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Contextual comparative remarks on a sustainable European regulatory model for synthetic biology in agri-food area

Giorgia Guerra *

1. Introduction: a perspective on the topic

The European consensus toward the adoption of the sustainability criterion as a pillar of the Green Deal policy brought to light, once again, the role that comparative legal studies play in assisting legal systems to develop agricultural technological progress in conformity to the One Health protection exigence [1]. This renewed logic will shape pragmatic regulatory choices in the food sector, determining a direct impact on areas attaining both consumers' health safety and environmental protection.

A tension is emerging between the increasingly transnational nature of agri-food production chain [2] and the crucial issues of the domestic circumstances

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[1] The EU Farm-to-Fork Strategy refers to the concept of One Health as an approach to tackle emerging problems (e.g. antimicrobial resistance) and it underlines the need for transdisciplinary approaches to move towards safe and sustainable food systems. On the concept of One Health see D. CERINI, *Sicurezza degli alimenti tra sostenibilità, benessere animale e gestione assicurativa dei rischi,* in M. TORSELLO, G. GUERRA (eds), *Temi e prospettive per un corso di diritto agroalimentare transnazionale e comparato*, Edizioni Scientifiche Italiane, Napoli, 2022, ps. 223-261. For a review of sustainable agriculture models (integrated agriculture, agroecology, precision agriculture, etc.), see E. CRISTIANI, *Quali regole per un'agricoltura "sostenibile"?*, in *Rivista di diritto agrario*, 4, 2019, p. 645 ss.

[2] It is meaningful that the Commission staff's working document on the status of new genomic techniques (footnote 53) confirms that most of the development is taking place outside the EU (page 2 of the document).

(e.g. traditions) that make a legal design acceptable for a specific social context. This strain will be the *fil rouge* of the following pages, where a European private law perspective on one of the most recent steps of agri-food progress, namely synthetic biology (from now on: SynBio), will be sketched out.

In sum, SynBio is an interdisciplinary field of engineering, chemical, information technology and biology aiming to develop new biological systems and impart new functions to living cells with potential applications in the food and feed system[3]. SynBio products will reach the market soon and they will inquire to be classified into already existing categories. Consequently, prior risk assessment and authorization will play a crucial role for the economic impact in Europe[4].

These products are likely to move towards their development through existing genetic modification and genome editing technologies[5]. For this reason, several past and recent well-known experiences about agri-food genetic manipulations will offer concrete data to reflect on SynBio.

Arguments from public controversy over genetically modified crops and foods will lead us to focus on the European context where, after the controversial ECJ ruling of 25 July 2018, C-528/16[6], new agri-food biotechnologies follow the path of genetically modified organisms (from now on: Gmos) being subjected to stringent process-based legislation.

SynBio is a significant case study of the fast-moving safety policy scenario and the tension with correlated social and ethical values. The European Union (EU) has started measures to structure the field, such as the appointment of a high-level expert group. However, research activities are still scattered across Europe.

The current characterization of modern risk has already been largely scrutinized by the interdisciplinary studies, namely science and technology studies (from now on: Sts), that are dedicated to analyze how law and regulation can successfully respond and adapt to biotech progress integrating both legal and non-legal tools (e.g. nudging mechanisms; education). Considering current legal challenges are faced throughout the lens of the sustainability criteria as a common goal of contemporary policies, the Sts perspective will be functional to understand correlated issues.

Based on these premises, the effort of this article will go beyond the attempt to classify new agri-food biotechnologies, to investigate how different features of

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[3] The inventor of SynBio is the American Scientist, Craig Venter, founder of the Synthetic Genomic company which on May 20, 2010 had announced the creation of a new form of life, an organism capable of reproducing itself, placed inside the cell of a bacteria.

[4] Briefly, there are two main ways of authorization of GMOs in Europe, depending on the goal of the applicant. Authorization for the deliberate release into the environment of a GMOs (according to Directive 2001/18/EC) is the "default" authorization.

[5] UK Nuffield Council on Bioethics, *Genome Editing*, 2016, p. 119, available at: https://www.nuffieldbioethics.org/assets/pdfs/Genome-editing-an-ethical-review.pdf.

[6] European Court of Justice, 25 July 2018, C-528/16, *Confédération Paysanne & others*, ECLI:EU:C:2018:583.

contexts need to be integrate into the regulatory process for enacting feasible biotech food regulation [7]. Comparative analysis will offer further understanding about the impact of local variations in biotechnology policy responding to social concreate demands. Recent debates on legal comparison focus on the choice of different approaches amongst hermeneutical, legal, empirical, functional, post-modern and others: admittedly all kind of methods in comparative law claim to use contextual knowledge, which exceeds pure legal knowledge to transform it into practice. Although interdisciplinary approaches seem to be uncontested helpful [8], it is remarkable that the ideal way to typically analyze contextual knowledge for regulatory purpose remains unclear [9]. The implicit purpose of the following pages will be to offer some insights on this point.

The structure of this article is linear and divided into three main parts. The first part considers the European Regulation of SynBio at the light of the main regulatory models already in force (§§ 2-3); the second one will emphasize the contradictions of the EU legal framework dedicated to agrifood biotechnology brought to light by contextual comparative law. Lastly, considering that European Authorities are aware of a lack of clarity and of the necessity of favoring consumers' awareness about SynBio, the regulatory coordinates matrix proposed by stakeholders of the responsible research innovation agenda will be take into account to delineate practical trajectories for a sustainable approach to new biotechnologies, in particular SynBio.

2. The European Regulation of synthetic crops and plants in a nutshell

Stringent requirement for sustainability in food consumption is driving the search for new food sources [10]. A brief description of the biotech regulatory field

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[7] See M. HOWLETT, A. MIGONE, *Explaining Local Variation in Agri-Food Biotechnology Policies: "Green" Genomics Regulation in Comparative Perspective*, in *Science and Public Policy*, 37, Issue 10, 2010, ps. 781-795. It develops a comparative framework for biotechnology policy to understand the evolution and differences in six countries (Italy, Spain, Australia, New Zeland, Canada and the US).

[8] 1nterdisciplinarity is an "approach to work" rather than a methodology: D. ANTISERI, *I fondamenti epistemologici del lavoro interdisciplinare*, Armando editore, Roma, 1972. It requires the capacity to proceed by problems, with a pragmatic view on the "entire jigsaw". The way to realize it mainly depends on the research question and the expected level of knowledge integration. For an overview of the taxonomy of interdisciplinary in comparative legal research concerning technology issues see G. GUERRA, *An Interdisciplinary Approach for Comparative Lawyers: Insights from the Fast Moving Field of Law and Technology*, in *German Law Review*, 19, n. 3, 2018, ps. 579-612 and its bibliographical references.

[9] See the workshop organized by Konrad Lachmayer "Objectives and Methods of a Contextual Analysis in Comparative Law" at the Hungarian Academy of Social Sciences, Budapest, on May 19, 2016.

