques themselves.

The Opinion's area-specific analyses are complemented by overarching considerations on long-debated questions revived by genome editing, notably about

⁴⁰ Commission Staff Working Document (EU Commission) Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, Brussels, [2021] 92 final, available at: https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf.

⁴¹ Idem, p. 2 of the document.

⁴² The European Commission requested the EGE to submit an Opinion and recommendations on genome editing, thereby following up on the EGE's Statement on Gene Editing, issued in January 2016 (EGE, 2016, Statement on Gene Editing, https://ec.europa.eu/info/publications/egestatements_en). On March 19, 2021 the European Group on Ethics in Science and Technologies published its Opinion on the ethics of genome editing analysing ethical questions raised by the application of genome editing in humans, animals and plants, and hence spans health, research, agriculture and environmental aspects. The EGE is calling for a wide-ranging and inclusive societal debate on genome editing, for efforts towards joint monitoring and learning with regard to both regulatory and scientific developments, and for international engagement towards global governance. This will be functional to examine how specifically the EU can and should shape governance and policies for genome editing. The Opinion aims at examining how specifically the EU can and should shape governance and policies for genome editing. More information available at: https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/eg_eu#latest.

the different meanings that ought to be attributed to humanness, naturalness and diversity.

EGE is invoking a wide-ranging and inclusive societal debate on genome editing, for initiatives towards shared team monitoring and learning pertaining to both regulatory and scientific developments, and for international engagement towards global governance.

The combined reading of all these documents is the clearest sign of a change of approach in the regulation of the new agri-food biotechnologies where the risk assessment and the preparation of regulatory response models are at the crossroads of a multiplicity of disciplinary contributions (scientific, sociological, etc..) that affect the development of the notion of risk⁴³.

As «public perception of new technologies is key to their market uptake»⁴⁴, it is now a given that the acceptance of a technology is also determined by the perception of its potential benefits: most people question the need and usefulness of precision agri-food biotechnologies⁴⁵.

To capture the impact of the perception of the social datum of risk in regulatory choices, an important contribution is offered by the economic analysis of law. In the report "On Mandatory Labeling, with Special Reference to Genetically Modified Foods"⁴⁶, the authoritative American jurist Cass Sunstein analyzed, through the lens

⁴³ The relationship scientific information-legal rule-consumer trust is conditioned by the impact of many factors that must be understood and included from the beginning in regulatory processes. The impact of the social perception of risk, for example, is a fact that the European legislator is increasingly taking into account in the choice of regulatory techniques used: more and more legislative procedures are inspired by participatory and inclusive processes of different actors, such as consumers, from the earliest stages of preparing the relevant legal documentation.

⁴⁴ Page 4 of the Study.

⁴⁵ A. Ronteltap, J.C.M. van Trijp, R. J. Renes, L. J. Frewer, 'Consumer Acceptance of Technology-based food innovations: lessons for future of nutrigenomics' (2007) 49 *Appetite* 1; P. Slovic, 'Perception of Risk' (1987) 236 *Science* 280.

⁴⁶ C. Sunstein, *On Mandatory Labeling with Special Reference to Genetically Modified Foods*, Report del 9.10.2016.

of this discipline, the obligation introduced in the USA - with the federal *GMO Labeling law* of 29.7.2016 - to indicate on the label the presence of GMOs⁴⁷.

The report starts from the observation of the absence of reliable scientific data to attest to the risks inherent in GMOs⁴⁸, and asks when governments should introduce mandatory information content and when mandatory information has desirable consequences for social welfare, as well as how to measure these effects. Another important issue raised by the report questions the right of the consumer to know the ingredients for the sole purpose of making food choices aimed at fulfilling his or her personality (benefit): in particular, it asks whether it is sufficient to justify additional precautionary measures, i.e. ad hoc labels (cost), even in the absence of scientific evidence about the risk of health damage related to GMOs. Sunstein notes that based on the data obtained from the interviews, mandatory labeling for GMOs was introduced "because members (i) demanded it without really being interested; and (ii) believing that GMOs are dangerous not based on existing scientific data"⁴⁹.

Understanding, then, the impact of the socio-demographic factor on the acceptance of new technologies is a key factor for policymakers to formulate meaningful government proposals, particularly in Europe, where options vary widely depending on the member state considered. In the collective imagination, for example, European consumers tend to be *risk-averse*⁵⁰. Despite the efforts of public

⁴⁷ *National Bioengineered Food Disclosure Standard*, Pub. L. No. 114-216 (2016) (codified at 7 U.S.C. § 1621 et seq. (2016)).

⁴⁸ Given that the scenario excludes irreversible and catastrophic damage from Gmos, the precautionary approach through *labels* or restrictions would be appropriate. The report notes that: «*the force of this response depends on the science: if there is a small or uncertain risk of serious harm, precautions may indeed be justified. If the risk is essentially zero, as many scientists have concluded, then precautions are difficult to justify. The discussion, though focused on GM foods, has implications for disclosure policies in general, which often raise difficult questions about hard-to-quantify benefits, the proper use of cost-benefit balancing, and the appropriate role of precautionary thinking*».

⁴⁹ Report, 5.

⁵⁰ The data indicating this attitude are given by Eurobarometer, *Europeans' attitudes towards animal cloning, analytical report. Survey requested by Directorate General Health and Consumers and coordinated by Directorate General Communication (European Commission)*, in *Flash eurobarometer*, Vol. 238, Brussels, The Gallup Organization, October 2008. However, authoritative American doctrine holds that European consumers would no longer be averse to the risk of American consumers, see C. Sunstein, *Il diritto della paura: oltre il principio di precauzione* (Il Mulino, 2010) 26.

authorities to increase their level of confidence in food safety, some new technologies - regardless of their potential benefits - have less uptake in society for this very reason.

