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MONICA COCCONI

The balance between science and policy in the public decision-making process: the EFSA case (European Food Safety Authority)

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MONICA COCCONI[*]

The balance between technique and policy in the public decision-making process: the EFSA case (European Food Safety Authority)[1]

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1. *Introduction. Technical and political legitimation of the decision-making process in food safety*

The paper highlights the role assumed by some fundamental principles of European law, specifically those of precaution and transparency, in redefining the perimeter of technology and politics in the public decision-making process.

The context is that of the disappearance of the logic of full scientific rationality at the basis of some public choices in a sector, such as that of food safety, in which the existence of a possible risk on their extent, leads to political determinations driven more by prudence than solely from scientific evidence[2].

The deterioration of certainty, in the scientific analysis of certain risk factors and in their scope, actually entails the re-expansion of some principles of European law, such as those of precaution and transparency, and the reduction of the explanatory value of others, such as those of independence and scientific authority of the subjects in charge of the evaluation. The effect of the former on the interpretation of the rules of European law on the boundaries between

[*] Professoressa associata di diritto amministrativo nel Dipartimento di Ingegneria e Architettura dell'Università di Parma. E-mail: monica.cocconi@unipr.it.

[1] Based on the conference report held at Unibo on 30 October 2020 entitled «La regolazione della sicurezza alimentare fra diritto, tecnica e mercato».

[2] In the fields of environmental and health protection, the strategies for addressing, regulating and minimizing the risk are very relevant for the competent administrative and political authorities, such as to characterize their action as «risk administrations», see in this sense F. DE LEONARDIS, *Il principio di precauzione nell'amministrazione di rischio*, Giuffré, Milano, 2005, p. 3 e *passim*; A. BARONE, *Il diritto del rischio*, Giuffré, Milano, 2006.

technology and politics is amplified and, consequently, the role of the latter on the same side is reduced.

The different balance between technique and policy that is thus defined does not reduce the legitimacy of the Authority responsible for risk assessment; indeed, the same is supported through additional elements that reduce its possible self-referentiality and, in this way, strengthen the public's trust in its technical capacity to assume its role[3].

The predominantly technical legitimacy underlying some political decisions in the food safety sector has in fact produced in recent years, not infrequently, the public perception of consequent non-neutral and non-rational choices.

The recent change in balance, however, does not involve a substitution of political discretion for technical expertise but the construction of a new synthesis through a more plural and circular decision-making process, based on different elements of legitimation. Political legitimacy therefore joins technical legitimacy in a new synergy in which the guarantee of the right to health assumes a pre-eminent value in the light of which other interests worthy of protection of European law are measured, such as those of freedom of trade and competition.

In reality, the logic behind this new equilibrium is in no way antithetical to the functioning of the European market which, on the contrary, mainly benefits from the circulation of food and feed whose safety is proven. As stated in the first recital of reg. n. 178 of 2002: «The free circulation of safe and wholesome food is a fundamental aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as to their social and economic interests».

The role of the principles is also played in the redefinition of some institutions and rules of European law which, in a context of greater uncertainty about the extent of the risk to health, influences both the technical assessment and that of risk management to an enrichment and a refinement of data and values taken into consideration in the final assumption of the public choice. The European judge contributes significantly to the definition of this new balance

[3] On EFSA's tendency, in these cases, to react with an "uncertainty intolerance", see M. VAN ASSELT and E. VOS, *Wrestling with Uncertain risks: EU Regulation of GMOs and the Uncertainty Parados*, in *Journal of Risk Research*, 2008, p. 281.

through a new interpretation of the principles and a redefinition of their scope on the rules of European law.

The European legislator has also intervened in the redefinition of this balance through the issue of reg. n. 1381 of 2019 on risk communication[4]. This European discipline, especially in modifying the provisions of reg. n. 178 of 2002 on transparency, aims to reduce the Authority's self-interest in the risk assessment phase but, at the same time, to increase public confidence in the overall risk analysis process.

As stated in recital 12: «The transparency of the risk assessment process contributes to the Authority acquiring greater legitimacy in the eyes of consumers and the public in fulfilling its mission, increases confidence in the work it carries out and democratically guarantees a greater responsibility of the Authority towards the citizens of the Union».

Furthermore, the issue of the regulation makes the original discipline of reg. n. 178 of 2002 as the "constitutional basis"[5] of the law relating to European food safety, especially in terms of guarantees of reliability, objectivity and transparency in the use of scientific studies based on risk assessment, on the participation of States and on communication of this to citizens and consumers.

The enrichment of the general constitutional basis is joined, in the composite structure of the right to food safety, also by the sectoral disciplines on individual food products such as those of novel food (EC regulation no. 258 of 1997) and plant protection products (EU regulation no. 1107 of 2009) which also contribute to the reorganization of the perimeter of technology and policy in the decision-making process.

The limit of this rebalancing is that it concerns principles that mainly affect the aspect of greater articulation and the procedural obligations of the

[4] This refers precisely to the reformulation of the objectives of risk communication (new art. 8-bis). In fact, the general principles of risk communication have been dictated (new art.8-ter), the General plan of risk communication has been formulated (new art.8-quater) and specific provisions have been dictated on the notification of studies by EFSA (new art.32-ter), on the consultation of interested third parties (new art.32-quater), on studies aimed at verifying the evidence used in the risk assessment process (new art. 32-quinquies) and on the subject of confidentiality of certain scientific data exposed in the request for confidential treatment and guarantee of industrial secrets (new art. 39 et seq.)

