Balancing Public Health and Environmental Protection and Economic Stakes? *Bayer CropScience* and the Court's Defence of the EU Socially Acceptable Risk Approach

Case C-499/18 P, *Bayer CropScience and Bayer* v. *Commission*, Judgment of the Court of Justice (First Chamber) of 6 May 2021, EU:C:2021:367.

I. Introduction

The COVID-19 pandemic has shed further light on the inherent fragility of technical-scientific knowledge and the evolutionary nature of the scientific enterprise. Science has a crucial role to play in the governance of uncertain risks to public health and the environment: however, it is no silver bullet. More than any other occurrences in the past years, the pandemic has reminded us that science is not infallible; nor should we assume that technical-scientific experts will always provide us with a single "correct" answer.

Different regulatory responses in the field of risk governance reflect the different extent to which regulators take persisting uncertainty and scientific complexity into account, and the different balance that they strike between different interests at stake. The determination of the legally relevant threshold of adverse effects is never a matter of "pure" science.[1] Rather, this determination results from three factors. The first factor is adherence to more or less prudential approaches to risk assessment.[2] This is a matter of risk assessment policy, which impacts the *evidence base* that regulators draw upon. The second factor is the extent to which regulators adhere to "sound science", i.e. conclusive scientific proof of the existence of a hazard and pathway by which a risk will materialise,[3] or focus on scientific insufficiency and different forms of uncertainty. This aspect concerns the *inferences* that regulators draw from the available scientific evidence. The third factor is the *level of protection* pursued; the extent to which regulators prioritise the economic cost-benefit effectiveness of risk regulation, as opposed to pursuing enhanced public health and environmental protection and considering other legitimate factors, comes into play.

Disagreements surrounding these three elements lie at the heart of all challenges to EU risk regulation acts which are deemed too restrictive. Disagreements surrounding the approach followed at the risk assessment stage and any ensuing scientific evaluations find expression in complaints on alleged manifest errors of assessment and an alleged misapplication of the precautionary principle. Complaints on the level of protection set by regulators and on the risk management measures enacted to comply with it, by contrast, feed into complaints on proportionality. Challenges brought by market

[1] For a detailed overview of this point, see Leonelli, *Transnational Narratives and Regulation of GMO Risks* (Hart Publishing, forthcoming 2021). For the first argument that the determination that a risk exists "cannot be a matter of pure science", developed through a different analysis of the relationship between available scientific evidence and findings of risk, see V Walker, "The Myth of Science as a 'Neutral Arbiter' for Triggering Precautions" (2003) 26 *Boston College International and Comparative Law Review* 197, at 198 ff.

[2] The terminology of "prudential" risk assessment is borrowed from European Commission, COM(2000)1 Final, *Communication from the Commission on the Precautionary Principle*, at 12, section 5.

[3] For this definition of the notion of "sound science" and a detailed analysis of this regulatory category, see Leonelli, op. cit. *supra* note 1. A "hazard" is defined as a biological, chemical or physical agent with the potential to cause adverse effects. A "risk" is a function of the probability of occurrence of adverse effects and the severity of these effects, consequential to exposure to a hazard.

actors usually follow this blueprint. Overall, the action for annulment that Bayer CropScience brought in Case T-429/13 is no exception.[4]

In a different vein, in the appeal case under analysis, Bayer CropScience took a different perspective and pursued a different strategy; indeed, the legal questions at stake in Case C-499/18 P[5] are much more complex than would appear at first sight. What is distinctive about the appeal in *Bayer CropScience* is the appellant's shift to a new and more sophisticated *procedural* focus. By three of its grounds of appeal, the appellant put forward a specific interpretation of the procedural requirements for the initiation and the application of the Plant Protection Products ("PPP") Regulation's[6] review of approval procedure. This interpretation would have had specific substantive effects in the circumstances of this case, as the appellant sought to *directly* reframe the application of the precautionary principle in the specific procedural context of the review of approval of pesticidal active substances. By two of the remaining grounds of appeal, the appellant relied on procedural requirements that the EU Courts have identified in their case law; however, it applied them to an extent which would have *indirectly* broadened the EU institutions' duty of evidence production.

For this reason, this case centres on procedural questions which have profound substantive implications. Through its sophisticated strategy on appeal, Bayer CropScience sought to indirectly shift the focus from questions surrounding the *sufficient safety* of a product or process and the *acceptability* of uncertain risks, to scientific proof of the *unsafety* of a product or process and regulatory *cost-benefit effectiveness*.

The Court forcefully defended the very foundations of the EU *socially acceptable risk* approach to the governance of uncertain risks:[7] adherence to a prudential approach to risk assessment, the pursuit of a high level of public health and environmental protection,[8] the centrality of the precautionary principle,[9] and the possibility for EU risk managers to take any other legitimate factors ("OLFs")[10] at stake into consideration. The unprecedented number of references to "precautionary"

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[4] Case T-429/13, *Bayer CropScience* v. *Commission* EU:T:2018:280.

[5] Opinion of AG Kokott in Case C-499/18 P, *Bayer CropScience and Bayer* v. *Commission* EU:C:2020:735; and Judgment in Case C-499/18 P, *Bayer CropScience and Bayer* v. *Commission* EU:C:2021:367.

[6] Regulation (EC) 1107/2009/EC of the European Parliament and of the Council of 21 Oct. 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009 L 309/1 ("PPP Regulation").

[7] For use of the terminology of "socially acceptable risk" approaches and an analysis of EU risk regulation through the lens of this ideal regulatory model, see Leonelli, op. cit. *supra* note 1.

[8] For reference to the principle that a high level of public health and environmental protection shall be pursued in the Union, see first and foremost Articles 114(3) and 191(2) of the Treaty on the Functioning of the European Union ("TFEU"); see the Consolidated Version of the Treaty on the Functioning of the European Union, OJ 2012, C 326.

[9] The principle is enshrined in Article 191(2) TFEU. In legislative acts, see for instance Recital (8) and Articles 1(4) and 13(2) of the PPP Regulation, cited *supra* note 6; Recital (21) and Articles 6(3) and 7(1) of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, OJ 2002, L 31/1 ("General Food Law"); Recital (8) and Articles 1(1) and 4(1) of Directive 2001/18/EC of the European Parliament and of the Council of 12 Mar. 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, OJ 2001, L106/1 ("Deliberate Release Directive"); and Recitals (9) and (69) and Article 1(3) of Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 Dec. 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, O.J. 2006, L 396/1 ("REACH").

[10] In legislative acts, see for instance Recital (19) and Articles 3(12), 5(1), 6(3) and 7(2) of the GFL; Article 13(2) of the PPP Regulation; Recitals (9), (57), (58) and (62) and Article 31(7)(d) of the Deliberate Release Directive; and Recital (32) and Articles 4(1) and 7(1) of Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 Sept.

risk management, "precautionary" measures and "uncertainty" illustrates the crucial relevance of the precautionary principle in *Bayer CropScience*.[11] The fundamental role of OLFs, usually overlooked by the EU Courts, also shines through the Judgment. Further, the Court's findings as regards economic considerations and impact assessment are going to have far-reaching implications, safeguarding precautionary risk management in all areas of EU risk regulation.

The second section provides an overview of the factual and legal background of the Case. The third section turns to a concise analysis of the Opinion of the Advocate General ("AG") and the Judgment of the Court ("ECJ"). The following section then assesses the distinctiveness of the appellant's position, the divergencies between the Opinion and the Judgment, and the implications of this decision. It respectively takes into consideration the Court's findings as regards the relevance of economic factors and impact assessment (sub-section A), the Court's strong assertion of the precautionary principle (sub-section B), and its acknowledgment of the relevance of OLFs in EU risk regulation (sub-section C). Through this analysis, section IV emphasises how the decision in *Bayer CropScience* has significantly reinforced the socially acceptable risk rationale of the EU system of risk regulation.

The ECJ's explicit and vigorous assertion of the specificities of EU risk regulation makes *Bayer CropScience* one of the most important cases decided in this field in recent years. Further, the Court's defence of the EU socially acceptable risk approach has two implications, in the broader context of challenges against acts which are deemed too restrictive. First, it puts the accent on the exercise of *administrative discretion* in *precautionary risk management* and in the *evaluation of other legitimate factors*, as opposed to the mere recognition of the EU risk manager's broad discretion in cases involving complex technical-scientific assessments.[12] Secondly, and consequently, it strengthens the case for the application by the EU Courts of a procedural standard of scrutiny, as opposed to more intrusive quasi-substantive review.[13]

II. The Factual and Legal Background of the Appeal Case

The review of the conditions of approval of two neonicotinoids was at stake in *Bayer CropScience*. Neonicotinoids are a class of pesticidal active substances, i.e. the main active components in a plurality of different pesticidal formulations (pesticides or plant protection products, "PPPs").[14]

2003 on Genetically Modified Foods O.J. 2003, L 268/1 ("GM Food and Feed Regulation"). See *infra*, section IV, sub-sections A and C, for a more detailed overview of this regulatory notion.

