Essays

Pesticides in Court: Ruling on the use of neonicotinoids in EU Member States

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PESTICIDES IN COURT: RULING ON THE USE OF NEONICOTINOIDS IN EU MEMBER STATES

ABSTRACT: In the last decades, neonicotinoid pesticides linked with bee decline have become a bone of contention in EU Member States. On the one hand, regulatory science provided by the European Food Safety Authority has been used in the interpretations established by the Court of Justice of the EU as regards the Commission's ban of some neonicotinoids. On the other, scientific uncertainty pertaining to these chemicals underpinned the adoption of emergency measures at the national level for restricted use of the pesticides concerned. Through the line of reasoning followed by the Court's rulings on the matter, this contribution illustrates the legal implications arising from relying on regulatory science as knowledge base that justifies both the legal invocation of the precautionary principle and the review of derogations at the national level.

KEYWORDS: Neonicotinoids; regulatory science; pesticides regulation; precautionary principle; transparency

SUMMARY: 1. Introduction – 2. The contested science of neonicotinoids – 3. The *Bayer CropScience* case – 3.1. On complaints – 3.2. Comments – 4. EU Member States and the emergency authorizations – 5. Regulatory science vis-à-vis transparency – 5.1. Neonicotinoids and risk assessment – 5.2. Transparency and confidentiality in the PPP Regulation – 6. Final remarks.

1. Introduction

The relationship between honeybees (*Apis mellifera*) and agricultural production is known to have complementary nature. On the one hand, the role played by pollinators in agriculture is mostly related to their significance for pollination and human nutrition.[1] Not only does apiculture make an important contribution to biodiversity through cross-pollination activities, but the variety and high quality of honey and other apiculture products confer nutritional and medicinal benefits. On the other hand, different agricultural land-use practices are specifically aimed at benefitting

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[1] S.G. POTTS, V.L. IMPERATRIZ-FONSECA, H.T. NGO (eds.), *The Assessment Report of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services on Pollinators, Pollination and Food Production*, IPBES – Secretariat of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, 2016.

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pollinators.[2] This mutual interaction explains why the colony losses documented in European Union's (EU) Member States in the last decades[3] have become a source of concern at the institutional level,[4] turning the spotlight on the urgency of a prompt response to reverse the trend.[5]

Already in 2008, the EU Parliament's Resolution on the situation in the beekeeping sector called on the Council and the Commission to give due consideration to the health of bees.[6] The document demanded, among other things, "to undertake research into the link which exists between bee mortality and the use of pesticides […], so that it can take appropriate measures as regards authorisation of such products".[7] Two years later, the Commission's Communication on honeybee health recognised how the apiculture sector needs specific actions aimed at protecting bee health proactively, taking into account the particularities of beekeeping, the different actors involved, and the principles of proportionality and subsidiarity.[8]

The EU Pollinators Initiative[9] that the Commission released in June 2018 has surely been a valid policy answer to those requests. The integrated approach to the decline of pollinators is pointed especially to generating actionable knowledge and addressing the issue's main known causes, while boosting stakeholder collaboration and engagement. Still, significant hindrances to tackling the loss of habitats in farming landscapes and the negative effects of pesticides remain.[10] Among the number of factors impacting upon the health of honeybees (including pests and disease, agricultural practices, invasive

[2] E.M. Giglioli, *Bee Safe – The Effects of Pollination of Bees and Other Pollinating Insects on the Environment, Health and Food Safety*, in *European Food and Feed Law review*, 5, 2019, 445-452, at 451.

[3] A. Nieto et al., *European Red List of Bees*, Luxembourg, 2014. From this report, prepared by the IUCN (International Union for Conservation of Nature), it emerges that 9.2 per cent of bees are considered threatened in all of Europe, while at the EU level, 9.1 per cent are threatened with extinction. A further 5.2 per cent of bees are considered near threatened in Europe. On this issue, see also H. Grab et al., *Agriculturally Dominated Landscapes Reduce Bee Phylogenetic Diversity and Pollination Services*, in *Science*, 363, 6424, 2019, 282-284.

[4] E. Capri, A. Marchis, *Bee Health in Europe – Facts & Figures 2013*, OPERA Research Center, 2013, https://operaresearch.eu/download/bee-health-in-europe-facts-figures-2013-2/ (accessed 24 May 2022). Unusual weakening of bee numbers and colony losses have been reported particularly in Western European countries, including France, Belgium, Switzerland, Germany, the UK, the Netherlands, Italy and Spain. See also S. Potts et al., *Status and Trends of European Pollinators. Key findings of the STEP project*, Sofia, 2015.

[5] E. Underwood, G. Darwin, E. Gerritsen, *Pollinator Initiatives in EU Member States: Success Factors and Gaps*, Report for European Commission under Contract for Provision of Technical Support Related to Target 2 of the EU Biodiversity Strategy to 2020 – Maintaining and Restoring Ecosystems and their Services, Institute for European Environmental Policy, London, 2017.

[6] European Parliament Resolution of 20 November 2008 on the situation in the beekeeping sector, P6_TA(2008)0567, para. 6.

[7] *Ibidem*, para. 9.

[8] Communication COM(2010) 714 final from the Commission to the European Parliament and the Council of 6 December 2010 on Honeybee Health, at 1.

[9] Communication COM(2018) 395 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 1 June 2018 on EU Pollinators Initiative.

[10] Report COM(2021) 261 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee of the Committee of the Regions of 27 May 2021 on Progress in the implementation of the EU Pollinators Initiative, at 15.

species and climate change),[11] the use of neonicotinoid insecticides (in short neonics) represents one of the main contested issues at play.[12]

Regulation (EC) 1107/2009[13] (or PPP Regulation) concerning the placing of plant protection products (PPPs or pesticides) on the market includes a specific requirement on honeybees, that prescribes a fact-based approach and an appropriate risk assessment of so-called "active substances" (that is, the main active constituents with pesticidal properties in a PPP).[14] This regime is underpinned by MRLs (maximum residue levels) for pesticide residues, which are set in the framework of Regulation (EC) 396/2005.[15]

In 2013, however, the approval in the EU of five neonics – namely clothianidin, imidacloprid, thiamethoxam, acetamiprid and thiacloprid[16] – as active substances for use in PPPs, has proved to be a bone of contention across Member States. The same year, the Commission restricted the use of PPPs and treated seeds containing the three neonics clothianidin, imidacloprid and thiamethoxam to protect honeybees. This legislative step led the groups of Bayer and Syngenta to bring a lawsuit before the Court of Justice of the EU (CJEU or Court) about procedural aspects of the review process of approval of pesticidal active substances.

In the meantime, several Member States (Romania, Bulgaria, Lithuania, Hungary, Finland, Latvia and Estonia) repeatedly granted emergency authorisations for some of the restricted uses of neonics, by applying for multiple derogations on major crops (i.e. maize, sunflower, rapeseed and beets). Such measures, though, seem difficult to reconcile with the strict conditions envisaged under the PPP

[11] EFSA (EUROPEAN FOOD SAFETY AUTHORITY), *Bee Mortality and Bee Surveillance in Europe*, 2009, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2009.EN-27 (accessed 24 May 2022).

[12] T.J. WOOD, D. GOULSON, *The Environmental Risks of Neonicotinoid Pesticides: A review of the evidence post 2013*, in *Environmental Science and Pollution Research*, 24, 2017, 17285-17325.

[13] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309/1.

[14] Pursuant to art. 2 of Reg. 1107/2009, active substances are those "substances including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products".

[15] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70/1.

[16] The neonicotinoid family includes also the substances dinotefuran, sulfoxaflor, nitenpyram, imidaclothiz, paichongding and cycloxaprid.

Regulation. Moreover, they diverge from the coalitions[17] and campaigns[18] that are flourishing in the fields of agriculture, health and environmental protection, to reform the pesticide risk analysis in Europe. These civic alliances are witness of the increased ethical concerns and awareness of the factors surrounding neonics pesticides, namely: their wide use in agriculture, the knowledge gaps concerning their safety for pollinators and the environment, and the disagreement existing among the actors involved. As a result, the "neonics dispute" – which calls to the mind the never ending quarrel on glyphosate[19] – has put under strain several provisions of the EU legal framework on pesticides, bringing issues of legitimacy and accountability to the forefront.

This contribution aims at scrutinising these tensions, starting from a general overview on the concept of regulatory science and its use in the assessment and management of uncertain risks (Section 2). This broad picture is prodromic to a deep analysis of the conflicts surrounding the science of neonics at the normative level. To this end, Sections 3 and 4 follow two parallel tracks, concerning the role played by the CJEU and EU Member States in dealing, respectively, with complaints on alleged manifest errors of assessment of neonics and the management of risks related to neonics, on the base of the level of protection pursued.

Through the line of reasoning followed by the Court's ruling on the matter, Sections 3 and 3.1 address, in particular, scientific and technical information provided since 2013 by the European Food Safety Authority (EFSA) as the agency in charge of risk assessment in the food chain.[20] A discussion on the use

[17] The coalition *Citizens for Science in Pesticide Regulation*, that is a European initiative consisting of around 100 European and international civil society organisations and institutions, launched a manifesto for "rigorous science, safe food, and a healthy environment" in the pursuit of a high level of protection from pesticides in Europe [see CITIZENS FOR SCIENCE IN PESTICIDE REGULATION – A EUROPEAN COALITION, *Rigorous Science, Safe Food, and A Healthy Environment*, https://www.pan-europe.info/sites/pan-europe.info/files/Citizens%20for%20Science%20in%20Pesticide%20Regulation_Manifesto_FINAL.pdf (accessed 25 May 2022)]. In 2022, 34 partnering research organizations from 20 European countries created the European Research Alliance *Towards a Chemical Pesticide-free Agriculture*, with the view to find innovative solutions for an agriculture free of chemical pesticides (see ERA PESTICIDE FREE, *European Research Alliance*, https://www.era-pesticidefree.eu/> (accessed 25 May 2022)).

[18] The campaign *Save bees and farmers!* was born to propose legal acts to: phase out synthetic pesticides by 2035, restore biodiversity and support farmers in the transition (see SAVE BEES AND FARMERS, *European Citizens' Initiative "Save Bees and Farmers!"*, https://www.savebeesandfarmers.eu/eng/ (accessed 25 May 2022).

[19] On the "glyphosate saga", see *European Journal of Risk Regulation* (EJRR), 11, 3, 2019, of the which includes contributions from the 2019 *Symposium on the Science and Politics of Glyphosate*.

[20] In 2002, EFSA was established by Regulation (EC) No 178/2002 (of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1) as an independent source of scientific advice, analysis of information and risk communication, which combines the highest standards of scientific expertise and excellence. The Authority contributes to the safety of the food and feed chain throughout three major tasks: by providing scientific advice to risk managers; by communicating on its outputs and risks to the public; and by cooperating with Member States and public bodies to foster a trusted food safety system in Europe. For a deep analysis, see A. ALEMANNO, S. GABBI (eds.), *Foundations of EU Food Law and Policy. Ten Years of the European Food Safety Authority*, London and New York, 2014; IDAIC (a cura di), *Commentario al Reg. (EC) N. 178/2002. La sicurezza alimentare nell'Unione europea*, in *Le nuove leggi civili commentate*, 1-2, 2003, 114 *et seq;* L. LEONE, *EFSA under Revision: Transparency and sustainability in the food chain*, in *Yearbook of European Law*, 39, 2020, 536-568; I. TRAPÈ, *I soggetti della valutazione del rischio: EFSA, autorità nazionali*, in P. BORGHI, I. CANFORA, A. DI LAURO, L. RUSSO (a cura di), *Trattato di diritto alimentare italiano e dell'Unione europea*, Milano, 2021, 213-221.

of regulatory science of neonics as knowledge base that justifies the legal invocation of the precautionary principle follows (Section 3.2). The analysis shows that, in cases involving complex technical-scientific assessments, the precautionary principle[21] works as the "guardian parameter" underpinning EU law, to assess the conformity of risk management measures with the objectives pursued at the institutional level. It calls for mapping the impact of different value judgements and problem-framing assumptions and avoiding the common pitfall of lack of transparency.[22] This approach is related to the anticipatory aspect inherent in precaution, that is the anticipation of the (political) judgment of the presence of signs of causality in absence of ascertained causal links between the risk and the damage.[23] Section 4 is then devoted to question the scientific reasons why some EU Member States chose to opt for emergency authorisations for the restricted use of the neonics in question. The investigation gives emphasis to the regulatory science which EFSA relied on to review governments' notifications, so as to elucidate the legal gaps lingering behind the notion of "emergency" when deciding in matters of science and risk governance. The analysis confirms that local preferences for how to assess the costs and benefits of risk-taking cannot be eliminated, as risk policy and regulatory science rest on deeply value-laden judgments and choices that are never based on merely scientific assumptions.[24]

All those reflections will allow, in Section 5, to put the accent on a final question of broader nature: How will the legal disputes on neonicotinoids contribute to redefine the risk assessment of PPPs in Europe? This issue will be elaborated, firstly, on the advancements achieved in producing the regulatory science of pesticides (Section 5.1) and, secondly, on the novel EU rules put forward in 2019 for greater transparency of risk assessment in the food chain (Section 5.2). Indeed, transparency of regulatory science, which guarantees the visibility of scientific information underpinning regulatory

[21] The precautionary principle was introduced internationally in 1992 by Principle 15 of the Rio Declaration on Environment and Development: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damages, lack of full scientific certainty shall nor be used as a reason for postponing cost-effective measures to prevent environment degradations". In Europe, after being presented by art. 130 R, para. 2 of the Maastricht Treaty as distinct and autonomous from the principle of prevention, the precautionary principle was qualified by the EU Commission as a general principle of the EU for human, animal, vegetable, and environmental health [see Communication COM(2000) 1 final from the Commission of 2 February 2000 on the Precautionary Principle]. As regards the food sector, the principle finds its statement in art. 7 of Reg. 178/2002. For critical and deep reflections on this matter, see *ex multis*: P. BORGHI, *The "Myth" of Precaution,* in AIDA-IFLA (ed.), *Innovation in Agri-food Law between Technology and Comparison*, Milano, 2019, 171-192; I. CANFORA, *Il principio di precauzione nella governance della sicurezza alimentare: rapporti tra fonti in un sistema multilivello*, in *Riv. Dir. Agr.*, 3, 2017, 447-475; E.C. FISHER, J.S. JONES, R. VON SCHOMBERG (eds.), *Implementing the Precautionary Principle: Perspectives and prospects*, Cheltenham (UK) and Northampton (MA, USA), 2006; M. SOLLINI, *Il principio di precauzione nella disciplina comunitaria della sicurezza alimentare: profili critico-ricostruttivi,* Milano, 2006.