[10] N. KNEŽEVIĆ, S. GRBAVAC, M. PALFI, M. BADANJAK SABOLOVIĆ, S. RIMAC BRNČIĆ, *Novel*

is a useful start, given the fact that very often the numerous varietal techniques has failed to distinguish between them, leading to the impoverishment of the debate [11]. A more in-depth analysis is left to other writings [12].

Investigating SynBio implies understanding its relationship to Gmos [13]. To acknowledge the importance, it should be considered that an evaluation of SynBio developments in agri-food has been requested on behalf of the European Commission tasking the EFSA to identify the need of risk assessment guidelines update.

Over the past decade, the emergence of methods and principles allowing for more efficient Gmos manufacturing has surpassed genetic modification as defined in the European Directives 2001/18/EC and 2009/41/EC and it will likely remain so in the foreseeable future.

As described in the I, II and III Opinions on Synthetic Biology commissioned by the European Commission, the definition, modularization and engineering concepts are defined as the main drivers for more expedient Gmos design, manufacture and exploitation [14]. Therefore, following the I Opinion, an operational definition derived from a working understanding of SynBio as a collection of conceptual advances: SynBio is the application of science, technology,

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Foods Legislation and Consumers Acceptance – The importance for food industry, in *Emirates Journal of Food and Agriculture*, 33(2), 2021, ps. 93-100.

[11] J. KLOPPENBURG, *Impeding Dispossession, Enabling Repression: Biological Open Source and the Recovery of Seed Sovereignty*, in *Journal Agrarian Change,* 10, Iss. 3, 2010, p. 381.

[12] See G. GUERRA, *Agri-food Biotechnologies Regulation in Comparative Perspective*, in *Opinio Juris in Comparatione*, 1, n. 1, 2021, ps. 1-43.

[13] See the Swiss Federal Ethics Committee on Non-Human Biotechnology (ECNH), *Synthetic biology – ethical considerations, Report*, 2010 available at https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/e-Synthetische_Bio_Broschuere.pdf.

[14] SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCHER (Scientific Committee on Health and Environmental Risks), SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), SCCS (Scientific Committee on Consumer Safety) wrote three Opinions on Synthetic Biology (SynBio) responding to the European Commission's questions. Opinion I (2014) is dedicated to the definition; Opinion II focused on the implications of likely developments in SynBio for humans, animals and the environment and whether existing health and environmental risk assessment practices of the European Union for GMOs are adequate for SynBio. Opinion III (2015) confined the scope of their analysis to the foreseeable future, acknowledging that its findings should be reviewed and updated again after several years, depending on the development of the SynBio. Outside the scope of the current mandates are specific, thorough analyses of social, governance, ethical and security implications as well as human embryonic research. On recent EFSA's SynBio evaluation see: EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), H. NAEGELI, J. L. BRESSON, T. DALMAY, I.C. DEWHURST, M.M. EPSTEIN, L.G. FIRBANK, P. GUERCHE, J. HEJATKO, F.J. MORENO, F. NOGUE, N. ROSTOKS, J.J. SANCHEZ SERRANO, G. SAVOINI, E. VEROMANN, F. VERONESI, J. CASACUBERTA, A. DE SCHRIJVER, A. MESSEAN, N. PATRON, M. ZURBRIGGEN, F. ALVAREZ, Y. DEVOS, A. GENNARO, F. STREISS, N. PAPADOPOULOU, E. MULLINS, *Scientific Opinion on the Evaluation of Existing Guidelines for their Adequacy for the Molecular Characterization and Environmental Risk Assessment of Genetically Modified Plants obtained through Synthetic Biology*, in *EFSA Journal*, 2021, 19(2), 21 ps. https://doi. org/10.2903/j.efsa.2021.6301.

and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms [15].

Based on the findings of the Opinion I «SynBio includes any activity that aims to modify the genetic material of living organisms as defined in the Cartagena Protocol on Biosafety. This does not exclude the consideration of non-viable, non-reproducing goods and materials generated by or through the use of such living Gmos. […] It is difficult to accurately define the relationship between genetic modification and SynBio on the basis of quantifiable and currently measurable inclusion and exclusion criteria» [16]. The Opinion proposes a list of specific criteria reflecting that SynBio covers any organism, system, material, product, or application resulting from introduction, assembly, or alteration of the genetic material in a living organism. Such criteria have been considered helpful guiding principles that specify whether or not a certain process, tool or product belongs to SynBio.

This definition has the advantage that it does not exclude the relevant and large body of risk assessment and safety guidelines developed over the past 40 years for Gmos. This work if needed can be extended to account for recent technological advances in SynBio.

As for Gmos, uncertainties associated with the development of synthetic life, cells or genomes are various: their potential impact on the environment; the conservation and sustainable use of biological diversity and human health. This is why, in Europe, a general claim for a precautionary approach in accordance with domestic legislation and other relevant international obligations is claimed to prevent the reduction or loss of biological diversity posed by organisms generated by SynBio. Consequently, due to the non clear relationship between Synbio and genetic modification, the principal legislative reference with key principles for protecting human health and environment is the EU Gmos regulatory framework. It relies on the approaches underlying, amongst others: recombinant DNA techniques; the direct introduction of heritable material into an organism; and cell fusion or hybridization techniques (Annex I, Part A of Directive 2009/41/EC and Annex I A Part I of Directive 2001/18/EC, see Annex V of this opinion). Therefore, risk assessment takes into account risks posed by the "process", used to generate Gmos.

In general, accepting a certain degree of simplification, three regulatory approaches can be distinguished worldwilde: (i) 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 authority [17].

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[15] Definition provided by Opinion I on Synthetic Biology 2014, available at: https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_044.pdf.

[16] SCENIHR *et al.*, *Opinion I*, cit.

[17] In the workshop organized by the Institute for Prospective Technological Studies in 2011, the different approaches used were compared by representatives from Argentina, Australia, Can-

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 «process» regulation [18] (see § 3).

A recent debate on whether process-based analysis should be applied for the regulatory oversight of certain novel techniques, namely new breeding techniques (from now on: Nbt), represents an ongoing experience for our analysis. Nbt have the potential to make the breeding process faster while lowering the production costs. In some cases, they enable for targeted changes in the genome, making them also indistinguishable from plants obtained by conventional breeding. Therefore, plants developed by Nbt that do not contain recombinant DNA in their genome are challenging the current Gmos legislation, and impacting on innovation (see § 4).

One crucial point emerged: process-based triggers for regulatory oversight might rapidly outgrow new biotechnology-based tools and approaches. In fact, the developments in plant breeding and the uncertainty of their regulatory status in Europe are included in several reports and statements arguing for a more flexible and product-based approach of the legislation [19] (see § 4) with direct consequences on SynBio regulatory perspective.

3. Different regulatory models in different contexts

Historically speaking, the genomics-related matters governance vary depending on the geopolitical contexts.

Legal systems are attentive not only to the type of technology employed, but above all to its specific uses, environment and health impact, and the type of risk analysis, as in countries with different socio-sanitary realities it has required

ada, the European Union, Japan and South Africa. Countries where GM crops are very widespread have initiated a phase of involvement of scientific experts for the assessment of the comparability of GMO-NBT products. Findings were 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. Few systems introduced a mixed system between the two models: 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 compared product without presuming it safe.

