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Position Paper

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This paper addresses specifically the content of Objective 1, lett. d) of the Project “The Food of Future – The Future of Food”, as outlined below:

“Elaborate guidelines and suggestions addressed to Legislators and policymakers on how to efficiently legislate topics characterized by a high degree of innovation and technicality and how to guarantee that these laws could keep up with rapid scientific and technological progress, also taking into account the uncertainties related to the actual scientific knowledge”

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I. Executive summary

The pursuance of goals of food security in its broadest understanding lie at the core of the UN Agenda 2030 for sustainable development. The achievement of more widespread access to food and the reduction of malnutrition may be enhanced by resorting to tools provided by relevant advancements undertaken by science and technology. The interaction between law, science and technological innovation requires acknowledging an inherent asymmetry between a social phenomenon that depends on the positive action of institutions tasked with normative powers and a more empirical field of studies, that applies an experimental methodology. This difference is reflected in the rather static nature of law as opposed to a peculiarly dynamic evolution of science, that is subject to falsification and replacement at a far faster pace. This asymmetry requires lawmakers to let go of a traditional *ex ante* approach to regulation of scientific innovations, based on planning schemes depending on the availability of sets of data that are certain and exhaustive. The need to rely on ever-changing tools makes it necessary to transition to a more flexible kind of regulatory approach, that accounts for adaptable instruments of legislation. This effort is justified also by the fact that insufficient datasets and increasing ranges of uncertainty make it easier to assess the hazards of new techniques of food manipulation, rather than identifying more specifically the risks underlying the resort to these methods in the agri-food sector. Indeed, the argument in favor of an outsourcing of policy decisions to science has proven utopian as the uncertainty mentioned above makes it impossible for science to provide anything close to truth to decision-makers (cp. A. Wildavsky, *Speaking Truth to Power. The Art and Craft of Policy Analysis*, New York, 2017). The traditional precautionary approach that has been a staple of all discussions addressed to tackle food safety concerns might therefore need to be reconsidered, at least in the horizon of scientific innovations whose most direct implications are unknown to the scientific community. This implies that science-based decision-making processes should be reassessed in first place, rather than discarding the precautionary principle altogether. The most immediate effect of these considerations may be the establishment and consolidation of procedural arrangements aimed at involving a wider plurality of actors in decision-making processes, with the intended goal of acquiring feedback and valuable input from a diverse pool of areas of expertise. In this regard, a similar approach takes after the so-called *One Health* paradigm, that postulates an effort to take into account the effects of regulatory choices upon a broader range of addressees, not limiting the assessment to human well being but accounting also for animal welfare and the long-term sustainability of the environment. Such considerations cast a light on the convenience to integrate scientific knowledge into a holistic decision-making process, that begs due deference to scientific findings and technological advancements but does not ultimately renounce its role of ultimate policymaker, that is accountable to the people. In this regard, an example is provided with specific reference to the authorization of new genomic techniques as a tool to fight more effectively some of the challenges that the UN Agenda 2030 sets to tackle. By highlighting the acknowledgement by the Court of Justice of the EU of the risks underlying an excessively strict interpretation of the provisions of the existing GMOs framework, this report provides some general guidelines to lawmakers for prospective legislative drafting addressed to this very same subject matter. The remarks benefit as well from the study report of the European Commission released in 2021 and the text of the regulation proposal dating back to 2023.

II. Background information

The present report addresses the challenges connected to the strive to combine technological and scientific innovations with the pursuance of sustainable agricultural and food systems. In this perspective, the effort undertaken is directed at exploring the avenues made available by the advancements of science and technology to contribute to the achievement of some of the sustainable development goals of the UN Agenda 2030. More specifically, the inquiry aims at providing guidelines and directions for lawmakers with the specific intent to pursue the goals of making easier the access to safe, nutritious and sufficient food for all (Target 2.1) and to eradicate all forms of malnutrition (Target 2.2).