This is why, according to what the EGE observed, ethical and moral concerns are more frequent and vary according to the geopolitical context and the background of the citizen, all of which undermine the solution that has been opted for years, concerning the identification of the threshold of safety (*safe enough*). Writes the panel:

«debates about genome editing often focus on the question about the conditions that would render it 'safe enough' for application. The Opinion draws attention to the importance of nuancing and resisting this framing, as it purports that it is enough for a given overall level of safety to be reached in order for a technology to be rolled out unhindered, and it limits reflections on ethics and governance to considerations about safety. Much to the contrary, ethics should serve to tackle broad governance questions about how technologies can serve our common goals and values, and not be limited to providing a 'last step' of 'ethics clearing' of a technology»⁵¹.

Understanding consumers' perceptions of risks and benefits, also based on socio-demographic and cultural data, is therefore a crucial step for the success of technoscientific progress⁵². These considerations are of fundamental importance as they will also influence the way of considering and regulating the institutions of agri-food law in general, for example, the fact that scientific information alone about agri-food technologies does not, therefore, automatically lead the consumer to the acceptance of technological risk⁵³.

The still uncertain framework in search of a solution at the European level reverberates at the national level. Member States made a variety of comments in relation to NGTs and established GMO techniques. They highlighted current problems in the GMO legislation and/or argued that it is obsolete, and called on the

⁵¹ European Group on Ethics in Science and New Technologies (EU Commission), *Opinion on Ethics of Genome Editing*, Opinion (n. 8).

⁵² L.J. Frewer, C. Howard, J.I. Aaron, 'Consumer Acceptance of transgenic crops' (1998) 52 *Pesticide Science* 388.

⁵³ C.M. Bruhn, 'Consumer acceptance of food innovations' (2008) 10(1) *Innovation: Management, Policy & Practice* 91.

Commission to clarify and/or define terminology and to clarify the legal status of NGTs in the current framework. The Study reported that most of the Member States highlighted the need to develop detection methods for NGTs integrating sustainability criteria⁵⁴.

Last January four decrees (nn. 208, 209, 211 e 212)⁵⁵ on issues ranging from Nbt to the marketing of seeds were discussed at the Italian Agriculture Commission of the House. Legislative decrees on which the Senate Agriculture Committee already expressed positive feedback last December. The Agriculture Committee of the House has slowed down the push to introduce New Breeding Techniques in Italian fields. It did so by approving the opinion schemes on the four legislative decrees with reservations⁵⁶.

Equally significant are the initiatives undertaken by the British government, among the first in the post-Brexit period. The Department for Environment Food and Rural Affairs has recently launched a consultation on gene editing that confirms the openness towards this type of technology in agriculture, and expresses concern about possible issues of "access to the EU market and compliance with the EU regulatory system", if the EU opts instead for a more restrictive regime⁵⁷.

⁵⁴ See page 49 of the Study document.

⁵⁵ The Italian decrees are available at: https://www.camera.it/leg18/99?shadow_organo_parlamentare=2813

⁵⁶ In other countries too, uncertainties remain. The French government is also considering how to respond to a ruling by the country's top administrative court requiring it to change its mutagenesis regulations in line with the EU court's decision, as France is the EU's largest agricultural producer and among EU members to have banned cultivation of GMO crops. England's farming minister announced earlier this month a public consultation on gene editing in agriculture, saying Britain's exit from the EU allowed it to set its own rules.

⁵⁷ Currently GMOs are defined in section 106 of the Environmental Protection Act 1990 as amended by Regulation 4 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2002/2443); techniques of GM are described in regulation 5.

According to the results of the consultation, the Department may change the legislation to amend the definition of a GMO as it applies in England during the post- Brexit period⁵⁸.

4. The main regulatory models and their foundational principles: (a) the substantial equivalence...

The increasingly transnational nature of agri-food issues implies the interest in the regulatory solutions adopted by different countries in order to classify modern biotechnologies⁵⁹. On the one hand, it is interesting to understand the different ways in which legal systems balance technological and scientific progress and safety; on the other hand, this is useful to assess the impact of an uneven legislative framework in the dynamics of transnational trade in seeds and food derived from these techniques.

The models of *governance* and regulation of genomics-related matters vary, therefore, depending on the geopolitical contexts, and for what has been said before it should be borne in mind that the *risk analysis* in countries with different socio-sanitary realities has imposed inevitably different definitions of risk on the basis of the social and political perception of the same⁶⁰. Each of these different socio-

⁵⁸ Cfr. Consultation procedure is available at: <https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/>. The consultation, confirmed by the UK Environment Secretary George Eustice at the Oxford Farming Conference on Wednesday (7 January), will focus on preventing gene-editing (GE) organisms from being regulated in the same way as genetically modified (GM) crops, according to a statement released by the UK government.

⁵⁹ It is meaningful that the Commission staff's working document on the status of new genomic techniques (see footnote 39) confirms that notwithstanding the considerable interest in EU, the most of the development is taking place outside the EU (page 2 of the document).