[5] On the qualification of Reg. n. 178 of 2002 as the constitutional basis of European food law, see M. RAMAJOLI, *La giuridificazione del settore alimentare*, in *Dir. Amm.*, n. 4, 2018, p. 657 which on this point refers to B. VAN DER MEULEN e M. VAN DER VEIDE, *European Food Law Handbook*, Wageningen, 2009, p. 253.

decision-making process, not the responsibility inherent in political decisions that can produce significant damage to individual and collective health. The greater procedural legitimacy of the decision-making process certainly generates greater trust in the consumer public but is not necessarily capable of ensuring the guarantee of the constitutional rights involved.

2. *The risk analysis process in public decisions related to food safety*

Public decisions, in the food safety sector, are the final outcome of a risk analysis procedure with a composite structure in which the risk management phase, which is the responsibility of the European Commission, is always preceded by a risk assessment phase; it is an essentially scientific evaluation, consisting of assessments and technical assessments, entrusted to the European Food Safety Authority (hereinafter, EFSA). The achievement of the function («the general objective of a high level of protection of human life and health», in art. 6 of the reg.) Is ensured by the articulation of the procedure through the dual phases of the analysis.

The ability of this procedure to perform its function is related to the coordination between these phases and between the authorities responsible for carrying out the related activities. As stated in recital 36 of reg. established, «to ensure greater coherence between the risk assessment, management and communication functions, a closer link should be created between those responsible for risk assessment and those responsible for risk management». The same coordination between the actors involved was evoked by art. 22, paragraph 8: «The Authority, the Commission and the Member States collaborate to promote effective coherence between the risk assessment, risk management and risk communication functions».

The choice of the European legislator, in fact, since the establishment, in the reg. n. 178 of 2002[6], had been that of not delineating EFSA as an effective regulatory Authority, i.e. with real decision-making powers in the proper sense[7]

[6] On the decision to establish a European Food Safety Authority see S. GABBI, *Dieci anni di Efsa: l'Autorità europea al cuore del sistema europeo per la sicurezza alimentare*, in C. RICCI (ed.), *La tutela multilivello del diritto alla sicurezza e qualità degli alimenti*, Giuffré Milano, 2012, pp. 241 ff., spec. pp. 242-244.

[7] In this sense, see S. CASSESE, *La nuova disciplina alimentare europea*, in S. CASSESE (ed.), *Per un'autorità nazionale della sicurezza alimentare*, Milano, Il Sole 24 ore 2002, 13; S. GABBI, *L'Autorità europea per la sicurezza alimentare. Genesi, aspetti problematici e prospettive di riforma*,

but with a prevalent function of scientific advice and assessment, legitimized by high expertise and adequate organizational features to fulfill this role[8]. As emerges, in effect, from art. 6 of reg. n. 178/2002: «The risk assessment is based on the scientific evidence available and is carried out in an independent, objective and transparent way».

At the same time, its establishment was not unrelated to the aim of ensuring greater harmonization of the regulation in the sector «while helping to avoid the fragmentation of the internal market due to the creation of unjustified or unnecessary obstacles to free movement of food and feed» (38 cons. of Reg. n. 178 of 2002).

It was precisely the ways in which this assessment had to be carried out that led the legislator to make the Authority, pursuant to art. 22, paragraph 7, «the reference point» of food safety «thanks to its independence, the scientific and technical quality of the opinions formulated and the information disseminated, the transparency of its procedures and methods of operation and the diligence in carrying out the tasks to it assigned».

These organizational characteristics, however, can assume an ambivalent role in ensuring the achievement of the function entrusted to the risk analysis process. The independence ensured by the Authority and the transparency guaranteed to its procedures and operating methods are configured within the organizational design outlined by reg. n. 178 of 2002, as fundamental conditions for preserving the reliability and scientific quality of the opinions formulated and of the information disseminated by the Authority.

The independence recognized to the main bodies of the Authority appears functional, in art. 37[9], to ensure its orientation to the general interest and the absence of conditioning by particular interests. The same logic appears to mark

Giuffré, Milano, 2009, p. 72; M. GNES, *Alimenti*, in *Trattato di diritto amministrativo europeo*, M.P. CHITI and G. GRECO (eds.), II ed., Giuffré, Milano, 2007, Volume 1, pp. 117 ff., p. 124 ff.

[8] Based on art. 22 of reg. n. 178/2002, «The Authority offers scientific advice and scientific and technical assistance for Community legislation and policies in all fields that have a direct or indirect impact on the safety of food and feed. It provides independent information on all matters falling within these fields and communicates the risks».

[9] 1. The members of the Management Board, the members of the Advisory Forum and the Executive Director undertake to act independently in the public interest. 2. The members of the Scientific Committee and Scientific Panels undertake to act independently of any external influence. To this end, they make a declaration of commitment and a declaration of interests in which they indicate the absence of interests that can be considered conflicting with their independence or direct or indirect interests that can be considered as such. Such declarations are made annually in writing.

the value of transparency which, pursuant to art. 38 of the same reg., involves both the decision-making process and the acts that constitute the outcome.

The impermeability that these organizational features should ensure, with respect to a possible influence of the Authority by political authorities and companies, appears to be a prerequisite for ensuring the authoritativeness of the technical activity exercised by it, which takes concrete form in the drafting of opinions and highly qualified assessments, to protect fundamental rights.

These same organizational features, however, can determine, at the same time, the risk of self-referentiality and arbitrariness in the formulation of opinions and technical assessments by the Authority.