[11] The term "precautionary" is used 36 times throughout the 27 pages of the Judgment, and the precautionary principle is employed as an interpretative tool throughout the examination of all the grounds of appeal.

[12] For a detailed analysis of the dichotomy of administrative discretion in precautionary risk management and (mere) administrative discretion in the case law of the EU Courts, see Leonelli, "Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why It Matters" (2020) 57 *CML Rev* 1773.

[13] In this respect, the Judgment also strengthens the case for an interpretation of the notion of a "manifest error of assessment" against the backdrop of the precautionary principle. For an in-depth analysis of the EU Courts' standard of review in cases involving risk regulation acts which are challenged for being too restrictive, including different interpretations of the notion of a "manifest error of assessment" under the procedural strand of review, see Leonelli, op. cit. *supra* note 12.

[14] Different PPPs are made up of one or more active substances, and a number of co-constituents; co-constituents may also be present in different quantities in different pesticidal formulations.

Pursuant to the PPP Regulation, active substances are approved and regulated at the EU level.[15] Upon receipt of an application for approval, an EU-wide procedure involving a Rapporteur Member State, the EFSA and the Commission ensues; the latter shall then submit its proposal for a Regulation to Comitology.[16] The first stage of this procedure involves an assessment of whether the active substance meets the Regulation's hazard-based cut-off criteria.[17] Where these are met, the relevant authorities will check compliance with the requirements of Article 4(2) and 4(3). These respectively provide that the residues of representative pesticidal formulations containing the active substance shall not have any harmful effects on human or animal health or any unacceptable effects on the environment, and that the representative pesticidal formulations shall not have any immediate or delayed harmful effects on human or animal health, directly or indirectly, or any unacceptable effects on plants, plant products and the environment.

Clothianidin and imidacloprid, both produced and marketed by the Bayer group, were originally approved at the EU level in 2006 and 2008. In 2010, in response to incidents causing losses of honeybee colonies, the Commission adopted additional restrictions for the use of these active substances.[18] Throughout 2011 and 2012, new scientific studies pointed to increasing evidence that exposure to neonicotinoids severely compromised the survival of colonies of honeybees and bumble-bees.[19] The Commission thus made a number of requests to the EFSA: these included a request to assess whether the doses employed in the new scientific studies were comparable to the doses to which bees were exposed in the EU, and a request to update the risk assessments for clothianidin and imidacloprid.[20]

The EFSA suggested that the concentrations of the substances tested in the new studies were probably higher than those normally found in crops throughout the EU; however, they could still be lower than the overall daily intake to which bees could be exposed in the EU. Overall, the EFSA laid emphasis on *data gaps* and on the *insufficiency* of the available data. It warned that "in the absence of certain additional data, estimates of intake had to be viewed with caution" and highlighted that "further research [had] to be carried out with different exposure levels or in other situations".[21] In its 2013 conclusions, the EFSA thus identified a high acute risk for honeybees from exposure to clothianidin and imidacloprid via dust drift, and a high acute risk for bees from exposure to residues of these active substances in nectar and pollen.[22] Importantly, the conclusions also underlined that considerable uncertainty persisted as to exposures in real life conditions and the existence of different pathways for the materialisation of risks to pollinating insects.[23]

The Commission had recourse to the review of approval procedure enshrined in Article 21 of the PPP Regulation. This Article provides that the Commission may review the approval of an active substance at any time. It shall take into account potential Member States' requests for a review of approval, in the light of new scientific and technical knowledge and monitoring data. When, in the

[15] PPPs, by contrast, are authorised and regulated at the Member State level, in the framework of the so-called "zonal system": see Recital (23) and Chapter III (Plant Protection Products) of the PPP Regulation, Articles 28 to 57 of the PPP Regulation, and Annex I to the Regulation.
[16] See Chapter II, Section 1 (Active Substances) of the PPP Regulation, Articles 4 to 24.
[17] See points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to the PPP Regulation. If these criteria are satisfied, compliance with the criteria of points 2 and 3 must be checked.
[18] See the reconstruction of the background to the case in the Opinion in Case C-499/18 P, *Bayer CropScience*, para 22.
[19] Case T-429/13, *Bayer CropScience*, paras 19 and 23.
[20] Opinion in Case C-499/18 P, *Bayer CropScience*, paras 17, 25 and 26.
[21] Case T-429/13, *Bayer CropScience*, para 24.
[22] Ibid, para 26. See also para 385.
[23] Ibid, para 27. See also paras 386 and 388.

light of new scientific and technical knowledge, it considers that there are indications that the substance no longer satisfies the approval criteria, it shall inform the Member States, the EFSA and the notifier of the active substance, setting a period for the latter to submit its comments; it may also ask the Member States and the EFSA for an opinion. Where the Commission concludes that the approval criteria are no longer satisfied, it shall withdraw or amend the approval of the active substance. The Commission found that the criteria of point 3.8.3 of Annex II to the PPP Regulation could no longer be deemed to be met: point 3.8.3 provides that an active substance shall only be approved if pesticidal formulations containing it will result in a *negligible* exposure of honeybees and *no unacceptable* acute or chronic effects on colony survival and development. In 2013, it thus adopted an Implementing Regulation amending the conditions of approval of clothianidin and imidacloprid and restricting the uses of these active substances.[24]

In Case T-429/13, Bayer CropScience challenged the 2013 Implementing Regulation. A "twin" challenge on the regulation of the insecticide fipronil was brought in Case T-584/13, *BASF*.[25] It is worth noting that more stringent risk management measures were enacted in 2018; PPPs containing clothianidin and imidacloprid are now only allowed for use in glass houses.[26] Although Bayer CropScience has not challenged the 2018 Regulation, in Case C-499/18 P the AG and the ECJ both found that the appellant still had an interest in bringing the proceedings under comment.[27] The following section provides a concise overview of the most relevant points in the AG's Opinion and the ECJ's Judgment.

III. The Opinion of AG Kokott and the Judgment of the Court

This section focuses on the three salient complaints of the appellant, which respectively targeted the conditions for the initiation of the review procedure and its application, the notion of "hypothetical risk" and the duty to conduct a risk assessment, and the absence of an impact assessment.[28] Sub-section A examines the Opinion of AG Kokott and the findings of the Judgment as regards the first ground of appeal, the first and fourth parts of the third ground of appeal, and the first part of the fourth ground of appeal. Sub-section B turns to an analysis of the second part of the fourth ground of appeal. Finally, sub-section C focuses on the sixth ground of appeal.

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[24] 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, O.J. 2013 L 139. For more details on the contents of the Implementing Regulation, see Case T-429/13, *Bayer CropScience*, para 29.

[25] Case T-584/13, *BASF Agro and Others* v. *Commission*, EU:T:2018:279.

[26] See Commission Implementing Regulation (EU) No 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions for approval of the active substance imidacloprid, O.J. 2018 L 132; and Commission Implementing Regulation (EU) No 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions for approval of the active substance clothianidin, O.J. 2018 L 132. The approval of clothianidin has now expired.

[27] Opinion in Case C-499/18 P, *Bayer CropScience*, paras 56 to 66; Judgment in Case C-499/18 P, *Bayer CropScience*, paras 36 et seq.

[28] The present analysis does not encompass the second ground of appeal, the second and the third part of the third ground of appeal, and the third part of the fourth ground of appeal; these were all swiftly rejected by the Court. However, it is still worth mentioning that the precautionary principle played a key role as an interpretive tool in the Court's examination.