Indeed, these concerns have become of pivotal importance against a background that foresees a steady rise in the world population with insufficient arrangements to provide food security for all human beings that will be inhabiting the planet in the next few decades. Acknowledging these challenges makes it necessary to elaborate medium to long-term strategies to tackle the insufficient supply of food all over the world and to reduce the already existing poverty, as well as preventing the spillover of socio-economic distress in countries where nowadays fewer risks of malnutrition and insufficient supply of adequate food exist. In this regard, scientific innovations may be a formidable asset to bolster wide-ranging efforts to provide food security for an increasing population. This has been highlighted also by the European Commission in its Communication devoted to *Safeguarding food security and reinforcing the resilience of food systems* (COM(2022) 133 final). More specifically, the Commission underlined that “Innovation through research, knowledge, technology, agro-ecology and adoption of best practices can mitigate pressure on input costs without hurting production capacity, leading to long-term progress in productivity to achieve the green transition ... [the Commission] is also assessing options for new rules on new genomic techniques, which have the potential to create plant varieties that are less susceptible to changing temperatures and climatic threats, more resistant to plant pests and more efficient in the use of fertiliser”.

To make these strategies possible, lawmakers must however be aware of the nature of and the risks associated with the most innovative processes occurring in science and technology. Legislative awareness is instrumental in driving the development of safe and equal agricultural and food supplies and to monitor the consumption of novel foods or of surrogates of food resources that were already part of the citizens’ diet. The proposals that will follow will be based upon the contextual background addressed above and they will be inspired by the idea that all remedies to the shortcomings of the current agri-food sector shall be driven by a holistic approach (*One Health* paradigm), as it will be articulated in the policy proposals.

III. Policy considerations and proposals

Addressing the relationship between law and science requires to take into account the inherent asymmetry of these two subjects: while law tends to be a static phenomenon – capable of evolving, although rather slowly at times – science is by definition dynamic and is often a driver of considerable changes also under the legal approach to several social issues. This difference is due also to the precarious duration of scientific assumptions, that are considered true within a specific timeframe until they are proven false and overcome by other theories, explanations or findings. Seeing as scientific knowledge is provisional and mobile, the relationship between law and science shall take into account this margin of uncertainty and accept the ever-changing nature of the interaction between science and law or politics. The reversible patterns that shape this relationship depend also on the acceptance of the potential of legal principles and rules to change over time, as the axiological framework underlying legislative choices and the interests pursued by a given community may vary.

The foregoing considerations bring about the convenience to address the regulatory choices undertaken in the past decades to discuss to what extent they fit the current landscape, where uncertainty shapes the relationship between law and innovation. More specifically, regulation has traditionally adopted an ex-ante approach aimed at planning thoroughly the instances when consensus existed concerning the authorization of given technological tools or scientific innovations. Such a regulatory framework may only work, however, where facts are not disputed and a baseline understanding of factual reality exists. By acknowledging the uncertainty embedded in new forms of production and manipulation of agricultural and food resources, the need for a shift to strategic regulation becomes apparent, as more flexible tools capable of adapting to changing factual backgrounds become pivotal in addressing the challenges associated with the implementation of scientific innovation in the agri-food industry.

The present considerations apply to novel foods entailing the use of innovative techniques of manipulation of biological material, such as the ones underlying cultured meat. This does not rule out a potential general validity of these guidelines for the overall category of novel foods. The guidelines apply also to other forms of technological innovation, such a new genomic techniques implying the genomic editing of cereals and all kinds of plants (so-called NGTs).

When addressing the above category, it is expedient to clarify that whether these tools contribute to foster food security is a question that must be considered along with food safety concerns, which this report will discuss in first place. The most relevant issue is to identify to what extent scientific advisors and political decision-makers are actually able to determine with a sufficient degree of precision the risks or hazards associated with the products that are the result of the manipulation that have been mentioned. By borrowing the categorization of the European Food Safety Authority (EFSA), risk is identified as the likelihood of causing harm, whereas hazard shall be understood as something that has the potential to harm. Any time the debate revolves around the authorization of technologies or scientific innovations that have been developed recently, there is shortage of data and studies concerning the effects on the well-being of the final consumers, especially over the long term. This implies that it is easier to assess the hazards associated with the resort to such tools, rather than the actual risks.