⁶⁰ See V. Sberveglieri, A. Pulvirenti, P. Giudici, 'Della valutazione quantitativa ai modelli di previsione dei rischi ignoti' L. Foffani, A. Doval Pais, D. Castronuovo, *La sicurezza agroalimentare nella prospettiva europea* (Giuffrè, 2014) 3. It has to be noted that «the regulation of GM crops has been challenges as inadequate, even biased, and in some settings as Brazil, India, and Mexico the planting of certain GM crops has been at times suspended, while in other regions, such as Europe, governing bodies have struggled to resolve the dilemma of how to stimulate the development of biotechnological innovation for the benefit of the economy and the environment while maintaining public legitimacy» (P. Macnaghten, M.G.L. Habets (n. 13).

technological contexts affects the nature of the activities which are regulated as well as the content of the regulations that are enacted⁶¹.

The different policy options depend, in fact, on the historical background of the central notions of environment and health, but also on the role that the legal systems attribute to the subjects entitled to perform a risk assessment with characteristics of third party, as well as the data that should be used and the way in which they should be collected. All of this influences the substantial differences in the *policies* of the different legal systems on biotechnology.

Accepting a good degree of simplification, one can distinguish three approaches circulating in the member states and non-European states: (i) the one based on the discipline of the techno-scientific process used to obtain the product; (ii) the one focused on the final product; and (iii) the one based on the prior request for assessment and definition of the discipline applicable to the competent authority⁶².

⁶¹ On this point see an interesting paper that develops a comparative framework for biotechnology policy analysis and applies this framework to help understand the evolution and differences in the regulatory regimes related to agri-food genomic innovations found in six countries (Italy, Spain, Australia, New Zealand, Canada and the US). Findings show that these governments have fostered different types of regulatory regimes over the last quarter century that are closely connected with the manner in which governments have pursued either promotional or precautionary orientations towards new technologies; and second whether regulatory policy-making has been driven by state or public actors and interest. See M. Howlett, A. Migone, 'Explaining local variation in agri-food biotechnology policies: "green" genomics regulation in comparative perspective' (2010) 37(10) *Science and Public Policy*, 781-792.

⁶² In the workshop organized by the Institute for Prospective Technological Studies (IPTS) in 2011, the different approaches used were compared, inviting representatives from Argentina, Australia, Canada, the European Union, Japan and South Africa. Countries where GMO crops are very widespread have initiated a phase of involvement of scientific experts for the assessment of the comparability of GMO-NBT products. The results have led to identify which mutagenicity specifications lead to products similar to those obtained with transgenesis, and which are not, and these situations are transposed in the *Gene Technology Act* of 2000 (Act No. 169 of 2000) and in the Gene Technology Regulations 2001 (Australian Government, Department of Health, Office of the Gene Technology Regulator, Gene Technology Regulations 2001 (made under Gene Technology Act), as amended on 16 July 2016, available at <https://www.legislation.gov.au/Details/F2016C00615>). Other orders, on the other hand, introduce a mixed system between the two models, or with some peculiarities: the Japanese system, for example, follows the American model based on the regulation of the product and the logic of substantial equivalence, which, however, is intended to qualify the comparator product which already exists on the market, and not to introduce a presumption of safety. The existence of a similar product on the market does not, in fact, prevent the analysis of further scientific data that

In brief, the regulatory models adopted by the various countries differ in relation to: the choice of administrative or legislative approach; the legislative technique employed (general or specific rules); the option for «product» or technological «process» regulation. The main contrast remains between the preventive-precautionary approach and that based, instead, predominantly on post-market risk management tools, such as controls and sanctions, which is promotional.

This last distinction is significant⁶³, mostly from a historical perspective, since even in light of the considerations made in the *Study*, the debate should focus on the definition of ad hoc *risk assessment* systems that are attentive not only to the type of technology employed, but above all to its specific uses.

Essentially, it is exemplified in two experiences: the European experience, historically developed around the idea of process, and the North American and Canadian experience for which the decisive criterion is the end-product rather than the manufacturing process of foods, and consequently the process according to which a food was produced is irrelevant⁶⁴.

These models are based on two different principles: the exquisitely European principle of precaution, and the North American principle of substantial equivalence.

could lead to a ban on GMO products (in 2003 the Japanese government signed the Cartagena Protocol on Biosafety, introducing the law of 19.2.2004). Possible exceptions for organisms obtained from cloning. Some non-eu countries determine the legal status of NBT by a case by case pre-submission consultation (see more information in the *Study*, page 24 of the document). Among the different countries that follow the European model, there is that of South Africa, which, with the *Genetically Modified Organisms Act* (G 18029) meets as many similar defining problems (*Government Gazette*, Vol. 383, No. 18029, 23 May 1997).

⁶³ Cfr. M. Lusser, E. Rodríguez Cerezo, ‘Comparative regulatory approaches for new plant breeding techniques. Workshop proceedings (European Commission, JRC Technical Report EUR 25237 EN, 2012)’ (2013) 30(5) *New Biotechnology*, 10.

⁶⁴ For a preliminary discussion of the distinction process-based and product-based approaches and its weakness see M. Ferrari, U. Izzo (n. 28); and also M. Ferrari, ‘Sicurezza alimentare e nuovi prodotti alimentari’, in G. Guerra, A. Muratorio, D. Ruggiu (eds), *La biologia sintetica in questione: una prima analisi giuridica* (Notizie Di Politeia, 2014) 89.

Due to the importance of this different source of inspiration, I will dedicate a brief consideration of each one starting from the substantial equivalence and dedicating the following paragraph to precaution (see § 5).

Substantial correspondence was designed in the 1990s as a risk assessment method. The principle emerged at an international level and was thereafter applied at a national level: the Organization for Economic Co-operation and Development (OECD) wanted to develop a risk assessment method that would liberalize trade in biotech products and incentivize regulatory harmonization⁶⁵. It was then adopted by the OECD and other international organizations. A determination of substantial equivalence between biotech and conventional foods minimizes the regulatory obstacles at an international level by standardizing the risk assessment parameters throughout countries.