A. The Grounds of Appeal on the PPP Regulation's Review Procedure

By its first ground of appeal, Bayer CropScience alleged that the General Court ("GC") had erred in law in finding that increasing scientific certainty surrounding the materialisation of risks for pollinating insects could be regarded as "new scientific and technical knowledge", within the meaning of Article 21 of the PPP Regulation.[29] On these grounds, it claimed that the preconditions for the opening of the review of approval procedure had not been met; indeed, the GC had found that "new scientific and technical knowledge" was the threshold for the application of Article 21. The GC noted that scientifically unsubstantiated suppositions, political considerations or reference to pre-existing data would not meet the requirement of "new scientific and technical knowledge". Upon this preliminary clarification, it found that scientific studies which cast further light on persisting uncertainty can be considered as "new scientific and technical knowledge", as long as they are based on new and more reliable methodologies; in other words, increasing awareness of *scientific uncertainty* and *scientific insufficiency* can qualify as "new scientific and technical knowledge". The appellant challenged this interpretation, claiming that the review of time-limited approvals of pesticidal active substances may be justified only in cases where the state of technical-scientific knowledge has changed.[30]

The AG followed a different line of reasoning, but still held that the GC's findings were vitiated by an error in law. The AG engaged in a textual analysis of Article 21, noting that the Commission may initiate the review procedure "at any time"; references to "new scientific and technical knowledge" apply to the specific case where a Member State has requested a review of approval, and to the Commission's duty to inform the Member States, the EFSA and the notifier of the active substance.[31] On these grounds, she stressed that other reasons may indeed justify the opening of the review procedure; for instance, regulatory amendments enacted to further strengthen public health and environmental protection.[32] This interpretation of Article 21 has been recently confirmed in *Blaise*.[33] The AG thus concluded that the GC's interpretation was vitiated by an error in law; nonetheless, this error could not cause the Judgment to be set aside, as it could not call into question the outcome of the GC's examination. The Court adhered to the Opinion in all respects.[34]

The second relevant point raised by the appellant regards the Commission's finding in the review procedure that the approval conditions were no longer met. By the first part of the third ground of appeal, Bayer CropScience raised some *general* points on the GC's finding that the Commission was fully entitled to take its decision on the basis of the EFSA's 2013 risk assessment, rather than waiting for the adoption of the EFSA's formal guidance and a more comprehensive evaluation.[35] As already explained, the EFSA's conclusions highlighted considerable uncertainties surrounding pollinator exposures in real life conditions and different pathways by which the relevant risks may materialise. The appellant took issue with the Commission's decision to take precautionary action, suggesting that it should have waited for a more thorough risk assessment.

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[29] Opinion in Case C-499/18 P, *Bayer CropScience*, para 71.
[30] Opinion, para 74.
[31] See *supra*, section II.
[32] Opinion, paras 75 to 78.
[33] Case C-616/17, *Blaise and Others* EU:C:2019:800, para 99.
[34] Opinion, para 81; Judgment, paras 45 to 56.
[35] In its risk assessment the EFSA had relied on a preparatory opinion adopted in May 2012, which preceded the drawing up and adoption of formal guidance; see Case T-429/13, *Bayer CropScience*, para 229.

This ground of appeal was swiftly rejected by the AG as unfounded.[36] Indeed, an acknowledgment of persisting uncertainty, scientific insufficiency and data gaps fully and entirely justifies recourse to the precautionary principle by the EU risk managers.[37] The Court took the same exact perspective, while more vigorously referring to the overarching tenets of the principle. The Judgment makes reference to the traditional definition of the precautionary principle, as enshrined in the EU Courts' case law.[38] Further, the Court expressly clarified that the precautionary principle does by no means require that the adoption of measures under the review of approval procedure "be deferred solely on the grounds that studies are under way which may call into question the available scientific evidence and technical data".[39]

In a different vein, by the first part of the fourth ground of appeal, the appellant challenged the findings of the GC's Judgment in the *specific* context of the review of approval procedure. This point relates to the grounds for a *finding that the approval conditions* are no longer met, in the context of the review procedure; the appellant's argument is connected and symmetrical to its point on the grounds for the initiation of the procedure. Bayer CropScience objected that the GC had erred in law "by failing to determine a degree of scientific certainty as to the materialisation of the alleged risk appropriate for the application of precautionary measures" in the context of the review of approval procedure.[40] Drawing on settled case law, including *Paraquat*, the GC had noted that it was sufficient for the Commission to provide solid and convincing evidence which may reasonably cast doubts as to the fact that the active substance would still meet the approval criteria of the PPP Regulation.[41] The appellant, on the other hand, claimed that "for measures which impinge on existing approvals, […] there is a need for a *higher degree of certainty* regarding the materialisation of the alleged risk" (emphasis added) than that which would be required in the context of an approval.[42] To substantiate its argument, Bayer CropScience referred to two specific cases: *Artegodan*[43] and *Fidenato*.[44]

The AG started by noting that Article 21(3) of the PPP Regulation does not prescribe any specific conditions for a withdrawal or amendment of an approval, other than a finding that the approval criteria are no longer satisfied.[45] After this premise, she found that "the degree of certainty [of a risk] can affect the assessment whether [that risk is] acceptable or unacceptable. Where there is a higher degree of certainty that a risk will materialise, lesser expected harm can outweigh the interest in the use of [an active substance] than were risks are less certain".[46] She elaborated further on this point, summarising the appellant's argument to the effect that "legal certainty and legitimate expectations as to the continued validity of the approval represent additional factors in the assessment, which become less significant only if there is *increased certainty* with regard to the materialisation

[36] Opinion, paras 98 to 109.
[37] Opinion, para 108 in particular. See also Case T-429/13, *Bayer CropScience*, paras 324 and 325.
[38] Judgment, para 80, citing Case C-616/17, *Blaise*, para 43.
[39] Judgment, para 82.
[40] Opinion, para 128.
[41] See the references in Case T-429/13, *Bayer CropScience*, para 142. This draws on the line of reasoning developed in Case T-229/04, *Sweden* v. *Commission* EU:T:2007:217 ("*Paraquat*"). The GC did not cite *Paraquat* in para 142; however, this case is cited in paras 116, 130 and 131 of the GC's decision. See *infra*, section IV, sub-section B.
[42] Opinion, para 130.
[43] Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan and Others* v. *Commission*, EU:T:2002:283. See *infra*, section IV, sub-section B.
[44] Case C-111/16, *Fidenato and Others* EU:C:2017:676. See *infra*, section IV, sub-section B.
[45] Opinion, para 131.
[46] Ibid, para 135.

of risks *compared with the first approval*" (emphasis added).[47] At the end of this examination, the AG backtracked; she thus acknowledged that the argument in favour of a higher threshold of scientific certainty as to the materialisation of a risk, in the context of the review procedure, is legally untenable.[48] As she noted, the safety threshold for the use of an active substance "cannot depend on whether or not the substance has already been approved".[49] For this reason, the AG *excluded* that a withdrawal or an amendment in the context of the review procedure may only be justified by a *higher degree of risk* or an *increased level of certainty of a risk* compared to the ones which may be of relevance in the original approval procedure.

The following paragraphs of the Opinion added a further layer of complexity. The AG noted that the appellant was correct in stating that "in principle, a decision-making basis which is unchanged compared with the [original] approval does not permit the Commission to modify its assessment whether certain […] effects are unacceptable. […] This applies a fortiori if […] the effects [of an approval] are limited in time".[50] However, as clarified in the following paragraphs of the Opinion, the relevant decision-making basis does not only include scientific evidence; a change in the applicable approval criteria could also alter the decision-making basis.[51] Overall, to draw a summary, the AG suggested that a withdrawal or amendment are justified under two different scenarios. First, where the approval criteria have changed and are no longer met. Secondly, where new evidence casts doubts on whether the approval criteria are still met; however, such new evidence *need not establish* a higher degree of risk or an increased level of scientific certainty compared to the ones which were of relevance in the original approval procedure.[52] Rather, this new evidence could point to increased uncertainty, an increased awareness of the insufficiency of the available evidence, or specific data gaps.

In the case under comment, the AG concluded that the relevant requirements for amendment or withdrawal had been met.[53] She thus suggested that this ground of appeal should be rejected as unfounded. The Court reached exactly the same conclusion. However, unlike the Opinion of AG Kokott, the Judgment does not at all engage with questions surrounding legal certainty and legitimate expectations. The Court emphasised that the provisions of the PPP Regulation are based on the precautionary principle. This principle also informs the review of approval procedure enshrined in Article 21.[54] By putting the precautionary principle front and centre stage, the Court thus simply stressed that "the Commission is not subject to a higher proof requirement with respect to active substances already approved than with respect to non-approved substances".[55]

B. The Ground of Appeal on "Hypothetical Risk"

[47] Ibid, para 136.
[48] Ibid, para 137.
[49] Ibid.
[50] Ibid, para 140.
[51] Ibid, para 143.
[52] Ibid, para 141: in essence, "the Commission must have new evidence which would have been sufficient in the initial approval procedure to limit the approval in this way from the outset".
[53] Ibid, paras 140 to 145. AG Kokott found that both requirements had been met in this case. First, the applicable decision-making criteria had changed as regards the protection of pollinators. In this respect, see also Case T-429/13, *Bayer CropScience*, para 135. Secondly, new evidence testifying to scientific insufficiency and data gaps had been produced.
[54] Judgment, paras 113 to 120.
[55] Ibid, para 116. See also paras 117 et seq.