Acknowledging this circumstance makes it compelling to rethink the regulatory strategy that has dominated the choices concerning food safety in Europe over the last decades. A strict application of the precautionary principle would advise preventing any effort to develop or employ any technology capable of presenting mere hazards to human health and to the environment. Indeed, doing so would entail curtailing the possibility to exercise the freedom of scientific research and the freedom of enterprise, as well as undermining some of the food security goals that represent a centerpiece of

the framework for a sustainable development, especially in the perspective of intergenerational sustainability. The inconvenience of invoking the precautionary principle too easily has been claimed both by the Court of Justice of the EU and, on a similar note, also by the Italian Constitutional Court. Notably, this latter has declared that “imposing limitations to the freedom of enterprise, on the basis of precautionary concerns directed at the protection of human health and the environment, may only be justified under a constitutional standpoint upon an assessment of the status of scientific knowledge based on empirical and experimental evidence validated by national and supranational institutions of renowned expertise and competence” (decision no. 116/2006).

Carving out a special reservation for science as an asset to facilitate more informed political decision-making brings about further issues that need to be addressed, specifically with reference to the authorities that should play a role in policymaking on scientific and technological innovations. If EFSA appears the natural go-to institution for all issues associated with food safety, it is far from settled what are the other bodies or even levels of governance that shall play a role in providing consulting to national or supranational legislators when they need to address subject matters requiring assessments that go beyond the mere profile of food safety. Any choice concerning the source of the expertise that is relied upon or even taken into consideration necessarily affects the outcome, as does the question presented to the scientific authority. It should not be forgotten that scientific assessments do not always follow linear processes, as they are influenced by the observation perspective that is chosen. The impossibility to have actual neutral processes of evaluation of the scientific innovations developed by the researchers must be taken into account anytime political decision-makers resort to scientific expertise to support their policy determinations.

The struggle to establish reasonable scientific assessment of the hazards and risks associated with the use of scientific innovations in the agri-food industry to pursue the sustainable development goals that have been outlined above requires supplemental considerations. The limited nature of the available dataset, both in terms of rough data and of time span to assess the medium or long-term impact of given tools and innovations – or even the pre-existing consumption of a kind of food in a different geographical context –, and the inherent scientific uncertainty put decision-makers before a crossroads. Depending on the degree of uncertainty intolerance, the actual outcome could be an unbearable inertia of lawmakers or the adoption of blatantly inadequate legislative remedies. Identifying reliable actors that shall be involved in debating the pros and cons of given regulatory choices in a transparent policymaking process is therefore crucial to equip the legislator with the necessary empirical knowledge to make up its mind on the most suitable regulatory framework, also in light of the interaction between the existing legal framework and the new tools developed by science and technology.

Against the backdrop of the general principles that shall be applied to shape all regulatory efforts concerning the implementation of scientific and technological innovations, some further remarks shall be devoted to specific legislative techniques for the authorization or restriction of the resort to similar tools for the development of sustainable agri-food systems, in pursuance of a maximization of the achievement of food security goals. In this regard, reference must be made to the traditional approaches for what concerns genetically modified organisms (GMOs), whose traditional regulation has followed a precautionary approach in Europe, whereas in the USA the oversight of regulatory authorities has mostly been oriented on the actual features of the final products provided to customers, regardless of the methods underlying its processing. Refraining from imposing a straightjacket in this subject matter is essential to avoid curtailing the advancement of science and technology, whose relationship with political decision-making is subject to fast and sudden changes.