[22] A. SALTELLI, S. FUNTOWICZ, *The Precautionary Principle: Implications for risk management strategies*, in *International Journal of Occupational Medicine and Environmental Health*, 17, 1, 2004, 47-58, at 55.

[23] The precautionary principle involves an anticipation of the threshold of relevance of potentially dangerous phenomena related to new products or technoscientific activities. It "translates" the need to represent in advance, and thus to prevent in advance, potentially harmful effects, particularly when the probability and extent of damages do not have sharp contours, but appear severe or irreversible. For an insightful overview, see M. TALLACCHINI, *Scienza e potere (Voce)*, in *Enciclopedia del diritto*, vol. *"Potere e costituzione"* (a cura di M. CARTABIA, M. RUOTOLO), Milano, 2023 (forthcoming).

[24] S. JASANOFF, *Transnational Risks and Multilevel Regulation: A cross-comparative perspective*, in *European Journal of Risk Regulation*, 2, 2013, 133-141, at 135.

decisions of high public salience, constitutes an imperative precondition for public forms of expert accountability.[25]

On this issue, Section 5.2 posits that the affirmation of transparency in the pesticide field, together with the correlated provisions on the confidentiality of data, are likely to enrich risk assessment with a more participatory approach, for the protection of environmental and (human and animal) health interests.

Against this overall backdrop, Section 6 presents some final reflections on the role of regulatory science in coping with uncertain risks, particularly when pursuing a more transparent and sustainable use of PPPs, together with the protection and restoration of pollinators. The core argument claims that only the plurality of evidence and sources of knowledges in risk assessment dynamics can trigger a radical move toward an innovative model of risk analysis in the pesticide field. That is, a model of production and management of regulatory science that engages with the complexity and pluralism of the knowledge about PPPs (and neonics, in particular), for the promotion of "a fundamental epistemic and normative shift from searching what to do, to choosing how to do it".[26]

2. The contested science of neonicotinoids

Regulatory science, a term coined by scientist Alan Moghissi, is the science produced as a source of evidence for policy purposes (marketing authorisation, definition of thresholds for exposure, use conditions, among others) by agencies dealing with issues based on scientific knowledge.[27] The expression refers thus to the use of scientific data to support science-based regulatory decision-making in matters spanning from the impact of new technologies and the toxicity of chemical substances, to the identification of acceptable levels of exposure.[28] The characterization of what it is and what knowledge should be embedded into regulatory science, though, has become increasingly complex, opening up to a growing number of social disciplines: from genetics, pharmacology and biostatistics, to clinical trial methodology and epidemiology, up to social sciences (such as decision sciences, risk assessment and communication sciences). Interestingly, it now tends to include the epistemology of trust in experts and policy formulations under conditions of public distrust.[29]

Regulatory science differs, in fact, from standard academic science as it aims at non-epistemic goals and values (like the generation of decision-relevant data under strict legal, time and budgetary constraints, or the rapid assessment of large numbers of substances). Besides, it is concretely "negotiated" in a constant dialogue between the (best) available knowledge (with the related problems of exclusion and inclusion of knowledge and experts), and the different specific application contexts (chemicals,

[25] E. Hickey, M. Weimer, *The Transparency of EU Agency Science – Towards a New Proactive Approach*, in *Common Market Law Review*, 59, 2022, 673-710, at 674.

[26] A. Benessia, S. Funtowicz, G. Bradshaw, F. Ferri, E.F. Ráez-Luna, C.P. Medina, *Hybridizing Sustainability: Towards a new praxis for the present human predicament*, in *Sustainability Science*, 7, 2012, 75-89, at 89.

[27] A. Moghissi, S.R. Straja, B.R. Love, D.K. Bride, *Innovation in Regulatory Science: Evolution of a new scientific discipline*, in *Technology & Innovation*, 16, 2014, 155-165.

[28] O. Todt, J.R. Alcázar, J.L. Luján, *Practical Values and Uncertainty in Regulatory Decision-making*, in *Social Epistemology*, 24, 4, 2010, 349-362, at 349.

[29] K.P. Whyte, R.P. Crease, *Trust, Expertise, and the Philosophy of Science*, in *Synthese*, 177, 2010, 411-425.

drugs, food, animal and human experimentation, etc.). Its legitimacy often involves that it is formulated in the light of public scrutiny, or subjected to public consultation, or evaluated by committees in which scientists and lay people collaborate.[30]

The main (albeit non-exclusive) object of "negotiation" concerns scientific uncertainty and its degree of acceptability in legal-political contexts. This aspect always leads to problems of testing and evaluating, controversial results, as well as biases and inability to detect and avert uncertainties.[31] Choices made about the standards of regulatory science to be used – from the criteria against which the objects are assessed, to the models and laboratory settings used for testing, up to the metrics and thresholds identified for classifications – have become object of controversy and critique.[32] They ignited debates between the policies of science and their related forms of social regulation, and on the construction of the concepts of risk and precaution.[33]

With reference to the insecticide family of neonics, activities carried out by scientific expertise through the years reflected the main components of regulatory science: the social relevance of its verdicts, as far as these directly affect animal health and the environment; the high degree of empirical underdetermination, due to the scarcity or indeterminacy of data; the methodologies chosen to measure the effects of the chemicals under examination; the urgency of rapidly producing outcomes under uncertainty.[34]

In the early '90s, neonicotinoid insecticides were introduced on the EU market to provide cost-effective and lost-lasting protection of crops against pests,[35] in the light of their high versatility in application methods[36] and the high target specificity.[37] As early as the end of the same decade, however, these systemic pesticides proved to represent a major risk for pollinators.[38] Scientific studies highlighted a significant link between the use of neonics, bee deaths and honeybee colony collapses across EU countries.[39] Further evidences[40] pinpointed several uncertainties on yields benefits from the use of neonics

[30] S. JASANOFF, *Procedural Choices in Regulatory Science*, in *Technology in Society*, 17, 3, 1995, 279-293, at 284.

[31] D. DEMORTAIN, *Expertise, Regulatory Science and the Evaluation of Technology and Risk: Introduction to the special issue*, in *Minerva*, 55, 2017, 139-159, at 142.

[32] D. MICHAELS, W. WAGNER, *Disclosure in Regulatory Science*, in *Science*, 302, 2003, 2073.

[33] S. JASANOFF, *The Practices of Objectivity in Regulatory Science*, in C. CAMIC, N. GROSS, M. LE LAMONT (eds.), *Social Knowledge in the Making*, Chicago, 2011, 306-338, at 307.

[34] A. SALTELLI, D.J DANKELBC, M. DI FIORE, N. HOLLANDE, M. PIGEONE, *Science, The Endless Frontier of Regulatory Capture*, in *Futures*, 135, 2022, 102860.

[35] P. JESCHKE, R. NAUEN, *Neonicotinoids — From Zero to Hero in Insecticide Chemistry*, in *Pest Management Science*, 64, 2008, 1084-1098.

[36] Neonics can be applied though either spaying, seed coating/seed-dressing, soil treatment, injection, and drenching.

[37] P. JESCHKE, R. NAUEN, M. SCHINDLER, A. ELBERT, *Overview of the Status and Global Strategy for Neonicotinoids*, in *Journal of agricultural and food chemistry*, 59, 7, 2010, 2897-2908.

[38] EASAC (EUROPEAN ACADEMIES SCIENCE ADVISORY COUNCIL), *Ecosystem Services, Agriculture and Neonicotinoids*, EASAC Policy Report 26, Halle/Saale, 2015.

[39] J. BONMATIN, C. GIORIO, F. SÁNCHEZ-BAYO, M.B. VAN LEXMOND, *An Update of the Worldwide Integrated Assessment (WIA) on Systemic Insecticides*, in *Environmental Science and Pollution Research,* 28, 2021, 11709-11715; M.L. HLADIK, A.R. MAIN, D. GOULSON, *Environmental Risks and Challenges Associated with Neonicotinoid Insecticides*, in *Environment Science and Technology*, 52, 6, 2018, 3329-3335.

[40] O. LUNDIN, G. MALSHER, C. HÖGFELDT, R. BOMMARCO, *Pest Management and Yield in Spring Oilseed Rape without Neonicotinoid Seed Treatments*, in *Crop Protection*, 137, 2020, 105261; I. MILOSAVLJEVIĆ, A.D. ESSER, K.M. MURPHY,

on different crops (wheat crops,[41] soybean[42] and maize[43] production). Additional studies demonstrated how time-cumulative toxicity associated with the spread of neonics in the environment inevitably affect ecosystem services,[44] as well as terrestrial[45] and aquatic[46] species.

Furthermore, scientific uncertainty surrounding this family of pesticides has always impacted on scientific estimates, analyses and conclusions on the risks connected to them. Legal academia listed four complexities in this respect, concerning the types and applications of neonics, the residues and possible routes of exposure for non-target species, the species affected, and the ecological contextual factors affecting the consequences of neonics exposure for different species.[47] As these complexities represent sources of ambiguity on validity and reliability of evidence, their use in risk assessment activities opened the door to unfinished dilemmas and discussions among public bodies, the scientific community and the industry.

Already in 2013, three scientific reports, released by EFSA at the EU Commission's request pursuant to art. 21(2) of Reg. 1107/2009,[48] outlined several concerns for bees as regards the risk assessment of neonics clothianidin, imidacloprid (both produced and marketed by the Bayer group) and

D.W. CROWDER, *Effects of Imidacloprid Seed Treatments on Crop Yields and Economic Returns of Cereal Crops*, in *Crop Protection*, 119, 2019, 166-171.

[41] S. MACFADYEN ET AL., *Reducing Insecticide Use in Broad-acre Grains Production: An Australian study*, in *PLoS One*, 2014, https://doi.org/10.1371/journal.pone.0089119.

[42] EPA (ENVIRONMENTAL PROTECTION AGENCY), *Benefits of Neonicotinoid Seed Treatments to Soybean Production*, 2014, https://www.epa.gov/sites/default/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf (accessed 26 May 2022).

[43] F. SGOLASTRA ET AL., *Healthy Honey Bees and Sustainable Maize Production: Why not?*, in *Bulletin of Insectology*, 70, 1, 2017, 156-160.

[44] F. SÁNCHEZ-BAYO, H.A. TENNEKES, *Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments*, in *International Journal of Environmental Research and Public Health*, 17, 5, 2020, 1629; D. GOULSON, J. THOMPSON, A. CROOMBS, *Rapid Rise in Toxic Load for Bees Revealed by Analysis of Pesticide Use in Great Britain*, in *PeerJ*, 2018, https://doi.org/10.7717/peerj.5255.

[45] M. CHAGNON ET AL., *Risks of Large-scale Use of Systemic Insecticides to Ecosystem Functioning and Services*, in *Environmental Science and Pollution Research*, 22, 1, 2014, 119-134.

[46] F. SÁNCHEZ-BAYO, K. GOKA, D. HAYASAKA, *Contamination of the Aquatic Environment with Neonicotinoids and its Implication for Ecosystems*, in *Frontiers in Environmental Science*, 4, 2016, 71.

[47] L. DRIVDAL, J.P. VAN DER SLUIJS, *WP2 Case Study: Neonicotinoid insecticides*, The RECIPES project, 2020, at 15-16, https://recipes-project.eu/sites/default/files/2021-03/D2_3_Neonics_Review.pdf (accessed 27 May 2022).

[48] The Commission's request followed a number of incidents occurred in 2008 and 2009, that involved the misuse of PPPs containing neonics. Since the incidents had resulted in losses of honeybee colonies, the Commission adopted Directive 2010/21/EU, amending Annex I to Dir. 91/414 as regards the specific provisions relating to clothianidin, thiamethoxam, fipronil and imidacloprid (OJ 2010 L 65/27). This measure strengthened the terms of approval of the substances in question as regards the protection of non-target organisms, in particular honeybees. In 2012, however, after the publication of two scientific studies on the sub-lethal effects on bees of neonics, EFSA was asked by the Commission to release a scientific opinion on the science underpinning the assessment of risks posed by PPPs to bees. The opinion drew attention, *inter alia*, to several weaknesses in the EPPO Guidance, that is the scheme for the assessment of risks posed by PPPs to bees drawn up by the European and Mediterranean Plant Protection Organisation (EPPO). EFSA subsequently developed its own guidance, without formally adopting it. See EFSA, *Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)*, in *EFSA Journal*, 11, 7, 2013, 3295.

thiamethoxam (produced and marketed by the Syngenta group).[49] Those active substances, firstly included in Annex I to Council Directive 91/414/EEC[50] concerning the placing of PPPs on the market, were then approved under Reg. 1107/2009 and are now listed in Part A of the Annex to Commission Implementing Regulation (EU) 540/2011.[51]

In its conclusions, EFSA identified a number of data gaps for each of the evaluated crops, together with specific high acute risks from dust exposure, from consumption of residues in contaminated pollen and nectar, and from exposure via guttation fluid. That scientific uncertainty pertaining to the long-term risk to honeybees led the Authority to conclude that none of the three neonics should be used in bee-attractive crops (including maize, oilseed rape and sunflower), with the exception of uses in greenhouses, of treatment of some crops after flowering and of winter cereals.