By the second part of the fourth ground of appeal, Bayer CropScience claimed that the GC had erred in law in its assessment of the prohibition of use of clothianidin and imidacloprid for foliar applications, and prohibition of non-professional uses. In both respects, the appellant complained that the GC had accepted the prohibitions despite the absence of a risk assessment by the EFSA; on these grounds, the appellant maintained that the measures were based on mere "hypothetical" considerations on potential risks.[56]

Starting from an analysis of the prohibition of foliar applications, the AG noted that Article 21(2) of the PPP Regulation affords the Commission discretion as to whether any specific scientific matters should be referred to the EFSA. For this reason, the absence of a risk assessment by the EFSA could not in itself call into question the prohibition.[57] After this preliminary clarification, the AG found that the GC had not permitted the enactment of measures based on a purely hypothetical approach. As the Opinion emphasises, the GC permitted the prohibition "only if and in so far as the Commission could reasonably assume that [foliar applications] posed similar risks to those posed by uses that had been assessed";[58] indeed, the GC had closely scrutinised the scientific substantiation of the measure and the studies produced by the Commission.[59] Thus, as the AG concluded, the GC had not accepted "mere conjecture which has not been scientifically verified as a reasonable assumption".[60] The Court fully adhered to the Opinion.[61]

By contrast, the AG found that the ban on non-professional uses was not substantiated by a risk assessment or sufficient scientific evidence. As explained in greater detail in the comments section, the GC had analysed the ban through the lens of proportionality review. It had laid particular emphasis on the risk manager's discretion in the setting of the intended level of protection and evaluation of OLFs: in the circumstances of the case, the relevant other legitimate factors encompassed a potential misuse of pesticidal products by non-professional users.[62] In this light, while acknowledging that the prohibition was not substantiated by specific scientific evidence, the GC had found that it was not manifestly inappropriate to achieve the relevant environmental protection goals.

In this respect, the AG suggested that the GC had incurred an error of law. She noted that the Commission had failed to carry out an assessment of the available scientific data, even though that assessment is a necessary precondition for the adoption of precautionary measures; from this perspective, the ban was based on mere conjecture. On these grounds, she suggested that the Judgment under appeal should be set aside to the extent that the GC had dismissed this point.[63] The Court, however, took a different view. The Judgment confirmed the validity of the GC's approach and the latter's examination of the matter under the umbrella of proportionality review. The Court laid particular emphasis on the fact that "it is for the institutions that are responsible for making political choices to determine the level of risk considered acceptable to society, that level of risk being determined *not only* on the basis of *strictly scientific considerations*, *but also* taking account of *social factors*, such as the feasibility of controls".[64] The Court thus concluded that, taking the degree of toxicity of these pesticidal active substances and the feasibility of controls into account, the GC had

[56] Opinion, para 156 and case law cited therein.
[57] Ibid, para 155.
[58] Ibid, para 157.
[59] Case T-429/13, *Bayer CropScience*, paras 534 to 545.
[60] Opinion, para 158.
[61] Judgment, paras 147 to 152.
[62] See *infra*, section IV, sub-section C.
[63] Opinion, para 168.
[64] Judgment, para 155.

not committed an error of law in finding that the prohibition was not manifestly inappropriate to achieve its objectives.[65]

C. The Ground of Appeal on Impact Assessment

By its sixth and final ground of appeal, Bayer CropScience complained about the GC's evaluations surrounding the duty for EU risk managers to conduct an impact assessment.[66] The Commission had produced a summary of a study on the economic effects of the review of approval, thus demonstrating that it had taken the advantages and disadvantages associated with the amendment of the approval into consideration. The appellant took issue with the GC's findings on the duty of (economic) evidence production of the Commission. More specifically, the GC had found that it was sufficient for the Commission to demonstrate that it had acquainted itself with the effects of the measure;[67] the scope and the format of the evaluation or the decision to conduct a formal impact assessment, by contrast, lie within the discretion of the Commission.[68] Further, Bayer CropScience lamented that the Commission did not have a complete overview of the availability and efficacy of pesticidal formulations containing different and alternative active substances.[69]

Drawing on the third indent of Article 191(3) TFEU, the AG argued that EU risk managers must take the advantages and the disadvantages of regulatory action into consideration and that the precautionary principle must be applied having regard to the principle of proportionality.[70] She rejected the Commission's argument that, in the context of a review of approval, it is sufficient for EU risk managers to take into consideration the adverse effects of an active substance; taking a different perspective, she claimed that "socio-economic concerns must also be considered, at least in so far as Article 21(3) […] allows a margin of discretion within which the Commission can apply the principle of proportionality".[71] After noting that such margin of discretion is excluded in respect of harmful effects on human health or groundwater, she found that the PPP Regulation's reference to "unacceptable" environmental adverse effects and "unacceptable" effects on pollinators affords EU risk managers some margins of manoeuvre. According to the Opinion, this implies that the Commission must assess the advantages and the disadvantages of the review of approval.[72] Despite the limited extent to which the EU Courts may engage in proportionality review, the AG added, the EU institutions must be able to show "that in adopting the act they actually exercised their discretion, [which] presupposes the taking into consideration of all the relevant factors and circumstances of the situation […]".[73] This duty to provide evidence, she argued, "must apply a fortiori to the exercise of implementing powers by the Commission".[74]

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[65] Ibid, paras 156 to 158.
[66] Case T-429/13, *Bayer CropScience*, paras 459 to 461.
[67] Ibid, para 460.
[68] Ibid, paras 459 and 460.
[69] Opinion, para 169. See also Case T-429/13, *Bayer CropScience*, para 461.
[70] Opinion, paras 170 and 171.
[71] Ibid, para 172.
[72] Ibid, paras 173 and 174.
[73] Ibid, para 175.
[74] Ibid. AG Kokott has always laid particular emphasis on the distinction and the differences between legislative and regulatory acts, in light of the democratic legitimacy of the legislative procedures. On these grounds, for instance, she has also defended the more restrictive standing criteria applicable to challenges to legislative acts, under the second limb of Article 263(4) TFEU: see the Opinion of Advocate General Kokott in Case C-583/11, *Inuit Tapiriit Kanatami and Others* v. *Parliament and Council* EU:C:2013:21, para 38.

Turning to the GC's treatment of this issue, she found that the Judgment was not vitiated by an error in law. The AG noted that the Commission is not under an obligation to conduct a formal and comprehensive impact assessment; the "form in which the source data are set out is immaterial", and the Commission may take any information source into account.[75] As regards the specific point on the analysis of the availability and characteristics of alternative PPPs, she found that the Commission had a comprehensive overview of alternative active substances approved at EU level. On the other hand, the Commission was not required to collect information on alternative PPPs authorised at Member State level. She thus concluded that the sixth ground of appeal was unfounded.

This was confirmed by the Court. However, the Judgment took a distinctive approach in that it did not focus on the questions surrounding the duty to conduct a formal impact assessment; rather, it laid particular emphasis on the text of Article 21 of the PPP Regulation. As the Court noted, Article 21(3) provides that the Commission shall withdraw or amend the approval of an active substance where the approval criteria laid out in Article 4 are no longer met. Thus, "by providing for the withdrawal or amendment [under those circumstances], [Article 21(3)] expressly incorporates the principle of proportionality which, according to settled case law, is one of the general principles of EU law".[76] As the Court added, Article 21 "does not impose any particular form or detailed rules to ensure compliance with it".[77] On these grounds, the Court expressly found that the GC had not erred in law "by referring to the wide margin of discretion enjoyed by the Commission when it decides *also* to carry out, *in addition to* [a] *risk assessment – which alone is prescribed by the above mentioned regulatory framework* – an examination of the positive and negative effects resulting from its action or inaction" (emphasis added).[78] As explained in detail in the comments section, this finding is of crucial importance.

IV. Comments: the Appellant's "Procedural Strategy", the Substantive Framing of the Issues at Stake and the Court's Stance

In the case under comment, the appellant pursued a very clever course of action. Bayer CropScience challenged the GC's Judgment indirectly, by reference to specific procedural aspects; this is the thread in Bayer CropScience's salient grounds of appeal. The AG acknowledged this, pointing to the appellant's "procedural strategy".[79] However, there is something more to this appeal case. While the arguments put forward by the appellant are procedural in nature, the appellant's strategy is characterised by a specific substantive framing of the issues at stake in this case. This substantive framing has far-reaching implications.

Sub-section A analyses the appellant's procedural point relating to the absence of an impact assessment. The appellant focused on the procedural preconditions for the EU risk managers' exercise of administrative discretion in precautionary risk management, and sought to *indirectly* broaden the risk managers' duty of (economic) evidence production. The Court rejected this interpretation. Most importantly, the Court's findings in this case have considerably reduced the relevance of economic

[75] Opinion, para 176.
[76] Judgment, para 166.
[77] Ibid, para 169.
[78] Ibid, para 172.
[79] Opinion, para 50.

considerations and impact assessments in the context of EU risk regulation. This, as the first sub-section illustrates, is the most important part of the Judgment.