[18] 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), in *New Biotechnology,* 30, Iss. 5, 2013, ps. 1-35.

[19] European Academies Science Advisory Council, *Planting the Future: Opportunities and Challenges for Using Crop Genetic Improvement Technologies for Sustainable Agriculture*, German National Academy of Sciences Leopoldina, 2013.

inevitably different definitions of risk on their social perception basis [20].

To start with a mere description, the two mentioned types are product/process based models: to make a long story short, the term process is referred to methods or techniques used to produce the crop plant (e.g. genetic modification); while the term product stands for the final crop and its characteristics [21].

They are expressed by two experiences: the European one, historically developed towards the idea of process, and the US one for which how the food was produced is irrelevant [22]. Notably, they both are based on two principles: the European principle of precaution, and the North American principle of substantial equivalence [23].

Essentially, the substantial equivalence was firstly designed at an international level in the 1990s when the Organization for Economic Co-operation and Development developed a risk assessment method to liberalize trade in biotech products and incentivize harmonization by standardizing the risk assessment parameters [24].

The latter adoption at a National level was, at first, in American policy, which has been already favorable to biotech development since the 1980s with the Coordinated Framework for the Regulation of Biotechnology [25].

Ideally, through the substantial equivalence approach the current regulations on health and safety protection are considered, as a presumption, as sufficiently

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[20] See V. SBERVEGLIERI, A. PULVIRENTI, P. GIUDICI, *Della valutazione quantitativa ai modelli di previsione dei rischi ignoti*, in L. FOFFANI, A. DOVAL PAIS, D. CASTRONUOVO (eds), *La sicurezza agroalimentare nella prospettiva europea*, Giuffrè, Milano, 2014, p. 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, *Breaking the impasse. Towards a forward-looking Governance Framework for Gene-Editing with Plants*, cit., p. 354.

[21] See the famous Asilomar Conference in 1975.

[22] For a preliminary discussion of the distinction see M. FERRARI, U. IZZO, *Diritto alimentare comparato. Regole del cibo e ruolo della tecnologia*, Il Mulino, Bologna, 2012.

[23] In 1989 the US National Research Council stated that: 1) the product of genetic modification and selection constitutes the primary basis for decision and not the process by which the product was obtained 2) although knowledge about the process used to produce a genetically modified organism is important the nature of the process is not useful for determining the amount of oversight, 3) organisms modified by modern molecular and cellular methods are governed by the same physical and biological laws as organisms produced by classical methods.

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

[25] Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 FR 23302, (June 26, 1986), available at: http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf. It was updated by the *National Strategy for Modernizing the Regulatory System for Biotechnology Products,* 2017.

appropriate as they were certain for companies [26]. Following this logic there is no specific need for a biotech regulation as these products are substantially equal to traditional ones, in the absence of opposite evidence. The final biochemical characteristics of the new Gm product are compared with the non-Gm counterparts already on the market, presuming to ensure safety with a "reasonable certainty" as modern biotechnology does not automatically produce foods that are "less safe than those developed using conventional techniques" [27]. At the contrary, if the result of the comparative compositional assessment of basic compounds differ significantly between a Gm product and its non-Gm counterparts, then a full risk assessment phase could be required. However, it has been already underlined that, in reality, the second situation is quite rare «since there are no cut-off thresholds for the potentially significant estimated differences that would trigger such an additional assessment. […] Ironically, that approach has never been applied in practice to new conventionally bred crops, but only to those developed by genetic engineering. The US regime for Gmos was, therefore, different from that for its non -Gm counterparts, despite being officially portrayed as if providing exactly the same treatment» [28].

Again at the International level, in the early 2000s, the concept of substantial equivalence was further refined by the 2000 FAO/WHO Joint Expert Consultation on Foods derived from Biotechnology. The goal was 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 confirmed that substantial equivalence was the most strategic approach to address safety assessment of biotech foods [29].

Notwithstanding the uncontested applicability of the substantial equivalence principle, even in US system as well, new forms of biotech seeds and species were debated even from an institutional point of view. The US institutional architecture in this area is notoriously fragmented compared to the European one for the different distribution of competences: in the American system, the same Authorities, or Agencies, are responsible of the functions of *risk assessment* and *risk management* even if they are in turn competent for different subjects assigned to each of them [30].

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[26] G. FERNÁNDEZ ALBÚJAR, B. VAN DER MEULEN, *The Legal GMO Concept Reassessment of the GMO Definition in the Light of New Breeding Techniques (NBTs)*, cit.

[27] 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.

[28] A. HILBECK, H. MEYER, B. WYNNE, *GMO Regulations and their Interpretation: how EFSA's Guidance on Risk Assessments of GMOs is Bound to Fail*, in *Environ Sci Eur,* 32, 2020, p. 54.

[29] FAO/WHO, *Expert Consultation on Biotechnology and Food Safety*, 1996, p. 4 of the document. See H. MILLER, *Substantial Equivalence: its Uses and Abuses*, in *Nature Biotechnology*, 17, 1999, p. 1042.

[30] It is worth to remember that the structure stimulates the reflection on the relationship between law and science, in particular whether law should express a clear position offering so-called

The different process-based regulation is traditionally rooted in European law. It is, at a first glance, shaped by the precautionary logic since from the early 2000s the regime for biotech foods was updated [31]. 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 (see contradictions under § 4).

The idea behind is that altering the hereditary material in an 'unnatural way' carries inherent risks that are expressed in the resulting organism (product). The new frameworks for biotech foods established by the Food and Feed Regulation and the Traceability Regulation for Gmos foods, as well as the 2015 Novel Foods Regulation for cloned foods, set much-awaited, strong precautionary EU procedures.

Before specific legislation came into force, restrictive policies on Gmos have been pursued by the European Union through different types of legal instruments [32]: the safeguard clauses have represented the most significant legal ones to allow Member States to derogate from European legislation and to maintain in force and/or introduce temporary national measures [33]. Within EU food law, the pivotal role played by the precautionary principle has compelled decision-makers to act carefully, 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. 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 feed [34].

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science-based solutions; whether it should depend on science; or whether it should orient the public aims of science, so-called policy-related science. For a pivotal reading on this subject see S. JASANOFF, *The Fifth Branch*, *Science Adivisers as Policymakers*, Harvard University Press, Cambridge, 1990; S. JASANOFF, *Science and Public Reason*, Routledge, London, 2012; M. TALLACCHINI, *Scienza e diritto. Prospettive di co-produzione*, in *Riv. fil. dir.*, I, 2, 2021, p. 313.

[31] 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 (eds), *The Oxford Handbook of International Environmental Law*, OUP, 2021.

[32] The recourse to the mechanism of notification in the presence of harmonization measures pursuant to art. 114, § 5, TFEU. See M.P. GENESIN, *La moratoria sulle coltivazioni transgeniche nell'ordinamento italiano: scenario attuale e prospettive future*, in *Resp. civ. e prev.*, 2015, p. 714.