It is known, in fact, that the scientific method is often characterized by a marked uncertainty that can lead to indicate different options or solutions, not entirely without scientific legitimacy but not all capable of satisfying, in the same way, the guarantee of interests. primary publics of the European legal system, such as those of health and the environment.

The existence of controversial scientific issues, however, and the need to highlight them through the activation of a fruitful collaboration between the different institutional actors involved had been explicitly evoked by the same founding regulation, in art. 30[10].

Moreover, the deference that generally characterizes the European judge's union on political decisions resulting from a previous technical discretion is, in the food safety sector, even more accentuated by the independence and scientific authority of the Authority[11]. Added to this is the non-decision-making nature of the acts entrusted to it, such as opinions and technical assessments, which cannot be directly challenged by the European judge but only through the political determinations of which they formed the basis[12].

[10] «The Authority supervises to ensure the timely identification of a potential source of discrepancy between its scientific opinions and those formulated by other bodies carrying out similar tasks. 2. Where the Authority identifies a potential source of discrepancy, it turns to the body in question to ensure that all relevant scientific information is shared and to identify potentially controversial scientific issues».

[11] Let me to refer to M. COCCONI, *I pareri dell'Autorità europea per la sicurezza alimentare e le garanzie del cittadino rispetto ai giudizi scientifici arbitrati e incerti*, in N. BASSI, J. ZILLER, *La formazione procedimentale della conoscenza scientifica ufficiale: il caso dell'Agenzia europea per la sicurezza alimentare (EFSA)*, Giappichelli, Torino, p. 21.

[12] More generally, on the subject, considered central by the science of administrative law, of the trade union of technical assessments, the literature is very wide, please refer, among others, to M.S. GIANNINI, *Il potere discrezionale della pubblica amministrazione. Concetti e problemi*, Giuffrè,

Furthermore, in some sectors, such as that relating to genetically modified organisms, territorial and morphological differences support the centrifugal forces towards an increase in the discretion entrusted to nation states to the detriment of the ability of the Authority's technical expertise to favor and legitimize a centripetal centralization political choices at the supranational level[13].

3. *Transparency of the decision-making process, reliability of scientific studies and accessibility of information*

It was precisely the widespread belief of a lack of transparency in the evaluation process undertaken by EFSA, anchored above all to the studies produced by the industry, in a context of uncertainty on the actual extent of the risk of a herbicide, to offer impetus to the enactment of the recent reg. n. 1381 of 2019[14]. The new regulation, in fact, mainly intervenes on risk communication, however, conceived as an essential moment in the overall process of risk analysis; the same is moved by the intention of restoring credibility to the procedure and

Milano, 1939; V. CERULLI IRELLI, *Note in tema di discrezionalità amministrativa e sindacato di legittimità*, in *Dir. Proc. amm*., n. 3/1984, p. 466 and following; M. DELSIGNORE, *Il sindacato del giudice sulle valutazioni tecniche: nuovi orientamenti del Consiglio di Stato*, in *Dir. Proc. amm*., n. 1/2000, p. 196 and following; P. LAZZARA, *Autorità indipendenti e discrezionalità*, Cedam, Padova, 2001, pp. 3 ff.; S. BACCARINI, *Giudice amministrativo e discrezionalità tecnica*, in *Dir. Proc. amm*., 2001; F. MERUSI, *Giustizia amministrativa e autorità amministrative indipendenti*, in *Dir. Amm*., n. 2/2002, p. 193. *Amplius*, F. G. SCOCA, (ed.), *Giustizia amministrativa*, Giappichelli, Torino, 2006.

[13] The regulation of GMOs is a much discussed issue in the science of administrative law, among others see D. BEVILACQUA, *La regolazione pubblica degli OGM tra tecnica e precauzione*, in *Riv. crit. dir. priv.*, n. 2/2016. On the possibility of States, even in the event of a positive opinion from EFSA, to preserve a more restrictive regulation, thanks to Dir. No. 412 of 2015, see M. PORPORA, *Gli OGM e la frammentazione della governance del settore alimentare*, in *Riv. it. dir. publ. com*., n. 6/2015.

[14] On this regulation, see the Portici Conference of 11-12 October 2019, whose Proceedings can be found in *Riv Dir. Al.* n. 3/2019 and the reports by A. GERMANÒ, *La trasparenza nella comunicazione del rischio: il reg. n. 1381/2019*, in *Riv. Dir. Al.*, July and September 2019, p. 102; A. JANNARELLI, *Trasparenza e sostenibilità nel Sistema Europeo della Food Law dopo il reg. 2019, n. 1381*, in *Riv. Dir. Al.*, n. 3/2010; M. FERRARI, *Comunicazione del rischio e comunicazione scientifica: spunti per un'analisi interdisciplinare e comparativa*, in *Riv. Dir. Al.*, n. 3/2019, p. 62. More generally, on the issue of the balance between transparency and safety in the circulation of agri-food products, see S. AMOROSINO, *Trasparenza, certezza e sicurezza dei prodotti e dei mercati agroalimentari: correlazioni e funzioni*, in *Riv. Dir. Alim*., n. 1/2015, p. 39.

to the Authority, in public opinion, significantly clouded by the events relating to the dangerousness of glyphosate present in plant protection products.