On the grounds of those scientific outputs[52] – considered by legal scholarship as "some sort of risk management advice"[53] – Regulation (EU) 485/2013[54] was adopted to restrict the use of the three pesticides belong to the neonicotinoid family.[55] The then novel rules added a further piece to the EU's overall strategy aimed at tackling the decline of bee population, by amending Reg.540/2011 as regards the conditions of approval of the active substances, and prohibiting the use and sale of seeds treated with PPPs containing those active substances.[56]

[49] See EFSA, *Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin*, in *EFSA Journal*, 11, 1, 2013, 3066; ID., *Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid*, in *EFSA Journal*, 11, 1, 20133068; ID., *Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam*, in *EFSA Journal*, 11, 1, 3067.

[50] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230/1.

[51] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, OJ L 153/1.

[52] For an overview of the EFSA's work starting from 2012 and a summary of the conclusions of the risk assessment for those active substances, see D. AUTERI ET AL., *Neonicotinoids and Bees: The case of the European regulatory risk assessment*, in *Science of the Total Environment*, 579, 2017, 966-971.

[53] A. ALEMANNO, *The Science, Law and Policy of Neonicotinoids and Bees: A new test case for the precautionary principle*, in *European Journal of Risk Regulation*, 2, 2013, 191-207, at 196.

[54] Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, OJ L 139/12.

[55] Art. 1 of Reg. 485/2013 introduced for the three substances covered, the following restrictions: prohibition of any non-professional use, indoors or outdoors; prohibition of uses for seed treatment or soil treatment on the following cereals when these are to be sown from January to June: barley, millet, oats, rice, rye, sorghum, triticale, wheat; prohibition of foliar treatments for the following cereals: barley, millet, oats, rice, rye, sorghum, triticale, wheat; prohibition of uses as seed treatment, soil treatment or foliar application for around 100 crops (including rapeseed, soya, sunflowers and maize), with the exception of uses in greenhouses and of foliar treatment after flowering. Art. 2, furthermore, prohibited the use and placing on the market of seeds of crops listed in Annex II which have been treated with PPP containing the substances covered, with the exception of seeds used in greenhouses.

[56] The Commission adopted also Implementing Regulation No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance, OJ L 219/22.

In August 2013, however, Bayer CropScience AG and Syngenta Crop Protection AG brought proceedings before the General Court for annulment of the prohibitions and restrictions set out in Reg. 485/2013 as regards the neonics clothianidin, thiamethoxam and imidacloprid (the "substances covered").[57] The arguments raised by the applicants against the EU Commission included, *inter alia*: the misinterpretation of the scientific data pertaining to the neonicotinoid family; the lack of evidence for the initiation of the review procedure; and the breach of both the precautionary principle and the principle of proportionality, in part due to the missed impact assessment of Reg. 485/2013.
The CJEU's dismissal of the actions brought by Bayer and Syngenta are relevant here for the line of reasoning followed by the Court with regard to: the scientific proof of the safety/unsafety of a product; the acceptability of uncertain risks on the base of a cost-benefit analysis; the interpretation and implementation of the precautionary principle in risk management activities; and the ramifications deriving from the use of scientific data in the risk assessment phase.
In what follows, the key arguments and reasonings shining through the judgment are summarized and discussed.

3. The Bayer CropScience case

Following a hazard-based approach,[58] Reg. 1107/2009 lays down a prior authorisation system, according to which substances can only be placed on the market if approved or authorised. While active substances are approved and regulated at the EU level, PPPs are authorized and regulated at the national level, in the framework of the so-called "zonal system."[59]
Compared to Dir. 91/414, Reg. 1107/2009 introduced specific new requirements for the approval of active substances. Point 3.8.3 of Annex II thereof, in particular, contains special requirements in relation to the exposure of honeybees and acute or chronic effects on colony survival and development. It specifies that exposure of honeybees to an active substance shall be only "negligible" or that its use shall not have "unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour". The burden of proving that the conditions for approval under art. 4 of Reg. 1107/2009 are met lies with the notifier, who should demonstrate that substances or products produced or placed on the market do not have any unacceptable effects on the environment.[60]
However, in the context of a review taking place before the end of the approval period, it is for the Commission to demonstrate that the conditions of approval are no longer met. In this respect,

[57] Joined Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* ECLI:EU:T:2018:280.
[58] Pursuant to Annex II, 3.6.2 to 3.6.5 of Reg. 1107/2009, substances which do not meet the EU's predetermined cut-off hazard criteria (i.e. persistent bioaccumulative and toxic, persistent organic pollutants, very persistent, very bioaccumulative, or endocrine disruptive) cannot be approved or their approval cannot be renewed. As a result, an active substance displaying some hazardous properties cannot be included by the Commission in the EU list, regardless of the likelihood of a risk (that is the hazard causing actual harm). On the concerns arising from the use of a hazard-based approach, see K. NORDLANDER, C. SIMON, H. PEARSON, *Hazard v. Risk in EU Chemicals Regulation*, in *European Journal of Risk Regulation*, 3, 2010, 239-250.
[59] See recital 23, arts 28 to 57 and Annex I of Regulation 1107/2002.
[60] Recital 8 of Regulation 1107/2009.

pursuant to art. 21(3) of PPP Regulation, the burden of proof is discharged if the Commission is able to demonstrate that, in the light of legislative changes of the conditions of approval, the data generated by studies carried out for the purposes of the initial approval were insufficient to identify all the risks for bees linked to the active substance concerned.

Given this normative picture, in the joined cases under examination the groups of Bayer and Syngenta raised several sets of complaints. They can be grouped into three prominent claims: the knowledge sources to be included into regulatory science production; the initiation and application of the review of approval procedure; the interpretation and implementation of the precautionary principle, in the light of a lack of impact assessment for risk management decisions.

3.1. On complaints

As to the first ground of appeal, art. 21(3) of PPP Regulation came under the lens of observation. The applicants complained, in this regard, that the Commission and EFSA allegedly applied methodologies and criteria that differed from those applicable at the time of the request for approval of the substances covered. Through a deep consideration of the arguments put forward by Bayer and Syngenta, the Court, though, did not find any errors in the application of art. 21(3) of Reg. 1107/2009.[61] This conclusion was supported, *inter alia*, by observations relating to the notion of "new scientific and technical knowledge", that is the threshold for the application of art. 21.

According to the Court, specifically, since that concept possesses both a temporal and a qualitative component,[62] the novelty should be referred to those "studies which have not yet been taken into account by EFSA or the Commission in an earlier assessment of the substance concerned, the results of which, as compared with the knowledge available at the time of the earlier assessment, raise concerns as to whether the conditions of approval in art. 4 of Reg. 1107/2009 are still satisfied".[63] This means that new scientific studies and new monitoring data which reveal novel forms of scientific uncertainty, or the insufficiency, or the indeterminacy of knowledge for a proper characterization of a risk, do qualify as "new scientific and technical knowledge".

In this case, scientific data considered by the Commission included three peer-reviewed studies published in 2012, and monitoring data gathered by national authorities. Their newness, the Court stated, correlates both to a more reliable methodology underpinning them (that allowed to increase the degree of certainty of the previous knowledge on the effects of neonics on bees),[64] and to the time of publication (that is, after the submission of the original dossier at the time of the first approval).

These arguments clearly confirm the necessity that a scientific risk assessment should be based on the best scientific data available, as it might prove central for the legitimacy and the transparency of the review – even though the Court did not discuss this peculiar point.[65]

[61] See *Bayer CropScience AG and Others v European Commission*, cit., 581.
[62] *Ibidem*, 162.
[63] *Ibidem*, 164.
[64] *Ibidem*, 179.
[65] E. Bozzini, E. Stokes, *Court Upholds Restrictions on Neonicotinoids – A Precautionary Approach to Evidence*, in *European Journal of Risk Regulation*, 9, 2018, 585-593, at 592.

A further set of complaints made by the applicants concerned two specific errors. First, a manifest error of assessment, since there was no evidence that the substances covered no longer satisfied the approval criteria laid down in art. 4 of Reg. 1107/2009. Second, a misapplication of the precautionary principle, given the applicants' considerations that: firstly, only purely hypothetical risks were taken into account; secondly, there was no adequate scientific assessment or cost/benefit analysis; thirdly, the measures taken were disproportionate.

In answering those claims, the General Court expressly invoked the precautionary principle, pointing out that the principle is ipso jure at the core of any act adopted on the basis of Reg. 1107/2009,[66] as it is apparent from recital 8[67] and art. 1(4) thereof.[68] It is applicable not only in cases in which the existence of a risk is not certain, but also where there is the proof of a risk, and where its acceptability needs to be assessed by the Commission.[69] In the light of this context, the Court's considerations put the accent on both the risk assessment and risk management of the three active substances contested.

As far as risk assessment is concerned, the Court stated that EFSA did not fail to take certain scientific studies into account,[70] nor it failed to conduct the risk assessment of the substances covered, of which EFSA's conclusions are the result, in accordance with scientific rules. Indeed, the Courts argued, "since the applicants have not established that the assessment was defective, the risks established in EFSA's conclusions must be deemed to be scientifically sound and cannot be considered, in general terms, to be hypothetical".[71] Moreover, in contrast with the applicants' allegations, the Court added that EFSA did not ignore the available monitoring data or risk mitigation measures, whose summary had been included in a devoted section of EFSA's conclusions.[72]

Moving on to the risk management measures taken by the Commission, the applicants submitted that the contested measures – namely, the ban on the use of thiamethoxam on "bee-attractive crops", the ban on the use of foliar sprays and the prohibition of non-professional uses outdoors and indoors – went beyond what was necessary to ensure the safe use of the substances covered and for the achievement of any legitimate objectives relating to bee health, thus breaching the principle of proportionality.[73] In discussing the applicants' arguments, the Court considered whether the contested measure were manifestly inappropriate for the objective pursued by the PPP Regulation, namely the protection of the environment and, in particular, the protection of bees.

In this regard, the General Court stated that, because of the applicants' failure to detail or to demonstrate the truth of their claims regarding the possible consequences for the environment of the

[66] See *Bayer CropScience AG and Others v European Commission*, cit., 339.

[67] Recital 8 of Reg. 1107/2009 states that the precautionary principle should be applied and that the regulation seeks to ensure that industry demonstrate that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

[68] According to art. 1(3) of Reg. 1107/2009, the purpose of the regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

[69] See *Bayer CropScience AG and Others v European Commission*, cit., 340.

[70] *Ibidem*, 355-382.

[71] *Ibidem*, 390.

[72] *Ibidem*, 374.

[73] *Ibidem*, 502.

replacement products,[74] and given that the Member States which had suspended certain uses of neonics for several years never reported any adverse effects on the environment,[75] the contested measure could not be characterised as manifestly inappropriate.[76]

Turning finally to the relevance of impact assessments in EU risk regulation, Bayer and Syngenta submitted that the Commission had failed to conduct a formal and comprehensive evaluation of the measures adopted, despite this being provided for in the Communication on the Precautionary Principle.[77] By recalling this document, the Court's findings outlined, instead, that it requires the examination of pros and cons in the risk management phase to be focused not only on an economic cost-benefit analysis, but also on all factors relevant for the purposes of decision-making. Besides, other analysis methods, such as those concerning the efficacy of possible options and their acceptability to the public, may also have to be taken into account.

With this scenario in mind, the Court affirmed that the Commission is not obliged to initiate a specific assessment procedure,[78] and it has discretion regarding the methods of analysis, which albeit "should" include an economic analysis, must in any event also include non-economic considerations. Besides, the General Court added, in certain circumstances interests such as the environment or health prevail on economic considerations.[79]

These observations well reflect how, throughout the years, the precautionary principle has come to stand up as a political and autonomous principle of the EU for human, animal, vegetable and environmental health, generally applicable throughout different areas of EU law within a unitary process of risk analysis.[80] Viewed in this status, it has acquired a completely new value, epistemologically and legally speaking, shifting from a mere prudential criterion to be adopted "in the lack of full scientific certainty",[81] to an epistemological approach to complex issues calling on Member States, stakeholders and the civil society to act more responsibly.[82]

Furthermore, the Court's statements put the political responsibility in the risk managers' hands to set the level of protection and threshold of acceptable risk, and to determine whether uncertain risks meet those levels of protection and threshold. In this vein, EU institutional actors are called to pay special

[74] *Ibidem*, 511.
[75] *Ibidem*, 514.
[76] *Ibidem*, 515.
[77] See *supra*, note 21.
[78] Contrary to this statement, however, scholars noted that in its 2017 Better Regulation Toolbox, the Commission seems to have taken a different path, as it claims that all precautionary measured should be based on a formal impact assessment (see E. BOZZINI, E. STOKES, *Court Upholds Restrictions on Neonicotinoids – A Precautionary Approach to Evidence*, cit., at 590).
[79] See *Bayer CropScience AG and Others v European Commission*, cit., 459.
[80] On the idea that the precautionary principle has attained the status of an autonomous principle of EU law rather than of an EU general principle, see J. SCOTT, *Legal Aspects of the Precautionary Principle. A British Academy Brexit Briefing*, 2018, at 16.
[81] See UN GENERAL ASSEMBLY, *Report of the United Nations Conference on Environment and Development*, Rio de Janeiro, 3-14 June 1992, Annex I – The Rio Declaration on Environment and Development, A/CONF.151/26 (Vol. I), Principle 15.
[82] M. TALLACCHINI, *Between Uncertainty and Responsibility. Precaution and the Complex Journey towards Reflexive Innovation*, in M.B.A. VAN ASSELT, M. EVERSON, E. VOS (eds.), *Trade, Health and the Environment. The European Union Put to the Test*, Abingdon/New York, 2014, 74-88, at 78.