Sub-section B focuses on the parallel grounds of appeal relating to the initiation and the application of the review of approval procedure. As this sub-section illustrates, the appellant's procedural interpretation of the relevant regulatory requirements *directly* sought to raise the substantive bar for the Commission to have recourse to the review procedure. The Court, by contrast, straight forwardly rejected the appellant's interpretative framing by expressly invoking the precautionary principle.

Finally, sub-section C turns to the appellant's procedural points on the absence of an ad hoc assessment of the risks posed by foliar applications and non-professional uses. The appellant "adjusted" to the perspective of the GC and took into express consideration the standard of review that it had employed in other parts of its decision. On these grounds, Bayer CropScience pointed to the Commission's failure to comply with the procedural preconditions that the EU Courts have identified for EU risk managers not to incur a manifest error of assessment. This argument is, in fact, perfectly compatible with the EU Courts' case law. By resorting to this construction, the appellant applied the EU Courts' own reasoning to an extent which would have, again, *indirectly* broadened the EU institutions' duty of (scientific) evidence production. It is thus all the more important that the Court rejected this ground of appeal, adhering to the GC's interpretation and expressly affirming the centrality of OLFs in EU risk regulation.

A. The Appellant's Attempt to Expand the Risk Manager's Duty of (Economic) Evidence Production: the Court and Impact Assessment

Since *Afton Chemical*, the ECJ has consistently held that the EU institutions are not bound by the results of an impact assessment.[80] However, throughout the years, market actors have increasingly pointed to the Commission's alleged duty to conduct an impact assessment; the underlying argument is that this is necessary to ensure that EU precautionary measures comply with the tenets of proportionality. In the "twin" *Bayer CropScience* and *BASF* cases, the GC held that the EU institutions must acquaint themselves with the economic and socio-economic effects of risk regulation measures and take "all relevant factors" into consideration for the purposes of decision-making.[81] In *BASF*, the GC found that the Commission had failed to demonstrate compliance with this requirement.[82] In *Bayer CropScience*, by contrast, the GC found that the Commission had met its burden of proof.

In its appeal, Bayer CropScience focused on the absence of a *formal* and *comprehensive* impact assessment. This was part of the appellant's specific procedural strategy. As already illustrated, the AG found that the Commission was not under an obligation to conduct one.[83] Indeed, the Court has always acknowledged the Commission's discretion in deciding whether to conduct a formal impact assessment.[84] For this reason, the appellant's complaint was unlikely to be successful. In its rejection of this ground of appeal, however, the Court went much further than the AG and

[80] Case C-343/09, *Afton Chemical*, EU:C:2010:419, para 30.
[81] Case T-584/13, *BASF*, paras 163, 170 and 172; and Case T-429/13, *Bayer CropScience*, para 460.
[82] Case T-584/13, *BASF*, para 172. For a more detailed analysis, see Leonelli, op. cit. *supra* note 12.
[83] Opinion in *Bayer CropScience*, para 176.
[84] See inter alia Case C-58/08, *Vodafone and Others* EU:C:2010:321, paras 55 et seq.; Case C-176/09, *Luxembourg* v. *Parliament and Council* EU:C:2011:290, para 65; and Case C-477/14, *Pillbox 38* EU:C:2016:324, paras 64 et seq.

stressed a different point. Ultimately, the ECJ did not examine the *conditions* under which the Commission should acquaint itself with the economic implications of risk regulation; rather, it focused on and enquired into the *existence* of such a duty.

As explained in section III, the AG had found that precautionary risk management must comply with the tenets of proportionality, and EU risk managers must take all the advantages and disadvantages of regulatory action into consideration.[85] Although they are not bound to conduct an impact assessment, the AG contended, the EU institutions must be able to show "that in adopting the act they actually exercised their discretion, [which] presupposes the taking into consideration of all the relevant factors and circumstances of the situation […]".[86] From a completely different perspective, the Judgment stressed that the provisions enshrined in Article 21(3) of the PPP Regulation *incorporate* the proportionality principle; in other words, when adopting the PPP Regulation, the legislator has struck a specific balance between *collective* and *individual* interests, *public health and environmental protection* and *economic* rights. As an analysis of this provision shows, the legislator simply provided that the Commission shall withdraw or amend the approval of an active substance where the approval criteria laid out in Article 4 are no longer met; these criteria, as already explained, refer to public health and environmental protection.[87] Unlike the AG, the Court thus found that the Commission was *not* under a specific duty to take all relevant economic factors into consideration and acquaint itself with the economic effects of the review of approval. A fortiori, the Commission enjoys a broad discretion when "it decides *also* to carry out, *in addition to* [a] *risk assessment – which alone is prescribed by the above mentioned regulatory framework* – an examination of the positive and negative effects resulting from its action or inaction" (emphasis added).[88]

This part of the Judgment is of fundamental importance. The Court's decision implies that cases like *BASF* will be differently decided in the future. This is very likely to put an end to the attempts by market actors to challenge precautionary risk management measures by reference to an alleged failure by the EU institutions to conduct an impact assessment or take all relevant economic factors into account. Indeed, it is worth stressing that *all* legislative frameworks in the field of EU risk regulation follow the same approach as the PPP Regulation; public health and environmental criteria play a prominent role in the context of approval or review of approval procedures, whereas strictly economic factors are not mentioned. For this reason, the Judgment in *Bayer CropScience* has far-reaching effects beyond the field of governance of pesticidal products.

This considerably strengthens the socially acceptable risk rationale of EU risk regulation. The pre-*Bayer CropScience* twofold focus on the absence of an impact assessment and on the Commission's duty to take all relevant economic factors into account was highly problematic, from an environmental and public health protection perspective. This point can be illustrated through specific examples.

First, if a duty to conduct a formal and comprehensive impact assessment applied, market actors could easily challenge the EU institutions for failing to *procedurally* take *all relevant factors* into consideration, when conducting an impact assessment. They could also challenge the selection and the quantification of specific economic and socio-economic data, within the relevant impact

[85] Opinion, paras 170 and 171.
[86] Ibid, para 175.
[87] See *supra*, section II.
[88] Judgment, para 172.

assessment. This hypothetical scenario would increase the Commission's duty of evidence production considerably. The Commission would have to prove that it has acquainted itself with all relevant aspects and that it has selected and considered all information in an appropriate way.[89] The burden of proof that all relevant factors have been taken into due consideration for the purposes of an impact assessment would lie with the Commission, and it would be very difficult to discharge. This scenario would give rise to endless procedural complaints by the applicants. To a lesser extent, the same considerations could apply even in the absence of a formal duty to conduct an impact assessment; an expansion of the EU Courts' review of whether the Commission has taken "all relevant factors" into account, building on the duty for EU institutions to acquaint themselves with all economic advantages and disadvantages, could have had the same result. Indeed, Bayer CropScience's reference to the alleged failure by the Commission to take account of alternative PPPs authorised at Member State level[90] demonstrates how easy it can be for market actors to challenge the Commission for failing to take all relevant factors into account.

Secondly, the recognition of a duty to conduct a formal impact assessment could have paved the way for a *quasi-substantive* scrutiny of the *evidence* relied upon by the EU institutions and relevant *inferences*. The EU Courts' quasi-substantive standard of review expands on the "all relevant factors" test, building on the EU institutions' duty to procedurally take all relevant factors into consideration. This scenario would have been similar to the one of *Bilbaína*,[91] and could have materialised in the context of the evaluation of the results of an impact assessment. Ultimately, market actors could have singled out specific data within an impact assessment and claimed that the EU institutions had failed to procedurally take them into due consideration for the purposes of final decision-making. To a lesser extent, yet again, the same considerations could apply even in the absence of a duty to conduct an impact assessment, i.e. by reference to the information taken into account by the Commission when acquainting itself with the implications of regulatory measures.

Finally, a duty to conduct a formal impact assessment and an expansion of the EU Courts' review of the duty to take economic factors into account could have also opened up new opportunities for market actors to challenge restrictive measures in *substantive* terms. These challenges could have taken two forms. Market actors might have sought to challenge restrictive measures in so far as their contents did not reflect the results of an impact assessment, i.e. for a failure by the EU institutions to comply with the *conclusions of the relevant impact assessment*. Alternatively, they could have used the results of an impact assessment or the relevant economic factors taken into account by the Commission to substantiate their claim that the relevant measures did not comply with the tenets of *proportionality*. This would have been extremely problematic.

In the field of risk regulation, appropriateness review enables the EU Courts to verify whether a risk management measure is appropriate to achieve its goals. Under necessity review, the EU Courts ultimately scrutinise whether less trade restrictive risk management measures could have been enacted to achieve the relevant public health and environmental goals. Finally, stricto sensu

[89] In the field of risk regulation, these would include inter alia the costs, benefits, advantages and disadvantages associated with the setting of alternative levels of protection, the existence of alternatives to the specific product or process, risk-risk trade-offs, the existence, availability and efficacy of alternative risk management measures, and the costs, benefits, advantages and disadvantages associated with alternative risk management measures.