The main reasons for the reform intervention were already explained in the 26th recital of the new regulation: «although the Authority has made significant progress in terms of transparency, the risk assessment process, in particular in the context of the authorization procedures concerning the supply chain food, is not always perceived as fully transparent». The intent of the legislator, therefore, was to perfect this phase of the risk analysis process to ensure that «the Authority functions efficiently and (to) improve the sustainability of its competences».

In summary, the changes introduced in the communication of risk had to make citizens more confident that the risk analysis was actually supported, as a whole, by the objective of ensuring a high level of protection of human health and the interests of consumers.

The new discipline aimed to achieve some fundamental reform objectives: to improve the provisions on transparency regarding the use of scientific studies placed at the basis of risk assessment, to increase the guarantees of reliability, objectivity and independence of the same, to strengthen the participation of States members to the evaluation process and, finally, to introduce more effective and transparent risk communication and dissemination of information to the public.

It therefore seemed essential, first of all, to guarantee certain qualities of risk communication so that it would be «transparent, uninterrupted and inclusive» during the overall analysis, with the participation of both risk assessment and risk management managers at European and national level.

The communication itself had to provoke, on the procedural side, interactive dynamics between the institutions involved and be able to «contribute to an open and participatory dialogue between all the interested parties in order to ensure that the prevalence of the public interest and the accuracy, completeness, transparency, consistency and accountability of information»[15].

Particular attention had to be paid, within the communication, not only to explain «in a precise, clear, complete, coherent, adequate and timely manner not only the results of the risk assessment», but also to clarify their contribution to the decision-making process («How these findings are then used to help

[15] See 4 *considerando*.

produce risk management decisions, along with other valid factors»)[16]. It was therefore appropriate to provide information to citizens on how risk management decisions were made and on the factors, beyond the results of the risk assessment, taken into account by risk managers, as well as on how these factors were been compared with each other.

The intensification of transparency in the risk assessment process was aimed not so much at weakening the role of the Authority but rather at restoring it greater legitimacy in the eyes of consumers and the public in fulfilling its mission, increasing confidence in its work. carried out and to ensure greater responsibility of the Authority towards the citizens and States of the Union.

The European judge recently took the same path in reviewing the refusal opposed by the Authority to some requests for access presented on the basis of Reg. (EC) no. 1049 of 2001 and no. 1367 of 2006[17]; first of all that of a Belgian citizen on the toxicity studies used to establish the daily dose of glyphosate («Acceptable Daily Intake»)[18]; a further one had been put forward by members of the European Parliament and concerned the parts «material, experimental conditions and methods» and «results and analysis» of studies concerning the carcinogenicity of glyphosate, contained in the same EFSA Report[19].

Glyphosate is a chemical used in pesticides - which are plant protection products - and is one of the most widely used herbicides in the European Union. It was included in the list of active substances from July 2002 to June 2012, after which the registration was temporarily extended until December 2015. For the purpose of renewing the approval of the active substance glyphosate, Germany, as a member state rapporteur, presented to the Commission and the European

[16] See 4 *considerando*.
[17] In this sense, see EU Court, Section VIII, 7 March 2019, Case T-716/14. In ruling on two requests for access to scientific studies on glyphosate - a chemical used in pesticides - rejected by the European Food Safety Authority (EFSA), the Court of the European Union established that the public's right to access information emissions into the environment necessarily prevail over the protection of commercial and industrial interests. Furthermore, this right does not only involve information on substances released into the environment but also in knowing their actual impact on this. On the question, see D. BEVILACQUA, *La trasparenza come garanzia di legittimazione e come strumento di tutela degli interessi «deboli»*, in *Gior. dir. amm.*, n. 5/2019, pp. 570-574.
[18] Mr. Anthony C. Tweedale with case T-716/14 with which the Court annulled the contested decision in the part in which EFSA denied the disclosure of all the studies requested, except for the names and signatures of the persons mentioned therein.
[19] The procedure (T-329/17), promoted by some MEPs Heidi Hautala, Michèle Rivasi, Benedek Jávor and Bart Staes.

Food Safety Authority (EFSA) a «draft renewal assessment report», published by EFSA on 12 March 2014.

In both procedural events, EFSA had not accepted the access on the grounds that the disclosure of such information could seriously harm the commercial and financial interests of the companies that had submitted the reports containing the studies; that the parts of these studies did not constitute information «[concerning] emissions into the environment» pursuant to the Aarhus regulation and that, therefore, there was no overriding public interest in their disclosure. Finally, the Authority held that access to parts of these studies was not necessary to verify whether the scientific risk assessment had been carried out in accordance with the regulation on the placing on the market of plant protection products.

The logic of the reasoning of the European judge is interesting first of all for the hierarchy outlined between the interests considered in the assessment, where the interests relating to information regarding emissions on the environment are conceived as prevailing over the protection of the commercial interests of the industries involved. In balancing the damage possibly produced by the denial of access, justified by the protection of the commercial strategy of the entrepreneurs involved, and therefore by their commercial and financial interests, with respect to the benefits obtainable with its acceptance with respect to primary public interests, such as health and healthy environment, the Court strongly leans towards the latter.

In annulling the refusal of access by the Authority, the Court in fact first of all recalls the presumption according to which the disclosure of information «[concerning] emissions into the environment», with the exception of that relating to investigations, constitutes an overriding public interest with respect to that relating to the protection of the commercial interests of a specific natural or legal person. It follows that the protection of these interests cannot in any way be opposed by an institution of the Union to the request aimed at obtaining the disclosure of such information.