The principle is rooted in American policy on the subject, which has been favorable to biotech development since the 1980s. In fact, the first *Coordinated Framework for the Regulation of Biotechnology* published by the *Office of Science and Technology Policy*⁶⁶, then updated in 2017 by the *National Strategy for Modernizing the Regulatory System for Biotechnology Products* which provides guidelines to the three authorities responsible for regulating food safety⁶⁷: *Food and Drug Administration* (FDA); *US Department of Agriculture* (USDA); and *Environmental Protection Agency* (EPA)⁶⁸ dates back to that period.

⁶⁵ See OECD, *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles* (OECD, 1993), p.14. The concept was first used in a US document. See FDA, *Statement of Policy: Foods Derived from New Plant Varieties* (1992) 57 Fed. Reg. 22984.

⁶⁶ Executive Office of the President, Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 FR 23302, at 23302-23303 (June 26, 1986), available at: http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

⁶⁷ The document *Modernizing the Regulatory System for Biotechnology Products* is available at: https://docs.wixstatic.com/ugd/ea7add_3e720bb3bd954da79ee611885d68ea91.pdf. See also the *National Strategy for Modernizing the Regulatory System for Biotechnology Products, Products of the emerging Technologies Interagency Policy Coordination Committee's Biotechnology Working Group*, 2016.

⁶⁸ The institutional architecture in this area is notoriously fragmented compared to the European one due to the different distribution of competences: while in the American system the functions of *risk assessment* and *risk management* are the responsibility of the same Authority, or Agencies, which are in turn competent for different subjects assigned to each of them.

The basic approach was to consider the current already operational regulations on health and safety protection as sufficiently appropriate⁶⁹, as they were certain and immediate for companies pertain to the hypothetical introduction of a new *ad hoc* law. In product-based model⁷⁰, there is no specific regulation dedicated to plants and food resulting from the use of biotechnology: these products are presumed to be substantially equal to traditional ones, in the absence of evidence to the contrary.

As regards the object whose safety is assessed, the final characteristics of the new product are compared with the presumed equivalent product already on the market, on the basis of the validity procedures of the scientific community⁷¹.

If substantial equivalence is present between two foods, no further premarket authorization or specific labeling is required for biotech foods⁷². Substantial equivalence, as a scientific concept, consists of two elements. First, substantial equivalence is based on an assumption of risk equivalence between biotech and conventional foods. The goal is not to establish an absolute level of safety, but to ensure with "reasonable certainty" that no harm to public health or the environment will result from novel foods. The reasoning is that modern biotechnology does not automatically produce foods that are "less safe than those developed using conventional techniques." In other words, biotech foods are not risk-free; they simply pose the same kinds of human health and food safety risks as conventional foods. Substantial equivalence involves a comparative analysis between biotech and conventional foods. One compares the chemical composition between the biotech and conventional food, as well as molecular, agronomic, and morphological

⁶⁹ G. Fernández Albújar, B. van der Meulen, *The Legal GMO Concept Reassessment of the GMO definition in the light of new breeding techniques (NBTs)* (n. 1)

⁷⁰ See *amplius* M. Ferrari, U. Izzo (n. 28) 191.

⁷¹ The FDA proceeds to a *pre-market approval* only when the new food differs substantially from the traditional one regarding its composition, structure or function. This can happen, for example, when novel food offers features normally not present in the traditional product that can trigger allergic reactions or other disorders. In the case of *novel foods* it often happens that the food has characters that are not present in its natural or traditional equivalent, it will have to be considered adulterated according to the *Food, Drug and Cosmetic Act (FDCA)*, 1992

⁷² See Food and Agriculture Organization (FAO), World Health Organization (WHO), *Expert Consultation on Biotechnology and Food Safety* (FAO/WHO, 1996); and FAO/WHO, *Expert Consultation on Foods derived from Biotechnology* (FAO/WHO, 2000).

characteristics, and nutritional (or anti-nutritional) components. In the early 2000s, the concept was further refined by the 2000 FAO/WHO Joint Expert Consultation on Foods Derived from Biotechnology. The goal is to determine whether the biotech food presents new or increased risks compared to its conventional counterpart, without affecting the health or nutritional status of consumers. The framework for this element of substantive equivalence benchmarking is more neutral and does not favor biotech foods. The FAO and WHO have also confirmed that substantial equivalence is "the most practical approach to address safety assessment" of biotech foods⁷³. It is part of the safety assessment of biotech foods and this assessment is framed as a positive scientific approach that favors these types of foods. However, it seems bizarre to assume that a new type of food should be considered as safe as a traditional food that would have been consumed within the last few hundred or thousand years. A related principle to that of substantial equivalence and crucial in the evaluation is based on the notion of GRAS, which is *generally recognized as safe*⁷⁴. According to the *Code of Federal Regulations*, a substance is generally recognized as safe based on the assessment of qualified experts and experience in evaluating the safety of substances directly or indirectly added to food. These evaluations are based on risk assessment processes or, in the case of substances used in foods prior to 1958, on data already available on the consumption of those foods, and food additives that are considered generally safe should not be subjected to pre-market approval. This principle is rooted in American policy on the subject, which has been favorable to biotech development since the 1980s, when the first Coordinated Framework for the Regulation of Biotechnology, published by the Office of Science and Technology Policy was published⁷⁵.

⁷³ FAO/WHO, *Expert Consultation on Biotechnology and Food Safety* (1996), p. 4 of the document.