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attention to the procedures for placing on the market products that have an impact on the environment and on human and animal health. In particular, they must ensure that these procedures meet – both in regulatory choices and interpretive parameters – the tenets of the principle guiding the risk assessment system.[83] That is, the precautionary principle, to the effectiveness of which are linked the procedural rules designed to ensure a proper risk assessment, together with the rules on transparency.

3.2. Comments

In the joined cases under analysis, it can be certainly recognised to the CJEU a crucial role in defending and strengthening the EU "socially acceptable risk approach."[84] The lawsuit perfectly mirrors how the legally relevant threshold of adverse effects relies on three intertwined factors: the adherence to more or less prudential approaches to risk assessment; the inferences drawn by regulators from the available scientific evidence; and the level of protection pursued in the light of all the legitimate factors involved in the matter.[85]

The judgment is thus of utmost relevance for risk regulation issues and, in particular, for the discussion it presents about the interpretation and application of the precautionary principle. On this aspect, the General Court reaffirmed what already argued in several previous rulings,[86] including the *Blaise* case[87] on the compatibility of the PPP Regulation with the precautionary principle.

In that judgment, the Court clearly stressed that a precautionary-based measure taken in the process of risk management presupposes a comprehensive assessment of the risk to health that is based on the most reliable scientific data available and the most recent results of international research, without having to wait until the reality and seriousness of that risk become fully apparent.[88] In the context of PPP regulation, for instance, this requirement is fulfilled by those rules prescribing that the procedures leading to the authorisation of a pesticide must necessarily include an assessment not only of the specific effects of the active substances contained in that product, but also of the cumulative effects of those substances, and their effects combined with other constituents of that product.

Noteworthy is that, in the same ruling, the Court stated that the benchmark for the validity of the PPP legislation in the application of the precautionary principle stands the necessity of a normative framework that provides the competent authorities with sufficient information to adequately assess the risk of the active substances and PPPs under review.[89] Even though the Court remained silent about the

[83] See I. CANFORA, *Innovazione tecnologica e protezione delle informazioni sensibili. L'evoluzione delle regole europee sulla trasparenza nella sicurezza alimentare*, cit., at 148.

[84] G.C. LEONELLI, *Balancing Public Health and Environmental Protection and Economic Stakes? Bayer CropScience and the Court's Defence of the EU Socially Acceptable Risk Approach*, in *Common Market Law Review*, 58, 2021, 1845-1874, at 1874.

[85] *Ibidem*, at 1846.

[86] Such as Case C-77/09, *Gowan Comércio Internacionale Serviços* EU:C:2010:803, 73-76; Case C-157/14, *Neptune Distribution* EU:C:2015:823, 81-82; Case C-151/17, *Swedish Match* EU:C:2018:938, 38.

[87] Case C-616/17, *Procureur de la République v Blaise and others* ECLI:EU:C:2019:800, 43, on which see A. BAILLEUX, *Don't Judge a Case by its Cover: The pesticides Regulation survives judicial scrutiny but is given new teeth: Blaise*, in *Common Market Law Review*, 57, 2020, 861-876.

[88] Case C-616/17, *Procureur de la République v Blaise and others*, cit., 43.

[89] *Ibidem*, 74.

practical application of this standard,[90] the statement reveals how the line between the stages of risk assessment and risk management is not as clear-cut as suggested by the General Court in the joined cases previously examined.

In *BayerCropScience*, indeed, not only has the Court separated out the claims relating to risk assessment from those pertaining to risk management, but it has also outlined that the former should be undertaken in an independent, objective and transparent manner.[91] As well known, since the study on risk governance published in the so-called Red Book[92] by the US National Research Council in 1983, US policy institutions have proceeded to separate "the analytic functions of developing risk assessments from the regulatory functions of making policy decisions".[93] The document was thus based on the explicit statement of a clear separation between the "facts" and "values" relating to risks, which in turn was translated into the clear distinction between "risk assessment" and "risk management". This was with the aim of preventing various political interests from influencing and manipulating scientific representations.

Consequently, while the risk assessment procedure is seen as a scientific activity of objective finding of facts, the risk management stage is meant as a chronologically later process, characterized by the examination of ethical concerns, economic costs and social values.[94] This distinction between risk assessment and risk management has been preserved also in the EU,[95] as the legal design of Reg. 178/2002 on food safety explicitly states.[96]

In more recent years, however, the EU has developed, for historical and political reasons,[97] a policy-related science model, which is pointed towards more democratic forms of science governance.[98] This means that EU science policy is increasingly orientated to make it explicit the normative questions that guide the assessment procedure, by complementing the scientific evaluation of risks with a risk management phase suitable to integrate different knowledges and languages.[99]

As some scholars sagaciously underlined, indeed, risk assessment is inescapably replete with non-epistemic values – political, social and ethical ones – which cannot be separated from the process of knowledge production, as they influence the choice of both topics and purposes that scientific research

[90] S. PAULINI, *Fact or Fiction? Case C-616/17 and the Compatibility of the EU Authorisation Procedure for Pesticides with the Precautionary Principle*, in *European Journal of Risk Regulation*, 11, 3, 2020, 481-497, at 494.

[91] See *Bayer CropScience AG and Others v European Commission*, cit., 117.

[92] NRC (NATIONAL RESEARCH COUNCIL), *Risk Assessment in the Federal Government: Managing the Process*, Washington (DC), 1983.

[93] *Ibidem*, at 1.

[94] *Ibidem*, at 3.

[95] In the food sector, this distinction is clearly indicated in art. 3(9) of Regulation 178/2002, on which see I. CANFORA, *I principi: principio di precauzione, analisi del rischio, trasparenza*, in P. BORGHI, I. CANFORA, A. DI LAURO, L. RUSSO (a cura di), *Trattato di diritto alimentare italiano e dell'Unione europea*, cit., 54-62; E. ROOK BASILE, *L'architettura della legislazione alimentare europea: Il reg. CE n. 178/2002*, in P. BORGHI, I. CANFORA, A. DI LAURO, L. RUSSO (a cura di), *Trattato di diritto alimentare italiano e dell'Unione europea*, cit., 38-45.

[96] See recitals 17-18 and art. 6 of Regulation 178/2002.

[97] This refers, in particular, to the Europe's transition from an economic entity to a political "organization".

[98] See M. TALLACCHINI, *Between Uncertainty and Responsibility. Precaution and the Complex Journey towards Reflexive Innovation*, cit., at 80-81.

[99] O. RENN ET AL., *Making Sense of Science for Policy under Conditions of Complexity and Uncertainty*, Berlin, 2019, at 79.

is expected to serve.[100] Consequently, uncertainty, dissent and criticism should be openly included, displayed and discussed in the analysis and assessments delivered by the expertise, in order to improve robustness in knowledge claims.[101]

The separatist theory has, in fact, clashed over the years with the position taken by some US federal agencies (such as the Environmental Protection Agency, EPA)[102] about the need for interactions between risk assessors and risk managers during the risk assessment process. This aspect requires risk assessment not to be understood as a sort of scientific control tool for precautionary policy decisions, as such exempted from the examination of values, assumptions, interpretative judgments and underlying social interests. Rather, it implies the application of a so-called "post-normal science version of risk assessment,"[103] where all safety issues are brought together by an extended peer community that includes participants grounded in a wide variety of knowledge bases.[104]

In brief, risk assessments should make better use of information from non-scientific sources (such as local knowledge from beekeepers, in our case), in order to clarify the value components and interests being at play in scientific research.[105]

On this point, the appeal[106] made in 2018 by Bayer CropScience and Bayer against the judgment of the General Court in Case T-429/13 deserves attention. In support of their appeal, the applicants relied on six grounds of complaint concerning, respectively, errors of law relating to the interpretation and application of art. 21(1) and (3) of Reg. 1107/2009, and errors of law relating to the application of precautionary measures.

In the light of the open-ended and conditional nature of the knowledge about neonics – as there is no consensus on the existence of conclusive evidence of harm – the groups of Bayer criticised the

[100] H. DOUGLAS, *Values in Social Science*, in N. CARTWRIGHT, E. MONTUSCHI (eds.), *Philosophy of Social Science: A New Introduction*, Oxford, 2014, 162 *et seq*., at 176.

[101] S.O. HANSSON, T. AVEN, *Is Risk Analysis Scientific?*, in *Risk Analysis*, 34, 2014, 1173 *et seq*., at 1176.

[102] "At EPA, risk assessment (evaluation of the science) and risk management (decision making, setting of policy) are not necessarily separate. We believe it is appropriate to involve decision makers from the beginning, as they typically initiate requests for risk assessments or analyses. Consequently, separating them entirely from the risk assessment process is neither logical nor desirable. Also, risk assessments typically are coordinated with the evaluations of economics, feasibility of remedies, and community concerns, for example, so that their results can be factored into decisions. […] Further, the NRC report on understanding risk supports the concept that risk assessment is conducted for the purpose of supporting risk management, and risk management considerations shape what is addressed in a risk characterization" [EPA (ENVIRONMENTAL PROTECTION AGENCY), *Risk Assessment Principles & Practices*, EPA/100/B-04/001, 2004, at 22].

[103] The expression "Post-normal science" (PNS) alludes to a set of practical insights in science for policy. It aims to assist scientists and stakeholders to work together when facts are uncertain, values are in dispute, stakes high, and decisions urgent. By refusing the idea that every practical problem can be reduced to a sum of simple technical problems, and against the arbitrary distinction between facts and values, PNS also shows the ineffectiveness of a problem-solving strategy that reduces policy questions to technical problems. See S. FUNTOWICZ, J.R. RAVETZ, *Science for the Post-normal Age*, in *Futures*, 25, 1993, 739-755.

[104] D. WALTNER-TOEWS, *Responding to Globalised Food-borne Disease: Risk assessment as post-normal science*, in *EFSA Journal*, 17, S1, 2019, 6.

[105] L. MAXIM, J. VAN DER SLUIJS, *Seed Dressing Systemic Insecticides and Honeybees*, in EEA (EUROPEAN ENVIRONMENT AGENCY), *Late Lessons from Early Warnings: Science, precaution, innovation,* EEA Report No 1, Copenhagen, 2013, 369-406, at 389.

[106] Case C-499/18 P, *Bayer CropScience AG and Bayer AG v European Commission* ECLI:EU:C:2021:367.

methodology underpinning the review process, contesting several aspects of the documentary trail of preparatory and advisory paperwork relied upon by the institutions in their measure.[107] In doing so, they complained the application of core principles of EU law (from subsidiarity to proportionality to precaution), through an allegation differing from the previous one for the accent put on the innovation argument.[108]

In line with the previous ruling, the CJEU dismissed all Bayer's claims. Two observations deserve to be outlined here. With reference to the precautionary principle, the Court affirmed that an "exhaustive risk assessment cannot be required in a situation where the precautionary principle is applied, which equates to a situation in which there is scientific uncertainty".[109] As for the level of risk considered acceptable to society, it remarked that the "level of risk is determined not only on the basis of strictly scientific considerations, but also taking account of social factors, such as the feasibility of controls,[110] […] since (they) are intended to ensure compliance with the instructions for the use of plant protection products containing active substances, compliance which, in turn, is likely to mitigate the impact of the use of such substances on the environment".[111]

Both these arguments confirm the intrinsic value of the precautionary principle in EU risk regulation. It is meant as a substantial component of the dynamic process of risk analysis, in which it acknowledges the limits of the linear scientific model, while not discarding a genuine scientific approach.[112] In so doing, it constitutes "testament to a new relationship with science, where it is consulted less for the knowledge which it has to offer than for the doubts and concerns which it is in a position to raise".[113] This is because the precautionary criterion requires being evaluated not as a prescriptive decision rule – which is impossible in the face of the epistemological uncertainty of scientific knowledge – but as a broad policy principle, through which to turn attention to a wide range of "non-reductive methods" that, in explaining the incomplete nature of knowledge, do not lead to mere science-based political decisions. Escaping from the technocratic capture of narrow risk assessment, precaution aspires to a more democratic view of the world under uncertainties, offering innovators the best patterns to adopt.[114]

[107] The main objection raised by Bayer was that the Commission reviewed and amended the approvals even though, in the view of Bayer, there was insufficient new scientific knowledge compared with the initial approval procedure. Bayer also called for a more in-depth scientific assessment of the risks posed by the active substances, based, in particular, on the EPPO (European and Mediterranean Plant Protection Organization) Guidance. It worth noticing here that in 2018 the EPPO Working Party on Plant Protection Products concluded that it no longer had the necessary expertise to oversee maintenance of the EPPO Guidance, which it therefore withdrew [EPPO, *Annual Report and Council Recommendations 2018*, in *EPPO Bulletin*, 49, 2019, 509 *et seq*., at 602].