The European judge therefore analyzes, for this purpose, the nature of the information contained in the studies to which access was requested to ascertain whether these studies actually invested information «[concerning] emissions into the environment», pursuant to the Aarhus regulation. An active substance contained in plant protection products, such as glyphosate, was considered by the Court, in its usual use, as intended to be released into the environment based on

its very function; its foreseeable emissions, therefore, cannot be considered merely hypothetical.

In the perspective outlined by the European judge, therefore, it must be considered that: «The emissions of glyphosate into the environment are therefore real. This active substance is in particular present in the form of residues in plants, water and food. The required studies are therefore aimed at establishing the carcinogenicity and toxicity of an active substance that is actually present in the environment».

The Court also responds to the Authority's argument that a simple link with emissions into the environment would not be sufficient for such studies to be included within the scope of the Aarhus regulation. The same highlights that the jurisprudence of the Court of Justice shows that the notion of «information concerning emissions into the environment», according to the Aarhus regulation, is not limited to information that allows the assessment of emissions as such, but includes also information on the effects produced by these emissions.

Therefore, on the basis of this broad interpretation, according to the European judge: «the public must have access not only to information on the emissions as such, but also to information regarding the more or less long-term consequences of said emissions on the state of the environment. Indeed, the public interest in accessing information on emissions into the environment is precisely not only to know what is, or predictably will be, released into the environment, but also to understand how the environment risks being damaged by the emissions in question».

The notion of «information relating to emissions into the environment» must therefore be interpreted as meaning that it includes not only information on emissions as such, i.e. information relating to the nature, composition, quantity, date and place of such emissions, but also data relating to the more or less long-term effects of these emissions on the environment. The accessible information will therefore necessarily have a qualified content, as it will not concern the data in and of itself but their disclosure must also allow the understanding of «the way in which the environment risks being compromised by emissions ... and how human health risks being affected by releases of glyphosate to the environment».

Their disclosure, including the way in which emissions can have an impact on the environment, is conceived as responding to a public interest prevailing over the commercial interest of the owners of the studios and therefore

had to be accepted without the Authority being able to oppose the prejudice possible achievable to these interests[20].

The innovations present in the rulings of the Court will certainly have a significant effect also on the *modus procedendi* of the European Authority and on the type of legitimacy it benefits from. The disclosure obligation imposed on the studies placed at the basis of the risk assessment, also investing relevant substantial profiles, will inevitably make their use more bound to obligations of impartiality and objectivity and less inclined to favor the commercial and financial interests of the industries that they provided.

Even the eventual review of the European judge on the final political determinations of risk management, although it will not be able to enter into the merits of the risk assessment entrusted to the Authority, will nevertheless be able to obtain the exhibition of the studies that were the basis for it if they invest emissions on the environment although they concern the commercial know-how of a company.

The systemic repercussions of the major procedural constraints imposed on the Authority's actions are evident in the perspective of giving greater reliability to the risk assessment carried out by it and thus restoring its credibility and legitimacy clouded by recent events relating to the analysis of the risk related to glyphosate.

In reality, the principle of transparency already represented, in the design of the founding regulation, a strong legitimacy of the Authority's work, since the latter was subtracted, by virtue of the independence recognized to it, from political and institutional control of both its organs and of its activity, in order to preserve its scientific authority[21]. The provision of incisive guarantees of transparency in the procedures and in the composition of the Authority's bodies also had to rebalance the subtraction of the merit of the Authority's technical-

[20] In a note Marco Affronte, MEP of the European group Verdi-ALE, said that «the sentence is a milestone, it is a victory in the fight against secrecy when it comes to the environmental and health risks of dangerous products such as glyphosate. From now on, the public and independent scientists will be able to see how the chemical giants write their product safety reports to obtain authorization». For Affronte «thanks to the publication of all available studies, in the future independent scientists will be able to double-check the research underlying the evaluations of pesticides. It is essential to have a regulatory system that works in the interest of human health, biodiversity and the environment, and not for corporate profit».

[21] On the principle of transparency in food safety, in a broader perspective than the one discussed here, see D. BEVILACQUA, *Il principio di trasparenza come strumento di accountability nella Codex Alimentaris Commission*, in *Riv. trim. dir. pubbl.*, n. 3/2007, p. 651.

scientific assessments from the trade union both by the judge and by other European institutions. It is thanks to these guarantees that an independent supranational institution, not endowed with representative legitimacy but with recognized technical expertise, was able to preserve the trust of its citizens in its inspiration for good governance.

A principle that constitutes a primary factor of the Authority's accountability, even before the univocity and certainty of the scientific opinions issued, as emerges from art. 30 of reg. institutive. In fact, if there are conflicting opinions, a joint document must be published, including the divergent opinions.

The emergence of cases in which the existence of controversial scientific issues was evident and characterized by high uncertainty as to the extent of the risk related to them have increasingly highlighted the need to accentuate transparency in the Authority's *modus procedendi*, also through the issue of the reg. n. 1381 of 2019[22]. In order to increase the reliability of the risk analysis, the objectives and principles of risk communication were thus clarified and the drafting of integrated communication plans involving the Authority and the Member States and the institutions responsible for management was envisaged. risk.

Finally, precisely in the face of situations of high scientific uncertainty about the danger and risk inherent in the commercialization of elements, the need to encourage, already in the risk assessment, a dialogue between experts and relevant stakeholders, equipped with recognized expertise, in relation to the outcome of this procedural phase.