⁷⁴ Based on the rule *Generally Recognized As Safe (GRAS)* expressed in the *Code of Federal Regulations* (part. 182), available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfjfr/CFRSearch.cfm?CFRPart=182>.

⁷⁵ About the Coordinated Framework for the Regulation of Biotechnology available at: <https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about/about>. It was updated in 2017 by the National Strategy for Modernizing the Regulatory System for Biotechnology Products, which provides guidelines to the three authorities responsible for regulating food safety.

On the whole, not only is substantial equivalence a scientific assessment but it is also strategic throughout the regulatory phase of biotech food regulation. If biotech foods are substantially correspondent to conventional foods, they are regulated likewise conventional foods. Substantial equivalence is a sort of tool for defining those new foods that do not bring up special intensive safety issues⁷⁶.

Turning back to the specific problem, the issue of the legal treatment of NBTs has been addressed in American law by the *United States Department of Agriculture* (USDA)⁷⁷ pertaining to the problem of threats to the ecosystem due to weeds. Many transgenic plants are obtained through the introduction, in a plant, of a gene derived from a weed. When this happens, the plant falls under the regulation of the USDA under the *Plant Protection Act* dedicated to import, trade and environmental protection against pesticides⁷⁸. If a plant does not fall under the Act, then trials can be conducted without the need for a notification process. The USDA, in other words, encourages innovation in the absence of risk⁷⁹.

In any case, depending on the nature and the use to which it is destined, the plant may also be subject to the controls foreseen by other Authorities, such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).

Some "slowdowns" may occur as a result of these Departments or Agencies. The FDA could establish its own guidelines regarding the health risks of using genetically modified corn, or regarding the use of gene editing in animals. The latter

⁷⁶ H. Miller, 'Substantial Equivalence: its Uses and Abuses' (1999) 17 *Nature Biotechnology* 1042.

⁷⁷ USDA, http://www.aphis.usda.gov/biotechnology/reg_loi.shtml.

⁷⁸ *The Plant Protection Act* (PPA part of Pub.L. 106-224) is a federal law enacted on 20 June 2000. The provisions are currently codified in 7 USCS §§ 7701 et seq.

⁷⁹ The Director of the USDA said: «*USDA seeks to allow innovation when there is no risk present. At the same time, I want to be clear to consumers that we will not be stepping away from our regulatory responsibilities. While these (plant breeding innovation) crops do not require regulatory oversight, we do have an important role to play in protecting plant health by evaluating products developed using modern biotechnology. This is a role USDA has played for more than 30 years, and one I will continue to take very seriously, as we work to modernize our technology-focused regulations.*». It was reported in the *National Grain and Feed Association* del 29.3.2018, available at: <https://www.ngfa.org/newsletter/usda-issues-statement-regulation-innovative-plant-breeding-techniques-ngfa-issues-response/>.

application is classified by the FDA as a form of gene therapy, regulated as a veterinary drug, which is subject to an onerous approval process for new drugs⁸⁰.

5....(continued) the precautionary logic

In line with the prominent and contexted role of the Precautionary principle in EU law, the precautionary logic has manifested itself over time in various ways in EU food system⁸¹.

In fact, it can be noted that restrictive policies on GMOs have been pursued by the European Union through different types of legal instruments: the recourse to the mechanism of notification in the presence of harmonization measures pursuant to art. 114, § 5, TFEU; the request for authorization to introduce a ban on the use of genetically modified seed varieties listed in the common catalog; the invocation of the safeguard clause pursuant to art. 114, § 10, TFEU, the application of the principle of coexistence⁸².

Among these, the safeguard clauses have represented the most significant legal instruments, wanted by the EU legislator to allow individual member states to derogate from European legislation and to maintain in force and/or introduce temporary national measures⁸³. This regulatory solution has, then, undergone a major change with the adoption of EU dir. no. 412/2015: a first step towards a

⁸⁰ U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine Guidance for Industry, *revision of Guidance #187, Regulation of Genetically Engineered Animals*, 2017, available at: www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf.

⁸¹ There are a great number of studies, articles and books focused on the role of the precautionary principle (PP) in International and EU law. See J. Peel, Precaution in L. Rajamani, J. Peel (ed.), *The Oxford Handbook of International Environmental Law* (OUP, 2021).

⁸² M. P. Genesin, 'La moratoria sulle coltivazioni transgeniche nell'ordinamento italiano: scenario attuale e prospettive future' (2015) Vol. 80/I *Resp. civ. e prev.* 714.

⁸³ The European legislator does not offer a definition of safeguard clauses. For a discussion of the issue please refer to A. Gratani, 'Il principio di precauzione nel diritto UE. Le misure di salvaguardia e la circolazione degli OGM (Nota a Corte di Giustizia dell'Unione europea, sez. III, 13 settembre 2017, causa C-111/16)' (2017) *Riv. giur. amb.* 661-675.

broader reform that from the matter of crops is now a source of inspiration for GMO-containing foods. The reform package promoted in the field of cultivation in 2015 is based on the opt-out rule (Articles 26-bis and 26-quater dir. no. 412/2015 EU)⁸⁴: member states are free to take national decisions to restrict or prohibit the use of GMOs in food or feed within their territory, when they have also been authorized at European level, without having to use the safeguard clause⁸⁵. This means that the Member State may prohibit the introduction of GM crops by invoking one or more "overriding factors" that do not conflict with the EFSA's assessment of risks to health and the environment. The "overriding factors" referred to in Art. 26-bis, para. 3, EU dir. no. 412/2015 could be invoked individually or in combination and cover a large number of reasons: a) environmental policy objectives; b) urban and rural planning; c) land use; d) socio-economic impacts; e) need to avoid the presence of GMOs in other products without prejudice to Art. 26-bis; f) agricultural policy objectives; g) public order⁸⁶.