[90] Rather than alternative active substances approved at EU level; see *supra* section III, sub-section C.

[91] See Case T-689/13, *Bilbaína de Alquitranes SA and others* v. *European Commission*, EU:T:2015:762, and Case C-691/15 P, *European Commission* v. *Bilbaína de Alquitranes SA and others*, EU:C:2017:882. For an analysis, see Leonelli, op. cit. *supra* note 12.

proportionality targets the balance between costs and benefits. Complaints on necessity thus focus on the risk management measures selected to comply with the intended level of protection; complaints on stricto sensu proportionality, by contrast, target the intended level of protection and the underlying balance between economic costs and public health and environmental benefits (stricto sensu cost-benefit effectiveness).

An intrusive review of the proportionality of EU risk regulation acts would have not done any justice to the overarching goals of EU risk regulation, including the evaluation of any relevant OLFs at stake. The notion of "OLFs" encompasses factors such as public opinion, the availability and efficacy of alternative risk management measures, the advantages, disadvantages and distributional stakes associated with risk regulation and with the adoption of different risk management measures, and the development of a long-term vision for more sustainable approaches in specific regulatory fields.[92]

A focus on the *necessity* and trade restrictiveness of risk management measures fails to do any justice to specific OLFs, such as distributional concerns. Further, less trade restrictive risk management measures may not be effective in practice; this can jeopardise the achievement of the intended level of protection. A focus on *existing alternatives to a product or process* also fails to do justice to OLFs; most importantly, the overarching tenets of the substitution principle,[93] and a long-term vision for more sustainable forms of development. Effective alternatives may not exist on the market at a given point in time; however, they may be developed by the industry, if a product or process is banned or restricted. In other cases, less effective but more sustainable products or processes may already be available; prohibitions or restrictions on hazardous products would then increase the use of more sustainable alternatives. Finally, a focus on the *cost-benefit effectiveness* (stricto sensu proportionality) of the level of protection pursued by regulatory measures is irreconcilable with the EU system of risk regulation. The intended level of protection pursued by EU regulators need not be cost-benefit effective; quite to the contrary, it is bound to be a "high" level of protection.[94]

As this concise analysis has shown, the applicants' increasing focus throughout the years on the Commission's duty to conduct an impact assessment and take all relevant economic factors into account posed considerable challenges to EU risk governance. In *Bayer CropScience*, the Court has gone further than expected. Not only has it confirmed that the Commission is *not* under an obligation to perform a formal impact assessment. It has also pointed to the legislative balance between public health or environmental protection and economic interests, stressing that the Commission is *not* obliged to take economic factors into account in its decision *unless* the relevant legislative acts require it. This is the most important part of the Judgment. This finding is bound to have far-reaching

[92] For an overview, see for instance the *Communication from the Commission on the Precautionary Principle*, cited *supra* note 2, at 19, sub-section 6.3.4, referencing "acceptability to the public", the "efficacy of alternative [risk management/regulatory] options" and "the socio-economic impact of the various [risk management/regulatory] options". See also *supra*, note 10, for references in legislative frameworks.

[93] Pursuant to this principle, hazardous products or processes should in so far as technically possible be replaced by less hazardous alternatives. The principle is enshrined in in Article 55 of REACH, and finds expression in the comparative assessment procedure of Article 50(1) of the PPP Regulation.

[94] EU risk managers are bound to pursue a high level of public health and environmental protection; see *supra*, note 8. See also Case T-429/13, *Bayer CropScience*, para 106, and the case law cited therein: "the protection of the environment takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders".

implications, and it has breathed new life into the socially acceptable risk foundations of the EU system.

B. From "New Scientific and Technical Knowledge" to Conclusive Scientific Proof of a Risk? The Court and the Precautionary Principle

By its first ground of appeal, the appellant suggested that increasing scientific certainty does not qualify as "new scientific and technical knowledge", within the meaning of Article 21 of the PPP Regulation. As already explained, this complaint focused on the preconditions for the opening of the review procedure. While recognising that the GC had erred in law, the AG and the ECJ rejected this ground of appeal.

The analysis of this complaint begs the question *what*, from the appellant's perspective, would have qualified as "new scientific and technical knowledge". The interpretation of the requirement that a measure shall be substantiated by "new scientific evidence" fell for consideration in the appeal brought in *Upper Austria*.[95] In this case, the Republic of Austria and the Upper Austria region sought the annulment of a 2003 Commission's Decision; by this Decision, the Commission had rejected Austria's request for a derogation from the 2001 Directive on the Deliberate Release of GMOs on the grounds of (what is now) Article 114(5) TFEU. Article 114(5) lays out a number of stringent conditions for the introduction of national measures derogating from a pre-existing harmonisation measure. The national measures must, inter alia, be based on new scientific evidence relating to the protection of the environment or the working environment. In her Opinion in *Upper Austria*, AG Sharpston found that "new conclusions drawn from existing data may constitute new scientific evidence",[96] as long as a clear explanation is provided of the reasons why the examination of the evidence should have led to different inferences and conclusions.[97] The ECJ, however, did not adhere to this interpretation. Overall, the criterion of "novelty" is not satisfied when different (i.e. precautionary) inferences are being drawn from the same, pre-existing data.

The ECJ's interpretation in *Upper Austria* is not dissimilar from the one provided by the GC in *Bayer CropScience*. The GC excluded that a re-assessment of pre-existing information could be regarded as "new scientific and technical knowledge"; in a different vein, it found that new scientific studies and new monitoring data which cast further light on scientific uncertainty qualify as such. The GC's interpretation is perfectly logical. Increasing scientific awareness of data gaps and of different forms of uncertainty is tantamount to "new scientific and technical knowledge" of the *insufficiency* of the available evidence for the purposes of an *adequate characterisation of a risk*. Clearly, this fully satisfies the requirements of Article 21 of the PPP Regulation.

It is unclear whether Bayer CropScience's ground of appeal and interpretation of this point drew on the findings of the Court of First Instance in *Artegodan*. In this case, the applicants sought and secured the annulment of the Commission's withdrawal of a number of marketing authorisations for medicinal products containing specific anorectic agents. The Commission had not produced any new scientific evidence on the uncertain risks posed by the anorectic agents; rather, it had relied on accumulated knowledge of the limited therapeutic efficacy (i.e. benefits) of these substances. The

[95] Joined Cases C-439/05 and C-454/05, *Land Oberösterreich and Austria* v. *Commission* EU:C:2007:510 ("*Upper Austria*").
[96] Opinion of AG Sharpston in Joined Cases C-439/05 and C-454/05, *Upper Austria* EU:C:2007:285, para 124.
[97] Ibid, para 138; however, see also para 134.

Court of First Instance found, inter alia, that accumulated knowledge of the therapeutic efficacy of a substance does not qualify as "new scientific evidence" and cannot justify the withdrawal of an authorisation.[98] It may be that Bayer CropScience indirectly relied on *Artegodan*; however, it is still worth noting that the background of the two cases is very different. First, unlike in *Artegodan*, new scientific studies were available to the Commission. Secondly, unlike in *Artegodan*, the new scientific studies and the new data related to the risks posed by neonicotinoids (rather than their benefits). The appellant did not dispute these points.

Against this backdrop, the logic of the first ground of appeal becomes somewhat clearer. The appellant sought to reframe the concept of the "novelty" of scientific evidence with a view to challenging the GC's determination that increasing awareness of scientific uncertainty and insufficiency counts as "new knowledge". Under the appellant's interpretation, only new scientific evidence pointing to *conclusive proof* of all *specific exposures* and *pathways for the materialisation of a risk* and providing an assessment of the *probability of occurrence of the relevant adverse effects and their severity* could qualify as "new technical and scientific knowledge". Overall, the appellant did *not* dispute the novelty *but* the nature of the evidence relied upon by the Commission. By pointing to the absence of a full characterisation of the risks posed by clothianidin and imidacloprid,[99] the appellant sought to associate the notion of "new technical and scientific knowledge" with "sound science". This exemplifies a problematic shift from the EU focus on the "sufficient safety" of a product, to a different focus on sound scientific proof of "unsafety". Such a shift is irreconcilable with the rationale of the EU system of risk regulation.