The activation of this dialogue, if regulated according to pre-established mechanisms that guarantee its impartiality, can produce positive effects precisely in the regulation of food safety, favoring scientific pluralism and the democratic nature of technical regulation, with an anticipation of the protection of citizens and companies through their involvement already in the procedural phase[23].

[22] See Considerando 8 and art. 1, paragraph 4, EU Reg. No. 1107 of 2009 which states: «The provisions of this regulation are based on the precautionary principle in order to ensure that the active substances or products placed on the market do not have harmful effects on human or animal health or the environment. In particular, Member States are not prevented from applying the precautionary principle when scientifically speaking uncertainties as to the risks that plant protection products that must be authorized in their territory pose to human and animal health or the environment».

[23] On the subject, see, recently, D. BEVILACQUA, *Regolazione sovranazionale e tutela degli interessi diffusi: garanzie procedurali e vincoli tecnico-scientifici*, in *Gior. dir. amm.*, n. 2/2017, pp. 227 ff.

4. *The importance of the precautionary principle in defining the boundaries of technique and politics*

The eventuality that risk analysis had to face a crack in scientific rationality to address a state of significant uncertainty was already contemplated in the Authority's founding regulation. In art. 7, in fact, the precautionary principle was envisaged as an expansion valve of the interim political risk management measures "necessary to guarantee the high level of health protection pursued by the Community". It was also made clear that such measures must comply with the principle of proportionality, in the sense that only the restrictions on trade indispensable to guaranteeing the aforementioned level of health protection were considered applicable.

Through the use of this principle, a public authority can, without having to scientifically prove that there is a causal link between the prohibited or limited activity and the expected risk, justify the introduction of a restrictive regulatory measure of economic or commercial freedom; in fact, it is sufficient for it to prove the state of scientific uncertainty and the possibility of the risk occurring[24]. The invocation of this principle therefore constitutes a further chance with respect to the technical-scientific assessments available to States to increase their discretion, in the face of a possible but uncertain risk, without being sacrificed by the harmonization needs of the common space.

The evolution of the jurisprudence of the European judge has given a significant expansion to the value of this principle which is gradually being qualified as a fundamental and general principle of the European legal system with a value not limited to the context of food safety[25]. As such, this is also considered applicable in the context of other Union policies, mainly for the protection of public health, as well as when the institutions of the European Union

[24] On the precautionary principle in general, see M. SOLLINI, *Il principio di precauzione nella disciplina comunitaria della sicurezza alimentare*, Giuffrè, Milano, 2006, pp. 68 and following; on the topic yes v. also G. MANFREDI, *Note sull'attuazione del principio di precauzione in diritto pubblico*, in Dir. *Pubbl*., 2004, pp. 1110 and following; R. FUSCO, *Autorizzazione dei pesticidi e principio di precauzione: il caso del glisofato*, in *Riv. Dir. Al.*, n. 4/2016, p. 45.

[25] See, to this effect, the judgments of 2 December 2004, Commission / Netherlands, C 41/02, EU: C: 2004: 762, paragraph 45; of 12 July 2005, Alliance for Natural Health and Others, C 154/04 and C 155/04, EU: C: 2005: 449, points 68, as well as of 22 December 2010, Gowan Comércio Internacional e Serviços, C 77/09 , EU: C: 2010: 803, paragraphs 71 and 72).

adopt, in the context of the common agricultural policy or the internal market policy, protective measures for human health.

The context in which we are witnessing this expansionary dynamic, thanks to the initiative of the European judge, is above all that of the sectoral disciplines relating to food safety relating to the marketing of certain products.

Compliance with this principle is required, for example, of the EU legislator when adopting rules relating to the placing on the market of plant protection products, such as those covered by reg. n. 1107 of 2009, mainly in order to guarantee, pursuant to art. 35 of the Charter of Fundamental Rights of the European Union, as well as art. 9 and art. 168, § 1, TFEU, a high level of protection of human health[26]. The rules envisaged must therefore provide an adequate regulatory framework to allow the competent authorities to have sufficient elements to assess the risks to human health deriving from certain products.

The Criminal Court of Foix had in fact questioned the European judge about the compatibility with the precautionary principle of the regulation which contemplated the ways in which the administrative authorities issue or deny the marketing authorization of plant protection products. The disputed provisions were those that appeared to give the manufacturer too high a discretion in identifying the substance qualified as «active» in its product; which allowed the analyzes and evaluations contained in the dossier to be carried out by the same producer; which did not guarantee taking into account the existence of multiple active substances in the same product and the possible multiple effect that could not derive; which did not include adequate testing for long-term toxicity.

The compatibility of the regulation with this principle is identified by the Court of Justice in the balance between the obligations attributed to the manufacturer, relating to the identification of the active substances present in the plant protection product but also in their cumulative and synergistic effect and those due to the Member State and to the 'Authority. In fact, it is up to the competent authorities, according to the regulation, to take into account the most

[26] See EU Court of Justice, Grand Section, 1 October 2019, case C 616/17, §§ 28-29 which is the result of an appeal by the Tribunal correctionnel de Foix against the Court of Justice of the European Union for interpretation of Regulation (EC) no. 1107/2009 of the Parliament and of the Council of 21 October 2009, relating to the placing on the market of plant protection products, regarding consistency with the precautionary principle. For a comment on this pronouncement, see D. BEVILACQUA, *La regolazione dei prodotti fitosanitari e il precautionary test*, in *Gior. dir. amm.*, n. 1/2020, pp. 69 ff.

reliable scientific data available, as well as the most recent results of international research, without in any way granting a preponderant role to the studies provided by the applicant.