⁸⁴ The package adopted by the Commission on 22.4.2015 includes the following documents: a Commission communication on the review of decision-making on genetically modified organisms; a proposal for a regulation allowing Member States to restrict or prohibit in their territories the use of Gmos in food or feed (Proposal for a Regulation of the European Parliament and of the Council amending the Regulation (EC) No. 1829/2003 as regards the possibility for Member States to restrict or prohibit the use of genetically modified food and feed on their territory [2015]); a European Parliament Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (Gmos) on their territory [2016] OJ Gen. Ser. 288/2016. The Directive entered into force on 11/12/2016.

⁸⁵ According to art. 23 dir. n. 18/2001 CE «where a Member State, on the basis of new or additional information which has become available after the date of authorization and which relates to the environmental risk assessment or a reassessment of existing information based on new or additional knowledge scientific, has reasonable grounds to believe that a GMO as or in a product duly notified and authorized in writing under this Directive poses a risk to human health or the environment, may temporarily restrict or prohibit its use or sale on its territory. The Member State shall ensure that, in the event of a serious risk, emergency measures, such as suspension or cessation of placing on the market, and public information, are implemented. The Member State shall immediately inform the Commission and the other Member States of the actions taken under this Article and give reasons for its decision, providing a new assessment of the environmental risk assessment, indicating whether and how the conditions of the authorization should be changed, or the authorization should be revoked and, if necessary».

⁸⁶ For a detailed analysis of the individual factors, please refer to De Sadeleer (n. 2).

In this way, a variable geometry system is outlined: the solutions adopted vary according to the different national choices. Often these choices are based on the operation of the precautionary principle. On the basis of art. 7 of EC Regulation n. 178/2002, states can have recourse to the precautionary principle only when it is clear that food could pose a serious risk to human health which cannot be adequately addressed by the member state. The Commission can adopt emergency measures, in case it fails to do so, the Member State is entitled to adopt emergency measures for genetically modified food and feed⁸⁷.

With regard to this mechanism, it is important to consider the relationship between the operation of the precautionary principle and art. 34 EC Reg. n. 1829/2003 which sets the rule for the adoption of emergency measures. In the case concerning the arbitrary introduction in 2013, in Italy, of the provisional emergency measure of the prohibition of the cultivation of maize varieties MON 810, for example, the conclusions of the Court of Justice, in Case C-111/16 of 13.9.2017 recall that the application of the precautionary principle is possible only for the protection of the general interest of health⁸⁸.

The level of uncertainty of the potential risk must, therefore, be subject to constant review by the public authorities, based on any new scientific data available. For this very reason, any restrictive measure must be proportionate and provisional in order to allow for the right balance between the high level of health protection and the functioning of the internal market based on the effective free movement of food and feed. Consequently, the precautionary principle cannot be invoked in order to circumvent or modify, making less stringent, the provisions provided for by art. 34. From a combined reading of art. 34 and the precautionary principle, Member States are not allowed to adopt arbitrary emergency measures based on the sole basis of this principle. Italy would have, therefore, introduced a safeguard measure in violation of the procedure laid down in art. 54 of Regulation n. 178/2002 EC, since it is possible to resort to protectionist measures only when, in

⁸⁷ See A. Monica, 'Osservazioni a Corte Giust. UE, III Sez., 13.9.2017, causa C-111/16, Fidenzato' (2017) *Riv. it. dir. pubbl. com.* 1585. As regards, instead, the operation of the precautionary principle in relation to Directive n. 18/2001 EC, it should be noted that recital 8 refers to the principle in the development and implementation of the same.

⁸⁸ ECJ case C-111/16, *Fidenzato* [2017], commented by A. Monica (n. 87)

the face of the non-action of the Commission, there is a "serious" and "manifest" risk to human health, animals or the environment the precautionary logic.

It is therefore necessary to fully understand the operation of the principles of precaution and prevention in the light of safeguard measures and the value of scientific evidence that underlies the presence or absence of an event-damage or an event-serious risk of damage. In this judgment, the Luxembourg judges clarify that Member States may not adopt emergency measures regarding genetically modified food and feed without evidence of a serious risk to health or the environment⁸⁹. The precautionary principle in art. 7 of Reg. n. 178/2002 EC and the procedure for the adoption of emergency measures, regulated by art. 34 of Reg. n. 1829/2003 EC, in conjunction with art. 53-54 of Reg. n. 178/2002 EC, respond to a need to take measures in accordance with the precautionary principle. The Regulation on food safety 178/2002 EC responds to a logic of risk that is based on different assumptions: the possibility of harmful effects on health and the persistence of a situation of scientific uncertainty, as regards the application of the precautionary principle; a serious risk to human health, animal health or the environment, however, for the application of emergency measures⁹⁰. Thus, where it is not established that a GM product is likely to pose a serious risk to health or the environment, neither the Commission nor the Member States have the power to take emergency measures such as a ban on cultivation (in this case, MON 810 maize).

⁸⁹ The reference for a preliminary ruling concerns the interpretation of Article 34 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1) and of Articles 53 and 54 of 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 (OJ 2002 L 268, p. 1). This request has been made in the context of criminal proceedings against Mr Giorgio Fidenzato and Mr Leandro and Mr Luciano Taboga, accused of having cultivated the genetically modified maize variety MON 810, in breach of the national legislation prohibiting such cultivation. CJEU, 13.9.2017, case C-111/16.