The same construction re-surfaced in the first part of the fourth ground of appeal, on the application of the review procedure; as already explained, this centred on the GC's alleged failure to identify a specific level of scientific certainty as to the materialisation of a risk which may justify an amendment or withdrawal of approval in the context of the review procedure. The GC had rightly cited the standard of proof laid out in *Paraquat*: all that is necessary for the EU institutions to take action is solid and convincing evidence which may reasonably cast doubts as to compliance with the approval criteria.[100] Indeed, as the EU Courts' traditional definition of the precautionary principle also confirms,[101] no specific *threshold of risk* and no specific *level of scientific certainty* is required for EU risk managers to take precautionary action. First, this reflects the EU Courts' consistent acknowledgment that the EU institutions enjoy a broad administrative discretion in cases involving complex technical-scientific evaluations; accordingly, only a manifest error of assessment may invalidate an EU act.[102] Secondly, in substantive terms, this reflects a recognition of the risk managers' twofold political responsibility: the responsibility to set the intended level of protection and threshold of acceptable risk, and to determine whether uncertain risks meet that level of protection and that threshold.[103] This lies at the heart of the *political* and *democratic legitimacy* of EU risk regulation.[104]

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[98] For a more detailed examination of this case, see Leonelli, op. cit. *supra* note 12.
[99] See *supra*, section II.
[100] See Case T-229/04, *Paraquat*, paras 161, 170 and 224.
[101] See Leonelli, op. cit. *supra* note 12.
[102] As consistently affirmed by the EU Courts: see Leonelli, op. cit. *supra* note 12. In Case T-429/13, *Bayer CropScience*, see paras 143 to 147.
[103] Ibid. In Case T-429/13, *Bayer CropScience*, see paras 122 to 126.
[104] Ibid. In Case T-429/13, *Bayer CropScience*, see para 122. See also the most famous findings in Case T-13/99, *Pfizer Animal Health SA* v. *Council*, EU:T:2002:209, paras 151 and 201, and Case T-70/99, *Alpharma* v. *Council*, EU:T:2002:210, para 164.

Judicial review of the "soundness" of the evidence base relied on by the risk manager,[105] just like judicial evaluations as to whether "sound" scientific proof of the existence of a hazard and materialisation of a risk has been provided,[106] are totally foreign to the Courts' review of EU risk regulation. The same applies to judicial identifications of a specific level of scientific certainty or a specific threshold of risk legitimising recourse to the precautionary principle. Indeed, this standard of scrutiny would be extremely problematic. First, in the face of scientific complexity and persisting uncertainty, "sound science" (or even what is presumed to be the "best" science) will not necessarily yield any factually correct answers. The boundaries between "facts" and "values" thus fade in the field of risk regulation,[107] and the EU Courts are deprived of any "factual" yardsticks. Secondly, evaluations as to how "certain" or "uncertain", "big" or "small" a risk is are totally irrelevant in the context of precautionary risk management; there is no value-free way out of the *acceptability* of a risk, no matter how "unlikely" or how "small" it may be. Nothing, besides a manifest error of assessment, may invalidate a decision that uncertain risks are not acceptable and not worth taking. Thirdly, and clearly, judicial determinations that EU risk managers should have regard to "sound science" (rather than persisting uncertainty) would irremediably encroach on the institutions' political evaluation as to whether a risk complies with the intended level of protection and meets the threshold of acceptable risk; the same applies to judicial determinations that a "sound" rather than a "prudential" evidence base should be adhered to. Finally, this form of substantive review would be extremely likely to result in inconsistencies throughout the case law.[108]

In this ground of appeal in *Bayer CropScience*, the appellant relied on both *Fidenato* and *Artegodan*. Reliance on the former case was misplaced. In *Fidenato*, the referring court enquired whether "considerations relating to the precautionary principle which go beyond the parameters of serious and evident risk to human or animal health or the environment […] justify the adoption of interim emergency measures [under Article 34 of the 2003 Regulation on GM Food and Feed]".[109] The ECJ reached the unsurprising conclusion that an interpretation in the light of the precautionary principle could not expand the specific scope of application of the emergency clause of Article 34.[110] However, and clearly, the factual and legal background of *Fidenato* and *Bayer CropScience* are completely different. More problematically, the decision in *Artegodan* may be interpreted in such a way as to suggest that a higher burden of scientific proof is required for the specific purposes of justifying a review of approval.[111] Although the Court of First Instance had focused on the "novelty" of the data relied on by the Commission, its very restrictive framing of the notion of "novelty" lends itself to this interpretation.

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[105] For instance, different (more or less prudential) approaches to risk assessment will influence the models employed at the hazard identification stage, the models and safety factors selected for the purposes of hazard characterisation, probabilistic modelling in the context of appraisal of exposures, and all relevant considerations surrounding variability. For a detailed analysis, see Leonelli, op. cit. *supra* note 1.

[106] See *supra* note 3.

[107] On the "illusory separation between values and science" in the field of risk regulation, see Lee, *EU Environmental Law, Governance and Decision-Making* (Hart Publishing, 2014), 249 et seq.; and Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing, 2007), 246.

[108] For example, for an analysis of the inconsistencies flowing from the application of the "all relevant factors" test in judicial review of EU risk regulation, see Leonelli, op. cit. *supra* note 12.

[109] Case C-111/16, *Fidenato*, para 22.

[110] Ibid, paras 46, 48 and 54. See also para 52.

[111] However, it is worth noting that the ECJ did not assess this point on appeal; see Case C-39/03 P, *Commission* v. *Artegodan and Others* EU:C:2003:418.

Overall, Bayer CropScience suggested that the evidence justifying an amendment or a withdrawal of approval should be "new technical and scientific knowledge" along the same lines of its interpretation in the first ground of appeal; the dichotomy of "sound science" and uncertainty thus re-emerged in this context. Despite the rejection of this ground of appeal, it is worth underscoring that the appellant's procedural strategy was quite effective. This is evident if the examination of this ground of appeal in the Opinion of AG Kokott is compared with the treatment of the first part of the third ground.[112] The appellant's traditional challenge to precautionary risk management was swiftly rejected. The procedural challenge in the context of the review procedure, by contrast, triggered a number of considerations on the extent to which "the degree of certainty [of a risk] can affect the assessment whether [that risk is] acceptable or unacceptable", on higher or lower categories of risk, and on the balance between individual trade rights and public interests. Clearly, from an environmental and public health protection perspective, these considerations are problematic.

This makes the Court's specific interpretation of these points all the more important. As already explained, the Judgment did not expand on any of these rather problematic aspects. The Court clearly focused on the centrality of the precautionary principle in the context of the PPP Regulation, confirming its crucial role for interpretative purposes. Thus, it simply and straight forwardly noted that the Commission cannot be subject to a higher proof requirement in the context of a review of approval, compared to the original approval procedure.[113] By so doing, the Judgment highlights the primacy of *collective* public health and environmental interests over *individual* trade and market interests; this reflects the overarching tenets of the precautionary principle, and strengthens the socially acceptable risk rationale of EU risk regulation.

C. From Proportionality Review to "Hypothetical Risk"? The Court and OLFs

The arguments raised by the appellant in the second part of the fourth ground of appeal (prohibitions on foliar applications and non-professional uses) are very clever. As anticipated, the appellant sought to transpose the GC's own standard of review to another part of the Judgment; in other words, it tried to fight the EU Courts with their own weapons. In order to appreciate the rationale of the appellant's procedural strategy fully, however, it is necessary to contextualise the appellant's position against the broader background of the case law in this field.

The EU Courts have always acknowledged that they tread a narrow path, when reviewing EU risk regulation measures which are challenged for being too restrictive. As already mentioned, they have consistently recognised that EU risk managers enjoy a broad discretion in the evaluation of complex technical-scientific matters; this discretion extends to fact-finding. For this reason, only a manifest error of assessment, a failure to comply with all relevant procedural requirements or a misuse of powers may result in the annulment of an EU act.[114] Traditionally, the EU Courts have laid particular emphasis on the EU institutions' exercise of their administrative discretion in precautionary risk management; accordingly, the notion of a manifest error of assessment has been set against the backdrop of the precautionary principle and interpreted by reference to its overarching tenets.[115] Under this line of case law, the EU Courts have identified two procedural preconditions for EU risk

[112] See *supra*, section III, sub-section A.
[113] Judgment, para 116.
[114] See *supra*, note 102, and the Opinion in *Bayer CropScience*, paras 50 and 51.
[115] For a detailed overview of different strands of case law, see Leonelli, *supra* note 12.

managers not to incur a manifest error of assessment. First, the relevant risks cannot be "hypothetical"; they cannot be founded on mere conjecture which has not been scientifically verified.[116] Secondly, and consequently, EU risk managers must ensure that their measures are based on the results of a risk assessment and on sufficiently reliable and cogent scientific evidence.[117]

In *Bayer CropScience*, the GC adhered to this strand of case law. It drew an express connection between the notions of administrative discretion and precautionary risk management; symmetrically, it examined the applicants' complaints on the alleged manifest errors and the complaints on an alleged misapplication of the precautionary principle together. When turning to the applicants' complaints on the prohibitions on foliar applications and non-professional uses, in a different vein, the GC chose to conduct its examination under the umbrella of proportionality. This is because these complaints relate to risk management and the enactment of specific risk management measures (prohibitions), rather than stricto sensu technical-scientific matters; indeed, the GC's choice is consistent with the case law of the EU Courts.[118]