Faced with the tests, studies and analyzes submitted in support of the request submitted by the manufacturer, the Member State will in fact have to carry out «an independent, objective and transparent evaluation» in the light of current scientific and technical knowledge and the same task will be up to the Authority. More specifically, the rapporteur Member State will have to prepare a draft evaluation report which is sent to the other Member States and to EFSA. The Authority can then organize a consultation between experts and request the Commission to consult its own Community reference laboratory, to which the applicant will have to provide samples and methods of analysis. The review of the approval of the active substance by the Commission is then allowed at any time, specifically if, in the light of new scientific or technical knowledge, there is reason to believe that the substance no longer meets the requirements of the regulation.

In this context, the expansive value of the precautionary principle, conceived not only as a general principle of the European legal system but also as a compatibility parameter of a legislative act of the European Union, is not affirmed in order to disregard or weaken the relevance of the technical-scientific assessments of the risk operated by the competent authorities. On the contrary, the verification of compatibility highlights and imposes its articulated and plural structure and constant consistency with current and most authoritative scientific and technical knowledge on the international scene.

The framework of scientific uncertainty, therefore, inevitably weakens the binding value of the technical-scientific assessments in favor of the discretionary political risk assessment ones but, at the same time, by imposing a plural comparison with these on the decision maker, it prevents this from taking decisions. arbitrary marketing policies, driven mainly by protectionist intentions.

The necessary synergy between the risk assessment and management phases is certainly strengthened and the need for close coordination between them is enhanced.

The role of the Authority, within this sector discipline, is in no way that of the exclusive actor of the technical-scientific risk assessment phase which is instead shared by different institutional subjects; the Authority itself acts as a transmission and reception belt for the analyzes, reports and studies they have

completed and made available. In this way, the risk of its self-referencing is certainly reduced and that of activating and receiving the evaluative skills of other institutional authorities is highlighted.

5. *The new balance between technology and politics in the food safety decision-making process*

The paper reconstructs the rich and interesting plot with which the legislator and the European judge have enriched the geometry and value of the principles and rules that affect the relationships between the assessment and management of the risk inherent in food safety, within the relative procedure. to his analysis. The redesign of this plot inevitably affects the role of the actors involved in these phases and the criteria that define their different legitimacy within the procedure, with respect to the assumption of final decisions and the care of the public interests involved.

The necessary context in which this plot develops and is analyzed is that of the state of uncertainty facing the technical issues addressed, together with the existence of a possible risk relating to the placing on the European market of certain food or feed products.

First of all, science almost never offers absolute and unambiguous certainties in the identification of risk but, as a rule, develops its results on the basis of successive approximations.

In reality, it has a reliable method based on the evidence of the facts and should, therefore, be as close as possible to the representation of the truth. Unfortunately, even in the scientific field, the interpretation or attention paid to certain factual evidence does not always translate into a unanimous opinion, and very often, what matters is the consensus among scientists.

Consent is a mark of agreement, a presumption of knowledge, which does not, however, lower the level of uncertainty.

For its part, politics sometimes turns to scientific authorities, often without questioning the value of the evidence or without always verifying whether that scientific consensus is more or less broad. In a sense, the political system is blind to the opinion of individual scientists.

When this happens, the opacities of science inevitably reverberate in the determinations made by politics[27].

Furthermore, scientific demonstrations can sometimes translate into non-aseptic judgments but conditioned by the dynamics of multiple interests[28]. In this case, not infrequent, it is very difficult to outline a clear boundary between discretionary choices and choices based on mere technical assessments or, more specifically, between assessment and risk management.

Furthermore, a pathological version of the relationship between technology and politics can also manifest itself in which political authorities use scientific evaluations in an unreasonable and arbitrary way, recognizing themselves the power to establish which is the most reliable and official scientific knowledge[29].

Finally, the same scientific evaluations can be permeated by fallibility and erroneous judgments that can be transmitted to the political determinations taken on the basis of their foundation. If the way forward of ideal science consists of conjectures and refutations, such as the title of a famous work by the philosopher of science Karl Popper[30], that is, progressing by falsifying one's previous theories, gradually approaching an ever more precise and complete understanding of truth, the reality of disciplines in which there are no laws without exception, such as biology and medicine, is much more complex[31]; errors and approximations, in these sectors, are therefore much more frequent and misleading.

In this case, the question arises of how to overcome and how to reconcile the diversity of positions through political action in the risk management phase.

The inability of science to offer a certain, unambiguous and objective solution regarding the causal link between certain political decisions and the

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[27] See *Scienza e politica: una «prescrizione» per il disastro*, in *Corriere*, June 26, 2020.
[28] D. BEVILACQUA, *Democratizzare la tecnica? La partecipazione alle decisioni degli esperti*, in N. BASSI, J. ZILLER (eds.), *La formazione procedimentale della conoscenza scientifica ufficiale*, cit., pp. 45 ff., spec. Pp. 51 ff. and bibliography cited there.
[29] S. JASANOFF, *Science at the Bar: Law, Science and Technology in America*, Harvard University Press, Cambridge, 1995, see also G. D'ANGELO, *Review to Sheila Jasanoff "Science at the Bar"*, in *Dir. Pubbl.*, 2002, pp. 731 ff.; cf. also N. IRTI, E. SEVERINO, *Dialogo su diritto e tecnica*, Laterza, Roma-Bari, 2001.
[30] K. R. POPPER, *Congetture e confutazioni. Lo sviluppo della conoscenza scientifica*, il Mulino, Bologna, 2009.
[31] A. LAVAZZA, *Conflitto fra scienza e politica? Solo una questione di metodo*, in *Avvenire*, 11 June 2020.

damage inflicted by this on the right to health or the environment of European citizens, produces the re-expansion of principles of European law that they have a procedural rather than a substantial dimension[32]. The expansion of these principles does not produce the effect of replacing the Authority's technical legitimacy with an exclusively political decision taken in the food safety sector on controversial scientific issues.