⁹⁰ See ECJ case C- 111/16. For a comment please refer to A. Gratani, 'Il principio di precauzione nel diritto UE. Le misure di salvaguardia e la circolazione degli OGM. Nota a Corte di Giustizia dell'Unione europea, (n. 83).

Generally speaking, within EU food law, the pivotal role played by the precautionary principle in cases of scientific uncertainty for foods has compelled decision-makers to act carefully and with foresight when deciding on biotech foods, and by so doing potentially ban such foods from being marketed in the EU. It would appear that the precautionary principle has become a cornerstone in the regulation of biotech foods. For this reason, cloned and GM foods are regulated under distinctive regimes. The authorization, labelling and traceability requirements for GM foods are harmonized by two complementary regulations, the Food and Feed Regulation and the Traceability Regulation (see more § 6).

6. Lights and shadows in European legislation: blurring the line between different approaches

Among the above described framework, key observations focused on the concrete operative regulatory mechanisms depict an interplay between precautionary measures and other European rules concretely based on substantial equivalence⁹¹.

From an historical point of view, within EU food law, the precautionary principle plays a pivotal role particularly starting from the early 2000s, when the EU regimes for biotech foods were updated and the process approach was implemented. It appears that the principle of substantial equivalence and the simplified procedure were discarded from these regimes as they were reputed too contentious and artificial. Anyway, this is not completely true as, notwithstanding the general and evident precautionary approach, a thorough analysis of the biotech regulatory regimes reveals that the older and more controversial concept of substantial equivalence is still present in the European regulation of biotech foods.

On one hand, the new and "improved" frameworks for biotech foods established by the Food and Feed Regulation and the Traceability Regulation for GM foods, and the 2015 Novel Foods Regulation for cloned foods, set much-

⁹¹ The issue was analysed by L. Petetin, 'Precaution and equivalence: the critical interplay in the EU biotech foods' (2017) 42(6) *E.L. Rev.* 831.

awaited, strong precautionary EU procedures. Cloned and GM foods are regulated under distinctive regimes. The authorization, labelling and traceability requirements for GM foods are harmonized by two complementary regulations, the Food and Feed Regulation and the Traceability Regulation. From 1 January 2018, the 2015 Novel Foods Regulation will update the regulatory framework for novel foods, inclusive of cloned foods, and repeal the 1997 Novel Foods Regulation, which also copes with cloned foods.

On the other hand, the principle of substantial equivalence swiftly became a pillar of risk regulation for modern agricultural biotechnology and the benchmark standard against which the safety of biotech foods in the EU would be assessed⁹², primarily through the Novel Food Regulation⁹³.

Substantial equivalence is the scientific criterion by which the evaluation of novel foods is weighed when an applicant notifies the placing on the market to the national competent authority. If a novel food is not substantially equivalent to an existing food, the food must undergo an "initial" safety assessment by the competent authority of a Member State, and may then proceed to premarket authorization, as an authorization decision is required⁹⁴.

If the novel food is "substantially equivalent" to an existing food, it falls under the scope of the simplified procedure that exists under art. 3 (4). In this instance, applicants would simply have to notify the European Commission of the placing of the food on the market. No specific pre-market approval is required to put the novel food on the market.

Moreover, the labelling of novel foods under the scope of the 1997 Novel Foods Regulation is based on the concept of substantial equivalence. Article

⁹² For more on Risk Regulation see E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing, 2010); J. Steele, *Risks and Legal Theory* (Oxford: Hart Publishing, 2004); and C.R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).

⁹³ The EU embraced the concept in the 1997 with *the Novel Food Regulation* (see art. 3(4)).

⁹⁴ See e.g. N. Salmon, 'A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO' (2002) 27 *E.L. Rev.* 138.

8(1)(a) ensures the labelling of a novel food if this food is "no longer equivalent to an existing food". In sum, if a novel food is claimed substantially equivalent to an existing food, no specific labelling is required. They are submitted to general labelling prerequisites. However, substantial equivalence meaningfully narrows consumer choice by demanding no specific mandatory labelling and no traceability. It also brings into questions the safety of biotech products if they only undergo minimal premarket authorization.

The dynamic between substantial equivalence and the precautionary principle is problematic and it prevents the existence of an adequate and efficient regulatory environment for EU biotech foods regulation and undermines a comprehensive precautionary approach towards such foods and the EU food system in general. Moreover, at a general perspective, we can observe that not only the two concepts seem contradictory, but they underline the limits of a vision that continue to compare the "promotional" US model versus the "preventive" EU model, leaving the floor for further necessary studies on the impact of local variations in biotechnology policy and regulation responding to social concrete demands.

7. Going beyond the existing regulatory models. Concluding remarks on a sustainable approach

The previous pages have explained the main regulatory models and issues of modern agri-food biotechnologies focusing, in particular, on the European context and the current debate on green gene editing techniques. This was performed with the aim to explore whether these different regulatory models bring up interpretation and implementation challenges still fit for purpose or needs to be "reconsidered" at the light of current drawbacks. Implicitly, the features for a sustainable model were investigated.

The analysis has revealed that European current legislative approach tries to reach the balance of different rights and interests experimenting practically a mix of different models: practically meaning, both the precautionary principle and substantial equivalence interplay in the field, despite an apparent and formal shift from substantial equivalence, which on the contrary still plays a strategic role in both the regulation and the assessment of biotech foods (§ 6). This picture appears even

more diversified when one examines the choices concretely opted for by the various Member States, in the light of their historical, social and political background (§ 3).