[108] In the introduction of the appeal, it is argued that "the Court of Justice's task is to guard against the precautionary principle becoming a universal incantation to block innovation". For a discussion on this aspect, see L. DRIVDAL, J.P. VAN DER SLUIJS, *WP2 Case Study: Neonicotinoid insecticides*, cit., at 33 *et seq*.

[109] See *Bayer CropScience AG and Bayer AG v European Commission*, cit., 81.

[110] *Ibidem*, 155.

[111] *Ibidem*, 156.

[112] N.M. DE SADELEER, *The Precautionary Principle in EU Law*, in *AV&S*, 5, 2010, 173-184, at 177.

[113] *Ibidem*, at 184.

[114] A. STIRLING, *Precaution in the Governance of Technology*, in R. BROWNSWORD, E. SCOTFORD, K. YEUNG (eds.), *The Oxford Handbook of Law, Regulation and Technology*, Oxford, 2017, 645-671, at 659.

4. EU Member States and emergency authorisations

As our analysis has shown so far, PPP Regulation displays specific features of EU risk governance.[115] One of them is represented by the pre-market authorisation, which puts on the applicant the burden of proof that the active substance (or the PPP) to place on the market is safe for health and the environment.[116] The assessment of active substances in pesticides and PPPs is instead delegated to EFSA, that is endowed with the task of conducting an independent, transparent and comprehensive four steps scientific activity.[117] In this context, that allocates responsibility for the safety of chemicals among private and public subjects, the Commission can adopt, *inter alia*, implementing acts in accordance with the comitology procedure.[118]

The stringent legal framework so defined – linking hard law (legislation and implementing acts) with soft law tools (non-legally binding documents[119] and scientific opinions and guidelines) – aims to guarantee health and environmental protection, through a hazard-based approach enshrined in the realm of the precautionary principle.[120]

A crucial role, in this respect, is also attributed to the Member States, which are empowered to adopt several measures in their territory – having restrictive[121] or emergency[122] or protective[123] nature – with the goal of responding to threats to health and the environment. Additionally, derogations from the regular authorisation process for limited and controlled use of a pesticide may be granted to a Member State, for a period not exceeding 120 days, in relation to a danger which cannot be contained by any other reasonable means. In this circumstance, according to art. 53(2) of PPP Regulation, "the Member State concerned shall immediately inform the other Member States and the Commission of the

[115] On this point, see N.M. DE SADELEER, *The EU Pesticides Regulation and the Glyphosate Controversy*, in *Jean Monnet Working Paper*, 6, 2020.

[116] See arts. 7, 8 and 33 of Regulation 1107/2009.

[117] Art. 12 of Regulation 1107/2009.

[118] Arts. 19 and 78 of Regulation 1107/2009.

[119] An example, in this regard, is the International Code of Conduct on Pesticide Management Guidelines on Highly Hazardous Pesticides published by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO). See WHO/FAO, *International Code of Conduct on Pesticide Management: Guidelines on highly hazardous pesticides*, Rome, 2016, https://apps.who.int/iris/bitstream/handle/10665/205561/9789241510417_eng.pdf?sequence=1&isAllowed=y (accessed 03 June 2022).

[120] A deep analysis of this legal picture is given by E. BOZZINI, *Pesticides Policy and Politics in the EU*, 2017.

[121] Art. 69 of Regulation 1107/2009.

[122] Art. 70 of Regulation 1107/2009.

[123] Art. 71 of Regulation 1107/2009. On the adoption of the protective measures, the CJEU ruled about the 2018 French decree prohibiting the use of acetamiprid, clothianidin, imidacloprid, thiacloprid and thiamethoxam. Specifically, the CJEU judged the validity of the communication made by the French Prime Minister to the Commission as regards the adoption of the decree. The Court concluded that "the communication of a national measure prohibiting the use of certain active substances falling within the scope of the harmonisation regulation must be regarded as the official provision of information on the need to take emergency measures where that communication contains a clear presentation of the evidence showing, first, that those active substances are likely to constitute a serious risk to human or animal health or to the environment and, second, that that risk cannot be controlled without the adoption, as a matter of urgency, of the measures taken by the Member State concerned, and where the Commission failed to ask that Member State whether that communication must be treated as the official provision of information under the regulation" (Case C-514/19, *Union des industries de la protection des plantes v Premier ministre and Others* ECLI:EU:C:2020:803).

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measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety".

Even though the term "emergency" is not legally defined, it seems imply both the requirements that a risk of harm is explicit, and that the unforeseeability of the risk is implicit. This interpretation comes, as scholarly reflection observed,[124] by examining the 1991 pesticide legislation, whose corresponding provision allowed derogations when "necessary because of an unforeseeable danger which cannot be contained by other means".[125]

The restricted use of neonics has been subject to significant tensions between EU Member States and the Commission with reference to derogations. This is because, as indicated by the Commission's guidelines pertaining to emergency measures, "the use of art. 53 should be exceptional, and restricted to cases of obvious dangers to plant production or ecosystems that cannot be contained by any other reasonable means. It shall not jeopardize the […] purposes of the regulation and shall be proportional in its sense. […] In particular, emergency authorisations should not be granted as a routine alternative to extensions of use or other forms of standard authorisation".[126]

In the context of neonics, their toxicological uncertainty has been used to postpone the changes requested by the EU stricter regulatory framework. Romania, Bulgaria, Lithuania, Hungary, Finland, Latvia and Estonia applied for multiple derogations on major crops, by granting emergency authorisations for some of the restricted uses, in accordance with the regulatory procedure referred to in art. 79(3) of PPP Regulation.

Although reasons related to the authorisations varied in individual Member States, due to the different territorial conditions and local crops, some considerations linked as a fil rouge the various notifications.[127] Neonicotinoid-based treatment, for instance, which was applied successfully in the Member States concerned, was considered as helpful to reduce infestation on crops. The use of treated seeds, instead, in the light of the lack of effective alternatives for the time being, was meant as "imperative" in areas where without such solutions, the spring crops would be compromised.

Mitigation measures adopted by each Member State, moreover, mostly consisted in performing seed treatment in professional seed treatment facilities by qualified personnel, following best agricultural practices. Area sown with treated seed were indicated with warning marks, while labelling of treated seed bags was done accordingly to art. 49(4) of Reg. 1107/2009. In some territories, such as Hungary, emergency authorisation was restricted to intensified production only, while seed treatment was not sowed when flowering weeds were present in the field and near the field, and where the bees were actively foraging.

[124] Y. EPSTEIN, G. CHAPRON, F. VERHEGGEN, *What is An Emergency? Neonicotinoids and Emergency Situations in Plant Protection in the EU*, in *Ambio*, 2022, https://doi.org/10.1007/s13280-022-01703-5.

[125] Art. 8(4) of Directive 91/414.

[126] EUROPEAN COMMISSION, *Working Document on Emergency Situations according to art. 53 of Regulation (EC) No 1107/2009*, SANCO/10087/2013 rev. 0, 2, 2013.

[127] Notifications of the emergency authorisations adopted by member States are publicly available on the website, https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home (accessed 05 June 2022).

All in all, this plurality of decisions taken at the national level brings to mind the model of so-called "epistemic subsidiarity"[128] that, on different legal grounds, was implemented by Directive (EU) 2015/432[129] to guarantee coexistence between GM (genetically modified) and non-GM crops.[130] In both cases, in fact, the differentiation conveyed through re-emphasis of national powers has been justified for the greater leeway it would allow in expressions of uncertainty, political preference and local values.[131] Though, choices made under the auspices of epistemic subsidiarity revealed not only differences in risk perception, but also how institutional designs being adopted in assessing and allocating the risks and costs of technoscience are shaped and governed by political preferences and national sociotechnical imaginaries. This is because both values and interests jointly contribute to framing national institutional arrangements and decisions on risk governance, making them far from united in their principles and procedures, especially under conditions of scientific and political uncertainty.[132] These considerations help explain why the Commission, in its attempt to monitor activities taken by Member States, straggled to accommodate differences without conflict and disagreement. In accordance with art. 53(2) of PPP legislation, in particular, it mandated EFSA to examine whether the repeated use of emergency authorisations granted for neonics in 2017 was justified by a danger which could not be contained by any other reasonable means. A first assessment was carried out by the Authority in 2018. Interestingly, authorisations were evaluated using a protocol[133] published by EFSA in 2017 to evaluate requests for use of an insecticide on the grounds that it is necessary to control a serious danger to plant health, within the context of art. 4(7) of Reg. 1107/2009.

[128] S. JASANOFF, *Transnational Risks and Multilevel Regulation: A cross-comparative perspective*, cit., at 135-136. Jasanoff defines "epistemic subsidiarity" as "the principle that protects legitimate local and national preferences for institutionalized modes of public reasoning". This principle, the Authors affirms, expresses "a polity's commitment to particular policy styles", thus reflecting "complex judgments about how to authorize rulership when of necessity many governmental decisions are highly technical and hence not accessible to the public as a whole".

[129] Directive (EU) N° 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, OJ L68/1, on which see S. POLI, *The Reform of the EU Legislation on GMOs: A journey to an unknown destination?*, in *European Journal of Risk Regulation*, 6, 4, 2015, 559-572.

[130] The reference is to the reform to the EU's genetically modified organisms (GMOs) regime made by Article 26b of Directive 2001/18/EC (as inserted by Directive 2015/432). It allows Member States to implement restrictions or prohibitions the cultivation of GMOs in their territory (in connection with an authorization procedure harmonized) for reasons that do not relate to issues of health and safety or the environment. This choice of presenting local governance as a solution to overcome the impasse in GMO decision-making has become a matter of debates and discussions. See L. BODIGUEL, *GMO, Conventional and Organic Crops: From coexistence to local governance*, in *Agriculture and Agricultural Science Procedia*, 8, 2016, 263-269; N. DE SADELEER, *Marketing and Cultivation of GMOs in the EU: An uncertain balance between centrifugal and centripetal forces*, in *European Journal of Risk Regulation*, 6, 4, 2015, 532-558; E. SIRSI, *Coexistence: A new perspective, a new field*, in *Agriculture and Agricultural Science Procedia*, 8, 2016, 449-454.

[131] M. GEELHOED, *Divided in Diversity: Reforming the EU's GMO regime*, in *Cambridge Yearbook of European Legal Studies*, 18, 2016, 20-44.

[132] S. JASANOFF, *Transnational Risks and Multilevel Regulation: A cross-comparative perspective*, cit., at 141.

[133] EFSA, *Protocol for the evaluation of data concerning the necessity of the application of insecticide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods*, 2017, doi:10.2903/sp.efsa.2017.EN-1201.

As this methodology does not cover measures taken by Member States to mitigate the risk to bees and the environment from neonics, EFSA's final reports considered only the justification for issuing the emergency authorisations. In 2020, in the light of the Authority's outcomes finding that for about one third of the products for which emergency authorisations were granted, alternatives would have been available,[134] the Commission took action to prevent unjustified derogations (specifically, for Romania[135] and Lithuania).[136]

The same year, a second mandate to EFSA followed the 2018 prohibition of all outdoor uses of the three neonics imidacloprid, thiamethoxam and clothianidin and the 2020 non-renewal of approval of thiacloprid, after which 11 EU countries repeatedly granted emergency authorisations for their use in sugar beets in 2020 and 2021. In the related notifications, reasons for derogations referred to the inadequacy, in sugar beet crops, of alternative non-insecticide methods for insect control, and to the unavailability of compensatory products. Very low risks to exposure via dust for environment, human and for honey bees were identified, as the seeds were pre-packed in one-hectare packing, and seeds could be handled and the drillings units filled without any contact to seeds. Notifications also indicated that "sowing of untreated seed would lead in loss of all or a substantial part of the harvest".

The evidence-based scrutiny performed by the Regulatory Fitness and Performance programme[137] (REFIT) evaluation on PPP Regulation showed concerns with regard to such emergency authorisations, because of their suitability to "negatively affect the protection of human health and the environment".[138] Further criticisms came from some NGOs, claiming that non-chemical methods were not sufficiently taken into consideration by Member States, so as to diminish the protection of human health and the environment. Moreover, while 82% of Member States notifications did not provide economic evidence of a "threat", the majority of them failed to provide any information to prove that the banned pesticides would have been used in a "limited and controlled" way.[139]

[134] EFSA's reports are available at: EFSA, *Neonicotinoids: EFSA evaluates emergency uses*, 21 June 2018, https://www.efsa.europa.eu/en/press/news/180621 (accessed 06 June 2022).

[135] Commission Implementing Decision (EU) 2020/152 of 3 February 2020 prohibiting Romania to repeat granting authorisations under art. 53(1) of Regulation (EC) No 1107/2009 for the plant protection products containing the active substance clothianidin or imidacloprid for use on Brassica napus against Phyllotreta spp. or Psylliodes spp. (notified under document C(2020) 458), OJ L 33/16.

[136] Commission Implementing Decision (EU) 2020/153 of 3 February 2020 prohibiting Lithuania to repeat granting authorisations under art. 53(1) of Regulation (EC) No 1107/2009 for the plant protection products containing the active substance thiamethoxam for use on spring rape against Phyllotreta spp. and/or Psylliodes spp. (notified under document C(2020) 464), OJ L 33/19.