[33] The European legislator does not offer a definition of safeguard clauses. For a discussion of the issue: 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*, in *Riv. giur. amb.*, 2017, ps. 661-674.

[34] See ECJ, 13 September 2017, case C- 111/16, Fidenato and others, EU:C:2017:617, cit. For a comment: A. GRATANI, *Il principio di precauzione nel diritto UE*, cit. In the case concerning the arbitrary introduction in 2013, in Italy, of the provisional emergency measure of the prohibition of the maize cultivation (varieties MON 810), the conclusions of the Court of Justice, in Case C-111/16

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. Consequently, the precautionary principle cannot be invoked in order to circumvent or modify, making less stringent the provisions of art. 34 EC Reg. 1829/2003. 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.

More precisely, in cultivation field, solutions adopted to balance the peculiar nature of risk and socio-political concerns about Gmos risk lead European Union to outline a variable geometry system: meaning that the solutions adopted vary according to the different national choices. 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) [35]: Member States are free to take decisions to restrict or prohibit the use of Gmos in food or feed within their territory, even if they have already been authorized at European level, without having to use the safeguard clause [36]. 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 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 order [37].

Truthfully, the differences between the EU and US appear to be not as great as they seem at first sight if we take a closer look to the way the precautionary principle is applied in Europe (*infra* § 4) or to the fact the concept of substantial equivalence became the basis for EFSA's comparative safety assessment approach. On the other hand, it is also meaningful how current US authorization procedures are carried out [38]. In both cases a risk assessment is required for authorization. In both the US and EU, the environmental risk assessment contains the same elements, such as a characterization of the crop, the probability of effects on non-target organisms, and the chances of outcrossing with wild relatives [39].

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recall that the application of the precautionary principle is possible only for the protection of the general interest of health. ECJ case C-111/16, *Fidenzato* [2017], commented by MONICA, *op. cit.*

[35] The package includes: 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 No. 1829/2003; a European Parliament Directive (EU) 2015/412 amending Directive 2001/18/EC, in *OJ Gen. Ser.* 288/2016. The Directive entered into force on 11/12/2016.

[36] See art. 23 dir. n. 18/2001 CE.

[37] For a detailed analysis of the individual factors, please refer to DE SADELEER, *op. cit.*

[38] With the limits on effectiveness pointed out at p. 8.

[39] The Netherlands Commission on Genetic Modification (COGEM) anticipated develop-

4. Different regulatory models in the same context (Europe): dealing with contradictions

Leaving behind the dichotomy of models described above, key observations focused on the concrete operative mechanisms used in European biotechnology Regulation: they depict an interplay between precautionary measures and other European rules based on substantial equivalence [40].

Notwithstanding the general precautionary approach, an analysis of the biotech regulatory regimes reveals that the older concept of substantial equivalence is still present: it swiftly became the benchmark standard against which the safety of biotech foods in the European Union would be assessed [41], primarily through the Novel Food Regulation [42]. Following the past Regulation of the 1997, if a novel food is not substantially equivalent to an existing one, the food must undergo an "initial" safety assessment by the competent authority of a Member State [43].

If the novel food is "substantially equivalent" to an existing food, it falls under the scope of art. 3(4) of the simplified procedure. 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, as well as the labelling procedure (art. 8(1)(a) [44].

The Regulation 258/97 was substituted by the Regulation (EU) 2015/2283 which improved the conditions under which food businesses can easily place new and innovative foods on the market, provided that they ensure a high standard of food safety for consumers [45]. As a result of new dispositions, the no-

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ments in synthetic biology, with the Report on Synthetic Biology – Update, 2013. COGEM Topic Report CGM/130117-01. http://www.cogem.net/index.cfm/en/publications/publicatie/synthetic-biology-update-2013.

[40] The issue was analyzed by L. PETETIN, *Precaution and Equivalence: the Critical Interplay in the EU Biotech Foods*, in *E.L. Rev.*, 42, Iss. 6, 2017, ps. 831-847.

[41] For more on Risk Regulation see E. FISHER, *Risk Regulation and Administrative Constitutionalism,* Hart Publishing, 2010; J. STEELE, *Risks and Legal Theory*, Hart Publishing, Oxford, 2004; and C.R. SUNSTEIN, *Laws of Fear: Beyond the Precautionary Principle*, Cambridge University Press, Cambridge, 2005.

[42] The EU embraced the concept in the 1997 with *the Novel Food Regulation* (see art. 3(4) n. 258/97, updated by the Reg. 2015/2283). For critical remarks on Reg. 2015/2283 see V. PANIZZA, *I nuovi alimenti ("Novel foods")*, in P. BORGHI, I. CANFORA, A. DI LAURO, L. RUSSO (eds), *Trattato di diritto alimentare italiano e dell'Unione europea*, Giuffrè, Milano, 2021, ps. 560-588.

[43] See N. SALMON, *A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO*, in *E.L. Rev.*, 27, 2002, p. 138.

[44] They are submitted to general labelling prerequisites. However, substantial equivalence meaningfully narrows consumer choice by demanding no specific mandatory labelling and no traceability.

[45] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of

tification procedure for the substantial equivalent food was eliminated with the automatic flattening of two concepts, new and innovative.

In the first case, an authorization procedure would have been required due to the absolute novelty of the food; in the second case, a notification procedure would have been sufficient, given the proven safety of the food from which these substances were obtained and the similarity with other products already known to the EU consumer.

A critical reading of the new Regulation underlines, however, the contradiction: the regulation of novel foods, which significantly limits the free marketing of this particular category of goods, must be considered an exceptional measure. For this reason, it is essential to identify the boundaries of the definition of novel food[46].

The dynamic between substantial equivalence and the precautionary principle is problematic and it prevents the existence of an efficient regulatory environment for EU biotech foods regulation undermining a comprehensive precautionary approach towards such foods and the EU food system in general.

At a general perspective, the analysis underlines 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 differences in policies responding to social concreate demands. In this sense, empirical data would be not only useful but also necessary.

Doubts emerged in recent EU case law when it ruled that organisms obtained by new mutagenesis techniques, in contrast to conventional mutagenesis techniques, are not exempted from the Gmos legislation[47].

The Court's interpretation – in the case ECJ C-528/16 of 25 July 2018 – is based on a 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 involve the use of chemical mutagenic agents; others involve the use of genetic engineering).

It is precisely in view of the context that the Court makes one of the central findings[48]: 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 Gmos legislation. The latter, therefore, applies in principle only to mutagenesis

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the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, in *OJ L* 327, 11 December 2015, ps. 1-22.

[46] V. PANIZZA, *I nuovi alimenti ("Novel foods")*, cit., p. 560.

[47] 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»*, in *Nuova giur. civ. comm.*, 2, part II, 2019, ps. 394-404.

[48] See paragraph 31 of decision: Court of Justice, 27 April 2017, C-535/15, *Pinckernelle*, ECLI:EU:C:2017:315.

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 transgenesis [49].