In this regard, any attempt to shape deliberative processes when it comes to the authorization of technological innovations shall be inspired to holistic approaches, aimed at fulfilling the ambition

of the so-called *One Health* paradigm. Addressing the concerns arising from an acknowledgement of the significance of regulatory choices in the agri-food sector for the well being of consumers but also for animal welfare and the sustainability of the environment for the benefit of current and future generations brings about unavoidable procedural implications. First, decision-making processes shall involve a plurality of actors, from representatives of distinct areas of expertise to policymakers that lack a scientific background to real life stakeholders such as citizens, who are the ultimate beneficiaries of food policies. Ensuring a distinctively diverse make-up of decision-making forums intends to guarantee that a well-rounded assessment of the risks associated with a full-scale deployment of such innovative tools is undertaken. The goal shall be the prevention of irreparable damages to human and animal health, combined with the mitigation of the drawbacks on the environment in terms of the consequences associated with the phenomenon of climate change.

Pursuing this holistic approach is instrumental in bringing to life the teaching of the Italian Constitutional Court that has been mentioned earlier. Notably, the relationship between science and political decision-making shall not translate into a flattening of policymaking into the scientific evidence presented by scientists. All references to the convenience of a precautionary-based approach shall in turn be justified upon scientific evidence, in an effort to make the legislator accountable for decisions that ultimately rest upon legislative and political discretion. Science is a useful tool for political decisions in subject matters where hazards and risks are measurable but cannot be the only and deciding factor for lawmakers to ultimately opt for a strict or more lenient policy in terms of resort to scientifically manipulated food resources in the agri-food industry. What appears crucial is establishing mechanisms and practical arrangements that bring together all the actors involved in the production, processing and distribution of food resources in order to allow for more comprehensive planning of the actual needs of different communities and to provide a further element to weigh against the hazards associated with food manipulative processes made possible by science and technology.

The above methodology could be experimented already in the context of so-called new genomic techniques (NGTs), where the scientific innovations have made it possible to cultivate plants that are more resistant to harsh weather conditions by manipulating their DNA, whilst still refraining from combining plants that would not otherwise enter into contact through spontaneous cross-fertilization in the ecosystem. All kinds of genomic editing (different from transgenesis) could therefore represent a frontier in the agricultural and food industry, providing for more efficient cultivation and ultimately offering a remedy to the shortage of food connected with environmental or geopolitical crisis. Whereas the Court of Justice of the EU originally refrained from finding that these methods of genomic editing qualified for the exemption provided for in the Annex I.B to the GMO Directive (*Confédération paysanne*, 2018), it has since adopted a more nuanced approach by holding that the indiscriminate exclusion of all organisms produced through mutagenesis would hamper the goals of the protection of human health (especially in terms of food security) and of the environment, thereby violating the precautionary principle (*Confédération paysanne*, 2023).

The turning point lies in the fact that it was held that focusing the oversight on the process alone neglects to consider to what extent the final product provided for human consumption features element that may harm the health of consumers. A radical and very strict interpretation of the precautionary principle, however, makes it likely that the exception specifically provided for in the relevant legislation is inoperative. It is worth noting that the issue has been addressed by the European Commission between the two decisions of the Court of Justice and the research efforts have been collected in an ad hoc study on the statute of NGTs that highlights the saliency of addressing the issue, especially in the context of the new “*Farm to Fork*” strategy of the EU within the broader Green New Deal. The study makes clear that regulatory measures at supranational level would be very useful to

prevent the consolidation of a patchwork of national regimes whose ultimate result would be to disrupt the achievement of the goals of the overall EU strategy. This appears all the more relevant if compared to the struggle of the EU to impose a uniform regulatory scheme for GMOs in general, especially in light of the re-expansion of the margin of discretion of the Member States after the 2015 Directive providing for a socio-economic exception to the framework of 2001.

Asymmetrical regulatory regimes would be detrimental to the harmonization of commerce and to the implementation of the Common Agricultural Policy within the Single Market, threatening the free circulation of goods as well as making the EU a less reliable commercial counterpart to third countries where food resources produced through NGTs are increasingly being exempted from GMOs legislative frameworks. Moreover, allowing for varying approaches within the EU would make it more likely that issues associated with product tracing arise in the phase of distribution.