The EU Courts have traditionally taken a very soft approach to proportionality review in this field; only measures which are manifestly inappropriate or which manifestly go beyond what is necessary will be sanctioned.[119] In *Bayer CropScience*, the GC followed this approach. First, it took into consideration the available scientific evidence and the Commission's findings on the effects of foliar applications. On these grounds, it found that the prohibition was not manifestly inappropriate to achieve its aim. Secondly, it turned to the prohibition of non-professional uses. Bayer CropScience maintained that a risk to bees due to non-professional uses would presuppose that "almost all gardeners use plant protection products containing the substances covered, failing which exposure would not reach levels having any relevance to bee health […]";[120] however, the Commission had not conducted any risk assessment. While acknowledging that the Commission had not relied on specific evidence, the GC found that the prohibition could not be deemed to be manifestly inappropriate. In making this finding, the GC laid particular emphasis on the risk manager's discretion in the evaluation of *OLFs*. Citing the General Food Law, it underlined that "scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decisions should be based, and […] [other legitimate factors] should be taken into account including *societal*, *economic*, *ethical* and *environmental factors* and the *feasibility of controls*" (emphasis added).[121] Accordingly, it concluded that the Commission was fully entitled to take these factors into account when determining the acceptability of the risks posed by neonicotinoids; notably, in this case, the Commission could consider potential misuses of pesticidal products by non-professional users.[122]

If analysed from the perspective of proportionality review, the GC's finding is legally tenable and perfectly consistent with the EU Courts' approach. OLFs such as the availability and efficacy of

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[116] Case T-13/99, *Pfizer*, paras 143 and 144, and Case T-70/99, *Alpharma*, paras 156 and 157.
[117] See e.g. Case T-13/99, *Pfizer*, paras 162 and 165, and Case T-70/99, *Alpharma*, para 175 and para 183.
[118] This trend is well established in the case law. For a very clear example, see Case T-257/07, *France* v. *Commission* EU:T:2011:444, where the GC neatly distinguished the two aspects.
[119] As acknowledged since Case C-331/88, *The Queen* v. *Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte: Fedesa and others* ("*Fedesa*"), EU:C:1990:391; Case C-157/96, *Ex parte National Farmers' Union and Others*, EU:C:1998:191 (*"BSE I"*); and Case C-180/96, *United Kingdom* v. *Council*, EU:C:1998:192 (*"BSE II"*).
[120] Case T-429/13, *Bayer CropScience*, para 548.
[121] Ibid, para 552, citing Recital (19) of the GFL, referenced *supra* note 9.
[122] Ibid, paras 552 and 556. Presumably, when setting the intended level of protection, the Commission had also weighed and balanced the (limited) societal interest to allow non-professional users to employ pesticides containing neonicotinoids vis-à-vis the potential environmental effects of misuses of these products.

risk management measures, or the advantages and disadvantages associated with a product or process, will influence the determination that a risk is acceptable and the selection of the appropriate risk management measures. Nor could the prohibition on non-professional uses be considered manifestly inappropriate to achieve the intended level of protection.

In its ground of appeal, however, Bayer CropScience shifted the focus from proportionality review and the GC's examination of the risk management measures to an analysis of the scientific substantiation of the measures. In so doing, it "adjusted" to the line of reasoning that the GC had followed in other parts of its decision and transposed it to the analysis of the prohibitions on foliar applications and non-professional uses. Thus, it challenged this part of the Judgment *on the grounds* of the standard of review that the GC had employed when considering manifest errors of assessment and alleged misapplications of the precautionary principle.[123] Bayer CropScience pointed to the procedural preconditions that the EU Courts have identified under this standard of review, with a view to ascertaining whether EU risk managers have incurred a manifest error of assessment in precautionary risk management: as briefly explained above, these preconditions are that a risk shall not be "hypothetical", and that risk management measures shall be based on sufficiently reliable and cogent scientific evidence.[124] As the AG's Opinion shows, the appellant used the very same wording employed by the Court of First Instance in *Pfizer* and *Alpharma* and by the GC in *Bayer CropScience*.

In the case of the prohibition on foliar applications, this construction could not succeed. In the case of the prohibition on non-professional uses, however, the appellant's clever argument prompted the AG to note that the Commission had not taken any scientific evidence into account; for this reason, the AG suggested that the measure was based on mere conjecture and on "hypothetical" risk. It is worth stressing that both the GC's findings and the appellant's construction (and AG's interpretation) are legally tenable and consistent with the EU Courts' case law. The examination of the prohibition on non-professional uses was thus open to both interpretative perspectives. Nonetheless, the appellant's interpretation would have indirectly expanded the EU institutions' duty of evidence production, putting the EU institutions under an increasing procedural pressure. The prohibitions on foliar applications and on non-professional uses targeted secondary uses of neonicotinoids. Further, the EFSA was acting under time constraints; this is the reason behind the lack of a comprehensive risk assessment.[125] In contexts of scientific complexity, and in rapidly evolving fields, a strict interpretation of the risk manager's duty of scientific justification is problematic. Such strict interpretation would undermine the risk manager's attempts to act promptly; this duty of – very detailed and very specific – evidence production would then encroach on precautionary risk management. Symmetrically, a finding in *Bayer CropScience* that the GC had erred in law would have strengthened (and indirectly expanded) the EU risk managers' duty of evidence production in contexts of scientific complexity.

The Court rejected the appellant's construction, embracing the GC's more deferential interpretation. In so doing, it has safeguarded EU precautionary risk management. Perhaps more importantly, however, the Court's focus on OLFs is of great importance. The crucial role of OLFs within the EU risk regulation system has been largely neglected by both the EU risk managers and

[123] Ibid, paras 334 to 341, showing that the GC clearly framed the notion of a manifest error of assessment against the backdrop of the precautionary principle, and analysed the complaints on alleged manifest errors and an alleged misapplication of the precautionary principle together.
[124] See *supra* notes 116 and 117, and Case T-429/13, *Bayer CropScience*, paras 115 to 121 and para 147.
[125] See for instance the reference in Case T-429/13, *Bayer CropScience*, para 533.

the EU Courts, in so far as these factors are clearly non-scientific in nature.[126] This reflects the dominant transnational discourse on (allegedly neutral and objective) "evidence-based" approaches, premised on the false assumption that the governance of uncertain risks can be a matter of "pure" science. By contrast, the Judgment in *Bayer CropScience* is distinctive in the express acknowledgment that the "level of [acceptable] 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" (emphasis added).[127] The Court accepted that OLFs *feed into* the determination of the intended level of protection and threshold of acceptable risk, influencing the finding that a risk is acceptable and worth taking. In this light, it concluded that the GC had not erred in law in finding that the prohibition on non-professional uses was not manifestly inappropriate. This perfectly responds to the socially acceptable risk rationale, and it has strengthened the role and relevance of OLFs in the context of EU risk regulation.

V. Conclusions: the Crucial Role of the Court in Defending Socially Acceptable Risk Approaches

In the case under comment, as the above sections have illustrated in detail, the appellant pursued a procedural strategy with far-reaching substantive implications. This is the thread in all the salient grounds of appeal. Overall, *Bayer CropScience* exemplifies an attempt to place EU risk managers under an increasing procedural pressure: an attempt which failed. The real tension underlying the case, however, is the substantive tension between *sufficient safety* and *unsafety*, *uncertainty* and "*sound science*", *OLFs* and *economic cost-benefit effectiveness*, *collective* stakes and *individual* trade rights.

A focus on the risk manager's duty to produce specific and detailed evidence on the unsafety of a product is irreconcilable with the regulatory philosophy of EU risk regulation. The determination that a product is sufficiently safe to be authorised lies at the heart of EU risk governance. Equally, a focus on impact assessment and on the Commission's duty of economic evidence production undermines the EU socially acceptable risk approach: enhanced levels of protection, precaution and OLFs should be taken into account to determine whether a risk is acceptable and worth taking. In *Bayer CropScience*, the Court has done more than could have been expected; it has played a crucial role in defending the EU socially acceptable risk approach.[128] It is thus fair to conclude that, more than any other case decided in recent years, the Judgment in *Bayer CropScience* has preserved the regulatory philosophy and the very foundations of the EU system of risk regulation.

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[126] For an exception in early case law in the field of risk governance, see the Opinion of AG Mischo in Case C-331/88, *Fedesa*, EU:C:1987:440, particularly at paras 23, 34, 35 and 39.
[127] Judgment, para 155.
[128] See *supra*, section I, for some further potential implications of this Case in the broader context of challenges involving EU risk regulation acts which are deemed too restrictive.