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 restrictions as explained above.

The interpretative solution of the Court has provoked various reactions. The accredited scientific literature has from the outset expressed many doubts, since the judges has subjected the results of the NBT to onerous pre-market evaluation tests in the absence of scientific evidence, concretely preventing Europe from easily disseminate technologies that contribute decisively to the problem of food security and positive environment impact [50].

There were several consequences of the Luxembourg decision. Notwithstanding the General Advocate's recognition of the need for a dynamic interpretation of legislative dispositions to respond to social evolution [51], the "frozen" interpretation of the Court, 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 Gmos Directive, fall under the exemption of mutagenesis, leave unaffected the possibility of prohibiting them on the basis of the operation of the opt-out clause.

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

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[49] Thus, it was noted in paragraph 48 of the judgment under review.

[50] The EPSO documents are fundamental Guidelines: the *European Plant Science Organisation* bring 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 which had already expressed the scientific evidence about the advantages and strengths of NPBTs in the paper *Crop Genetic Improvement Technologies*, Brussels, 26 February 2015 (with updates of 18 December 2015 and 12 January 2017), available on the same website.

[51] The Advocate General Bobek advocated a dynamic interpretation at point 100 of the Opinion where he worte: «generally speaking, interpretation of the law, and in particular of indeterminate notions contained in the law, must be dynamic. It must react to the societal evolution, both technical and social. Moral categories evolve over time: 'degrading treatment' in 1818 likely meant something quite different to what it means in 2018. The same goes for the more technical definitions, such as that of a 'vehicle' or 'means of communication'. The suggestion that the interpretation of such notions ought to be 'frozen' in the factual or societal circumstances that prevailed when those notions were passed into law would represent a singularly originalist approach to legal interpretation, not frequently encountered on this side of the Atlantic». See the Opinion of Advocate General Bobek delivered on 18 January 2018 on the case C-528/16, *Confédération paysanne and Others*, C-528/16, ECLI:EU:C:2018:20.

What should be carefully considered 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 of genome-edited food and feed products of plant origin [52], considering the compliance with the Gm food and feed legislation.

In 2021 the EU Commission, in response to the Decision 2019/1904 of the European Council [53], published the staff working document 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) [54]. In sum, it confirms that organisms obtained through new genomic techniques are subject to the Gmos legislation. However developments in biotechnology, combined with a lack of definitions or the ones that resulted unclear are still ambiguous to interpretate, potentially leading to regulatory uncertainty [55].

This status quo reverberates at the national level. Member States made a variety of comments in relation to these techniques: they highlighted the Gmos legislation is obsolete [56], and asked to the Commission to clarify the legal status of NGTs. The Study reported that most of the Member States highlighted the need to develop detection methods integrating sustainability criteria [57].

These different regulatory models bringing up 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 interests experimenting 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 regula-

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[52] European Network of GMOs 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.

[53] 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.

[54] 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_modbio_ngt_eu-study.pdf.

[55] Idem., p. 2 of the document.

[56] Lastly see the Società Italiana Genetica Agraria's proposal for a new definition at http://www.geneticagraria.it/home.asp.

[57] See page 49 of the Study document.

tion and the assessment of novel foods. 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.

A preliminary conclusion confirmed what the doctrinal debate has underlined for long time: a regulation of new biotechnological process mainly inspired to precaution could lead to an assessment of risks and potentialities of modern products unrelated to empirical data. Actual risks of the final product resulting from this process have to be assessed, 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 subjected to special legislation. Even though it is an immense political hurdle to overcome, a modification of the Directive 2001/18 or a new legislation is currently the only way for policy makers to realign the interpretation of the ECJ with the existing practice.

In future perspective, a case by case evaluation is widely recognized as an appropriate approach, while the current model, as long as designed, could obstacle the proposition of a model in line with contemporary objectives.

5. Constructive remarks from comparative law to go beyond the "safe enough" logic

The analysis of the political options for biotech regulation could benefit of the recent trajectories in comparative legal studies which will be functional to investigate which "ingredients" could compose a suitable regulatory model promoting biotech foods respectful of contextual variables. This paragraph will frame the discussion into the comparative law methodology that make this goal feasible, while the following one (§ 6) will examine the components more in detail.

The idea of comparison *in* law transcends the understanding of law as a body of norms and doctrines[58], and grasps the structural elements of different contexts thanks to the flexibility and multi-functionality offered by the comparative perspective. This is the reason why "law in context" cannot be isolated from other methods[59]. There is a general common consensus that methods of comparative law are complementary and interdependent.

Most likely, within the academic path that intends comparative law as inter-

[58] M. SIEMS, *New Directions in Comparative Law*, in M. REIMANN, R. ZIMMERMANN (eds), *The Oxford Handbook of Comparative Law*, 2nd edition, Oxford University Press, Oxford, 2019. For a reflection on the attempted comparisons, and their criticalities, see H.E. CHODOSH, *Comparing Comparisons: in Search of Methodology*, in *Iowa L. Rev.*, 84, 1999, p. 1025. See E. ÖRÜCÜ, D. NELKEN (eds), *Comparative Law: A Handbook*, Hart-Publishing, Oxford, 2007.

[59] M. VAN HOECKE, *Methodology of Comparative Legal Research*, cit., p. 16.

disciplinary by its very nature [60], fruitful experimenting researches to trace the distinctive features of a context could be included [61]. Since 1990s, in fact, the focus of comparative law has shifted more towards social studies [62], and the idea of legal culture [63].

This trend is part of an evolutionary framework that has affected, in similar terms, other social disciplines which have innovated their research methods towards an increasingly complex reality by drawing trajectories of interdisciplinary analysis [64]. Since the end of the twentieth century, a closer correlation between legal comparison and the heterogeneous field of social studies has manifested itself: some of the boundary lines traditionally set between them have become obsolete in the light of the emblematic changes that have characterized, in an expansive sense, the epistemological foundations of law, human sciences and social sciences [65]. This is the reason why it is not surprising to note that recent comparative law researchers dedicate a keen attention to pragmatical data to understand how law is perceived, interpreted and applied [66].