Rather, it emerges the need for close coordination and greater synergy between the two phases of the risk analysis which identifies in the final communication the place where the point of balance between technique and politics is welded with the transparency towards the citizens of the evaluations. made and the political decisions taken.

It is no coincidence that a decisive step towards this expansive dynamic of the principles of European law is that in which the legislator intervenes on the improvement of the risk communication phase through the reg. n. 1381 of 2019.

The declared intent is to restore credibility to the role of the Authority by strengthening the conviction among European citizens that the exercise of its competences is effectively aimed at the achievement of public health and environmental interests and not at satisfying interests. industrial and commercial.

The refinement of this phase takes place by making the exercise of evaluation less exclusive and self-referential, which is open to dialogue with both management managers and external experts and, at the same time, strengthening the link, also on a communicative level, between this phase and the determinations of risk assessment. This greater articulation gives greater reliability to the results of the assessment and, consequently, to the political decisions made below.

Finally, through the communication of risk, what has been described by an authoritative doctrine as a «regulation by information» is also expressed, i.e. regulation, for example that attributable to the European Chemicals Agency (ECHA) which is expresses through the imposition of disclosure obligations on economic operators. These obligations consist in making transparent the existence and intensity of a risk related to the use of a specific good or service relating, for example, to its components.

[32] In this perspective, see E. CHITI, *I principi della valutazione del rischio nel settore della sicurezza alimentare*, in N. BASSI, J. ZILLER (eds.), *La formazione procedimentale della conoscenza scientifica ufficiale*, cit., 10 ff.

The rulings of the European judge on the Authority's rejection of access to information on environmental emissions are also based on the same logic. These assign a precise hierarchy to the interest relating to the environment, assigning it a prevailing weight over commercial and industrial ones and indeed also requiring the Authority to disclose information relating to the way in which emissions on the environment contribute to producing a injury to health.

Also in the strategy of the European judge it is clear the intention to give back to the Authority a legitimacy related not only to its technical expertise but also to its projection towards the protection of public interests prevailing over the defense of mere industrial and commercial interests.

In the same perspective, it seems to be necessary to interpret the expansive dynamics that the European judge gives to the precautionary principle which becomes the parameter in the light of which to verify the compatibility of the rules on authorization procedures for the marketing of food products.

The expansion of the principle of European law does not aim at reducing the risk assessment phase but at removing its exclusivity from the Authority in order to make it the result of a plural comparison also with the Member States and to achieve a closer synergy between this and the action of risk management policy makers.

Finally, it is up to the political authorities to represent the right link between scientific assessments and the communication and acceptance, by European citizens, of the risks inherent in the marketing or otherwise of certain food products.

The redefinition of borders and the re-establishment of virtuous synergies between technology and politics is a decisive step for the technical and political authorities involved to fulfill their specific responsibilities, in the interest of European citizens and the protection of the fundamental rights involved in their actions.

ABSTRACT

Monica Cocconi - *The balance between technique and policy in the public decision-making process: the EFSA case (European Food Safety Authority)*

The paper highlights the role assumed by some fundamental principles of European law, specifically those of precaution and transparency, in redefining the perimeter of technology and politics in the public decision-making process.

The context is that of the disappearance of the logic of full scientific rationality at the basis of some public choices in a sector, such as that of food safety, in which the existence of a possible risk on their extent, leads to political determinations driven more by prudence than solely from scientific evidence.

The deterioration of certainty, in the scientific analysis of certain risk factors and in their scope, actually entails the re-expansion of some principles of European law, such as those of precaution and transparency, and the reduction of the explanatory value of others, such as those of independence and scientific authority of the subjects in charge of the evaluation.

KEYWORDS: *Precaution*; *Transparency*; *Indipendence and scientific Authority*

Monica Cocconi - *Il bilanciamento tra tecnica e politica nel processo decisionale pubblico: il caso EFSA (Autorità Europea per la Sicurezza Alimentare)*

Il contributo sottolinea il ruolo assunto da alcuni principi fondamentali del diritto europeo, in particolare dai principi di precauzione e trasparenza,

nella ridefinizione del perimetro di tecnologia e politiche nell'ambito del processo decisionale pubblico.

Il contesto è quello della scomparsa della logica della piena razionalità scientifica alla base di alcune scelte pubbliche in un determinato settore, come quello della sicurezza alimentare, dove l'esistenza di un possibile rischio sulla loro portata conduce a determinazioni politiche guidate più dalla prudenza che esclusivamente dall'evidenza scientifica.

Il deterioramento della certezza nell'analisi scientifica di alcuni fattori di rischio e nella loro portata, oggi comporta la ri-espansione di alcuni principi del diritto europeo, come quelli di precauzione e di trasparenza, e la riduzione del valore esplicativo di altri, come quelli di indipendenza e di autorevolezza scientifica dei soggetti incaricati della valutazione.

PAROLE-CHIAVE: *Precauzione; Trasparenza; Indipendenza e autorevolezza scientifica.*