The above considerations appear to have brought about a first tangible result in the submission of a regulation proposal by the European Commission in July 2023 (Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625). The text adopts a thorough approach aimed at discussing and regulating specifically the above techniques and sets a framework to differentiate their legal regime from the one applicable to GMOs. More specifically, the regulation of NGTs shall be subject to the appropriate level of regulatory oversight allowing farmers to access innovations and fostering the competitiveness of the European agri-food sector. The inadequacy of the current legislative framework, that refers to the GMOs legal regime, makes a compelling case for the establishment of new rules and procedures specifically addressed to NGTs. This strategy strives to combine a high level of protection of human and animal health and of the environment, with the goal of enhancing the development and commercialization of plants and vegetal products instrumental to the pursuance of the innovation and sustainability goals of the European Green Deal and the well-functioning of the internal market.

In this regard, NGTs would be classified in two categories: those that present elements that could be obtained also from natural and conventional techniques of plant breeding would be exempted from the application of the GMOs regime; for all the others, the GMOs regime would apply, but Member States could not exclude the cultivation of these plants on their territories. The justification for this prospective change of approach lies in the acknowledgment of the fact that, according to EFSA, targeted mutagenesis and cisgenesis do not imply significant risks for human health, animal welfare or the environment. It must also be noted that the demand for NGTs is on a rising pace and the implementation of this agricultural methods would contribute to the reduction of the emissions of pesticides as well as to the development of a more enhanced autonomy of the EU from agricultural imports.

It is apparent that the proposed regulation sacrifices – at least to some extent – most stances favorable to a subsidiarity-based approach to issues impacting the agri-food sector. In this regard, it would be desirable that the discussion of the text shaped the prospective regulatory schemes in terms that take into due account the relevance of local dynamics in authorizing or restricting the cultivation or the circulation of food resources obtained through NGTs. That notwithstanding, the remarks articulated above make clear the need for a comprehensive approach that defers, at least in its broader principles, to the systems of multilevel governance that are already in place in Europe. The main takeaway that current and future legislators shall consider is the inadequacy of legislation that dates back to two decades ago to shape the framework of phenomena that have made extraordinary steps forward over the past few years, requiring positive and more thorough regulation to keep up with the ambitious sustainable development goals set in the UN Agenda 2030.

IV. Conclusions and overall findings

Against the backdrop that has been sketched above, the present report proposes a few guidelines that lawmakers dealing with the implementation and integration of scientific and technological innovations in the agri-food sector might want to consider in order to promote a responsible political decision and ensure a sufficient supply of safe and adequate food for all:

- acknowledge the uncertainty surrounding new scientific forms of food manipulation and the inability of scientific research to provide more than estimates on the actual risks of large-scale consumption of these food resources
- reject clear-cut or one-size-fits-all remedies that conflate all kinds of genome editing in a unique category, opting instead for tailored frameworks and case-by-case assessments
- give preference to permissive regulatory schemes when it is possible to detect only hazards that do not exceed a pre-determined threshold
- provide for bans or multi-layered authorization procedures only when risks associated with the features of final products exist
- classify the sources of knowledge for each area of expertise to build a comprehensive taxonomy of the authorities for each of these areas
- ensure that scientific authorities are questioned after the perimeter of the inquiry has been delimited, so that scientists answer specific questions but do not dictate policy implications
- build a pluralist deliberative environment, fostering cooperation between different areas of expertise rather than competition between them and ensuring that non-scientist effectively take part to shaping policy decisions, alongside representative of the citizenry
- provide explicit guidance to consulting authorities as to the centrality of a holistic approach that is inspired to the *One Health* paradigm
- advocate for the practicability and convenience of exceptions in general legislative frameworks, accounting for specific instances that deserve peculiar legal treatment
- pursue the harmonization of the legislative regime of new genomic techniques and all systems of genome editing throughout the EU to be able to implement the scheme agreed upon within the Common Agricultural Policy
- account for the importance of the input and enforcement of these policy decisions by local communities and authorities, fulfilling the EU's commitment to subsidiarity in implementing the goals of the Treaties

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