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[60] See the Trento Manifest, V Thesis, 1987. It can be found in A. GAMABARO, P.G. MONATERI, R. SACCO, *Comparazione giuridica*, 3 Digesto, 4 ed., *Discipline privatistiche*, 52, 1988. For an English translation, see R. SACCO, *AJCL*, 39, n. 6, 1991, ps. 27-29. In his law-in-context approach, Rodolfo Sacco has been focusing on what has made the law as it is, 'legal formants'. In this approach it is notably the legal context which seems to be most important: constitutional and legislative rules, case law, and legal doctrine, but also 'implied patterns' and other hidden elements, such as world views, influencing the way law is interpreted and handled. He calls them 'cryptotypes'. R. SACCO, *Legal Formants. A Dynamic Approach to Comparative Law*, in *American Journal of Comparative Law*, 1991, ps. 1-34 (part I) and ps. 343-401 (part II). Besides others see M.A. GLENDON, P. CAROZZA, C.B. PICKER, *Comparative Legal Traditions in a Nutshell*, 3d ed., West Academic Publishing Co., St. Paul, 2008; U. MATTEI, *An Opportunity not to be missed: The Future of Comparative Law in the United States*, in *Am. J. Comp. L.*, 46, 1998, p. 709. Some comparatists underlined the functional method includes a law-in-context method. See E. ÖRÜCÜ, *Developing Comparative Law*, in E. ÖRÜCÜ, D. NELKEN (eds), *Comparative Law: A Handbook*, Hart Publishing, Oxford, 2007, p. 62. In general, to exemplify the explicit openness of comparative law to non-legal knowledge, see P.G. MONATERI, *Methods of Comparative Law*, Edward Elgar Pub, Cheltenham, 2013; G. SAMUEL, *Methodology in Law and Comparative Law: Contributions from the Sciences and Social Sciences*, in M. VAN HOECKE (ed.), *Methodologies of Legal Research: which Kind of Method for What Kind of Discipline*, Bloomsburry, 2011, p. 35.

[61] E.g. H. SPAMANN, *Empirical Comparative Law*, in *Annual Review of Law and Social Science*, 11, 2015, ps. 131-153.

[62] U. KISCHEL, *Comparative Law*, Oxford University Press, Oxford, 2019.

[63] D. NELKEN, *Using the Concept of Legal Culture*, in *Australian Journal of Legal Philosophy*, 29, n. 1, 2004; and D. NELKEN, *Comparative Legal Research and Legal Culture: Facts, Approaches, and Values*, in *Annual Review of Law and Social Science,* 12(1), 2016.

[64] To the evolution of the comparative method has been dedicated the section cases and issues of the journal *Diritto pubblico comparato e europeo*, in *DPCE Online*, 1, 2020.

[65] This evolution is widely reported A. RILES, *Comparative Law and Socio-Legal Studies*, in M. REIMANN, R. ZIMMERMANN (eds), *The Oxford Handbook of Comparative Law*, II ed., Oxford University Press, Oxford, 2019, p. 773.

[66] VAN HOECKE, M. WARRINGTON, *Legal Cultures, Legal Paradigms and Legal Doctrine: To-*

In short, the contextual approach weight in depth «the various factors surround law» [67]. Notwithstanding the claim that this approach lack of an orthodox method [68], it could lead to design an effective and socially desirable biotech regulation, coherent to balance the European innovation goal and cultural food policy. In this way, uncertainty can be reduced by adopting governance mechanisms capable of coordinating the interaction between different agents [69] (see more infra § 6).

Public perceptions and food culture are crucial elements for determining the acceptance of a model of governance in a domain where "technological risks" [70], unlike simple risks (e.g. car accidents), cannot be calculated according to traditional technocratic models, namely as a statistically foreseeable function of probability [71].

The establishment of the risk and safety threshold showed the mobile borders between the various priorities – technological innovation, safety culture and protection of tradition – depending on the considered geopolitical context.

In the previous pages, leading cases exemplified this peculiarity and lead to reflect on the new frontiers of SynBio. Besides all: (i) what is a new product in some contexts could represent a food of tradition for other legal experiences (novel foods case); (ii) the protection of the traditional identity of agro-food products has already occurred as a reaction of Member States to the risk of simplification of traditional values caused by the imposition of hygienic and sani-

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wards a New Model for Comparative Law, in *International and Comparative Law Quarterly,* vol. 47, 1998, ps. 495-536. On contextual comparative law see U. KISCHEL, *Comparative Law*, Oxford University Press, Oxford, 2019; e J. HUSA, *Methodology of Comparative Law Today: from Paradoxes to Flexibility?*, in *Rev. intern. de droit comparé*, 58, 4, 2006, ps. 1095-1117. Conversely, for an exam of the rule-oriented approach see the milestone publication on the functional approach see K. ZWEIGERT, H. KOTZ (eds), *An introduction to Comparative Law*, 3ed, 1998; and M. GRAZIADEI, *The Functionalist Heritage*, in P. LEGRAND, R. MUNDAY (eds), *Comparative Legal Studies: Traditions and Transitions*, Cambridge, 2003, ps. 100-128; see also R. MICHAELS, *The Functional Method of Comparative Law*, in M. REIMANN, R. ZIMMERMANN (eds), *The Oxford Handbook of Comparative Law*, 2nd ed., 2019.

[67] In these terms J. HUSA, *Methodology of Comparative Law today: from Paradoxes to Flexibility?*, in *Revue international de droit comparé*, 58, n. 4, 2006, p. 1099. For an example of the use of contextual comparative law in case law, even if in a completely different field, see the argumentations of the ECJ in *Sahin v. Turkey* (ECtHR), App. 44774/98.

[68] J. HUSA, *Methodology of Comparative Law today: from Paradoxes to Flexibility?*, cit., p. 1108.

[69] On the social relevance of uncertainty see M. TALLACCHINI, *La costruzione giuridica dei rischi e la partecipazione del pubblico alle decisioni science-based*, in AA.VV., *Scienza e diritto nel prisma del diritto comparato*, Giappichelli, Torino, 2004, p. 339.

[70] 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*, in *European Journal of Risk Regulation*, 7, No. 3, 2016, ps. 469-474.

[71] M. GRAZIADEI, *Modernisation and Risk Regulation in the Italian Food Sector*, in M. DYSON (ed.), *Regulating Risk through Private law*, Intersentia, 2018, p. 347-359; M. WEIMER, L. MARIN, *The Role of Law in Managing the Tension between Risk and Innovation*, cit.

tary standards imposed at European level for industrial production [72]. Moreover, (iii) not every result of technological innovation must automatically be subjected to a more stringent legislation: it depends on the understanding of the relationship between law, science and innovation (see gene editing; CRISPR-Cas9 cases) [73]. Furthermore, in society the perception of what is considered a Gmos has changed, while it has not in legal terms.

A good example of the impact of the perception of the social datum of risk in regulatory choices is offered by the economic analysis of law. In the report "On Mandatory Labeling, with Special Reference to Genetically Modified Foods" [74], the American jurist Cass Sunstein analyzed the duty to label the presence of Gmos introduced in the US federal *Gmo Labeling law* in 2016 [75].

The report observes the absence of scientific data to attest the risks inherent in Gmos, and investigates when governments should introduce mandatory information to the benefit of social welfare, questioning the consumer's right to know the ingredients for the sole purpose of making food choices in line with their personality. Sunstein noted that based on survey results, mandatory labeling for Gmos was introduced "because members demanded it without really being interested; and believed that Gmos are dangerous even in the absence of scientific data" [76]. Consequently, scientific information about agri-food technologies would not, therefore, automatically have lead the consumer to the acceptance of technological risk.

Despite the efforts of public 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.

These are key factors for policymakers to formulate meaningful government proposals. Particularly in Europe, where options vary widely depending on the member state considered [77], and where, in the collective imagination, consumers tend to be *risk-adverse* [78].