[137] The REFIT programme aims to assess "the accomplishment of the objectives, the efficacy of the enforcement as well as the effectiveness of the pesticides legislation", as well as to "identify the problems of compliance and underline which factors hinder the achievement of the objectives of the legislation". See Report COM(2020) 208 final from the Commission to the European Parliament and the Council of 20 May 2020 on the Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides.

[138] *Ibidem*, at 101.

[139] PAN EUROPE/CLIENTEARTH/EUROPEAN BEEKEEPING CORDINATION/ROMAPIS, *Bee Emergency Call - How some Member States are threatening bees by allowing the use of prohibited pesticides and how the Commission does nothing to stop them*, 2017, https://www.clientearth.org/media/5pigvs34/2017-02-15-bee-emergency-call-coll-en.pdf (accessed 15 June 2022), at 4.

The assessments completed by EFSA concluded that 17 emergency authorisations were justified, either because no alternative products or methods (chemical or non-chemical) were available, or because there was a risk that the pest could become resistant to available alternative products.[140] As outlined by the Court of Auditors, however, 43 of 73 notifications sent by Member States to the Commission in the years 2018 and 2019 did not include information on research activities conducted to find alternative methods.[141] Of the 30 providing information on alternatives, 11 referred merely to monitoring projects of the impact of neonics on bees.

From this overall backdrop, national governance of neonics has not lived up to the overarching tenets of the precautionary principle, by relying, instead, on a "business as usual" approach as it emerges from those applications (86%) applied for with industry involvement.[142] Indeed, the EU Parliament had explicitly called on the Commission to guarantee a minimum standard of notifications on derogations, including the need for Member States to provide complete and detailed explanations, and to make those notifications public.[143] In addition, the Strasburg-based institution had considered it important for EFSA to investigate the effect of substitution, as well as the availability of non-chemical methods.[144]

These shortcomings have also been put under strong criticism by some environmental NGOs and beekeepers, who claimed the Authority's scientific reports for being of "poor quality." In a letter[145] sent to the EU Commission and EFSA in November 2021, Pesticide Action Network Europe lamented, in particular, the unsuitability of the protocol used by EFSA to assess derogations based on art. 53, as well as the Authority's disregard of all non-chemical methods of pest control, independently of their (claimed) feasibility, effectiveness and rate of application.

The NGO, moreover, blamed EFSA for have based its work on information received from Member States, whose notifications focused on the information received from the agricultural sector. These complaints followed an action[146] that the same association, together with Nature et Progrès and a beekeeper, brought to the Belgian Council of State against six emergency authorisations granted by Belgium in 2019 to allow for the marketing and treatment of seeds with thiamethoxam and clothianidin. According to the NGOs, the scope of art. 53 of PPP Regulation does not include the placing on

[140] See the reports at: EFSA, *Neonicotinoids: EFSA assesses emergency uses on sugar beet in 2020/21*, 18 November 2021, https://www.efsa.europa.eu/en/news/neonicotinoids-efsa-assesses-emergency-uses-sugar-beet-202021 (accessed 07 June 2022).

[141] EU Court of Auditors, *Protection of Wild Pollinators in the EU – Commission initiatives have not borne fruit*, Special Report No 15/2020, 60.

[142] See PAN Europe/ClientEarth/European Beekeeping Cordination/ROMAPIS, *Bee Emergency Call - How some Member States are threatening bees by allowing the use of prohibited pesticides and how the Commission does nothing to stop them*, cit., at 4.

[143] European Parliament Resolution of 18 December 2019 on the EU Pollinators Initiative (2019/2803(RSP), P9_TA(2019)0104, 22-23.

[144] *Ibidem*, 22-23.

[145] See PAN-Europe, *Concerning: Bees at risk: abuses on derogations for neonicotinoids*, 29 November 2021, https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/Letters/EFSA_assessments.pdf (accessed 07 June 2022).

[146] Case C-162/21, Request for a preliminary ruling from the Conseil d'État (Belgium) lodged on 11 March 2021 – Pesticide Action Network Europe ASBL, Nature et Progrès Belgique ASBL, TN v État belge, represented by the Ministre des Classes moyennes, des Indépendants, des P.M.E., de l'Agriculture et de l'Intégration sociale, chargé des Grandes villes, OJ 2021/C 242/08.

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the market or sowing in the field of seeds treated with the substances in question.[147] A further plea concerned the notion of "emergency," as the applicants affirmed that derogating authorisations were issued as a preventive measure, with a view to fulfilling an economic profitability imperative, thus not complying with the conditions set by art. 53.[148]

Against these arguments, which highlighted also the risks posed by neonics to certain animals other than the targeted pests,[149] the Belgian State contested both the relevance of the studies presented and the reasons put forward for prohibiting the use of those chemicals.[150] Beet industry representatives, furthermore, claimed that the annulment of the contested measures would cause a significant loss of profitability for sugar beet factories and could, in the long term, result in the closure of (a part of) the sugar industry in Belgium.[151]

The Court is thus called to interpret the meaning of the notions "emergency", "special circumstances" and "any other reasonable means." These dilemmas will require to scrutinize several points. First, whether derogations can be granted for substances that have previously been approved, but later were explicitly banned after an evaluation of their potential harm. Second, whether the use of pesticide coated seeds in outdoor crops can be considered as an emergency measure (given that the use of such seeds implies that the prospective danger is not unexpected). Third, whether art. 53 of Reg. 1107/2009 covers situations in which the occurrence of a danger is, on the one hand, not certain but only plausible and, on the other hand, foreseeable, common and even cyclical. Fourth, whether art. 53 is to be interpreted as giving equal importance, in the light of recital 8 of PPP Regulation, to ensuring a high level of protection of human and animal health and the environment, together with safeguarding the competitiveness of EU agriculture.

The Court's decision will thus have to focus on the scientific evidence and the scope lingering behind the notion of "emergency" in the context of derogating from the pesticide legislation. In so doing, the recourse to the precautionary principle will require much more than a mere ponderation of harm to non-financially compensable interests (i.e. the cumulative risks to bees and the environment) against harm to financially compensable interests (namely, those of the beet industry). Framing emergency authorisations in contexts of uncertainty, scientific ignorance and scientific pluralism, in fact, asks that "other legitimate factors" are given the due attention they deserve.

This is because, under a "socially acceptable risk approach" to risk governance, values at stake and the pervasiveness of any potential adverse effects need to be taken into proper consideration when defining the level of protection pursued. As scholarly work highlighted, "allowing emergency derogation when the harm to be prevented is regular and foreseeable, and alternative means of preventing the harm are available, undermines both the ban and the intent of the pesticide regulation".[152]

[147] *Ibidem*, 26.
[148] *Ibidem*, 47.
[149] *Ibidem*, 5.
[150] According to the Belgian State, indeed, conditions of use of the products in question "ensure that they do not pose an unacceptable risk to honey bees and require, in general, that the cultivation of bee-attractive plants be avoided for five years following the harvest resulting from the sowing of the treated seeds" (*Ibidem*, 7).
[151] *Ibidem*, 9.
[152] Y. EPSTEIN, G. CHAPRON, F. VERHEGGEN, *EU Court to Rule on Banned Pesticide Use*, in *Science*, 373, 6552, 2021, 290.

Arguably, a help for the Court's expected decision might come, *inter alia*, from the updated guidance released in January 2021 by the Commission to better explain the process for application of emergency measures.[153] The non-binding document is, indeed, much more detailed in providing guidelines on the procedure and on the information required both in applications and to justify an application. It clarifies, for instance, that derogations can be granted for "a plant protection product containing a substance that is not approved in the EU, never approved since an application for approval was never submitted, no longer approved or for which an evaluation for approval is ongoing".[154] In specifying so, and in requiring the use of the Plant Protection Products Application Management System[155] (PPPAMS) to manage the workflow of emergency applications and authorisations, the guidance provides further clarification on the granting of emergency authorisation for the treatment of seeds and the sale and use of treated seeds, while furthering consistent data collection and practices between Member States.

5. Regulatory science vis-à-vis transparency

Reflections presented so far called into question the relationship between risk assessment and risk management procedures in the pesticide field, as well as the criteria surrounding the application of emergency authorisations in the face of the impossible separation of facts from values. Certainly, the question on whether derogations in plant protection can be foreseeable, common or predictable – and to what extent they should – implies a rigorous attention to all degrees of scientific uncertainty, indeterminacy and ambiguity, in the pursuit of the level of protection pursued.[156]

The identification of the threshold of legally relevant adverse effects is never a matter of "pure" science, since both the precautionary principle and other legitimate factors do matter in "socially acceptable risk approaches." This brings a core question to the forefront: What normative implications arise for the governance of neonics from the overall picture depicted in the present analysis?

5.1. Neonicotinoids and risk assessment

Certainly, the CJEU's judgments will not have a big effect from a substantial stance. In the time since the cases were brought in 2013, in fact, the contested measures regarding the three active substances have been superseded by the 2018 Commission Implementing Regulations amending the conditions

[153] EUROPEAN COMMISSION, *Guidance on Emergency Situations according to art. 53 of Regulation (EC) No 1107/2009*, SANCO/10087/2013 rev. 1, 2021.

[154] *Ibidem*, at 6.

[155] On this tool, see EUROPEAN COMMISSION, *Procedure to apply for authorisation of a PPP*, https://ec.europa.eu/food/plants/pesticides/authorisation-plant-protection-products/ppp-auth_en (accessed 08 June 2022).

[156] A. PATTERSON, C. MCLEAN, *The Precautionary Principle at Work: The case of neonicotinoids and the health of bees*, in *Science and Public Policy*, 46, 3, 2019, 441-449, at 443.

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of approval of the active substances imidacloprid,[157] clothianidin[158] and thiamethoxam.[159] The novel rules banned all outdoor uses of the three substances, while permitting only the use in permanent greenhouses.[160] Yet, as our work has shown, both the Court's rulings and the issue on emergency authorisations offer fertile ground for the theoretical discussion about the role of risk regulation in the pesticide field. In this respect, two main avenues present themselves: one pertains to the risk assessment phase; the second deals with the principle of transparency.

As far as risk assessment is concerned, both the "socially acceptable risk approach" and the precautionary principle ask for three prominent elements to be embedded in it.

First, the adoption of a more holistic bee risk assessment accounting for the complexity of the environmental context in which bees live, namely: for the temporal and spatial dimensions of exposure and for the co-occurrence of multiple compounds that can interact among themselves and with other stressors.[161] Second, the need to tackle scientific misconduct by improving the robustness and reliability of the pesticide regulatory framework,[162] for instance through the review and amendment of out-of-date or biased guidance documents and methodologies, and through the integration of the most up-to date scientific practices[163] by the risk assessors.[164] Third, the need to take as far as possible into account, in the pesticide chemical risk assessment phase, the social-behavioural factors and the "applied behaviour science" input, with the purpose of better defining problems at the formulation stage.[165]

This innovative perspective is gradually emerging from the activities undertaken by EFSA over the past years as regards the assessment of neonics. Since 2013, in fact, the Authority has carried out an extensive data collection exercise and two consultations with pesticide experts in the EU Member States in

[157] Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid, OJ L 132/31.

[158] Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin, OJ L 132/35.

[159] Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam, OJ L 132/40.

[160] Consequently, the approval of these substances expired on 31 January 2019, 30 April 2019 and 1 December 2020, respectively.

[161] F. SGOLASTRA ET AL., *Bees and Pesticide Regulation: Lessons from the neonicotinoid experience*, in *Biological Conservation*, 241, 2020, 108356.

[162] Storck and others suggested, in this respect, that "pre-authorisation changes may include (i) the reduction of the time lag between the market introduction of a new pesticide and the awareness of risks, (ii) the commitment of one authority regulating both active substances and PPPs, (iii) the assignment of environmental risk assessment studies to anonymous accredited subcontractors, (iv) redefining which transformation products are considered 'relevant', and (v) a limitation of the rapidly evolving pesticide market" (V. STORCK, D.G. KARPOUZAS, F. MARTIN-LAURENT, *Towards a Better Pesticide Policy for the European Union*, in *Science of the Total Environment*, 57, 2017, 1027-1033).

[163] Such as the FAO Pesticide Registration Toolkit, which provides practical guidance on conducting risk assessments for pesticide registration or review of existing registrations [FAO, *Pesticide Registration Toolkit: Make better registration decisions*, https://www.fao.org/3/ca3814en/ca3814en.pdf (accessed 08 June 2022)].

[164] C. ROBINSON ET AL., *Achieving a High Level of Protection from Pesticides in Europe: Problems with the current risk assessment procedure and solutions*, in *European Journal of Risk Regulation*, 11, 2020, 450-480, at 479.

[165] M. CALLIERA, A. MARCHIS, G. SACCHETTINI, E. CAPRI, *Stakeholder Consultations and Opportunities for Integrating Socio-behavioural Factors into the Pesticide Risk Analysis Process*, in *Environmental Science and Pollution Research*, 23, 3, 2016, 2937-2947, at 2947.

order to updated its risk assessments of the three chemicals in question. In 2019, furthermore, the Commission mandated EFSA to review the 2013 guidance document for assessing the potential risk posed by PPPs to bees, in order to guarantee a full implementation of the scientific document in the authorisation process of active substances, as required by the PPP legislation. The mandate included several terms of references, spanning from taking into account the feedback from Member States and stakeholders, to providing a review on bee background mortality and a reviewed list of bee-attractive crops. In addition, reviews of the risk assessment methodologies (in light of novel scientific research and developments) and of the requirements for higher tier testing were requested to strengthen the environmental risk assessment process of PPPs.[166]

A first response came from the 2021 EFSA's scientific opinion,[167] which set out an integrated, holistic framework for assessing the combined effects of multiple stressors on honeybee, including, together with the cumulative and synergistic effects of pesticides, also issues related to the genetic variety of bees, pathogens, bee management practices and colony environment. Parallelly, alongside its policy started in 2014 with the purpose of becoming an Open Science organization,[168] driven by the values of openness and transparency, EFSA supported the EU Bee Partnership (EUBP) in the development of an online data platform.[169] The objective is to protect bee and pollinator health through the gathering and sharing of all relevant knowledge and data on bee health and beekeeping.