A preliminary conclusion confirmed what the doctrinal debate has underlined for long time: a regulation of the biotechnological process – mainly inspired to precaution - could lead to an assessment of the risks and potentialities of modern products unrelated to empirical data. It is necessary to assess the actual risks of the final product resulting from this process, thus avoiding that products similar in outcome are differentiated according to the characteristics of the technology, or that some technologies are not subject to consumer warnings despite being capable of accomplishing similar results to those subject to special legislation.

So far, from a legislative point of view, in future perspective, a case by case evaluation is widely recognized as an appropriate approach (see § 5), while the current model, as long as designed, could obstacle the proposition of a suitable model in line with current objectives.

Secondly, following the considerations developed in the paper, it underlined that a case-by-case determination of NGT products status through a pre-submission consultation will be more aligned with the current policy recommendations. The analysis did a step forward identifying some necessary ingredients for implementing a legislative model in line with current scientific development and social exigencies: a merely safety-based risk assessment may not be sufficient to promote sustainability and contribute to the objectives of the European Green Deal and especially the ones expressed in the “farm to fork” and biodiversity strategies; benefits contributing to sustainability would also need to be assessed as a suitable mechanism to accompany risk assessment may be required.

Policy instruments are needed to make the legislation more enduring, future-proof and uniformly applied. This is due to the fact that attempting to upgrade sustainability and guaranteeing safety would lead to overcome the choice between product-based or process-based exemption of NGT products, other than the coverage of NGT products under GMO legislation.

From a constructive point of view, thus, it would be worth considering the need for specific risk assessment criteria for NGTs as a starting point: it has been shown that the incorporated rigid risk-assessment guidance in EU legislation makes

difficult to adjust it to scientific enhancement in order to be in line with social expectations. This consideration was the premise to find out what ingredients are outlining as suitable and necessary for a successful regulatory model promoting biotech foods worshipful of traditions and vice-versa: genome editing policies should consider not only risk assessment but also broader evaluations, including the societal value of genome-editing applications.

Ethical considerations have to incorporate scientific data and vice-versa, as ethical aspects of innovation in biotechnology should be viewed in light of the resulting organisms and intended uses rather than the technology used. In addition to safety, some countries already take additional factors into account in the final assessment/authorization of GMO, these also apply to NGT products and include ethical aspects, social acceptance, sustainable development, commercial and production impact, and perspective and benefits for indigenous people.

These will be some preliminary strategic approaches for designing an effective and socially desirable biotech regulation, coherent to balance the EU innovation objective and cultural food policy, compliant with the comprehensive EU responsible research and innovation policy⁹⁵. A system designed in this way should more appropriately respond to the need of sustainability in a field, as the food one is, where sustainability goes beyond the environment and can entail seed and food security, safety, nutrition, competitiveness and social aspects.

Nevertheless, peculiarities of the genome editing technologies should be considered: if on the one hand, they require a “global” governance approach, on the

⁹⁵ Responsible Research and Innovation (RRI) is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation. It implies that societal actors (researchers, citizens, policy makers, business, third sector organizations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society. For more information see: <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation>. Several studies seek to operationalize the definition of RRI. They individualize four dimensions of responsible innovation: anticipation (A), inclusion (I), reflexivity (R) and responsiveness (R): the so called AIRR framework is useful for discussing and responding to questions pertaining to the broader impacts of science and technology. Some scholars use this framework to set out a forward-looking governance framework for gene editing: see P. Macnaghten, M.G.L. Habets (n. 13).

other hand it is difficult to take regulatory measures of worldwide scope that are efficient and respected by all States, so that these commit to ensuring compliance in their respective territories. It is not easy to identify criteria for the governance of genome-editing.

This requires reflection on the “forms” of uncertainties, on the rights and implied values, namely human dignity, solidarity, tradition, on the expectations set by this strategy, and on the limits and principles that should govern its implementation, as for example safety, effectiveness, efficiency, transparency, common good. As well as sustainability, also safety has to be framed in its broadest interpretation, including psychological, social and environmental spheres, as well as issues about who gets to decide what is safe enough, and by which processes⁹⁶. Previous US analysis – reported in this paper - has already face this need: the 2016 US report on GMO mandatory labelling law was a proper past example of these exigences (see § 3).

What is reputed ‘safe enough’ is extremely context-dependent (compare §§ 4 and 5). What would be needed is the relevance of the entire decision issue to take safe, well reasoned responsible decisions in order to outweigh both the pros and the cons; indeed to consider not just the risks and costs but also the possible advantages, in the widest extent, and the distribution thereof.

The Green Deal has speeded up this switch and made the need for a more holistic, horizontal approach urgent, as it brings “all the tools and solutions under one roof” in order to cater to the quickly changing demands from society and evolving policy frameworks.

Anyway, whereas the Commission has determined a clear travel direction in food policy strategies, questions persist over how these aspirations will be implemented with a keen eye to social context peculiarities, such as for example the identification of the precise meaningful factors that can “measure” if the regulatory choice is suitable to balance the chosen model with local adaptations.

Taking these peculiarities into account in the revision of the regulatory model would help consumers to place greater trust in the legislator’s pragmatic decisions to

⁹⁶ This is also remarked by the EGE Opinion (n. 42).

guide them towards solutions that are increasingly compatible with the reasons for protecting health in a comprehensive way, namely *One Health*⁹⁷.

⁹⁷ For a detailed and clear explanation of the One Health concept and its impact on food law see D. Cerini, 'Sicurezza degli alimenti tra sostenibilità, benessere animale e gestione assicurativa dei rischi', M. Torsello (ed.), forthcoming.