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[72] C. LOSAVIO, *Le regole comunitarie e nazionali relative all'igiene dei prodotti*, in L. COSTATO, A. GERMANÒ, E. ROOK BASILE (eds), *Trattato di diritto agrario*, Milano, 2011, p. 183.

[73] The case is treated by A. DI LAURO, *Mercato agroalimentare e innovazione tecnologica*, in P. BORGHI, I. CANFORA, A. DI LAURO, L. RUSSO (eds), *Trattato*, cit., p. 544 e ss.

[74] C. SUNSTEIN, *On Mandatory Labeling with Special Reference to Genetically Modified Foods*, Report, October 9, 2016.

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

[76] Report, 5.

[77] L.J. FREWER, C. HOWARD, J.I. AARON, *Consumer Acceptance of Transgenic Crops*, in *Pesticide Science*, 52, 1998, ps. 388-393.

[78] 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

Within the specific field of SynBio, different ontological conceptions of life, the ethics of responsibility, social inclinations on the living organisms uses undermine the solution that has been opted for years, concerning the identification of the threshold of safety, namely the "safe enough" threshold with established criteria (e.g. consumers' expectations; safety standards).

Considerations on contexts were clearly valorized by the European Group on Ethics in Science and New Technologies (from now on: Ege) in the Opinion n. 32 on Ethics of Genome Editing [79]. According to what observed: «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» [80].

The document promotes an holistic approach to include also non-measurable components [81]. In recent legislation there are attempts to address uncertainty by reducing the distance between understanding the true degree of risk (scientific fact) and the adopted legal measures on the basis of assessments that are not strictly scientific. It happened, for example, with the introduction of the Directive no. 350/2018 where environmental impact experience is considered for EU environmental risk assessment of Gmos [82].

American doctrine holds that European consumers would no longer be averse to the risk in comparison to American consumers, see C. SUNSTEIN, *Il diritto della paura: oltre il principio di precauzione*, Il Mulino, Bologna, 2010, ps. 26-27.

[79] The European Commission requested the EGE to submit 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 EGE published the Opinion on the ethics of genome editing. The experts' group 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. The Opinion aims at examining how specifically the EU 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/ege_en#latest.

[80] EGE, *Opinion on Ethics of Genome Editing*, cit.

[81] This is new, as a matter of fact, for long time, questions concerning the socio-economic, ethical and wider ecological impacts on the technology have been excluded see S. JASANOFF, *Commentary: Between Risk and Precaution – reassessing the Future of GM Crops*, in *Journal of Risk Research*, 3, Iss. 3, 2000, ps. 277-282.

[82] Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms C/2018/1371, in *OJ L* 67, 9 March 2018, ps. 30-45.

In practical terms 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.

Based on the Study most of the ethical concerns relate to how these techniques are used, rather than the techniques themselves. It might be part of the artificial/original ethical considerations which are sharpened in public debates since the 1990s.

Long-debated questions revived by genome editing, notably about the different meanings that ought to be attributed to humanness, naturalness and diversity will be a clear sign of a change of approach in the regulation of the new agri-food biotechnologies since legislative procedures are inspired by participatory processes of different actors, such as consumers representatives, from the earliest stages of preparing the relevant legal documentation [83].

As «public perception of new technologies is key to their market uptake» [84], it is now a given that the acceptance of a technology is also determined by the perception of its potential benefits: most people questioned the need and usefulness of precision agri-food biotechnologies [85]. In this sense, for example, it seems to be misleading the extension of the labelling rules using the reference to Gmos when NBT are at stake.

The costs of regulatory uncertainty should push for an update of the risk assessment to take into account the several sustainability aspects studying the variations across the contexts (see § 6), as ethical concerns should be raised by the use but also by the non-use of technological and scientific progress [86]. A reflection on which research tools are functional is fitting for the purpose as well.

6. How to find a matrix of regulatory coordinates: conclusions

The importance to consider the regulation in context clearly emerged from the closer look to the biotech agri-food legislative landscape sketched out (§ 4).

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[83] See the Commissie Genetische Modificatie (COGEM), *Report on the Nature of Nature. A Study on the Use and Meaning of Nature and (Un)naturalness in the Literature on Genetic Modification*, 2022, available at: https://cogem.net/en/news/on-the-nature-of-nature-a-research-report/.

[84] See p. 4 of the Study.

[85] A. RONTELTAP, J.C.M. VAN TRIJP, R.J. RENES, L.J. FREWER (eds), *Consumer Acceptance of Technology-based Food Innovations: Lessons for Future of Nutrigenomics*, in *Appetite*, 49, 2007, ps. 1-17; P. SLOVIC, *Perception of Risk*, in *Science*, 236, 1987, ps. 280-285.

[86] In these terms: E. SIRSI, *Gli alimenti geneticamente modificati*, in P. BORGHI, I CANFORA, A DI LAURO, L. RUSSO (eds), *Trattato*, cit., ps. 548-559, and p. 559.

Henceforth, to reflect on a suitable regulatory model for SynBio in European context, two final considerations can be delineated towards: (i) the awareness of the essential "dimensions" of agri-food sustainability; (ii) the individualization of the variables, and research methods, to build a responsible regulation, having regard to the different types and weight of uncertainties.

As stated in introduction, the starting observation is that sustainability criterion contains all the directories to assess new agrifood technologies encompassing the "safe enough logic" towards a more inclusive direction. The idea of sustainability in Europe is inspired to the realization of the UN Agenda for Sustainable Development Goals [87]. The European Legislator's intent is clearly to achieve it through a threefold dimension: environmental, social and economic ones. Following the European Green Deal Strategy [88], the environmental dimension of sustainability seeks to realize a neutral and positive environmental and food impact; the social declination guarantees healthy and nutritious food that is environmentally sound, animal welfare friendly and responsive to dietary preferences; lastly, economic sustainability protects access to foods, equity, and competitiveness along the food chain.

The composite EU regulatory framework (EU Farm to Fork Strategy; EU Strategy on Biodiversity [89]) achieves sustainable goal by identifying macro political objectives, declined into specific objectives and translated into quantified targets (e.g., pesticide reductions, improved animal welfare, etc.). The way for implementation is not only the legislative one [90], as several aims will be realize by Member States as part of future programming of the Common Agricultural Policy (CAP 2023-2027) [91].

Given the common European consensus on the multi-faced meaning of sustainability, the Union aims at developing it along the entire agricultural process and food supply chain: through food production, stimulating compliant food

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[87] FAO, *Food and Agriculture: Key to Achieving the 2030 Agenda for Sustainable Development*, 2016.

[88] European Commission, *The European Green Deal*, 640 final, 11 December 2019, p. 2.

[89] European Commission Communication, *EU Biodiversity Strategy for 2030 Bringing nature back into our lives*, COM/2020/380 final, 20 May 2020.

[90] M. MARTI, *Research for AGRI Committee. The Farm to Fork Strategy Implications for Agriculture and the CAP*, European Parliament, Policy Department for Structural and Cohesion Policies, Brussels, 2020, 10. For a reading on the coordination matter between legislations for a sustainable agriculture and food chain see M. ALABRESE, *Politiche climatiche, politiche agricole e il bisogno di coordinamento*, in *Riv. dir. agr.*, I, 2020, p. 618 ss.