All these initiatives are significant for their potential role in democratizing regulatory science, while engaging stakeholders and lay people in scientific deliberations and decisions.[170] This would be in accordance with those provisions of General Food Law (that is Reg. 178/2002) calling on the Authority to "be an organisation open to contacts with consumers and other interested groups",[171] and to work "with a high level of transparency",[172] so as to "enable Member States to become more closely involved in scientific procedures".[173]

At the same time, EFSA's activities seem to perfectly run hand in hand with the 2019 legal reform that the EU adopted as a ground-breaking legal tool to enhance transparency and sustainability of risk assessment in the food chain. This leads to the second aspect mentioned above, that is the increasingly role that the principle of transparency is acquiring within the "socially acceptable risk approach" to the pesticide field.

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[166] The finalisation of the guidance is scheduled by the end of September 2022. See EFSA, *Outline of the revision of the Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) (EFSA 2013)*, 2021, https://www.efsa.europa.eu/sites/default/files/2021-11/outline-bee-guidance-revision-2021.pdf (accessed 09 June 2022).

[167] EFSA, *A Systems-based Approach to the Environmental Risk Assessment of Multiple Stressors in Honey Bees*, in *EFSA Journal*, 19, 05, 2021, 6607.

[168] EFSA, *Discussion Paper - Transformation to an "Open EFSA"*, 2014, https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/openefsadiscussionpaper14.pdf (accessed 09 June 2022).

[169] The platform is available at: EU BEE PARTNERSHIP, *Prototype Platform on Bee Health*, https://bee-ppp.eu/ (accessed 10 June 2022).

[170] L. LEONE, *Towards New "Digital Insights". The Value of Open Data for Food Information in Europe*, in *Rivista di diritto alimentare*, 3, 2017, 4-19, at 11.

[171] Recital 56 of Regulation 178/2022.

[172] Art. 38(1) of Regulation 178/2202.

[173] Recital 51 of Regulation 178/2202.

5.2. Transparency and confidentiality in the PPP Regulation

Regulation (EU) 2019/1381[174] was adopted in response to the *EU Citizen Initiative to ban glyphosate*,[175] in order to increase the transparency of authorisation processes covering the agri-food chain and with the aim of rethinking risk assessment for greater openness and sustainability in the food domain. It reformed the legal cornerstone of the EU food sector (namely, Reg. 178/2002), by enhancing the transparency rules about the scientific studies underpinning risk assessment, increasing the guarantees of reliability and independence of such studies, together with improving EFSA's governance and developing a more effective risk communication.[176] The analysis of these novel rules extends the bounds of this contribution.

Worthy to be outlined here is that, despite recasting the debate on the analytical separation of risk assessment from risk management, the renewed normative picture aims, in brief, at addressing the three prominent themes linked to the principle of transparency, namely: clarity of the rules and data used in decision-making; public access to all kind of information; stakeholders' and public consultation and engagement in decision-making.[177] The hallmark of the new legislative design lies, in fact, on the need to combine the risk assessment process – which starts with the scientific studies submitted by companies and ends with the approval (or the denial) of the product in question by the authorities – with the widest public engagement and scientific expertise. To this end, it provides EFSA with a toolkit of transparency rules (which enlarge the public access to information, while addressing the confidentiality of data) affecting several areas, that of PPPs included.

This is because, as the present analysis has shown, since the regime established by the PPP Regulation is characterised by the inter-play of different actors working together on highly technical (in both scientific and legal terms) matters at different levels of governance, a balanced coexistence between the public interest in transparency and industrial interests in confidentiality is difficult to be ensured.[178] Hence, several rules related to the transparency of active substance authorisation underwent some changes in order to meet the broader general goals pursued by Reg. 2019/1381.

As regards the approval procedure of pesticides, in particular, art. 7 of PPP Regulation has been amended by requiring the application be submitted "in accordance with standard data formats, where

[174] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231/1. For a deep analysis of the novelties introduced by this legislation, see *Rivista di diritto alimentare*, Special Issue 3, 2019 http://www.rivistadirittoalimentare.it/index.php (accessed 11 June 2022).

[175] See EUROPEAN UNION, *Ban glyphosate and protect people and the environment from toxic pesticides*, https://europa.eu/citizens-initiative/ban-glyphosate-and-protect-people-and-environment-toxic-pesticides_en (accessed 11 June 2022).

[176] The reform is discussed by L. LEONE, *EFSA under Revision: Transparency and sustainability in the food chain*, in *Yearbook of European Law*, cit.

[177] For a broad overview on transparency in EU law, see H.C.H. HOFMANN, *General Principles of EU Law and EU Administrative Law*, in C. BARNARD, S. PEERS (eds.), *European Union Law*, Oxford, 2014, 207 *et seq*.

[178] A critical analysis on the different levels of transparency existing within the regime established by the PPP Regulation is carried out by O. HAMLYN, *Shadow Zones: Transparency and pesticides regulation in the European Union*, in *Cambridge Yearbook of European Legal Studies*, 21, 2019, 243-272.

they exist pursuant to art. 39f of Reg. 178/2002". This provision facilitates public scrutiny, by making the accessibility of documents to the public uniform, while combining innovation and products' safety through the participatory engagement of all economic actors in the approval procedure.

Data formats present, indeed, three peculiar aspects, in that they shall: "not be based on proprietary standards; ensure interoperability with existing data submission approaches to the extent possible; be user-friendly and adapted for the use by small and medium-sized enterprises".[179] On the private autonomy side, this new approach is expected to lead companies to calibrate their R&D activities with the increased civic interests in environmental and safety protection, and in the logic of enhancing social responsibility profiles.[180]

In addition, Reg. 2019/1381 gives the applicant, when submitting the application, the possibility to request to treat certain information (including certain parts of the dossier) as confidential. Member States shall assess the request and, after consultation with the Authority, the rapporteur Member States shall decide what information is to be treated as confidential.[181] This rule needs thus to be read in combination with the broader public interest provision *ex* art. 39(2)(a) and (d) of GFL, according to which data relating to the manufacturing process and quantitative substance composition cannot be kept confidential if relevant to assessing safety.

A further novel rule concerns transparency of the dossiers. In this respect, the Authority is asked to make the applicant's dossier available to the public, without delay. Exceptions are admitted in relation to any information to which the rapporteur Member State has granted confidential treatment.[182]

The third issue reformed by Reg. 2019/1381 deals, instead, with public access to the information for renewal. In this respect, art. 7 of the novel Regulation states that an applicant may submit a request to treat certain parts of the information on the complete composition of a PPP submitted as confidential, accompanied by verifiable justification. Confidential treatment may be granted, however, only "where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree". Where Member States assess confidentiality requests, they, the Commission and the Authority shall take the necessary measures so that information for which confidential treatment has been granted is not made public.

Nonetheless, the disclosure is permitted when urgent action is essential to protect human health, animal health or the environment, such as in emergency situations. The disclosure is, instead, compulsory with regard to "information which forms part of the conclusions of the scientific outputs delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment". Hence, the need to apply the principle of the high level of protection of public health and the environment in the EU makes the public interest in safety ahead the rights of applicants, so as to guarantee an innovative proactive approach to transparency of regulatory science.

[179] Art. 39f of Regulation 178/2002, as amended by Regulation 2019/1381.

[180] I. CANFORA, *Innovazione tecnologica e protezione delle informazioni sensibili. L'evoluzione delle regole europee sulla trasparenza nella sicurezza alimentare*, in S. CARMIGNANI, N. LUCIFERO (a cura di), *Le regole del mercato agroalimentare sicurezza e concorrenza. Diritti nazionali, regole europee e convenzioni internazionali su agricoltura, alimentazione, ambiente. Atti del convegno di Firenze del 21 e 22 novembre 2019 in onore della Prof.ssa Eva Rook Basile*, Napoli, 2020, 139-154, at 150.

[181] Art. 7(3) of Regulation 1107/2009, as amended by Regulation 2019/1381.

[182] Art. 10 of Regulation 1107/2009, as amended by Regulation 2019/1381.

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This set of rules shall be applied without prejudice to EU legislation dealing with public access to information.[183] Likewise, it needs to be linked with the more general provisions laid down by Reg. 2019/1381 on transparency, confidentiality and communication.[184] In this respect, for instance, studies commissioned to private laboratories in the light of an authorisation under EU food law need to be registered,[185] while EFSA is empowered to commission further scientific studies for the performance of its mission.[186] A similar task is recognised to the Commission in the risk management phase, with the possibility to request verification studies – albeit within the limits of proportionality linked to cases of serious controversies or conflicting scientific results. This power of discretion, as pinpointed by scholarly work, can potentially "represent a bridge between the scientific and the societal aspects of pesticides authorisation and, additionally, to mitigate, in exceptional cases, the prevalence of industry-originated studies".[187]

All things considered, the reformed provisions of PPP Regulation, as embedded in Reg. 2019/1381, bring some innovations to the legal architecture on pesticides, by partially reshaping the modalities through which to guarantee transparency in the production of expert evidence in risk assessment and foster public involvement for the benefit of science and society. In this vein, they seem to implement the core objectives of "proactive transparency," that correlate with fostering an open and regular dialogue with civil society and coherence of the Union's actions,[188] while legitimising public functions in the pursuit of public interest. This advanced model of risk assessment is in fact meant as a pioneering locus of data- and value-sharing, that is suitable to balance environmental and health protection with private commercial interests connected to usage and disclosure of commercially sensitive data (formula, production methods, etc.), while coping with scientific uncertainty and indeterminacy through diversification of actionable knowledges and the widest public access to information.[189]

In this process of rethinking of the idea of knowledge production, science – understood as the knowledge describing nature beyond common perception, according to controlled observation, empirical confirmation and interpretive models of phenomena – ends up constituting only one part of the knowledge to be acquired and implemented in regulatory choices.

This last consideration prompts our discussion to some final reflections on the matter.

[183] Specifically, Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC, OJ L 41/26; Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145/43; Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, OJ L 264/13.

[184] Specifically, arts 39 to 39e of Regulation 178/2002, as amended by Regulation 2019/1381.

[185] Regulation 1381/2019, art. 1(4) inserting art. 32b into Regulation 178/2002.

[186] Regulation 1381/2019, art. 1(4) inserting art. 32c into Regulation 178/2002.

[187] M. MORVILLO, *Glyphosate Effect: Has the glyphosate controversy affected the EU's regulatory epistemology?*, in *European Journal of Risk Regulation*, 11, 2020, 422-435, at 431.

[188] See Treaty on European Union (TEU), art. 11.

[189] L. DRIVDAL, J.P. DER SLUIJS, *Pollinator Conservation Requires a Stronger and Broader Application of the Precautionary Principle*, in *Current Opinion in Insect Science*, 46, 2021, 95-105, at 103.

6. Final remarks

In 2020, with Implementing Regulation (EU) 2020/23, the Commission did not renew the approval of the active substance thiacloprid,[190] following EFSA's conclusion[191] published on the outcome of the peer review of risk assessment. This piece of legislation is the last – but not least – decision concerning the issue at the centre of the investigation presented here: the recourse to the regulatory science of neonics, its meaning and use in risk assessments and its implementation in risk management measures. The examination has been developed around these traits, by trying to question and elucidate the core factors at the stake when deciding in contexts of manifold uncertainties. In the judgments of neonics and bee health, the CJEU embraced the precautionary principle to dismiss in their entirety the actions brought by Bayer and Syngenta as regards the restrictions introduced in Europe against the insecticides clothianidin, thiamethoxam and imidacloprid, because of the risks these substances pose to bees. Against criticism from the appellants of many of the scientific studies showing adverse effects on bees and other insects resulting from neonics, the Court confirmed the Commission's entitlement to review the approval of the chemicals in question. According to the CJEU, the Commission fully demonstrated that, in the view of the normative framework referring to the substances contested and bees health, EFSA's findings warranted the conclusion that the three neonics no longer satisfied the approval criteria.

On the other hand, many EU Member States supported the case put forward by agrochemical industries in their denials that there may be a problem with neonicotinoid products. In its 2018 mandate, indeed, EFSA concluded that around 25 per cent of the evaluated authorisations were not scientifically justified. The frequent use of emergency authorisations represents, thus, a signal of a dysfunctional PPP authorisation procedure,[192] while the "lack of scientific certainty" about neonics provided a rationale and justification for administrative discretion at the national level.[193]

These divergent, and often conflicting, perspectives at play unveil how different official experts adopt their own preferred risk assessment policy assumptions, asking and answering dissimilar sets of

[190] Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 concerning the non-renewal of the approval of the active substance thiacloprid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 8/8.

[191] EFSA, *Peer Review of the Pesticide Risk Assessment of the Active Substance Thiacloprid*, in *EFSA Journal*, 17(02), 2019, 5595.

[192] Commission Staff Working Document SWD/2020/87 final of 20 May 2020 accompanying the document Report from the Commission to the European Parliament and the Council – Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, at 33.

[193] This situation led several NGOs to call on the Commission to properly implement the provisions of the PPP Regulation. Specifically, they requested to: systematically scrutinise the notifications submitted by Member States for every emergency authorisation that is granted by a Member State more than once; propose to withdraw the relevant emergency authorisation that do not comply with the conditions of Article 53; require applicants to prove their compliance with the principles of Integrated Pest Management (IPM) before an emergency authorisation is granted; clarify that emergency authorisation requests from industry must be rejected by Member States (PAN EUROPE/CLIENTEARTH/EUROPEAN BEEKEEPING CORDINATION/ROMAPIS, *Bee Emergency Call - How some Member States are threatening bees by allowing the use of prohibited pesticides and how the Commission does nothing to stop them*, cit., at 4-5).

questions through mathematical models, analytical chemistry and applied biology. This leads to gathering, reviewing and interpreting differing bodies of evidence, and often judging those bodies of evidence against diverse criteria.[194]

The couplet of risk and radical uncertainty in decision-making is still far from being definitely acknowledged by political responsibility. Disputes on knowledge and use of pesticides, and of neonics in particular, continue to light the public debate worldwide, according to each country's laws and science policy models.[195] Scientific reasons correlate to gaps and complexity that surround the three fields of the knowledge involved in the process of approval of a PPP, that is agronomical performance, human toxicology and environmental toxicology. [196]

[194] E. MILLSTONE, *Science and Decision-making. Can We both Distinguish and Reconcile Science and Politics?*, in M.B.A. VAN ASSELT, M. EVERSON, E. VOS (eds), *Trade, Health and the Environment. The European Union Put to the Test* , cit., 47-73, at 68.

[195] In the USA, for instance, the Environmental Protection Agency (EPA) released in 2020 proposed interim decisions [see EPA, *Proposed Interim Registration Review Decision for Neonicotinoids*, https://www.epa.gov/pollinator-protection/proposed-interim-registration-review-decision-neonicotinoids (accessed 11 June 2022)] for the neonics acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam. They are for the adoption of management measures that can help keep pesticides on the intended target and reduce the amount used on crops associated with potential ecological risks. The suggested measures range from the use of additional personal protective equipment to address potential occupational risks, to restrictions on when pesticides can be applied to blooming crops (in order to limit exposure to bees), up to the adoption of proper labelling for homeowners. In the meantime, a lawsuit is pending before the US District Court for the Northern District of California with refence to the declaratory and equitable relief challenging the failure of EPA to answer the 2017 petition filed by the Center for Food Safety and the Pesticide Action Network North America [THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, Case No. 21-9640, *Center for Food Safety and Pesticide Action Network North America v. United States Environmental Protection Agency and Michael Regan, Administrator, United States Environmental Protection Agency*, https://fingfx.thomsonreuters.com/gfx/legaldocs/jnvwearnbvw/LawsuitCFS.pdf (accessed 11 June 2022)]. In the 43 pages scientific and legal document, the Plaintiffs called on EPA to close a regulatory loophole that allows seeds coated with neonics to evade the registration and labelling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In Canada, instead, the scientific authority Health Canada began in 2012 re-evaluations of the neonics clothianidin, imidacloprid and thiamethoxam, to address growing concerns around bee health. After extensive research, review and public consultations, Health Canada completed its re-evaluations and issued proposed decisions in 2017 and 2018 for the three chemicals, cancelling some uses of them, while changing other conditions of use (such as restricting the timing of application). All documents are available at: GOVERNMENT OF CANADA, *Health Canada releases final pollinator re-evaluation decisions for neonicotinoid pesticides*, 11 April 2019, https://www.canada.ca/en/health-canada/news/2019/04/some-cancellations-and-new-restrictions-to-protect-bees-and-other-pollinators.html (accessed 11 June 2022).

[196] The glyphosate saga is a perfect example in this respect. In the EU, a further case showing the conflicts surrounding the use of pesticides comes from the lawsuit brought on February 2016 by PesticideActionNetwork Europe (PAN-Europe) before the Ombudsman [EUROPEAN OMBUDSMAN, *Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides)*, https://www.ombudsman.europa.eu/it/decision/en/64069 (accessed 12 June 2022)]. PAN-Europe contested to the Commission: the approval of potentially unsafe PPPs, the disregard of data gaps in the risk assessment, the failure to adopt appropriate risk mitigation measures and to control Member States' compliance with those measures. By agreeing with PAN-Europe, the Ombudsman made a set of recommendations to the Commission, in conformity with EU pesticide law. For an analysis of the Ombudsman's decision, see A. DE VRIES-STOTIJN, *The European Ombudsman Urges the European Commission to Abandon its Unlawful Pesticide Approval Practice*, in *European Journal of Risk Regulation*, 2, 2016, 413-415.

While some policy reports condemn chemicals for their catastrophic impacts on the environment and human health,[197] and scientific studies call the idea that chemical treatments could be cut without affecting farm profits,[198] big industry considers pesticides, if not a panacea, certainly important tools to fight pests and diseases.[199] True is that the neonics disputes perfectly fit in the conflicts and developments that have depicted EU agri-food law since its advent on the institutional scene. The role played by regulatory science in the law- and policy-making at the EU level, the complexity and presumed objectivity ascribed to expert-based decisions, and the contested use of the precautionary principle in risk analysis, all lie at the heart of the "neonics saga".

In recent years, several resolutions from the EU Parliament called for the full implementation of the PPP legislations, the improvement of the Union's authorisation procedure for pesticides, the transition towards low-risk pesticides, as well as for the reduction of pesticide dependency and the development of better risk indicators.[200] In stressing the need to apply the precautionary principle to protect domestic and wild pollinators,[201] the Parliament asked the Commission to extend the ban imposed on imidacloprid, clothianidin and thiamethoxam to all neonicotinoid-based pesticides.[202] Interestingly for our analysis, is the request "to include scientific and technological developments for new approach methods in regulatory science, with a view to improving the predictivity of regulatory testing and replacing the use of animals".[203]

Certainly, improvements made by the Commission on the relevant guidance on emergency authorisations will surely prove useful to clarify the criteria when derogations can be granted. Probably, though, the suggestion from the REFIT about an Implementing Regulation setting out such criteria in a legally binding way should be seriously taken into account for the years to come.[204]

The positive trust-enhancing effect of the precautionary principle may play its crucial role in this respect. The CJEU's rulings have marked the operational criteria of the principle, ascribing to the institutions the adoption of protective measures in situations of uncertainty as to the existence or extent of risks – including risks to the environment – without having to wait until the reality and seriousness of those risks become fully apparent. The next step should be that of implementing the precautionary principle in risk assessment so as to get the overall process of risk governance more sensitive to, and

[197] See UNITED NATIONS, *Special Rapporteur on the Right to Food*, https://www.ohchr.org/en/special-procedures/sr-food (accessed 28 June 2022).

[198] M. LECHENET, F. DESSAINT, G. PY, D. MAKOWSKI, N. MUNIER-JOLAIN, *Reducing Pesticide Use while Preserving Crop Productivity and Profitability on Arable Farms*, in *Nature Plants*, 3, 2107, 17008.

[199] M. BRUINS, *The Impact of the Ban on Neonicotinoids*, 7 December 2017, https://european-seed.com/2017/12/impact-ban-neonicotinoids/ (accessed 28 June 2022).

[200] See European Parliament Resolution of 16 January 2019 on the Union's authorisation procedure for pesticides, (2018/2153(INI)), P8_TA(2019)0023; European Parliament Resolution of 12 February 2019 on the implementation of Directive 2009/128/EC on the sustainable use of pesticides, (2017/2284(INI)), P8_TA(2019)0082; European Parliament Resolution of 10 July 2020 on the Chemicals Strategy for Sustainability, (2020/2531(RSP)), P9_TA(2020)0201, 85.

[201] European Parliament Resolution of 18 December 2019 on the EU Pollinators Initiative, cit., 5.

[202] *Ibidem*, 21.

[203] European Parliament Resolution of 16 January 2019 on the Union's authorisation procedure for pesticides, cit., 30.

[204] Report COM(2020) 208 final, cit., 2.3.

narrowly focused on, states of knowledge characterised by uncertainties and/or ignorance and/or ambiguity and/or gaps.[205]

So defined, the politicized nature of precaution may have its room of manoeuvre in acknowledging epistemological dissonance, while reconciling Member States' administrative discretion with EU PPP policy. This would be fitting within the broader context of the European Green Deal,[206] that aims at shifting to a fair, healthy and environmentally-friendly agri-food system. At the same time, it would be consistent with the specific goals of reducing the use and risk of chemical pesticides (and of more hazardous pesticides) by 2030, as strongly pursued by the Common Agricultural Policy (CAP) 2023-2027,[207] the Farm-to-Fork strategy,[208] the Biodiversity Strategy,[209] the EU Pollinators Initiative[210] and the EU Chemicals Strategy for sustainability.[211]

Meanwhile, weaknesses of the pesticide legislations are the reasons why different influential actors[212] on the institutional stage suggested opting – albeit with subtle different proposals – for a centralized PPP authorisation process, taking experience from other regulatory areas (such as that of novel foods).[213] A uniform assessment of both active substances and PPPs at the EU level, they argued, would improve transparency and monitoring of the entire process, while simplifying implementation of Reg. 2019/1381.

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[205] For thoughtful reflections on this aspect, see N.T. HOLM, M. DREYER (eds), *Precaution for Responsible Innovation - Guidance on the application of the precautionary principle in the EU*, RECIPES project, 2022, https://recipes-project.eu/sites/default/files/2022-01/RECIPES%20D3.2%20Report%20on%20Tools%20Guidelines%20and%20Recommendations.pdf (accessed 20 June 2022).

[206] Communication COM/2019/640 final from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions of 11 December 2019 on The European Green Deal.

[207] See EUROPEAN COMMISSION, *The New Common Agricultural Policy: 2023-27*, <https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/new-cap-2023-27_en> (accessed 12 June 2022).

[208] Communication COM/2020/381 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee Of The Regions of 20 May 2020 on A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system.

[209] Communication COM(2020) 380 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 20 May 2020 on EU Biodiversity Strategy for 2030 - Bringing nature back into our lives.

[210] See COM(2018) 395 final, cit.

[211] Communication COM/2020/667 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 14 October 2020 on the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment.

[212] SAM (SCIENTIFIC ADVICE MECHANISM), *EU Authorisation Processes of Plant Protection Products from a Scientific Point of View*, Scientific Opinion No 5, Luxembourg, 2018; SAPEA (SCIENCE ADVICE FOR POLICY BY EUROPEAN ACADEMIES), *Improving Authorisation Processes for Plant Protection Products in Europe: A scientific perspective on the potential risks to human health*, Opinion No 5, Berlin, 2018; EUROPEAN PARLIAMENT, *Report on the Union's Authorisation Procedure for Pesticides*, (2018/2153(INI)), P8_TA(2019)0023.

[213] See 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 the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327/1.

Along a parallel binary, two proposals for a Regulation on the sustainable use of PPPs (SUD)[214] and a Regulation on statistics on agricultural input and output (SAIO)[215] are under discussion at the institutional level. The former aims to reduce the risks and impacts of pesticide use on human health and the environment, as well as to promote the use of integrated pest management (IPM) [216] and alternatives to chemical pesticides. The latter addresses the collection and publication of annual pesticide use data, with the purpose of prescribing mandatory annual data collection in a harmonized electronic format at a meaningful level of detail.[217]

Despite criticisms that some NGOs highlighted on the legal texts under negotiation,[218] both these reforms confirm the institutional willingness to guarantee a full implementation of the principles of transparency and sustainability in the PPPs field. The new "proactive transparency" envisaged for food risk assessment, which promotes more democratic mechanisms of public accountability, is surely a promising change in this direction.

[214] Proposal COM(2022) 305 final from the Commission of 22 June 2022 for a Regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115.

[215] Proposal COM(2021) 37 from the Commission of 2 February 2021 for a Regulation of the European Parliament and of the Council on statistics on agricultural input and output and repealing Regulations (EC) No 1165/2008, (EC) No 543/2009, (EC) No 1185/2009 and Council Directive 96/16/EC.

[216] The impact of the restrictions of neonics on pest management practices has been addressed by J. KATHAGE ET AL., *The Impact of Restrictions on Neonicotinoid and Fipronil Insecticides on Pest Management in Maize, Oilseed Rape and Sunflower in Eight European Union Regions*, in *Pest Management Science*, 74, 2018, 88-99.

[217] See EUROPEAN PARLIAMENT, *Legislative Train Schedule*, https://www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-saio#:~:text=On%202%20February%202021%2C%20the,its%20collection%20and%20industrial%20processing (accessed 12 June 2022).

[218] See PAN EUROPE, *EU Commission draft Sustainable Use of Pesticides Regulation undermines the objectives of the European Green Deal*, Press Release, 4 February 2022, https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/press-releases/PR%20with%20LIFE%20logo/EU%20Commission%20draft%20Sustainable%20Use%20of%20Pesticides%20Regulation%20undermines%20the%20objectives%20of%20the%20European%20Green%20Deal.pdf (accessed 28 June 2022); CLIENTEARTH/FRIENDS OF THE EARTH AUSTRIA/GLOBAL 2000/PAN EUROPE, *Evaluation of the outcome of the trilogue held on 2 June on the reform of pesticides statistics*, 6 June 2022, https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/press-releases/Analysis%20Outcome%20Trilogue%20SAIO%2006-06-22.pdf (accessed 28 June 2022).