[91] In June 2021, the Council and the European Parliament reached a provisional political agreement on the future of the Common Agricultural Policy (CAP) 2023-2027 in response to a legal proposal tabled in 2018 by the European Commission. The European Commission presented its proposal for the common agricultural policy (CAP) reform in 2018, introducing a new way of working to modernize and simplify the EU's policy on agriculture. Following extensive negotiations between Authorities, agreement was reached, and the new CAP was formally adopted on 2 December 2021. It is due to be implemented from 1 January 2023.

processing, wholesale and retail to promote the shift to healthy diets, and to struggle with the problem of food waste.

In sum, food sustainability is an ambitious challenge, complex in its realization, and Europe addresses it with systemic interventions, such as the Green Deal, to overcome the fragmentation of policies that currently affect food systems.

It is still early to measure the success of the European efforts with particular attention to high-tech food, but these premises help to move towards the propositional and final part of this paper (ii). Following the three dimensions of sustainability it's worth to consider what can lead to a regulation of SynBio highly accepted, and through which research tools.

At this purpose, taking advantages of the openness of comparative law (see § 5), legal analysis could benefit of the contribute of other disciplines. Besides all, the initially mentioned Sts and the social science scholarship for a responsible research and innovation agenda (see *infra*) could trace the innovation trajectories with articulations of broader societal values enriching the study of the context. Moreover, it is synergic the most recent vision integrating empirical testing to check the assumptions of law and its effectivity [92].

Reading European actions under this perspective implies to grant a key role to the interpretative lens of the responsible research and innovation (from now on: Rri) policy in the field of converging technologies. In 2011 the European commissioner, Von Schomberg, described it as a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability, and societal desirability of the innovation process and its marketable products to allow a proper embedding of scientific and technological advances in our society [93].

A parallel movement within the studies of risk regulation indicates that the analysis must go beyond the narrower notions of risk and safety, to discuss the social purpose of technological innovation and the cultural context within which technological change takes shape. In fact, «the risk discourse is as complex and multifaceted as other inter- and transdisciplinary discourses of our time, which deal with terms and concepts that are in some way perceived to fundamentally reflect current changes of paradigms across modern western societies (such as for instance the terms "globalization" or "digitalization")» [94]. It

[92] "Empirical research in comparative law" has become popular in the US and it is slowly gaining ground in Europe as well, is a kind of modest legal sociology just aiming at checking implicit assumptions of the law or the effect and efficiency of legislation. M. SIEMS, *Comparative Law*, 3rd ed., Cambridge University Press, Cambridge, 2022; M. SIEMS, *New Directions in Comparative Law*, cit., ps. 852-874.

[93] R. VON SCHOMBERG, *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields*, Luxembourg, Publications Office of the European Union, 2011, ps. 7-17. European Commission, *Options for Strengthening Responsible Research and Innovation*, Luxemburg, 2013.

[94] In these terms: M. WEIMER, *The Origins of Risk as an Idea and the Future of Risk Regulation*, in *European Journal of Risk Regulation*, 8, 1, 2017, ps. 10-17, p. 11.

can be deducted that to concretize Rri strategy, ethical and social issues should be integrated in the discourse *ab origine*, and it represents an indispensable starting point to base technological development on the respect of the values of the Union referred in Article 2 of the TEU.

To sum up, it goes without a word that the Rri process in European context can not be disregarded, having a regulatory design that reflect values of the legal system, applied ethics and the idea to reach responsive risk governance through a participatory process [95].

There is not jet clarity about the specific techno-legal parameters to realize it. Nevertheless, once again, considerations about an Rri framework for gene-editing offer helpful insights. Scholars proposed, in fact, to operationalize the Rri following four functional criteria for decision-makers to shape gene editing development in line with social values: anticipation, inclusion, reflexivity and responsiveness [96]. The first one refers to the capacity to questioning and struggling with "what if…" scenarios, embracing socio-economic and ethical-cultural considerations [97]. This mental operation would require a systematic contextualization of the technoscience impacts as a sort of precondition.

Inclusion refers to the need of building a participatory regulatory approach involving all stakeholders from the beginning, not only scientists, but even ethicists as their considerations are not a conclusive landing point but are necessary to shape regulation *by design*. Reflexivity indicates the awareness that a particular framing of an issue may not be universally accepted recognizing the limits of knowledge, from which derives, for example, the importance in agri-food law of paying attention to the relationship between consumers' health and environment [98]. Lastly, responsiveness is, in sum, the ability to shape the regulation following the three Rri dimensions just described.

Borrowing from this reasoning important insights, a European sustainable regulatory model for SynBio will let the endemic features emerge, as confirmed the need to encompass the "safe enough" culture in favor of an holistic approach to safety. A participatory and interactive regulatory process will individ-

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[95] B.J. KOOPS, *The Concepts, Approaches and Applications of Responsible Innovation. An Introduction*, in B.J. KOOPS *et al.* (eds), *Responsible Innovation 2: Concepts, Approaches and Applications*, Springer, Dordrecht, 2015, ps. 4-5.

[96] The dimensions were recently proposed and explained by P. MACNAGHTEN, G.J.L. HABETS (eds), *Breaking the impasse: Towards a forward-looking Governance Framework for Gene Editing. with Plants*, in *Plants People Planet*, 2, 2020, ps. 353-365, spec. p. 359.

[97] Techniques for developing creativity in the legal field have been studied by G. PASCUZZI, *La creatività del giurista. Tecniche e strategie dell'innovazione giuridica*, 2ª ed., il Mulino, Bologna, 2018. See, in particular, the jurist's cognitive techniques for interdisciplinary studies.

[98] In this sense it is instructive the ways to face the issues of neo-liberal collectivization of global agriculture (cross-fertilization GM crops issues) on questions of freedom and sovereignty, see P. HERVEY, *An anthropological Perspective on the Promise and Threat of GM Crops*, in P. MCNAGHTEN, S. CARRO RIPARALDA (eds), *Governing Agricultural Sustainability: Global Lessons from GM Crops*, Routledge, London, 2015, ps. 174-178.

ualize the elements for the specific European context. Furthermore, due to the non-legal nature of the elements described above to design a sustainable regulation, empirical investigations in comparative research will be carried by the various methods adopted in social sciences (such as both qualitative and quantitative methods).

One conclusive note: ultimately, legal education is in need of a transformative change to convert into a full lawyers' preparation to take on the challenges to understand socio-cultural context and needs. Lawyer needs to strengthen suitable cognitive instruments, and comparison can provide them since the relation between legal and technological changes has been one of its privileged field of investigation. Now with keen attention to empirical research tools.

It is a delicate balance between what could constitute European acceptable SynBio practices and functional legal instruments that deserves to be reached. This will serve the scope in a field where the global nature of food chain requires both a cautionary and valuable approach to mitigate cultural differences and build the foundations for a sharing core idea of sustainability.